Monash Health

Research Support Services
Monash Health
Level 2, I Block
246 Clayton Road
Clayton, Victoria 3168

Tel (03) 9594 4611
Fax (03) 9594 6306
Email: research@monashhealth.org

16 March 2022

Prof Ben Mol
Monash Health
Obstetrics and Gynecology
246 Clayton Road
Clayton VIC 3168

Dear Researcher,

Study Title: A pilot feasibility randomised controlled trial investigating the effect of viral transmission mitigation measures on the incidence of preterm birth in high-risk pregnant women

ERM Reference Number: HREC/84541/MonH-2022-302345(v1)
Monash Health Local Reference: RES-22-0000-122A

We advise that the above project was reviewed by the Monash Health Human Research Ethics Committee at its meeting on 10 March 2022 and was approved subject to the following conditions.

The responses are to be reviewed outside of the Committee by the Medical Administrator and Research Support Services staff.

1. Submission of a response to the following Ethical Issues:

a. Monash Health is providing HREC Review Only for the following sites:
- Monash Health, VIC;

b. Submission of a revised Human Research Ethics Application with the following amendments:

i. As this is a clinical trial, revise Q3.14 to state that data will be retained for a minimum of 15 years in accordance with the TGA: ICH Guideline for Good Clinical Practice;

ii. The Principal Investigator's signature on the Human Research Ethics Application form;

iii. Q2.2.2.1 indicates that specific consent will be obtained, which is inconsistent to Q3.17 which states that data will be stored for future related research, i.e., extended consent. As the Protocol and Participant Information and Consent Form do not refer to future research, question Q3.17 should be revised accordingly;

iv. Under Q3.14, remove the text 'in accordance with the Monash University research guidelines';

c. Submission of a revised Victorian Specific Module with the following amendments:

i. Revise (2.7(d)(i) and 2.7(f)) to state that data will be retained for a minimum of 15 years;

ii. Under 2.7(f) remove the text 'in accordance with the Monash University research guidelines';

d. Submission of a revised Protocol with the following amendments:

i. Additional detail is required for the inclusion/exclusion criteria, i.e.:

a. Will multiple pregnancies (typically included in high risk for preterm delivery) be included in recruitment if they have not had a previous preterm birth?

b. Inclusion criteria states a previous preterm birth (<34 weeks), so it is not clear how subgroup analysis can include primiparous versus parous women;

c. It is not clear how potential participants will be assessed at baseline as 'unlikely to comply with the intervention';

ii. Clarification of whether the research team will be involved in the care team of potential participants creating an unequal or dependent relationship. The researchers are requested to address this issue;

iii. Descriptions of recruitment differ between the Human Research Ethics Application, the Protocol and Victorian Specific Module. In the Human Research Ethics Application it is not clear if permission to contact will be obtained from participants by the clinician (doctor or midwife) providing initial study information during a clinic visit, i.e., do they obtain permission to pass on contact details prior to contact by the research team? Alternatively, the Protocol indicates potential participants will be screened by a member of the clinical team familiar with the inclusion criteria who will explain the trial details prior to consent. It is also noted the Participant Information and Consent Form asks potential participants to contact the researcher, which is also not consistent with the Human Research Ethics Application which indicates the researchers will contact participants using information from BOS, and the Protocol that indicates the women will be contacted in clinic;

iv. Clarification is required on how participant information will be shared and written consent will be obtained if telehealth/limited site visits are still in progress;

v. Addition consideration is required under the section Benefits and Risks Assessment. The researchers identify social isolation as a potential risk, but there are broader risks associated with burden on self and others. The selection criteria specifies women who have had a previous preterm delivery, hence the researchers should consider risks associated with caring for other children, e.g. attending school and childcare. In addition, the proposed intervention may impose burdens on others such as other household supports (partner, family) due to social isolation;

vi. Under the section Privacy, additional detail is required to explain how data will be collected from the Services Victoria app and the privacy strategy. It is not

explicitly stated whether the participant will provide this information or if it will be extracted from another source;

vii. On page 16, clarification on the composition of the Medical Education Technology Committee (METC) who will approve the protocol and will be notified of all serious adverse events;

viii. On page 19, remove the text 'in accordance with the Monash University research guidelines';

ix. On page 19, revise to state that data will be retained for a minimum of 15 years;

x. As the study is not funded, it is not clear where the resources are provided, e.g., researchers/staff who will require training to undertake data entry;

e. Submission of a revised Participant Information and Consent Form with the following amendments:

i. It is requested that some of the language is revised into lay terms e.g., cervical cerclage; mitigation;

ii. On page 4, revise to state 'we will store your information for a minimum of 15 years. After this period, we may dispose of the information…'

iii. On pages 4-5, reformat the heading 'Clinical contact person' to appear above the table. It is acceptable for Dr Daniel Rolnik to be the clinical contact person, however in the interest of clarity, revise the preceding sentence which refers to Dr Rolnik as the 'principal study doctor';

f. Submission of the participant diary;

g. Submission of the fortnightly surveys to assess mood and quality of life, case report forms and self-report diary;

h. Submission of the ANZCTR clinical trial registration number or other registry details;

i. Submission of a Curriculum Vitae and Good Clinical Practice Certificate for the Principal Investigator.

2. Submission of the following Site Specific Assessment Items:

a. Submission of a Site Specific Assessment Application for the study at Monash Health with all of the researchers' signatures and Head of Department's signature. Once this has been uploaded on the ERM website, please email research@monashhealth.org with the Project ID reference from ERM. Please ensure the email also attaches the Site Specific Assessment Form and any supporting documents.

It is requested that any responses be submitted as follows:

- Inclusion of covering letter identifying the project number and title of the application;
- The covering letter must clearly refer to the individual items mentioned in this letter together with a response to that item listed beneath;
- All documents should detail the changes made, including all additions and changes to the text and ~~strike through~~ any deleted original text and highlight in **bold** or by <u>underline</u> any new text;

- A new version number and date is required in the footer of each page of any revised Patient Information Sheet. Please ensure that any Consent Forms are correspondingly updated.

The project cannot commence until all the conditions outlined have been complied with and a final HREC Review Approval and Site Specific Authorisation have been issued. If the conditions are not fulfilled **within three months,** conditional approval may be withdrawn and a new application may need to be submitted if the project is to proceed.

If you should have any queries about your project, please contact the Research Support Services team via email research@monashhealth.org or via telephone: Julie Gephart on (03) 9594 4090, Katharine Mahoney on (03) 9594 4748, or Sarah Niazmand on (03) 9594 4747.

The HREC wishes you and your colleagues every success in your research.

Yours sincerely,

Deborah Dell
Director, Research Operations

cc: Ms Renise Teh, Pharmacy, Monash Health
cc: Dr Daniel Rolnik

All correspondence in regard to this study must be uploaded on ERM with both the Monash Health Reference Number and the Project ID. Upon uploading, please also email the responses and all attachments to research@monashhealth.org along with both the Monash Health Reference Number and the ERM Project ID.