Study Consents

Optimizing Treatment Interventions for Moms 2.0

NCT03833245

Document Date: 11/24/2020

Consent and Authorization Document

BACKGROUND

You are being invited to take part in a research study to test an intervention that may help you engage better in health care while you are pregnant and after you give birth to your baby (called prenatal or postnatal care hereafter in this document), mental health care (such as treatment for depression), and social services in the community (such as any needed help with housing, food, transportation). The method used in this study is a patient navigator that will help connect participants with health care, drug/alcohol treatment, or other needed services in the community. A patient navigator is like a personal health coach, or health concierge, or a case manager who will meet with you regularly and provide assistance to help you engage in care. Specifically, the navigator will help you identify your health, mental health, and social needs. With your needs identified, the navigator will work to help get you involved in these services and provide support for you to stay in them during and two months after your pregnancy. This study and the navigator do not replace your prenatal care or the need to take any medication prescribed to you whatsoever. This study is designed to help you stay involved with your care. This study is being conducted by Dr. Gerald Cochran from the University of Utah and is supported by the Centers for Disease Control and Prevention, National Center for Injury Prevention.

You are being asked to be in this study because you are 18 years old or older, are pregnant, dependent on opioids, and possibly meet other requirements that make you able to be in this study. Opioids are drugs like pain pills and heroin, and opioid dependence means that you have had serious physical, social, and/or personal problems because of your opioid use. The other criteria you must meet to get into this study are that you have not had serious mental health problems in the last 30 days, and you are planning to keep your baby to delivery. After the researcher has explained the study to you and before you sign this form, you will be asked a few questions about the study to make sure you understand the study. If incorrect answers are given, you will receive further instructions and be retested until your answers are correct. After signing the consent form, you will get a signed copy of it to keep.

STUDY PROCEDURES

If you agree to take part in this study, several things will happen for research purposes only. You may have up to 14 study visits during an 11 month period with the patient navigator. Your study visits will take place at the hospital, in our designated research office, at clinics, virtually, or other locations in the community.

Screening

You will receive a screening to make sure you are eligible to participate in this study. This screening will include verifying your opioid dependence in your medical record; verifying in your medical record that you have not had a psychotic (for example, hallucinations and seeing things that others cannot) or manic (for example, have had out of control energy that has led to problems in your life) mental health episode in the last 30 days; completing a questionnaire about your drug use, and asking whether or not you plan to deliver your baby. You also may be asked to provide a urine drug screen.

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Baseline Visit:
During the first study visit, you will be asked to fill out and sign a contact information form and a HIPAA Release of Protected Health Information Form. You will also complete an assessment with a study team member and your answers will be entered into a research database. This first visit may last up to 2 hours.

- **Locator Information Form**
  We will use this form to help us keep in touch with you and remind you of study follow-up visits. The locator form will collect information about how to contact you for your follow-up visits. We will also ask for contact information for at least 2 other persons who may know how to find you should your contact information change and we cannot find you. For the people that you give the contact information, you will also need to let them know you are in this study (so that it is not unexpected if we need to call them). However, what you tell them about the study is entirely up to you. If we reach any of these people, we will not tell them you are in the study, and we will not tell them the purpose of the study. We will ask them if they know how we can reach you. If we are unable to reach you with the information you have provided on the locator form, we may use publically available data on the Internet in an effort to find updated contact information for you. All reminders will be made in a private manner. We will ask you to update this contact information at the follow-up visits and at other times during the study, as needed. In the event you are no longer in this study, your Locator Information Form will stay with your other identifiable study documents and will be treated as protected information and will be kept in a locked file cabinet and secured computer database. Patients must be able to provide at least 2 collateral contacts to participate in the study.

- **HIPAA Release of Protected Health Information Form**
  You will complete HIPAA Authorization and/or medical record release forms throughout the study, as needed. Signing this consent form will allow us to review your medical records. We are requesting to look at your medical records in the University of Utah Health Science Center in order to review your eligibility to participate in this study (opioid dependence diagnosis and mental health history in the past 30 days). After the project is done, we will use the information to understand how your health care went while you were in this study, this is to say, we will review information about your health care visits. If you receive health care or services outside of the University of Utah system, we will also ask you to sign a release form that will allow us to get your records from those other health care services, so we can see how your health care was while you were in this study. This information will only be put into your research records; your research information will not be placed in your medical records. This identifiable medical record information will be made available to members of the research team for an indefinite period of time. Your authorization is also valid for an indefinite period of time. You will be offered copies of all forms to keep for your records.

- **Interview**
  After filling out the study forms, you will complete an assessment with a study staff member. The interview will ask questions about you, your health, your sex life, and drug and alcohol use.

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A staff member may read questions to you from a computer and type your answers into the research database. The interview will take about one hour to complete. You may skip any questions you don't want to answer. You can also stop the interview at any time.

- **Randomization**
  Part of this research trial involves comparing different treatments. One group will get one treatment and another group will get a different treatment. In this study, you will be put in one group or the other by random chance. This means that a computer will decide by chance which group a person is in, not the doctors running the trial. The two groups are Patient Navigation or Standard Care.

- **Patient Navigation**
  You will receive individual counseling and help with linking to pre- and postnatal care, drug/alcohol treatment, and other community resources (as needed) from a patient navigator. The counseling sessions will discuss your health, any barriers you have to accessing care, and try to help motivate you to participate in other community services (such as housing, food access, transportation). These motivational sessions are intended to help you explore positive and negative aspects of engaging in care or participating in programs. This study and the navigator do not replace your prenatal care or the need to take your medication whatsoever. This study is designed to help you stay involved with your care.

  You will be invited back to participate in 10 patient navigation sessions during the course of your pregnancy; sessions will last 1-1 ½ hours. These sessions will also help you prepare for going to visits with your health care and other service providers, such as thinking of questions you might have and having all of the necessary paperwork completed. The navigator can also go to appointments with you to give you support. The navigator will not interfere with your care and will only assist you as much as you are comfortable. Sessions will also include talking with the navigator about how your care or social service visits have gone and helping to resolve any concerns you might have in going back or continuing your involvement with the care or service.

  You will also be invited back to participate in 4 patient navigation sessions following the delivery of your baby; these sessions will be similar to those that you will have had before you delivered with the exception that the navigator can also help you make arrangements for your baby to get any needed health care or other services. If you are not able to attend sessions in person, the navigator can visit you virtually, at home (if there is a private place to talk), or meet you in another place in the community.

- **Standard Care**
  The standard care group will involve you talking to a hospital social worker. This social worker will ask you about some different health or social services that might be helpful for you. The hospital social worker may also make a suggestion about you getting in contact with a doctor to get prescribed medicine to help you not use opioids any more. The social worker may give you a call to check in on how you are doing and feeling.

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Before Delivery and after Delivery Intervention Completion Follow-up Visits:
We will ask you to come for follow up visits after the completion of the prenatal portion and after the completion of the postnatal portion of the intervention. These visits will last for about 1 to 1 ½ hours each.

During these follow-up visits you will:

1. Update your locator form.
2. Complete an assessment like you did for the baseline visit. Again, the assessment will ask questions about you, your health, your sex life, and drug and alcohol use.
3. Complete urine drug screening test. You will urinate (pee) in a cup. The urine will be tested to find out if you have recently used drugs.

Results of tests to determine recent drug and/or alcohol use will ***not*** affect your study participation.

AUDIO RECORDINGS:
We would like to audio record some of your sessions with the patient navigator. The purpose of this is to confirm that the study staff member is running the session correctly and for the study team to understand the content of the sessions.

- Recordings will be reviewed by members of the research team who are trained to review recordings.
- Recordings will be identified by number only. Your name will not be noted by the study staff or reviewer on any recordings.
- You may choose to stop being recorded at any time and can still be in the study. This decision will not change your care in any way.
- All study recordings will be kept in locked file cabinets and/or password protected computers. Only study staff will have access to them. Study records (including audio recordings) will be stored for at least 7 years.
- Information from the recordings may be published or shared in study reports in aggregate to help describe the sessions and how they were conducted, but your name or other data that might reveal who you are will not be revealed in any reports or writings that may result from this study.

By checking yes and writing your initials below, you permit the researchers to record your session and use it for their research. Again, if you choose not to have the sessions recorded you may still take part in the study.

_____ Yes _____ No _____ Initials

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RISKS

One risk of being in this study is a break in privacy. You will be asked questions about private, personal matters, and information about your mental health and health care will be collected from your medical record. Assessments will ask about your demographics, how often you take your medication, substance use, and other health conditions you may have, such as pain, depression, etc.

Some answers you give in the research visits (like whether you use illegal drugs or have ever been arrested) might put you at risk if other people find out. To keep what you say private, your study records will use a code number instead of your name. We will protect your records by keeping all your materials in locked file cabinets or secure password-protected computer files away from clinic records. Only research staff will have access to your private information. Any information on computers is only available to research staff. Despite taking all of the safety measures mentioned above, there is a risk that your privacy will be broken.

There are no known psychological risks associated with the interview questionnaires, procedures, or counseling in this study. It is possible that discussion of sensitive topics such as substance use may cause emotional discomfort in some participants. There may also be risks of emotional distress, inconvenience and possible loss of privacy and confidentiality associated with taking part in a research study. The study may include risks that are unknown at this time. If you decide to take part in this study, there is no guarantee that your health will improve.

UNFORESEEABLE RISKS

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS

You may not get any direct benefit from being in this study. But, you may benefit by going to a clinic to receive prenatal care and/or substance use treatment. You may also benefit from learning more about maternal health and/or substance use. Also, information gained from this study may help to improve health care and substance use treatment for opioid dependent pregnant women in the future. Also, it may be the case that we find that you need more help as a result of this evaluation, you will be referred to other treatments, doctors, clinics and/or therapists who may be able to help you. If we find that you need some other treatment after the completion of this study, you will be given an appropriate referral.

ALTERNATIVE PROCEDURES

You may choose not to be in this study. If you choose not to take part in or to stop participating in this study, you will receive your regular care and/or treatment. These treatments include regular care outside of this study. You may also choose no treatment. If you wish, you may seek prenatal care and/or substance use treatment by yourself. You should talk about other treatment options with your doctor. Make sure that you understand all of your choices before you decide to take part in the study. You may also withdraw from the study and still have these other treatments available to you.

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PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact Jerry Cochran at 801-213-0654. If you think you may have been injured from being in this study, please call Project Coordinator at 801-213-0799 or (412) 523-8187. The project coordinator can be reached at this number during regular business hours, 9-5pm.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah Hospital, as it is to all sick or injured people. The University of Utah Hospital has not set aside any money to pay the costs for such care. The University of Utah Hospital will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

Your participation in this research study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this form. Your decision will have no effect on your relationship with or the medical care you receive through University of Utah Health or affiliated health care providers.

Your doctor may be an investigator in this research study, and as an investigator, is interested both in your medical care and in the conduct of this research. Before entering this study or at any time during the research, you may discuss your care with another doctor who is in no way associated with this research project. You are not obligated to participate in any research study offered by your doctor.

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We may contact you in the future for participation in one or more additional studies. If we do so, you will have the option to participate or not, and a new informed consent document will be reviewed with you regarding the study for your consideration.

RIGHT OF INVESTIGATOR TO WITHDRAW PARTICIPANTS
The researchers may withdraw you from participation if you act in a way that is harmful or disruptive, for failure to follow study procedures, the sponsor's withdrawal of the study, or if otherwise deemed appropriate.

COSTS AND COMPENSATION TO PARTICIPANTS
The parts of your care that would normally be done as standard treatment such as prenatal care visits or opioid treatment will be billed to you or your insurance company.

You will receive up to $245 for participation in this study over 11 months. You will be paid in the form of a pre-paid gift card. Payment will be made after completion of the following activities:

Payment Schedule

Study Visit	Length of Visit	Payment
Baseline assessment	2 hours	$30
Prenatal intervention follow-up assessment	1 – 1½ hours	$40
Postnatal follow-up assessment at 2 months after delivery	1 – 1½ hours	$50
Follow up assessment at 6 months	1 – 1½ hours	$75
Completion of all 3 assessment bonus	---	$50
TOTAL (For all visits attended)		**$245**

Please note, you will not be paid for participation in the navigation sessions; you will only be paid for completing the assessments listed above. However, you may receive $10 compensation for each visit for parking or travel expenses in the case you are assigned into the patient navigation group.

NEW INFORMATION
Sometimes during the course of a research project, new information becomes available about the patient navigation intervention that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw at that time, your research doctor will make arrangements for your medical care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your medical care to continue.

NUMBER OF PARTICIPANTS
We expect to enroll 61 participants at University of Utah. We also expect to enroll 61 participants at the Magee Women's Hospital of UPMC in Pittsburgh PA.

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AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study. This is the information we will use and include in our research records:

- Demographic and identifying information like name, address telephone number, and email address
- Social Security Number (you are able to not tell us your Social Security Number, but, we would not be able to compensate you if you decided to do so)
- Related medical information about you like current and past medications or therapies, how often you attended prenatal care or other health care appointments, behavioral health conditions, and outcomes related to your delivery and the care of your baby
- All assessments that will be done in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- To help us protect your privacy, we have obtained a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

  The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities if you report or the study staff witnesses that you may cause harm to yourself or others (harm may include things such as suicidal thoughts/actions, child abuse or neglect, or violence towards others). This information will be voluntarily reported to the proper authorities.

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Similarly, if you report or study staff witnesses that you are being harmed, that information will be voluntarily reported as required to the proper authorities. In rare cases, identifiable records may be released in response to an order by a court of law.

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  - Members of the research team and University of Utah Health Sciences Center;
  - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights;
  - Other academic research centers we are working with: Magee Women's Hospital of UPMC
  - The study sponsor: Centers for Disease Control and Prevention

- If we share your identifying information with groups outside of University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health Sciences Center

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

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CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date

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CONSENT COMPREHENSION ASSESSMENT

Optimizing Pregnancy and Treatment Interventions for Moms (OPTI-Mom) study

Instructions to participant: Please answer either "true" or "false" to each of the following questions.

1.	I do not have to take part in this study to receive care at this hospital.	True	False
2.	The decision to take part in this study is up to me.	True	False
3.	I can withdraw from the study at any time.	True	False
4.	My participation in the study will last for up to about 11 months	True	False
5.	The study will involve me providing urine specimens.	True	False

_____	_____	_____
Printed name of participant	Signature of participant	Date

_____	_____	_____
Printed name of person administering assessment	Signature	Date

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- **HIPAA Release of Protected Health Information Form**
  You will complete HIPAA Authorization and/or medical record release forms throughout the study, as needed. Signing this consent form will allow us to review your medical records. We are requesting to look at your medical records in the Magee-Women's Hospital of UPMC in order to review your eligibility to participate in this study (opioid dependence diagnosis and mental health history in the past 30 days). After the project is done, we will use the information to understand how your health care went while you were in this study, this is to say, we will review information about your health care visits. If you receive health care or services outside of the Magee-Women's system, we will also ask you to sign a release form that will allow us to get your records from those other health care services, so we can see how your health care was while you were in this study. This information will only be put into your research records; your research information will not be placed in your medical records. This identifiable medical record information will be made available to members of the research team for an indefinite period of time. Your authorization is also valid for an indefinite period of time. You will be offered copies of all forms to keep for your records.

- **Interview**
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  If you are not able to attend sessions in person, the navigator can visit you virtually, at home (if there is a private place to talk), or meet you in another place in the community.

- **Standard Care**
  The standard care group will involve you talking to a hospital social worker. This social worker will ask you about some different health or social services that might be helpful for you. The hospital social worker may also make a suggestion about you getting in contact with a doctor to

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get prescribed medicine to help you not use opioids any more. The social worker may give you a call to check in on how you are doing and feeling.

Before Delivery and after Delivery Intervention Completion Follow-up Visits:
We will ask you to come for follow up visits after the completion of the prenatal portion and after the completion of the postnatal portion of the intervention. These visits will last for about 1 to 1 ½ hours each.

During these follow-up visits you will:

1. Update your locator form.
2. Complete an assessment like you did for the baseline visit. Again, the assessment will ask questions about you, your health, your sex life, and drug and alcohol use.
3. Complete urine drug screening test. You will urinate (pee) in a cup. The urine will be tested to find out if you have recently used drugs.

Results of tests to determine recent drug and/or alcohol use will ***not*** affect your study participation.

AUDIO RECORDINGS:
We would like to audio record some of your sessions with the patient navigator. The purpose of this is to confirm that the study staff member is running the session correctly and for the study team to understand the content of the sessions.

- Recordings will be reviewed by members of the research team who are trained to review recordings.
- Recordings will be identified by number only. Your name will not be noted by the study staff or reviewer on any recordings.
- You may choose to stop being recorded at any time and can still be in the study. This decision will not change your care in any way.
- All study recordings will be kept in locked file cabinets and/or password protected computers. Only study staff will have access to them. Study records (including audio recordings) will be stored for at least 7 years.
- Information from the recordings may be published or shared in study reports in aggregate to help describe the sessions and how they were conducted, but your name or other data that might reveal who you are will not be revealed in any reports or writings that may result from this study.

By checking yes and writing your initials below, you permit the researchers to record your session and use it for their research. Again, if you choose not to have the sessions recorded you may still take part in the study.

_____ Yes _____ No _____ Initials

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RISKS

One risk of being in this study is a break in privacy. You will be asked questions about private, personal matters, and information about your mental health and health care will be collected from your medical record. Assessments will ask about your demographics, how often you take your medication, substance use, and other health conditions you may have, such as pain, depression, etc.

Some answers you give in the research visits (like whether you use illegal drugs or have ever been arrested) might put you at risk if other people find out. To keep what you say private, your study records will use a code number instead of your name. We will protect your records by keeping all your materials in locked file cabinets or secure password-protected computer files away from clinic records. Only research staff will have access to your private information. Any information on computers is only available to research staff. Despite taking all of the safety measures mentioned above, there is a risk that your privacy will be broken.

There are no known psychological risks associated with the interview questionnaires, procedures, or counseling in this study. It is possible that discussion of sensitive topics such as substance use may cause emotional discomfort in some participants. There may also be risks of emotional distress, inconvenience and possible loss of privacy and confidentiality associated with taking part in a research study. The study may include risks that are unknown at this time. If you decide to take part in this study, there is no guarantee that your health will improve.

UNFORESEEABLE RISKS

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS

You may not get any direct benefit from being in this study. But, you may benefit by going to a clinic to receive prenatal care and/or substance use treatment. You may also benefit from learning more about maternal health and/or substance use. Also, information gained from this study may help to improve health care and substance use treatment for opioid dependent pregnant women in the future. Also, it may be the case that we find that you need more help as a result of this evaluation, you will be referred to other treatments, doctors, clinics and/or therapists who may be able to help you. If we find that you need some other treatment after the completion of this study, you will be given an appropriate referral.

ALTERNATIVE PROCEDURES

You may choose not to be in this study. If you choose not to take part in or to stop participating in this study, you will receive your regular care and/or treatment. These treatments include regular care outside of this study. You may also choose no treatment. If you wish, you may seek prenatal care and/or substance use treatment by yourself. You should talk about other treatment options with your doctor. Make sure that you understand all of your choices before you decide to take part in the study. You may also withdraw from the study and still have these other treatments available to you.

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PERSON TO CONTACT

If you have questions, complaints or concerns about this study, or if you think you may have been injured from being in this study, please contact Dr. Kranz at (412) 641-3537. The study team can be reached at this number during regular business hours, 9-5pm EST.

You may also contact the Human Subjects Protection Advocate at the University of Pittsburgh's IRB Office, 1-866-212-2668.

Institutional Review Board: The University of Utah's Institutional Review Board (IRB) is serving as the central IRB for this study. Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

Who will pay if I am injured as a result of taking part in this study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

VOLUNTARY PARTICIPATION

Your participation in this research study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this form. Your decision will have no effect on your relationship with or the medical care you receive at a UPMC hospital or affiliated health care provider or the University of Pittsburgh.

Your doctor may be an investigator in this research study, and as an investigator, is interested both in your medical care and in the conduct of this research. Before entering this study or at any time during the research, you may discuss your care with another doctor who is in no way associated with this research project. You are not obligated to participate in any research study offered by your doctor.

We may contact you in the future for participation in one or more additional studies. If we do so, you will have the option to participate or not, and a new informed consent document will be reviewed with you regarding the study for your consideration.

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RIGHT OF INVESTIGATOR TO WITHDRAW PARTICIPANTS
The researchers may withdraw you from participation if you act in a way that is harmful or disruptive, for failure to follow study procedures, the sponsor's withdrawal of the study, or if otherwise deemed appropriate.

COSTS AND COMPENSATION TO PARTICIPANTS
The parts of your care that would normally be done as standard treatment such as prenatal care visits or opioid treatment will be billed to you or your insurance company.

You will receive up to $245 for participation in this study over 11 months. You will be paid in the form of a pre-paid gift card. Payment will be made after completion of the following activities:

Payment Schedule

Study Visit	Length of Visit	Payment
Baseline assessment	2 hours	$30
Prenatal intervention follow-up assessment	1 – 1½ hours	$40
Postnatal follow-up assessment at 2 months after delivery	1 – 1½ hours	$50
Follow up assessment at 6 months	1 – 1½ hours	$75
Completion of all 3 assessment bonus	---	$50
TOTAL (For all visits attended)		**$245**

Please note, you will not be paid for participation in the navigation sessions; you will only be paid for completing the assessments listed above. However, you may receive $10 compensation for each visit for parking or travel expenses in the case you are assigned into the patient navigation group.

Note, payment received as compensation for participation in research is considered taxable income for a research subject. If payments are more than $600 in any one calendar year, University of Pittsburgh is required to report this information to the Internal Revenue Service (IRS). Research subject payments exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the research subject and a copy will be sent to the IRS.

NEW INFORMATION
Sometimes during the course of a research project, new information becomes available about the patient navigation intervention that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw at that time, your research doctor will make arrangements for your medical care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your medical care to continue.

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NUMBER OF PARTICIPANTS

We expect to enroll 61 participants at the Magee-Women's Hospital of UPMC. We also expect to enroll 61 participants at the University of Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study. This is the information we will use and include in our research records:

- Demographic and identifying information like name, address telephone number, and email address
- Social Security Number (you are able to not tell us your Social Security Number, but, we would not be able to compensate you if you decided to do so)
- Related medical information about you like current and past medications or therapies, how often you attended prenatal care or other health care appointments, behavioral health conditions, and outcomes related to your delivery and the care of your baby
- All assessments that will be done in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- To help us protect your privacy, we have obtained a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities if you report or the study staff witnesses that you may cause harm to yourself or others (harm may include things such as suicidal thoughts/actions, child abuse or neglect, or violence towards others). This information will be voluntarily reported to the proper authorities. Similarly, if you report or study staff witnesses that you are being harmed, that information will be voluntarily reported as required to the proper authorities. In rare cases, identifiable records may be released in response to an order by a court of law.

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  - Members of the research team and Magee-Women's Hospital of UPMC;
  - The Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights;
  - Other academic research centers we are working with: University of Utah Health
  - The study sponsor: Centers for Disease control and Prevention

- If we share your identifying information with groups outside of University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at Magee Women's Hospital of UPMC.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

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CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date

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CONSENT COMPREHENSION ASSESSMENT

Optimizing Pregnancy and Treatment Interventions for Moms (OPTI-Mom) study

Instructions to participant: Please answer either "true" or "false" to each of the following questions.

1.	I do not have to take part in this study to receive care at this hospital.	True	False
2.	The decision to take part in this study is up to me.	True	False
3.	I can withdraw from the study at any time.	True	False
4.	My participation in the study will last for up to about 11 months	True	False
5.	The study will involve me providing urine specimens.	True	False

_____	_____	_____
Printed name of participant	Signature of participant	Date

_____	_____	_____
Printed name of person administering assessment	Signature	Date

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