

PARTICIPANT INFORMATION SHEET - CLINICAL RESEARCH PROJECT

Study Title: Mother and Child 2020 (MC2020)

Protocol Number: 2020.ETH.00159

Principal Investigator: Professor Christopher Nolan

For full list of investigators go to: <https://medicalschoo.anu.edu.au/MC2020study>

Research Site/s:

Australian National University, ACT

University of Canberra, ACT

University of Wollongong, NSW

Canberra Health Services, ACT

Illawarra Shoalhaven Local Health District, NSW

Murrumbidgee Local Health District, NSW

Southern NSW Local Health District, NSW

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. What is the purpose of this study?

This study aims to assess the impacts of the 2019/20 bushfires and more recently COVID-19 (coronavirus) on the health and well-being of pregnant women, new mothers and their babies.

The Australian 2019/20 bushfire season was long and severe with many people affected. The risks that bushfires and smoke pose on pregnant mothers and their unborn and newly born babies is not known.

Following on from the bushfires has been the COVID-19 (coronavirus) pandemic which changed the way of living for practically everybody, including mothers and babies. If not directly affected by COVID-19 infection, the community lockdowns have changed access to usual health care, usual work, and interactions with family and friends.

It is hoped the results of this study will help us to advise governments, health care providers and pregnant mothers and their families/friends on how best to respond to similar and different crises in the future to protect the health and wellbeing of mothers and their babies.

This study will involve recent mothers and their unborn and recently born babies from the ACT & South-East NSW region.

While initial funding will allow the researchers to study the impact of bushfires and COVID-19 on MC2020 mothers and babies for 12 months, it is hoped additional funding will enable longer term follow-up (e.g. of the children through kindergarten and school).

2. Why have I been invited to participate in this study?

Many pregnant and new mothers in this region experienced:

- Due to bushfires
 - Prolonged bushfire smoke exposure
 - Actual bushfires
 - Evacuation and personal loss (lives, housing, livelihood, sacred sites, cultural lands)

and/or

- Due to COVID-19
 - Disruption of normal living as a consequence of the pandemic

You are eligible to participate in this study if on the **01st February 2020** you were:

- A mother of a newborn baby no older than 3 months of age
- Pregnant at any stage (ie: early, middle and late pregnancy)
- Within 3 months of becoming pregnant (ie: you became pregnant by 30th April 2020)

3. What if I don't want to take part in this study or if I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether or not you participate. You may also consider involving the father of your baby in deciding your participation and that of your baby. If you decide not to participate, it will not affect the treatment you or your baby receives now or in the future. Whatever your decision, it will not affect your relationship with the health care professionals caring for you.

New information about the MC2020 study, including continuation beyond the first year, is likely to become available during the course of the study. At every stage you will be given the option to continue or withdraw.

You may withdraw yourself and your baby from the study at any time and for any reason or no reason. If you are unfortunate to have a pregnancy loss or neonatal death you are able to withdraw from the study at any time if this is your preference. Please tell the study team that you wish to withdraw from the study. Information that has been collected about you and your baby, prior to your withdrawal, will continue to be used in the data analysis. No new information will be collected or used about you and your baby after you have withdrawn from the study.

4. What does this study involve?

This study will be conducted up to the time your child will be 5 years old.

Involvement for the majority of mothers and babies is by a series of four questionnaires to be answered within the first 12 months. The questions can be answered on-line or using paper forms if you would prefer.

1) Bushfire questionnaire: is to be completed on registration as a participant in the study. This questionnaire asks about:

- You and your day to day life circumstances before the bushfires
- Your physical health and psychological wellbeing
- Some information about your previous pregnancies and some information on your latest pregnancy
- About where you were and how much you were affected by the bushfires

2) COVID-19 questionnaire: is to be completed within 2 weeks of the bushfire questionnaire. This questionnaire asks about:

- Your experiences of the COVID-19 pandemic (so far)
- Your previous pregnancies and children
- Your diet and exercise
- Your psychological wellbeing and sleep quality

3) Pregnancy questionnaire: is to be completed once your baby (babies if you have a multiple pregnancy) is 3 months old. If your baby is already this age or older, you will be asked to complete the pregnancy questionnaire 2 weeks after the COVID19 questionnaire. This questionnaire asks about:

- The pregnancy care you received
- The birth of your baby
- The feeding and development of your baby
- The challenges these crises might have had on the way you care for your baby
- Your own health and wellbeing as a new mother

If you had twins or a multiple pregnancy, you will be able to provide details on each of your babies.

If you were unfortunate to have a pregnancy loss (eg: miscarriage, stillbirth or neonatal death), you can still complete the pregnancy questionnaire, but you will not need to answer questions not relevant to you.

4) Bushfire/COVID-19 follow-up questionnaire: is to be completed in November 2020, about 12 months after the 2019/20 bushfire crisis started in this region.

This questionnaire will focus on:

- How your day to day life circumstances may have changed following the bushfires and COVID-19
- Your physical health and psychological wellbeing

Each questionnaire will take 20-30 minute to complete. You don't need to complete any of the questionnaires all in the one go. The on-line version will automatically save your answers and you will be able to re-start where you left off. If you need help to complete the questionnaires, please contact us and we will arrange this. You can call: 02 5124 2549 or text 0421268459 and we will get back to you.

Medical records review and data linkage: Combining the information from the questionnaires with information about you and your baby held within hospital medical records and within a variety of health system data bases (using a methodology called Data Linkage) is a way to strengthen the quality of this type of research. If you participate in the study, you will have the option to allow the research team to use hospital medical records review and data linkage methods (up until your child reaches the age of 5 years) to obtain information on your health and that of your baby. The health system data that we may access include the Perinatal Data Collection (PDC) data bases, the Admitted Patient Data Collection/Care (APDC) databases and the kindergarten health checks of ACT Health and NSW Health, as well as Medicare and the Pharmaceutical Benefits Scheme data. Information collected from these sources will be stored as de-identified data in the MC2020 research data base.

MC2020 substudies:

Your involvement in substudies will be optional. If you are interested in being contacted about participating in interview/focus group discussions or any of the other substudies, you will be able to indicate this in the consent form at the end of the participant information sheet.

- **Interview and focus group discussion substudies:** In order to study more deeply the experiences of pregnant women and mothers of newborns as a consequence of the bushfire and COVID-19 crises, the research team will be conducting some interview and focus group discussions with MC2020 participants.
- **Other substudies:** As the project proceeds, we are expecting additional substudies will be developed that may involve more detailed physical examination of yourself and/or your baby and obtaining bio-samples such as blood, urine (and possibly placenta if you have not yet had your baby yet).

Potential extension of MC2020 study:

The MC2020 study may be extended beyond 5 years such that the much longer-term effects of the MC2020 bushfire/COVID19 year on health and well-being of mothers and their children can be determined. Future involvement would likely involve completion of additional questionnaires and physical examinations of you and/or your child. As with the current study, you would be invited to continue voluntary participation at the time and you will have the opportunity to agree to continue participation through re-consenting to this or you will be able to decline further participation.

5. How is this study being paid for?

The study is being paid for by the Australian National University, College of Health and Medicine through an internal research grant. Participation in this study will not cost you anything. Participants will not be paid for their involvement in the questionnaires of the MC2020 study.

6. Are there risks to me in taking part in this study?

As this study does not include trial of any new treatments or interventions the risks are low for you and your baby. However, involvement in the study could lead you to experience an

increased level of anxiety or stress through being reminded of the bushfire and/or COVID-19 crises and/or of difficulties you may have experienced through your pregnancy. If you do experience an increased level of stress, contact details are provided at the end of this document on how you can get support.

While the findings of this study should help us find ways to improve the health and wellbeing of mothers and babies through future bushfires, pandemics and major crises, it is important for you to be aware that your participation in this study may not directly benefit you.

7. What if something goes wrong?

If you suffer any psychological trauma, injuries or complications as a result of this study, you should contact the study team as soon as possible, who will assist you in arranging appropriate psychological health and/or medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

8. Who is organising and funding the research?

This study is being conducted by the study team headed by Professor Christopher Nolan, ANU Medical School and Department of Endocrinology, The Canberra Hospital. The study is being funded by the Australian National University.

No investigator or member of the research staff will receive a personal financial benefit from your involvement in this study. The researchers declare no personal conflict of interest relevant to the undertaking of this study.

9. How will my confidentiality be protected?

Confidentiality will be protected according to privacy laws. Information collected for research purposes about you and your child will be de-identified and kept under a computer generated project ID number, rather than your name and your child's name. The MC2020 researchers will have unrestricted future use of the de-identified research data.

A list of ID numbers and subjects' contact details will be maintained separately and securely by the MC2020 data custodians and Professor Nolan in encrypted password protected files.

Following Good Clinical Research Practice, all data obtained from this project will be held securely by Professor Nolan for a minimum of 15 years. However, it is intended to keep the study data indefinitely. This is because the data becomes more powerful for research, as ongoing data accumulates in larger longitudinal datasets. Applications for access to the de-identified data by external researchers to the MC2020 research team may be made. However, before such access can be granted by the MC2020 research team, a Human Research Ethics Committee approval of this access will also be required.

10. What happens with the results?

Progress of MC2020 research will be posted on the MC2020 website and information will be made public through various public forums.

We also intend to present the results of this project at scientific meetings and to publish them in scientific journals. Those journal articles will be available from the lead researchers on request. The results will also be reported to the ACT, NSW and Australian governments. In all publication and reports, information will be provided in such a way that you cannot be identified.

Non-identifiable summary data (meta data) and publications arising from this research will be made available within an ANU open access data repository.

11. What should I do if I want to discuss this study further before I decide?

When you have read this information, you may ask the researchers questions by calling the number below. There is an option to leave a message and we will get back to you. You are also able to down-load this information and take it away to discuss with your family, friends, treating doctor or any other person you choose. Telephone: 02 5124 2549.

12. Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

13. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by the ACT Health Human Research Ethics Committee. If you have any concerns or complaints about the conduct of this study, and do not feel comfortable discussing this with study staff, you may contact the Committee secretariat who is nominated to receive complaints about research projects. You should contact the secretariat on 02 6174 7968 or ethics@act.gov.au

The ethical aspects of this research have also been approved by the ANU Human Research Ethics Committee (Protocol 2020/520). If you have any concerns or complaints about how this research has been conducted, you may also contact:

Ethics Manager
The ANU Human Research Ethics Committee
The Australian National University
Telephone: 02 6125 3427
Email: Human.Ethics.Officer@anu.edu.au

In collecting your personal information within this research, the ANU must comply with the Privacy Act 1988. The ANU Privacy Policy is available at https://policies.anu.edu.au/ppl/document/ANUP_010007 and it contains information about how a person can:

- Access or seek correction to their personal information;
- Complain about a breach of an Australian Privacy Principle by ANU, and how ANU will handle the complaint.

this research causes you distress that needs urgent attention, please call

- Lifeline: 131114
- ACT Mental Health Triage Service: (02) 6205 1065 or 1800 629 354
- NSW Mental Health Help Line: 1800 011 511
- SANDS (Miscarriage, stillbirth and neonatal death support) 1300 072637

Or you can leave a message with the study team: Telephone: 02 5124 2549

Thank you for taking the time to consider this study.