UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Peripartum Cardiomyopathy Registry (PPCM-R)
Principal Investigator:	Jennifer Lewey, MD, MPH The University of Pennsylvania Perelman School of Medicine Phone: (267) 588-2327
Sponsor	National Institutes of Health

Research Study Summary for Potential Participants
You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. You can contact Dr. Lewey, the principal investigator, at any time. Her contact information is at the top of this form. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

Why am I being asked to volunteer?
You are being invited to participate in a research study because you have been diagnosed with peripartum cardiomyopathy. If you decide to participate, you will be asked to give electronic consent. Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

What is the purpose of this research study?
Our goal is to better understand the patient experience and long-term outcomes of patients with peripartum cardiomyopathy. We believe that this information will help improve the diagnosis and treatment of patients with peripartum cardiomyopathy in the future.

How long will I be in the study?
If you agree to take part, your participation will last for 10 years. After completing the baseline survey, you will be asked to complete shorter surveys every 6-12 months.

What am I being asked to do?
The study involves two parts: using the registry to complete online surveys and medical record review by our study team.

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Surveys. You will be asked to complete an online survey using the registry website, which is HIPAA compliant. The survey will ask about your peripartum cardiomyopathy diagnosis, symptoms, medical history, and quality of life. We will also send you follow-up surveys to complete using the registry website. We will remind you about follow-up surveys by email or phone.

Medical record review. You will be asked to share your medical records through the registry website. You will be able to share records through your patient portal via a secure platform, or you can upload a PDF copy of your records. We will look at your medical records to collect information about your medical history, presenting symptoms, diagnostic tests used to determine your diagnosis of peripartum cardiomyopathy, follow-up testing since your diagnosis, and any complications you may have had related to your diagnosis. We will complete a registry form as we collect the data. Once the form is complete, the data will be stored in a secure electronic database and combined with data from other patients for analysis. If you have any further medical records related to your diagnosis, we request that you upload those through the registry website. We will collect data on any changes to your medical history, treatments, cardiac testing, and any new complications. All additional data forms will be stored in the secure electronic database.

What are the possible risks or discomforts?
Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to the research team. The principal risk involved in this study is loss of confidentiality of your data. There is minimal risk that completing online surveys about your medical history and psychological health may cause you to experience temporary discomfort.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?
You are not expected to get any benefit from being in this research study. The knowledge gained from this study may help other people diagnosed with peripartum cardiomyopathy in the future.

What other choices do I have if I do not participate?
You can choose to not participate in this study.

Will I be paid for being in this study?
There is no payment for you participating in this study.

Will I have to pay for anything?
There is no cost to you for participating in this study.

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When is the study over? Can I leave the study before it ends?
This study is expected to end after all participants have completed all the surveys and all information has been collected. This study may also be stopped at any time by your physician or the study Sponsor without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor or the study Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. You may do this by contacting the investigator noted on page one of this form. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?
We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

To minimize this risk and protect your confidentiality we will take the following steps:

1) All data collected through the study registry (ppcmr.org) will be stored in a password protected secure database hosted and maintained by Ordinal Data, Inc. There are several technical features that Ordinal Data, Inc uses to protect your confidentiality. The hosting facility is SSAE-16 and Safe Harbor compliant. The facility uses VMWare to virtualize servers and all servers are backed up daily. Backups are encrypted and stored in an alternate center. The application keeps participant health data and identity data in separate data repositories. Records are linked with a key that is encrypted with a one-way hash. This ensures that unauthorized access to health information is prevented.
2) When your data is used for analysis, all data will be stored in a secure database that resides in a password protected secure web site supported by the University of Pennsylvania. Only study personnel will have access to the database. All efforts, within reason, will be made to keep your information confidential. We will protect your confidentiality by removing your name and other personal information from the information we collect about you. The information will be coded with a number that will not directly identify you. Only the study personnel will know who you are and be able to tell which information is yours.
3) The only "identifiable" information in the database will be dates (date of diagnosis, date of survey completion, etc.) Your email address will also be accessible to the study personnel, as the primary means of study communication will be via email. The study team will receive and store identifiable health information, but they will only use de-identified information for use in research analysis. We will try to keep your study information confidential but cannot guarantee your confidentiality will be maintained. The law may force us to give your personal information to others.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will information about this study be available to the public?
A description of the study results may be available to the public. This description will not include information that can identify you.

What may happen to my information collected on this study?
Future Use of Data and/or Specimens
Your identifiable information will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and only applies to the information collected on this study.

Your information may be stored and used for future research purposes for an indefinite amount of time. There are no plans to tell you about any of the specific research that will be done. Possible future research may include additional analyses of health outcomes. We may share your identifiable information with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies.

We will not follow up with you to tell you about the specific research that will be done. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation. You will not be given the results from testing that may be performed on your identifiable specimens as a part of future research.

The following identifiers will be retained with your information: name, date of birth, and dates that you received medical care. There is a possible risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality by assigning each sample a unique random identifier that will be separately linked to any personal identifiers. We will share only the unique random identifiers without personal identifiers.

You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by improving our understanding of health and disease, improving healthcare and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information, or have changed your mind, you can contact Dr. Jennifer Lewey at 267-588-2327

Will I receive the results of research testing that may be relevant to my health?
Many of tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

What information about me may be collected, used or shared with others?
We will collect and use the following information during the study:

- Name, address, telephone number, date of birth, email address
- Personal and family medical history
- Results from physical examinations, tests or procedures
- Any relevant information in your medical records

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Where may my information be stored?
Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The investigator for the study and the study team at the University of Pennsylvania
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?
- Dr. Sarah Thordsen is a co-investigator on the study. She and her study team at the University of Wisconsin at Madison will have access to the data.
- Ordinal Data Inc. will have access to the data for maintenance and technical support purposes.
- The National Institutes of Health

Oversight organizations
- The U. S. Office of Human Research Protections (OHRP)

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:
- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Participant HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?
If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you electronically sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your protected health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that protected health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____ _____
Name of Participant [type] Date

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