University of Minnesota
Division of Environmental Health Sciences,
School of Public Health
and HealthPartners

CONSENT FORM

Title: Self Reported Stress and Cortisol Measurement: Development of an Optimized Measure of Chronic Stress in Pregnancy

UMN IRB HSC# XXXX
Principal Investigator: Patricia M. McGovern, Ph.D.

Co-Investigators: Patricia Fontaine, M.D, MS.
Supported by: National Institute of Child Health and Human Development

You are being invited to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this study and what we will do with the information that you give us about you and your health. Please read this carefully and ask any questions you have before you agree to be in this research study.

What is the reason for doing this study?

This study is being done to learn more about stress in women during pregnancy. We want to find out if the way the body responds to stress is different in different women and how we can best measure stress in pregnancy. We hope to find this out by checking stress hormone levels and by looking for genetic differences that might explain the different response to stress in different women.

You are being invited to take part in this study because you are a woman getting pregnancy care at a HealthPartners clinic that is collaborating in this study.

Who is conducting this study?

This study is being conducted at eight locations across the country. In Minnesota, the Principal Investigator is Patricia M. McGovern, Ph.D. of the Division of Environmental Health Sciences, School of Public Health, University of Minnesota. The study is sponsored by the National Institute of Health's Eunice Kennedy Shriver National Institute of Child Health and Human Development.

What you will be asked to do if you choose to be in this study?

You will be asked to:

1. Come to our study office at 1100 Washington Avenue, Minneapolis, two times over a period of 12-14 weeks.

- At each visit you will be interviewed in-person by a trained study researcher. These confidential interviews will take place in private room.

- At each visit, you will complete two questionnaires. One asks questions about the stress you may have in your life. The other one asks questions about yourself, your overall health and the health your pregnancy.

- At the first visit you will be asked to give about 5 teaspoons (23.5mL) of blood.

- At the second visit you will be asked to give about 3 teaspoons of blood. We will look for certain chemical changes in your blood that may be genetic markers of stress. A portion of the blood you provide will be stored for future research on maternal stress which may include genetic studies.

- At each visit you will be asked to provide a hair sample. We will only take a small section of hair about the width of a pencil. We will take if from an area not easily seen at the back of your neck. Longer hair from above would fall and cover the area where the sample is taken. The hair sample will be cut, not pulled. We will use the hair sample to measure your stress hormone levels over time.

- Each visit should last about two hours.

2. Provide six saliva samples at home over a two-day period after each of your two visits. You will be asked to provide a saliva sample when you wake up, 30 minutes later, and at bedtime. About 1 and 1/3 teaspoons of saliva will be collected over each 48 hour period. We will look for certain chemical changes in your saliva that may be genetic markers of stress.

3. Provide an overnight urine sample. You will be given a container in which to collect all urine that you pass between 8 PM on the last night and 8 AM the next morning.

4. Give us permission to request your medical records which may include your medical history and pregnancy history. In some cases we may also request your child's medical record for information such as how many days your baby was admitted to the hospital.

What are the benefits of being in the study?

There is no direct benefit from being in the study.

What are the risks if I choose to be in the study?

You may feel emotionally uncomfortable when answering questions regarding stressors in your life.

When blood is drawn, you may feel minor discomfort or pain. There may be local bruising or bleeding at the puncture site. There is no risk associated with saliva collection or hair collection.

Although strict confidentiality procedures are in place to protect your personal information and maintain your privacy, there is always some small chance of inadvertent disclosure.

Will I know results from the study?

The testing done on your blood, hair, urine and saliva for this study and for future studies is for medical research only. Individual results will not be used in medical decisions and they will not be available to you or your doctor. We will tell you the overall results of the study when it is completed. We will also give you information on ways to cope with stress and reduce stress in your life.

Are there any financial costs to being in this study?

There will be no costs to you for being in this study.

To thank you for being in the study, you will be paid up to a total of $150, depending on if you complete the study visits.

- You will be given $50 after completing your study visit and blood draw and hair and urine collection.
- You will be given an additional $25 after returning your initial saliva samples.
- You will be given another $25 after you complete your second study visit, blood draw, and hair and urine collection.
- You will be given a final $50 after you return your second saliva sample.
- Your samples will be used only for research and will not be sold. The research done with your blood samples may lead to the development of new products in the future. No compensation will be given to you now or in the future for the use of these samples.

What if I am injured?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think you have suffered a research related injury, let your health care provide know right away and please also let us know by calling our Study Center (# 612-626-5437).

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Questions will be answered by Patricia M. McGovern, Ph.D., Principal Investigator. You can call her at (612) 625-7429. You may also call Jill Cordes, R.N., Clinical Coordinator, who can be reached at (612) 626-8160 or toll free at (800) 825-2227. If you would like to talk to someone other than the researcher, you are encouraged to contact the Fairview Research Helpline at 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at University of Minnesota Medical Center, Fairview-Riverside Campus, 2200 Riverside Avenue, Minneapolis, MN 55455.

What are my rights as a research subject?

Participation in this study is strictly voluntary. Your decision whether or not to be in this study will not affect your current or future relations with the University of Minnesota or HealthPartners. If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether to continue or stop being in the study. You are free to choose to stop being in the study at any time. You are free to choose not to answer particular questions if you do not want to.

If you decide now to join this study and later change your mind, you may write to Patricia M. McGovern, Ph.D., Principal Investigator, University of Minnesota, Suite 102, 1100 Washington Avenue South, Minneapolis, MN 55415 and inform her of your decision. Information that has already been collected may be used or disclosed for research purposes.

What will you do to protect my confidentiality and privacy?

We are committed to respect your privacy and to keep your personal information confidential. The information you provide us will be kept private and used only for scientific purposes by the researchers involved in the study. Your name and other identifying information will be kept separate from all the other information we collect from you. Only a unique study identification number will ever be used to identify your information. Study data shared among the eight study centers will not include any personal identity information. Study data will be presented and published only in ways that will protect your confidentiality.

The blood, hair, urine, and saliva samples you provide will not have your name on them; they will be identified by a number only. This includes the blood sample that is stored for future use.

The risks to you from genetic research are very low. In the event of an unexpected breach of confidentiality, a federal law (Genetic Information Non-Discrimination Act, GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you through research studies such as this. If you have concerns about GINA or the risk of research on genetic information, please ask the study staff.

Your protected health information created or received for the purpose of this study is protected under a federal regulation known as HIPAA. You will be asked to sign a HIPAA authorization so that your information can be released to and by us for use in this study.

Your records may be reviewed by regulatory authorities to make sure the study is being conducted appropriately. Because of this, confidentiality is not absolute. However, people reviewing research records for any purpose are required by law to keep your identity confidential.

Consent Summary:

I have been given time to read his consent form and the study has been explained to me
If I had questions, I received answers. A copy of this consent form has been given to me.

Participant Signature	Printed Name	Date

Researcher Signature	Printed Name	Date