



Institutional Review Board (IRB) FWA 00003979

February 2, 2017

To: Jan Olmstead
Email: janolmstead@aihc-wa.com
Project: Maternal Infant Early Childhood Home Visiting
NWIC IRB Project Number: # 2017-04

Approval Date: 2/1/2017
Approval Expiration Date: 1/31/2018 (364 days after approval date)
Review Process: Expedited IRB review
Approval Category: Approval
Risk Category: NOT greater than minimal risk

Dear Ms. Jan Olmstead:

The Northwest Indian College IRB reviewed the conditions for your protocol *Maternal Infant Early Childhood Home Visiting* on February 2. Your research was **APPROVED**.

DETAILS

The NWIC IRB answered the following questions for its review (per the NWIC IRB regulations in the NWIC IRB Manual and also 45 CFR §46.111).

- Were 6 potential risks to participants minimized during researcher's interaction with them?
- Were 6 potential risks to participants minimized in the dissemination of results?
- Were 6 potential benefits to participants maximized throughout the research?
- Were minimized potential risks reasonable compared with maximized potential benefits?
- Was selection of participants equitable?
- Were privacy of participants and confidentiality of data maintained?
- If vulnerable populations participated, were their special protections included?
- Was the annual report to the IRB sufficient to monitor the project?
- Were the informed consent processes and documents appropriate?

The IRB considered each question for both individual and also tribe/community participants. The 6 potential risks and benefits were: physical; psychological; social; economic; legal; and dignitary (National Bioethics Advisory Commission; *Ethical and Policy Issues in Research Involving Human Participants: Volume I*. DHHS; Aug 2001: p.71).

Please submit the next NWIC IRB Renewal / Close-out Form at least six (6) weeks before the **Approval Expiration Date** noted above to request either Renewal, or alternately Close-out the protocol for NWIC IRB purposes.

A copy of your informed consent form, which has been approved and **stamped** by the IRB, must be given to each study participant. As you conduct your research, please remember that:

1. Participants are volunteers or are involved in regular educational programs; they thus are free to withdraw from the research at any time without penalty.
2. Unless the NWIC IRB has approved a waiver for your project, you must fully inform participants by both written and oral explanation about the project; all participants must sign or approve electronically or verbally an informed consent form. (For minors / children, the parent or guardian must sign a permission form.)
3. You must protect the participants' confidentiality and their anonymity if your project includes that as well. The presentation of the data should not put them at risk of any negative consequences.

You must submit any proposed changes for IRB approval at least 6 weeks before you want to implement them. Access to the data is specified and restricted by the researcher and the department. If any irregularities or unexpected events occur, please report those immediately to the IRB Office. You must report any problems or adverse events resulting from implementation of this protocol to the IRB.

Please submit to the NWIC IRB both a description of the development of any planned dissemination (poster presentation, publication, etc.), and also the dissemination itself, at least two weeks before the date of dissemination. The reason is that this IRB protects Tribes and Tribal-based institutions from potential stigmatization during the dissemination process. The IRB reviews and verifies that the dissemination process is followed in the research plan approved by the NWIC IRB.

Your research is important work and we look forward to observing your progress through the NWIC IRB annual reviews. Please contact the NWIC IRB at (360) 392-4224 or irb@nwic.edu if you have any questions.

Thank you,



Dave Oreiro
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