

University of Wisconsin - Madison
Research Participant Information and Consent Form
and
Authorization to Use Protected Health Information for Research

Study Title: Pregnancy Considerations, Trajectories, and Outcomes among Prenatal Care Patients

Principal Investigator:

Dr. Jenny Higgins

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Description of the research

You are invited to participate in a confidential research study at the University of Wisconsin about pregnant people in our state. The purpose of this research is to understand the experiences of Wisconsinites who are exploring pregnancy options, how those experiences and decision-making may have been affected by recent policy changes, and how these changes may affect Wisconsinites' overall health and social wellbeing.

You have been asked to participate in this research because you are a resident of Wisconsin, you are currently pregnant, and you are attending your first prenatal care visit for this pregnancy at a UW Health Clinic or Wingra Clinic.

What will my participation involve?

If you decide to participate in this research, you will be invited to take a confidential survey. If you complete that survey and want to continue participating, you will be invited to take up to two additional surveys, which will take place four and ten months later. All surveys will be delivered to you via email or SMS text, and you can complete the survey on your phone, a computer, or other electronic device.

Your initial participation will last approximately 25 to 30 minutes. If you are interested in participating in follow-up surveys, each one could take 10 to 15 minutes. **You will be paid** for completing each of these surveys.

In addition to surveys, you may have the opportunity to participate in a 60-90 minute interview about your experience.

If you participate in this study, we would like to be able to access your electronic medical record (EMR), as well as your baby's, should you give birth through UW Health. We would use that information to track changes in your, and your baby's, health and wellbeing over the time of your study participation (first prenatal visit through up to 10 months later). This information could include medical history relevant to this pregnancy and health records related to this birth and this child. We will get this information from your health care providers; you would not have to provide it to us.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Things you tell the researchers about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your pregnancy-related diagnoses; billing records; and other information about your pregnancy, including any births. We will get this information from your health care providers.

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Jenny Higgins, at UW Collaborative for Reproductive Equity, 1300 University Avenue, Medical Sciences Center 4245, Madison, WI 53706.

Are there any risks to me?

It is possible you may feel some emotional discomfort while answering the questions, although some people appreciate the opportunity to provide information about their pregnancy experiences. Please know that this is a voluntary process that you can end at any time.

Are there any benefits to me?

We don't expect any direct benefits to you from participating in this study. But we expect that results from this research can be used to help pregnant people in the future.

Will I be compensated for my participation?

Yes. If you participate in this study, you will receive \$30 for completing the initial survey and \$20 for each follow-up survey. If you participate in the add-on interview, you will receive \$75. Someone who participates in each part of the study (three surveys) and the interview would earn \$145.

Each part of the study is paid separately, so you will only be compensated for those surveys you choose to complete. The baseline survey is the minimum requirement. If you choose not to complete the baseline survey, you will not receive a payment and will not be invited to participate in follow-up surveys.

We reserve the right to withhold compensation and discontinue your participation in the study if any of the information you provide indicates that you are ineligible or providing inconsistent (or fraudulent) responses.

What if I am younger than 18?

You do not require a parent or guardian's permission to participate in this study.

How will my confidentiality be protected?

This study is confidential. Neither your name nor any other identifiable information will be published. Data will be stored under encryption and password protection.

If you participate in this study, we would like to be able to access your electronic medical record (EMR), as well as your baby's, should you give birth through UW Health. We have put a number of safeguards in place to make sure this information stays private. We will not share any of your personal health records with others. If you agree to allow us to access your EMR, please initial the statement at the bottom of this form.

Authorizing the research team to use your and your baby's PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once we share your identifiable health information outside UW-Madison, the HIPAA Privacy Rule may no longer protect it. However, we try to make sure that everyone who sees your health information keeps it confidential.

Whom should I contact if I have questions?

You may ask any questions about the research at any time. If you have questions, concerns, or complaints, or think that participating in the research has hurt you, please reach out to the research team or contact the Principal Investigator Dr. Jenny Higgins at 608-890-4622.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, you can call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

Participation is voluntary. If you decide not to participate or to withdraw from the study, you may do so without penalty.

By clicking yes below, you indicate that you have read this consent form, had an opportunity to ask any questions about your participation in this research, and voluntarily consent to participate.

This study is collecting information from you, some from the survey and some from the EMR. We would like to make your information from only the survey available for other

research studies that may be done in the future without additional consent from you. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your information may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your information indefinitely. To get your information, future researchers must seek approval from this institution and review by an IRB may be required.

Your name and other information we think could identify you, such as your date of birth or medical record number, will be removed from any information you provide before it is shared with other researchers. Researchers cannot easily link your identifying information to the information. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your information. In either case, we cannot reduce the risk to zero.

Participating in this study means you agree to share your information. You can change your mind later, but researchers might still use your information if it has already been shared or have been de-identified and can't be removed. If you do not want your information used for other research studies, then tell the researchers by writing to the Lead Researcher, Jenny Higgins, at UW Collaborative for Reproductive Equity, 1300 University Avenue, Medical Sciences Center 4245, Madison, WI 53706.

We may share survey responses with researchers at other institutions. We will remove direct identifiers about you, such as your name, date of birth and other information we think could be used to identify you. However, we cannot guarantee there is no risk you could be identified. Information in free text fields such as those in survey responses may contain details that could be used with other available information to identify you (such as an employer name, job title or rare diagnosis).

Do you agree to participate in this study?

- Yes
- No

Do you agree to give permission for the UW research team to access your EMR data?

- Yes
- No

Do you give permission for the UW research team to access your child's EMR data?

- Yes
- No

Do you give permission to be quoted directly in publications without your name or identifying details?

- Yes
- No

If you wish to receive a copy of this form for your records, you can visit (insert bitly link)