DATA USE AND NON-DISCLOSURE AGREEMENT CONCERNING PROTECTED HEALTH INFORMATION OR OTHER CONFIDENTIAL INFORMATION

Michigan Department of Health and Human Services

Project Title: _____

Data Recipient: _____

Organization: _____

Address: _____

_____

Phone: _____ **e-mail:** _____

In accordance with this agreement, data are provided by the Michigan Department of Health and Human Services (MDHHS), **Bureau of Epidemiology and Population Health, Division for Vital Records and Health Statistics** on **upon execution of this agreement and on the condition that the required fee for the data has been paid** to the Data Recipient.

The parties agree to the provisions specified in this Agreement, the Health Insurance Portability and Accountability Act (HIPAA), and all other applicable public health, research, and confidentiality laws.

SECTION 1: DATA SOURCE, PURPOSE, USE, DESCRIPTION, APPROVAL (IF HUMAN SUBJECT RESEARCH)

What is the Source of the Requested Data? *(e.g., Vital Records, Health Statistics, Cancer Surveillance, Medicaid, etc.)*

What is the Data Recipient's Purpose for, and Specific Use of, the Data?

1. Describe why these data are requested *(e.g., Research, Statistics, Public Health, Health Care Operations, Administration of the Medicaid Program).*

2. Describe how the data will be used/disclosed, or incorporate by reference and attach a copy of the research protocol, work plan, or request letter that details the purpose and use of data, etc.

   .

3. Describe the data requested indicating amount, type, by what medium the data will be provided, and whether the data recipient is granted access to the data warehouse or state archives.

   a. Specify the data elements *(e.g., age, gender, etc.)* and time periods *(e.g., January 2003 through January 2005)*.

   b. Specify if the data requested is identifiable, de-identified, or a limited data set as defined by HIPAA.

   c. Specify the medium requested *(e.g., electronic, hard copy, etc.).*

   d. Specify if direct access to the data warehouse or state archives is requested.

Research Project: *Complete this box if requested data will be used for human subjects research.*

Is Institutional Review Board (IRB) (human subjects research) approval required? If YES, MDHHS Approval Number..... *(Attach MDHHS Approval Form)*	☐ YES ☐ NO Approval Number
Is HIPAA Informed Consent/Authorization Waiver Required? If YES, MDHHS Approval Number (if above IRB approval not required) ..... *(Attach HIPAA Waiver Authorization, if relevant.)*	☐ YES ☐ NO Approval Number

SECTION 2: AGREEMENT CONDITIONS

With regard to data provided under this agreement, the Data Recipient agrees to:

1. Use and disclose the data only in accordance with this agreement, or as otherwise required by law;

2. Limit access to these data only to those described and authorized in this agreement; *(MDHHS may require the specific identification of the person(s) or the agency/division/office that is permitted access. Identify if needed.)*

3. Use appropriate safeguards to prevent use or disclosure of the information other than as provided by this agreement; *(MDHHS sponsor may require description of the security procedures that will be in place and followed.)*

4. Report to the responsible MDHHS sponsor any use or disclosure of information that is not provided for by this data use agreement;

5. Ensure that any agent(s) or subcontractor(s) who access these data agree to the same restrictions and conditions that apply to the data recipient; *(MDHHS sponsor may stipulate that release of data to a subcontractor cannot be done without the written authorization of MDHHS.)* MDHHS signatures constitute MDHHS authorization for the release of the data covered by this agreement to the specified agents and subcontractors listed below:

6. Make no attempt to identify or contact the individuals, providers, or health plans within the data provided unless approved in this agreement; (*Describe any agreed upon exceptions if needed.)* .

7. Data recipient must provide MDHHS at least thirty days to review and provide comments on papers, publications, or presentations that the data recipient plans to submit for publication or presentation. Data recipient agrees that it will not publish or disseminate any protected health information, personally identifiable information, or data that might make it possible, directly or indirectly, to identify an individual. Data recipient must acknowledge the MDHHS program as appropriate (e.g., source of data, etc.), assume full responsibility for the analysis and interpretation of the data, and provide a copy of the publication or presentation to MDHHS. To the extent data recipient requires technical assistance in analyzing or interpreting the data and when such assistance goes beyond providing non-manipulated data, MDHHS reserves the right to request that these activities be considered a substantial contribution to the research being conducted and that the provision of such assistance may warrant MDHHS be considered as a research collaborator or co-author in any resulting publications or presentations;

8. Return or destroy all originals and copies of any potentially identifiable information upon completion of project, or upon request, unless otherwise approved in this agreement. This includes, but is not limited to: magnetic tape, micro disk files, paper records, etc. If not returned to the MDHHS, then the data must be destroyed; e.g., use a CD/DVD shredder to destroy CD Roms, DVDs, etc., erase floppy/zip disks using a magnet, shred paper records, clean computer hard drives with a program designed to wipe a disk by overwriting, etc.;

9. Not use the data provided to engage in any method, act, or practice which constitutes a commercial solicitation or advertisement of goods, services, or real estate to consumers; and

10. Not use the data provided as a basis for legal, administrative or other actions which may affect particular individuals or establishments as a result of their specific identification in this project.

The MDHHS may cancel this agreement with proper notice.

The unauthorized use or disclosure of confidential information is punishable by imprisonment or fine or both under state and federal laws specific to the data released.

I, the data recipient, have read, understand, and agree to the above conditions.

DATA RECIPIENT SIGNATURE:

Name of Responsible Data Recipient (Type or Print)	Title
Signature of Responsible Data Recipient	Date

MDHHS SIGNATURES:

MDHHS SPONSOR

Name of Responsible MDHHS Sponsor (Type or Print)	Title
Signature of Responsible MDHHS Sponsor	Date

MDHHS RESPONSIBLE PARTY

Name of MDHHS Director, Bureau Director, or Delegated Authority (Type or Print)	Title
Signature of MDHHS Director, Bureau Director, or Delegated Authority	Date

AUTHORITY: This form is acceptable to the Michigan Department of Health and Human Services as compliant with HIPAA privacy regulations, 45 CFR Parts 160 and 164 as amended.

COMPLETION: Is required if disclosure is requested.

M-CARES Research Protocol

December 6, 2017

1. Specific Aims

M-CARES aims to quantify the effects of increasing the affordability of contraceptives on U.S. families. The study aims to provide both *comprehensive* evidence (relating to multiple aspects of women's lives) on the value of making contraception affordable and *long-term* evidence (relating to following women). Our analysis will use the randomization of vouchers together with surveys and administrative data to estimate the short-run and long-run causal effects of subsidizing highly effective contraceptive methods for U.S. women.

Over the course of the study, these rich data allow us to provide novel experimental evidence on outcomes such as contraceptive use, pregnancy, and childbearing. A central contribution of our analysis is that administrative data collected over a longer-term also allow us to consider a very wide range of *additional* outcomes, for which there has been no experimental evidence for the U.S. These include physical health and health care use; educational attainment and labor-market outcomes; relationship quality; mental health and well-being; standard of living; and receipt of public benefits.

Survey data and administrative data provide complementary perspectives on women's lives. A great advantage of administrative data is that they contain information from the universe (or a random sample) of the study population, which limits the role of non-response (Ashenfelter and Plant 1990). In addition, administrative data measure many outcomes better than self-reports on surveys, which ameliorates the potentially large role of this source of measurement error (Bound et al. 2001). We supplement administrative data with surveys about dimensions of women's lives not captured in administrative data (for instance, pregnancies, physical and mental health, relationship quality, and overall life satisfaction).

M-CARES aims to answer the following questions:

1. How does greater financial access to reproductive health care affect women's choice of contraceptive method, unintended pregnancy, and childbearing?

2. How does greater financial access to reproductive health care affect the lives of women? We will measure the short- and long-term effects of this intervention on many outcomes including,
   a. attitudes about and use of reproductive health care;
   b. physical health and health care use;
   c. educational attainment and labor market outcomes;
   d. relationship quality;
   e. mental health and well-being;
   f. participation in programs;
   g. financial security; and
   h. neighborhood quality.

3. How do the changes in #2 affect the lives of women's children? We will measure the short and long-term effects of this intervention on many outcomes including,
   a. health and health care use;
   b. education and work;
   c. juvenile criminal justice records;

d. mental health and well-being;
e. participation in programs;
f. financial security; and
g. neighborhood quality.

M-CARES has the potential to transform public policy knowledge about the impacts of reproductive health care on U.S. women and their families.

2. Background Research

M-CARES was motivated by several commonly cited findings. Nearly half of all pregnancies in the U.S. are unintended, and unintended pregnancies are five times more likely to occur for poor women relative to more affluent women (Sedgh et al. 2014, Finer and Zolna 2016). They are also significantly more common among young and minority women.

Evidence regarding the potential costs of unintended pregnancies for individuals, society, and the economy is less commonly cited. In 2011, 42 percent of unintended pregnancies (excluding miscarriages) ended in abortion (Finer and Zolna 2016). Roughly two thirds of unplanned births were funded by public insurance programs, primarily Medicaid (Sonnfield and Kost 2015). Quasi-experimental evidence suggests that unintended pregnancies have a variety of long-term implications for the lives of women and their families. Evidence that exploits changes in legislation permitting young women access to the Pill and the roll-out of the first federally funded family planning clinics in the U.S. suggests that unintended pregnancies in the 1960s and 1970s reduced women's educational attainment, employment, career advancement, and family incomes (Goldin and Katz 2002, Bailey 2006, Hock 2008, Bailey et al. 2012). They may also result in decreased marital stability and increased public assistance expenditures (Bailey 2013, Bailey et al. 2016). Ultimately, unplanned pregnancy may limit the life opportunities for children, contributing to the cycle of poverty (Ananat and Hungerman 2012, Bailey et al. 2016).

Behavioral barriers such as inconsistent or inappropriate method use often result in contraceptive failures. Forty-one percent of unintended pregnancies occur among women who are using contraception in the month they become pregnant (Sonfield et al. 2014), suggesting that greater use of methods which do not require adherence (such as LARCs) may reduce high rates of unintended pregnancy. Although lack of provider training and contraceptive counseling are important barriers to increasing adoption of LARCs (Harper et al. 2015), financial barriers remain significant as LARCs have larger up-front costs compared to other reversible methods (Trussell 2011).

Financial barriers to contraceptive access are likely to become more salient in the near future. President Donald J. Trump and the Republican-controlled Congress have promised to pass sizable funding cuts for reproductive health services. These plans include cuts of public funds to organizations like Planned Parenthood (Republican Party 2016), which includes cutting both Title X funding as well as Planned Parenthood's ability to receive Medicaid funds. Second, proposed cuts to Medicaid (via block granting to states) are likely to cause significant cuts to reproductive health services for low income women. Both of these changes threaten to eliminate funding for the 8 million women currently served using public funds (Sonfield and Benson Gold 2012). In addition, changes to the Affordable Care Act (ACA) may increase financial burdens among women with private insurance for receiving family planning services and reduce

insurance coverage, thereby increasing the need for publicly-funded services as their funding is diminished.[1]

Observational evidence suggests that the elimination of public funding for family planning services would increase rates of unintended pregnancy in the U.S. by 68 percent (Frost et al. 2016) and that the public costs of these births would increase by 75 percent (Frost et al. 2014). Strong inferences about the policy effects of such cuts, however, are tempered by well-known limitations of observational evidence. The main critique of previous research is that it is *not based on a randomized control trial (RCT)*. In addition, research on the effects on children does not help understand the effects of affordable contraception on older children. M-CARES will provide novel experimental evidence to inform this policy discussion. M-CARES allows us to test some of these findings using the rigor of an RCT with highly reliable and *comprehensive* administrative data. Given the very important policy debate over the ACA's contraceptive mandate, we feel it is especially critical to quantify in the most rigorous way possible the effects of making contraception free to lower income women on their (1) own outcomes (e.g., education, work and career, public program benefit use, tax payments) as well as (2) their children's outcomes (e.g., education, child welfare, economic resources of parents). Previous research has tended to focus on contraceptive use and pregnancy. Our aim is to quantify how unintended childbirth and the intervention of making contraception affordable may affect many dimensions of women's lives as well as their families.

Moreover, the use of administrative data allows us to study the *long-term effects* of this intervention on the lives of women and their families. The benefit of using records over a long period of time is that we can document -- in an extremely comprehensive fashion -- the life-time effects of a simple (and fairly inexpensive) policy intervention. Evidence like this is crucial to informing the cost-benefit analyses regarding funding reproductive health care.

M-CARES can potentially provide a very large benefit to society and for public policy for providing new evidence on these questions. This document describes our aims, the data sources we wish to use, our security protocols for protecting these data, and our statistical methodology.

3. M-CARE Study Design and Inclusion Criteria

There are two groups of individuals who will participate in this research:

1. Recruits: These are the women who consent to be in the study and provide their consent to be interviewed in surveys and followed in administrative records. They will also be given the vouchers for contraception. Recruits will be studied to answer questions #1 and #2.
2. Children: These are the Children of Recruits. We ask the Recruits (the Children's mothers) for the names, dates of birth, and places of birth of their Children and Recruits' consent to link these Children to their administrative data. We do NOT survey Children or intervene with Children directly. We request a waiver of consent for the Children's inclusion in the study until the turn 18. At age 18, we will consent Children directly to continue participating in the study if we receive further funding. Children will be studied to answer questions #3.

The population of interest for Recruits are women at risk of unintended pregnancy in the U.S. For logistical reasons, M-CARES focuses on women in Michigan. Table 1 shows that Michigan women are very similar in their socio-demographic characteristics to women in the U.S. The one exception to this is that Michigan

[1] The ACA increased access to reliable contraceptives and family planning services for women with insurance, by increasing insurance coverage, requiring health insurance policies to cover family planning services, and reducing copays for these services (Frost et al. 2016).

has significantly fewer Latina residents. Michigan also falls around the national median of many key behaviors related to contraceptive use, such as cohabitation, marriage, age at first birth, nonmarital childbearing, and teenage childbearing (Lesthaeghe and Neidert 2006).

Table 1. Comparison of Women in Michigan to Women in the U.S. (excluding Michigan)

	U.S. women 18-35 years old		Michigan women 18-35 years old	
	Mean	S.D.	Mean	S.D.
White (non-Hispanic)	0.511	(0.500)	0.662	(0.473)
Black (non-Hispanic)	0.166	(0.372)	0.197	(0.398)
Hispanic	0.234	(0.423)	0.069	(0.253)
Married	0.268	(0.443)	0.246	(0.431)
High school graduate	0.877	(0.328)	0.905	(0.294)
College degree	0.310	(0.462)	0.295	(0.456)
Wage income ($2016)	15,120	(17,220)	13,932	(15,399)
Number of kids less than 5 years old	0.339	(0.633)	0.349	(0.652)

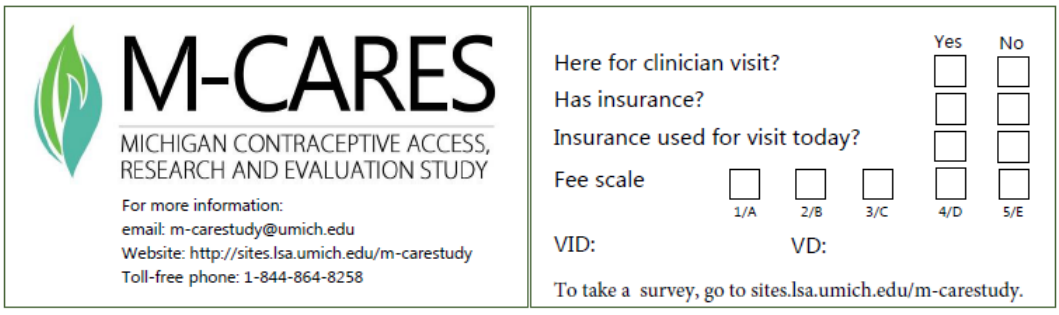
Source: 2015 American Community Survey. Sample: women ages 18-35 with family income ≤$80,000 in $2016.

A. Recruitment

We will recruit 5,500 women at PPMI clinics at 11 sites in Michigan. (We expect 5,000 of these women will be eligible to participate in the voucher component of the project.) Although our original proposal said SRO would conduct the analysis, we have decided to contract with NORC to do this recruitment. NORC is an internationally recognized firm in survey research and Randomized Control Trials. NORC will hire and train surveyors to recruit women in PPMI clinic waiting rooms.

At check-in at PPMI, all patients will receive a small business card with the relevant boxes checked (see uploaded business card in section 8-1.8, Figure 1). Per the surveyor oral script (uploaded section 8-1.8), NORC surveyors will ask each patient to show them the business card and if she'd like to participate in the study. Showing the business card to the surveyor avoids the need to have a conversation about private matters in a public waiting room. In the PPMI waiting room, the surveyor only confirms verbally that prospective subjects are between the ages of 18 and 35.

Figure 1. M-CARES Card Received at Check-in



B. Informed Consent

Provided the patient meets these criteria and agrees, an electronic tablet will walk each woman through the informed consent process with assistance from a professional survey worker as needed. She will be informed that, if she is eligible to participate in the voucher portion of the study, participation means that she agrees to:

(1). Be contacted to complete subsequent surveys;
(2). Consent to use her and her children's (current and future) administrative data (which requires providing private information such as name, date of birth, social security number (SSN), and contact information for Recruits and name, date of birth, and place of birth for children.

Enrollment will be conducted on the electronic tablet, which will encode consent responses. If a woman consents to participate, she becomes a Recruit. (See informed consent appended with this IRB.)

C. Inclusion Criteria

If the woman consents to participate, she becomes a "Recruit." She then takes a confidential survey 1 on a secure tablet which will not reveal her information to others in the waiting room or the surveyor. Subjects are advised that they can stop taking the survey at any time. Answers to the survey questions will determine if the Recruit meets the inclusion criteria for the voucher portion of the study, allow us to examine who selects to be in the voucher study, and maintains the Recruit's privacy. (See survey 1 appended to this IRB). We expect at least 90 percent of Recruits to be eligible.

Participating in the voucher portion of the study requires that the

1. Woman is between ages 18 and 35
2. Fee scale 2 to 5 (and family income>federal poverty line)
2. She is not pregnant and does not wish to become pregnant in the next 12 months,
3. She is at PPMI for a clinician visit;
4. She is able to and at risk of getting pregnant,
5. She has no insurance for her visit and, therefore, may have out-of-pocket costs for contraception.

We select women who are younger than 36 years old, because fertility declines rapidly with age so women over age 35 may not be as susceptible to unplanned pregnancy. Because our study cannot reduce financial barriers to contraception among women who do not have out-of-pocket costs for a PPMI visit, we limit our recruitment to women who have no insurance for contraceptive services and have family incomes over the poverty line and, therefore, would have some out-of-pocket under the PPMI payment model. We also limit our recruitment to women who will see a clinician at PPMI, because these are the PPMI patients who can use a voucher for contraception that same day. Clinician visits are the vast majority of PPMI patient visits, but typically exclude walk-ins and other non-contraception related visits. If a woman is ineligible to participate because she is not at PPMI for a clinician visit, she can schedule a clinician visit and return and enroll in the M-CARES at that time.

If a woman meets the inclusion criteria for participation in the voucher part of the study, she will be asked to provide personal identifying information (PII) such as name, SSN, date of birth, contact information as well as the names, dates of birth, and place of birth of her children (if she has any). (Note: We wait to collect PII until after survey 1 determines if the woman meets our inclusion criteria. We will not collect PII for women who do not meet these inclusion criteria.) We will also include her Children in the study by following them in administrative data.

To maintain the Recruit's privacy, all survey answers and personal identifying information can be entered directly into the tablet and the subject can ask the surveyor any questions.

In summary, we will recruit 5,500 women and we expect them to have around 2,500 children. In total, we will therefore have 8,000 study participants.

D. Intervention: Voucher Assignment

The intervention then begins. At the conclusion of the subject's enrollment, the tablet will randomize eligible Recruits to receive PPMI vouchers (which we call "PPMI gift cards") and, for women randomized to receive a voucher, display the dollar amount of the gift card and a voucher identification number (VID) on the tablet. The surveyor will write down the VID and the voucher amount (VD) on the business card and return the card to the woman. For Recruits who do not receive a voucher, the surveyor will only write down the VID on the business card. (We choose to use the cryptic abbreviation VD to minimize the disappointment of Recruits who are not selected to receive a voucher.) The VID will also allow the Recruit to log in to take a survey using study website.

Each eligible Recruit has an equal chance of receiving a voucher. Vouchers will be individually assigned and linked to name, birth date, and date of enrollment to prevent trading or giving away the vouchers. Vouchers can be used for *any* contraceptives and related services at PPMI for up to 100 days, and Recruits may return to the PPMI clinic multiple times to redeem them if desired.[2] The voucher amounts reflect the total out-of-pocket costs for an uninsured woman to have a Liletta IUD inserted after applying the PPMI the sliding scale (see Table 2). Liletta is the lowest cost IUD which costs $492, including insertion and the medically required pregnancy test, for patients with a fee scale of 5/E. Out-of-pocket costs for women without insurance and fee scale 2/B to 4/E are lower as indicated.

Although the voucher amounts are determined as the PPMI price for the Liletta, Recruits can use the voucher to purchase *any* type of contraceptives within 100 days. The voucher could, for instance, be used to select a more expensive IUD (e.g., the Mirena), but Recruits would pay out of pocket for the cost exceeding the voucher. The voucher could also be used for birth control pills, injections, hormonal patches, or any other kind of birth control (excluding abortion).

Table 2. Exact Voucher Amounts by Income Group and Voucher Category

Women's Income Group	PPMI Sliding Scale: % of Fee Charged	Randomly Assigned Voucher Amounts toward Remaining Out of Pocket Cost	
</= 100% FPL	0%	*No voucher assigned*	
101-150% FPL	25%	$0	$123
151-200% FPL	50%	$0	$246
201-250% FPL	75%	$0	$369
>/= 251% FPL	100%	$0	$492

Note: FPL=Federal Poverty Line.

In addition, the tablet will encourage Recruits to talk about the benefits and risks of each method with their health care providers. After this, the Recruit will proceed with her appointment as planned. There will be

[2] "Related services" are services medically required for the use of a specific contraceptive device. For an IUD, related services include a pregnancy test and insertion in addition to the device.

no intervention with Recruits outside the waiting room. All contraceptive decisions and discussions with health care providers will take place in the clinic after recruitment.

Following the Recruit's clinical visit, we will invite her to take a 25-minute baseline survey in the PPMI waiting room. We will offer the Recruit $60 cash to take the baseline survey in the clinic or $40 to take it online after she leaves the clinic. Over the 5 years following enrollment, we will ask the Recruits to take two more 30-minute surveys earning up to $50 for each one. We will also link Recruits and their Children to administrative records.

For Recruits not using any or all of their voucher dollars the first day, we will send reminders by email and text. The reminders will read, "Our records show that can still use $XXX of your gift card at Planned Parenthood for contraceptives. Call Planned Parenthood (XXX-XXX-XXXX) to make an appointment today. Use M-CARES VID number XXXX to use these funds." We will follow up by phone if they do not use their voucher.

4. Data Sources

A central contribution of our analysis is that a combination of survey data and administrative data provide complementary perspectives on how financial access to contraceptives shapes the lives of women and their children.

We include a summary of the data available from each data source here as well as a detailed description of the data sources and linking procedures.

A. Survey 1

Answers to its questions determine if a woman meets the inclusion criteria to participate in the voucher part of the study and also gather pre-randomization information. This information allows us to examine differences between the eligible and ineligible population as well as the correlates of study participation. In addition to the eligibility questions, it gathers socio-demographic characteristics (age, race, marital and cohabitation status, number of children, and education), information about the reason and payment for the PPMI visit, childbearing history, the use of contraceptives, and contraceptive method satisfaction.

B. Baseline Survey

The 25-minute baseline survey asks more detailed questions about how the participant used the voucher or, if she did not, why not; any changes in contraceptive use (or intent to change contraceptive use) since the screening survey; work and income; school enrollment; religion; birth and pregnancy history; birth control and healthcare access; plans for the future; childhood environment; attitudes and beliefs about contraception, relationship quality; and physical and mental health. Follow up surveys will be administered by internet (with email /text reminders) and, for non-respondents, follow ups will be by mail and phone. The baseline survey will be administered only to Recruits eligible to participate in the voucher part of the study.

C. Subsequent Surveys

We will also follow M-CARES participants in subsequent surveys currently scheduled for 2 years and 4 years after recruitment. These surveys will be designed to measure the long-term effects of this intervention in many dimensions and include many of the same questions as the baseline survey: attitudes about and use of reproductive health care; pregnancies (including plans and intentions) and their outcomes; physical health and health care use; educational attainment and labor-market outcomes; relationship quality; mental health and well-being; and participation in programs. We do not yet have follow-up surveys drafted,

because we are waiting on the year 1 results to inform their construction. We will submit them as amendments to this IRB once they are drafted.

These surveys will be broken into small pieces and rolled out over different times. Follow up surveys will be approximately 30 minutes in total and have reimbursements of up to $50 for completion. Follow up surveys will be administered by internet (with email /text reminders) and, for non-respondents, follow ups will be by mail and phone. As in the case of the baseline survey, follow-up surveys will be administered only to Recruits eligible to participate in the voucher part of the study.

D. Privacy

NORC maintains a strong reputation for complying with the requirements of state and federal data protection laws and regulations such as CIPSEA and the Privacy Act of 1974. NORC staff are required to complete annual trainings focused on data use agreements, ethical conduct, and data confidentiality. NORC has developed a detailed approach to maintaining data security and continues to bring its projects into compliance with systems security regulations including FISMA, NIST 800.53, and FIPS. Access to confidential data is restricted to authorized project personnel. Data is stored on the secured NORC network and is only exchanged via encrypted format. NORC facilities are also secured with keycard access required in addition to security cameras. The servers and wiring closets are placed in locked rooms which are only accessible to authorized staff via a security code. NORC will transfer the survey data to Michigan using a Secure File Transfer protocol.

To provide protections against subject identification, no listings or descriptions of individual cases will be printed or emailed. Only anonymized output will be suitable for printing, email, or publication. Examples of this include descriptive statistics and parameters from statistical regression models.

Individuals with access to M-CARES study data are called “approved personnel.” Approved personnel will be briefed on the license conditions and the data protection plan prior to receiving access to the restricted data and again annually each December for the duration of the project. Specifically, all approved personnel will agree to and sign a Data Use Agreement (appended with the security protocol).

Any potential breaches will be reported immediately.

E. Storing and Securing PII and Survey Data

The process of storing and analyzing survey data is intended to minimize the risk of unauthorized disclosure of sensitive information.

NORC collects consents and survey data on electronic tablets. NORC maintains a strong reputation for complying with the requirements of state and federal data protection laws and regulations such as CIPSEA and the Privacy Act of 1974. NORC staff are required to complete annual trainings focused on data use agreements, ethical conduct, and data confidentiality. NORC has developed a detailed approach to maintaining data security and continues to bring its projects into compliance with systems security regulations including FISMA, NIST 800.53, and FIPS. Access to confidential data is restricted to authorized project staff. Data is stored on the secured NORC network and is only exchanged via encrypted format. NORC facilities are also secured with keycard access required in addition to security cameras. The servers and wiring closets are placed in locked rooms which are only accessible to authorized staff via a security code. NORC will not analyze the data. NORC will retain collected consent and survey data for 7 years—this includes the 5 years of our study and an additional two years in case we obtain funding to conduct another survey. Back up tapes are destroyed after 7 years. NORC will not use these data for any purpose other than the proposed M-CARES research.

NORC will first collect the consents and survey data on electronic tablets. When tablets are at rest, they will be password protected. Only the trained surveyors can log in with a pin to initiate an interview. After the completion of a survey or after the tablet has been unused for 5 minutes, the tablet will require a log-in to continue the survey or initiate a new survey.

NORC takes device and application security very seriously. Device and software logins are designed to use a specifically encrypted challenge/response technology. All NORC devices and applications that manage case and response data protect against unauthorized access and restrict authorized access to the minimum necessary level. They administer least privilege, password protected access rights to safeguard PII and individual privacy information. There is also a time out security measure for sessions that are inactive for a given period of time. For their interviewing devices, NORC uses AirWatch technology, a multi-layered approach to data security that encrypts sensitive data and secures access to the user all the way to the network, including automatic revocation of access if compliance policies are violated or an employee leaves the company.

NORC will transfer the encrypted and password protected data to UM using secure file transfer protocol.

Once we receive the data from NORC, we will follow the general process as outlined in the "Diagram of Data" figure. When the survey data and consent forms are received from NORC, Bailey and Karimova will store surveys and consent forms (dataset 1 in "Diagram of Data", Figure 2) on M+Box in a file that is encrypted and password-protected and with access restricted only to Bailey and Karimova.

The first step in the data processing will be to replace individually identifying information on the surveys with coded identifiers. Working in a locked office, Bailey and Karimova will remove PII (names, SSNs, dates of birth, addresses, contact information, and social media information) from the records and add a numeric identification code, birth days (without the year), and broad geographic codes. The cross-walk dataset that links these codes to names will be stored in a separate password protected file on M+Box (see security protocol for additional details). Only Bailey and Karimova will have access to this crosswalk file and PII (dataset 2 in "Diagram of Data.") All analysis will be conducted with data that contains coded identifiers and other survey variables (dataset 3 in "Diagram of Data").

F. Administrative Data Linking

We will link M-CARES Recruits and Children to administrative records which are detailed in the next section.

We will link Recruits to (1) PPMI patient records; (2) credit reports; (3) tax data; (4) birth and death certificates; (5) Decennial Census, American Community Surveys (ACS), and Current Population Survey (CPS) Annual Social and Economic Supplement (ASEC); (6) Education data (K-college and National Student Clearinghouse, NSC); (7) program participation; (8) Michigan criminal justice records; (9) Michigan child welfare and justice records; (10) employment and earnings records; and (11) health insurance claims.

(Numbers correspond to numbering in the next section outlining the content of these records; see also discussion in section 24 of the IRB).

We will link Children to a subset of these records, including (4) birth and death certificates; (5) Decennial Census, ACS, and CPS-ASEC; (6) Education data (K-college and National Student Clearinghouse, NSC); (7) program participation; (9) Michigan child welfare and justice records; (10) employment and earnings records; and (11) health insurance claims.

The process of linking to these administrative files is intended to minimize the risk of unauthorized disclosure of sensitive information. Following the process laid out in in “Diagram of Data,” our linking process follows these steps.

From the survey file (dataset 1 in “Diagram of Data”) we will create an administrative data link file (“Admin Data Link”) for Recruits and Children and share this via encryted drive with agencies. For Recruits, the Admin Data Link file will include PII including full name, date of birth, address, and SSN in addition to a subset of variables from survey data, which we will call Z variables (dataset 4 in “Diagram of Data”). For Children, the Admin Data Link file will include PII including full name, date of birth, and place of birth in addition to a subset of variables from survey data, which we will call Z variables (dataset 6 in “Diagram of Data”).

These Z variables include information about whether the individual received a voucher and the voucher amount as well as a subset of answers to survey questions that allow us to construct covariates and conduct heterogeneity tests. To make sure that no sensitive information is revealed to agencies, the Z variables will be masked. The masking process will create generic labels for variable names and answers. For instance, a question like "how many children have you had?" will be stored under the variable name Q15 with numeric answers 0 to 20. The Admin Data Link will be stored in encrypted format on an encrypted drive to be shared with agencies who will link to administrative data.

Agencies will then link Recruits and Children to data, remove PII, and give the M-CARES team access to these administrative data with coded identifiers or statistical results. The process is similar for different agencies, but we outline specifics for each administrative dataset.

The result of this process is that the M-CARES team will have access to and analyze separate coded administrative data files for Recruits (datasets listed under 5 in “Diagram of Data”) and Children (datasets listed under 7 in “Diagram of Data”).

G. Details about Administrative Data Sources and Linking

This section describes the contents of these administrative data records and provides more linking and access details. This is also discussed in section 24 of the IRB.

Some agencies require that we have IRB approval in order to send us a data use agreement—even as an example. We have included as many as we have been able to secure. Once we receive IRB approval and initiate this process with agencies, we will update the IRB with any proposed modifications that are specific to certain agencies. We will also include updated data use agreements in section 24.

(1) PPMI Data

These records contain detailed information on Recruits’ socio-demographic information, physical health information, pregnancy and childbearing history, medical history, their PPMI visits (at all PPMI clinics), including the date of the visit, details on diagnoses and procedures and services provided, and payment method and payment amount. The method of payment for the services on the records allows us to identify the services obtained with the M-CARES voucher. We rely on these data in part to estimate how pregnancies, abortions, childbearing, and contraceptive use is affected by voucher receipt. We expect to link all Recruits to their PPMI records (going back to the date of participant’s first PPMI visit and up to 2023, the end of the study). The date of Recruit’s enrollment from survey 1 allows us to separate patient history data into pre- and post-intervention periods.

We will provide PPMI with the Admin Data Link File (dataset 4 in “Diagram of Data”). PPMI will use this information to locate Recruits’ patient records and will provide the M-CARES research team a coded set

of records using an encrypted drive (one of the datasets listed as 5-Agency). The codes corresponding to individuals will be determined by PPMI, so the codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

(2) Credit Reports

Recruits' credit records contain rich information on their credit history, including credit accounts' payment status, outstanding balance, credit limit, delinquency, and payment history. Based on results of previous work, we expect to link almost all M-CARES Recruits to credit records. We will use this data to study the impact of voucher assignment on financial security.

Credit data will be requested from Transunion and Equifax. We will provide Equifax and Transunion with an Admin Data Link File (dataset 4 in "Diagram of Data"). Equifax and Transunion will link the data, remove identifying information from the dataset and send the MCARES research team coded records using an encrypted drive (one of the datasets listed as 5-Agency in "Diagram of Data"). (This process is consistent with the Fair Credit Reporting Act). The codes corresponding to individuals will be determined by Transunion and Equifax independently, so these codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

(3) Tax records

Tax data will be used from both the Census Bureau and the OTA. These data allow us to link Recruits to the universe of all tax filers from 1996 to the present (end date will be updated as time moves forward). Tax data allow us to characterize tax filing, before and after the intervention, in terms of (1) living circumstances (living with parents, single headship, living with married or unmarried partner, etc.), (2) the number of children in household (and when they were born and age at first birth), (3) homeownership, and (4) neighborhood quality (an important metric for standard of living). In addition, tax data allow us to assess (5) college enrollment (via tax credits for these expenditures), (6) exact income from wage earnings in the household, (7) receipt/eligibility of the Earned Income Tax Credit, and (8) eligibility for other public assistance programs. Every M-CARES Recruit who files taxes can be linked to tax data.

For access to these records through OTA, we will provide OTA with the Admin Data Link file (dataset 4 in "Diagram of Data"), which will enable linking to codes called Personal Identification Keys (PIKs). Census will then provide access to M-CARES team to a coded (PIK'd) version of these data in the UM-RDC (dataset listed as 5-OTA in "Diagram of Data"). OTA will NOT provide the data to researchers outside of OTA. Instead, Elena Patel, OTA employee and M-CARES team member, will conduct analyses with these data at OTA. OTA will analyze these data and review them for confidentiality before disclosing descriptive statistics and regression output to the M-CARES team outside of OTA.

For data obtained through the Census Bureau, we will provide Census with the Admin Data Link File, which will enable the Census Bureau to link to PIKs. Census will then remove PII from the linked file and provide access to the PIK'd data file in the University of Michigan Research Data Center (UM-RDC). All data with PIKs can be linked together, but RDC data cannot be re-linked to individual PII or survey data. This would violate federal data confidentiality requirements. Moreover, Census data cannot be linked to administrative data sources from other agencies as other agencies use different coded identifiers. These data are listed a as 5-Census (for Recruits) and 7-Census (for Children) on "Diagram of Data."

The UM-RDC provides a very secure data-processing environment that is de jure part of the Census Bureau. The UM-RDC and the Census Bureau have very strict procedures for guaranteeing the confidentiality of the restricted data. The UM-RDC's data security plan has been reviewed and approved by the three

institutions. The track record of effectiveness of these data safeguarding measures is extremely high. All researchers using these data must also obtain special security clearance (SSS) from the Census Bureau. There are very strict Census Bureau guidelines about reporting results from analyses. The Census Bureau will review and approve all output to ensure that direct and indirect identification of individuals is not possible from disclosed output before it is removed from the UM-RDC.

(4) Birth and Death Certificates

These include birth and death certificates from the Michigan Department of Health and Human Services (MDHHS) and comparable agencies other states when applicable (this is only applicable in cases where, for example, if the birth of a child happens out of state).

Birth records contains the date of birth, including mother, infant, and father's personal identifying information (full name, date of birth, father social security number, address, race, education, and occupation); hospital; plurality; health conditions of the newborn; mother's health information, morbidity, and pregnancy risk factors; previous births and outcomes; onset of and characteristics of labor and method of delivery. They also contain information on source of payment for the birth.

Death records contain date of death, members of household, and cause of death.

We will provide Michigan Department of Health and Human Services (MDHHS) or comparable agency in other states) with the Admin Data Link File (datasets 4 and 6 in "Diagram of Data"), which allows MDHHS to locate birth and death certificates of Recruits and their Children. We expect to find approximately 77 percent of Recruits and 90 percent of their Children in these data. MDHHS will link the data, remove PII and replace with codes, and send the M-CARES research team a coded set of records using an encrypted drive (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data"). The codes corresponding to individuals will be determined by MDHHS independently, so these codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

(5) Decennial Census, American Community Survey (ACS), Current Population Survey (CPS) Annual Social and Economic Supplement (ASEC)

The 2000, 2010, 2020 (expected), and 2030 (expected) Censuses contain the data compiled from the questions asked of all people in every housing unit in the U.S. This includes a detailed enumeration of everyone in the U.S. population by sex, age, race or Hispanic or Latino origin. In addition, variables indicating relationship to household head and marital status allow us to characterize all children living in the household and sub-family. Available census variables allow us to characterize every Recruit, before and after the intervention, in terms of the following characteristics: (1) living circumstances (living with parents, single headship, living with married or unmarried partner, etc.), (2) the number of children in household (and when they were born and age at first birth), (3) renter/owner status, (4) incarceration status, and (5) neighborhood quality (an important metric for standard of living). Additionally, we can identify these outcomes for race/ethnicity subgroups. As long as the Children were alive, we also expect to link them to these records.

ACS and CPS ASEC data will contain information for a random sample of M-CARES Recruits and their Children. If the sample overlap is large enough, we will use these records as a supplement to the Census. These surveys allows us to characterize Recruits and their Children in a similar way as the Census, but on a more frequent or updated basis.

For data obtained through the Census Bureau, we will provide Census with the Admin Data Link File, which will enable the Census Bureau to link to PIKs. Census will then remove PII from the linked file and provide access to the PIK'd data file in the University of Michigan Research Data Center (UM-RDC). All data with PIKs can be linked together, but RDC data cannot be re-linked to individual PII or survey data. This would violate federal data confidentiality requirements. Moreover, Census data cannot be linked to administrative data sources from other agencies as other agencies use different coded identifiers. These data are listed a as 5-Census (for Recruits) and 7-Census (for Children) on "Diagram of Data." See also previous discussion of the UM-RDC.

(6) Education records

We will use two types of administrative sources for education data, the National Student Clearinghouse (NSC) and Michigan education data (K-college).

The National Student Clearinghouse (NSC) was originally was tied to the student loan industry and gathered enrollment data from participating colleges. The purpose of the database was to allow the loan industry to confirm that a borrower was enrolled and therefore eligible to defer repayment of student loans. Consistent with this history, the NSC today tracks enrollment (but not credits or major) and whether a student has graduated and degree earned. As of 2012, the NSC started using the Classification of Instructional Programs to record a student's major (http://nces.ed.gov/ipeds/cipcode/).

To access these data, we will send NSC the Admin Data Link file (datasets 4 and 6 in "Diagram of Data"). NSC will link the data, remove PII from the dataset, and send the MCARES research team a coded set of records using an encrypted drive (datasets listed as 5-Agency and 7-Agency in "Diagram of Data"). The codes corresponding to individuals will be determined by NSC, so the codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

To supplement NSC data, we will link our Recruits and their Children to Michigan public education data. We will not be able to link Recruits of their Children who obtained education outside of the state. Michigan public education data contain administrative school records, which report school attendance, promotion to the next grade, grades, and graduation date.

To access these data, we will send school districts the Admin Data Link file (datasets 4 and 6 in "Diagram of Data"). School districts will link the data, remove identifying information from the dataset, and send the M-CARES research team a coded set of records using an encrypted drive (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data"). The codes corresponding to individuals will be determined by school districts independently, so these codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

(7) Program participation

These records include Supplemental Nutritional Assistance Program (SNAP), Temporary Assistance for Needy Families (TANF), and Medicaid MSIS and Medicaid T-MSIS. They are located at the Census Bureau and at OTA. They will be linked to M-CARES Recruits of their Children using the same process as described for OTA and Census data.

For access to these records through the Census and OTA, we will provide Census with the Admin Data Link file (datasets 4 and 6 in "Diagram of Data"), which will enable linking to PIKs. Census will then provide access to M-CARES team to a coded (PIK'd) version of these data in the UM-RDC (datasets listed as 5-Census, 5-OTA, 7-Census, 7-OTA in "Diagram of Data"). See also previous discussion of the UM-RDC. OTA will NOT provide the data to researchers outside of OTA. Instead, Elena Patel, OTA employee

and M-CARES team member, will conduct analyses with these data at OTA. OTA will analyze these data and review them for confidentiality before disclosing descriptive statistics and regression output to the M-CARES team outside of OTA.

(8) Michigan criminal justice records

These data track an individual on a quarterly basis, collecting information their arrests, prison entries, and incarceration status (these data are not state-specific and include records from all contributing data providers). Beginning summer 2018, these records will be available in the UM-RDC.

These records will be linked using the same process as described for other Census Data. We will provide Census with the Admin Data Link file (dataset 4 in "Diagram of Data"), which will enable linking to PIKs. Census will then provide access to M-CARES team to a coded (PIK'd) version of these data in the UM-RDC (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data"). All data with PIKs can be linked together, but RDC data cannot be re-linked to individual PII or survey data. This would violate federal data confidentiality requirements. Moreover, Census data cannot be linked to administrative data sources from other agencies as other agencies use different coded identifiers. See also previous discussion of the UM-RDC.

(9) Michigan child welfare and justice records

These data contain information on the name and date of birth of children in state records containing allegations of abuse/neglect and foster care placements and official delinquency petitions for the State of Michigan.

We will send Michigan Child and Adolescent Data Lab (MCAD, housed at the University of Michigan, School of Social Work: http://ssw-datalab.org/about/) the Admin Data Link file. We will send MCAD the Admin Data Link file (datasets 4 and 6 in "Diagram of Data"), and MCAD will link the data, remove PII from the dataset, and send the M-CARES research team a coded set of records using an encrypted drive (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data"). (This process is consistent with their agreement with the State of Michigan.) The codes corresponding to individuals will be determined by MCAD independently, so the codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

(10) Employment and Earnings Records

Although these records are not yet available from the State of Michigan or federal government, we have included them in our consent. Because we expect them to become available in the near future, we have, therefore, included them in our consent. These records include information on quarterly earnings, employment, unemployment benefits, taxes paid by the employee and the employer(s) to the state, income from different sources, disability income, and the number of different employer(s). These records may become available through OTA, the Census Bureau, or through the State of Michigan directly. Depending upon how these records become available, we will follow either the OTA, Census Bureau, or agency protocols laid out above and in our Diagram of Data for linking and storing these data.

(11) Health Insurance Claims

Although these records are not yet available, they are being assembled through a project at the University of Michigan. Because we expect them to become available in the near future, we have, therefore, included them in our consent. These records include information such as the date of a visit to a service provider, service provider, services obtained, payment methods and amounts, the name of the clinic, medical and

physical diagnosis codes. Depending upon how these records become available and the Data Use Agreements that govern their use, we submit an amendment to the IRB and follow the protocols laid out here for agency data for linking them and storing these data.

5. Statistical Design

Our study is interested in how increasing the affordability to contraceptives affects outcomes. Let Y_i be an outcome in for individual, i. We estimate both the reduced-form effects and the two-stage least squares estimates of receiving a voucher for contraceptives. The reduced-form equation is

$$Y_i = \tau Voucher_i + \boldsymbol{X}_i'\boldsymbol{\beta_1} + \gamma_c + \varepsilon_{1i}, \quad (1)$$

where $Voucher_i$ is a binary variable equal to 1 if an individual i is selected to receive a voucher and 0 otherwise; $\boldsymbol{X}_i$ is a set of exogenous covariates; γ_c is a set of clinic fixed effects which will absorb between-clinic variation in physician recommendations, availability of appointments, and unobserved characteristics of patients; and ε_{1i} is the error term.

The main coefficient of interest, τ, often called the "intention-to-treat" (ITT) estimate, captures the average difference in means in an outcome between the treatment group (individuals randomly selected to receive a voucher) and the control group (individuals not selected to receive a voucher). The ITT estimate answers the policy question: what is the net, causal effect of reducing out-of-pocket costs for contraceptives (capped at the cost of a generic IUD) to zero for women seeking reproductive health care on outcomes?

Another relevant policy question is: what is the causal effect of increasing the efficacy of contraceptives that women use? The answer to this question differs from the ITT estimate for several reasons. First, not all women offered a voucher will alter the efficacy of their contraceptive methods. Second, even if a woman switches to a more effective method initially, she may not remain on a more effective method for the duration of our study.[3] In addition, some women who switch to more effective methods would have done so even without the voucher. Finally, women in our control group may switch to more effective contraceptives without receiving a voucher.

We, therefore, estimate the effect of increasing access to contraceptives within the following two-equation model, where the first-stage equation is

$$Contraceptive\ Efficacy_i = \pi_1 Voucher_i + \mathbf{X}_i'\pi_2 + \gamma_c + \varepsilon_{2i}, \quad (2)$$

and the second-stage equation is

$$Y_i = \delta_1 Contraceptive\ Efficacy_i + \mathbf{X}_i'\delta_2 + \gamma_c + \varepsilon_{3i}. \quad (3)$$

Estimating this model using two-stage least squares (2SLS), the estimate of δ_1 is given by the ratio of the reduced form and first stage coefficients (τ / π_1).

In the absence of an experiment, we expect that contraceptive use and outcomes are correlated with unobservable factors, which render OLS estimates of δ_1 biased and inconsistent. Direct comparisons between women who use more effective methods and those who do not may capture a variety of differences between the groups. For instance, more career-interested women with higher expected wage growth and may desire fewer children and also be more likely to use more effective contraceptives. Therefore, comparing the wages of women using more effective contraceptives with those of women using other methods may conflate differences in women's career investments with the effect of more reliable

[3] One study found that around 7 percent of nulliparious women who selected IUDs had them removed (Brockmeyer et al. 2008).

contraceptives.). The advantage of randomizing $Voucher_i$ breaks this endogeneity and provides a valid instrument for $Contraceptive\ Efficacy_i$.

The causal interpretation of the 2SLS estimate turns on two main identifying assumptions: financial barriers (i.e., out-of-pocket costs) are both (1) relevant to women's decisions about which contraceptive method to use and that (2) voucher assignment is exogenous and excludable. This study is premised on assumption (1) that financial barriers matter, which is born out of a variety of studies regarding the determinants of heath care utilization (see Finkelstein et al. (2012) for an overview). Moreover, the randomization in the study ensures that the exogenous assignment of vouchers in (2) is met.

Excludability is more difficult to test and requires that receiving a voucher for contraceptives have an effect on outcomes *only* by increasing the efficacy of contraceptives. This assumption seems plausible as the voucher can only be used for contraceptives at PPMI. Moreover, women in both the treatment and control groups receive cash benefits for completing the screening and baseline surveys, implying that the effects of these cash benefits should be the same in the two groups.

One alternative channel could be that vouchers increase spending on other categories for women already intending to purchase an expensive contraceptive method on the day they enroll in M-CARES. For these women, the voucher would act as a cash transfer, allowing the women to spend money saved for contraceptives on something besides contraceptives in the short term (e.g., her credit card payment or rent). To examine the empirical importance of this channel, we ask women on survey 1 about the reason for their PPMI visit and which method they plan to get that day. We will also examine whether a woman's total debt (as measured on her credit reports) is reduced in the month she enrolls in the intervention for women who had already planned to get an expensive contraceptive. These analyses may suggest adjustments to the analysis if there is a quantitatively important violation of the exclusion restriction.

It is possible that receiving a voucher can have other effects on outcomes (e.g., a voucher can imbue a recipient with a positive or optimistic feeling), but it seems unlikely that this indirect effect would influence outcomes in multiple domains over the many years in the study.

Under these assumptions, we interpret the 2SLS estimate as the local average treatment effect, or LATE (Imbens and Angrist 1994). The 2SLS estimate, δ_1, identifies the causal effect of contraceptive efficacy among the women who shift the efficacy of their contraceptives after receiving a voucher and who would not have shifted their contraceptive efficacy without the voucher.

We will estimate heteroskedasticity-robust Huber-White standard errors for all analyses (Huber 1967, White 1980). In models that consider the evolution of outcomes across time, we will additionally cluster standard errors at the level of an individual participant.

6. Qualifications of the Research Team

Martha Bailey (Professor of Economics and Research Professor, Population Studies Center) is the PI of the project. Bailey has authored multiple articles on the effects of contraceptive access on women's lives, childbearing, and the economy and brings internationally recognized expertise in demography, economics, econometrics, and reproductive health policy. As PI of several NIH and NSF funded initiatives, she has rich experience managing large and interdisciplinary projects.

Bailey has also recruited a team of experts to the M-CARE study, including

1. Dr. Vanessa Dalton (M.D. specializing in Obstetrics and Gynecology and Medical Director of Planned Parenthood of Michigan, PPMI),

2. Prof. Jennifer Barber (Associate Director of the Population Studies Center, and Professor of Sociology at the University of Michigan; expert in fertility decisions and survey research),

3. Prof. Daniel Eisenberg (Professor of Health Policy and Management, University of Michigan; PI of the national Healthy Minds Study and national expert in mental health), and

4. Alfia Karimova is an Assistant Research Scientist at the PSC. She recently completed a Ph.D. at the University of Toronto and has expertise in demographic and health policy.

There are two researchers external to the University of Michigan (UM) who will be engaged in this research by virtue of conducting analysis and co-authoring papers with the study team. We request that UM provide oversight for their activities. (They will complete the required paperwork after the IRB approves the study.)

1. Elena Patel works at the Office of Tax Analysis and is an expert in the use of U.S. tax records. Elena has access to identifiable data by virtue of her job at the Census Bureau. Elena will participate in this project by conducting analyses with tax records with coded identifiers and co-authoring papers.

2. Katie Genadek is a U.S. Census Bureau employee and health and labor economist. She has expertise in working with restricted Census information and will be instrumental in conducting analyses with these records. Katie has access to identifiable data by virtue of her job at the Census Bureau. Katie will participate in this project by conducting analyses with administrative data using coded identifiers and co-authoring papers.

Finally, NORC at the University of Chicago has partnered with us to conduct the survey research. NORC is an internationally recognized firm in survey research and Randomized Control Trials. NORC will hire and train surveyors to recruit women in PPMI clinic waiting rooms. NORC's IRB will provide oversight for their activities.

In addition, we have advisors on this project who will not be engaged via recruitment, have access to identifiable or coded data, or conduct analyses of coded data. However, these advisors will frequently discuss the project with the project team:

1. Julia Kohn of Planned Parenthood will serve as a senior advisor to this project. Julia has access to identifiable data by virtue of her job at the Planned Parenthood.

2. The PPMI affiliate (has committed to supporting and participating in this study and has close ties with the University of Michigan where other researchers in reproductive health work and collaborate. We have uploaded a letter of collaboration with this proposal.

7. References

Ananat, E. O. and D. Hungerman (2012). "The power of The pill for The next generation: Oral contraception's effects On fertility, abortion, And maternal And child characteristics." Review of Economics and Statistics 94(1): 37-51.

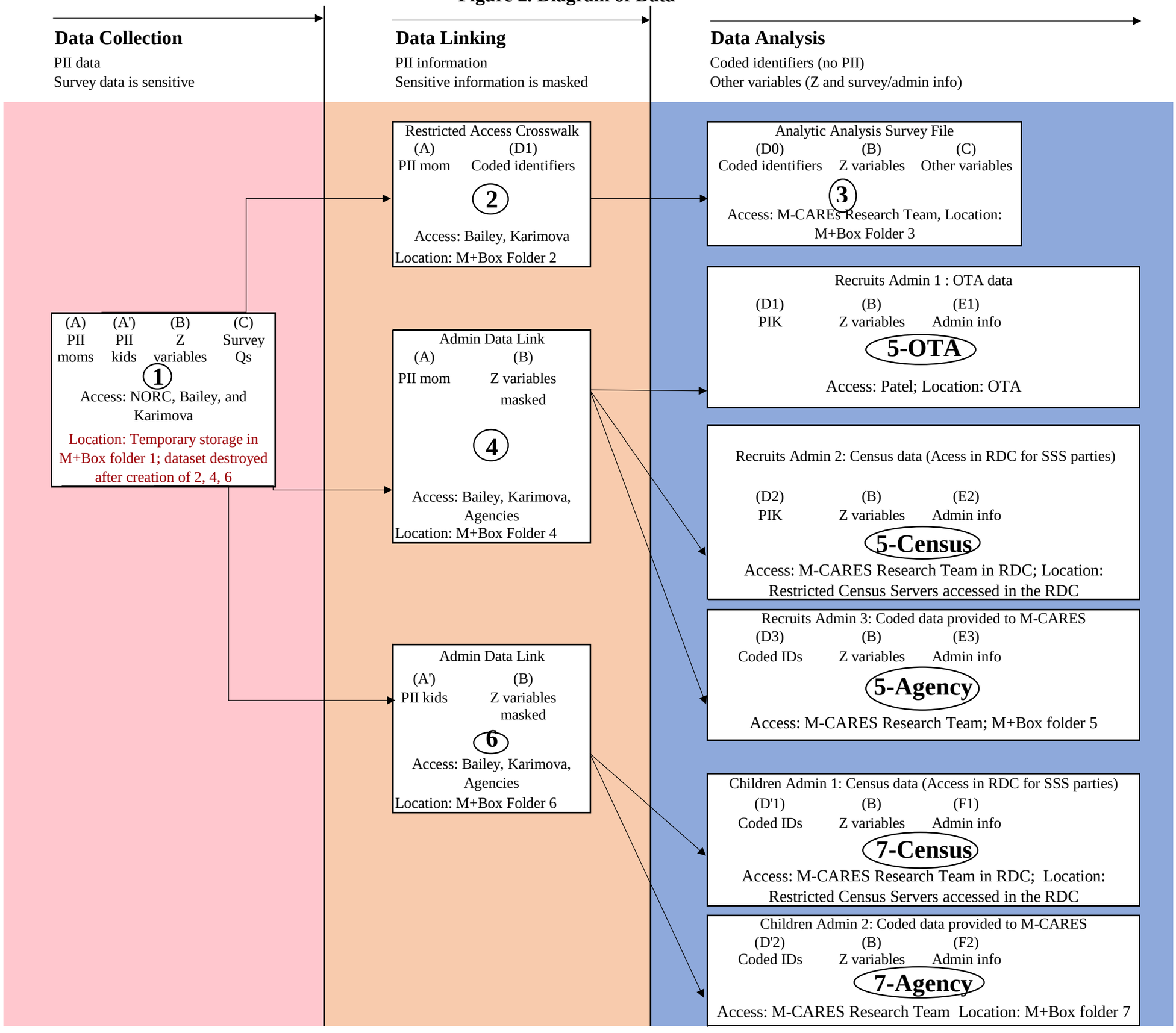
Ashenfelter, O. and M. W. Plant (1990). "Nonparametric Estimates of the Labor-Supply Effects of Negative Income Tax Programs." Journal of Labor Economics 8(1): S396-S415.

Bailey, M. J. (2013). "Fifty Years of U.S. Family Planning: New Evidence on the Long-Run Effects of Increasing Access to Contraception." Brookings Papers on Economic Activity Spring: 341-409.

Bailey, M. J. (2006). "More Power to the Pill: The Impact of Contraceptive Freedom on Women's Lifecycle Labor Supply." Quarterly Journal of Economics 121(1): 289-320.

Bailey, M. J., B. J. Hershbein and A. R. Miller (2012). "The Opt-in Revolution? Contraception and the Gender Gap in Wages." American Economic Journal: Applied Economics 4(3): 225-254.
Bailey, M. J., O. Malkova and Z. McLaren (2016). "Do Family Planning Programs Increase Children's Opportunities? Evidence from the War on Poverty and the Early Years of Title X." Retrieved June 13, 2016. Available at http://www-personal.umich.edu/~baileymj/Bailey_Malkova_McLaren.pdf.
Bound, J., C. Brown and N. Mathiowetz, Eds. (2001). Measurement Error in Survey Data. Handbook of Econometrics. Amsterdam: Elsevier.
Brockmeyer, A., M. Kishen and A. Webb (2008). "Experience of Iud/Ius Insertions and Clinical Performance in Nulliparous Women–a Pilot Study." The European Journal of Contraception & Reproductive Health Care 13(3): 248-254.
Finer, L. B. and M. R. Zolna (2016). "Declines in Unintended Pregnancy in the United States, 2008–2011." New England Journal of Medicine 374(9): 843-852.
Finkelstein, A., S. Taubman, B. Wright, M. Bernstein, J. Gruber, J. P. Newhouse, H. Allen and K. Baicker (2012). "The Oregon Health Insurance Experiment: Evidence from the First Year." The Quarterly Journal of Economics 127(3): 1057-1106.
Frost, J. J., L. Frohwirth and M. R. Zolna (2016). "Contraceptive Needs and Services, 2014 Update." Retrieved 1/4/2017. Available at https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.
Frost, J. J., A. Sonnfield, M. R. Zolna and L. B. Finer (2014). "Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the Us Publicly Funded Family Planning Program." Milbank Quarterly.
Goldin, C. and L. F. Katz (2002). "The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions." Journal of Political Economy 110(4): 730-770.
Harper, C. C., C. H. Rocca, K. M. Thompson, J. Morfesis, S. Goodman, P. D. Darney, C. L. Westoff and J. J. Speidel (2015). "Reductions in Pregnancy Rates in the USA with Long-Acting Reversible Contraception: A Cluster Randomised Trial." The Lancet 386(9993): 562-568.
Hock, H. (2008). "The Pill and the College Attainment of American Women and Men." Retrieved September 14, 2016. Available at ftp://econpapers.fsu.edu/RePEc/fsu/wpaper/wp2007_10_01.pdf.
Huber, P. J. (1967). "The Behavior of Maximum Likelihood Estimates under Nonstandard Conditions." Proceedings of the Fifth Berkeley Symposium on Mathematical Statistics and Probability. 1: 221–233.
Imbens, G. W. and J. D. Angrist (1994). "Identification and Estimation of Local Average Treatment Effects." Econometrica 62(2): 467-475.
Lesthaeghe, R. J. and L. Neidert (2006). "The Second Demographic Transition in the United States: Exception or Textbook Example? ." Population and Development Review 32(4): 669-698.
Republican Party (2016). "Republican Platform 2016." Retrieved 1/4/2017. Available at https://prod-static-ngop-pbl.s3.amazonaws.com/media/documents/DRAFT_12_FINAL%5B1%5D-ben_1468872234.pdf.
Sedgh, G., S. Singh and R. Hussain (2014). "Intended and Unintended Pregnancies Worldwide in 2012 and Recent Trends." Studies in family planning 45(3): 301-314.
Sonfield, A. and R. Benson Gold (2012). "Public Funding for Family Planning, Sterilization and Abortion Services, Fy 1980–2010." Retrieved 1/4/2017. Available at https://www.guttmacher.org/sites/default/files/report_pdf/public-funding-fp-2010.pdf.
Sonfield, A., K. Hasstedt and R. B. Gold (2014). "Moving Forward: Family Planning in the Era of Health Reform." Retrieved January 26, 2017. Available at https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.
Sonnfield, A. and K. Kost (2015). "Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010." Retrieved January 20, 2017. Available at http://www.guttmacher.org/pubs/public-costs-of-UP-2010.pdf.
Trussell, J. (2011). "Contraceptive Failure in the United States." Contraception 83(5): 397-404.
White, H. (1980). "A Heteroskedasticity-Consistent Covariance Matrix Estimator and a Direct Test for Heteroskedasticity." Econometrica 48: 817–830.

Figure 2. Diagram of Data



Data Use Agreement

This data use agreement (the "Agreement") is by and between the **Washtenaw Intermediate School District** (the "Provider") and the Regents of the University of Michigan, a Michigan constitutional corporation with its principal place of business in Ann Arbor, Michigan ("User") and is effective as of the date of the last signature affixed below (the "Effective Date").

WHEREAS, The Provider maintains certain information that User wishes to use and/or disclose for research, public health, or other purposes:

NOW, THEREFORE, the parties, in consideration of the mutual promises and obligations set forth herein, the sufficiency of which is hereby acknowledged, and intending to be legally bound, agree as follows:

1. The Provider shall provide User with access to **administrative school records including demographic data, school attendance, promotion to the next grade, grades, and graduation date** (the "Data") in accordance with the terms and conditions of this Agreement.
2. User share only provide access to the Data to any employee who has a need to know for completion of the Purposes (the "Authorized Parties"), which are authorized to use the Data or any part of it on behalf of User and have been made aware of and read the terms of this Agreement:
3. User, and any Authorized Party of User's behalf, may use the Data only for the purposes of research related to the evaluation of the effectiveness of the **UM M-CARES** (the "Purpose").
4. User agrees as follows:
    a. The transfer of the Data to the User grants to the User no rights in the Data other than those specifically set forth in this Agreement.
    b. Not to use or further disclose the Data or any information contained therein other than as necessary for the Purpose as permitted by this Agreement or required by applicable law.
    c. To use appropriate technical, administrative, and procedural safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement.
    d. To report to the Provider within five (5) days any use or disclosure of the Data or any part of it not provided for by this Agreement of which User or any Authorized Party becomes aware.
    e. To ensure that any agents, including subcontractors, to whom User or an Authorized Party provides the Data or any part of it to agree to the same restrictions and conditions that apply to the User and Authorized Parties under this Agreement.
    f. Not to use the information contained in the Data to contact the individual whose information is contained in the data under any circumstance.
    g. To return or destroy the Data at the completion of the Purpose identified above in section 3.
    h. To provide a copy of any publication or public release from the course and performance of the Purpose under this Agreement to Provider not less than twenty (20) days prior to the date of release for Provider to review and comment on such publication.
5. This Agreement shall begin as of the Effective Date and conclude when Data have been destroyed or returned per section 4 (g), above.
6. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employee, officers, or directors to the extent permitted by law.
7. In the event Provider becomes aware of any use of the Data or any part of it that is not authorized under this Agreement or required by applicable law, Provider may terminate this Agreement upon notice.

WHEREFORE, the parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement.

THE REGENTS OF THE UNIVERSITY OF MICHIGAN PROVIDER

Signature: _____ Signature: _____

Name (Printed): _____ Name (Printed): _____

Title: _____ Title: _____

Date: _____ Date: _____

LIMITED DATA USE AGREEMENT

THIS AGREEMENT is entered into on this ____ day of _____, 20__, by and between [name of affiliate] _____, located at [address] _____ (herein after "Covered Entity") and [name of recipient] _____, located at [address] _____ (herein after "Recipient")(collectively the "Parties").

WHEREAS, Covered Entity will make available and/or transfer to Recipient information contained in a Limited Data Set for purposes of Research, Public Health or Healthcare Operations.

WHEREAS, The information in this Limited Data Set is confidential and afforded special treatment and protection under the Privacy Regulation.

WHEREAS, Recipient agrees that it will use and disclose the Limited Data Set according to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, Covered Entity and Recipient agree as follows:

I. Definitions

The following terms shall have the meaning ascribed to them in this Section. Other capitalized terms shall have the meaning ascribed to them in the context in which they first appear. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Rule.

(a) Agreement. "Agreement" refers to this Limited Data Use agreement between the Parties. This Agreement contains the mandatory requirements of a Limited Data Use agreement found at 45 CFR 164.512(e)(4).

(c) Covered Entity. "Covered Entity" shall have the same meaning as the term "Covered Entity" in 45 CFR 164.501 and, in this Agreement, shall also refer to [name of affiliate].

(d) Healthcare Operations. "Healthcare Operations" shall have the same meaning as the term "Healthcare Operations" in 45 CFR 164.501.

(e) Individual. "Individual" shall have the same meaning as the term "individual" in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

(f) Limited Data Set. "Limited Data Set" shall mean Protected Health Information that excludes the following direct identifiers of the Individual or of relatives, employers, or household members of the Individual: 1) Name; 2) Postal address information, other than town, city, State or zip code; 3) Telephone numbers; 4) Fax numbers; 5) Electronic mail addresses;

6) Social security numbers; 7) Medical record numbers; 8) Health plan beneficiary numbers; 9) Account numbers; 10) Certificate/license numbers; 11) Vehicle identifiers and serial numbers, including license plates; 12) Device identifiers and serial numbers; 13) Web Universal Resource Locators ("URLs"); 14) Internet Protocol ("IP") address numbers; 15) Biometric identifiers, including finger and voice prints; and 16) Full-face photographic images and comparable images. *See* 45 CFR 164.512(e)(2).

(g) Privacy Rule. "Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.

(h) Protected Health Information or PHI. "Protected Health Information" or "PHI" shall have the same meaning as the term "Protected Health Information" in 45 CFR 164.501, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

(i) Public Health. "Public Health" shall have the same meaning as the term "Public Health Activities" in 45 CFR 164.512(b).

(j) Research. "Research" shall have the same meaning as the term "research" in 45 CFR 164.501.

(k) Required By Law. "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR 164.501.

(l) Secretary. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his/her designee.

II. Permitted Uses and Disclosures by Recipient

Recipient is authorized to use information in the Limited Data Set only for Research, Public Health or Healthcare Operations purposes, as follows: [describe the uses]

_____
_____
_____

III. Persons Permitted To Uses And Receive The Limited Data Sets

Recipient agrees that the following persons only shall be permitted to use or receive information in the Limited Data Set: [fill-in name of individual(s)]

_____
_____
_____

IV. Obligations Of Recipient

(a) Recipient agrees not to use or further disclose any information in the Limited Data Set other than as permitted by this Agreement or as otherwise Required By Law.

(b) Recipient agrees to use appropriate safeguards to prevent any use or disclosure of information in the Limited Data Set not expressly permitted in this Agreement.

(c) Recipient agrees to report to Covered Entity any use or disclosure of information from the Limited Data Set not provided for in this Agreement and that Recipient becomes aware of.

(d) Recipient agrees to ensure that its agents, including any subcontractors to whom Recipient provides information from the Limited Data Set, abide by the same restrictions and conditions that apply to the Recipient under this Agreement.

(e) Recipient agrees that it will not attempt to identify or contact any Individuals from the information contained in the Limited Data Set.

IN WITNESS WHEREOF, Covered Entity and Recipient have caused this Agreement to be signed and delivered by their duly authorized representatives, as of the date set forth below.

COVERED ENTITY	**RECIPIENT**
By:_____	**By:**_____
Print Name:_____	**Print Name:**_____
Title:_____	**Title:**_____
Date: _____	**Date:** _____

Christopher Bergtold <bergtold@umich.edu>

10:43 AM (1 hour ago)

to Martha, me, Stephanie

Thanks Martha! As discussed, the only payments that should be processed through our office are the incentives, as the university will have tax reporting obligations related to these payments. Each individual has the potential to earn a maximum of $70 in a calendar year. This would fall into a Tier 1 and we would only need the name and address information for those that receive payment. As I mentioned on the phone, these incentive payments are considered taxable income and participants are still required to self report this as non-employment earnings on their taxes. In terms of the language you should use in your consent form regarding potential tax implications, please work with the IRB to determine what is most appropriate. As the IRB has determined the "credit" constitutes an intervention rather than an incentive, these payments should NOT come through the HSIP office. I would recommend connecting with the IRB to determine if there is anything you will need to do for those that do receive the intervention. Please let me know if you need any additional information! Thanks, Chris

UNIVERSITY OF MICHIGAN
eResearch.umich.edu

Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS) • 2800 Plymouth Rd., Building 520, Room 1170, Ann Arbor, MI 48109-2800 • phone (734) 936-0933 • fax (734) 998-9171 • irbhsbs@umich.edu

To: Dr. Martha Bailey

From:

Thad Polk

Cc:

Alfia	Karimova
Stephanie	Hart
Elena	Patel
Katie	Genadek
Martha	Bailey
Jennifer	Barber
Vanessa	Dalton
Daniel	Eisenberg

Subject: Initial Study Approval for [HUM00132909]

SUBMISSION INFORMATION:
Study Title: The Michigan Contraceptive Access, Research, and Evaluation Study (M-CARES)
Full Study Title (if applicable):
Study eResearch ID: HUM00132909
Date of this Notification from IRB: 4/23/2018
Review: Full Committee
Initial IRB Approval Date: 12/21/2017
Current IRB Approval Period: **12/21/2017 - 12/20/2018**
Expiration Date:Approval for this expires at **11:59 p.m. on 12/20/2018**
UM Federalwide Assurance (FWA): FWA00004969 (For the current FWA expiration date, please visit the UM HRPP Webpage)
OHRP IRB Registration Number(s): IRB00000245

Approved Risk Level(s):

Name	Risk Level
HUM00132909	No more than minimal risk

NOTICE OF IRB APPROVAL AND CONDITIONS:
The IRB HSBS has reviewed and approved the study referenced above. The IRB determined that the proposed research conforms with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

APPROVAL PERIOD AND EXPIRATION:
The approval period for this study is listed above. Please note the expiration date. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-

established, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

APPROVED STUDY DOCUMENTS:
You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the "Currently Approved Documents" section on the "Documents" tab.

RENEWAL/TERMINATION:
At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

AMENDMENTS:
All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:
You must inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or others.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-and-other-required-reporting), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate hazards to the subject, implement the change and report via an ORIO and/or amendment submission within 7 days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

SUBMITTING VIA eRESEARCH:
You can access the online forms for continuing review, amendments, and AEs/ORIOs in the eResearch workspace for this approved study (referenced above).

MORE INFORMATION:
You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: http://research-compliance.umich.edu/human-subjects.

Thad A. Polk

Thad Polk
Chair, IRB HSBS

Frequently Asked Questions about M-CARES

Why am I not eligible to be in this study?

Only women ages 18 to 35 who are at risk of getting pregnant, who want to avoid getting pregnant, and who face out-of-pocket costs for contraceptives at PPMI are eligible for the study.

Will participating take a lot of my time?

The first survey will take about 25 minutes to complete, and the second and the third surveys will take about 30 minutes each. We will use your personal information (name, date of birth, contact information, and social security number) to access your administrative records and save you time filling out surveys.

Who will see the information I provide for this study?

Your privacy is very important to M-CARES. We will keep your personal information, survey responses, and administrative records completely confidential. All of your responses will be encrypted and stored on password-protected computers. We plan to publish the results of this study, but we will not publish any information that would identify you or a family member.

Why didn't I get a gift card for contraception?

We know money for contraception can be very important, and that is why we are doing this study. Even if you don't get a gift card, you can still earn up to $170 by participating in the study and completing surveys. We will ask you some questions to determine if you are eligible for a gift card to be used for any contraceptives at PPMI. Half of the those eligible will get this gift card. A computer will decide this at random, meaning you will be equally likely to get a gift card or to not get a gift card.

More questions?

Please email us at m-carestudy@umich.edu or call us toll-free at 1-844-864-8258.

M-CARES research project is conducted by:

the University of Michigan

and NORC at the University of Chicago,

in collaboration with Planned Parenthood of Michigan.

The research team at the University of Michigan includes Martha Bailey, PhD, Principal Investigator; Jennifer Barber, PhD; Vanessa Dalton, MD, MPH; Daniel Eisenberg, PhD; and Alfia Karimova, PhD.

M-CARES is sponsored by the Laura and John Arnold Foundation.

M-CARES

MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

Evaluating how affordable contraception affects women and families.

M-CARES would like your help!

M-CARES aims to help women afford contraception so they can avoid pregnancies they don't want. Study results may help policymakers understand how clinics like Planned Parenthood matter for the women who use them.

M-CARES needs 5,500 volunteers, ages 18 to 35, who are at risk of getting pregnant, who want to avoid getting pregnant, and who face out-of-pocket costs for contraceptives at PPMI.

For these volunteers, M-CARES wants to learn about their lives, including:

- Contraception, pregnancies, and childbearing
- Health and use of health care
- Schooling and training
- Work hours, jobs, earnings, and financial success
- Romantic and sexual relationships
- Parenting and children
- Hopes and dreams for the future
- Overall well-being

M-CARES appreciates your participation!

Your participation requires that you:

- Sign up after taking a short survey to determine eligibility (10 minutes).
- Complete an initial survey (about 25 minutes).
- Complete two follow-up online surveys (about 30 minutes each).
- Provide your personal information so that M-CARES can link to your administrative records.

If you participate in M-CARES, you can expect:

- Your personal information will be kept secure and confidential.
- $10 cash today for taking a short survey.
- $60 cash today for completing the first survey at Planned Parenthood ($40 if you take it later).
- Up to $100 for completing 2 more surveys in the next 5 years.
- The chance to win a gift card for contraception at Planned Parenthood.

If you sign up for M-CARES, you may withdraw from the study at any time by emailing us at: m-carestudy@umich.edu

UNIVERSITY OF MICHIGAN
INSITITUTE FOR SOCIAL RESEARCH

M-CARES
MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

Summary of Consent

We invite you to be part of the Michigan Contraceptive Access, Research, and Evaluation Study (M-CARES). M-CARES will study how more affordable contraception can help families. The information provided by you will be used for research that is relevant for public policies, health services, and education programs.

For your help, you may earn up to $170 for taking surveys. Half of the eligible women will get a gift card of up to $492 to be used for contraceptives at any Planned Parenthood of Michigan (PPMI). This gift card can be used in the next 100 days.

Some important information about agreeing to be in this study:

- You choose whether to participate. It is completely up to you.
- Your decision to participate will not affect your ability to receive services at PPMI.

If you agree to participate, we will ask you to:

- Take two surveys:
  - a 5-minute survey now ($10) and
  - a 25-minute survey after your visit if you are eligible (up to $60).
- Take two 30-minute surveys (up to $50 each) in the next 5 years.

On all of the surveys, you may skip answering any questions you want, and you will still earn money for taking them.

- Share your personal information (for example: your name, date of birth, social security number, and contact information) and give us permission to use your "administrative records" going back 20 years and going forward 30 years
  - "Administrative records" describe records that are collected about you (or your children) by the government or other agencies. They include records on employment, earnings, tax returns, credit history and debt, Planned Parenthood visits, birth and death certificates, education, health insurance claims, criminal charges and arrests, participation in governmental programs, and child welfare and juvenile crime.
- Share your children's names, dates of birth, and places of birth and give permission to use their administrative records. Your consent today will also apply to the administrative records for any children you may have in future.
- Be contacted about participating in other studies in the future.

Your privacy is very important to us. We plan to publish the study results, but please know that:

- Surveys and administrative data will be used for research only.
- We will not include any information in publications that would identify you.
- Information identifying you will be stored separately from your survey answers and data from your administrative records – in an encrypted data file at the University of Michigan (UM).
- Survey answers will be stored securely in a data bank at UM.
- Data from administrative records will be stored and managed in accordance with very strict laws governing access to them.
- You may take the surveys in a private setting of your choice.
- We have obtained a Certificate of Confidentiality from the National Institutes of Health so we cannot be forced to disclose study information that may identify you, even if ordered by a court.

If you have any questions about the study, please call Dr. Martha J. Bailey, Ph.D. (toll-free) at the Institute for Social Research: (844) 864-8258. If you have any questions regarding your rights as a research participant, please contact the University of Michigan Institutional Review Board, 734-936-0933, 540 East Liberty Street, Suite 202, Ann Arbor, MI 48104-2210, irbhsbs@umich.edu.

You will receive a copy of this form by email and, if you request it, a printed copy today.

Consent to Participate in M-CARES

We invite you to be part of the Michigan Contraceptive Access, Research, and Evaluation Study (M-CARES). M-CARES will study how more affordable contraception can help families. The information provided by you will be used for research that is relevant for public policies, health services, and education programs. NORC at University of Chicago will collect the consent and survey data on behalf of the University of Michigan. The study is paid for by the Laura and John Arnold Foundation.

Description of Your Involvement

If you agree to be part of the study, we will ask you to take a 5-minute survey on a tablet about your life. To determine if you are eligible for a gift card, we will ask about your age, your fee scale at Planned Parenthood of Michigan (PPMI), your visit today, and about whether you are at risk of an unintended pregnancy. We will use these responses in M-CARES even if you are not eligible for the gift card.

If you are eligible, you may receive a gift card of up to $492 to be used for any contraceptives at PPMI. The amount of the gift card is determined by how much you would have to pay today for a Liletta IUD (if you wanted one), so that most contraceptives at PPMI will be free to you. You may use this gift card in the next 100 days. Half of eligible women will get this gift card, and a computer will decide this at random, meaning you will be equally likely to get a gift card or to not get a gift card.

If you are eligible, we will ask you to take surveys about your life, including your health and well-being, contraception, pregnancies, abortion, education and work, your childhood, relationships, sexual activity, your children (if any), and plans for the future.

- a 25-minute survey today
- two 30-minute surveys over the next 5 years sent in pieces at different times.

To participate in this study, you will need to consent to release your administrative records and, if you have children, now or in future, your children's administrative records to us for purposes of the study. We use the term "administrative records" to refer to data that have already been collected or will be collected about you and your children by the government or other agencies. [Click for a complete list.] They include information about:

- employment, earnings, and taxes;
- education (examples: grades, classes, test scores, and financial aid),
- credit history and debt,
- Planned Parenthood visits,
- health insurance claims,
- birth and deaths,
- criminal charges and arrests,
- participation in public programs, and
- child welfare and juvenile crime.

We will look at these records going forward 30 years and back 20 years. We will examine records for 30 years because we wish to understand whether affordable contraceptives have long-term effects. We will look at records going back 20 years to study how your background matters for these long-term effects. To collect and use these administrative records, we need:

- your signature on two separate consents to release administrative records, one relating to health information and one relating to administrative records more generally,
- your full legal name and date of birth,
- the full legal names, dates of birth, and place of birth for your children (if you have any),

- your social security number, and
- your street address.

In order to contact you in the future, we also ask for your phone number, social media contacts, and the contact information of people who would know where you are if your address changes.

Benefits of Participation

If you are selected to receive a gift card, you may benefit directly from this study by having more money to spend on contraceptives of your choice. If you do not receive a gift card, you may still benefit from what is learned in this study.

Risks and Discomforts of Participation

There may be some risk or discomfort from your participation in this research. Some of the questions in the survey may be sensitive for some people. You can choose not to answer a question or stop participating in this study any time. There is also a risk of unauthorized access to your data. We will take all possible steps to protect your data and privacy as we describe below.

Compensation for Participation

For your participation in this research project, you may earn up to $170 for taking surveys about your life. These include $10 for taking a 5-minute survey, $60 for taking a 25-minute survey today or $40 for taking it at another convenient time, and up to $50 each for taking two more 30-minute surveys over the next 5 years.

Confidentiality

Your privacy is very important to us. We plan to publish the results of this study, but know that

- Surveys and administrative data will be used for research only.
- We will not include any information in publications that would identify you.
- All information identifying you or your children will be removed from survey data or administrative records before we analyze the data.
- Information identifying you will be stored separately from your survey answers and data from administrative records – in an encrypted data bank at the University of Michigan (UM).
- Survey answers will be stored securely in a data bank at UM. Data from administrative records will be stored and managed in accordance with very strict laws governing access to them.
- You may take the surveys in a private setting of your choice.
- This project holds a Certificate of Confidentiality (CoC) that offers additional protections for your identifiable research information and records. The most important protection is that members of the research team cannot be forced to disclose or provide any of your private identifiable information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding unless you provide permission. Disclosure of your research information may only occur in limited specific instances. For the full detailed description of the CoC protections and exceptions to those protections, please refer to the CoC attachment at this link: https://m-carestudy.org.

It is possible that other people may need to see the information you give us as part of the study. These people work for the University of Michigan and government offices that are responsible for making sure the research is done safely and properly.

Storage and Future Use of Data

NORC will retain your survey data for 7 years so that it can send you two more surveys. After 7 years NORC will destroy any M-CARES data it has about you. The University of Michigan will store your data to use for future research studies. Your name and any other identifying information will be stored securely and separately from your survey answers and data from administrative records, as described above. Research data may be shared with other investigators but will never

contain any information that could identify you. We may use these data to contact you in the future, to ask you to participate in a follow-up study. At that time you will be able to say no, if you choose.

Voluntary Nature of the Study
Participating in M-CARES is completely voluntary. Your decision to participate in M-CARES will not affect your ability to receive services at Planned Parenthood. If you decide to participate now, you may change your mind and stop at any time.

If you decide to withdraw from this study, you must send an email to m-carestudy@umich.edu. If you do, we will not contact you asking you to take surveys and we will not collect any new administrative records regarding you or your children. We will destroy any information that could identify you from our data bank. However, we will still use survey answers that you have already provided and any administrative records regarding you or your children that have already been shared with us.

Contact Information
If you have any questions about this research, you may contact the University of Michigan toll free at (844) 864-8258 or email m-carestudy@umich.edu or the Project Director, Dr. Bailey, at (734) 647-6874.

Contact Information for Questions about Your Rights as a Research Participant
If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researchers, please contact the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board, 2800 Plymouth Rd. Building 520, Room 1169, Ann Arbor, MI 48109-2800, (734) 936-0933, or toll free, (866) 936-0933, irbhsbs@umich.edu.

Consent
By signing this document, you are agreeing to be in M-CARES. You are agreeing to the release your administrative records, as defined in this consent, to the University of Michigan for its use as part of the M-CARE study. You are agreeing to release your children's administrative records, including any children you have now or may have in the future to the University of Michigan for its use as part of the M-CARE study. You will receive a copy of this form by email and, if you request it, a printed copy today. Be sure that we have answered any questions you have about the study and that you understand what you are being asked to do. You may contact the researchers if you think of a question later.

I consent to participate in the M-CARE study. I consent to the release of my administrative records, and those of any children I have now or in future, to the University of Michigan for use as part of the M-CARE study.

_____ _____
Printed Name Signature Date

Please provide your date of birth and social security number. *As a reminder, this information allows us to collect your administrative records. We will keep your information confidential.*

Date of Birth: MM/DD/YYYY ``` Social Security Number: ###-##-#####

Please provide the names, dates, and places of birth of your children:

Child's Name: _____ Date of Birth: MM/DD/YYYY Place of birth: Town/City, State

Child's Name: _____ Date of Birth: MM/DD/YYYY Place of birth: Town/City, State

Child's Name: _____ Date of Birth: MM/DD/YYYY Place of birth: Town/City, State

Child's Name: _____ Date of Birth: MM/DD/YYYY Place of birth: Town/City, State

UNIVERSITY OF MICHIGAN
INSITITUTE FOR SOCIAL RESEARCH

M-CARES
MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

Consent to Release of Administrative Records to M-CARES

To whom it may concern:

I consent to the release of all of my administrative records in your possession – including all records containing personally identifiable information as described in the attached appendix – to the University of Michigan for its use as part of the M-CARE study.

This Consent is voluntarily given and does not have an expiration date.

_____ _____
Printed Name Signature
Date: _____

I further consent to the release of all of my children's administrative records in your possession – including all records containing personally identifiable information as described in the attached appendix – to the University of Michigan for use as part of the M-CARE study.

This Consent is voluntarily given and does not have an expiration date.

_____ _____
Printed Name Signature
Date: _____

Consent to Release of Protected Health Information to M-CARES

To whom it may concern:

I consent to the release of all of my protected health information in your possession – including all records containing protected health information as described in the attached appendix – to the University of Michigan for its use as part of the M-CARE study.

This Consent is voluntarily given and does not have an expiration date.

_____ _____
Printed Name Signature

Date: _____

I further consent to the release of my children's protected health information in your possession – including all records containing protected health information as described in the attached appendix – to the University of Michigan for its use as part of the M-CARE study.

_____ _____
Printed Name Signature

Date: _____

Appendix 1. Administrative Data Sources

Type of data	Information in these records
Administrative, census, and survey data collected by or at the Census Bureau and/or U.S. Bureau of Labor Statistics	IRS 1040s, living conditions, household structure, number of children in the household (and when they were born), renter/owner status, incarceration or residence in group quarters, neighborhood quality, race, age, marital status, education, earnings, employment, and government program participation (examples: Medicaid, Supplemental Nutritional Assistance Program (SNAP), Temporary Assistance for Needy Families (TANF), disability, Medicare, Supplemental Nutritional Program for Women, Infants, and Children (WIC)
Michigan employment and earnings records	Quarterly earnings, employment, unemployment benefits, taxes paid by the employee and the employer(s) to the state, income from different sources, disability income, and employer(s).
Tax data	Number of dependents in the household, marital status, homeownership, college enrollment, all income and sources of income, all employers, taxes, receipt/eligibility of Earned Income Tax Credit, eligibility for other government programs (examples: Medicaid, SNAP, TANF, Medicare).
Credit reports	From Transunion and Equifax. These include measures of indebtedness and financial strain, payment of bills, on-time payment, delinquency, and credit score.
Education records from institutions (K-12 and postsecondary) within the State of Michigan	Educational enrollment, educational attainment, achievement test scores, absenteeism, school delinquency, type of school enrolled in (example: high school, middle school), promotion to the next grade, grades, and graduation dates.
National Student Clearinghouse	Educational enrollment, the beginning and ending date that a student is enrolled during each term, whether a student is enrolled full or part-time, private or public school, type of school or college (example: four-year, two-year) enrolled in, student's major, whether a student has earned a degree, and the date the degree is earned.
Michigan criminal justice records	Arrests, prison entries, incarceration status.
Michigan child welfare and juvenile crime records	Records of allegations of abuse/neglect, foster care placements, official delinquency petitions for the State of Michigan, juvenile crime records
Michigan government program participation and benefits	Programs include Medicaid, SNAP, TANF, Unemployment Insurance, Disability, Child Health Insurance, Family Independence Program, Food Assistance Program, Head Start, Low Income Home Energy Assistance, School Breakfast and Lunch Program, Special Milk Program; and WIC.

Appendix 2. Protected Health Information Data Sources

Type of data	Information in these records
Planned Parenthood of Michigan patient records	Information about your visits to Planned Parenthood: the date of the visit, services obtained, payment methods and amounts, the name of the clinic. Your health information from Planned Parenthood: the date of your last menstrual period, medical and physical diagnosis codes, and results of a physical examination.
Vital records	These include birth and death certificates from the Michigan Department of Health and Human Services (MDHHS) and comparable agencies other states when applicable (this is only applicable in cases where, for example, if the birth of a child happens out of state). Birth certificates: the date of birth of each child; location of birth; attendant at birth; plurality of birth, health conditions of the newborn; pre-natal care; gestational length; mother's health information; morbidity; pregnancy risk factors; previous births and outcomes; onset of and characteristics of labor and method of delivery; payment information; marital status at birth, mother education and occupation; father age, race, education and occupation. Death certificates: Date of death, members of household, cause of death
Health insurance claims	Date of the visit, service provider, services obtained, payment methods and amounts, the name of the clinic, medical and physical diagnosis codes.
Administrative, census, and survey data collected by or at the Census Bureau and U.S. Bureau of Labor Statistics	Program participation in Medicaid, Medicare, disability insurance, and information about insurance coverage. Health information, payment information, and information about visits to health care providers from public records (e.g., Medicaid and Medicare).

Data Use Agreement (DUA) for M-CARES Survey and Administrative Data

M-CARES participants have given their consent for the M-CARES research team to use their survey and administrative data. Individuals with access to M-CARES survey data and administrative data are called "approved personnel." All approved personnel must read and sign this DUA that ensures s/he will protect the confidentiality of M-CARES participants and the security of their data.

Protections laid out in the informed consent for study participants include:

- Survey data and administrative data will be used for research only.
- M-CARES will not include any information in publications that would identify an individual.
- All information identifying an individual has been removed from survey data or administrative records before data analysis. Information identifying individuals has been stored securely and separately from survey answers and administrative data in an encrypted data bank to which only the Bailey and Karimova have access.
- Survey answers must be stored securely in a data bank.
- Administrative records must be stored and managed in accordance with very strict laws governing access to them.
- We have obtained a Certificate of Confidentiality (COC) from the National Institutes of Health so we cannot be forced to disclose study information that may identify individuals, even if ordered by a court.

In addition to agreeing to comply with the protections above, I also agree to the following data use precautions when using the M-CARES data:

- I will not attempt to access the restricted identifying information of M-CARES participants.
- I will not release, nor permit others to release the data or any part of them, to any person who is not approved personnel on the M-CARE study.
- I understand that the only persons to be allowed access to the data are approved personnel who have been authorized to work with the data and have, prior to being granted access to the data, read and signed this DUA statement.
- I will not attempt to use the data nor permit others to use them to learn the identity of any person included in the data set;
- I will not attempt to link nor permit others to attempt to link any M-CARES data with individually identifiable records from sources not listed in the informed consent form.
- I will ensure that all statistical information in such a way as to avoid inadvertent disclosure. For example:
  - No data on an identifiable case should be derivable through subtraction or other calculation from the combination of tables in a given publication
  - No data should permit disclosure when used in combination with other known data.
- If I should inadvertently discover the identity of any person or establishment, then (a) I will make no use of this knowledge, (b) I will immediately advise the PI of M-CARES of the incident, (c) I will safeguard or destroy the information that would identify an individual or establishment, and (d) I will inform no one else of the discovered identity.
- I will only store M-CARES data on M+Box or on a computer approved in this proposal.
- I will enable Duo 2-factor authentication on my UM account to comply with data security protocols.

- I will not use the Box-Sync feature of M+Box.
- I will delete any coded data from my approved computer as soon as they are no longer required for the analysis.
- I will report any inadvertent or advertent data breach immediately to the PI of M-CARES.
- I will automatically cease to be approved personnel if I leave the M-CARES project.

My signature below confirms that I have read and agreed to protect the confidentiality of M-CARES participants and the security of their data as laid out in this Data Use Agreement. I will immediately lose access to the data if I fail to comply with this Data Use Agreement.

Name: _____ Signature: _____ Date: _____

Computer approved for use with this proposal:

Number:

Room:

Address:

Confirm password protected: Yes/No

Confirm office can be secured: Yes/No

Confirm Duo 2-factor authentication enabled on UM account: Yes/No

PI Name: _____ Signature: _____ Date: _____

IRB ABBREVIATED INITIAL REVIEW APPLICATION

Michigan Department of Health and Human Services

Institutional Review Board for the Protection of Human Research Subjects
333 South Grand Avenue, PO Box 30195
Lansing, MI 48909
Email: MDHHS-IRB@michigan.gov Phone: 517-241-1928 Fax: 517-241-1200

1.1	Project Title **Michigan Contraceptive Access, Research, and Evaluation Study**
	Alternative Title **M-CARES**

1.2	Responsible Department Employee **Barbara Derman**
	Phone **517-335-8696**
	Email **dermanb@michigan.gov**
	ID Mail Address **3-21 Washington Sq. Building, 109 W. Michigan Avenue, Lansing, MI 48913**

Note: The Responsible Department Employee must have a Michigan.gov email address, have completed CITI Human Research Protections Training within the past 3 years, and have Bureau Director or equivalent approval to submit applications to the Institutional Review Board. Applications must be submitted from the email address of the Responsible Department Employee to MDHHS-IRB@michigan.gov.

1.3	MDHHS Administration **Public Health Administration**
	Bureau or Office **Family Health Services**
	Authorizing Supervisor (Bureau Director/Equivalent) **Lynette Biery**
	Email for Authorizing Supervisor **bieryl@michigan.gov**

1.4	Primary Investigator **Martha Bailey**
	Title **Professor of Economics, Research Professor at Institute of Social Research - Population Studies Center**
	Organization **University of Michigan**
	Phone **(734) 647-6874**
	Email **baileymj@umich.edu**

1.5	Is this project federally funded? ☐ Yes ☒ No	
	If yes, specify the federal agency	
	Grant or Contract Number	

1.6	Non-Federal funding source(s) if applicable	**Laura and John Arnold Foundation**
	Grant or Contract Number	**N023506**

1.7	Is this project subject to FDA regulations? ☐ Yes ☒ No		
	If yes, please specify below which FDA-regulated test articles will be used		
	☐ No test article used		
	☐ Drug or biologic used	IND #	Trial Phase
	☐ Device used	IDE #	Risk Level

1.8	What date do you plan to begin this project?	**05/29/18**
	What date do you plan to complete this project?	**06/22/22**

1.9	Will another organization's IRB review this project?	☒ Yes ☐ No
	If yes, please list the organization(s) here	**University of Michigan - Health Sciences and Behavioral Sciences IRB**

1.10	Are you requesting an IRB Authorization Agreement to rely on the review provided by another organization?	☒ Yes ☐ No
	If yes, please list the organization's FWA # here	**FWA00004969**
	If yes, please list the IRB's Registration # here	**IRB00000245**

1.11	Describe any conflicts of interest that could be perceived to compromise the integrity of the project
	N/a

Instructions for Submitting your Application

Note: This abbreviated application should only be used when another institution is providing IRB review of this project in addition to MDHHS. MDHHS may perform a full review of the protocol as submitted to the other institution's IRB and may request modifications. Approval by another institution's IRB does not guarantee approval at MDHHS.

1. Verify all elements of section 1 are complete.
2. Attach all materials submitted to the other organization's IRB (e.g., IRB application, study protocol, data collection tools, informed consent documentations, etc.) with this abbreviated application.
3. If approval has already been granted by another IRB, attach the notice of approval.
4. Ensure approval by the Responsible Department Employee (note: Responsible Department Employees should perform a programmatic review to ensure MDHHS involvement in the project is appropriate, and should serve as the first line in identifying and addressing human research protection issues that may be pertinent to the project).
5. The Responsible Department Employee should indicate approval and submit the complete application by emailing all documents from his or her MDHHS email account to MDHHS-IRB@michigan.gov.

Completion of the MDHHS IRB Initial Review Application (DCH-1277) is required for IRB Review at MDHHS when the MDHHS IRB is the only IRB reviewing the project, or when MDHHS has primary responsibility for the project. Do not submit this abbreviated application if no other IRB will review this protocol.

Authority: Code of Federal Regulations Title 45 Part 46

M-CARES

MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

For more information:
email: m-carestudy@umich.edu
Website: http://sites.lsa.umich.edu/m-carestudy
Toll-free phone: 1-844-864-8258

	Yes	No
Here for clinician visit?	☐	☐
Has insurance?	☐	☐
Insurance used for visit today?	☐	☐

Fee scale ☐ 1/A ☐ 2/B ☐ 3/C ☐ 4/D ☐ 5/E

VID: VD:

To take a survey, go to sites.lsa.umich.edu/m-carestudy.

M-CARES
MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

Oral Script for Surveyor

Once the patient checks in, the surveyor will approach the patient and say:

- Hello, my name is [surveyor's first name]. The University of Michigan is conducting a study to learn about how the cost of contraception affects women and families. Here [HAND WOMAN A BROCHURE] is a brochure that describes the study and the eligibility requirements. This study wants to help policymakers understand how clinics like Planned Parenthood matter for the women who use them.

- Have you already enrolled in M-CARES?
    - [If patient says "yes":] Thank you for participating!
    - [If patient says "no":] You could be eligible to be in the study if you are 18 to 35 years old, would like to avoid pregnancy this year, and would have to pay yourself for services today. If you are eligible, the study will pay you for your time taking surveys and some participants could receive a gift card that you could use for contraceptives at Planned Parenthood in the next 100 days. Would you be interested in participating in this study?

If the patient says she is interested, the surveyor asks:

- Are you between the ages of 18 and 35?

If the patient says no, the surveyor says:

- Unfortunately, that means you are not eligible to participate. Thank you very much for your time.

If the patient says yes, the surveyor asks:

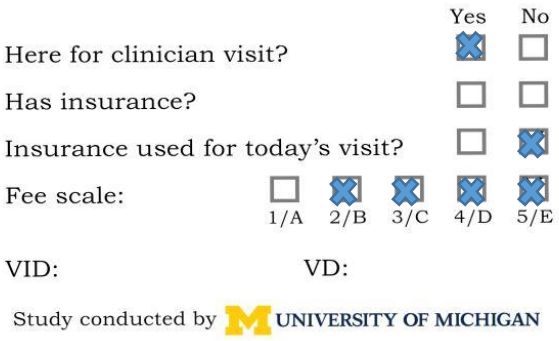
- Did you receive an M-CARES card when you signed in today? Can you please hand me the card?

If the business card has the following answers marked:

Here for clinician visit? – Yes

Insurance used for visit today? – No

Fee scale - 2/B, 3/C, 4/D, or 5/E



Then the surveyor says:

- Great. You could be eligible for the M-CARE study. Would you be willing to take a short survey to find out? It will take you about 5 minutes and we will reimburse you $10 in cash for your time. [SURVEYOR ENTERS FEE SCALE IN TABLET AND HANDS TO PARTICIPANT].

If the business card notes fee scale 1 (i.e., contraceptive services free), insurance will cover today's visit, or not here for a clinician visit -, the surveyor says:

- It looks like you wouldn't have to pay yourself for services today, so you are not eligible for the M-CARE study. If that doesn't seem right, perhaps confirm this with the receptionist. Thank you very much for your time.

[FOR ELIBIGLE AND INTERESTED PATIENTS: PATIENTS INDIVIDUALS READ CONSENT ON THE TABLET WHILE SURVEYOR STANDS BY AND CAN ASK QUESTIONS OF THE SURVEYOR]

Once the individual has read and asked questions and filled out the tablet, the tablet prompts the woman to hand the tablet back to the surveyor. The surveyor says:

- I want to confirm your consent.

- Do you agree to take surveys today and be contacted in the future to take surveys?

- Do you also agree to release administrative records for yourself and for your current children to the M-CARE study for this research?

- Do you give us permission to use your and your children's "administrative records" going back 20 years and going forward 30 years?

- Do you understand that your consent today will also apply to any children you may have in future? With your consent, we will access and use their administrative records as well.

[SURVEYOR CLICKS YES/NO ON THE TABLET FOR EACH ANSWER]

If the patient says no to any of the questions, the surveyor says:

- That's ok. You must agree to all of these terms to participate in M-CARES. Thank you for your time.

From:	Derman, Barbara (DHHS)
To:	Horste, Ian (DHHS)
Cc:	Charest, Deanna (DHHS)
Subject:	Reproductive Health Research Study
Date:	Thursday, May 03, 2018 3:40:31 PM
Attachments:	UM_IRB_03272018.pdf MCARES MDCH Abbr IRB4.23.18.docx IRB_approval.pdf mcares_consent_v36_v2.pdf CAARA mcares_proposal_approved.pdf Description of Research v14.pdf Agreement VR - MDHHS.pdf DCH-1294.pdf Diagram of Data v2.pdf Example of Data Use Agreement_Washtenaw County School District_4 4 17.pdf Example PPMI LIMITED DATA USE AGREEMENT.pdf M-CARES_brochure_submit.pdf HSIP email.pdf MCARES_DUA_v6_submit.pdf MCARESbusiness_card_for_PPMI_checkin_v8.pdf Security_Protocol_v12_submit.pdf oral_script_v17.pdf Survey1_v1.pdf Survey2_v1.pdf UNIVERSITY OF MICHIGAN FULLY EXECUTED ANALYTICAL SERVICES SCHEDULE.PDF Bailey CoC March 2018.pdf

---

Good afternoon Ian,
Back almost a year ago, we received initial inquiries about a research project that UM researchers aimed to develop with Planned Parenthood of Michigan (PPMI) to study long term impacts of subsidized family planning services. (see email chain below) This project will involve Title X family Planning clients of the Planned Parenthood program. Planned Parenthood is a sub-recipient of the MDHHS Title X Family Planning program. You had given me information regarding what they need submit to our MDHHS IRB, including an abbreviated IRB application, U of M IRB approval, and project materials. Attached are 21 documents submitted by U of M and PPMI.

Please let me know if you need further information. Thank you.

Barbara (Quess) Derman, MSW
Public Health Consultant, Reproductive & Preconception Health
Michigan Department of Health and Human Services
109 W. Michigan Ave, 3rd Floor, Lansing, Michigan 48913
Phone: 517-335-8696 DermanB@michigan.gov
.....

Approved.

Sent from my iPhone

On Apr 23, 2018, at 3:26 PM, Dunbar, Paulette Dobynes (DHHS) <dunbarp@michigan.gov> wrote:Lynette, we need your approval to submit the **IRB ABBREVIATED INITIAL REVIEW APPLICATION (attachment MCARES MDCH Abbr IRB.docx)** for this research project that will involve Title X users to get MDHHS IRB approval. U of MI IRB approval is attached (UM IRB 03272018.pdf). We in MIHD are supportive of the research and Quess Derman will serve as the Responsible Department Employee and will submit upon receiving your approval to do so. There are numerous

other explanatory documents available for review if you would like to view; let us know.

Here is a brief description of the study:
The University of Michigan M-CARES is working to develop a research project to evaluate the impact of making contraceptives more affordable and accessible to families in the U.S. They would work with Planned Parenthood of Michigan family planning (including Title X) clients in this project to evaluate long term impacts of access to more affordable contraception. The project goal is to develop long term evidence on the value of making contraception affordable, using randomized vouchers together with surveys and administrative data to evaluate short and long term effects of subsidizing highly effective contraceptive methods.

Paulette,
You may recall that the University of Michigan M-CARES, working with the Family Planning Fellowship program approach us this winter about working with Title X clients of the Planned Parenthood of Michigan (PPMI) to study short and long term impacts of making contraceptives more affordable and accessible. We indicated that to include Title X clients in a research project, that project must be approved by the MDHHS IRB. When I contacted Ian at the MDHHS IRB, he suggested they wait for their UM IRB and submit that plus their protocol, consent form and relevant agreements and forms for their study using the MDHHS Abbreviated IRB request form (see this as the first attachment.) They have now obtained their UM IRB approval which we can submit along with the abbreviated form. I have signed as staff and did the updated training. ***We now need to send to Lynette for Bureau level approval. See section 1.3 on the first attached form.*** (that is a new signature requirement on this form since the last one of these I did.)

Here is a brief description of the study:
The University of Michigan M-CARES is working to develop a research project to evaluate the impact of making contraceptives more affordable and accessible to families in the U.S. They would work with Planned Parenthood of Michigan family planning (including Title X) clients in this project to evaluate long term impacts of access to more affordable contraception. The project goal is to develop long term evidence on the value of making contraception affordable, using randomized vouchers together with surveys and administrative data to evaluate short and long term effects of subsidizing highly effective contraceptive methods.

Barbara (Quess) Derman, MSW
Public Health Consultant, Reproductive & Preconception Health
Michigan Department of Health and Human Services
109 W. Michigan Ave, 3rd Floor, Lansing, Michigan 48913
Phone: 517-335-8696 DermanB@michigan.gov

From: Derman, Barbara (DHHS)
Sent: Monday, April 09, 2018 6:11 PM
To: Charest, Deanna (DHHS) <CharestD@michigan.gov>
Subject: FW: MDHHS IRB Question

You may recall quite a while ago I worked with Vanessa Dalton to initiate MDHHS IRB approval for

this UM research project on contraceptive access. Her research coordinator sent me this partially completed MDCH abbreviated IRB application which I received from Ian Horste here at MDHHS. He indicated materials and examples of forms that they should submit along with their approval from the UM IRB board.

So now she has finally collected the needed documents and the last thing attached (Bailey CoC March 2018) is a letter from UM IRB that states approving the study with contingencies.

I think I need to complete section 1.3 of the first document (abbreviated IRB request) with Lynette's approval? Wanted to check with you.. Do you want me to send to Lynette with a brief description of the study? Or process?

Barbara (Quess) Derman, MSW
Public Health Consultant, Reproductive & Preconception Health
Michigan Department of Health and Human Services
109 W. Michigan Ave, 3rd Floor, Lansing, Michigan 48913
Phone: 517-335-8696 DermanB@michigan.gov

From: Roxanne Harfmann [mailto:Roxanne.Harfmann@ppmi.org]
Sent: Thursday, March 29, 2018 12:52 PM
To: Derman, Barbara (DHHS) <DermanB@michigan.gov>
Cc: Vanessa Dalton <Vanessa.Dalton@ppmi.org>
Subject: RE: MDHHS IRB Question

Hello Barbara,

I'm the research coordinator for Planned Parenthood of Michigan and I'm currently working with a team at UMich on the Michigan Contraceptive Access, Research, and Evaluation Study (M-CARES). Vanessa Dalton gave me your information – I believe you've discussed working with us as the Responsible Department Employee for the study team's application to the MDHHS IRB. We're hoping to start this process in order to obtain MDHHS IRB approval.

Attached is our MDHHS IRB application and supporting materials (including a PDF copy of the UMich IRB application and all other documents submitted to their IRB). In our MDHHS IRB application, can you help us by providing your Authorizing Supervisor information required for section 1.3?

Approval from the UMich IRB is pending, but expected soon. Once we have the notice of approval, we can forward the letter to be added to the other documents accompanying our MDHHS IRB application. If you have any questions or need anything else, please feel free to contact me or Vanessa.

All the best,

Roxanne Harfmann
Research Coordinator

Planned Parenthood of Michigan
P: 734.926.4802

From: Dalton, Vanessa
Sent: Thursday, November 30, 2017 1:10 PM
To: Harfmann, Roxanne
Subject: FW: IRB Question

We can get this paperwork going – but we need IRB approval beforehand. That is our best chance to avoid full committee I think.

This is for the MCARES study. Can you help me get started?

From: Derman, Barbara (DHHS) [mailto:DermanB@michigan.gov]
Sent: Friday, September 08, 2017 1:02 PM
To: Dalton, Vanessa <daltonvk@med.umich.edu>; Danielle Terry <Danielle.Terry@ppmi.org>; Tammara Warren <tammara.warren@ppmi.org>; Gulau, Natalie <ngulau@med.umich.edu>
Subject: FW: IRB Question

See below regarding initiating the IRB approval request. Attached is the abbreviated form that can be submitted with a pdf fo the University application, study protocol, consent forms and data collection tools, etc)

From: Horste, Ian (DHHS)
Sent: Thursday, April 27, 2017 2:44 PM
To: Derman, Barbara (DHHS) <DermanB@michigan.gov>
Cc: Harp, Roberta (DHHS) <HarpR@michigan.gov>
Subject: RE: IRB Question

That is correct. If an application for this research has already been prepared for the U of M IRB, you may submit the abbreviated form as long as it is accompanied by all of the materials that were submitted to the U of M IRB (e.g., a pdf of the U of M IRB application, study protocol, informed consent documents, data collection tools, etc.).

From: Derman, Barbara (DHHS)
Sent: Thursday, April 27, 2017 2:38 PM
To: Horste, Ian (DHHS) <HorsteI@michigan.gov>
Cc: Harp, Roberta (DHHS) <HarpR@michigan.gov>
Subject: RE: IRB Question

Thank you Ian. I'll do the refresher course and be ready to go. I'll ask the agency, but assume that the U of M researchers will have gone through their IRB as well. If that is the case, I would have them complete the abbreviated application. Is that correct?

Barbara (Quess) Derman, MSW
Public Health Consultant, Reproductive & Preconception Health

Michigan Department of Health and Human Services
109 W. Michigan Ave, 3rd Floor, Lansing, Michigan 48913
Phone: 517-335-8696 Fax: 517-335-8822 Cell: 517-449-5968
DermanB@michigan.gov

From: Horste, Ian (DHHS)
Sent: Thursday, April 27, 2017 2:27 PM
To: Derman, Barbara (DHHS) <DermanB@michigan.gov>
Cc: Harp, Roberta (DHHS) <HarpR@michigan.gov>
Subject: RE: IRB Question

Hello Barbara,

To serve as a Responsible Department Employee or Primary Investigator, we do ask that you update your training through the CITI Program if it was completed more than 3 years ago. Because you have already completed a training, you should be eligible to complete a refresher course instead of a basic course. The refresher courses are much shorter than the basic course you would have completed previously. In the system I find your username with CITI is: dermanb. With that information, you should be able to log in (or reset your password and log in) and maintain your current CITI Program status. If you have questions about this training requirement or problems logging in, feel free to contact me or my assistant Robbie Harp (copied on this message) for assistance.

If you have other questions about working with the IRB or submitting a new application, don't hesitate to contact me. Regards,
-Ian

Ian A. Horste, MPH
Institutional Review Board Administrator/Chair
Michigan Department of Health and Human Services
517-284-4840
www.michigan.gov/irb

From: Derman, Barbara (DHHS)
Sent: Thursday, April 27, 2017 2:07 PM
To: Horste, Ian (DHHS) <HorsteI@michigan.gov>; MDHHS-IRB <MDHHS-IRB@michigan.gov>
Subject: IRB Question

Good afternoon Ian,
I am a program consultant with the Michigan Title X Family Planning program. I have a question from one of the sub-recipient agencies of our program regarding a plan to conduct of a non-clinical

research project which would involve interviewing of Title X clients. The project under consideration would be conducted by researchers at University of Michigan.

Several years ago in my same position, working with another sub-recipient agency conducting a clinical research project I did an MDCH IRB training to allow me to work with that project to obtain IRB approval. I just viewed your online webinar on the MDHHS IRB and I am guessing that I need to renew that approval to assist with this current project.

Please let me know if that is correct and what the process is. I am happy to register and review the CITIprogram course if that is what is needed. Please just let me know what I should do. Thank you.

Barbara (Quess) Derman, MSW
Public Health Consultant, Reproductive & Preconception Health
Michigan Department of Health and Human Services
109 W. Michigan Ave, 3rd Floor, Lansing, Michigan 48913
Phone: 517-335-8696 Fax: 517-335-8822 Cell: 517-449-5968
DermanB@michigan.gov

M-CARES Security Protocol, December 6, 2017

1. **What is the nature of the data?**
    a. Electronic (text, audio, video, binary), hardcopy files, or biological specimens?

The data are electronic.

    b. Do the data contain protected health information, personal identifying information or other sensitive information? If yes, please precisely describe what these are (see Table 1, page 3).

The data contain

- *personal identifying information, such as name, street address, birth date, telephone number, email address, social media accounts, and social security number;*
- *protected health information, such as patient's health information and medical records.*
- *sensitive information on intimate partner violence and abortions.*

    c. Are identifiers retained and linked to the data? Who will have access to the data? Who will have access to the identifiers?

Please see the detailed discussion in our Research Protocol, including sections 4 (especially sections D, E, and F), section 5, and especially Figure 2 ("Data Diagram") uploaded in IRB section 5.

NORC and Bailey and Karimova will initially have access to the identifiers. UM's process will strip and code the identifiers, thus anonymizing the data. UM's process of storing and analyzing the data is intended to minimize the risk of unauthorized disclosure of sensitive information.

NORC will first collect survey data on electronic tablets (see details of tablet security below). NORC will not use these data for any purpose other than the proposed M-CARES research, and will then transfer the data to UM. NORC will retain the data for 7 years—this includes the 5 years of our study and an additional two years in case we obtain funding to conduct another survey. Back up tapes are destroyed after 7 years. NORC will not use these data for any purpose other than the proposed M-CARES research. NORC's IRB will retain oversight over their engaged activities and the destruction of the data.

Once we receive the data from NORC, UM will follow the general process as outlined in the "Diagram of Data" (figure 2 in research protocol in section 5 of IRB). When the survey data and consent forms are received from NORC, Bailey and Karimova will store surveys and consent forms (dataset 1 in "Diagram of Data", Figure 2) on M+Box in a file that is encrypted and password-protected and with access restricted only to Bailey and Karimova. No other researchers will have access to this file.

    d. Are the data stripped of identifiers and the identifiers destroyed (anonymized data)? When will this take place?

Survey Data

The survey data are stripped of identifiers and will be coded. The first step in the data processing will be to replace individually identifying information on the surveys with coded identifiers. Working in a locked office, Bailey and Karimova will remove PII (names, SSNs, dates of birth, addresses, contact information, and social media information) from the records and add a numeric identification code, birth days (month-year), and broad geographic codes. The cross-walk dataset that links these codes to names will be stored in a separate password protected file on M+Box. This crosswalk, a Stata file, will be encrypted with WinZip encrypting to the highest (AES256) level before uploading to M+Box. Bailey and Karimova

will both have Duo 2-factor authentication enabled on their UM accounts. Only Bailey and Karimova will have access to this crosswalk file and PII (dataset 2 in "Diagram of Data"). All analysis will be conducted with data that contains coded identifiers (anonymized) and other survey variables (dataset 3 in "Diagram of Data").

Individuals with access to M-CARES study data are called "approved personnel." Approved personnel will be briefed on the license conditions and the data protection plan prior to receiving access to the restricted data and again annually each December for the duration of the project. Specifically, all approved personnel will agree to and sign a Data Use Agreement (appended in Section 44l).

Any potential breaches will be reported immediately.

The identifiers will be kept in a secure location separate from survey answers. They will not be destroyed. Identifiers will be used to follow up with study participants for planned surveys and linking respondents to their administrative data. They may also be used to contact respondents to invite them to participate in future studies.

Administrative Data

The process is slightly different for administrative data. We will link M-CARES Recruits and Children to administrative records which are detailed in the next section.

We will link Recruits to (1) PPMI patient records; (2) credit reports; (3) tax data; (4) birth and death certificates; (5) Decennial Census, American Community Surveys (ACS), and Current Population Survey (CPS) Annual Social and Economic Supplement (ASEC); (6) Education data (K-college and National Student Clearinghouse, NSC); (7) program participation; (8) Michigan criminal justice records; (9) Michigan child welfare and justice records; (10) employment and earnings records; and (11) health insurance claims. (Numbers correspond to numbering in the next section outlining the content of these records; see also discussion in section 24 of the IRB).

We will link Children's to a subset of these records, including (4) birth and death certificates; (5) Decennial Census, ACS, and CPS-ASEC; (6) Education data (K-college and National Student Clearinghouse, NSC); (7) program participation; (9) Michigan child welfare and justice records; (10) employment and earnings records; and (11) health insurance claims.

The process of linking to these administrative files is intended to minimize the risk of unauthorized disclosure of sensitive information. Following the process laid out in in "Diagram of Data," our linking process follows these steps.

From the survey file (dataset 1 in "Diagram of Data") we will create an administrative data link file ("Admin Data Link") for Recruits and Children and share this with agencies. For Recruits, the Admin Data Link file will include PII including full name, date of birth, address, and SSN in addition to a subset of variables from survey data, which we will call Z variables (dataset 4 in "Diagram of Data"). For Children, the Admin Data Link file will include PII including full name, date of birth, and place of birth in addition to a subset of variables from survey data, which we will call Z variables (dataset 6 in "Diagram of Data").

These Z variables include information about whether the individual received a voucher and the voucher amount as well as a subset of answers to survey questions that allow us to construct covariates and

conduct heterogeneity tests. To make sure that no sensitive information is revealed to agencies, the Z variables will be masked. The masking process will create generic labels for variable names and answers. For instance, a question like "how many children have you had?" will be stored under the variable name Q15 with numeric answers 0 to 20. The Admin Data Link will be stored in encrypted format on an encrypted drive to be shared with agencies who will link to administrative data.

Agencies will then link Recruits and Children to data, remove PII, and give the M-CARES team access to these administrative data with coded identifiers or statistical results. The process is similar for different agencies, but we outline specifics for each administrative dataset.

The result of this process is that approved personnel on the M-CARES team will have access to and analyze separate coded (anonymized) administrative data files for Recruits (datasets listed under 5 in "Diagram of Data") and Children (datasets listed under 7 in "Diagram of Data").

e. Are identifiers de-linked from the data and managed by use of a code? How are the identifiers, data files and key managed and secured? Who will have access to the identifiers, data files and key?

The data are stripped of identifiers and will be coded as noted above. The identifiers, data files and the cross-walk file will only be accessible to the PI (Bailey) and Karimova. These data will be stored on a restricted-access drive – M+Box, which adheres to the highest industry standards for security. It is approved by the University of Michigan for storing and sharing sensitive data.

2. Where and how will the data be stored and what security measures will be used for each?

a. Personal computer or laptop? University computer or laptop; location? Office file cabinet? Thumb/jump drive? Departmental or other U-M server; name and/or location?

NORC will first collect the consents and survey data on electronic tablets. When tablets are at rest, they will be password protected. Only the trained surveyors can log in with a pin to initiate an interview. After the completion of a survey or after the tablet has been unused for 5 minutes, the tablet will require a log-in to continue the survey or initiate a new survey. NORC takes device and application security very seriously. NORC strictly adheres to demanding procedures when dealing with these issues. Device and software logins are designed to use a specifically encrypted challenge/response technology. All NORC devices and applications that manage case and response data protect against unauthorized access and restrict authorized access to the minimum necessary level. They administer least privilege, password protected access rights to safeguard PII and individual privacy information. There is also a time out security measure for sessions that are inactive for a given period of time. For their interviewing devices, NORC uses AirWatch technology, a multi-layered approach to data security that encrypts sensitive data and secures access to the user all the way to the network, including automatic revocation of access if compliance policies are violated or an employee leaves the company.

Data is stored on the secured NORC network and is only exchanged via encrypted, password-protected format. NORC facilities are also secured with keycard access required in addition to security cameras. The servers and wiring closets are placed in locked rooms which are only accessible to authorized staff via a

security code. NORC will transfer the encrypted and password protected data to UM using secure file transfer protocol.

At U-M, data will be stored in three places:

- *Restricted cross-walk between PII and codes will be stored on M+Box and encrypted by WinZip at the highest (AES256) level. The file will also be password protected with a complex password of at least 12 characters that will never be shared by email and will only be known to Bailey and Karimova. All survey answers will be removed from this file. Only Bailey and Karimova will have access.*
- *Admin Link File will contain PII and masked Z variables (as described above). Only Bailey and Karimova and administrators at the relevant agencies will have access. These files will also be encrypted with WipZip at the highest (AES256) level and password-protectedwith a different password and posted on M+Box for sharing with the relevant agencies. Access for these administrators will be limited to the time they need to download the file. We will require them to use Duo-2 factor authentication to access M+Box. We will also provide the complex password of at least 12 characters to the agency agent by telephone. Agency access to the data will be eliminated by Bailey and Karimova immediately after the data transfer has been completed.*
- *The coded survey answers will be stored on M-Box as well. They will be in a separate folder. These files will not be encrypted. Only the M-CARES approved personnel will have access. We will, however, require approved personnel to use Duo-2 factor authentication on their approved computers to access M+Box.*

b. What security measures will be used with each (password protected; encryption; locked file cabinet in locked office, 128 bit encryption, etc.)?

NORC facilities are secured with keycard access required in addition to security cameras. The servers and wiring closets are placed in locked rooms which are only accessible to authorized staff via a security code.

At U-M, personal computers are password-protected, offices are locked, in a building (ISR) which is locked after hours. In addition, M+Box will require a password and 2-factor authentication and M+Box folders will be shared only with approved personnel (requires signing DUA, appended). Finally, the Admin Link File and Cross-walk files will be encrypted by WinZip at the highest (AES256) level and locked with passwords.

c. Who will have access to the computer/laptop/server/or files?

At NORC, access to confidential data is restricted to authorized project personnel.
At U-M, access will vary based on the relevant information. See sections 2a and 2b for details.

3. How will data be transmitted or transported?

a. How will electronic files be transmitted? What measures are in place for secure transmission of data?

NORC will transfer the survey data to U-M using a Secure File Transfer protocol.

UM will share Win Zip encrypted, password protected files on M+Box (which additionally requires a password and 2-factor authentication) with relevant agencies. The password will never be emailed—it will be provided only by phone.

b. How will hardcopy files be transported?

There are no hardcopy files.

c. How are the files and data protected while in transmission or when transported?

See sections 2 and 3a.

4. **When and how will data or records be deleted or destroyed?**

NORC's files will be retained for 7 years and destroyed according to their policies. NORC's IRB retains oversight of their data destruction.

Per the informed consent, UM will not destroy or delete the data. Data will be retained for future research.

5. **Will cloud-computing resources be used?** (refer to UM policies at https://www.safecomputing.umich.edu/protect-the-u/protect-your-unit/safely-use-the-cloud/um-google and at https://www.safecomputing.umich.edu/protect-the-u/protect-your-unit/safely-use-the-cloud)
    a. What is the resource and what is the privacy policy for the resource?

M-CARES will use M+Box. We will require a password and 2-factor authentication for all users. We will not use the Box-Sync feature.

6. **Will online data collection services be used?**
    a. What is the service/host? How is the survey accessed? How are data accessed by the study team? Will any non-secure services be used to access, collect, or transmit data (e.g., public portals, administrator logins, public WiFi networks, or public computers)?
    b. How are data moved/transmitted from the online host to the local storage device (computer, laptop, server, thumb drive, etc.)?
    c. Will the data be purged from the online host once downloaded to the local device? How and when?
    d. If the data are identifiable and sensitive, are confidentiality agreements in place with outside consultants or vendors?

The security of data collection will be managed by NORC. NORC's activities will be regulated by its IRB, but we summarize its security measures here, which answer 6a-6d.

Tablet Security. NORC takes device and application security very seriously. NORC strictly adheres to demanding procedures when dealing with these issues. Device and software logins are designed to use a specifically encrypted challenge/response technology. All NORC devices and applications that manage case and response data protect against unauthorized access and restrict authorized access to the

minimum necessary level. They administer least privilege, password protected access rights to safeguard PII and individual privacy information. There is also a time out security measure for sessions that are inactive for a given period of time. For their interviewing devices, NORC uses AirWatch technology, a multi-layered approach to data security that encrypts sensitive data and secures access to the user all the way to the network, including automatic revocation of access if compliance policies are violated or an employee leaves the company.

Physical Security / Facilities. NORC takes great care to enforce physical security measures specifically designed to ensure that access to confidential data is restricted to only those who possess the need, as well as the authorization, to review the information. At the data center, all NORC personnel must check in with the front desk upon arrival, where an access badge is issued granting them access only to the area(s) where NORC equipment resides. Individuals entering the facility must surrender his or her government issued ID until their access card is returned upon departure. Outside visitors are required to have an escort at all times in addition to being issued an access badge. After hours entry requires a user to identify himself or herself prior to entering the building, stating name, organization and a pre-defined password via intercom communication to a data center engineer on duty. Vendors must be pre-authorized by a designated NORC representative to either access the tenant cage or be escorted by a designated facility employee.

Network Data Security. NORC requires the use of internal network data storage services to store all project-related data files. Partitioned network storage is provided for each project to mitigate the potential for data loss due to accidents, computer equipment malfunction, corruption, unauthorized security breaches, or human error, and to administer access rights regarding privacy issues related to both legal and contractual obligations. Wide arrays of network security precautions are undertaken by NORC to ensure the proper storage of all project data.

In addition, NORC publishes internal standards around data transmittal that are strictly followed. These include the transfer and receipt of all personally identifiable information (PII) and protected health information (PHI) in an encrypted format utilizing FIPS 140-2 compliance, transmitting all company confidential documents or files with password protection or in an encrypted format, and the transfer of all data utilizing the NIST-800-53 security framework. NORC's PII protection and encryption process complies with the OMB Memorandum M-06-16, "Protection of Sensitive Agency Information", "DOT Information Technology and Information Assurance Policy Number 2006-22: Implementation of DOT's Protection of Personally Identifiable Information (PII).", and OMB's "Guidance on Agency Survey and Statistical Information Collections"

Encrypted Data and Communications. All remote access to internal NORC computing resources requires two-factor authentication and encrypted channels. Only secure, encrypted file transfers are used when exchanging files with clients and/or partners over the Internet using an approved mode of transport like the secure file transfer protocol (SFTP). All of NORC's laptop computers are provisioned with an automatic full disk encryption system to protect against loss of sensitive data should any of these machines be lost or stolen. All data used by NORC staff is stored within and transmitted on NORC's private network and is secured as per our highest standard protocol. Should a project obligation require that the data be electronically transmitted to or from NORC's secure, private network, standard protocol dictates that encryption technology be used. Due to the variety of data delivery requirements that projects may demand, any enhanced electronic transfer security can be addressed within alternative protocols.

Access Control / Authentication. NORC follows the least privilege data access model, meaning that users have visibility only to the data for which they have been approved. All unique user credentials and associated permissions are subject to the controls and standards maintained by NORC's Information Technology (IT) department. Passwords must be changed on a regular basis, in addition to meeting stringent requirements for length and complexity.

Backup and Retrieval Procedures. All data that currently resides on the NORC network is electronically backed up on a nightly basis. Any archived information is quickly retrievable. Only a limited number of NORC's IT personnel are authorized to request the retrieval of these data media. This retrieval process requires a strict identification and authorization procedure. Backups made for the purpose of disaster recovery have a retention period of 30 days, after which time the backup data is destroyed unless there are specific project requirements. NORC maintains a Disaster Recovery Plan as part of its standard operating procedure, so that in the event of a major system outage, production systems can quickly be restored and normal operations resumed.

Unauthorized Access. All attempts to access NORC's network are tracked, internally and externally. Our internal tracking allows for four attempts, after which the account is temporarily locked. It can only be unlocked by an authorized individual from the technical support team, who will review each situation prior to unlocking the account. If the behavior continues, after twenty failed login attempts or more than twice a day, an email will be generated to the Infrastructure (ISO) team. An authorized IT personnel will review these emails and assess the resolution. If it is a valid user with the proper security to access the account, s/he will be contacted and assistance will be provided. If it is not a valid user the issue will be escalated to the proper channels within the project or company. These policies apply to access via a smart phone or wireless network as well. To protect against unauthorized access from outside the NORC network, there is a firewall that prevents anyone from getting to a network login. The only method of getting through the firewall would be through the virtual private network (VPN) or a secure externally facing server, which would require an active User ID and password.

System Audits. NORC cooperates with all federal and independent agencies that require system audits and in the past has met or exceeded all such requirements. NORC maintains strict internal requirements in its processes for compliance with the National Institute of Standards and Technology (NIST) Special Publication 800-53 Revision 4 recommendations. NORC currently has government projects that require similar compliance via other regulations (e.g. IRS Publication 4812) and recent audits by projects have found that our systems meet or exceed the applicable requirements. NORC has projects underway for the Federal Reserve Board, Bureau of Labor Statistics, the Centers for Disease Control (CDC), and Health and Human Services (HHS) that require independent audits to confirm compliance and are willing to submit to periodic site reviews to confirm compliance, if necessary. In each case NORC has successfully met the NIST and other standards. NORC has received authorization to operate (ATO) from the following government agencies:

- *HHS/Office of Minority Health*
- *Centers for Disease Control*
- *National Institutes of Health*
- *Bureau of Labor Statistics*
- *US Department of Commerce – Bureau of the Census*
- *Department of Labor*

NORC's security standard and process also includes the documentation, testing, and provision of a System Security Plan (SSP), Contingency Plan, Configuration Management Plan, and others as required.

Personnel Security and Procedures. NORC conducts a pre-employment background investigation on each new or returning employee (if the returning employee has been gone for over one year or has not previously had a background investigation conducted). Additionally, NORC may require employees transferring to a new project or different department to undergo a new background investigation. Offers to new hires are contingent upon the satisfactory completion of a background investigation, and all NORC employees must complete a Commitment to Confidentiality form as a condition of employment. During this training process, the information security controls and concepts are presented and rules for following the procedures are clearly outlined. On an annual basis, employees are required to secure their commitment to the protocols and concepts by taking a "test" and re-signing the commitment form. In addition, all staff members receive security training specific to the project to which they are assigned, resulting in security clearances up the level required by their role within the project, as needed.. At the time of hiring, the staff also must read and sign a legally binding pledge upholding the confidentiality provisions established under the Privacy Act of 1974.

7. **Will any datasets be used?**
    a. Is there a Memo of Understanding (MOU) or Data Use Agreement (DUA) associated with the use of these data?

We do not yet have executed DUAs from administrative agencies. We have uploaded unexecuted DUAs to section 24 unexecuted DUAs from similar projects whenever possible. Once we obtain an executed DUA from agencies, we will submit an amendment to the IRB with these additions.

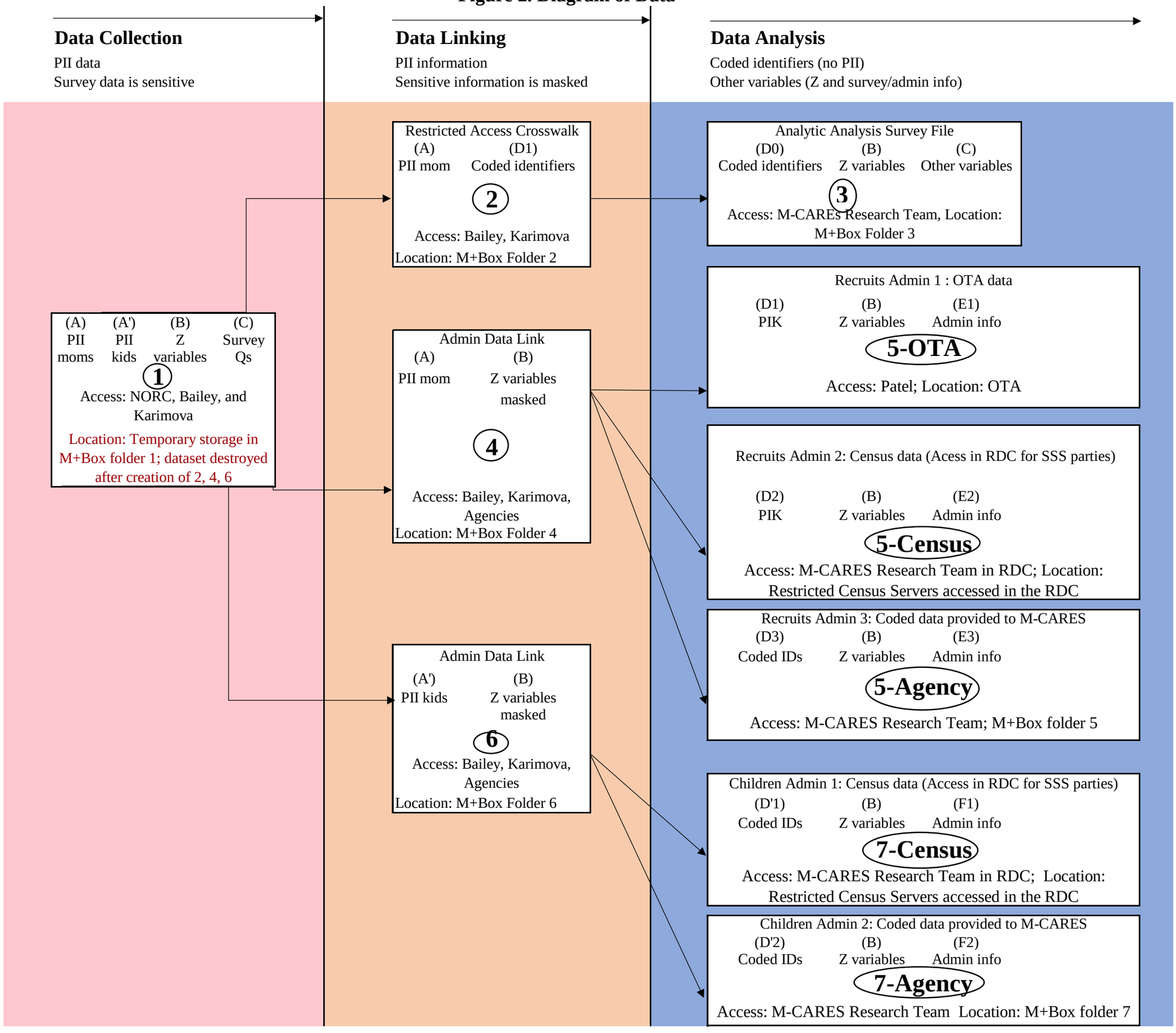
We have also created a DUA (appended in Section 44) that will govern the use of coded survey and administrative data for M-CARES "approved personnel" after this has been shared with us.

    b. Does your security plan include all requirements contained in the MOU/DUA?

We do not yet have the agency DUAs, but we will ensure that our security protocol meets or exceeds the requirements of DUAs.

Once the data are at Michigan, our security plan for the use of administrative and survey data includes all of the provisions in our appended DUA.

Figure 2. Diagram of Data



Introductory screen for interviewer—click the logo to start

M-CARES

MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

Interviewer, please touch the logo and enter your response to the first question.

Surveyor Confirm Can Take Screen

1. Interviewer enter payment scale

Interviewer, please indicate the fee scale on the small [color] card given to the woman by PPMI.

1/A
2/B
3/C
4/D
5/E

2. Interviewer confirmation of payment scale

[Print Q1 and Q1 answer.] (The following could also be a pop-up box.)

Is your answer correct?

No [SKIP to Q1]
Yes [If YES and Q1=1, STOP SURVEY: GO TO FIRST SCREEN WITH LOGO]

Interviewer please hand the tablet to the respondent.

Invitation to be in M-CARES

Summary of Consent

Main Consent

Introductory screen for respondent—click the logo to start

M-CARES

MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

Thank you for taking this survey.

The survey should take you around 5 minutes and you will receive $10 in cash.

If you are eligible, we will ask you to provide your personal information in order to collect your administrative records. Providing this information will also take about 5 minutes.

Please ask the interviewer if you have any questions or need any help.

Screen

3. Already enrolled in M-CARES

Have you already signed up for M-CARES?
Yes
No [GO TO Q5]

4. Confirmation of payment scale

(As a pop-up box on the same screen:) Is it correct that you have already signed up for M-CARES?
Yes, it is [If YES, STOP SURVEY: PRINT BOX BELOW]
No, it isn't [SKIP to Q3]

5. Payment category

When you checked in at Planned Parenthood today, you received a small M-CARES card with your fee scale. Which box is checked?

1/A
2/B
3/C
4/D
5/E
[If Q2=Q1, SKIP to Q7]

6. Confirmation of payment scale

(As a pop-up box on the same screen:) Can you confirm that the fee scale you entered is the same as on your M-CARES card?

Yes, it is [If YES and Q5=1, STOP SURVEY: GO TO FIRST SCREEN WITH LOGO]
[If YES and Q5≠Q1, PRINT BOX BELOW]
[If YES and Q5=Q1 and Q3≠1 , GO TO Q7]

No, it isn't [SKIP to Q5]

Your answer differs from what you told the interviewer.
Please hand the tablet back to the interviewer.

[After 30 seconds, GO TO FIRST SCREEN WITH LOGO]

7. Age

[If Q3=Q1]: How old are you?

____ [Integer 0-99]

8. Confirmation of age

[If Q3=Q1 and Q7<18 or Q7>35] (As a pop-up box on the same screen:) Can you confirm your age is entered correctly?

Yes, it is [If YES and Q7<18 or Q7>35, STOP SURVEY AND PRINT BOX:

Unfortunately, based on your age, you are ineligible to participate in this study. Please hand the tablet back to the interviewer.

No, it isn't [SKIP to Q7]

After 30 seconds, GO TO FIRST SCREEN WITH LOGO.

Demographic characteristics

9. Race

Which of these groups *best* describes your racial/ethnic background? (Choose all that apply.)

American Indian, Alaskan Native or Native Hawaiian
Asian or Pacific Islander
Black, African, or African American
Hispanic or Latino
White
Another race/ethnicity:_____

10. Marital status

Which of the following best describes your current relationship status? (Choose one answer.)

Married
Not married, but in a committed relationship
Not married, but in a relationship
Not in a relationship [SKIP TO Q12]

11. Living with partner

Are you currently living with your [if Q10=Married: spouse/ if Q10=Not married but in a committed relationship or Not married but in a relationship: romantic partner]?

Yes
No

12. Partner male

In the last 12 months, have you have sex with a man?

Yes
No

13. Educational completion

What is the highest degree or level of school you have COMPLETED? If currently enrolled, mark the previous grade or highest degree received. (Choose one answer.)

No schooling completed
Grade 1 through 11 [if select, ask: Specify grade:____ [accept 1 or two integers 1-11]
12th grade [Roll out below if select]
- NO DIPLOMA
- Regular high school diploma
- GED or alternative credential

College or some college [Roll out below if select]
- Some college credit, but less than 1 year of college credit
- 1 or more years of college credit, no degree
- Associate's degree (for example: AA, AS)
- Bachelor's degree (for example: BA, BS)

More than a bachelor's degree [Roll out below if select]
- Master's degree (for example: MA, MS, MEng, MEd, MSW, MBA)
- Professional degree (for example: MD, DDS, DVM, LLB, JD)
- Doctorate degree (for example: PhD, EdD)

PPMI questions

14. Clinician visit

Is your visit today with a clinician? (This is indicated on your small M-CARES card.)

Yes
No

15. Reason for your visit today

What is the reason for your visit today? (Check all that apply).

Family planning services or to get a method to avoid or delay pregnancy (condoms, pills, intrauterine device, contraceptive implant, etc.)
Acute problem or illness
Pregnancy test or pregnancy counseling
Screening or treatment for sexually transmitted infection
Routine examination (pelvic exam, pap smear or breast exam)
Plan B (or morning after pill)
Abortion (or abortion Pill)
Other: _____

16. Planned Contraceptive

[IF Q15=" Family planning services or to get a method to avoid or delay pregnancy (condoms, pills, intrauterine device, contraceptive implant, etc.)]
What family planning services or methods to avoid or delay pregnancy do you plan to get today?

Birth control pills
Condoms
Shot (for example: Depo-Provera)
Intrauterine device or IUD (for example: Liletta, Mirena, Paragard, or Skyla)
Withdrawal
Ring (for example: NuvaRing)
Patch (for example: Ortho Evra)
Implant (for example: Nexplanon)
"Morning after pill" or emergency contraception
Abstinence or not having vaginal sex
Rhythm method or natural family planning
Something else: _____

17. Payment method

Do you have health insurance? (This can be found on the card you received at check-in.)

Yes
No

18. Out-of-pocket costs

Do you expect to pay yourself for any of the costs for your office visit today?

Yes
No
Don't know

19. Out-of-pocket costs for method

If you were to get a method to avoid or delay pregnancy today, would you expect to pay for any of the costs yourself?

Yes
No
Don't know

Childbearing History

20. Times have you given birth

How many live births have you had?

_____ [Integer 0-10]

21. Fecundity

Some women are not physically able to get pregnant or give birth [Q20=0 ?/Q20>0 another time?]. As far as you know, is it physically possible for you to get pregnant [Q20=0 ?/Q20>0 again?]

Yes [SKIP TO Q23]
No

22. Why sterile?

Why do you think it is impossible for you to get pregnant or give birth [Q20=0?/Q20>0 again?]

I had surgery (for example: hysterectomy, tubes tied, eggs removed)
Other:_____

23. Pregnant

Are you pregnant now or do you think you might be pregnant now?

Pregnant now
Think you might be pregnant now but are not sure
Not pregnant now [SKIP TO Q25]

24. Trying to get pregnant

Were you trying to get pregnant?

Yes [SKIP TO Q26]
No

25. Want to get pregnant in next 12 months

Do you want to get pregnant in the next 12 months?

Yes
No

Birth control

26. Currently using birth control

[IF Q23≠Pregnant Now] In the past month, have you used any method to prevent or delay pregnancy?
[IF Q23=Pregnant Now] In the month before you got pregnant, were you using any method to prevent or delay pregnancy?

Yes
No [SKIP TO ELIGIBILITY SCREEN]

27. Birth control method

In the past month, what methods have you used to prevent or delay pregnancy? (Choose all that apply.)

Birth control pills
Condoms
Shot (for example: Depo-Provera)
Intrauterine device or IUD (for example: Liletta, Mirena, Paragard, or Skyla)
Withdrawal
Ring (for example: NuvaRing)
Patch (for example: Ortho Evra)
Implant (for example: Nexplanon)
"Morning after pill" or emergency contraception
Abstinence or not having vaginal sex
Rhythm method or natural family planning
Something else: _____

28. Main birth control method

[If Q27 more than one answer]: In the past month, what is the main method that you have used to prevent or delay pregnancy? (Choose one answer.)

[Print answers to Q27 and allow respondents to select]

Method Satisfaction

29. Method satisfaction

How satisfied are you with this method?

Very satisfied [SKIP TO CONSENT]
Pretty satisfied
Neutral
Unsatisfied
Very unsatisfied

30. Why not satisfied

What is the one main reason you are not very satisfied with this method? (Choose all that apply.)

Too expensive
Too difficult to obtain the method
Too difficult to use
Partner does not like it
You have side effects or are worried you might have side effects
You worry that the method will not work
The method does not protect against disease
The method decreases your sexual pleasure
Other:_____

Non-Participant Consent

ELIGIBILITY SCREEN: IF SCREEN POSITIVE [Q1 = [2-5], Q3 = [2-5], Q7 = [18-35], Q12=Yes, Q14=Yes, Q21=Yes; Q23=Not Sure or Not Pregnant, Q25=No], SKIP TO INVITATION AND CONSENT.

31. Non-Participant consent to contact

We may be interested in getting in touch with you in the future about a different survey. May we have your name and contact information so that we might contact you in the future to ask you about your life and experiences?

Yes
No [GO TO LAST SCREEN FOR NONPARTICIPANTS]

32. Nonparticipant Name

What is your full, legal name?

_____

33. Nonparticipant Cell Phone

What is the best phone number where you can be reached?

Phone number _____ [Computer should require 10 digits; first digit of area code should be between 2 and 9; array these numbers between dashes and not allow dashed entries]

34. Nonparticipant Email

What is your email address?

_____

35. Nonparticipant Address

What is your current address?

Street Address _____
Apt_____
City_____
State_____
Zip_____

36. Nonparticipant Social media contact information

Please indicate social media accounts where we can reach you. For example, Facebook, Instagram, etc.

_____ _____ _____ _____ _____

37. Nonparticipant Close contacts #1

What is the name of a person we could reach out to in the future to help us locate you?

First name _____
Last name _____
Email
Telephone

38. Nonparticipant close contact relationship

How do you know this person? Is s/he your: (Choose one answer.)

Parent
Spouse/partner
Sibling
Other relative
Friend
Neighbor
Other: _____

39. Nonparticipant Close contacts #2

What is the name of a second person we could reach out to in the future to help us locate you?

First name _____
Last name _____
Email_____
Telephone_____

40. Nonparticipant close contact #2 relationship

How do you know this person? Is s/he your: (Choose one answer.)

Parent
Spouse/partner
Sibling
Other relative
Friend
Neighbor
Other: _____

Last Screen for Nonparticipants

M-CARES
MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

Thank you so much for your time! Hand the tablet back to the interviewer, and she will give you $10 for participating.

Please contact us if you have any questions about the M-CARE study. You can call us toll-free at

1-844-864-8258

or email m-carestudy@umich.edu.

For study updates, visit http://sites.lsa.umich.edu/m-carestudy

Consent to Use Administrative Records and PHI

[We only ask for this consent from eligible individuals who choose to participate.]

Consent to Release Admin Records

Consent to Release PHI (HIPAA)

Last Screen for Participants

M-CARES
MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

Thank you so much for your time! Hand the tablet back to the interviewer, and she will give you $10 for participating.

[If voucher=Yes:] She will also write your voucher number (VID) and dollar amount on your M-CARES card.

[If voucher=No:] She will also write your voucher number (VID) on your M-CARES card.

Before leaving the clinic today, please remember to take another survey. It will take about 25 minutes and you will receive **$60 in cash for completing it today at the clinic**. If you choose to take the survey later, you will instead receive $40 for completing it.

Please contact us if you have any questions about the M-CARE study. You can call us toll-free at

1-844-864-8258

or email m-carestudy@umich.edu.

For study updates, visit http://sites.lsa.umich.edu/m-carestudy

Interviewer Observations

41. Interviewer enter PIN

Surveyor please enter your PIN

_____ [several digits]

42. Perceived interest

Overall, how great was R's interest in the survey?

Very high
Fairly high
Average
Fairly low
Very low

43. Perceived suspicion

How suspicious did respondent seem to be about the study before the survey?

Not at all suspicious
Somewhat suspicious
Very suspicious

44. Visible disabilities

Does the respondent have any visible disabilities?

Yes. Specify:_____
No
Don't Know

45. Apparent intelligence

Rate the respondent's apparent intelligence

Very high
Fairly high
Average
Fairly low
Very low

GO TO FIRST SCREEN WITH LOGO TO BEGIN NEXT SURVEY.

Introductory screen—click the logo to start

Thank you for taking time for this survey. It should take you around 25 minutes. Please ask the interviewer if you have any questions.

[If data of screening survey=date initiating this baseline survey]:

You will receive $60 in cash for taking this survey *today* at the clinic. If you choose to take the survey later, you will instead receive $40.

[If data of screening survey<date initiating this baseline survey]:

You will receive $40 for taking this survey. We will give you the $40 in cash if you are in a Planned Parenthood clinic. We will give you an electronic gift card if you are taking this survey outside of the clinic.

Link individual to screener and voucher information

1. Please enter your VID, Name and Date of Birth

[IF USING A PERSONALIZED HYPERLINK, SKIP TO Q2]: This is located on the card you received at check-in; you also should have received a text and email with this information.

VID: _____ [This is located on the card you received at check-in]
Last name: _____
Date of birth: _____
[NORC, use name and DOB to validate no typo in VID.]

2. Confirm first and last name

Please confirm this information is correct. *As a reminder, this information allows us to follow up with you and collect your administrative records. We will keep your information strictly confidential.*

Preload first and last name
Social security number
Telephone
Email
Address

Yes [SKIP TO Q5] ☐ No ☐

3. Update personal information

Please update or add information below. *As a reminder, this information allows us to follow up with you and collect your administrative records. We will keep your information strictly confidential.*

Update	Add	
☐		First and last name: _____
☐		Social security number: _____
☐	☐	Telephone: : _____
☐	☐	Email: _____
☐	☐	Address: _____

4. Reconfirm personal information

Please confirm this information is correct. *As a reminder, this information allows us to follow up with you and collect your administrative records. We will keep your information strictly confidential.*

Preload first and last name updated from Q3
Telephone updated from Q3
Email updated from Q3
Address updated from Q3

Yes ☐ No[SKIP TO Q3] ☐

Voucher and PPMI use

[ONLY FOR WOMEN WHO GOT A VOUCHER]

5. Voucher Value

What was the dollar value of the gift card that you received [if today's date=screen date: today?] /[if date>screen date: at your last visit to Planned Parenthood?] (This is listed on the small M-CARES card you received.)

___[Integer 1-500]

6. Same-Day Use

Did you use your gift card at Planned Parenthood?

Yes ☐ No ☐ [SKIP TO Q9]

7. Any Money Left On Voucher

Do you have any money left on your gift card?

Yes ☐ No ☐ [SKIP TO Q12]

8. How Much Voucher

How much money is left?
___ [Integer 1-600] [SKIP TO Q10]

Remember you can spend this gift card until [DATE+ 100 days].

9. Why Did Not Use

[Clarification: SKIP IF Q6=YES]Why didn't you use the gift card?

I did not have any costs (for example: I have insurance, Planned Parenthood did not charge)
I did not need any services
I did not have time to use it
I forgot to use it
I do not want to use it [SKIP TO Q12]
Other:_____

10. Intend to Use Gift Card

Do you plan to use the gift card in the future?

Yes, I have already scheduled an appointment to use it
Yes, but I have not scheduled an appointment yet
No, I do not plan to use the gift card [SKIP TO Q12]

If your needs change, remember you can spend this gift card until [DATE+ 100 days].

11. How Will You Use Gift Card

How do you plan to use the gift card?

Intrauterine device or IUD (for example: Liletta, Mirena, Paragard, or Skyla)
Shot (for example: Depo-Provera)
Birth control pills
Ring (for example: NuvaRing)
Patch
Implant (for example: Nexplanon)
"Morning after pill" or emergency contraception
Something else: _____
Don't know

[FOR ALL WOMEN EVEN THOSE WHO DID NOT GET A VOUCHER]

12. Discussed birth control

At [if today's date=screen date: today's] /[if today's date>screen date: your last] Planned Parenthood visit, did you talk with your provider about methods to prevent or delay pregnancy?

Yes ☐ No ☐

13. Change birth control method for nonusers

[if SURVEY_1_Q26=NO]: Before [if today's date=screen date: today's] /[if today's date>screen date: your last] Planned Parenthood visit, you told us that you were not using any method to prevent or delay pregnancy. Has that changed?

Yes ☐ [SKIP TO Q15] No ☐ [SKIP TO Q16]

14. Change birth control method for current users

[if SURVEY_1_Q26=YES]: Before [if today's date=screen date: today's] /[if today's date>screen date: your last] Planned Parenthood visit, you told us that you were using the following method(s) to prevent or delay pregnancy: [PRINT SCREEN_Q27 ANSWER].

Are you still using [if one SCREEN_Q27 ANSWER: this method]/ [if more than one SCREEN_Q27 ANSWER: these methods]?

Yes, and I plan to continue this method [SKIP TO Q16]
Yes, but I plan to change or add a new method soon
No, I changed my method

15. New method change

Which new methods of contraception [Q14=Yes, but…: are you planning to use to prevent or delay pregnancy? / Q14=No or Q13=Yes: are you using to prevent or delay pregnancy?] (Choose all that apply.)

Birth control pills
Condoms
Shot (for example: Depo-Provera)
Intrauterine device or IUD (for example: Liletta, Mirena, Paragard, or Skyla)
Withdrawal
Ring (for example: NuvaRing)
Patch (for example: Ortho Evra)
Implant (for example: Nexplanon)
"Morning after pill" or emergency contraception
Abstinence or not having vaginal sex
Rhythm method or natural family planning
Something else: _____
[Q14=Yes, but…] I plan to stop using any method

16. Rate care

At [if today's date=screen date: today's] /[if today's date>screen date: your last] visit to Planned Parenthood, how satisfied were you with the care you received?

Very dissatisfied	Somewhat dissatisfied	Neutral	Satisfied	Very satisfied
☐	☐	☐	☐	☐

Work and Income

17. Working for Pay

Are you currently working for pay? (Working for pay can be anything someone does for pay – a full-time or part-time job or jobs like childcare, housecleaning, yard work, errands, etc.)

Yes ☐ No ☐

18. Current job

What kind of work do you [if Q17="No": usually do when you are working. That is, what is your usual job or occupation?/ [if Q17="Yes": do? That is, what is your current job or occupation?]

____

19. Want a job

Did you look for work at any time during the last 12 months?

Yes ☐ No ☐

20. Currently looking for work

[if Q17="No"]: Are you currently looking for paid work, either full or part-time?

Yes ☐ No ☐

21. Hours per week

How many hours per week [Q17=YES: do you usually work at your main job?]/[Q17=NO: would you like to work]?

____ [Integer 0-99]

22. Income category

Which of the following categories best describes your total household income from all sources?

$0 to $4,999
$5,000 to $14,999
$15,000 to $24,999
$25,000 to $49,999
$50,000 to $74,999
$75,000 to $99,999
$100,000 to $149,999
$150,000 or higher
Don't know

School enrollment

23. Educational enrollment

Are you currently enrolled in school?

Yes ☐ No ☐ [SKIP TO Q25]

24. School

What kind of school do you attend?

Grades 1-12 →[If select, ask:]Specify grade: ____ [Accept grade 1-12]
Vocational, technical, or trade school →[If select, ask:] What kind?_____:
2-year junior or community college
4-year college
Other:_____

Religion

25. Religious preference

In terms of your religious preference, are you Protestant, Catholic, Jewish, Muslim, no religion, or something else?

Protestant
Catholic
Jewish
Muslim
Something else:_____
No religion

26. Religion - attendance

How often do you usually attend religious services?

Several times a week	Once a week	A few times a month	Once a month	Less than once per month	Never
☐	☐	☐	☐	☐	☐

27. Religion - daily

Please let us know if you agree with the following statements.

You employ religious or spiritual beliefs as a basis for how to act and live on a daily basis.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐

28. Religion – Bible

The Bible is God's word and everything happened or will happen pretty much as it says.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐

My religion is not based on the Bible
☐

Birth History

29. Times given birth

In our first survey, you told us that you have given birth [PRELOAD ANSWER TO SURVEY_1_Q20] times. Is that right?

Yes
☐ [SURVEY FILLS in Q30 with SURVEY_1_Q20 ANSWER and SKIP TO Q31]

No
☐

30. CORRECTED Times given birth

What is the correct number of times that you have given birth?

___ [Integer 0-10]

31. Times pregnant

How many times have you ever been pregnant? (If you are pregnant today, please count it.)

___ [Integer 0-20]

32. Times miscarriage

How many times have you had a miscarriage or stillbirth?

___ [Integer 0-20]

33. Times abortion

How many times have you ever had an abortion? (If you are having an abortion today, please count it.)

___ [Integer 0-20]

34. Age at menses

How old were you when you had your first period (menses, menstrual period)?

___ [Integer 8-20] [SKIP TO Q36]
Don't know

35. Age at first menses guess

If you're not sure, can you give us your best guess? About how old do you think you were when you had your first period?

Before age 12
Age 12-13
Age 14-15
Age 16-17
Age 18
Older than age 18

36. Age at first sex

How old were you the first time you had sexual intercourse? Sexual intercourse is when a man puts his penis into a woman's vagina.

Never had sexual intercourse [SKIP TO Q43]
____ [Integer 0-35] [SKIP TO Q38]
Don't know

37. Age at first sex guess

If you're not sure, can you give us your best guess? About how old do you think you were when you first had sexual intercourse?

Before age 15
Age 15-17
Age 18-19
Age 20-21
Age 22-25
Age 25 or older

Child Information

38. Number co-resident children

How many of the children you have given birth to have lived with you?

___[INTEGER 0- ANSWER Q30]

39. Child information

Earlier you told us that these are your children. Is this list complete and correct? *As a reminder, we will keep this information strictly confidential.*

[PRINT INFORMATION on names and dob FROM CONSENT FORM]

Yes [SKIP TO Q42] No

☐ ☐

40. Update child roster

Please update this information. *As a reminder, we will keep this information strictly confidential.*

[PRINT INFORMATION ON NAMES AND DOB FROM CONSENT FORM AND ALLOW FOR CHANGES]

41. Reconfirm child information

Is this list complete and correct? *As a reminder, we will keep this information strictly confidential.*

[PRINT INFORMATION on names and dob FROM Q40]

Yes No [SKIP TO Q40]

☐ ☐

42. Add child POB

Will you also add the city/town and state where each child was born? *As a reminder, this information allows us to collect your children's administrative records. We will keep this information strictly confidential.*

[PRINT INFORMATION on names and dob FROM Q40 AND ALLOW FOR COUNTRY, STATE AND CITY OF BIRTH]

Birth control and healthcare access

43. Usual place of care

Is there a particular doctor's office, clinic, health center, or other place that you usually go if you are sick or need advice about your general health?

Yes ☐ No ☐

44. Have usual place for birth control

Is there a particular doctor's office, clinic, health center, or other place that you usually go, if you need contraception (services or methods for avoiding or delaying pregnancy)?

Yes ☐ No ☐ [SKIP TO Q46]

45. Usual place for birth control

Where do you usually go if you need contraception (services or methods for avoiding or delaying pregnancy)?

Planned Parenthood
Health Center
Doctor's office
Pharmacy
Other:_____

46. Delay in care

In the last 12 months, have you delayed getting medical care, tests, or treatments you or a doctor believed necessary?

Yes	No
☐	☐ [SKIP TO Q50]

47. Reason delayed medical care

What is the reason you delayed getting medical care, tests, or treatments that you or a doctor believed necessary? (Choose all that apply.)

Could not afford it	[IF YES, ASK Q48]
Did not have time	[IF YES, ASK Q49]
Could not get transportation	[SKIP TO Q50]
Did not know where to go	[SKIP TO Q50]
A doctor or provider refused to give me services	[SKIP TO Q50]
Partner, family member, or a friend prevented me from seeking care	[SKIP TO Q50]
Other:_____	[SKIP TO Q50]

48. Reason medical care -Afford

Why were you unable to afford care? (Choose all that apply.)

Insurance company would not approve/cover/or pay for care
Doctor refused to accept family's insurance plan
Did not have insurance
Could not afford insurance co-pay
Other:_____

49. Reason medical care-Time

Why did you not have time to get care? (Choose all that apply.)

Could not get child care
Could not take time off work or school
Too many other things to do
Services take too long or require many visits
Other:_____

50. Delay in birth control

In the last 12 months, have you delayed getting contraception (services or methods to help you avoid or delay pregnancy)?

Yes	No
☐	☐ [SKIP TO Q54]

51. Reason delayed birth control

What is the reason you delayed getting contraception (services or methods to help you avoid or delay pregnancy)? (Choose all that apply.)

Could not afford it	[IF YES, ASK Q52]
Did not have time	[IF YES, ASK Q53]
Could not get transportation	[SKIP TO Q54]
Did not know where to go	[SKIP TO Q54]
A doctor or provider refused to give me services	[SKIP TO Q54]
Partner, family member, or a friend prevented me from getting birth control	[SKIP TO Q54]
Other:_____	[SKIP TO Q54]

52. Reason delay birth control – could not afford

Why could you not afford to get contraception (services or methods to help you avoid or delay pregnancy)? (Choose all that apply.)

Insurance company would not approve/cover/or pay for care
Doctor refused to accept family's insurance plan
Did not have insurance
Could not afford insurance co-pay
Other:_____

53. Reason delay birth control – time

Why did not you have time to get contraception (services or methods to help you avoid or delay pregnancy)? (Choose all that apply.)

Could not get child care
Could not take time off work or school
Too many other things to do
The services take too long or require many visits
Other:_____

Plans for the future

54. Positive Desire To Have A Baby

As you know, getting pregnant and having a baby is a big event, one that has a lot of consequences. Most people have some positive and some negative feelings about getting pregnant and having a child. For this reason we are going to ask you about how much you *want* to get pregnant and how much you want to *avoid* getting pregnant.

How much do you want to get pregnant in the next 12 months?

Want to get pregnant:

Not at all → Extremely

☐ ☐ ☐ ☐ ☐ ☐

Don't know
☐

55. Negative Desire To Have Baby

How much do you want to avoid getting pregnant in the next 12 months?

Want to *avoid* getting pregnant:

Not at all → Extremely

☐ ☐ ☐ ☐ ☐ ☐

Don't know
☐

56. Coombs Scale A

The number of children people expect to have and want to have are not always the same.

If you could have just the number you want, what number of children would you want to have when your family is completed?

____[Integer 0-20]
If 0 or Don't know [SKIP TO Q59]

57. Coombs Scale B

Now, we would like to know how you feel about some other possible family sizes.

If you could not have [Q56], would you want to have [Q56 – 1] or [Q56 + 1] children?

[Q56 – 1] [SKIP TO Q59 if [Q56 – 1]==0]
[Q56 + 1]
Don't know [SKIP TO Q59]

58. Coombs Scale C

[IF Q57< Q56]: And if you did not have [Q57], would you rather have [Q57-1] or [Q57+2]?
[IF Q57> Q56]: And if you did not have [Q57], would you rather have [Q57-2] or [Q57+1]?

59. Don't know Number of Children Expect To Have

Sometimes what people want and what they expect are different, because they are not able to do what they want.

How many children do you expect to have?

____ [Integer 0-20]

60. Desire Marriage?

[UNIVERSE: R is not currently married—SCREENER Q10≠married]: How much do you want to get married?

Not at all ⟶ Very much

☐ ☐ ☐ ☐ ☐

61. Marital Status – Expectation to be Married at age 40

[UNIVERSE: all respondents]: What are the chances you will be married at age 40?

Very unlikely ⟶ Extremely Likely

☐ ☐ ☐ ☐ ☐

62. Expectation to be in a committed relationship at age 40

[UNIVERSE: all respondents]:What are the chances you will have a long-term committed relationship or a commitment ceremony before age 40?

Very unlikely ⟶ Extremely Likely

☐ ☐ ☐ ☐ ☐

63. Highest Degree Completed R Expects

As things now stand, what do you think is the highest degree or level of school you will complete by the time you are finished with school?

[MINIMUM DEGREE IN LIST SHOULD BE ANSWER TO SCREENER Q11; repeat options above minimum from ANSWERS TO SCREENER Q11]

64. Want To Go To School Future

How much do you want to enroll in school in the future?

Not at all ⟶ Very much

☐ ☐ ☐ ☐ ☐

65. Does R Want To Work Outside Home At Age 40?

Now I would like to ask you about your future plans.

When you are age 40, about how many hours per week would you like to be working for pay?

_____[Integer 0-99]
0 [SKIP TO Q68]

66. Kind of Job At Age 40

When you are age 40, what kind of job you would like to be doing?

Same as current job [SKIP TO Q68]
Some other job
Caring for family (not working for pay) [SKIP TO Q68]
Other

67. Occupation Aspiration At Age 40

When you are age 40, what other kind of job would you like to be doing?

_____

68. Expected Ability To Achieve Occupation Aspiration At Age 40

When you are age 40, what do you are the chances you will be doing the job you would like to be doing?

Very unlikely ⟶ Extremely Likely
☐ ☐ ☐ ☐ ☐

Childhood environment

69. Nativity

Where were you born?

In the U.S. [SKIP TO Q70]
In another country

70. Other Country

In which country were you born?

Country: _____ [SKIP TO Q72]

71. US town/city state

Where in the U.S. were you born?

City/town: _____
State:_____ [use scrolldown menu]

72. Most Of The Time Lived With

With whom did you live for the most of the time when you were growing up? (Choose all that apply.)

Biological mother
Biological father
Step-mother
Step-father
Adoptive mother
Adoptive father
Grandmother
Grandfather
Other relative(s)
Foster mother
Foster father
Institution

73. Mother Education

[ASK IF Q72=Biological mother, step mother, foster mother, or grandmother]: What is the highest level of education your [mother/step-mother/foster mother/grandmother] completed?

Less than high school
High school diploma or GED
Some college
Bachelor's degree or more
Don't know

74. Biological Parents Married

Were your biological parents married to each other at the time you were born?

Yes ☐ No ☐ Don't know ☐

75. Number of Biological Mother's Children

How many children did your biological mother have?

_____ [Integer 1-20]
Don't know

76. Biological Mother's Age At First Birth

How old was your biological mother when she had her first child?

Less than 18 years
18-19 Years
20-24 Years
25-29 Years
30 or older
Don't know

77. Childhood Financial Security

When you were growing up, how difficult was it for your family financially?

Not at all → Very much

☐ ☐ ☐ ☐ ☐

78. Parents Own Home

When you were growing up, did your parents or guardians own their own home?

Yes ☐ No ☐ Don't know ☐

79. Receive Public Assistance

When you were you were growing up, did your family ever receive government benefits, like food stamps (SNAP), welfare (TANF, AFDC), WIC, Medicaid, or Social Security?

Yes ☐ No ☐ Don't know ☐

80. Childhood Library Card

When you were growing up, did you or anyone else living with you have a library card?

Yes ☐ No ☐ Don't know ☐

Attitudes and Beliefs about Contraception

Now we would like to get your opinions on a few things about contraception. By "contraception," we mean *anything that can help delay or prevent getting pregnant* (for example: birth control pills, shots, implants, IUDs, condoms, etc.).

81. Difficult to find time

It is difficult to find the time to go to a doctor's appointment to get contraception.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

82. Birth Control Is Expensive

In general, contraception is too expensive to buy.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

83. Too Much Planning To Have Birth Control

It takes too much planning ahead of time to use contraception when you're going to have sex.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

84. Birth Control Is A Hassle

In general, contraception is too much of a hassle to use.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

85. Birth Control Makes You Sick

Using contraception is likely to make a woman feel sick.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

86. Birth Control Interferes With Sexual Enjoyment

Using contraception interferes with sexual enjoyment.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

87. Condom A Sign Of Mistrust

If a woman asks her partner to use a condom, he will think that she does not trust him.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

Relationship quality

UNIVERSE: SURVEY_1_Q10 ≠"Not in a relationship". If SURVEY_1_Q10 ="Not in a relationship", skip to Q102. If SURVEY_1_Q10 ≠"Not in a relationship", ask:

[if baseline survey date=screen date: Earlier today] /[if baseline survey date >screen date: When first filled out our survey], you told us that you were _____ [SURVEY_1_Q10≠"Not in a relationship: We would like to ask you a few questions about your partner.

88. Time with Partner

During the past four weeks, have you and that partner spent a lot of time together?

Yes ☐ No ☐

89. Exclusive Relationship

Have you and that partner ever agreed to have a special romantic relationship ONLY with each other, and no one else?

Yes ☐ No ☐

90. Partner Desire Pregnancy

How much do you think that partner wants you to get pregnant during the next 12 months?

Not at all ⟶ Extremely

☐ ☐ ☐ ☐ ☐ ☐

91. Disrespectful Treatment

In the past 4 weeks, has *anyone* you were dating or going out with:

Sworn at you, called you names, insulted you, or treated you disrespectfully?

Yes ☐ No ☐

92. ViolentThreat

Threatened you with violence?

Yes ☐ No ☐

93. Violent Treatment

Pushed you, hit you, or threw something at you that could hurt?Yes ☐ No ☐

94. Insist Sex

Insisted on having sex with you when you did not want to?

Yes ☐ No ☐

95. Threaten to Make Have Sex

Used threats to make you have sex with him?

Yes ☐ No ☐

96. Used Force to Make have Sex

Used force (hitting, holding down, using a weapon) to make you have sex with him?

Yes ☐ No ☐

97. Told Not Use Birth Control

If SURVEY_1_Q12=Men: Told you not to use any birth control (like the pill, shot, ring, etc.)?

Yes ☐ No ☐

98. Taken Away Birth Control

If SURVEY_1_Q12=Men: Taken your birth control (like pills) away from you or kept you from going to the clinic to get birth control?

Yes ☐ No ☐

99. Force Sex No Condom

If SURVEY_1_Q12=Men: Made you have sex without a condom so you would get pregnant?

Yes ☐ No ☐

100. Taken Off Condom

If SURVEY_1_Q12=Men: Taken off the condom while you were having sex, so you would get pregnant?

Yes ☐ No ☐

101. Put Holes in Condom

If SURVEY_1_Q12= Man: Put holes in the condom or broken the condom on purpose so you would get pregnant?

Yes ☐ No ☐

SF-12v2

102. Satisfaction with life

Overall, how satisfied are you with life as a whole these days?

Least satisfied → Most satisfied
0 10
_____ [Scale 0-10]

103. General health

In general, would you say your health is:

Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent ☐

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

104. Health: moderate activities

Moderate activities, such as moving a table, pushing a vaccum cleaner, bowling or playing golf?

No, not limited at all ☐ Yes, limited a little ☐ Yes, limited a lot ☐

105. Health: climbing stairs

Climbing several flights of stairs

No, not limited at all ☐ Yes, limited a little ☐ Yes, limited a lot ☐

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

106. Physical health problems: Accomplished less than you would like

Accomplished less than you would like

None of the time	A little of the time	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

107. Physical problems: Work less careful

Were limited in the kind of work or other activities

None of the time	A little of the time	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

108. Emotional problems: Accomplished less than you would like

Accomplished less than you would like

None of the time	A little of the time	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

109. Emotional problems: Work less careful

Did work or other activities less carefully than usual

None of the time	A little of the time	Some of the time	Most of the time	All of the time
☐	☐	☐	☐	☐

110. Pain interfere

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

111. Calm and peaceful

Have you felt calm and peaceful?

None of the time ☐ A little of the time ☐ Some of the time ☐ Most of the time ☐ All of the time ☐

112. Lots of energy

Did you have a lot of energy?

None of the time ☐ A little of the time ☐ Some of the time ☐ Most of the time ☐ All of the time ☐

113. Downhearted

Have you felt downhearted and depressed?

None of the time ☐ A little of the time ☐ Some of the time ☐ Most of the time ☐ All of the time ☐

114. Health interfere with social activities

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

None of the time ☐ A little of the time ☐ Some of the time ☐ Most of the time ☐ All of the time ☐

Fatalism

How much do you agree with the following statements?

115. Things Happen to Me

In life, things just seem to happen to me.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

116. Pregnancy Should Be Planned

Pregnancy is something that should be planned.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

117. Pregnancy Happens When Your Time

It doesn't matter whether you use birth control or not; when it is your time to get pregnant, it will happen.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

118. Pregnancy Blessing

Every pregnancy is a blessing.

Strongly disagree → Strongly agree

☐ ☐ ☐ ☐ ☐

Last screen for respondents who complete the survey:

M-CARES
MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

Thank you so much for taking this survey! This information will be used to understand how contraception can help women and families.

[If data of screening survey=date of baseline survey]: Please return your tablet to the interviewer and you will receive $60 in cash.

[If data of screening survey<date of baseline survey]: You will receive $40 for taking this survey. If you are in a Planned Parenthood clinic, we will give you the $40 in cash. If you are taking this survey outside of the clinic, the money will be mailed to you as a gift card.

We thank you in advance for participating in future surveys.

Please contact us if you have any questions about the M-CARE study. You can call us toll-free at

1-844-864-8258

or email us at m-carestudy@umich.edu.

For study updates, visit http://sites.lsa.umich.edu/m-carestudy.

For respondents who do not complete the survey:

M-CARES
MICHIGAN CONTRACEPTIVE ACCESS, RESEARCH AND EVALUATION STUDY

Thank you so much for taking this survey! This information will be used to understand how contraception can help women and families.

We estimate you have XXXX minutes left to complete the survey.

To continue where you left off, click [here.]

If you need to finish at another time, please log back in at this [XXXXX] using your VIN [list] (also on your M-CARES card) to complete it.

Please contact us if you have any questions about the M-CARE study. You can call us toll-free at

1-844-864-8258

or email us at m-carestudy@umich.edu.

For study updates, visit http://sites.lsa.umich.edu/m-carestudy.

eRESEARCH | REGULATORY MANAGEMENT

Date: Tuesday, March 27, 2018 10:14:05 AM Print

01. General Study Information

All questions marked with a red asterisk (*) require a response. Questions without a red asterisk may or may not require a response, depending on those questions' applicability to this study.

1.1* Study Title:

The Michigan Contraceptive Access, Research, and Evaluation Study (M-CARES)

1.1.1 Full Study Title:

1.1.2 If there are other U-M studies related to this project, enter the eResearch ID number (HUM#) or IRBMED Legacy study number. Examples of related projects include, but are not limited to:

- Projects funded under the same grant
- IRBMED Legacy study being migrated into eResearch
- Previously approved Umbrella applications (such as Center Grants or approvals for release of funding)
- Previously approved projects for which this is a follow up study

1.2* Principal Investigator:

Martha Bailey
Note: If the user is not in the system, you may Create A New User Account...

1.3 Study Team Members:

Study Team Member	Study Team Role	Appointment Dept	Appointment Selection Complete?	Student	Friend Account	COI Review Required	Edit Rights	Accepted Role?	PEERRS Human Subjects?
Martha Bailey	PI	LSA Economics	Yes	no	No	no	yes	N/A	yes
Jennifer Barber	Co-Investigator	SRC-Family Demography	Yes	no	No	no	no	Yes	yes
Vanessa Dalton	Co-Investigator	Obstetrics and Gynecology Dept	Yes	no	No	yes	no	Yes	yes
Daniel Eisenberg	Co-Investigator	Health Management and Policy	Yes	no	No	no	yes	Yes	yes
Alfia Karimova	Co-Investigator	Population Studies Center	Yes	no	No	no	yes	Yes	yes
Katie Genadek	Other		N/A	no	Yes	no	no	Yes	no
Elena Patel	Other		N/A	no	Yes	no	no	Yes	yes
Stephanie Hart	Administrative Staff	Population Studies Center	Yes	no	No	no	yes	N/A	yes

1.8* Project Summary:

M-CARES will use large-scale administrative data complemented by follow-up surveys and a randomized control trial (RCT) to estimate the causal impact of greater financial access to contraception on a comprehensive set of outcomes. Outcomes include contraceptive use, pregnancy, childbearing, and parenting strategies; partnership decisions and relationship quality; health and health care use; education, labor market success, and public assistance receipt; financial security; neighborhood quality; mental health and stress; and life plans. The resulting estimates will inform a more complete understanding of the costs and benefits of financial access to contraception and, therefore, the investment value of related policies and programs.

1.9* Select the appropriate IRB:

Health Sciences and Behavioral Sciences

1.10* *Estimated* Study Start Date (Not required for IRBMED): (mm/dd/yyyy)

1/1/2018

1.11* *Estimated* Duration of Study:

5 years

01-1. Application Type

1-1.1* Select the appropriate application type.

Standard, non-exempt, research project

01-2. Standard Study Information

1-2.1* Who initiated this study?

Investigator

If other, please specify:

1-2.2* Are you or any students working on this project being paid from a federally funded training grant?

○ Yes ● **No**

1-2.3 This study is currently associated with the following department. To associate this research with a different department, click Select. If the department has defaulted to "student", click select to specify the department through which this application is being submitted.

Population Studies Center

1-2.4 Will the study utilize resources from the following centers?

Select all that apply:

There are no items to display

1-2.6* Has the scientific merit of this study already been peer reviewed (i.e., reviewed by one or more recognized authorities on the subject)?

● **Yes** ○ No

1-2.6.1* List the peer-review organization(s).

Peer Review Organization
External sponsor review process (e.g. study selection)

1-2.7* Is this a clinical trial?

○ Yes ● **No**

Study Team Detail

1.4 Team Member:

Martha Bailey

Preferred email: baileymj@umich.edu
Business phone 734-647-6874
Business address: Economics 207 Lorch 48109-1220

1.5 Function with respect to project:

PI

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
CV_Bailey.doc	0.08

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

No

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

Study Team Detail

1.4 Team Member:

Jennifer Barber

Preferred email: jebarber@umich.edu
Business phone 734-647-6324
Business address: SRC-Family and Demography 2258 ISR 48109-1248

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
barbercv.doc	0.02
Jennifer Barber CV	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

No

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

Study Team Detail

1.4 Team Member:

Vanessa Dalton

Preferred email: daltonvk@umich.edu
Business phone 734-764-8429
Business address: OB/GYN L4000 Womens SPC 5276 48109-5276

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
Dalton CV	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

Yes

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

I am an expert witness for Bayer

Study Team Detail

1.4 Team Member:

Daniel Eisenberg

Preferred email: daneis@umich.edu
Business phone 734-763-1414
Business address: Population Studies Center 2116 ISR-Thompson 48104-1248

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
Eisenberg CV	0.10

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

No

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

Study Team Detail

1.4 Team Member:

Alfia Karimova

Preferred email: akarimov@umich.edu
Business phone 734-764-4080
Business address: ISR 426 Thompson St #2270 48104-1248

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
AlfiaKarimova_CV.pdf	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

No

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

Study Team Detail

1.4 Team Member:

Katie Genadek

Preferred email: katie.genadek@colorado.edu

Business phone

Business address: Institute of Behavioral Science Room RMRDC University of Colorado Boulder 483 UCB 80309

1.5 Function with respect to project:

Other

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
IMG_0128.PNG	0.01
IMG_0129.PNG	0.01

Financial Interest Screening Questions for Study Team Members Not Affiliated with the University of Michigan: Required for all roles except Administrative Staff

Below, you be asked several questions intended to identify Financial Interests and relationships that may be relevant to **THIS RESEARCH**. These may include Intellectual Property Interests (IP interests), as well as relationships with entities whose interests may affect/be affected by this research. If relevant to this research, you should also consider companies that compete commercially with the research sponsor or the manufacturer of the study drug, device or other investigational item if you know that the competitor's Financial Interests would reasonably appear to be affected by this research.

In relation to **THIS RESEARCH**, for the past 12 months, do you or your Family member (your spouse, domestic partner, or dependent) have or anticipate having any of the following Financial Interests:

F1. Are any *activities* or *relationships* with an entity, whether paid or unpaid, where that entity's financial interests could be affected by this research? Examples include service on a board of directors, service on a scientific advisory board, consultant, officer, manager, or partner.

No

F2. An *Equity Interest* in any publicly traded or privately owned entity whose financial interests could be affected by this research, including but not limited to shares of stock or stock options? DO NOT include equity held in a mutual, pension, or investment fund over which you have no control with regard to investment decisions.

No

F3. An investorship or ownership interest in any *Intellectual Property (IP)* that is being tested, evaluated, developed in, or its commercial value will be affected by this research? This includes IP that is the subject of a copyright, issued patent or a patent application (regardless of whether it has been licensed or optioned).

No

F4. Any payments over $5,000 (USD) received for the past 12 months (apart from any

payments from the University of Michigan), including salary, honoraria, fees, or other forms of compensation or anything of value, from any entity that has a financial interest in this research?

No

F5. If any of the above is answered "yes", you must complete this form and upload the completed form below.

Study Team Detail

1.4 Team Member:

Elena Patel

Preferred email:	elena.patel@treasury.gov		
Business phone			
Business address:	Department of the Treasury, Office of Tax Analysis 1500 Pennsylvania Avenue, NW	1500 Pennsylvania Ave NW	20220

1.5 Function with respect to project:

Other

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
Patel CV	0.01

Financial Interest Screening Questions for Study Team Members Not Affiliated with the University of Michigan: Required for all roles except Administrative Staff

Below, you be asked several questions intended to identify Financial Interests and relationships that may be relevant to **THIS RESEARCH**. These may include Intellectual Property Interests (IP interests), as well as relationships with entities whose interests may affect/be affected by this research. If relevant to this research, you should also consider companies that compete commercially with the research sponsor or the manufacturer of the study drug, device or other investigational item if you know that the competitor's Financial Interests would reasonably appear to be affected by this research.

In relation to **THIS RESEARCH**, for the past 12 months, do you or your Family member (your spouse, domestic partner, or dependent) have or anticipate having any of the following Financial Interests:

F1. Are any *activities* or *relationships* with an entity, whether paid or unpaid, where that entity's financial interests could be affected by this research? Examples include service on a board of directors, service on a scientific advisory board, consultant, officer, manager, or partner.

No

F2. An *Equity Interest* in any publicly traded or privately owned entity whose financial interests could be affected by this research, including but not limited to shares of stock or stock options? DO NOT include equity held in a mutual, pension, or investment fund over which you have no control with regard to investment decisions.

No

F3. An investorship or ownership interest in any *Intellectual Property (IP)* that is being tested,

evaluated, developed in, or its commercial value will be affected by this research? This includes IP that is the subject of a copyright, issued patent or a patent application (regardless of whether it has been licensed or optioned).

No

F4. Any payments over $5,000 (USD) received for the past 12 months (apart from any payments from the University of Michigan), including salary, honoraria, fees, or other forms of compensation or anything of value, from any entity that has a financial interest in this research?

No

F5. If any of the above is answered "yes", you must complete this form and upload the completed form below.

Study Team Detail

1.4 Team Member:

Stephanie Hart

Preferred email:	skhart@umich.edu	
Business phone	734-647-9998	
Business address:	PSC-ISR	426 Thompson St Rm 2280 48104-1248

1.5 Function with respect to project:

Administrative Staff

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
Hart_CV_06.2015.pdf	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

No

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

02. Sponsor/Support Information

The following sections request details about the current or pending sponsorship/support of this study. Consider all of the choices below and complete the appropriate sections.
* Note: At least one of the following sections must be answered. Multiple sponsors or sources of support must be added one at a time.

2.1 External Sponsor(s)/Support:

	Type	Name	Other Direct Sponsor/Support	Support Type	Has PAF?
View	Private - Foundations or other external organizations		Laura and John Arnold Foundation	Financial	yes

2.5 Internal UM Sponsor(s)/Support: [Including department or PI discretionary funding]

Type	Department Sponsor	Support Type
There are no items to display		

2.8 Check here if the proposed study does not require external or internal sponsorship or support:

☐

External Sponsor Detail

2.2* Direct Sponsor/Support:

If the Direct Sponsor/Support does not appear in the Select list, enter the name of the Direct Sponsor/Support below:

Laura and John Arnold Foundation

2.2.1* Sponsor Type:

Private - Foundations or other external organizations

If other, please specify:

2.2.2* Support Type:

Financial

2.2.3* Is the support confirmed?

● **Yes** ○ No

2.2.4* Is there an existing Proposal Approval Form (PAF) for this IRB Application

● **Yes** ○ No

2.2.5* Please select the PAF(s) associated with this study. Clicking the Add button will allow for the selection of a PAF based on selected criteria. After the PAF(s) has been associated with the human subjects research application, clicking on the PAF link will access the Proposal Management system and will display the current PAF information. Access to the PAF is based on account information in the Proposal Management system.

Proposal ID
17-PAF00309

2.3* Is this a subcontract to UM?

○ Yes ● **No**

03. UM Study Functions

3.1* Indicate all functions that will be performed at University of Michigan locations.

Select all that apply:

Interaction (e.g., information gathering, survey, interview, focus groups, etc.)

Secondary data collection (e.g., medical chart review, data abstraction from existing records, etc.)

Primary or secondary analysis (data/specimen)

Storage (data and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify.

03-1. Performance Sites

3-1.1* Performance Sites:

Location	Country	"Engaged" in the research?	Performance Site Type	Site Function
Census Bureau	USA	yes		Storage,Analysis
NORC	USA	yes		Storage,Interaction,Recruitment
Office of Tax Analysis (OTA)	USA	yes		Storage,Analysis
Planned Parenthood of Michigan (PPMI)	USA	no		Other
University of Michigan	USA	yes		Storage,Interaction,Analysis,Secondary data collection

Performance Site Detail

3-1.2* Location or Institution:

Census Bureau

3-1.3 Address:

City Washington, DC
State DC
Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:

Primary or secondary analysis (data/specimen)

Storage (data and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify:

3-1.5* Will this site be "engaged" in the conduct of the research?

● **Yes** ○ No

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version
Census Proposal Approval	0.01

Performance Site Detail

3-1.2* Location or Institution:

NORC

3-1.3 Address:

City
State
Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:

Recruitment (including screening)

Interaction (e.g., information gathering, survey, interview, focus groups, etc.)

Storage (data and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify:

3-1.5* Will this site be "engaged" in the conduct of the research?

● **Yes** ○ No

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version
There are no items to display	

Performance Site Detail

3-1.2* Location or Institution:

Office of Tax Analysis (OTA)

3-1.3 Address:

City Washington, D.C.
State DC
Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:

Primary or secondary analysis (data/specimen)

Storage (data and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify:

3-1.5* Will this site be "engaged" in the conduct of the research?

● **Yes** ○ No

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version
There are no items to display	

Performance Site Detail

3-1.2* Location or Institution:

Planned Parenthood of Michigan (PPMI)

3-1.3 Address:

City
State MI
Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:

Other

If other, please specify:

3-1.5* Will this site be "engaged" in the conduct of the research?

○ Yes ● **No**

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version
Letter of Support from PPMI	0.01

Performance Site Detail

3-1.2* Location or Institution:

University of Michigan

3-1.3 Address:

City
State
Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:

Interaction (e.g., information gathering, survey, interview, focus groups, etc.)

Secondary data collection (e.g., medical chart review, data abstraction from existing records, etc.)

Primary or secondary analysis (data/specimen)

Storage (data and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify:

3-1.5* Will this site be "engaged" in the conduct of the research?

● **Yes** ○ No

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

FWA00004969

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version
There are no items to display	

05. Research Design

5.1* Is there a stand-alone scientific protocol document and/or research plan associated with this application?

● **Yes** ○ No

5.1.1* Click ADD to attach the document(s) electronically.

Name	Version
Diagram of Data	0.04
Research Protocol	0.03

5.1.2* Indicate the section where each of the following are covered in the attached protocol:

Objective	Section 1, Specific Aims
Specific Aim/Hypothesis	Section 1, Specific Aims
Background Information	Section 2, Background Research
Methodology	Section 3, M-CARES Design, and Section 4, Data Sources (see also our Data Security Protocol uploaded in section 44)
Statistical Design	Section 5, Statistical Design

5.1.3* Study team Experience: Briefly outline the experience and competence of the study team to pursue the proposed study.

See also section 6 of Research Protocol:

Martha Bailey (Professor of Economics and Research Professor, Population Studies Center) is the PI of the project. Bailey has authored multiple articles on the effects of contraceptive access on women's lives, childbearing, and the economy and brings internationally recognized expertise in demography, economics, econometrics, and reproductive health policy. As PI of several NIH and NSF funded initiatives, she has rich experience managing large and interdisciplinary projects.

Bailey has also recruited a team of experts to the M-CARE study, including
1. Dr. Vanessa Dalton (M.D. specializing in Obstetrics and Gynecology and Medical Director of Planned Parenthood of Michigan, PPMI),
2. Prof. Jennifer Barber (Associate Director of the Population Studies Center, and Professor of Sociology at the University of Michigan; expert in fertility decisions and survey research),
3. Prof. Daniel Eisenberg (Professor of Health Policy and Management, University of Michigan; PI of the national Healthy Minds Study and national expert in mental health), and
4. Alfia Karimova is an Assistant Research Scientist at the PSC. She recently completed a Ph.D. at the University of Toronto and has expertise in demographic and health policy.

There are two researchers external to the University of Michigan (UM) who will be engaged in this research by virtue of conducting analysis and co-authoring papers with the study team. We request that UM provide oversight for their activities. (They will complete the required paperwork after the IRB approves the study.)
1. Elena Patel works at the Office of Tax Analysis and is an expert in the use of U.S. tax records. Elena has access to identifiable data by virtue of her job at the Census Bureau. Elena will participate in this project by conducting analyses with tax records with coded identifiers and co-authoring papers.
2. Katie Genadek is a U.S. Census Bureau employee and health and labor economist. She has expertise in working with restricted Census information and will be instrumental in conducting analyses with these records. Katie has access to identifiable data by virtue of her job at the Census Bureau. Katie will participate in this project by conducting analyses with administrative data using coded identifiers and co-authoring papers.

Finally, NORC at the University of Chicago has partnered with us to conduct the survey research. NORC is an internationally recognized firm in survey research and Randomized Control Trials. NORC will hire and train surveyors to recruit women in PPMI clinic waiting rooms. NORC's IRB is ceding oversight to UM's IRB.

In addition, we have advisors on this project who will not be engaged via recruitment, have access to identifiable or coded data, or conduct analyses of coded data. However, these advisors will frequently discuss the project with the project team:
1. Julia Kohn of Planned Parenthood will serve as a senior advisor to this project. Julia has access to identifiable data by virtue of her job at the Planned Parenthood.
2. The PPMI affiliate (has committed to supporting and participating in this study and has close ties with the University of Michigan where other researchers in reproductive health work and collaborate. We have uploaded a letter of collaboration with this proposal.

5.2* Will the involvement of ANY subjects in this study be limited to analysis of their existing data or specimens?

● **Yes** ○ No

5.2.1* How many subjects are represented in the data or specimens to be analyzed?

8000*(do not enter commas, dots, or special characters)*

5.3* Will the study involve recruitment and/or participation of subjects in order to produce new data (e.g., surveys, interaction, intervention)? *[Require sections 8-1 and 11-3]*

● **Yes** ○ No

5.4* List the inclusion and exclusion criteria for this study population and/or data set. (If covered in attached protocol, indicate section)

See section 3.D. in attached research protocol. There are two parts to our study. One active intervention with Recruits and another that follows the Children of the Recruits.

For the Recruits, all patients between the ages of 18 and 35 with a "fee scale" of 2-5 will be included in survey 1 (Fee scale 2-5 means that these women have out of pocket costs for a visit to a PPMI clinic (family income>federal poverty line).

Participating in the voucher portion of the study requires that the
1. Woman is between ages 18 and 35
2. Fee scale 2 to 5 (and family income>federal poverty line)
2. She is not pregnant and does not wish to become pregnant in the next 12 months,
3. She is at PPMI for a clinician visit;
4. She is able to and at risk of getting pregnant,
5. She has no insurance for her visit and, therefore, may have out-of-pocket costs for contraception.

We will also include the Recruits' Children who are under 18 in a second part of the study. The involvement of Recruits' Children in our research is limited to the analysis of their existing data as long as they are under the age of 18.

5.5 Identify any racial, ethnic, or gender group(s) that will be specifically excluded from participation in this research study and provide a compelling justification for such exclusion:

Men will be excluded because they cannot become biologically pregnant.

5.6* Indicate the age range (in years) of the subject population in this study.

Minimum Age: 0
Maximum Age: 35If no upper limit, enter "999"

06. Benefits and Risks

6.1 * Describe the potential benefits of this research to society.

To date, no study has examined the short- and longer-term returns to reducing financial barriers to contraception on the outcomes of women and their families.
A central contribution of our analysis is that a combination of survey data and administrative data provide complementary perspectives on how financial access to contraceptives shapes the lives of women and their children.
Bailey's research in the in the 1960s (using the methodology of "natural experiments") shows that children born after family planning programs started (relative to children born in the same county before these programs started) lived in households with much higher incomes, lower poverty rates, and with parents more likely to live together. Cohorts whose mothers' had access to contraception also went on to get more education and earn more in the labor market. The main critique of this research is that it is observational--not based on a randomized control trial. In addition, it cannot study the effects of more affordable contraception on older children. The M-CARE study allows us to test some of these findings using the rigor of an RCT with highly reliable administrative data.

The benefit of using records over a long period of time is that we can document -- in an extremely comprehensive fashion -- the short and long-term effects of a simple policy intervention. Given the very important policy debate over the ACA's contraceptive mandate, we feel it is especially critical to quantify in the most rigorous way possible the effects of making contraception free to lower income women on her (1) own outcomes (e.g., education, work and career, public program benefit use, tax payments) as well as (2) her children's outcomes (e.g., education, child welfare, economic resources of parents).
In summary, we believe there is a very large benefit to society and for public policy for providing new evidence on these questions.

Once complete, M-CARES will transform public policy knowledge that is critical to making decisions about funding reproductive health care.

6.2 * Will results of the research be communicated back to the subjects?

● **Yes** ○ No

6.2.1 * Explain the plan and process.

We will publish the research results and post these findings on the M-CARES study participant website after 5 years (or after the last resulting publication is published). After this, we will continue to update this website with research findings.

6.3 * Describe any direct risks to the public or community, which could result from this research?

There are no risks to the public or community.

6.4 * Does this project involve study arms that have differing levels of benefit or risks to subjects?

○ Yes ● **No**

6.5 * Benefits and Risks:

Click "Add" to begin entering the benefit and risk level detail information associated with this study.

	Name	Risk Level	Direct Benefit
View	HUM00132909	No more than minimal risk	yes

Benefits and Risk Level Detail

If a study involves multiple arms or phases that pose different levels of risk or direct benefits to subjects, then create an entry for each arm or phase using the "OK and Add Another" option at the bottom of this page. Only one entry is necessary if the risk level and the direct benefit to subjects is the same for the entire project, even if the study involves multiple arms or phases.

6.5.1 * Name of Arm (experimental group, study wave, etc.)

HUM00132909

6.5.2 * Description of Arm (experimental group, study wave, etc.)

6.6 * Are there potential direct benefits of this research to the subjects?

● **Yes** ○ No

6.6.1 * Describe the potential direct benefits.

Half of the women ages 18-35 who participate will receive a voucher that could alleviate financial barriers in selecting their preferred method of contraception.

6.7 * Provide a description of the foreseeable risks to subjects. For studies involving multiple arms or phases, enter the risks for this arm or phase only.
Provide a description of the foreseeable risks to the subjects.
For EACH identified risk, include:

- **Likelihood of the risk,**
- **Seriousness to the subject; and**
- **What measures will be taken to minimize the risk (for example, study design includes the substitution of procedures already being performed on the subject for diagnostic or treatment purposes, or in a study of Post-Traumatic Stress Disorder, the investigator takes steps to identify, manage, or refer as appropriate, subjects for whom the study may evoke very difficult emotions)**

If possible, please use the following categories to assess the likelihood:

- **"Common" (i.e., approximate incidence > 25%)**
- **"Likely" (i.e., approximate incidence of 10-25%)**
- **"Infrequent" (i.e., approximate incidence of 1-10%)**
- **"Rare" (i.e., approximate incidence < 1%):**

The minimal risks relate to the privacy of Recruit responses and the confidentiality of their data. As documented later in this IRB, we will make great efforts to protect respondent privacy (by using encrypted tablets) and confidentiality (by using encrypted networks and passwords; removing individual identifiers from survey data before analyses; and using coded datafiles from administrative records). We expect that any breech of privacy or confidentiality should be extremely unlikely.

6.8 * What is the level of risk of harm to the subjects, resulting from this arm of the research? For studies involving multiple arms or phases, enter the level of risk for this arm or phase only.

No more than minimal risk

6.9 * Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits.

The minimal risk to study participants (Recruits and their Children) is the potential for unauthorized disclosure of sensitive information. As we document in our data security and confidentiality discussions of this IRB, we will make great efforts to protect respondent privacy (by using encrypted tablets) and confidentiality (by using encrypted networks and passwords and removing individual identifiers from data before analysis begins). In addition, all administrative data (detailed in section 24) will be coded. These steps ensure that there is no more than minimal risk related to the privacy of participants' responses and the confidentiality of their data.

The anticipated benefits of the study are that some subjects will receive a voucher that could alleviate financial barriers to selecting their preferred method of contraception. In addition, all participants stand to benefit from the gain in scientific knowledge associated with this proposal.

07. Special Considerations

7.1* Does this study involve human tissue or biological specimens (use, collection, or secondary analysis) (e.g. blood, urine, bone marrow, skin, etc.)? [Require Section 18]

○ Yes ● **No**

7.2* Does this study involve the secondary analysis of a pre-existing data set, including data associated with any specimens identified in response to question 7.1? [Require Section 24]

● **Yes** ○ No

7.3* Will the research involve the access, collection, use, maintenance, or disclosure of protected health information (PHI)? PHI is:

- **information about a subject's past, present, or future physical or mental health, the provision of healthcare to a subject, or payment for the provision of healthcare to a subject; AND**
- **maintained by a HIPAA-covered entity (e.g. healthcare provider, healthcare plan, or healthcare clearinghouse).**

[Require Section 25]

● **Yes** ○ No

07-1. Special Considerations - Continued

7-1.1* Will subjects receive payment or other incentives for their participation in the study? [Require Section 13]

● **Yes** ○ No

7-1.2* Will subjects undergo healthcare-related treatments or procedures (standard of care and/or research) as part of the study? [Require Section 14]

○ Yes ● **No**

7-1.3* Does this study involve the deception or concealment of subjects? [Require Section 27]

○ Yes ● **No**

7-1.4* Excluding routine email correspondence, does this study involve the use of the Internet or email as an integral part of the research design or will sensitive information be transmitted by e-mail? [Require Section 28]

● **Yes** ○ No

7-1.5* Will the study collect data using surveys, interviews, or focus groups? [Require Section 29]

● **Yes** ○ No

7-1.6* Does this study require subjects to listen to an audio recording or view images? [Require Section 31]

○ Yes ● **No**

7-1.7* Will any drugs, biologics, radiopharmaceuticals, nutritional (e.g., herbal or alternative medication) supplements or other material be administered, implanted, or applied to the subjects as the object of the study? [Require Section 15]

○ Yes ● **No**

7-1.8* Will the study involve a placebo (drug, device, procedure, intervention, surgery, etc.) control group? [Require Section 17]

○ Yes ● **No**

7-1.9* Will the study involve human embryonic stem cells (hESCs) or induced pluripotent stem cells? [Require Section 19]

○ Yes ● **No**

7-1.10* Will the study have a Data and Safety Monitoring Plan (DSMP)? [Require Section 32]

○ Yes ● **No**

7-2. Special Consideration - Continued

7-2.1* Will any devices be used, administered, implanted, or applied to the subjects, or will human specimens be used to test in vitro diagnostic devices? [IRBMED Applications Require Section 16]

○ Yes ● **No**

7-2.2* Is the research testing or utilizing a health-related mobile software application that is:

- Designed for a handheld (e.g., smartphone) or wearable mobile device (e.g., exercise tracking), or
- Tailored to a mobile platform (i.e., a handheld commercial or off-the-shelf computing platform, with or without wireless connectivity) but executed (run) from a server

and the mobile software application/platform performs any of the following:

- Uses a built-in feature of a device such as light, vibration, or camera to perform a medical device function.
- Connects or links to an existing device to control its operation, function, or energy source.
- Uses patient-specific data from a connected device including a sensor or electrode to monitor, manipulate, calculate, or analyze information.
- Conveys diagnostic information, or provides education materials or encouragement.
- Performs calculations, conversions, measurements or interpretations.

○ Yes ● **No**

7-2.3* Will the subjects be exposed to any ionizing radiation during the course of this study? [Require Section 21]

○ Yes ● **No**

7-2.4* Will any organs, tissues, or cells from humans (including fetal tissue) or animals be administered to the subjects for the purposes of this study? [Require Section 22]

○ Yes ● **No**

7-2.5* Does this study involve a gene transfer intervention or an intervention based on recombinant DNA technology? [Require Section 23]

○ Yes ● **No**

08. Subject Participation

8.1* Please indicate the number of subjects to be enrolled from ALL study locations to achieve the goal of the study:

8000

8.2* Enter the estimated number of subjects to be enrolled at each University of Michigan site:

Location or Institution	Total
Census Bureau	
Adults	0
Children	0
Planned Parenthood of Michigan (PPMI)	
Adults	0
Children	0
University of Michigan	
Adults	5500
Children	2500
Office of Tax Analysis (OTA)	
Adults	0
Children	0
NORC	
Adults	0
Children	0
Total from all University of Michigan sites:	**8000**

08-1. Subject Recruitment

8-1.1* At what point in the study are you planning on beginning the recruitment of subjects?

0-2 years after approval

8-1.2* Indicate which of the following established subject pools, if any, will be used for recruitment.

Select all that apply:

N/A

Provide Related UM IRB Project Number or Subject Pool Description:

8-1.3* Describe the manner in which potential study subjects will be recruited. List how, when, who will recruit and where they will be recruited. Include any provisions to protect or maintain subject privacy.

See Research Protocol in Section 5.

We will recruit 5,500 women into the study in 11 PPMI clinic waiting rooms over a period of 12-14 months. We have contracted with NORC to do this recruitment. NORC will hire and train surveyors to recruit women in PPMI clinic waiting rooms. After asking women a few questions (outlined in Oral Script appended with this IRB), tablet computers will walk each woman through the informed consent process with assistance from a professional survey worker as needed. No personal r sensitive information will be discussed in PPMI waiting rooms.

Enrollment and will be conducted on the electronic tablet, which will encode consent responses. If a women consents to participate and is eligible for the M-CARES voucher, we will collect her personal identifying information such as name, SSN, date of birth, as well as contact information. For her children, we will collect name and date of birth. This will allow us to follow up with women and also collect their administrative records from private and governmental agencies. (See informed consent form appended to this IRB).

NORC will recruit subjects and is an internationally recognized firm. NORC maintains a strong reputation for complying with the requirements of state and federal data protection laws and regulations such as CIPSEA and the Privacy Act of 1974. NORC staff are required to complete annual trainings focused on data use agreements, ethical conduct, and data confidentiality. NORC has developed a detailed approach to maintaining data security and continues to bring its projects into compliance with systems security regulations including FISMA, NIST 800.53, and FIPS. Access to confidential data is restricted to authorized project staff. Data is stored on the secured NORC network and is only exchanged via encrypted format. NORC facilities are also secured with keycard access required in addition to security cameras. The servers and wiring closets are placed in locked rooms which are only accessible to authorized staff via a security code.

NORC will provide encrypted data from the survey 1, the baseline survey, and the consent form to the research team via Secure File Transfer Protocol.

8-1.3.1 If applicable, how will prospective subjects' healthcare providers (e.g., physician, dentist, etc.) be involved in the recruitment and/or be notified of their individual patients' participation in the study?

N/A. All recruitment will take place in the PPMI lobby before participants meet with their health care providers.

8-1.4* Explain how the recruitment strategy is equitable and represents the population required for the study. If the information is covered in the attached protocol, please indicate section.

Because we are interested in studying a group of women who may have an unintended pregnancy in the next five years because they cannot afford reliable contraception, we focus our recruitment on

adult women of childbearing age (18-35) who are not pregnant and who do not wish to become pregnant in the next 12 months. We also recruit only women who are fecund. We select women who are younger than 36 years old, because fertility declines rapidly with age so women over age 35 may not be as susceptible to unplanned pregnancy.

We also limit our recruitment to women who will see a clinician at PPMI, because these are the PPMI patients who can use a voucher for contraception that same day. Clinician visits are the vast majority of PPMI patient visits, but typically exclude walk-ins and other non-contraception related visits. If a woman is ineligible to participate because she is not at PPMI for a clinician visit, she can schedule a clinician visit and return and enroll in the M-CARES at that time.

Because we our study cannot reduce financial barriers to contraception among women who do not have out-of-pocket costs for a PPMI visit, we limit our recruitment to women who have no insurance covering contraceptive services and family incomes over the poverty line and, therefore, would have some out-of-pocket costs for contraception as part of their visit to PPMI.

8-1.5* Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their initial enrollment into the study?

○ Yes ● **No**

8-1.6* Indicate which methods will be used for recruitment?

Check all that apply:

Face-to-face contact (e.g. during a health care visit or an interview at a home address, etc.)

If other please specify:

8-1.7 How will any email, address, and/or telephone lists be obtained?

8-1.8* What materials will be used for recruitment? The IRB must approve all recruitment materials.

See Help for important information regarding the requirements for recruitment materials

Check all that apply:

Pre-screening questions

Oral scripts

Other

If other please specify:

A small business card all women receive at check-in at PPMI.
A brochure with information about the study that will be available in PPMI.

If Web pages will be used, provide the Web address (URL) for the location where the pages will be posted (also upload the content of the pages below):

http://sites.lsa.umich.edu/m-carestudy

Upload recruitment materials here:

See Help for more information about working with documents (e.g. uploading, downloading, and editing).

Name	Version
Business Card for Check-In	0.02
Oral Script	0.04
Recruitment Brochure	0.03
Survey 1	0.01

☐ **Check here if any of the materials are not available electronically.**

Note: Study Teams are encouraged to scan and upload documents. See Help for a list of sites with scanning facilities

09. Survey Populations

9.1* Is the study limited to a survey of either:

- The general adult population (aged 18 or older); or
- A subgroup of the general population which does not specifically target:

- Pregnant women and/or fetuses
- Lactating women
- Women of child-bearing potential
- Prisoners
- Cognitively impaired adults
- College students
- Economically or educationally disadvantaged persons
- Patients of the study team
- Employees, students or trainees of the study team
- Family members of the study team

where the survey is the sole interaction with the subject and does not pose more than minimal risk?

○ Yes ● **No**

09-1. Subject Populations

9-1.1* Is the research designed to include or allow the following populations?

Select all that apply

- [x] **Normal, healthy subjects**
- [x] **Adults** *age 18 and older*
- [ ] **Minors able to consent** *to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (e.g. emancipated minors or minors seeking treatment for certain conditions.)*
- [x] **Children and/or Viable Neonates** *(i.e. persons who have not yet reached the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted) [Require Sections 33 and 41]*
- [ ] **Neonates of uncertain viability and/or nonviable neonates** (do not check this box if the research is solely retrospective. For retrospective research regarding neonates of uncertain viability, check the box for 'Children'. See Help for additional information.) [Require Section 34]
- [ ] **Individuals and/or products involving human in vitro fertilization**
- [ ] **Pregnant women and/or fetuses** [Require Sections 35 and 41]
- [ ] **Lactating women** [Require Section 36]
- [x] **Women of child-bearing potential** [Require Section 37]
- [ ] **Prisoners** (If the research includes a study population that is likely to become incarcerated during the conduct of the research, also select this category) [Require Section 38 and 41]
- [ ] **Cognitively impaired adults** [Require Sections 39 and 41]
- [ ] **College students** [Require Sections 40 and 41]
- [x] **Economically or educationally disadvantaged persons** [Require Section 41]
- [ ] **Patients of the study team** [Require Section 41]
- [ ] **Employees, students or trainees of the study team** [Require Section 41]
- [ ] **Family members of the study team** [Require Section 41]
- [ ] **Unknown, unspecified population**

10. Informed Consent - Adults

10.1* What type of informed consent will be obtained from adults or minors legally able to consent to treatments or procedures involved in the research?

Select all that apply:

Comprehensive written

10.1.2* Describe the process to seek and obtain informed consent and/or assent from adults. If requesting a waiver of documentation of assent, provide justification here.

NORC will hire and train surveyors to recruit women in PPMI clinic waiting rooms.
At check-in at PPMI, all patients will receive a small business card with the relevant boxes checked (see uploaded business card in section 8-1.8, Figure 1 in research protocol). Per the surveyor oral script (uploaded section 8-1.8), NORC surveyors will ask each patient to show them the business card and if she'd like to participate in the study. Showing the business card to the surveyor avoids the need to have a public conversation about private matters in a public waiting room. In the PPMI waiting room, the surveyor only confirms verbally that prospective subjects are between the ages of 18 and 35 with a "fee scale" of 2-5.

Provided the patient meets these criteria and agrees, an electronic tablet will walk each woman through the informed consent process with assistance from a professional survey worker as needed. She will be informed that participation means that she agrees to:
(1). Be contacted to complete subsequent surveys;
(2). Consent to use her and her children's administrative data (which requires providing private information such as name, date of birth, social security number (SSN), and contact information for Recruits and name, date of birth, and place of birth for children.

Enrollment will be conducted on the electronic tablet, which will encode consent responses. If a women consents to participate, she becomes a Recruit. (See informed consent appended with this IRB.)

10.1.3* Is the cognitive capacity of the subjects expected to change significantly during the study?

○ Yes ● **No**

10. Informed Assent - Children

10.2* What types of informed assent for children and parental consent/permission will be obtained?
NOTE "Parent" or "Parental" below refers to parent or guardian. See Help **for important instructions on selecting the appropriate category or categories.**

Select all that apply:

Request for waiver of oral or written child assent requirement

Parent comprehensive written consent/permission

10.2.1* Waiver of assent is requested because:

Check all that apply:

Research presents no more than minimal risk, assent is not practicable, waiver will not impact the rights and welfare of subjects, and as appropriate, subjects will be provided with additional pertinent information after participation.
Study offers important benefit unavailable outside of the research

10.2.2* Describe the process to seek and obtain informed assent for children and parental consent/permission (e.g., setting, timing, personnel involved, arrangements for answering subject questions before and after the consent is signed).

We are asking Recruits for their written consent to follow their Children in administrative records.

M-CARES involves minimal risk to Children--we only follow them in existing administrative records. M-CARES will not interact with Children in any way. Also, Children will not typically accompany their mothers (the Recruits) to PPMI, so direct consent will be infeasible. We, therefore, request a waiver of Children's assent to participate in M-CARES.

10.2.3* What criteria will be used to determine whether or not a child's assent to participate will be obtained, whether that assent will be oral or written, and whether documentation of the child's assent (e.g., signature on the assent form) will be obtained? If documentation of child's assent is to be waived, provide a justification.

We will obtain the Recruit's written consent for her Children's participation. We request that the Children's assent be waived.

There are two reasons why we request this:

1. M-CARES involves only minimal risk to Children-- we only follow Children in administrative records (records that already exist). M-CARES will not interact with children in any way.

2. Obtaining direct assent for children is also infeasible. Children will not typically accompany their mothers (the Recruits) to PPMI, so direct assent will be infeasible without hiring surveyor to visit children's home (which is cost prohibitive).

Because we will obtain (1) mothers' consent for her children and (2) the study involves no intervention with children and, therefore, minimal risk and (3) children's assent is infeasible, we request a waiver of Children's assent to participate in M-CARES.

10.2.4* Are any of the following changes expected in the status of child subjects during the study?

Check all that apply:

Child subject reaches the age of majority

10.2.4.1 If applicable, describe the plan to re-assent or obtain consent from the subject if any of the changes occur.

We will only follow only Children who are under the age of majority (18) until they reach the age of majority. Pending additional funding, we will ask adult Children to participate in our study (if they are already 18 when their mother enrolls) or continue in our study just before they reach the legal age of majority (if they reach age 18 during our study).

10-1. Informed Consent

10-1.1* All documents related to consent, assent, permission, and or debriefing documents, including oral scripts must be uploaded here. If you are requesting a waiver of documentation of informed consent, upload a copy of any written materials to be provided to participants, and provide a written description of any information to be provided orally.

Name	Version
Consent Form	0.01

10-1.2* Will the subjects be audiotaped, videotaped, or photographed (identifiable images of subject) during the research?

○ Yes ● **No**

10-1.3* Is there a substantial likelihood that the research will be conducted among a non-English-speaking population?

○ Yes ● **No**

10-1.4* Indicate which anticipated costs could be the full or partial responsibility of the subject.

Check all that apply:

Cost of routine health care that would be incurred for this condition if the subject were not participating in the research study

Check all that apply:

No anticipated costs

If other, please specify:

10-1.5* Is the study designed to collect identifiable information from primary research subjects about other individuals, including family members?

○ Yes ● **No**

10-1.6* At the conclusion of this study, will specimens and/or data be retained for future research use?

● **Yes** ○ No

10-1.7* Does the informed consent document explicitly notify subjects that their data and/or specimens will be stored for future research?

● **Yes** ○ No

10-1.8* Are subjects required to agree to retention of their data and/or specimens as a condition of participating in the research?

● **Yes** ○ No

10-1.8.1* Provide a justification for this requirement. If the information is included in the attached protocol, please indicate section.

Recruits can opt out of future surveys and being contacted at any time by writing an email to our study.

However, if we have already linked to their administrative data (which will be coded) or their survey (which will also be coded), we cannot unlink without revealing the identity of the coded individual. We have now clarified this in the consent form.

It says that “If you decide to withdraw from this study, you must send an email to m-carestudy@umich.edu. We will not contact you asking you to take surveys. We will remove any information that will link you to your data, but we will still use survey answers and administrative records that have already been shared with us.”

11. Confidentiality/Security/Privacy

11.1* Will the study team access any data that is linked to a subject's identity by name or other identifier or code? [Require Section 11-1]

● **Yes** ○ No

11.2* Explain how the subjects' privacy will be protected.

All patients will receive a small business card at check in with the relevant boxes checked. Per the oral script we uploaded, patients will be asked if they want to participate. If so, they will be asked to show the surveyor to show this small business card to the surveyor if she'd like to participate in the study. Showing the business card to the surveyor avoids the need to have a conversation about private matters in a public waiting room. In the waiting room, the surveyor only confirms verbally that prospective subjects are between the ages of 18 and 35 with a "pay scale" of 2-5.

The Recruit then takes a confidential survey 1 on a secure tablet which will not reveal her information to others in the waiting room or the surveyor. Answers to the questions will determine if a woman meets the inclusion criteria. Recruits are advised that they can stop taking the survey at any time. (See survey 1 appended to this IRB.)

To maintain the Recruit's privacy, all personal identifying information can be entered directly into the tablet and the Recruit can ask the surveyor any questions. At the conclusion of enrollment, the tablet will tell the surveyor whether the Recruit received a voucher and how much. It will also assign every subject an ID number (VID). Both the VID and the voucher amount (if any, denoted VD for "Voucher Dollars") will be written on the small business card and returned to the respondent. We choose to use the cryptic abbreviation VD to minimize the disappointment of Recruits who are not selected to receive a voucher.

This process ensures that subjects' privacy will be protected as much as possible during the survey process and study enrollment.

The baseline and follow up surveys can be taken on a tablet in the clinic or in another convenient and more private location with internet access of the subject's choosing.

11.3* How will the study team protect research records, data, and/or specimens against inappropriate use or disclosure, or malicious or accidental loss or destruction in order to protect the confidentiality of subject data?

Select all that apply:

- Locked office
- Restricted access
- Access rights terminated when authorized users leave the project or unit
- Secure laptop
- Individual ID plus password protection
- Encryption of digital data
- Security software (firewall, anti-virus, anti-intrusion) is installed and regularly updated on all servers, workstations, laptops, and other devices used in the project
- Safe disposition/destruction of data or devices, as appropriate (e.g., shredding paper documents, destroying disks or thumb drives, secure erasure of electronic media)

If other please specify:
We will also make use of the UM-RDC to examine administrative records available through the Census Bureau. The UM-RDC provides a very secure data-processing environment that is de jure part of the Census Bureau. The UM-RDC and the Census Bureau have very strict procedures for guaranteeing the confidentiality of the restricted data. The UM-RDC's data security plan has been reviewed and approved by the three institutions. The track record of effectiveness of these data safeguarding measures is extremely high. All researchers using these data must also obtain special security clearance (SSS) from the Census Bureau. There are very strict Census Bureau guidelines about reporting results from analyses. The Census Bureau will review and approve all output to ensure that direct and indirect identification of individuals is not possible from disclosed output before it is removed from the UM-RDC.

11.4* Does either statement apply to this research:
Research has NIH funding and will include identifiable sensitive information, identifiable biospecimens, or individual human-level genomic data/biospecimens that, if revealed, might place the subjects at even a small risk for personal safety, criminal or civil liability, or damage to their financial standing, employability, insurability, or reputation.

or

Research has no NIH funding and will include identifiable, sensitive information or identifiable biospecimens that, if revealed, might place the subjects at risk for personal safety, criminal or civil liability, or damage to their financial standing, employability, insurability, or reputation. [Require Section 11-2]

● **Yes** ○ No

11.5* Will data be provided to a repository as part of a data sharing agreement?

○ Yes ● **No**

11.6* What will happen to the data and/or any specimens at the conclusion of this study?

Select all that apply:

Retain for future research use - requires Section 11-4

11-1. Identifiable Data

Completion of this section is required based on the response provided to question 11.1.

11-1.1* Indicate how subjects are identified in the research records.

Select all that apply:

Direct Identifiers stored on data record (e.g., name, initials, phone number, SSN, or medical record number, stored on data record)

Coded or Indirect Identifiers - data record includes a link to direct identifiers (e.g., name, initials, phone number, SSN, or medical record number linked to data record but stored separately)

11-1.2* Explain the necessity for collecting or maintaining data linked to subjects' identities. If the information is covered in the attached protocol, please indicate section.

We must collect individual information such as name,date of birth, address, and SSN in order to link subjects to their administrative records.

11-1.3* How long will the identifiers be retained?

Per the informed consent, we will retain the individual survey records for future research studies unless the Recruit opts out of the study.

11-1.4* Will individually identifiable sensitive data be accessed, collected, used, maintained, or disclosed in the study?

● **Yes** ○ No

11-1.4.1* Will a continuous, periodic, or automatic feed of sensitive data be set up to provide data directly from any University information system (e.g., M-Pathways, U-M Data Warehouse, CareWeb)?

○ Yes ● **No**

11-1.4.2* Will sensitive data be accessed by individuals who are not University employees?

● **Yes** ○ No

11-1.4.3* Will sensitive data be stored on or accessed from computer equipment that is not maintained and supported by a University IT services provider (e.g., ITS, MCIT, MSIS) - such as home computers, grant-funded computers, etc.?

● **Yes** ○ No

11-1.4.4* Will sensitive data be stored on portable devices (e.g., laptops, PDAs, flash drives) in unencrypted form?

● **Yes** ○ No

11-2. Certificate of Confidentiality

Completion of this section is required based on the response provided in Section 11

11-2.1* Is there a Certificate of Confidentiality (CoC), or will one be obtained, for this research? (If NIH funded, answer "Yes")

● **Yes** ○ No

11-2.1.1* Select the answer that applies to your CoC:

I will apply for a CoC (no NIH award)

11-2.2* Describe any measures or procedures that will be employed to prevent others from learning about subjects' participation in this study through forced disclosure (i.e., under subpoena).

The process of storing and analyzing survey data is intended to minimize the risk of unauthorized disclosure of sensitive information. (For more detail than in this section, please see our Data Security Protocol uploaded in section 44.)

Recruitment and consent data

NORC will first collect the consents and survey data on electronic tablets. NORC maintains a strong reputation for complying with the requirements of state and federal data protection laws and regulations such as CIPSEA and the Privacy Act of 1974. NORC staff are required to complete annual trainings focused on data use agreements, ethical conduct, and data confidentiality. NORC has developed a detailed approach to maintaining data security and continues to bring its projects into compliance with systems security regulations including FISMA, NIST 800.53, and FIPS. Access to confidential data is restricted to authorized project staff. Data is stored on the secured NORC network and is only exchanged via encrypted format. NORC facilities are also secured with keycard access required in addition to security cameras. The servers and wiring closets are placed in locked rooms which are only accessible to authorized staff via a security code. NORC will retain the data for 7 years —this includes the 5 years of our study and an addition two years in case we obtain funding to conduct another survey. Back up tapes are destroyed after 7 years. NORC will not use these data for any purpose other than the proposed M-CARES research. NORC's IRB is ceding oversight to UM's IRB.

For the survey data and consent forms:
The general process is outlined in our appended protocol under Study Design and Data Sources. The number in this section refer to numbers in the "Diagram of Data" document, which is also appended with our protocol.

When the survey data and consent forms are received from NORC, Bailey and Karimova will store surveys and consent forms (dataset 1 in "Diagram of Data") on M+Box in a file that is encrypted and password-protected and with access restricted only to Bailey and Karimova.

The first step in the data processing will be to replace individually identifying information on the surveys with coded identifiers. Working in a locked office, Bailey and Karimova will remove PII (names, SSNs, dates of birth, addresses, contact information, and social media information) from the records and add a numeric identification code, birth days (without the year), and broad geographic codes. The cross-walk dataset that links these codes to names and store this file in a separate password protected file on M+Box. Only Bailey and Karimova will have access to this crosswalk file and PII (dataset 2 in "Diagram of Data.") All analysis will be conducted with data that contains coded identifiers and other survey variables (dataset 3 in "Diagram of Data").

The coded records and any derivative data will be stored on a restricted-access drive – M-Box, which adheres to the highest industry standards for security. It is approved by the University of Michigan for storing and sharing sensitive data.

To provide protections against subject identification, no listings or descriptions of individual cases will be printed or emailed. Only anonymized output will be suitable for printing, email, or publication. Examples of this include descriptive statistics and parameters from a statistical regression models.

Individuals with access to the coded and derivative data are called "approved personnel." Approved personnel will be briefed on the license conditions and the data protection plan prior to receiving access to the restricted data and again annually each August for the duration of the project. Specifically, all approved personnel will agree to and sign a Data Use Agreement (uploaded in section 44). If an individual leaves the M-CARES project, s/he will no longer be part of the approved personnel.

Any potential breaches will be reported immediately.

For administrative records:
We will link M-CARES Recruits and Children to administrative records which are detailed in section 24.

We will link Recruits to (1) PPMI patient records; (2) credit reports; (3) tax data; (4) birth and death certificates; (5) Decennial Census, American Community Surveys (ACS), and Current Population Survey (CPS) Annual Social and Economic Supplement (ASEC); (6) Education data (K-college and National Student Clearinghouse, NSC); (7) program participation; (8) Michigan criminal justice records; (9) Michigan child welfare and justice records, (10) Employment and Earnings Records; and (11) Health Insurance Claims. (Numbers correspond to numbering in the next section outlining the content of these records; see also discussion in section 24 of the IRB).

We will link Children's to a subset of these records, including (4) birth and death certificates; (5) Decennial Census, ACS, and CPS-ASEC; (6) Education data (K-college and National Student Clearinghouse, NSC); (7) program participation; (9) Michigan child welfare and justice records, (10) Employment and Earnings Records; and (11) Health Insurance Claims.

The process of linking to these administrative files is intended to minimize the risk of unauthorized disclosure of sensitive information. Following the process laid out in in "Diagram of Data," our linking process follows these steps.

From the survey file (dataset 1 in "Diagram of Data") we will create an administrative data link file ("Admin Data Link") for Recruits and Children and share this via encrypted drive with agencies. For Recruits, the Admin Data Link file will include PII including full name, date of birth, address, and SSN in addition to a subset of variables from survey data, which we will call Z variables (dataset 4 in "Diagram of Data"). For Children, the Admin Data Link file will include PII including full name, date of birth, and place of birth in addition to a subset of variables from survey data, which we will call Z variables (dataset 6 in "Diagram of Data").

These Z variables include information about whether the individual received a voucher and the voucher amount as well as a subset of answers to survey questions that allow us to construct covariates and conduct heterogeneity tests. To make sure that no sensitive information is revealed to agencies, the Z variables will be masked. The masking process will create generic labels for variable names and answers. For instance, a question like "how many children have you had?" will be stored under the variable name Q15 with numeric answers 0 to 20. The Admin Data Link will be stored in encrypted format on an encrypted drive to be shared with agencies who will link to administrative data.

Agencies will then link Recruits and Children to data, remove PII, and give the M-CARES team access to these administrative data with coded identifiers or statistical results. The process is similar for different agencies, but we outline specifics for each administrative dataset.

The result of this process is that the M-CARES team will have access to and analyze separate coded administrative data files for Recruits (datasets listed under 5 in “Diagram of Data”) and Children (datasets listed under 7 in “Diagram of Data”).

We discuss content of each dataset in section 24.

11-3. End of Subject Participation

11-3.1* What specific criteria will be used to prematurely end a particular subject's participation in the study (If covered in attached protocol or informed consent, indicate specific location).

No criteria will be used by the researchers to end a subject's participation prematurely. However, subjects can opt out of the study at any time with a written email to us as outlined in the consent.

11-3.2* If a participant withdraws from the research, what is the plan to use, disclose, store, or destroy the participant's data and/or specimen?

If a Recruit withdraws from the research, we will no longer collect any information about her or use her survey information in future publications. We will also destroy any information that will link the Recruit to her data.

However, if we have already linked to their administrative data (which will be coded) or their survey (which will also be coded), we cannot un-link without revealing the identity of a coded individual.

Therefore, we will continue to use coded survey data and administrative data even if a subject withdraws from the study. This is clearly represented in the informed consent.

11-4. Retention of Data and/or Specimens Detail

Retention may be for future research by the investigator and/or the creation of a bank or repository.

Completion of this section is required based on the response provided to question 11.6.

11-4.1* What is the intent or purpose of retaining the data and/or specimens?

The informed consent notes that we will retain data for future research. We will retain the data so that we can continue to follow individuals in administrative data for the duration of the study and contact individuals to participate in future studies.

Over the course of our study, we will maintain a website and send periodic newsletters by email (we anticipate once per year) to maintain contact with our subjects. The newsletter will allow them to provide us updates about their lives and we will also provide them updates about the study. We will also invite subjects to update their contact information.

11-4.2* Where will you store the data and/or specimens?

UM and Other Institutions

If Other Institutions, please specify:
NORC will initially collect the data and then transfer to UM for analysis.
The Census Bureau will store PIK'd (coded) data in a secure account in the Research Data Center.
The Office of Tax Analysis will store PIK'd (coded) data on its secure servers.

11-4.3* Describe the arrangements for the storage conditions, management, and security of the data and/or specimens. Include the following as applicable:

- ***Personnel access to data and/or specimens***
- ***Whether identifiers will be removed and the key to any code destroyed***
- ***For coded data and/or specimens, indicate who holds key to the code and where it is stored in relation to the data and/or specimens***
- ***Storage plan***
- ***Plan to protect privacy in transfer to other collaborators.***

This is repeated from section 11-2. (For more detail than in this section, please see our Data Security Protocol uploaded in section 44.)

The process of storing and analyzing survey data is intended to minimize the risk of unauthorized disclosure of sensitive information.

Recruitment and consent data

NORC will first collect the consents and survey data on electronic tablets. NORC maintains a strong reputation for complying with the requirements of state and federal data protection laws and regulations such as CIPSEA and the Privacy Act of 1974. NORC staff are required to complete annual trainings focused on data use agreements, ethical conduct, and data confidentiality. NORC has developed a detailed approach to maintaining data security and continues to bring its projects into compliance with systems security regulations including FISMA, NIST 800.53, and FIPS. Access to confidential data is restricted to authorized project staff. Data is stored on the secured NORC network and is only exchanged via encrypted format. NORC facilities are also secured with keycard access required in addition to security cameras. The servers and wiring closets are placed in locked rooms which are only accessible to authorized staff via a security code. NORC will retain the data for 7 years —this includes the 5 years of our study and an addition two years in case we obtain funding to conduct another survey. Back up tapes are destroyed after 7 years. NORC will not use these data for any purpose other than the proposed M-CARES research.

For the survey data and consent forms:

The general process is outlined in our appended protocol under Study Design and Data Sources. The number in this section refer to numbers in the “Diagram of Data” document, which is also appended with our protocol.

When the survey data and consent forms are received from NORC, Bailey and Karimova will store surveys and consent forms (dataset 1 in “Diagram of Data”) on M+Box in a file that is encrypted and password-protected and with access restricted only to Bailey and Karimova.

The first step in the data processing will be to replace individually identifying information on the surveys with coded identifiers. Working in a locked office, Bailey and Karimova will remove PII (names, SSNs, dates of birth, addresses, contact information, and social media information) from the records and add a numeric identification code, birth days (without the year), and broad geographic codes. The cross-walk dataset that links these codes to names and store this file in a separate password protected file on M+Box. Only Bailey and Karimova will have access to this crosswalk file and PII (dataset 2 in “Diagram of Data.”) All analysis will be conducted with data that contains coded identifiers and other survey variables (dataset 3 in “Diagram of Data”).

The coded records and any derivative data will be stored on a restricted-access drive – M-Box, which adheres to the highest industry standards for security. It is approved by the University of Michigan for storing and sharing sensitive data.

To provide protections against subject identification, no listings or descriptions of individual cases will be printed or emailed. Only anonymized output will be suitable for printing, email, or publication. Examples of this include descriptive statistics and parameters from a statistical regression models.

Individuals with access to the coded and derivative data are called “approved personnel.” Approved personnel will be briefed on the license conditions and the data protection plan prior to receiving access to the restricted data and again annually each August for the duration of the project. Specifically, all approved personnel will agree to and sign a Data Use Agreement (appended in section 44). If an individual leaves the M-CARES project, s/he will no longer be part of the approved personnel. Any potential breaches will be reported immediately.

For administrative records:
We will link M-CARES Recruits and Children to administrative records which are detailed in section 24.

We will link Recruits to (1) PPMI patient records; (2) credit reports; (3) tax data; (4) birth and death certificates; (5) Decennial Census, American Community Surveys (ACS), and Current Population Survey (CPS) Annual Social and Economic Supplement (ASEC); (6) Education data (K-college and National Student Clearinghouse, NSC); (7) program participation; (8) Michigan criminal justice records; and (9) Michigan child welfare and justice records; (10) Employment and Earnings Records; and (11) Health Insurance Claims. (Numbers correspond to numbering in the next section outlining the content of these records; see also discussion in section 24 of the IRB).

We will link Children’s to a subset of these records, including (4) birth and death certificates; (5) Decennial Census, ACS, and CPS-ASEC; (6) Education data (K-college and National Student Clearinghouse, NSC); (7) program participation; (9) Michigan child welfare and justice records, (10) Employment and Earnings Records; and (11) Health Insurance Claims.
The process of linking to these administrative files is intended to minimize the risk of unauthorized disclosure of sensitive information. Following the process laid out in in “Diagram of Data,” our linking process follows these steps.

From the survey file (dataset 1 in “Diagram of Data”) we will create an administrative data link file (“Admin Data Link”) for Recruits and Children and share this via encrypted drive with agencies. For Recruits, the Admin Data Link file will include PII including full name, date of birth, address, and SSN in addition to a subset of variables from survey data, which we will call Z variables (dataset 4 in “Diagram of Data”). For Children, the Admin Data Link file will include PII including full name, date of birth, and place of birth in addition to a subset of variables from survey data, which we will call Z variables (dataset 6 in “Diagram of Data”).

These Z variables include information about whether the individual received a voucher and the voucher amount as well as a subset of answers to survey questions that allow us to construct covariates and conduct heterogeneity tests. To make sure that no sensitive information is revealed to agencies, the Z variables will be masked. The masking process will create generic labels for variable names and answers. For instance, a question like "how many children have you had?" will be stored under the variable name Q15 with numeric answers 0 to 20. The Admin Data Link will be stored in encrypted format on an encrypted drive to be shared with agencies who will link to administrative data.

Agencies will then link Recruits and Children to data, remove PII, and give the M-CARES team access to these administrative data with coded identifiers or statistical results. The process is similar for different agencies, but we outline specifics for each administrative dataset.

The result of this process is that the M-CARES team will have access to and analyze separate coded administrative data files for Recruits (datasets listed under 5 in “Diagram of Data”) and Children (datasets listed under 7 in “Diagram of Data”).

We discuss content of each dataset in section 24.

13. Subject Payments Or Other Incentives

Completion of this section is required based on the response provided to question 7-1.1 or 7-3.3.

13.1* Indicate all payments or other incentives provided to subjects for their participation in this study:

Select all that apply:

Payment Voucher

If other, please specify:

13.2* If the subject is a child (under the age of majority), are any of the payments or incentives intended for the parent/guardian of the child?

No

13.3* Estimate the maximum total payment (including cash, checks, gift cards, and other cash-equivalent incentives) that an individual subject could receive for participating in this research in a single calendar year.

$26-$100

13.3.1* Please indicate what information you will be collecting from subjects in order to distribute their incentive or compensation.

Select all that apply:

Name

Address

Email

Social Security Number (SSN)

13.4* Describe the frequency of the payments or incentives. If applicable, list any healthcare procedure(s) that will be provided to subjects at no charge.

These payments are reimbursements for a Recruits' time spent taking surveys. These include $10 for taking a 5-minute survey, $60 for taking a 25-minute survey the same day or $40 for taking it at another convenient time, and up to $50 each for taking two more 30-minute surveys over the next 5 years.

13.5* What is the justification for offering these payments or incentives?

These surveys will take time, concentration, and effort. We offer payments are reimbursements for a Recruits' time spent taking surveys and as a token of appreciation for their effort.

13.6* What is the plan to compensate subjects withdrawing from the research prior to completing the entire study.

Recruits will be compensated after taken subsequent surveys. If Recruits withdraw before taking a survey, they will not be paid for taking it.

24. Secondary Data Analysis

Completion of this section is required based on the response provided to either question 4-1.1 or 7.2.

24.1* List each pre-existing data set that will be used in the study.

Name	Identifying Info	Is Publicly Available
(1) PPMI records	These records contain detailed information on Recruits' socio-demographic information, physical health information, pregnancy and childbearing history, medical history, their PPMI visits (at all PPMI clinics), including the date of the visit, details on diagnoses and procedures and services provided, and payment method and payment amount. The method of payment for the services on the records allows us to identify the services obtained with the M-CARES voucher. We rely on these data in part to estimate how pregnancies, abortions, childbearing, and contraceptive use is affected by voucher receipt. We expect to link all Recruits to their PPMI records (going back to the date of participant's first PPMI visit and up to 2023, the end of the study). The date of Recruit's enrollment from survey 1 allows us to separate patient history data into pre- and post-intervention periods. We will provide PPMI with the Admin Data Link File (dataset 4 in "Diagram of Data"). PPMI will use this information to locate Recruits' patient records and will provide the M-CARES research team a coded set of records using an encrypted drive (one of the datasets listed as 5-Agency). The codes corresponding to individuals will be determined by PPMI, so the codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.	no
(10) Employment and Earnings Records	These records are not yet available from the State of Michigan or federal government. Because we expect them to become available in the near future, we have, therefore, included them in our consent. These records include information on quarterly earnings, employment, unemployment benefits, taxes paid by the employee and the employer(s) to the state, income from different sources, disability income, and the number of different employer(s). These records may become available through OTA, the Census Bureau, or through the State of Michigan directly. Depending upon how these records become available, we will follow either the OTA, Census Bureau, or agency protocols laid out above and in our Diagram of Data for linking and storing these data.	no
(11) Health Insurance Claims at University of Michigan	These records are not yet available for researchers, but they are being assembled through a project at the University of Michigan. Because we expect them to become available in the near future, we have included them in our consent. These records include information such as the date of a visit to a service provider, service provider, services obtained, payment methods and amounts, the name of the clinic, medical and physical diagnosis codes. Depending upon how these records become available and the Data Use Agreements that govern their use, we submit an amendment to the IRB and follow the protocols laid out here for agency data for linking them and storing these data.	no
(2) Credit reports	Recruits' credit records contain rich information on their credit history, including credit accounts' payment status, outstanding balance, credit limit, delinquency, and payment history. Based on results of previous work, we expect to link almost all M-CARES Recruits to credit records. We will use this data to study the impact of voucher assignment on financial security. Credit data will be requested from Transunion and Equifax. We will provide Equifax and Transunion with with an Admin Data Link File (dataset 4 in "Diagram of Data"). Equifax and Transunion will link the data, remove identifying information from the dataset and send the MCARES research team coded records using an encrypted drive (one of the datasets listed as 5-Agency in "Diagram of Data"). (This process is consistent with the Fair Credit Reporting Act). The codes corresponding to individuals will be determined by Transunion and Equifax independently, so these codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.	no
(3) Tax data	Tax data will be used from both the Census Bureau and the OTA. These data allow us to link Recruits to the universe of all tax filers from 1996 to the present (end date will be updated as time moves forward). Tax data allow us to characterize tax filing, before and after the intervention, in terms of (1) living circumstances (living with parents, single headship, living with married or unmarried partner, etc.), (2) the number of children in household (and when they were born and age at first birth), (3) homeownership, and (4) neighborhood quality (an important metric for standard of living). In addition, tax data allow us to assess (5) college enrollment (via tax credits for these expenditures), (6) exact income from wage earnings in the household, (7) receipt/eligibility of the Earned Income Tax Credit, and (8) eligibility for other public assistance programs. Every M-CARES Recruit who files taxes can be linked to tax data. For access to these records through the Census and OTA, we will provide Census with the Admin Data Link file (dataset 4 in "Diagram of Data"), which will enable linking to PIKs. Census will then provide access to M-CARES team to a coded (PIK'd) version of these data in the UM-RDC (dataset listed as 5-OTA in "Diagram of Data"). OTA will NOT provide the data to researchers outside of OTA. Instead, Elena Patel, OTA employee and M-CARES team member, will conduct analyses with these data at OTA. OTA will analyze these data and review them for confidentiality before disclosing descriptive statistics and regression output to the M-CARES team outside of OTA.	no

Name	Identifying Info	Is Publicly Available
(4) Birth and death certificates	These include birth and death certificates from the Michigan Department of Health and Human Services (MDHHS) and comparable agencies other states when applicable (this is only applicable in cases where, for example, if the birth of a child happens out of state). Birth records the date of birth of each child; location of birth; attendant at birth; plurality of birth, health conditions of the newborn; pre-natal care; gestational length; mother's health information; morbidity; pregnancy risk factors; previous births and outcomes; onset of and characteristics of labor and method of delivery; payment information; marital status at birth, mother education and occupation; father age, race, education and occupation. Death records contain date of death, members of household, and cause of death. We will provide Michigan Department of Health and Human Services (MDHHS) with the Admin Data Link File (datasets 4 and 6 in "Diagram of Data"), which allows MDHHS to locate birth certificates of Recruits and their Children. We expect to find approximately 77 percent of Recruits and 90 percent of their Children in these data. MDHHS will link the data, remove PII and replace with codes, and send the M-CARES research team a coded set of records using an encrypted drive (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data"). The codes corresponding to individuals will be determined by MDHHS independently, so these codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.	no
(5) Decennial Census data, American Community Survey (ACS), and Current Population Survey (CPS) Annual Social and Economic Supplement	The 2000, 2010, 2020 (expected), and 2030 (expected) Censuses contain the data compiled from the questions asked of all people in every housing unit in the U.S. This includes a detailed enumeration of everyone in the U.S. population by sex, age, race or Hispanic or Latino origin. In addition, variables indicating relationship to household head and marital status allow us to characterize all children living in the household and sub-family. Available census variables allow us to characterize every Recruit, before and after the intervention, in terms of the following characteristics: (1) living circumstances (living with parents, single headship, living with married or unmarried partner, etc.), (2) the number of children in household (and when they were born and age at first birth), (3) renter/owner status, (4) incarceration status, and (5) neighborhood quality (an important metric for standard of living). Additionally, we can identify these outcomes for race/ethnicity subgroups. As long as the Children were alive, we also expect to link them to these records. ACS and CPS ASEC data will contain information for a random sample of M-CARES Recruits and their Children. If the sample overlap is large enough, we will use these records as a supplement to the Census. These surveys allows us to characterize Recruits and their Children in a similar way as the Census, but on a more frequent or updated basis. We will provide Census with the Admin Data Link File (datasets 4 and 6 in "Diagram of Data"). Census will then provide access to MCARES team to a coded (PIK'd) version of these data in the UM-RDC (datasets listed as 5-Census and 7-Census in "Diagram of Data").	no
(6A) National Student Clearinghouse (NSC) records	We will use two types of administrative sources for education data, the National Student Clearinghouse (NSC) and Michigan education data (K-college). The National Student Clearinghouse (NSC) was originally was tied to the student loan industry and gathered enrollment data from participating colleges. The purpose of the database was to allow the loan industry to confirm that a borrower was enrolled and therefore eligible to defer repayment of student loans. Consistent with this history, the NSC today tracks enrollment (but not credits or major) and whether a student has graduated and degree earned. As of 2012, the NSC started using the Classification of Instructional Programs to record a student's major (http://nces.ed.gov/ipeds/cipcode/). To access these data, we will send NSC the Admin Data Link file (datasets 4 and 6 in "Diagram of Data"). NSC will link the data, remove PII from the dataset, and send the MCARES research team a coded set of records using an encrypted drive (datasets listed as 5-Agency and 7-Agency in "Diagram of Data"). The codes corresponding to individuals will be determined by NSC, so the codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.	no
(6B) Michigan education data (K-college)	We will use two types of administrative sources for education data, the National Student Clearinghouse (NSC) and Michigan education data (K-college). To supplement NSC data, we will link our Recruits and their Children to Michigan public education data. We will not be able to link Recruits of their Children who obtained education outside of the state. Michigan public education data contain administrative school records, which report school attendance, promotion to the next grade, grades, and graduation date. To access these data, we will send school districts the Admin Data Link file (datasets 4 and 6 in "Diagram of Data") . School districts will link the data, remove identifying information from the dataset, and send the M-CARES research team a coded set of records using an encrypted drive (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data"). The codes corresponding to individuals will be determined by school districts independently, so these codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.	no

Name	Identifying Info	Is Publicly Available
(7) Program participation data	These records include Supplemental Nutritional Assistance Program (SNAP), Temporary Assistance for Needy Families (TANF), and Medicaid MSIS and Medicaid T-MSIS. They are located at the Census Bureau and at OTA. They will be linked to M-CARES Recruits of their Children using the same process as described for OTA and Census data. For access to these records through the Census and OTA, we will provide Census with the Admin Data Link file (datasets 4 and 6 in “Diagram of Data”), which will enable linking to PIKs. Census will then provide access to M-CARES team to a coded (PIK’d) version of these data in the UM-RDC (datasets listed as 5-Census, 5-OTA, 7-Census, 7-OTA in “Diagram of Data”). OTA will NOT provide the data to researchers outside of OTA. Instead, Elena Patel, OTA employee and M-CARES team member, will conduct analyses with these data at OTA. OTA will analyze these data and review them for confidentiality before disclosing descriptive statistics and regression output to the M-CARES team outside of OTA.	no
(8) Michigan criminal justice records	These data track an individual on a quarterly basis, collecting information their arrests, prison entries, and incarceration status (these data are not state-specific and include records from all contributing data providers). Beginning summer 2018, these records will be available in the UM-RDC. These records will be linked using the same process as described for other Census Data. We will provide Census with the Admin Data Link file (dataset 4 in “Diagram of Data”), which will enable linking to PIKs. Census will then provide access to M-CARES team to a coded (PIK’d) version of these data in the UM-RDC (datasets of the type listed as 5-Agency and 7-Agency in “Diagram of Data”). All data with PIKs can be linked together, but RDC data cannot be re-linked to individual PII or survey data. This would violate federal data confidentiality requirements. Moreover, Census data cannot be linked to administrative data sources from other agencies as other agencies use different coded identifiers. See also previous discussion of the UM-RDC. These records will be linked using the same process as described for other Census Data. We will provide Census with the Admin Data Link file (dataset 4 in “Diagram of Data”), which will enable linking to PIKs. Census will then provide access to M-CARES team to a coded (PIK’d) version of these data in the UM-RDC (datasets of the type listed as 5-Agency and 7-Agency in “Diagram of Data”).	no
(9) Michigan child welfare and juvenile crime records	These data contain information on the name and date of birth of children in state records containing allegations of abuse/neglect and foster care placements and official delinquency petitions for the State of Michigan. We will send Michigan Child and Adolescent Data Lab (MCAD, housed at the University of Michigan, School of Social Work: http://ssw-datalab.org/about/) the Admin Data Link file. We will send MCAD the Admin Data Link file (datasets 4 and 6 in “Diagram of Data”), and MCAD will link the data, remove PII from the dataset, and send the M-CARES research team a coded set of records using an encrypted drive (datasets of the type listed as 5-Agency and 7-Agency in “Diagram of Data”). (This process is consistent with their agreement with the State of Michigan.) The codes corresponding to individuals will be determined by MCAD independently, so the codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.	no

Secondary Data Set Detail

24.2* Name and source/location of data set:

(1) PPMI records

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

These records contain detailed information on Recruits’ socio-demographic information, physical health information, pregnancy and childbearing history, medical history, their PPMI visits (at all PPMI clinics), including the date of the visit, details on diagnoses and procedures and services provided, and payment method and payment amount. The method of payment for the services on the records allows us to identify the services obtained with the M-CARES voucher. We rely on these data in part to estimate how pregnancies, abortions, childbearing, and contraceptive use is affected by voucher receipt. We expect to link all Recruits to their PPMI records (going back to the date of participant’s first PPMI visit and up to 2023, the end of the study). The date of Recruit’s enrollment from survey 1 allows us to separate patient history data into pre- and post-intervention periods.
We will provide PPMI with the Admin Data Link File (dataset 4 in “Diagram of Data”). PPMI will use this information to locate Recruits’ patient records and will provide the M-CARES research team a coded set of records using an encrypted drive (one of the datasets listed as 5-Agency). The codes corresponding to individuals will be determined by PPMI, so the codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
Example Unexecuted DUA with Planned Parenthood	0.01

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(10) Employment and Earnings Records

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

These records are not yet available from the State of Michigan or federal government. Because we expect them to become available in the near future, we have, therefore, included them in our consent. These records include information on quarterly earnings, employment, unemployment benefits, taxes paid by the employee and the employer(s) to the state, income from different sources, disability income, and the number of different employer(s).

These records may become available through OTA, the Census Bureau, or through the State of Michigan directly. Depending upon how these records become available, we will follow either the OTA, Census Bureau, or agency protocols laid out above and in our Diagram of Data for linking and storing these data.

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
There are no items to display	

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(11) Health Insurance Claims at University of Michigan

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

These records are not yet available for researchers, but they are being assembled through a project at the University of Michigan. Because we expect them to become available in the near future, we have included them in our consent. These records include information such as the date of a visit to a service provider, service provider, services obtained, payment methods and amounts, the name of the clinic, medical and physical diagnosis codes.

Depending upon how these records become available and the Data Use Agreements that govern their use, we submit an amendment to the IRB and follow the protocols laid out here for agency data for linking them and storing these data.

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
There are no items to display	

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(2) Credit reports

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

Recruits' credit records contain rich information on their credit history, including credit accounts' payment status, outstanding balance, credit limit, delinquency, and payment history. Based on results of previous work, we expect to link almost all M-CARES Recruits to credit records. We will use this data to study the impact of voucher assignment on financial security.
Credit data will be requested from Transunion and Equifax. We will provide Equifax and Transunion with with an Admin Data Link File (dataset 4 in "Diagram of Data"). Equifax and Transunion will link the data, remove identifying information from the dataset and send the MCARES research team coded records using an encrypted drive (one of the datasets listed as 5-Agency in "Diagram of Data"). (This process is consistent with the Fair Credit Reporting Act). The codes corresponding to individuals will be determined by Transunion and Equifax independently, so these codes will NOT allow the linking of

these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
Experian Data Use Agreement (EXAMPLE, NOT FOR THIS STUDY)	0.01

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(3) Tax data

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

Tax data will be used from both the Census Bureau and the OTA. These data allow us to link Recruits to the universe of all tax filers from 1996 to the present (end date will be updated as time moves forward). Tax data allow us to characterize tax filing, before and after the intervention, in terms of (1) living circumstances (living with parents, single headship, living with married or unmarried partner, etc.), (2) the number of children in household (and when they were born and age at first birth), (3) homeownership, and (4) neighborhood quality (an important metric for standard of living). In addition, tax data allow us to assess (5) college enrollment (via tax credits for these expenditures), (6) exact income from wage earnings in the household, (7) receipt/eligibility of the Earned Income Tax Credit, and (8) eligibility for other public assistance programs. Every M-CARES Recruit who files taxes can be linked to tax data.
For access to these records through the Census and OTA, we will provide Census with the Admin Data Link file (dataset 4 in "Diagram of Data"), which will enable linking to PIKs. Census will then provide access to M-CARES team to a coded (PIK'd) version of these data in the UM-RDC (dataset listed as 5-OTA in "Diagram of Data"). OTA will NOT provide the data to researchers outside of OTA. Instead, Elena Patel, OTA employee and M-CARES team member, will conduct analyses with these data at OTA. OTA will analyze these data and review them for confidentiality before disclosing descriptive statistics and regression output to the M-CARES team outside of OTA.

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
CAARA mcares_proposal_approved.pdf	0.01

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(4) Birth and death certificates

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

These include birth and death certificates from the Michigan Department of Health and Human Services (MDHHS) and comparable agencies other states when applicable (this is only applicable in cases where, for example, if the birth of a child happens out of state).

Birth records the date of birth of each child; location of birth; attendant at birth; plurality of birth, health conditions of the newborn; pre-natal care; gestational length; mother's health information; morbidity; pregnancy risk factors; previous births and outcomes; onset of and characteristics of labor and method of delivery; payment information; marital status at birth, mother education and occupation; father age, race, education and occupation.

Death records contain date of death, members of household, and cause of death.

We will provide Michigan Department of Health and Human Services (MDHHS) with the Admin Data Link File (datasets 4 and 6 in "Diagram of Data"), which allows MDHHS to locate birth certificates of Recruits and their Children. We expect to find approximately 77 percent of Recruits and 90 percent of their Children in these data. MDHHS will link the data, remove PII and replace with codes, and send the M-CARES research team a coded set of records using an encrypted drive (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data"). The codes corresponding to individuals will be determined by MDHHS independently, so these codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
Agreement VR - MDHHS.doc	0.01
DCH-1294.doc	0.01

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of

identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(5) Decennial Census data, American Community Survey (ACS), and Current Population Survey (CPS) Annual Social and Economic Supplement

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

The 2000, 2010, 2020 (expected), and 2030 (expected) Censuses contain the data compiled from the questions asked of all people in every housing unit in the U.S. This includes a detailed enumeration of everyone in the U.S. population by sex, age, race or Hispanic or Latino origin. In addition, variables indicating relationship to household head and marital status allow us to characterize all children living in the household and sub-family. Available census variables allow us to characterize every Recruit, before and after the intervention, in terms of the following characteristics: (1) living circumstances (living with parents, single headship, living with married or unmarried partner, etc.), (2) the number of children in household (and when they were born and age at first birth), (3) renter/owner status, (4) incarceration status, and (5) neighborhood quality (an important metric for standard of living). Additionally, we can identify these outcomes for race/ethnicity subgroups. As long as the Children were alive, we also expect to link them to these records.
ACS and CPS ASEC data will contain information for a random sample of M-CARES Recruits and their Children. If the sample overlap is large enough, we will use these records as a supplement to the Census. These surveys allows us to characterize Recruits and their Children in a similar way as the Census, but on a more frequent or updated basis.
We will provide Census with the Admin Data Link File (datasets 4 and 6 in "Diagram of Data"). Census will then provide access to MCARES team to a coded (PIK'd) version of these data in the UM-RDC (datasets listed as 5-Census and 7-Census in "Diagram of Data").

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
CAARA mcares_proposal_approved.pdf	0.01

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(6A) National Student Clearinghouse (NSC) records

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

We will use two types of administrative sources for education data, the National Student Clearinghouse (NSC) and Michigan education data (K-college).
The National Student Clearinghouse (NSC) was originally was tied to the student loan industry and gathered enrollment data from participating colleges. The purpose of the database was to allow the loan industry to confirm that a borrower was enrolled and therefore eligible to defer repayment of student loans. Consistent with this history, the NSC today tracks enrollment (but not credits or major) and whether a student has graduated and degree earned. As of 2012, the NSC started using the Classification of Instructional Programs to record a student's major (http://nces.ed.gov/ipeds/cipcode/). To access these data, we will send NSC the Admin Data Link file (datasets 4 and 6 in "Diagram of Data"). NSC will link the data, remove PII from the dataset, and send the MCARES research team a coded set of records using an encrypted drive (datasets listed as 5-Agency and 7-Agency in "Diagram of Data"). The codes corresponding to individuals will be determined by NSC, so the codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
There are no items to display	

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(6B) Michigan education data (K-college)

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

We will use two types of administrative sources for education data, the National Student Clearinghouse (NSC) and Michigan education data (K-college).

To supplement NSC data, we will link our Recruits and their Children to Michigan public education data. We will not be able to link Recruits of their Children who obtained education outside of the state. Michigan public education data contain administrative school records, which report school attendance, promotion to the next grade, grades, and graduation date.
To access these data, we will send school districts the Admin Data Link file (datasets 4 and 6 in "Diagram of Data") . School districts will link the data, remove identifying information from the dataset, and send the M-CARES research team a coded set of records using an encrypted drive (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data"). The codes corresponding to individuals will be determined by school districts independently, so these codes will NOT allow the

linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
Example Unexecuted Agreement with Washtenaw School District	0.01

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(7) Program participation data

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

These records include Supplemental Nutritional Assistance Program (SNAP), Temporary Assistance for Needy Families (TANF), and Medicaid MSIS and Medicaid T-MSIS. They are located at the Census Bureau and at OTA. They will be linked to M-CARES Recruits of their Children using the same process as described for OTA and Census data.
For access to these records through the Census and OTA, we will provide Census with the Admin Data Link file (datasets 4 and 6 in "Diagram of Data"), which will enable linking to PIKs. Census will then provide access to M-CARES team to a coded (PIK'd) version of these data in the UM-RDC (datasets listed as 5-Census, 5-OTA, 7-Census, 7-OTA in "Diagram of Data"). OTA will NOT provide the data to researchers outside of OTA. Instead, Elena Patel, OTA employee and M-CARES team member, will conduct analyses with these data at OTA. OTA will analyze these data and review them for confidentiality before disclosing descriptive statistics and regression output to the M-CARES team outside of OTA.

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
CAARA mcares_proposal_approved.pdf	0.01

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(8) Michigan criminal justice records

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

These data track an individual on a quarterly basis, collecting information their arrests, prison entries, and incarceration status (these data are not state-specific and include records from all contributing data providers). Beginning summer 2018, these records will be available in the UM-RDC.
These records will be linked using the same process as described for other Census Data. We will provide Census with the Admin Data Link file (dataset 4 in "Diagram of Data"), which will enable linking to PIKs. Census will then provide access to M-CARES team to a coded (PIK'd) version of these data in the UM-RDC (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data"). All data with PIKs can be linked together, but RDC data cannot be re-linked to individual PII or survey data. This would violate federal data confidentiality requirements. Moreover, Census data cannot be linked to administrative data sources from other agencies as other agencies use different coded identifiers. See also previous discussion of the UM-RDC.

These records will be linked using the same process as described for other Census Data. We will provide Census with the Admin Data Link file (dataset 4 in "Diagram of Data"), which will enable linking to PIKs. Census will then provide access to M-CARES team to a coded (PIK'd) version of these data in the UM-RDC (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data").

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
There are no items to display	

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

Secondary Data Set Detail

24.2* Name and source/location of data set:

(9) Michigan child welfare and juvenile crime records

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

These data contain information on the name and date of birth of children in state records containing allegations of abuse/neglect and foster care placements and official delinquency petitions for the State of Michigan.
We will send Michigan Child and Adolescent Data Lab (MCAD, housed at the University of Michigan, School of Social Work: http://ssw-datalab.org/about/) the Admin Data Link file. We will send MCAD the Admin Data Link file (datasets 4 and 6 in "Diagram of Data"), and MCAD will link the data, remove PII from the dataset, and send the M-CARES research team a coded set of records using an encrypted drive (datasets of the type listed as 5-Agency and 7-Agency in "Diagram of Data"). (This process is consistent with their agreement with the State of Michigan.) The codes corresponding to individuals will be determined by MCAD independently, so the codes will NOT allow the linking of these data to other admin records, PII, or survey data beyond what is in the Admin Data Link file.

24.4* Is the data set you are analyzing publicly available?

○ Yes ● **No**

24.5* Does the data set contain:

Identifier
Coded Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
Example Unexecuted Agreement for Juvenile Criminal Records	0.01

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

Yes

24.8* Will you have access to a key that deciphers the code, thereby enabling linkage of identifying information to an individual subject's private information or samples?

○ Yes ● **No**

24.8.1* Identify the mechanism that precludes access to the codes, and upload (in Question 24.6) copies of any agreements or documents that explain these protections.

Honest broker (centralized custodian who controls data and will not release codes or IDs)

If other, please specify:

25. HIPAA Covered Components

Completion of this section is required based on the response provided to question 4-1.1, 5-1.3, 7.3, or 7-3.2.

25.1* Select all sources of HIPAA-regulated data used, received, or analyzed in the study:

Entity
External non-federal entity holding PHI *Examples: community hospital; tertiary care center; private health insurance company*
External federal entity holding PHI *Examples: Veterans' Affairs Hospital system; Centers for Medicare/Medicaid Services(CMS), including ResDAC; Healthcare Cost and Utilization Project (HCUP)*

25-1. Protected Health Information/HIPAA

Completion of this section is required based on the responses to questions 4-1.1, 5-1.3, 7.3, or 7-3.2 and question 25.1.

25-1.1* Identify the PHI to be used.

Select all that apply:
Hospital/doctor's office records, including test results and dental records
AIDS/HIV, STD, or other serious communicable disease records (including testing, diagnosis, treatment, and outcomes records)
Health plan/health insurance records
Any records relating to condition, the treatment received, and response to the treatment
Billing information
Demographic information
Personal identifiers

If other, please specify:

25-1.2* Explain why the PHI listed above is the minimum necessary to conduct the study.

We will examine PHI records obtained from Planned Parenthood, the Michigan (PPMI), vital statistics agencies like the Michigan Department of Health and Human Services (MDHHS), and health insurance claims (which include health information and medical records).

PPMI records contain information on the date of visits, services obtained, payment methods and amounts, the name of the clinic, and insurance type. They also contain information on health including the date of your last menstrual period, diagnosis codes, and results of physical examinations. These records provide key health outcomes that allow us to understand how financial barriers to contraceptives affect women and their families,

Vital records include birth and death certificates. Birth certificates contain the date of each child birth, hospital, the health conditions of the newborn, mother's health information and pregnancy risk factors; previous births and outcomes; onset of and characteristics of labor and method of delivery. They also contain information on source of payment for the birth. These records provide key health outcomes that allow us to understand how financial barriers to contraceptives affect women's pregnancies and maternal and infant health.

These include birth and death certificates from the Michigan Department of Health and Human Services (MDHHS) and comparable agencies other states when applicable (this is only applicable in cases where, for example, if the birth of a child happens out of state).
Birth records contains the date of birth, including mother, infant, and father's personal identifying information (full name, date of birth, father social security number, address, race, education, and occupation); hospital; plurality; health conditions of the newborn; mother's health information, morbidity, and pregnancy risk factors; previous births and outcomes; onset of and characteristics of labor and method of delivery. They also contain information on source of payment for the birth. Death records contain date of death, members of household, and cause of death.

Finally, other agencies collect health information and insurance claims. In the future, we hope to get information from health insurance claims. Although these records are not yet available, they are being assembled through a project at the University of Michigan. Because we expect them to become available in the near future, we have, therefore, included them in our consent. These records include information such as the date of a visit to a service provider, service provider, services obtained, payment methods and amounts, the name of the clinic, medical and physical diagnosis codes. These records would provide information on eligibility and use of public health insurance. Because many unintended births are paid for using public health insurance, the use of health care and public health insurance is a key outcome in understanding how financial barriers to contraceptives may have implications for expenditures on public programs as well as children's access to health insurance and maternal and child health.

25-1.3* Will HIPAA authorization for access to the PHI be obtained for all or some subjects?

Yes, always - HIPAA authorization was/will be obtained from all subjects

25-1.3.1* If HIPAA authorization for access to the PHI will be obtained from some or all subjects before their data is collected, used or disclosed (including for eligibility determination or recruitment), indicate the document/process to be used:

Integrated with informed consent document/process (All IRBMED apps must select this)

If other, please specify:

28. Internet/Email

Completion of this section is required based on the response provided to question 7-1.4.

28.1* Please explain the specific information technology resources that will be utilized.

NORC will recruit subjects using tablet computers and conduct subject surveys (including the baseline and follow-up surveys) using the internet. The details of this data collection are outlined in our Data Security Protocol in section 44.

We will maintain a website and send periodic newsletters by email to maintain contact with our subjects. We will also invite subjects to update their contact information.

28.2* Please explain the electronic security measures that will be employed to protect the privacy of the research subjects and the integrity of the information.

Survey and Consent Data
NORC will recruit subjects and is an internationally recognized firm. NORC maintains a strong reputation for complying with the requirements of state and federal data protection laws and regulations such as CIPSEA and the Privacy Act of 1974. NORC staff are required to complete annual trainings focused on data use agreements, ethical conduct, and data confidentiality. NORC has developed a detailed approach to maintaining data security and continues to bring its projects into compliance with systems security regulations including FISMA, NIST 800.53, and FIPS. Access to confidential data is restricted to authorized project staff. Data is stored on the secured NORC network and is only exchanged via encrypted format. NORC facilities are also secured with keycard access required in addition to security cameras. The servers and wiring closets are placed in locked rooms which are only accessible to authorized staff via a security code. NORC will transfer the survey data to Michigan using a Secure File Transfer protocol. NORC's IRB is ceding oversight to UM's IRB for these activities.

Once we receive the data from NORC, we will follow the general process as outlined in the “Diagram of Data” figure. When the survey data and consent forms are received from NORC, Bailey and Karimova will store surveys and consent forms (dataset 1 in “Diagram of Data”, Figure 2) on M+Box in a file that is encrypted and password-protected and with access restricted only to Bailey and Karimova.

The first step in the data processing will be to replace individually identifying information on the surveys with coded identifiers. Working in a locked office, Bailey and Karimova will remove PII (names, SSNs, dates of birth, addresses, contact information, and social media information) from the records and add a numeric identification code, birth days (without the year), and broad geographic codes. The cross-walk dataset that links these codes to names will be stored in a separate password protected file on M+Box. Only Bailey and Karimova will have access to this crosswalk file and PII (dataset 2 in “Diagram of Data.”) All analysis will be conducted with data that contains coded identifiers and other survey variables (dataset 3 in “Diagram of Data”).

Administrative Data Linking
We will link M-CARES Recruits and Children to administrative records which are detailed in the next section. We will link Recruits to (1) PPMI patient records; (2) credit reports; (3) tax data; (4) birth and death certificates; (5) Decennial Census, American Community Surveys (ACS), and Current Population Survey (CPS) Annual Social and Economic Supplement (ASEC); (6) Education data (K-college and National Student Clearinghouse, NSC); (7) program participation; (8) Michigan criminal justice records; (9) Michigan child welfare and justice records; (10) Employment and Earnings Records ; and (11) Health Insurance Claims. (Numbers correspond to numbering in the next section outlining the content of these records; see also discussion in section 24 of the IRB).

We will link Children’s to a subset of these records, including (4) birth and death certificates; (5) Decennial Census, ACS, and CPS-ASEC; (6) Education data (K-college and National Student Clearinghouse, NSC); (7) program participation; (9) Michigan child welfare and justice records, (10) Employment and Earnings Records; and (11) Health Insurance Claims.

The process of linking to these administrative files is intended to minimize the risk of unauthorized disclosure of sensitive information. Following the process laid out in in “Diagram of Data,” our linking process follows these steps.

From the survey file (dataset 1 in “Diagram of Data”) we will create an administrative data link file (“Admin Data Link”) for Recruits and Children and share this via encrypted drive with agencies. For Recruits, the Admin Data Link file will include PII including full name, date of birth, address, and SSN in addition to a subset of variables from survey data, which we will call Z variables (dataset 4). For Children, the Admin Data Link file will include PII including full name, date of birth, and place of birth in addition to a subset of variables from survey data, which we will call Z variables (dataset 6).

These Z variables include information about whether the individual received a voucher and the voucher amount as well as a subset of answers to survey questions that allow us to construct covariates and conduct heterogeneity tests. To make sure that no sensitive information is revealed to agencies, the Z variables will be masked. The masking process will create generic labels for variable names and answers. For instance, a question like "how many children have you had?" will be stored under the variable name Q15 with numeric answers 0 to 20. The Admin Data Link will be stored in encrypted format on an encrypted drive to be shared with agencies who will link to administrative data.

Agencies will then link Recruits and Children to data, remove PII, and give the M-CARES team access to these administrative data with coded identifiers or statistical results. The process is similar for different agencies, but we outline specifics for each administrative dataset.

The result of this process is that the M-CARES team will have access to and analyze separate coded administrative data files for Recruits (datasets listed under 5 in “Diagram of Data”) and Children (datasets listed under 7 in “Diagram of Data”).

We discuss this in more detail in the appended research protocol in section 5 (Research Methodology) and section 24. We also discuss data electronic security measures in detail in our Data Security Protocol in section 44.

28.3* Will representatives or advocates of the "community" under study be consulted in order to understand their expectations of privacy on the Internet or via email?

○ Yes ● **No**

28.3.1* Explain.

We believe the electronic security measures that we employ provide highest feasible protections for their privacy and unauthorized disclosure of sensitive information. Please see Data Security Protocol in section 44.

28.4* If the results will be published or presented, will the pseudonyms/screen names of individuals studied be disguised?

N/A

28.4.1* Explain.

No screen names, pseudonyms, or personal information will be published or presented.

29. Survey Research

Completion of this section is required based on the response provided to question 7-1.5.

29.1* Provide a list of all surveys and interviews used in the study:

Name	# of Questions	Duration	Sensitive?	Disturbing?
(2) Baseline survey	118	25 minutes	yes	no

29.13* Will the research involve the use of focus groups?

○ Yes ● **No**

29.14* Is any of the material disturbing?

○ Yes ● **No**

Survey Detail

29.2* Survey or interview name:

(2) Baseline survey

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

Electronic tablet in PPMI lobby or internet or, if non-respondent, follow ups by email, text, mail, and telephone

29.5* What is the predicted response rate?

80 %

29.6* What is the total number of questions?

118

29.7* What is the anticipated cumulative amount of time required for each subject?

25 minutes

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

● **Yes** ○ No

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

○ Yes ● **No**

29.12* Upload the survey instrument here.

Name	Version
Baseline survey	0.04

33. Children - Interaction/Intervention Studies

Completion of this section is required based on the response provided to questions in Section 6 and 9-1.1.

33.1* For each research activity conducted with children, indicate the member(s) of the study team that will conduct the activity and briefly describe their expertise with children.

No member of the study team has experience interacting with children. However, there will be no direct interaction with children. Children will participate passively in M-CARES through the collection of their administrative records.

33.2* Describe the adequacy of the research facilities to accommodate children participating in this study.

Children not participated actively in M-CARES. We will only follow them in their administrative records. Facilities for children are not relevant to this study.

33.3* Permitted Categories of Research: The federal policy and regulations governing human subject protections specify that research involving children must fall into one of the following permitted categories. Check all categories of permitted research that apply to this study. The information provided here must be consistent with the information in Section 6.

Regulatory Category	Criteria
The research does not involve greater than minimal risk [45 CFR 46.404].	

33.3.1* Provide a justification for how the study complies with the selected requirement.

There is no more than minimal risk. Children will only participate passively in M-CARES through the collection of their administrative records. The only risk this study poses to children is the unauthorized access to their information. As outlined in our Data Security Protocol, we have taken many steps to minimize the risk of unauthorized disclosure of information.

33.4* Does the study require the involvement of children with any physical or mental incapacities?

○ Yes ● **No**

37. Women of Child Bearing Potential

Completion of this section is required based on the response provided to question 9-1.1.

37.1* Is there a potential that any of the study procedures pose significant physical or psychological risks to women who are or may be pregnant, or to a fetus?

○ Yes ● **No**

41. Subjects Vulnerable to Coercion

Completion of this section is required based on the response provided to question 9-1.1, 9-2.1, or 9-3.1

The following subject populations, vulnerable to coercion or undue influence, have been identified for inclusion in the study.

Children

Economically or Educationally Deprived

41.1* What is the justification for the inclusion of these subject populations?

Our study is about financial access to contraception. We, therefore, include women who may be economically and educationally deprived, because they may need contraception but may not be able to pay for their contraception.

41.2* Describe the additional safeguards that have been included in this study to protect the rights and welfare of these subjects.

All Recruits are free to use the M-CARES voucher to choose any contraceptive method or none at all. No study participant is compelled to select any contraceptive method or participate in the study against her will. Every participant may enroll in the study and opt out at any time.

In addition our surveyor oral script requires surveyors to confirm with participants their consent by repeating the provisions after they have accepted on a tablet.

44. Additional Supporting Documents

44.1 Please upload any additional supporting documents related to your study that have not already been uploaded. Examples include, but are not limited to, data collection sheets, newsletters, subject brochures, and instructional brochures.

Name	Version
Data Security Protocol	0.08
Dec_recruitment_brochure_track_changes	0.05
DUA	0.01
HSIP email.pdf	0.01
Mar_Consent_Trackchanges	0.02
Nov_Diagram of Data	0.01
Nov_Oral_Script	0.03
Nov_Research Protocol	0.01

45. End of Application

Documents Reminder
Following is a list of items you have indicated are pending or cannot be provided electronically.
These items will be added to the list of outstanding contingencies, and should be promptly submitted to the IRB and any other required compliance committees. Failure to do so may delay review of the application.

- Certificate of Confidentiality
  Jump to 11. Confidentiality/Security

The form was successfully submitted. Click 'Exit' or 'Finish' to leave the form.

EXPERIAN
ANALYTICAL SERVICES SCHEDULE

This Analytical Services Schedule ("Schedule") supplements the Subscriber Service Agreement, dated December 18, 2000 ("Agreement") between Experian and Client.

1. Application. For the purposes of this Schedule, "Services" shall mean the analysis services provided by the Decision Analytics division of Experian to Client as described in further detail below.

2. Term. This Schedule shall commence on the Schedule Effective Date and continue in force until completion of the Services; provided, however that the provisions of Section 7 shall survive any termination of this Schedule for so long as Client retains possession and/or control of the Depersonalized Data delivered under this Schedule.

3. Services to be Performed.

Client shall provide, or cause a third party to provide, the HUD data required for Experian to perform the Services under this Schedule.

Experian will append calculated VantageScore 3.0 scores, Income Insight, Insight W2, up to 200 Premier Attribute v1.2 values.

Experian will receive a data file from Clarity with its data elements appended and will match the Experian and Clarity files to create a combined Depersonalized Data file.

Experian will deliver a Depersonalized Data file to Client, for a one-time study for analytical purposes only, with calculated VantageScore 3.0 score, Income Insight, Insight W2, and up to 200 calculated Premier Attributes v1.2 values, subject to the provisions of this Schedule and in particular, Section 7 below.

4. Project Schedule. To be mutually agreed upon by the parties.

5. Payment. The fee for the Services under this Schedule is $100,000*, due and payable 100% upon execution of this Schedule.

*Pricing covers: (a) pull of twelve (12) Experian archives; (b) append of calculated VantageScore 3.0 score, Income Insight, Insight W2, and up to 200 calculated Premier Attributes v1.2 values; match up of Experian and Clarity files to create a combined Depersonalized Data file, and delivery of that Depersonalized Data file to Client.

6. Data Use. Client represents to Experian that Client has the authority to provide and/or cause a third party to provide the HUD data to Experian required for performance of the Services. Experian may use Client's consumer data for general product research and development after extraction of information identifying Client and the consumer whose records are utilized.

7. Depersonalized (Coded) Data.

A. Depersonalized Data means certain data about consumers possessed by Experian and retained for modeling and research purposes which has consumers' identifying information coded or masked. Upon Client's request, Experian will provide the Depersonalized Data that may also include a record identifier. Client certifies to Experian that Client has no known ability to, and will not seek to (a) link the Depersonalized Data or record identifier to the individual identity of the consumer, including but not limited to, name, address, social security number, or customer account number, whose credit data is contained in or used to prepare the Services, or (b) otherwise identify the individual identity of the consumer whose credit data is contained in or used to prepare the Depersonalized Data.

B. Client agrees that it will not, either directly or indirectly, itself or through any agent or third party, without the prior written consent of Experian, request, compile, store, maintain, resell or use the Services (including any of the information contained in the Services) to build its own credit reporting database. Client further agrees that it will not disclose the Depersonalized Data, including but not limited to any research results that utilize the Depersonalized Data, to any third parties. Client shall be solely responsible for assuring the secure and confidential manner in which it stores, delivers and transmits the Services to its authorized employee users. Client shall, at a minimum, comply with Experian's standard access security requirements.

C. The Services may use consumer credit to estimate a consumer's income and/or a consumer's assets. Client acknowledges that Experian does not obtain or verify consumer income data or consumer asset data. Client shall not use the Services, in whole or in part, as a basis for any adverse action involving the consumer. Client acknowledges that Client must determine if the Services are appropriate to meet compliance with any of Client's legal or regulatory requirements. If Debt-to-Income Insight^{SM} Services are involved, Client acknowledges the Debt-to-Income Insight^{SM} calculation is created based on estimated income from the Income Insight^{SM} model and the aggregated debt attribute(s) selected by Client. If Debt-to-Income Insight W2^{SM} Services are involved, Client acknowledges the Debt-to-Income Insight W2^{SM} calculation is created based on estimated income from the Income Insight W2^{SM} model and the aggregated debt attributes(s) selected by Client.

D. VantageScores delivered as part of the Depersonalized Data file delivered under this Schedule are subject to the terms and conditions of the VantageScore Supplement to be executed by Client prior to delivery of that score to Client, in addition to the terms and conditions of this Section 7.

EXPERIAN
ANALYTICAL SERVICES SCHEDULE

E. Notwithstanding the foregoing, as Experian has authorized Client to utilize Depersonalized (Coded) Data for Client's one-time study for analytical purposes only, the following terms and conditions will apply: 1) Client will send Experian a copy of study prior to any sharing by Client with any third party, including but not limited to, publication or submission for publication, so Experian may review and edit study prior to any publication; 2) Experian has the right to deny use of Experian name as a data source for the study; and 3) Experian has the right to limit distribution of publication to a finite entity or group. For the avoidance of doubt, in no event shall Client be authorized to utilize Fair Isaac scores. Client will destroy the Depersonalized Data once the study is complete.

8. Miscellaneous. Subject to written approval by Client, Client agrees that Experian may promote that Experian is a provider of the Services to Client and that Experian may use Client's name, logo and statements in its marketing and public relations material. In addition, Client agrees to furnish to Experian examples and case studies on its successful use of the Services, which information may be utilized by Experian in Experian's marketing, sales and public relations materials, subject to written approval by Client. Upon mutual consent, Client may serve as a client reference for Experian with potential customers. Client will respond promptly to reference and marketing/publicity requests and such requests will not be unreasonably withheld.

This Schedule, together with the Agreement as amended herein constitutes the entire agreement between the parties with respect to the Services provided hereunder and supersedes all prior proposals and agreements, both written and oral, and all other written and oral communications between the parties.

Experian Information Solutions, Inc.

By: Lisa Hazan
Signature (Duly Authorized Representative Only)

Name: Lisa Hazan
Print

Title: Contracts Counsel

Schedule Effective Date: May 4, 2017

Regents of the University of Michigan
Print or Type Full Legal Name of Company

By: David Walters
Signature (Duly Authorized Representative Only)

Name: DAVID WALTERS
Print

Title: PROCUREMENT AGENT

Michigan Department of Health and Human Services
Institutional Review Board for the Protection of Human Research Subjects
South Grand Building, 5th Floor, 333 S. Grand Ave., P.O. Box 30195, Lansing, MI 48909
E-mail: MDHHS-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

DETERMINATION NOTICE

To:	**Barbara Derman**	Responsible Department Employee
From:	**Ian A. Horste**	Institutional Review Board Chair
CC:	**Lynette Biery**	Authorizing Bureau/Office Director

MDHHS IRB Log #: 201805-03-NR **Date Received: 05/03/2018**

Study Title: Michigan Contraceptive Access, Research, and Evaluation Study

Primary Investigator(s): Martha Bailey

Funding Source(s): Laura and John Arnold Foundation

Committee Action/Determination Type:

- ☐ Tabled
- ☒ Not human subjects research
- ☐ Exempt human subjects research
- ☐ Approved by expedited review
- ☐ Approved by expedited review with modifications required
- ☐ Approved by full committee review
- ☐ Approved by full committee review with modifications required
- ☐ Disapproved

Comments: Although this activity includes human subjects research, it does not appear that MDHHS is engaged in that research. Materials provided to the MDHHS IRB indicate appropriate IRB review is ongoing for engaged entities and that efforts to protect human subjects are well documented. When MDHHS is not engaged in research, ongoing oversight by the MDHHS IRB is not required.

Chair Signature: Ian A Horste **Determination Date: 05/22/2018**

Expiration Date*: N/A

**Human subjects' research must not continue after this date without MDHHS IRB approval documented on a separate determination notice.*

The MDHHS IRB must approve any change to this study protocol or to approved study documents. Approval of changes must precede implementation, unless a change is necessary to eliminate an apparent immediate hazard to research subjects. The Primary Investigator and Responsible Department Employee must see that any unexpected problem or adverse event in the research is reported as soon as possible (usually within 48 hours of discovery) to the MDHHS IRB administrative office at (517) 241-1928 or MDHHS-IRB@michigan.gov.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES
VITAL RECORDS AND HEALTH STATISTICS SECTION
Agreement for the Use of the Michigan Vital Records Data

I, _____ **agree:**

1. That the vital records data obtained from the Michigan Department of Health and Human Services will be used only in regard to work outlined in the request for access to these data.

2. That these data are confidential. Information that would permit identification of a particular individual or establishment therein described, either directly or indirectly, will be carefully restricted to only those persons working directly on this project.

3. That the information furnished shall be used only for those statistical, administrative, or research purposes specified in writing by the user to the Department pursuant to the provision of MCL 333.2883 and 333.2888. Any future use of the data upon completion of the work will be submitted for approval to the State Registrar. Furthermore, the user shall not use this information to engage in any method, act, or practice which constitutes a commercial solicitation or advertisement of goods, services, or real estate to consumers.

4. That improper use of these data is an illegal act. Identifiable or potentially identifiable information will not be released to anyone or any institution without prior written approval by the Michigan Department of Health and Human Services. No data will be published or released in any form that would permit identification of a particular individual or establishment therein described.

5. That the Michigan Department of Health and Human Services retains ownership of all data supplies under the terms of this agreement. Data files will not be copied for retention or resold or otherwise provided to another person or agency. All data shall be returned to the Department or destroyed upon termination of this agreement or upon completion of this agreement.

6. That all identifiable and potentially identifiable information will be held confidential and will be processed and disposed when no longer necessary so as to insure these data are not accessed inappropriately. Appropriate procedures will be used to guard against access to these data by inappropriate and unauthorized individuals.

I have read and understand the implications of this agreement.

_____
Signature

_____
Title

_____
Organization

_____
Date

Subscribed and sworn before me this _____ day of _____ 20____, a

Notary Public in and for _____ County, Michigan.

Notary Public's Signature_____

Notary Public's Name - Printed or Typed_____

My Commission expires on _____, 20

Misuse of confidential vital records information is punishable by imprisonment or fine or both (MCL 333.2898) while *unauthorized release of confidential information from a medical research project is punishable by imprisonment or fine or both (MCL 333.2638)*

HEALTH SCIENCES &
BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

March 28, 2018

Martha Bailey, Ph.D.
Economics
University of Michigan
Ann Arbor, MI 48109-1220

Dear Dr. Bailey:

The study, *The Michigan Contraceptive Access, Research, and Evaluation Study (M-CARES)* (HUM00132909), was reviewed at a convened meeting of the Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS) at the University of Michigan on December 21, 2017. The IRB-HSBS determined to approve the study with contingencies. In addition to the surveys included in the submission, the following recruitment and consent documents were considered as part of the review:

Recruitment Document(s)
Business Card for Check-In v.02
Oral Script v.04
Recruitment Brochure v.03
Survey 1 v.01

Informed Consent Document(s)
mcares_consent_v36_submit

Survey Instruments
Baseline survey v.04

As of March 28, 2018, all contingencies were met except to obtain a Certificate of Confidentiality (CoC) for the study. When the CoC is obtained for the research, the study will comply with regulations for human subjects protections in 45 CFR 46.111.

Upon receipt of the CoC, you must upload the documentation to the study application. Once the application is approved, the consent and recruitment documents will be stamped with the approval date.

Please note: Research activities with subjects may not begin until the CoC has been obtained and added to the application.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Mary Donnelly

Mary E. Donnelly, MBA, CIP
Full Board Administrator / Senior Research Compliance Specialist
Health Sciences and Behavioral Sciences Institutional Review Board
University of Michigan

Building 520, Suite 1169
2800 Plymouth Road
Ann Arbor, MI 48189-2800

Phone: 734-936-0933
Fax: 734-936-1852
Email: irbhsbs@umich.edu

CARRA Evidence-Building Project Proposal

Project #:
FY2017 - ___

Project title
The impact of subsidized contraception and reproductive health care on women's outcomes
Principal investigator name(s), affiliation, phone, email
Katie Genadek, US Census Bureau, 612-227-7238, Katie.r.genadek@census.gov
Researchers needing special sworn status (SSS), affiliation, phone, email
Martha Bailey, University of Michigan, baileymj@umich.edu (has SSS) Alfia Karimova, University of Michigan, akarimov@umich.edu (cannot get SSS for 2 years)

Planned project start date	Planned project end date
9/1/2017	8/31/2022

Project abstract or summary
This study will evaluate the effect of varying levels of subsidized reproductive health care using a randomized control trial (RCT) on later life outcomes for women. Women seeking care will randomly be assigned a voucher amount between $0 and $X to be used toward any reproductive health care services within 3 months, where X is the maximum out of pocket expenditure. Each voucher will be individually assigned to prevent participants trading or giving away the vouchers. The research design implies that some women will face different prices for their contraception method choices. We will then link the women in the RCT to administrative and survey data to get their earlier individual and household characteristics and later life outcomes, including education, employment, income, assistance receipt, household characteristics, and health care use and outcomes. The RCT provides the treatment and the control group, as well as the varying subsidy levels so we can estimate the effect of contraception coverage and type on these later life outcomes.

Project methods
We will use personally identifiable information from participants in the MCARES randomized control trial (RCT) and to PIK individuals and link them to the administrative and survey data collected as part of the RCT indicated. We can then use the RCT design to estimate the effects of subsidized reproductive health care on later life outcomes by comparing the treated to the untreated individuals. We will make these comparisons in a regression framework and will include covariates from our baseline survey and earlier linked survey and census data to increase precision. We will have extensive information on RCT participants from the baseline and follow up surveys, so we will be able to assess balance between the groups and linkage bias. While the initial analyses will use short-term outcomes from the linked census and survey data, we hope to continue linking the RCT participants to the ongoing data sets in the future.

Project timeline	
Output, deliverable, or task description	**Planned date**
Working paper	2019
Publications	2020-

Project source data files	
External files from researcher, if any;	MCARES survey data collected as part of project

United States Census Bureau

Include authority to use data	
Files held at Census, including years and geography	We request unswapped data as we will be working with small sample sizes. We understand future years are not yet available and some records are not yet available, but we are requesting access for when they become available. ACS 2001-present (and continuing), with PIKs; 2000 and 2010 decennial Census, with PIKs; IRS 1040s 1996-present (and continuing); Medicaid (MSIS) 2012-present (and continuing); Medicaid T-MSIS 2014-present (and continuing), CPS ASEC 2000-2019, with PIKS; MI TANF 2010 + future years as available; MI SNAP 2010 + future years as available
Linkage description (PIK, MAFID, other)	Will PIK the MCARES data using PII and then link it to the surveys, censuses and administrative data specified.
Special data requirements, if any	Will need data sharing agreement with MCARES/University of Michigan
Access mode (FSRDC, Census HQ, VDI, etc.)	Genadek VDI, other researchers University of Michigan RDC
Software needed to conduct analysis	

Attachments, if any (list file names)
Census Benefits 5 and 6: By linking Randomized Control Trial (RCT) data for women and the follow up longitudinal surveys to 1040 tax records and Title 13 Census and survey data, the Census Bureau can evaluate and enhance their data collection. We will also compare responses to similar questions and provide feedback on response variation by questions type.

To be completed by designated Census Bureau-CARRA staff	
CARRA point(s) of contact	Carla Medalia
Data acquisition agreement, if needed	None
DMS project number(s)	249
Data owners required to give project approvals, if any	All datasets are approved for the project

SIGNATURES

Amy O'Hara

Date: 6/30/17

Amy O'Hara, Chief
Center for Administrative Records Research and Applications,
U.S. Census Bureau

Date:_____

Katie Genadek, Principal Investigator
Economist, CES and CARRA, Census Bureau

United States Census Bureau