University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Consent Form: PACT for the Cure – Determination of PPD or PPP Case Status

Consent form version date: 1/5/16
IRB study # 15-2165
Study: Genomics of Postpartum depression–Action towards Causes and Treatment (gPACT)
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Study contact email: PACT.questions@med.unc.edu

What are some general things you should know about research studies?
You are being asked to take part in a research study. Research studies try to obtain new knowledge. This new information may help people in the future. You will not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You can refuse to join. If you join, you can leave the study for any reason at any time. Deciding not to be in the study or leaving the study will not affect your relationship with the researcher, your health care provider, or the University of North Carolina.

You will be e-mailed a copy of this consent form. If you have any questions, please e-mail PACT.questions@med.unc.edu at any time.

What is the purpose of this study?
The purpose of this research study is to understand the genetic risks of postpartum depression (PPD) and postpartum psychosis (PPP). PPD is the leading cause of maternal morbidity and mortality and a critical public health threat around the world. PPD afflicts one in seven women and has serious consequences for children and families. We do not have a complete understanding of the causes of PPD and cannot predict who is at risk. We urgently need this knowledge to improve the detection, prevention, and treatment of PPD. In addition, PPP is a rare but potentially devastating postpartum mood disorder that has been poorly studied. We want to study women with both PPD and PPP.

What will happen if you take part in the study?
This study will ask questions about your postpartum experience. It will ask you questions about mood and anxiety symptoms in the postpartum period over the course of your lifetime. It will also ask about a history of mania or psychosis in the postpartum period. You will be given feedback about your responses to the questions.

We will send notices on your phone asking you to complete any questions after your initial enrollment. Lastly, you will receive notices when we update the app with new questions or features. We will send notices on your phone asking you to complete these tasks and surveys.

You may choose to complete any additional questions at your convenience. You can use the notification settings on your device for the study app to control or turn off the notifications if you don't want anyone else to become aware you are in the study (by hearing a notification tone, for example).

If you agree to participate this is what you will be asked to do:

- **Download a mobile app (free):** You need to have the research app on your iOS device in order to participate in this study.
    - View information that describes the purposes of the study.
    - Complete a screening questionnaire to determine if you are eligible or not for the study.
    - Demonstrate you understand the study by taking a short quiz.
    - Consent to participate in the study.
- **Register an account:** Once you give your consent, all participants will complete an electronic registration process through the app. Registration will include entering your email address and other general information about yourself.
- **Postpartum depression and psychosis questionnaire:** We will ask you to answer questions about your pregnancy history and your mood following the birth of your child/children.
    - These questions will help us to understand if you experienced PPD or PPP following the birth of your child/children.
    - Once you have answered these questions, you will have the chance to come back to the app and answer other questionnaires.
    - You may choose to leave any questions you do not wish to answer blank.

Some women who experienced PPD or PPP will be asked if they would like to participate in a second part of the study. In the second part of the study, selected women will be asked to submit a sample of their genetic material (DNA) to help researchers determine how genes affect the development of PPD and PPP. If you are selected for the second part of the study, you will be notified through your PACT app and by e-mail with details about how to participate.

Are there any reasons you should not be in this study?

You should not be in this study if you do not live in the United States, are under 18 years old at the time of enrollment, if you are male, or if you have never been pregnant.

How many people will take part in this study?

The number of people expected to take part in this research study is difficult to predict, but our intention is to enroll at least 150,000 participants.

How long will your part in this study last?

Your initial participation in this study will last between 15-30 minutes, though we are hopeful that you will continue to use the app to answer all optional study questions. These additional questions could take up to an hour answer.

You can keep the PACT app on your phone for as long as you like. There will be ongoing updates to the app that will allow you to learn more about PPD. You can choose to receive or not to receive updates about the study.

We would like your permission to communicate with you in the future. Some contacts will be just to make sure we know if your contact details are still accurate. Other contacts will be to invite you to participate in a new research study. We will probably do this a few times per year.

Additionally, some women who experienced PPD or PPP will be asked if they would like to participate in a second part of the study. In the second part of the study, selected women will be asked to submit a saliva sample to help researchers determine how genes affect the development of PPD and PPP. If you are selected for the second part of the study, you will be notified through your PACT app and by e-mail with details about how to participate.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation. You will be alerted of any new information via notifications in the PACT app and by e-mail.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. While you may gain some insight into previous postpartum depression, you will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

There are risks, discomforts and inconveniences associated with any research study. These deserve careful thought.

- There is an infrequent chance that you may experience some emotional distress during the research study. This study may involve difficult subject matter, including recalling past events that may cause emotional discomfort. However, you have several resources available should this happen. The app has a built-in resource section for PPD support and directions to gain access to services close to you. Keep in mind that you have the chance to skip any question that makes you uncomfortable or to stop participation at any point.
- Breach of confidentiality may occur as the research study takes place on your mobile device. Other people may glimpse the study notifications and/or reminders on your phone and realize you are enrolled in this study.
- Data collected in this study will count against your existing mobile data plan. You can limit the impact of this by only using the app while connected to WiFi.
- There might be risks from being in this study that we are unaware of at this time. If we learn of a new risk that could change your decision to be in this study, we will notify you via the

app or by e-mail.

Will you receive anything for being in this study?
Completion of questionnaires will result in some feedback regarding symptom severity and also include resources for seeking help for PPD and/or PPP. There will be no other incentives for taking part in this study.

Will it cost you anything to be in this study?
There is no cost to you to participate in this study. However, using the PACT app will count against your mobile data plan. You can limit the impact of this by only using the app while connected to WiFi.

How will my personal information be kept confidential?
We will keep confidential your name and any other personal information we learn about you. Your personal identifying information will not be given out to anyone. We will take the following steps to ensure confidentiality. A research code will be assigned to you and your name will not be used. This code cannot be used to directly identify you. Information about the code will be kept in a secure system. The only people who will have access to your individual identity are the UNC study personnel listed at the top of this consent form, and the people who work under them. All data you provide will be encrypted and securely transmitted to servers at UNC-Chapel Hill. Your name will never be used in publications or presentations when the results of the study become available.

Voluntary Participation
You do not have to be in this study if you don't want to. You will not lose any benefits or access to treatment that you otherwise are entitled to if you don't want to be in this study.

Withdrawal from the study
You can leave the study at any time without giving any reason, and without penalty. If you wish to leave the study, email the researchers at PACT.questions@med.unc.edu. We will remove your health information from the study databases.

Who is sponsoring this study?
This research is funded by UNC and the Foundation of Hope (http://www.walkforhope.com). However, we need more funding, and UNC researchers are conducting fund-raising including personal donation and philanthropy.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, complaints, or concerns you should contact the research team at PACT.questions@med.unc.edu.

What if you have questions about your rights as a research participant?
If you have questions about your rights as a research subject, contact the UNC Institutional

Review Board on Research Involving Human Subjects by email at IRB_subjects@unc.edu.

Consent: Participant's Agreement:
If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

A copy of this form will be emailed to you for you to keep.

_____	_____	_____
Name	Signature	Date