PARTICIPANT INFORMATION AND CONSENT FORM

Version 15: Dated 29th July 2016

Site: Alfred Hospital, Alfred Health

Full Project Title: The National Register of Antipsychotic Medication in Pregnancy (NRAMP)

Principal Researcher: Professor Jayashri Kulkarni
Associate Researcher: Ms Heather Gilbert

This Participant Information and Consent Form is seven (7) pages long. Please make sure you have all the pages.

1. Your consent:
You are invited to take part in this project.

This Participant Information contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend, or your local health worker. Feel free to do this.

Once you understand what the project is about, and if you agree to take part in it, you will be asked to sign the Consent Forms. By signing the Consent Forms you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Participant Information and Consent Form to keep as a record.

2. Purpose and Background:
The purpose of this project is to gather accurate information regarding the current care of women with mental illness, who become pregnant, to help establish the best management during pregnancy, birth and for the first year of the baby’s life. This would ensure that clinical treating teams (ie: doctor, nurse, case manager) are able to provide the most appropriate, safe and evidence-based practice available to mother and baby.

It is thought that a total of 500 women, from across Australia, will participate in this project.

Previous experience has shown that women with mental illness have the same desire as other women to have a baby. Such women are frequently treated with antipsychotic medication, which may affect the developing baby, however, changing or ceasing the medication could also put mother and baby at risk. It is therefore essential to gather accurate information regarding the current care of women with mental illness, who become pregnant, to help establish the best management during pregnancy, birth and for the first year of the baby’s life. This would ensure that clinical treating teams (ie: doctor, nurse, case manager) are able to provide the most appropriate, safe and evidence-based practice available to mother and baby.
You are invited to participate in this research project because this project aims to improve the health of women with mental illness, and the wellbeing of their babies. It is important to have a thorough understanding of antipsychotic medications as related to their use in pregnancy, to improve the management and mental health of mother and baby. This in turn will allow for a better experience of pregnancy and birth, and enhance the development of parenting skills.

3. Procedures:
Participation in this observational project will involve the establishment of an Australia-wide register/database of women with mental illness who become pregnant, and will follow the pathway of mother and baby during pregnancy, birth, and for the first year of the baby's life. During your pregnancy, information will be gathered at approximately six weekly intervals via telephone and/or face to face interviews, and will include medical history, diagnosis, symptoms and medications; obstetric history and outcomes of delivery; and the baby's health and wellbeing. Further details relating to your medical history may also be obtained, with your permission, from the clinical treating team involved in your care. During the first year of your baby's life, the researcher will contact you when your baby is six weeks, twelve weeks, six months and one year of age, to ask you about the health of you and your baby, and about your experiences of being a mother.

4. Possible benefits:
Possible benefits include the ongoing contact and relationship you will have with the researcher, who will be a health professional. Your clinical treating team will also develop an increased awareness of your needs during pregnancy, including your experiences of motherhood. You will be contributing directly towards the development of the best management for women with mental illness who become/or wish to become pregnant, thereby helping other mothers and babies in the future.

5. Possible risks:
Possible risks, side effects and discomforts could include feelings of sadness which may result from informing the researcher about life experiences. This study does not include any role for the researcher in the management of women with mental illness, or the pregnancy. It is important to understand that any concern held by the researcher for the safety of mother or baby would be directed to the appropriate clinical treating team. There may be additional unforseen or unknown risks.

6. Privacy, Confidentiality and Disclosure of Information:
Any information obtained in connection with this project, and which can identify any individual, will remain confidential. It will be disclosed only with your permission, except as required by law. If you give us your permission by signing the Consent Forms, we plan to publish the results once the project has concluded. In any publication, information will be provided in such a way that you cannot be identified. Once you have signed the Consent Forms, you will be allocated an identification number to maintain confidentiality. Information about you will be restricted to the researchers directly involved, unless there are clear management issues, when the information will be shared with your clinical treating team. Participant information will be stored in a locked filing cabinet, within a locked office, with access available to researchers involved in the project only.

7. New information arising during the project:
During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and your clinical treating team will be informed of this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.
8. Results of the project:
When this project is completed it is hoped that the results will be made available to clinical treating teams as evidence-based guidelines, for the enhanced management of women with mental illness who become pregnant. This has the ability to provide a direct benefit to women in this population group. We also plan to make the results known by publication in appropriate and reputable journals, and through presentations at conferences and seminars where applicable.

9. Further information or any problems:
If you require further information or if you have any problems concerning this project, you can contact the principal researcher. The researchers responsible for this project are Professor Jayashri Kulkarni and Ms Heather Gilbert.

Research students may join this study on an annual basis to conduct their own research projects. They have access to participant data included in the NRAMP database, however this data is coded, with all participant identifiers removed. This means that participant information may be used in the future for further research in this area. Ethics approval has been granted for this activity.

10. Other issues:
If you have any complaints about any aspect of this project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

Name: Ms Rowan Frew,
Position: Ethics Manager, Research and Ethics Unit, Alfred Hospital
Phone: (03) 9076-3848

Or
Name: Ms Alison Woods
Position: Ethics Manager, Ethics Committee, Monash University
Phone: (03) 9905-5490

You will need to tell Ms Frew/ Ms Woods the name of (one of) the researchers given in section 9 above.

11. Participation is Voluntary:
Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Alfred Hospital. Before you make your decision, a member of the research team will be available for you to ask any questions you may have about the research project. You can ask for any information you want. Sign the Consent Forms only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team before you do so. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

12. NRAMP Experiences in Research Survey:
At the close of your involvement with the study, you will be invited to take part in an ‘NRAMP Experiences in Research Survey’. This will be posted to you following the final interview, in the postnatal phase of the study, and will discuss your experience as a participant in The National Register of Antipsychotic Medication in Pregnancy (NRAMP) study.
Your responses, which will remain confidential, will enable us to improve our research methods for present and future study participants. Completed surveys can be returned to the study co-ordinator in the stamped addressed envelope provided. Participation in this survey is optional.

13. **Ethical guidelines:**
This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (March 2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of The Alfred Hospital.

14. **Reimbursement for your costs:**
You will not be paid for your participation in this project.
PARTICIPANT CONSENT FORM

Version 15:  Dated 29th July 2016

Site:   Monash Alfred Psychiatry Research Centre (MAPrc), Alfred Hospital

Full Project Title:  The National Register of Antipsychotic Medication in Pregnancy (NRAMP)

I have read, or have had read to me in my first language, and I understand the Participant Information Version 15:  Dated 29th July 2016

I freely agree to participate in this project according to the conditions in the Participant Information.

I understand that my relevant medical records and that of my baby may be made available to the researchers.

I will be given a copy of the Participant Information and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

Participant:  (printed) ____________________________________________

Signature: ____________________________________________ Date: __________________

Witness: to Participant’s Signature (printed) ____________________________________________

Signature: ____________________________________________ Date: __________________

Declaration by Researcher:  I have given a verbal explanation of the research project, its procedures and risks and I believe the participant has understood that explanation.

Researcher:  (printed) ____________________________________________

Signature: ____________________________________________ Date: __________________

Note:  All parties signing the Consent Form must date their own signature.

Please return to:
Ms Heather Gilbert
Monash Alfred Psychiatry Research Centre (MAPrc)
Level 4, 607 St Kilda Rd
Melbourne
Victoria, 3004
MEDICAL INFORMATION CONSENT FORM

Version 15: Dated 29th July 2016

Site: Monash Alfred Psychiatry Research Centre (MAPrc), Alfred Hospital

Full Project Title: The National Register of Antipsychotic Medication in Pregnancy (NRAMP)

I, ________________________________________________________________________________________, give my permission for __________________________________________, of the Monash Alfred Psychiatry Research Centre (MAPrc), to contact my doctors: ____________________________________________________________

________________________________________________________________________________________

at the following addresses and phone numbers: ________________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

to discuss the psychiatric/obstetric condition for which I receive treatment, and any related concerns, for the purpose of confirming my details as part of my participation in the study, The National Register of Antipsychotic Medication in Pregnancy (NRAMP).

Participant: (printed) ________________________________________________________________

Signature: ___________________________________________________________________________

Date: ________________________________________________________________________________

Please return to:
Ms Heather Gilbert
Monash Alfred Psychiatry Research Centre (MAPrc)
Level 4, 607 St Kilda Rd
Melbourne
Victoria, 3004
REVOCATION OF CONSENT FORM

Full project title:
The National Register of Antipsychotic Medication in Pregnancy (NRAMP)

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment, or my relationship, with Alfred Health.

Participant: (printed) __________________________________________________________

Signature: ___________________________________________________________________

Date: ______________________________________________________________________