CONSENT TO PARTICIPATE IN RESEARCH

Dartmouth-Hitchcock Medical Center

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INTRODUCTION

You are being asked to participate in a research registry. It is important that you read the following explanation of the proposed procedures. This form describes the purpose, procedures, benefits, and risks of participating in the registry. You have the right to withdraw from the registry at any time. At the end of the form you will be asked if you agree to take part in the registry. If you agree, you will be asked to electronically sign this consent form by pushing a button.

You may print this consent form and show it to family, your doctors, and your friends before you sign it. You may want to discuss it with them to help you decide if you want to be part of the registry.

PURPOSE

The purpose of this registry is to collect data on long term health outcomes of individuals and to maintain a list of those who can be contacted about participating in research studies of infertility treatment including health risks. Recruits will be individuals who have had trouble conceiving a pregnancy as well as individuals who had no trouble conceiving as a comparison group. We will also include egg donors, sperm donors and women who have been gestational/ surrogate carriers.

BACKGROUND

Infertility is a major health problem in the U.S. It affects approximately 4 million reproductive age women, almost 60,000 of whom undergo assisted reproductive technology (ART) procedures each year. ART currently results in over 35,000 U.S. live births and more than 50,000 babies a year. Most of these babies are healthy. However, studies suggest that a greater than average number of ART babies have health problems. There may also be adverse health effects for women who have ART and other infertility procedures. We do not know the extent of these problems because studies that attempt to define the risks have had small numbers of study subjects or used inappropriate comparison groups. So far, studies have been unable to distinguish the effects of treatments from the effects of the infertility diagnosis. We thus have a very limited understanding of the health problems caused by

treatment. **We are developing a registry of study volunteers who will be available for future studies of infertility disease and treatment** in order to improve research in this field.

The group of volunteers will constitute the Infertility Family Research Registry (IFRR).
We are asking you to participate in this registry because, either have had difficulty conceiving a pregnancy, because conceiving a pregnancy was easy for you and your information will be helpful for comparison purposes, or because you have participated in fertility treatment by serving as an egg donor, sperm donor, or carrier/surrogate.

GENERAL INFORMATION ABOUT THE REGISTRY

- We expect approximately 30,000 individuals to enroll.
- The registry will continue to get new recruits and to update information on recruits indefinitely.
- You may participate for as long or as short a time as you wish but we suggest that you remain enrolled indefinitely and that you update your registry information as this information changes.
- We will publish periodic updates of information on participant characteristics and health status from the information that you enter into the registry. We will provide summaries of the studies that use registry volunteers. All published information will be in aggregate. No individual information will be published at any time.

REGISTRY PROCEDURES

General overview (as applicable):

- Your initial involvement in the registry will include signing this consent form and filling out the survey questions either online or on paper.
- You will be asked at least once a year to update the information you have entered about your health and the health of any children you may have.
- You will periodically be contacted by researchers who will ask if you would like to participate in additional surveys or study protocols. Each of these protocols will be explained to you BEFORE you enroll. You may enroll or not as you choose. Being part of this registry does NOT obligate you to participate in any of the proposed studies.
- If you choose to participate in a study, you will be given detailed information about the study investigators and protocols. You will be asked to sign an additional consent form that describes that study's protocols and procedures. Contact information for you will NOT be released to the researcher until you have given your permission. All study protocols that we offer to registry volunteers will have human subjects protection approvals from their host institutions.

Details of Procedures:

- To be part of this registry you will need to sign onto our website, create a password, and complete the initial online survey. This can also be done on paper and mailed to us.
- There are no other procedures for you to follow as part of this registry.

Other Important Information:

- We ask that you periodically log onto the registry website and update the information on your health status, treatment history, and the birth and health of any children. We also want you to update any additional procedures you undergo for fertility treatment and any birth outcomes you may experience.

Additional Information for Volunteers Recruited at Participating Centers:

- Some volunteers to this registry will have been recruited by a letter sent to you from your provider if your provider is located at a participating center. If you are one of these volunteers, you will have been sent an access code that you will enter on the personal information screen once you have signed this consent form. For these volunteers, we will send information to your provider containing your name and date of birth that will let them know that you have joined the registry in response to their letter. If you do not wish us to send them this information, do not sign this consent and do not join the registry
- For those volunteers who were not sent a letter and did not receive an access code, this section does not apply to you.

RISKS

- The only risk to being part of this registry is a very slim chance of loss of confidentiality for your information. We have taken a number of precautions to reduce this risk including: password protection and encryption of computer files; maintenance of good computer security practices; requiring your consent in advance of releasing your name to researchers.

Information for Women and Men

Both women and men may participate in this registry. You and your spouse/ partner are both welcome to log onto the website and enter information. Each of you will be asked to separately approve this consent.

NEW FINDINGS

We will periodically post summary information on registry participants. No individual will ever be identified in these summaries. This information will be published in periodic newsletters and will be available to volunteers on the IFRR website. By signing this form you are giving us permission to use the information you enter in these summaries.

BENEFITS

There is currently very little information about the health risks of infertility treatments. Adverse health effects have been reported but not confirmed. We do not know whether these adverse effects are the results of fertility treatments or are caused by the underlying conditions that are part of the disease of infertility. This registry will help us to gain knowledge of the health risks of this disease and the available treatments.

CONTACT INFORMATION IN THE EVENT OF AN EMERGENCY

- If you have questions or concerns about this registry please call 603-653-9900 or contact us through the IFRR website at www.ifrr-registry.org.

COSTS OF PARTICIPATION

- There are no costs for participation.

COMPENSATION FOR PARTICIPATION

- We currently do not offer any payment for being part of this registry.

VOLUNTARY PARTICIPATION

Your participation in this registry is completely VOLUNTARY. Your refusal to participate or your withdrawal from the registry will involve no penalty or loss of benefits to which you are entitled. You may stop your participation at any time without affecting your ongoing medical care. If you withdraw from the registry we will continue to retain any information you have already given us but no additional information will be added and we will no longer contact you to participate in studies.

REMOVAL FROM THE REGISTRY

This consent form will be signed by electronic signature (pressing a button online). A copy of the consent will be sent to the email address you have given us. If this email is returned unclaimed we will assume that your email address is incorrect. If this occurs we may remove your name from the registry. Doing this helps to keep us from enrolling people who log onto this site with false information.

CONFIDENTIALITY

The data collected for this study are self-reported, however, these data are considered Protected Health Information (PHI), and are covered by the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules.

How will your privacy be protected?

The information collected as data for this study includes: The information you will enter into the IFRR database including demographics, health history, reproductive history, infertility treatment history, delivery and child data (if any).

How long will study data be maintained?

Data collected for this study will be maintained for as long as the study continues. Since we are looking at long term health outcomes, this could be many years. At the end of the study all data including identifiers (name, dates, etc) will be destroyed.

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. Your data are maintained on a secure, encrypted, password protected server at the Geisel School of Medicine at Dartmouth. No information is printed and all reports of data are summaries. No individualized personal data are ever reported.

For volunteers recruited at participating centers, information will be transferred to participating investigators at these centers using a secure, encrypted, password protected server or through an encrypted, password protected flash drive with password sent separately.

The information collected for this study will be used only for the purposes of research as stated earlier in this form.

Who may use or see your health information?

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the Principal Investigator plus others working on this study at Dartmouth Medical School, Dartmouth-Hitchcock Medical Center and elsewhere.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- The Committee for the Protection of Human Subjects (CPHS) at Dartmouth College
- Baylor College of Medicine
- For volunteers recruited by letter at participating institutions, the Institutional Review Board at the institution that recruited you will also have acscess to your data

Your permission to use your health information for this study will not end until the study is completed.

It is possible for a court or government official to order the release of study data including information about you.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at Dartmouth are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you should not take part in this study.

If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

QUESTIONS ABOUT THE REGISTRY

- If you have questions or concerns about the registry, you can contact Judy Stern, PhD at 603-653-9900 or the Society for Assisted Reproductive Technology at 205-978-5000 x 109.
- If you have questions about your rights as a research subject, other concerns about the research, or you are unable to reach the investigator, you can contact: The Office of the Committee for the Protection of Human Subjects at Dartmouth College (603)-646-6482 during normal business hours.

VOLUNTEER'S STATEMENT:

I agree to participate in the Infertility Family Research Registry. Any questions I may have had about the registry have been answered to my satisfaction. I understand that I may contact Judy Stern, PhD or the Society for Assisted Reproductive Technology if I have any more questions about taking part in this registry.

I understand that my participation in this research registry is voluntary and that I may end my participation at any time without harming my future medical care or losing any benefits to which I might be entitled.

By agreeing to this form, I have not waived any of my legal rights.

I agree to participate in this registry.

_____ _____

Registry Participant (electronic signature) Date

_____

Typed Participant's Name