22nd March 2018

Women's & Children's Hospital

Research Secretariat
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A/Prof B Muhlhausler
Head, Food and Nutrition Group
School of Agriculture, Food and Wine
Waite Campus, University of Adelaide
PMB 1
GLEN OSMOND SA 5064

Dear A/Prof Muhlhausler

Re: The short-term impact of dietary fat and sugar intake on breast milk composition: The Diet and Breast Milk Composition Study. HREC/17/WCHN/182. Ethics expiry date: 31/03/2021.

Lead HREC for the above study for the following institutions/sites:

Women's and Children's Health Network

I refer to your letter dated 8th March 2018 in which you responded to matters raised by the WCHN Human Research Ethics Committee at its 6th December 2017 meeting. I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

Specifically, the following documents have been noted/approved:

Document	*Version*	*Date*
Diet and Breast Milk Composition Study Flyer	1	15 November 2017
Diet and Breast milk Composition Trial Consent to contact	1.0	05 March 2018
Diet and Breast milk Composition Trial Antenatal Screening Form	1.0	16 November 2017
Diet and Breast milk Composition Trial CRF	1.0	21 November 2017
Diet and Breast Milk Composition Study Brochure	1.0	21 February 2018
Diet and Breast Milk Composition Trial Adverse effects	1.0	16 November 2017
Patient Information Sheet/Consent Form: Diet and Breast milk composition Trial PIS and Consent form	1.0	05 March 2018
Protocol: Diet and Breast Milk Composition Trial Protocol	1.0	21 February 2018
Diet and Breast milk Composition Trial Postnatal Ward Screening Log	1.0	20 February 2018
HREA Application: AU/1/4C6239		22 November 2017
Response to Request for Further Information: Response Letter		08 March 2018
Diet and Breast milk Composition Trial Postnatal Screening Form	1.0	21 November 2017

This letter constitutes advice on ethical consideration only. You must not commence this research project at a site until you have obtained separate research governance approval from the site concerned. A copy of this letter should be forwarded to all site investigators for submission to the relevant Research Governance Officer.

At the WCHN, or any other SA Health site, separate authorisation from the Chief Executive or delegate of that site must be obtained through a Site Specific Assessment (SSA) request. For information on this process at the WCHN, please contact the WCHN Research Governance Officer, Ms Camilla Liddy (telephone 8161 6688, email camilla.liddy@ sa.gov.au).

I remind you 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 progress of the study, and a final report when it is completed to the WCHN Research Governance Officer. It is your responsibility to provide these reports, without reminder. The proforma for the report may be found on the WCHN Research Governance and Ethics website.

Approval is given for three years only. If the study is more prolonged than this, an extension request should be submitted unless there are significant modifications, in which case a new submission may be required. Please note the expiry date in the title above and include it in any future communications.

Yours sincerely

TAMARA ZUTLEVICS (DR)
CHAIR
WCHN HUMAN RESEARCH ETHICS COMMITTEE

WOMEN'S AND CHILDRENS HEALTH NETWORK (WCHN)

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

REGISTERING OF CLINICAL TRIALS

The WCHN Human Research Ethics Committee (HREC) and Drug and Therapeutics Committee Clinical Trials Group (DTC) would like to draw researcher's attention to a joint editorial issued by members of the International Committee of Medical Journal Editors (ICMJE) which appeared in *The New England Journal of Medicine* June 9, 2005. ICMJE members stated that,

In September 2004, the members of the International Committee of Medical Journal Editors (ICMJE) published a joint editorial aimed at promoting registration of all clinical trials. We stated that we will consider a trial for publication only if it has been registered before the enrolment of the first patient. This policy applies to trials that start recruiting on or after July 1, 2005.

For further information regarding the registering of trials researchers are directed to the above mentioned editorial – http://content.nejm.org/cgi/reprint/352/23/2436.pdf

In Australia, the National Health Medical Research Committee has set up the Australian Clinical Trials Registry (ACTR) which researchers can access. It is a national online register of clinical trials being undertaken in Australia. The ACTR includes trials from the full spectrum of therapeutic areas. It has nationwide coverage of all clinical trials involving Australian researchers or Australian participants. General information on the registry can be found at http://www.actr.org.au

Any project that prospectively assigns human participants to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome (ICMJE definition) should be registered, including early phase uncontrolled trials (phase I) in patients or healthy volunteers (WHO Recommendation). If in doubt, registration is recommended. The REC is unable to register clinical trials. Consequently, those researchers seeking to register their trials will need to do so themselves.

Please bring this notice to the attention of all researchers and potential researchers in your department.

In keeping with the above, it is a WCHN HREC requirement for trials to be registered before enrolment of the first patient.

Newsletter Issue 2, Dec 2006 for the Registry may be accessed at http://actr.org.au/docs/ACTRNewsletterIssue221Dec06.pdf