Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: The Contraceptive Choice Center: an innovative health services delivery and payment model

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314-747-4393

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are seeking care here at The Contraceptive Choice Center at Washington University in St. Louis (WUSM). The Center will use an innovative model for contraceptive care, which will provide high-quality family planning services for women and aims to reduce unintended pregnancies. The purpose of this research study is to evaluate this innovative model by collecting data from participants including patient satisfaction with healthcare visit, any use of the IUD and implant, percent of patients starting contraceptive method on the day of the visit, insurance coverage, continuation of contraceptive method, and unintended pregnancy or birth over time.

WHAT WILL HAPPEN DURING THIS STUDY?

Enrollment today will take place here at the Contraceptive Choice Center and will take approximately 45 minutes to complete, and includes the following procedures:

- Informed consent
- Collection of contact information
- Signature of Medical Record Information
- Baseline Clinical Form
- Baseline Questionnaire

After your visit with your healthcare provider, you will fill out an addition survey which will take approximately 5 minutes:

- Participant Satisfaction Survey

We will then contact you over the phone for follow-up interviews at 3 months, 6 months, and every 6 months after you enroll in the study until December 31, 2017. The interviews will require about 15 minutes to complete.

You are free at any time to refuse to answer any question.

In this study, we will obtain copies of your medical record(s) from your visit with the Contraceptive Choice Center. The information we request from your provider(s) would be related to this study. For example we will request information about pregnancy, contraception, sexually transmitted infections, and Pap smear results. We will also include information about your past medical history, your diagnosis, today's physical exam information, your height, weight, pulse, blood pressure, etc. We may also ask for permission to obtain copies of your medical record(s) from other healthcare providers. By giving your permission for us to obtain copies of your medical record information, your provider(s) may know that you are part of this research study.

If we are not able to get in touch with you for a follow up survey we may use electronic resources such as Intelius.com, Department of Motor Vehicle records, address updates from the U.S. Postal Service, and contact information from your medical provider to update your contact information. We will then attempt to contact you using this new information.

WILL YOU COLLECT MY SOCIAL SECURITY NUMBER?

You will be asked to provide your social security number on a form that is sent to the tax office here at Washington University. The reason for collecting your social security number is for tax purposes and may be necessary for sharing data with the Center for Medicare and Medicaid Services if they pay for your medical care.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 10,000 women will take part in this study conducted by investigators at Washington University

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, you will be contacted for follow-up interviews at 3 months, 6 months, and every 6 months until December 31, 2017. These follow-up phone interviews will take approximately 15 minutes each**.**

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You may experience some emotional discomfort when answering some of the questions. You have the right to refuse to answer any question for any reason.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, if this model of family planning care can be shown to be successful, this may aid in other clinics using this model of care. This could improve the provision of family planning services to women in many settings.

WHAT OTHER OPTIONS ARE THERE?

Taking part in this study is completely voluntary. You may choose not to take part in this study or you may withdraw your consent at any time. The study team can provide you with information about other healthcare facilities where you may seek contraceptive care without participating in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a gift card will be mailed to you.

You will receive a QuikTrip or Target gift card in the amount of $20 for completion of your enrollment visit. You will receive a $10 gift card after the completion of each of your follow-up surveys.

WHO IS FUNDING THIS STUDY?

The Center for Medicare and Medicaid Services (CMS) is funding this research study. This means that the Washington University is receiving payments from CMS to support the activities that are required to

conduct the study. No one on the research team will receive a direct payment or increase in salary from CMS for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- Public health agencies to complete public health reporting requirements
- University representatives, to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- As part of the research, CMS will conduct an independent evaluation of this project. This means that we will share your data with CMS for the purpose of the evaluation. This data may include information obtained from your insurance company about insurance claims. CMS will follow the same procedures for confidentiality as we follow at Washington University.

To help protect your confidentiality, we will obtain informed consent in a private setting with a closed door at the center with a trained member of the study team. Follow-up telephone surveys will be completed by study staff located in the offices at the Division of Clinical Research. The staff is located behind a closed, locked door and cannot be overheard by persons not associated with the Division of Clinical Research. We will use our best efforts to keep the information about you that we gather during the study secure by training members of the study staff to properly keep information private by keeping coded files behind two locked doors at all times. All electronic files will be password protected and only accessible to study staff.

If we write a report or article about this study or share the study data set with anyone other than CMS, we will do so in such a way that you cannot be directly identified.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- Your treatment or the care given by any health provider.
- Your insurance payment or enrollment in any health plans.
- Any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu (or use the direct link: http://hrpo.wustl.edu/participants/withdrawing-from-a-study/) or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Reminders for appointments and follow up surveys

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document or call the main number at **314-747-0800.**

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time you won't be penalized or lose any benefits for which you otherwise qualify. We can direct you to other providers of family planning services.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study.

If you decide to leave the study early, we will ask you to contact us on the telephone to tell us you would like to withdraw from the study.

If you withdraw from the study we will ask your permission to continue to collect health information from other records. Should this occur, we will ask your permission prior to collecting this information.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research

study earlier than planned. This might happen for no reason, or because you are not compliant with study follow-up, or in our judgment we do not think it would not be safe for you to continue, or because the funding for the research study has ended.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact **The Contraceptive Choice Center at 314-747-0800**. If you feel that you have been harmed in any way by your participation in this study, please contact **Dr. Tessa Madden at 314-747-6495.**

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wusm.wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 12/14/15.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

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(Name of Person who Obtained Consent - printed)