

## Study Information Sheet

HRC Protocol Number: **02-P-001596**

Principal Investigator: **Lee S. Cohen**

Protocol Title: **A Prospective Follow-up of Psychiatric Disturbances in Women across the Reproductive Life Cycle**

### **Study Information:**

This is a research study in the form of a data repository. The purpose of this research is to collect information about women who have experienced psychiatric disturbances during their lifetime, and to match participants to future research studies. The research is funded by internal funding at the Perinatal and Reproductive Psychiatry Program. We obtained your information either because you are prior clinical patient and/or research participant with the Program, or because you submitted a general interest form through our website, [womensmentalhealth.org](http://womensmentalhealth.org). We are asking you to participate because your information may be helpful in better understanding women's mental health and psychiatric health, and because you may be eligible for participation in future research studies, depending on your psychiatric history and other health factors.

You will not be compensated for participation in the data repository, but you may be compensated if you choose to participate in future studies.

### **How we will Collect and Manage your Personal Information:**

#### **AUTHORIZATION TO USE OR RELEASE INDIVIDUAL HEALTH INFORMATION FOR RESEARCH**

*We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy.*

Federal law requires Partners HealthCare System, Inc. and its affiliated hospitals, researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health and conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below. If you agree to the described uses within Partners and sharing of your protected health information outside of Partners, then after reading this entire document, please sign your name at the end on the line provided. If you have questions, you may ask the researcher who is reviewing the informed consent for the research with you or you can contact the researcher listed under Study Contacts at

the end of this document. This confidential statement is an updated and expanded version of the confidentiality section contained at the end of the consent form you have already signed.

1. What protected health information about me will be used or shared with others during this research?
  - Existing medical records
  - New health information created from study-related tests, procedures, visits, and/or questionnaires, as described in the attached consent form.
2. Why will protected health information about me be used or shared with others?
  - The main reasons include:
    - To conduct and oversee the research described in the attached consent form;
    - To ensure the research meets legal, institutional, and accreditation requirements; and
    - To conduct public service activities (including reporting of adverse events or situations where you or others may be at risk of harm)
  - Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this study may become part of your hospital record because the information may be necessary for your medical care. (You will also be given the Partners Notice for Use and Sharing of Protected Health Information, which provides more information about how Partners and its affiliates use and share protected health information.)
3. Who will use or share protected health information about me?
  - Partners and its affiliated researchers and entities participating in the research, as described in the informed consent form, will use and share your protected health information. In addition, the Partners review board that oversees the research at Partners and its affiliated staff who have a need to access this information to carry out their responsibilities (for example, oversight, quality improvement, and billing) will be able to use and share your protected health information.
4. With whom outside of Partners may my protected health information be shared?

All reasonable efforts will be made to protect the confidentiality of your protected health information, which may be shared with the following others for the reasons noted above:

  - Outside individuals or entities that have a need to access this information to perform functions on behalf of Partners and its affiliates (for example, data storage companies, insurers, or legal advisors).
  - the sponsor(s) of the study, its subcontractors, and its agents: \_\_\_\_\_
  - Other researchers and medical centers participating in this research, if applicable. Your de-identified health information may be used or shared with other researchers without your additional informed consent.
  - Federal and State agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
  - Hospital accrediting agencies
  - A data safety monitoring board organized to oversee this research, if applicable.
  - Other, specify: Data Repository

We recognize that some of those who receive protected health information may not have to satisfy the privacy requirements that we do and may redisclose it, so we share this information only if necessary and we use all reasonable effort to request that those who receive it take steps to protect your privacy.

5. For how long will protected health information about me be used or shared with others?
  - There is not scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process, during which information may be analyzed and re-analyzed in light of scientific and medical advances, or reviewed for quality assurance, oversight, or other purposes.
6. Statement of privacy rights:
  - You have the right to withdraw your permission for the researchers and participating Partners entities to use or share your protected health information. We will not be able to withdraw all of the information that already has been used or shared with others to carry out the research or any information that has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure the quality of the study. If you withdraw your permission, you cannot participate further in the research. If you want to withdraw your permission, you must do so in writing by contacting the research listed as the Study Contact on the attached informed consent form.
  - You have the right to choose not to sign this form. If you decide not to sign, you cannot participate in this research study. However, refusing to sign will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.
  - You have the right to request access to your protected health information that is used or shared during this research and that relates to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed under Study Contacts on the informed consent form.

### **Risks and Benefits Associated with this Study**

Participating in this research study involves minimal risk. The questionnaire includes questions that are personal and that ask specifically about your health. Although it is hoped that you will answer all questions, you may skip any questions that you choose not to answer without jeopardizing your status in the study. There is no direct benefit associated with participation in this study.

#### *Who may I contact if I have questions?*

Dr. Lee Cohen is in charge of this research study. You can call him at (617) 724-0816 M-F 9am-5pm EST.

If you want to speak with someone not directly involved in this research study, please contact the Partners Human Research Committee office at (857)-282-1900.