Genetics Education and Equity in Maternal Fetal Medicine: A Pilot Feasibility Randomized Controlled Trial to Assess Impact of a Video Education Tool on Decisional Conflict Among Prenatal Patients (GEM)

Protocol ID: 1721550

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KEY INFORMATION

We are asking you to take part in a **research study**.

It is completely **voluntary**. You can choose not to participate.

It involves some education and surveys about **prenatal genetic testing**

The education and initial survey will take about **10 minutes** to complete. The subsequent 2 surveys will take **10 minutes each**.

You will be compensated $30 Amazon gift certificate for your time ($10 for each survey). You will be compensated midway through the study (after the second survey).

INFORMED CONSENT FOR RESEARCH

Project Title:	The GEM Trial: Genetics Education and Equity in Maternal Fetal Medicine
Version Date:	October 29, 2024
Principal Investigator:	Margaret Thorsen, MD, Telephone 401 274-1122 Melissa Russo, MD

Introduction

Please read this form carefully. The purpose of this form is to provide you with important information about you taking part in a research study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If any of the statements or words in this form are unclear, please let us know. We would be happy to answer any questions. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Taking part in this research study is up to you. If you decide to take part in this research study, we will ask you to sign this form. If you choose to participate, you will provide consent by signing this form electronically. You may request a printed unsigned hard copy of this form for your records. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff. The people in charge of this study are Margaret Thorsen and Melissa Russo. We will refer to these persons as the "researcher" throughout this form.

A. The Nature, Duration and Purpose of This Trial:

What is the purpose of this study?

The purpose of this study is to determine how best to inform and support pregnant patients in making choices about prenatal genetic testing.

Why am I being asked to take part in this research?

You are being asked to take part in this study because you are currently pregnant and receiving prenatal care.

One hundred forty patients will take part in this research study at Women and Infants Hospital.

How long will I take part in this study? How much of my time will this research take?

If you agree to take part, your participation will take ~30 minutes total: 10 minutes at your first ultrasound appointment (watching a video and completing a survey), 10 minutes to do a follow up survey within two weeks of your new OB appointment, and 10 minutes for a final survey 6-10 weeks from then. Specifically, you will be asked to answer a series of questions based on prenatal genetics. The follow up surveys may be completed at a revisit prenatal appointment or via phone or via email depending on the most convenient and accessible way for you to participate.

The Means By Which The Study Is To Be Conducted:

What will I be asked to do? What will happen if I take part in this research study? What are the study procedures?

This is an educational research study. If you agree to be in this study, we will ask you to do the following things:

- Complete three questionaries about yourself and your experience learning about genetics and making decisions about prenatal genetic testing (30 minutes total- 10 minutes per survey). This is not part of routine care but is part of the study.

- We will assign you by chance, like a coin toss, to one of two education groups. Each group will receive standard prenatal genetics counseling from their maternity care provider (doctor, midwife, or nurse practitioner). One group will also watch an educational video series and receive an educational handout that

summarizes its content. You and the researcher cannot choose your study group. You will have a 50% chance of being assigned to either study group.

- You will complete a survey on the day of your new ultrasound about yourself and your genetic counseling experience (10 minutes). This is not part of routine care but is part of the study.

- At two subsequent appointments (or via phone or email), the researcher will contact you to complete two additional surveys, (each 10 minutes). This is not part of routine care but is part of the study.

- If you agree to participate, you will allow us to enter your medical record to obtain information about your pregnancy care including: zip code, insurance type, dates of your prenatal appointments and delivery, anxiety screening score, family history, which genetic testing options you chose and results, which prenatal care group you are a part of. The above information will be kept separate from your name and will be confidential and anonymous.

- You have a choice about whether or not to complete the surveys. If you do participate, you are free to skip questions or discontinue at any time.

Do you have to take part in the study?

No, this study is completely voluntary. Participating (or not) will not affect your care.

B. The Risks, Hazards, and Discomforts of the Study:

Will there be any risks of taking part in this study?

Participating in this study poses minimal risk to you. The primary risk is loss of confidentiality. Through all stages of data collection, storage, sharing, and analysis, your privacy and confidentiality will be protected, with these exceptions: the research team is required to report child abuse and neglect, or substantial risk of harm to self or others to state or local authorities.

A number of efforts will be made to keep your information confidential. These are outlined in the Privacy and Confidentiality of this form. Despite these efforts, it may be possible to identify you based on the information in these databases and other public information (including information you tell people or post about yourself). The risk of this happening is currently very low.

We will be collecting information about you, your pregnancy and your delivery. While every attempt will be made to keep this information confidential, there is a small risk to

you that others could see sensitive personal information about you, which could cause embarrassment. Your personal information will only be disclosed outside of research personnel on this study if required by law, which is extremely unlikely. If the data we collect in this study is shared with researchers outside of Women and Infants, personal identifying data will not be shared. After the study is complete, your name and medical record number will be deleted so that the information collected cannot be linked to you.

If you decide not to join the study, your antepartum, intrapartum, and postpartum care will be unchanged. You do not need to join this study to get treatment or breastfeeding resources already provided to all mothers delivering at Women and Infants Hospital.

C. The Possible Benefit Or Lack Of Benefit To Myself:

Are there any benefits from being in this research?

You may or may not benefit from taking part in this study. We cannot guarantee or promise that you will receive any direct benefit by participating in this study. Possible benefits to you include additional prenatal genetic counselling education prior to delivery. The knowledge gained from this study may help providers develop educational materials to support patients in the future. If you chose to participate in this study, your antepartum, intrapartum, and postpartum care will be unchanged and will include all treatment and prenatal genetic testing services provided to all mothers delivering at Women and Infants Hospital.

D. The Possible Alternative Procedures:

What alternatives are available? If I do not want to take part in this research study, what options do I have?

You may choose not to take part in this research study. Participation in this study is voluntary. Choosing not to participate in the study will not affect your antepartum, intrapartum, and postpartum care and will include all treatment and prenatal genetic testing services provided to all mothers delivering at Women and Infants Hospital.

What if I want to stop? Can I stop participation?

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will be kept confidential. You cannot withdraw information collected prior to your withdrawal. To revoke your Authorization, submit a request in writing to the investigator: Margaret Thorsen, 101 Dudley Street, Providence, RI 02905 or mthorsen@wihri.org.

The researcher may take you out of this study without your permission. This may happen because:

- You have abnormal ultrasound results or a miscarriage
- Other administrative reasons like changing to a new practice location

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

E. Financial Information

Who is funding this research study?

The Departments of Obstetrics and Gynecology and Maternal Fetal Medicine at Women & Infants Hospital, and the Dr. Veronica Petersen ’55 and Dr. Robert A. Petersen Educational Enhancement Fund at the Warren Alpert Medical School of Brown University are funding this research.

Please ask Margaret Thorsen if you have any questions about how this study is funded.

What if you have questions, suggestions, or concerns?

The investigators in charge of this study are Margaret Thorsen, MD and Melissa Russo, MD of Women & Infants Hospital. If you have questions, suggestions, or concerns, you can contact us at: 401-277-1122 or mthorsen@wihri.org If you have questions, suggestions, or concerns about your rights as a volunteer in this research, contact Women & Infants Hospital Director of IRB Administration between 8:00 am and 5:00 pm, Mon-Fri at 401-453-7677.

Will I be paid for my participation?

You will be compensated $30 Amazon gift certificate for your time ($10 for each survey). You will be compensated midway through the study (after the second survey).

Will it cost me anything to participate?

There is no cost to you for participation in the study. However, while you are in this research study, the cost of your routine clinical care will be billed to you/your insurance company in the usual way. If your insurance does not pay for all the costs, you will be responsible for the remaining costs, including any co-payments and deductibles as required by your insurance. If you do not have insurance, you will be responsible for the costs of your routine care.

Will there be any additional costs?

There are no study-related costs to you for taking part in this research study.

F. Privacy and Confidentiality

How will you keep my information protected/confidential?

We will keep the records of this study confidential by storing your name and an assigned study identification in REDCap, which is a secure and password protected database. A second coded database of your answers and personal health information, along with your study identification number, will be stored on a separate database within REDCap. This way your survey answers and your personal information will not be directly linked to your name. We will make every effort to keep your records confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The following people or groups may review your study records for purposes such as quality control or safety:

- The Researcher and any member of her research team
- Authorized members of Woman and Infants Hospital who may need to see your information, such as administrative staff members and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study)
- The sponsor or funding agency for this study
- Federal and state agencies that oversee or review research (such as the HHS Office of Human Research Protection or the Food and Drug Administration, if applicable)

The results of this study may also be used for teaching, publications, or presentations at professional meetings to inform other doctors and health professionals. We will keep your identity private in any publication or presentation about the study. If your individual results are discussed, your identity will be protected by using a code number or pseudonym rather than your name or other identifying information.

By law, WIH is required to protect your private information. The investigator and staff involved in the study will keep your private information collected for the study strictly confidential. Please refer to the section at the end of this document titled “Authorization to Use or Disclose Health Information for a Research Study” that explains more specifically how your personal information will be protected.

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

Accessing the Educational Videos via QR Code:
If you are randomized to the educational video group, you will be given an educational handout that summarizes the video content. The handout will have QR codes that link to the videos if you wish to rewatch them on your own device. This is **optional**.

The QR codes link to an external website. It's important to understand the potential risks with accessing an external link:

- External Site Security: The video is hosted on a third-party platform, which operates independently from our institution. We cannot guarantee the security measures they have in place, which may expose your data to unauthorized access.
- Data Collection: The third-party site may collect information such as your IP address or viewing behavior when you access the video. This data is governed by the site's privacy policy, which may differ from **our** data privacy (as aforementioned, any survey data you complete or chart variables extracted **will be confidential and anonymous**).
- Risk of Breach: If the third-party site experiences a security breach, your data related to accessing the video could be compromised."

What will be done with my data and specimens (if applicable) when this study is over?

Your data will not be used for any future research after this study is complete.

Women & Infants Hospital of Rhode Island

HIPAA Authorization

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

Project Title:	The GEM Trial: Genetics Education and Equity in Maternal Fetal Medicine
Version Date:	October 29, 2024
Principal Investigator:	Margaret Thorsen, MD, Telephone 401 274-1122 Melissa Russo, MD

What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. **HIPAA** (Health Insurance Portability and Accountability Act of 1996) is United States legislation that provides data privacy and security provisions for safeguarding medical information. Under these laws, the Women and Infants Hospital cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the institution or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must electronically sign this form for consent and authorization. You may request a printed unsigned hard copy of this form for your records. Authorization is separate from and in addition to informed consent, although the two forms may be combined into one document. This form describes the different ways that WIH can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by WIH it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

By signing this document, you are permitting Women & Infants Hospital (WIH) and the doctors, nurses and other staff involved in this research to use your personal health information collected about you for research purposes within our institution. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you. You are also allowing WIH staff to disclose your personal health information to outside organizations or people involved with the processing of this study as described in this document.

Why is my health information needed?

The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent. If you sign this

document, you give WIH permission to collect, use or disclose (release) your health information that identifies you for the research study described above.

What health information will be used and disclosed for this research?

The health information that we may use or disclose (release) for this research includes:

- Information from your medical records at WIH which will be coded in our analysis.

The information we will look at from your medical record includes: maternal age, language preferences, pregnancy plurality, history of genetic screening or counseling in this pregnancy, known fetal anomalies or abnormal nuchal translucency in this pregnancy, whether or not donor oocyte used in this pregnancy, early pregnancy loss in this pregnancy, dates of your appointments and postpartum hospitalization, insurance status, zip code, whether patient did carrier screening testing, routine anxiety score, family history conducted or not, type of genetic testing ordered and outcomes, whether and at what gestational age the patient saw a genetic counselor, whether or not post-natal genetic testing was ordered on the baby, and type of provider caring for patient during pregnancy

Who may use or disclose my health information during the research?

Researchers and others need to review and/or record your research records to conduct this research, assure the quality of the data and to analyze the data. The health information listed above may be used by and/or disclosed (released) to:

The health information listed above may be used by and/or disclosed (released) to:

- Members of the research team and other authorized staff at WIH;
- People from agencies and organizations that perform independent accreditation and oversight of research.

Researchers will need to review and record your medical records to conduct this research, assure the quality of the data and analyze the data. Your health information may be used by and disclosed to members of the research team at Women and Infants, or in rare cases organizations that perform accreditation and research oversight, such as the WIH IRB. Some of these organizations who receive your health information may not be required to protect it in accordance with Federal privacy laws (such as the Privacy Rule). If permitted by law, they may be allowed to share your information with others without your permission. If all information that can identify you is removed from your health information, the remaining information may be used or disclosed for other purposes. No publication or public presentation about the research described above will reveal your identity without another authorization from you.

WIH is required by law to protect your health information. The research staff will only allow access to your health information collected for this study to the groups listed above for the purposes stated. By signing this document, you authorize WIH to use and/or disclose (release) your health information for this research.

Federal and State law requires us to review any inadvertent disclosure (release) or inappropriate access of your health information that we become aware of. If we become aware your information has been inadvertently disclosed (released) or inappropriately accessed, Compliance Services at Care New England will complete an investigation to determine if there is a breach of your individual health information that requires us to notify you.

Am I required to sign this Authorization?

You do not have to sign this Authorization. Your decision to sign or not sign this form will not affect your standard medical treatment, payment or enrollment in any health plans or affect your eligibility for benefits. However, if you choose not to sign this form, you may not take part in this research study.

Women and Infants Hospital will continue to provide you with health care services even if you refuse to sign this authorization form.

Can I withdraw my Authorization?

You may change your mind and revoke (take back) this Authorization at any time.

If you revoke this Authorization, you may no longer participate in the research described in this Authorization.

Even if you revoke this Authorization, WIH and Margaret Thorsen may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. Your request to revoke this Authorization becomes effective when WIH receives it.

To revoke this Authorization, you must submit a request in writing to the investigator: **Margaret Thorsen, 101 Dudley Street, Providence, RI 02905 or mthorsen@wihri.org**

Does my Authorization Expire?

This Authorization expires with the conclusion of the research study. By signing this form, you are giving us permission to collect your health information only for this research study (not for future unspecified research).

Will you be able to access your records?

You will be able to request access to the information we collect from you for the study when the study is completed. During your participation in this study, you will not be able

to access the results of the tests, surveys, and evaluations we do for the research study. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.

Signature Page

Consent to Take Part in this Research and Authorization to Use and Disclose Health Information for the Research

SIGNATURE OF PERSON OBTAINING CONSENT AND AUTHORIZATION
The research study and consent form have been explained to you by:

_____
Name of Person Obtaining Consent/Authorization

_____ _____
Signature of Person Obtaining Consent/Authorization Date

SIGNATURE OF SUBJECT
By signing this form, you are indicating that you have read the information in this consent form including risks and possible benefits; You have been given the chance to ask questions and your questions have been answered to your satisfaction; and you agree to participate in the research study and agree to allow your health information to be used and shared as described above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study.

_____
Name of Subject

_____ _____
Signature of Subject Date

_____
Telephone number

_____
Email address