

3rd July 2017



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and
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Dear Sarah and Lynette

Re: Fetal Virtopsy: The Value of MDCT as an Adjunct to Conventional Investigations in Pregnancy Losses. REC2448/6/2020

Thank you for your letter dated 31st May 2017. At its meeting on 28th June 2017, the WCHN Human Research Ethics Committee approved the use of the consent provided in the revised *SA Health Authority for Hospital Post-Mortem Examination* form on the grounds that the form now notes that as part of the autopsy digital photographs and radiology may be used. The Committee also understands that post-mortem examinations have evolved since the initial application was submitted and that imaging/photography is now standardly used in post mortems; your comment is sought on this point.

Your request to extend ethical approval for a further three years was approved. Please note the amended approval number above reflecting the extension, and use it in any future communications.

The consideration of annual reports is now part of research governance monitoring. Please ensure that an annual report for the study is provided to the WCHN Research Governance Officer, Ms Camilla Liddy.

I remind you continued approval is given subject to:

- immediate notification of any serious or unexpected adverse events to participants;
- immediate notification of any unforeseen events that might affect continued ethical acceptability of the project;
- submission of any proposed changes to the original protocol. Changes must be approved by the Committee before they are implemented;
- immediate advice, giving reasons, if the protocol is discontinued before its completion;
- submission of an annual report on the study's progress and a final report on completion to the WCHN Research Governance Officer. It is your responsibility to provide these reports, without reminder from the Committee.

I also remind you of the institution's research governance requirements. If the study involves non WCHN staff or students, a signed Confidentiality Agreement is to be provided to Ms C Liddy, Research Governance Officer, WCHN Research Secretariat. Additionally, if they visit any WCHN site or access identifiable patient information, a verified copy of their Department for Communities & Social Inclusion (DCSI) National Criminal History Record Check (Child related employment screening) is to be provided to Ms Liddy and the Human Resources Department. The study may continue on this proviso.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Tamara Zutlevics'.

TAMARA ZUTLEVICS (DR)
CHAIR
WCHN HUMAN RESEARCH ETHICS COMMITTEE



Government
of South Australia
SA Health