Medical College of Wisconsin
INTRODUCTION TO THE INFORMED CONSENT

Observational Study for Outcomes in Participants` with Peripartum Cardiomyopathy.

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The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study by calling Dr. Sarah Thordsen at 414 -955-6938 or by email to: ppcmr@mcw.edu

You do not have to be in this research study. You can stop being in this study at any time by email to the above address. At that time, we will stop getting any more data about you but, the health data we stored before you withdrew your consent may still be used for analysis.

1. **What is the purpose of this study?**

You are being asked to take part in this research study because you have a diagnosis of peripartum cardiomyopathy (PPCM). The aim of this observational registry is to document a few important medical details of patients like you to help doctors understand more about PPCM. We believe that this information will help improve the diagnosis and treatment of patients like you in the future.

2. **What will happen and how long will you be in the study?**

If you consent to participate, we will collect information about you from you (and we will not be contacting or communicating with any of your doctors) beginning with the time of your diagnosis and continuing into the future. There will be no in person visits associated with this registry.

Initial Enrollment and Surveys:
You may only participate if you provide your informed consent by providing your e-signature on this form. If you have any questions about the informed consent document or this process, please contact Dr. Sarah Thordsen at 414-955-8844. After consent is obtained, you will have access to your account on PPCM-R. From there, you can download a copy of your signed informed consent (ICF) document for your records.

Then you will be asked to complete surveys about your PPCM diagnosis,

related treatments, and symptoms and medical history. After completing the surveys, we request that you upload a copy of your cardiology and obstetric medical records via a PDF or via a PDF or via interface with 1upHealth. We will review your medical records to collect information about your medical history, presenting symptoms, medications, physical exam, diagnostic tests used to determine your diagnosis of PPCM, your treatment and any complications you may have had related to the treatment of your disease. 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.

Follow-up surveys:
Unless you withdraw, we will continue to contact you via e-mail or phone call to complete follow up surveys or new surveys as new areas of research are developed. If you have any further medical records related to your treatment, we request that you upload those. We will collect data on any changes to your medical history, new medications you may be using, diagnostic tests and any new complications that may have occurred since you last uploaded your records. All additional data forms will be stored in the secure electronic database.

3. **Will it cost me anything to participate?** No.

4. **Are there any risks to me in participating in the research?**

There are no physical risks associated with this research.

Some of the survey questions assess psychological health. There is a slight risk that answering the questions may cause you distress.

There is also the risk of your information not being kept confidential. However, we will take all reasonable steps to protect your identity and information.

The first step we will take is to deidentify your information (data). That means that we will remove your name, address, and any other personal identifying information such as medical records number from your medical information to prevent anyone but the researchers from linking your identity with your medical data.

Your research records will be accessed by the following non MCW researchers: Dr. Zoltan Arany, MD PhD and Dr. Jennifer Lewey MD, MPH. Additionally, clinical research staff associated with Drs Thordsen, Arany or Lewey at MCW and University of Pennsylvania may review and organize the data.

Your data may be viewed only as needed for storage and maintenance purposes by Ordinal Data, Inc who will manage our registry. Ordinal Data systems and the researchers understand privacy rules and regulations and are bound to comply with them to keep your data safe and not reveal your identity.

The company AbioMed, Inc. who is funding part of this research will only have access to de-identified data for a subset of participants with a concurrent diagnosis of cardiogenic shock. However, the identities of research participants like you will not be shared with them.

Research funding from the University of Pennsylvania, Medical College of Wisconsin or other available sources may also be used to fund this project.

The company 1upHealth will be available as an option for transferring your electronic health record information to PPCM-R from your healthcare organization.

Your email address, or phone number if you provide one, will be used by the research team to provide the initial and follow up research surveys as well as any other research-related correspondence. Your email address will only be used to contact you and will not be linked with your medical data.

So, while there is the potential risk of loss of confidentiality, the steps outlined above are intended to ensure that all your data will be accessed, collected and stored securely and confidentially. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

5. Are there any benefits to me from participating in this research?

There is no direct benefit to you but your participation may provide information that may help other people who have a similar medical problem in the future.

6. Will I be paid for participating?

We very much appreciate the time and effort you will spend in participating in the research. We are not offering any payment to you.

7. Reasons why you may be removed from participating:

Some examples of why researchers may need to end your participation in the study include: the researcher believes that it is not in your best

interest to stay in the study, you become ineligible to participate, you do not follow instructions from the researchers, or the study is suspended or canceled.

8. How can I stop participating?

You are free to stop participating at any time. If you leave, there will be no penalty to you. If you choose to tell the researchers why you are leaving the registry, your reasons may be kept as part of the research record. If you decide to leave the registry before it is finished, please tell one of the persons listed below. The medical information held about you if you choose to withdraw will be destroyed. Information already used will continue to be used for the research.

9. Who to call for any questions or in case you believe you have suffered harm by participating in the research:

If you should have any questions about this research study or if you feel you have been harmed by being a part of this study, please feel free to contact Dr. Sarah Thordsen at 414 -955-6938 or ppcmr@mcw.edu.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call MCW/Froedtert Hospital Research Subject Advocate at (414)- 955-8844.

10. Confidentiality:

Your study records and data 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.

The 1upHealth Platform is a HIPAA and SSAE-16 compliant PAAS built on the latest cloud technology with field-level security. The hosting facility is also certified by ISO 27001, HITRUST, and FedRAMP. All data is backed up daily. Backups are encrypted and stored in an alternate center to allow for the fastest possible restoration of service in the event of a disaster. All Data is encrypted at rest and in transit. 1upHealth Platform capabilities are performant and responsive regardless of whether they're being used to retrieve a single patient encounter or to conduct a complex query across billions of resources.

Dr. Thordsen and co-investigators Dr. Arany and Dr. Lewey will have access

to the database. Ordinal Data Inc. will have access to the database for maintenance and technical support purposes only. 1upHealth will have access to your data if you choose to use this service to transfer information from your health care provider to PPCM-R. Abiomed Inc. will only have access to de-identified data from a subset of participants with a diagnosis of PPCM complicated by cardiogenic shock. De-identified information will be used for research analysis.

All efforts, within reason, will be made to keep your information confidential. 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.

Medical College of Wisconsin may share your information, without identifiers, to others or use it for other research projects not listed in this form. The Medical College of Wisconsin, Dr. Sarah Thordsen and her staff will comply with all laws regarding the protection of your privacy. There are no plans to pay you for the use or transfer of this de-identified information.

The following identifiers will be kept and stored separately from your other health data: name, E-mail addresses birth date and any other personal identifiers.

Once the data is collected, analyzed, and of no further use, the dataset will be destroyed. However, it is not planned that a point will be reached where the data will be of no use.

If your data is used in future research, confidentiality will be maintained in the same way as in this study and the risks and benefits of any future research are the same as this study. You can contact the Dr. Thordsen with any questions about future use and storage of your data.

Your data will be analyzed in aggregate. The results of this study could be published in an article but would not include any information that would let others know who you are.

You will not be informed of any of the results from this or any future research.

Authorization to Use/Disclose Protected Health Information
You are authorizing the researchers to use **the health information** you upload to the database **for the purpose of the research and in the manner described in *this form* and for no other purposes.**

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.

- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive an electronic signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.