PARTICIPANT INFORMATION AND CONSENT FORM

Version 3: Dated 4th October 2018

Site: Monash Alfred Psychiatry research centre (MAPrc), Alfred Health

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

Principal Researcher: Professor Jayashri Kulkarni
Perinatal Psychiatrist: Dr Carolyn Breadon
Associate Researcher: Ms Alisa Turbić

This Participant Information and Consent Form is seven (6) 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 the study.

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 Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

Direct assessment of children will be conducted upon NRAMP researcher obtaining informed consent from the child's legal guardian by their signing of the Participant Consent Form, which will be witnessed by a person who has the capacity to understand the merits, risks and procedures of the research.

Where consent is given by a person authorised by law, the NRAMP researcher will explain to the participant, as far as possible, what the research is about and what participation involves.

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

2. Purpose and Background:

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.

The purpose of this project is to gather accurate information regarding the current care of women with mental illness who become pregnant, in order to establish the best management during pregnancy, birth and for the first five years of the child's life. This would ensure that clinical treating teams (ie: doctor, nurse, case manager) can 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.

This project aims to improve the health of women with mental illness, and the wellbeing of their offspring. 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 child. This in turn will allow for a better experience of pregnancy and birth, and enhance the development of parenting skills.

3. Procedures:

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 five years of the child's life. Eligible women can decide to participate in the study anytime between conception and up to 12 months after the birth of their child. Data is collected at the antenatal (at each trimester) and postnatal (at 6 weeks and each trimester) stages via telephone, email and/or face to face interviews. The collected data includes medical history, diagnosis, symptoms and medications; obstetric history and outcomes of delivery; parental attachment and parenting heath; and the child's health and wellbeing. During the first year of your baby's life, the researcher will contact you when your baby is six weeks old, then at three, six and 12 months old, to ask you about the health of you and your child, and about your experiences of being a mother. The researcher will also contact you at three and/or five years of the child's life. This will be by either telephone or face to face interview to gather information regarding child's cognitive developmental milestones and progress. Each interview will last 30-60 minutes.

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 may develop an increased awareness of your needs during pregnancy, including your experiences of motherhood should there be clear management issues identified by the researcher. 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 children 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 project 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 child would be directed to the appropriate clinical treating team. There may be additional unforeseen or unknown risks.

As the Principal Investigator of the study is a medical practitioner, all concerns about harm will be reported to police under the Children Youth and Families Act (Section 182).

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. We intend 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 Form, you will be allocated an identification number to maintain confidentiality. This identification number will be used in place of your personal details when your data is entered into a secure electronic database.

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 via email. The researchers responsible for this project are:

Professor Jayashri Kulkarni
Email: jayashri.kulkarni@monash.edu

Dr Carolyn Breadon
Email: carolyn.breadon@monash.edu

Ms Alisa Turbić
Telephone: (03) 9076 6591
Email: maprc-nramp@monash.edu

The study is currently funded by Janssen confirmed for $50,000 per year for each of 2018 and 2019 with further extension of funding possible after that.

Research students may join this project 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. Future related research projects will require separate ethics approval.

10. Other issues:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name: Complaints Officer, Office of Ethics & Research Governance, Alfred Health
Telephone: (03) 9076 3619
Email: research@alfred.org.au

Please quote the following Alfred Health project number: 422/18.

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 Form 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. The collected data upon withdrawal will be deleted from your electronic records and any hard copies shredded and discarded into confidential waste bin.

12. NRAMP Experiences in Research Survey:

At the close of your involvement with the project, you will be invited to take part in an 'NRAMP Experiences in Research Survey'. This will be posted to you following the final interview and will discuss your experience as a participant in NRAMP.

Your responses, which will remain confidential, will enable us to improve our research methods for present and future participants. Completed surveys can be returned to the project coordinator in the stamped addressed envelope provided. Participation in this survey is optional.

13. Ethical guidelines:

This project has been approved by the Alfred Hospital Ethics Committee and 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.

14. Reimbursement for your costs:

You will not be paid for your participation in this project.

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I have read, or have had read to me in my first language and I understand the Participant Information **Version 3: Dated 4th October 2018**

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

I understand that my relevant information and that of my child (up to five years of age) will be made available to the NRAMP 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: _____

Participant's next of kin: (printed) _____

Next of kin contact number:_____

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 via post, email or fax to:

Ms Alisa Turbić
Monash Alfred Psychiatry Research Centre (MAPrc)
Level 4, 607 St Kilda Rd
Melbourne
Victoria, 3004
Fax: (03) 9903 0762
Email: maprc-nramp@monash.edu

REVOCATION OF CONSENT FORM

Version 3: Dated 4th October 2018

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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: _____