Curtin University

Memorandum

To	Professor Jane Scott, Public Health
From	Professor Peter O'Leary, Chair, Human Research Ethics Committee
Subject	Protocol Approval **HR 82/2014**
Date	14 May 2014
Copy	Professor Bruce Maycock Public Health Professor Yvonne Hauck Public Health Professor Satvinder Dhaliwal, Public Health Professor Peter Howat, Public Health Associate Professor Sharyn Burns, Public Health Associate Professor Suzanne Robinson, Public Health Professor Colin Binns, Public Health Dr Roslyn Giglia, Public Health

Office of Research and Development
Human Research Ethics Committee

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Thank you for providing the additional information for the project titled "*Parent infant feeding initiative (PIFI): a study to enhance breastfeeding duration*". The information you have provided has satisfactorily addressed the queries raised by the Committee. Your application is now **approved**.

- You have ethics clearance to undertake the research as stated in your proposal.
- The approval number for your project is **HR 82/2014.** *Please quote this number in any future correspondence.*
- Approval of this project is for a period of four years **15-05-2014** to **15-05-2018**.
- Your approval has the following conditions:
  i) Annual progress reports on the project must be submitted to the Ethics Office.
- **It is your responsibility, as the researcher, to meet the conditions outlined above and to retain the necessary records demonstrating that these have been completed.**

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **Progress Report** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development annually.

Our website https://research.curtin.edu.au/guides/ethics/non_low_risk_hrec_forms.cfm contains all other relevant forms including:

- Completion Report (to be completed when a project has ceased)
- Amendment Request (to be completed at any time changes/amendments occur)
- Adverse Event Notification Form (If a serious or unexpected adverse event occurs)

Yours sincerely

Professor Peter O'Leary
Chair Human Research Ethics Committee

Standard conditions of ethics approval

These standard conditions apply to all research approved by the Curtin University Human Research Ethics Committee. It is the responsibility of each researcher named on the application to ensure these conditions are met.

1. **Compliance.** Conduct your research in accordance with the application as it has been approved and keep appropriate records.
    a. **Monitoring** - Assist the Committee to monitor the conduct of the approved research by completing promptly and returning all project review forms that are sent to you.
    b. **Annual report** - Submit an annual report on or before the anniversary of the approval.
    c. **Extensions** - If you are likely to need more time to conduct your research than is already approved, complete a new application six weeks before the current approval expires.
    d. **Changes to protocol** - Any changes to the protocol are to be approved by the Committee before being implemented.
    e. **Changes to researcher details** - Advise the Committee of any changes in the contact details of the researchers involved in the approved study.
    f. **Discontinuation** - You must inform the Committee, giving reasons, if the research is not conducted or is discontinued before the expected completion date.
    g. **Closure** - Submit a final report when the research is completed. Include details of when data will be destroyed, and how, or if any future use is planned for the data.
    h. **Candidacy** - If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Faculty Graduate Studies Committee.
2. **Adverse events**. Consider what might constitute an adverse event and what actions may be needed if an adverse event occurs. Follow the procedures for reporting and addressing adverse events (http://research.curtin.edu.au/guides/adverse.cfm).Where appropriate, provide an adverse events protocol. The following are examples of adverse events:
    a. Complaints
    b. Harm to participants. This includes physical, emotional, psychological, economic, legal, social and cultural harm (NS Section 2)
    c. Loss of data or breaches of data security
    d. Legal challenges to the research
3. **Data management plan.** Have a Data Management Plan consistent with the University's recordkeeping policy. This will include such things as how the data are to be stored, for how long, and who has authorised access.
4. **Publication**. Where practicable, ensure the results of the research are made available to participants in a way that is timely and clear (NS 1.5). Unless prohibited from doing so by contractual obligations, ensure the results of the research are published in a manner that will allow public scrutiny (NS 1.3, d). Inform the Committee of any constraints on publication.
5. **Police checks and other clearances**. All necessary clearances, such as Working with Children Checks, first aid certificates and vaccination certificates, must be obtained before entering a site to conduct research.
6. **Participant information.** All information for participants must be approved by the HREC before being given to the participants or made available to the public.
    a. **University logo**. All participant information and consent forms must contain the Curtin University logo and University contact details for the researchers. Private contact details should not be used.
    b. **Standard statement**. All participant information forms must contain the HREC standard statement.

        This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 82/2014). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

    c. **Plain language**. All participant information must be in plain language that will be easily understood by the participants.

Please direct all communication through the Research Ethics Office

Curtin University

HREC Progress Report

The Form is to be completed and returned to *the Secretary, Human Research Ethics Committee, c/- Office of Research & Development.* hrec@curtin.edu.au

If a Form C Co-ordinator, approved your application please submit your completed form to your school Form C Co-ordinator.

Annual completion of this form fulfils researchers' obligations under section 5.5.5 of the National Statement on Ethical Conduct in Human Research.

All questions must be answered or the Form will not be processed.

Approval Number:	
PROJECT TITLE:	

1	**Please confirm the project is proceeding exactly as specified in the protocol.**	**YES☐**	**NO☐**
If NO, please provide details_____ *(Attach additional comments on a separate sheet of paper if necessary)*			
2	**Have any ethics related issues emerged in regard to this project since you received Ethics' Committee approval? (e.g. breach of confidentiality, harm caused, inadequate consent or disputes on these).**	**YES☐**	**NO☐**
If yes, please provide details_____ *(Attach additional comments on a separate sheet of paper if necessary)*			
3	**Have any ethics related issues in regard to this project been brought to your attention by others? (e.g. study respondents, organisations that have given consent, colleagues, the general community etc).**	**YES☐**	**NO☐**
If yes, please provide details _____ *(Attach additional comments on a separate sheet of paper if necessary)*			
4	**Please outline the progress made to date. (e.g. Number of participants recruited; Data collected / analysed; Papers published)**	**YES☐**	**NO☐**
(Attach additional comments on a separate sheet of paper if necessary)			
5	**Please detail what arrangements have been made for the ongoing storage and security of the research records in accordance with the Western Australian University Sector Disposal Authority (WAUSDA).** http://uim.curtin.edu.au		
(Attach additional comments on a separate sheet of paper if necessary)			

Investigator:		**Signature:**	
		Date:	
Co-Investigator:		**Signature:**	

School/Department:			
Head of Area: *Or equivalent*		**Signature:**	
Date:			

Office Use Only
APPROVED:_____ DATE: _____/_____/_____