

PregSourceSM: Crowdsourcing to Understand Pregnancy Observations of Daily Living from Pregnant Women

Protocol Number: T-CH-0901: PregSourceSM

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Lead Study Investigator: Caroline Signore, MD, MPH
Deputy Director, Division of Extramural Research, NICHD
6100 Executive Blvd Rm 4B03
Bethesda, MD 20892
301-496-5577
signorec@mail.nih.gov

Associate Investigator(s): Catherine Spong, MD, NICHD
Stephanie Wilson Archer, MA, NICHD
Sujata Bardhan, PhD, NICHD
Lisa Kaeser, JD, NICHD
Melissa Parisi, MD PhD, NICHD

Research Coordinator(s): Vanessa Rangel Miller, MS CGC MBA, PatientCrossroads, Inc.
Debbie Jae, MS, PatientCrossroads, Inc.

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Informed Consent for PregSourceSM

Please read this electronic consent form carefully. For more information, visit the Frequently Asked Questions (FAQs) at <https://PregSourceSM.nih.gov>. You can also contact the PregSourceSM Coordinators or the lead researcher, Dr. Caroline Signore, at PregSource@nih.gov with any other questions related to PregSourceSM. You will be able to print the entire PregSourceSM consent text to keep a written statement regarding the research.

Note: Taking part in PregSourceSM is your choice.

What is PregSourceSM?

PregSourceSM is a health research study led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, which is part of the National Institutes of Health. We are asking pregnant women to tell us about their health, from morning sickness and sleep patterns, to medical problems and other health-related information. We also will ask about how their babies are doing after birth.

Why are we doing the study?

We are doing this study to learn what happens to women physically and emotionally during pregnancy and after giving birth. We hope to learn the following:

- Effects of pregnancy on women's lives
- Challenges some women face, such as issues related to a disability or chronic health problem
- Features common to many pregnancies

The information we gather in this study may help us find ways to improve health for pregnant women in the future.

What will I have to do in the study?

The only thing you have to do in this study is give us information about your pregnancy. We also may ask you to complete online "games" to see how your memory and other skills change over time. You will enter information throughout your pregnancy and during your baby's development into online surveys and trackers via a website and/or mobile application ("app").

What are the benefits of joining the study?

By taking part in PregSourceSM, you can:

- See how your pregnancy experiences compare to those of other women in the study.
- Easily share your health information with your health care provider.
- Access information about pregnancy and your baby's development from health and other resources that you can trust.

You may not benefit directly from joining PregSourceSM. But giving your health information might help us find better ways to care for pregnant women and their babies in the future.

What are the risks of joining the study?

Physical Risks

Because PregSourceSM focuses on gathering information, joining the study does not pose any known physical risks. You can skip any question that you do not want to answer.

Please note that, when comparing your pregnancy experiences to others in PregSourceSM, you may learn something that is different than what you expected. Each person is unique, and each pregnancy is unique.

Taking part in PregSourceSM is not meant to take the place of medical advice, diagnosis, or treatment from your health care provider. You should always seek the advice of your health care provider with any questions or concerns you may have about your health, your pregnancy, or your baby's health.

Risk of Release of Personal Information

One possible risk of taking part in PregSourceSM is the loss or release of personal information from a database security "break in" or breach. If a breach occurs, we will let you know as soon as possible.

We store your data in a secure database with multiple safety features. An independent security expert checks our system regularly. PregSourceSM also complies with all of the following:

- The Health Insurance Portability and Accountability Act (also called HIPAA)
- The Code of Federal Regulations, 45 CFR Part 46 subpart D
- Federal Information Security Management Act of 2002 (FISMA), 44 U.S.C. § 3541

Even though we are using many tools and practices to keep information secure, we cannot guarantee security of:

- Data on your computer or mobile device, or
- Information while it is transmitting to the PregSourceSM database.

PregSourceSM also has a Certificate of Confidentiality (CoC). The CoC means we can refuse to share personal information about anyone taking part in the study in response to legal demands. Additional information is available in the FAQs.

What happens after I join the study?

Once you decide to join, we will ask you some general questions about your health history.

Then, as you go through your pregnancy, we will contact you regularly to ask more questions about how you are feeling. We will also contact you after your baby is born to ask about your and your baby's health.

You can use PregSourceSM to keep track of the following:

- Weight
- Morning sickness or nausea
- Sleep
- Medications, supplements, and alternate therapies
- Exercise and physical activity
- Overall health

What happens to the information I share with PregSourceSM?

Using computer tools and formulas, researchers will group and organize all the information to look for patterns or issues common to many women. For instance, the data could show which women are more likely to have severe morning sickness. Or, it could show that most women have some “spotting” during their second trimester.

Researchers will not know who you are even when they are organizing and studying the information. We will remove your name, street address, and other personal information to “de-identify” the data, as a way to keeping your information confidential. Only PregSourceSM Coordinators, who are trained to protect your privacy, will have access to information about you who are.

PregSourceSM also may share de-identified data with other studies to help uncover new topics for future studies. But neither the researchers for other databases, nor the PregSourceSM researchers will know who you are from the shared data.

All personal identifiable information collected in PregSourceSM complies with Title 45, Code of Federal Regulations, Part 46, subpart D. The authority to collect this information is under 42 USC [*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) – **42 USC 285g**].

Will researchers contact me?

No. Researchers and physicians cannot directly contact any PregSourceSM participants. Only PregSourceSM Coordinators will contact you directly.

If you say we can contact you about joining other studies, we may let you know about other research studies that you might want/be able to take part in. We will give you the study information, and then you can decide if you want to contact the study leaders to learn more. We will not share your contact information with the researchers.

What if I no longer want to take part in PregSourceSM?

If you no longer want to take part in PregSourceSM, you can simply stop giving information. You can also change your profile so that the system stops sending you reminders and messages.

If you want to remove your information from the database, you can contact the PregSourceSM Coordinators to do so. But we cannot get back any de-identified data already shared with scientists, others in PregSourceSM, or other studies before you made your request and we have time to process it.

Will I be paid to take part in PregSourceSM?

You will not receive any money for taking part in this study. There also is no cost to join PregSourceSM.

What if I have other questions?

You can contact the PregSourceSM Coordinators or the lead researcher, Dr. Caroline Signore, at PregSource@nih.gov with any other questions.

Consent - if PregSourceSM participant is 18 or older:

For the purposes of the consent form below, "I", "my", "you" and "your" refers to the pregnant woman who is giving consent.

Please type the full name of the person giving consent:

By consenting, I agree to the following:

- I have read the informed consent document. I have had a chance to ask questions and get answers, and I have no other questions at this time.
- I understand the purposes, risks, and benefits of taking part in PregSourceSM.
- I understand that taking part in PregSourceSM is entirely my choice.
- If I change my mind and no longer want to take part in PregSourceSM, I am free to do so and do not have to give any reason.
- I agree to allow PregSourceSM Coordinators to contact me by email.

☐ I am the participant (pregnant woman), and I am 18 years of age or older. I consent to take part in PregSourceSM.

Profile Information

Please provide the following information for the pregnant woman (the account holder), and click “Create Account” at the bottom of the screen.

First Name:	<input type="text"/>	*
Last Name:	<input type="text"/>	*
Email:	<input type="text"/>	* (?)
Confirm Email:	<input type="text"/>	* (?)
Username:	<input type="text"/>	* (?)

Please enter a valid password. No spaces, at least 8 characters and contain at least one lowercase letter, one uppercase letter, one number and one special character. For example: Example@1. In an effort to maintain security, you will be required to reset your password at regular intervals.

Password:	<input type="password"/>	* (?)
Re-enter Password:	<input type="password"/>	* (?)

☐ I agree to the [Terms and Conditions](#) and the [Privacy Policy](#).

Please [print](#) a copy of this consent document for your records.

Please enter the code below



<input type="text"/>	* (?)
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Create account