

**ATTACHMENT D:**  
**MULTI-SITE IMPLEMENTATION EVALUATION OF TRIBAL HOME VISITING**  
**(MUSE)**

- 1. Documentation of Initial IRB Approval**
- 2. Documentation of Amendment Approval for Waiver of Parental Consent for Minor Caregivers (Ages 14-17)**

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB number for the described information collection is 0970-0521 and the expiration date is 12/31/2021.

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University of Colorado Hospital  
Denver Health Medical Center  
Veteran's Administration Medical Center  
Children's Hospital Colorado  
University of Colorado Denver  
Colorado Prevention Center

## **Certificate of Approval**

09-Apr-2018

**Investigator:** Nancy Whitesell  
**Subject:** COMIRB Protocol 18-0109 Initial Application  
**Review Date:** 06-Apr-2018  
**Effective Date:** 06-Apr-2018  
**Expiration Date:** 05-Apr-2019  
**Sponsor(s):** Administration for Children and Families/DHHS~  
**Title:** Multi-Site Implementation Evaluation of Tribal Home Visiting

**Submission ID:** APP001-1

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### **SUBMISSION DESCRIPTION:**

Initial expedited submission

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**Your COMIRB Initial Application submission APP001-1 has been APPROVED until the expiration date listed above. The investigator will need to submit this research for Continuing Review at least 45 days prior to the expiration date.**

Study personnel are approved to conduct the research as described in the documents approved by COMIRB, which are listed below the REVIEW DETAILS section.

Please carefully review the REVIEW DETAILS section because COMIRB may have made red-line changes (i.e. revisions) to the submitted documents prior to approving them. The investigator can submit an amendment to revise the documents if the investigator does not agree with the red-line changes. The REVIEW DETAILS section may also include important information from the reviewer(s) and COMIRB staff.

Effective May 23, 2017, COMIRB will only approval-stamp consent documents (e.g. consent forms, assent forms, information sheets, etc.) and local advertisements. Stamped copies of these documents are available for download through COMIRB's electronic submission website, eRA(InfoEd). COMIRB approval letters will continue to list all reviewed and approved documents.

**[Click here for instructions on how to retrieve stamped documents.](#)**









the subject's first language or use a Consent Short Form, as approved for the study.

- Inform COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policies and Procedures.
- Maintain approval for the research. COMIRB approval is generally given in one year increments, but the period may be shorter. Research is required to be submitted for continuing review and re-approval at least 45 days prior to the expiration date. If a study's approval expires, investigators must stop all research activities immediately (including data analysis) and contact the COMIRB office for guidance.
- Remain actively engaged in the conduct of the research. The investigator must ensure that all enrolled participants are appropriate for the study prior to study procedures beginning.

Information on how to submit changes (amendments) to your study, requests for continuing review, and reports of unanticipated problems to COMIRB can be found on the COMIRB website <http://www.ucdenver.edu/research/comirb/training/>.

Contact COMIRB with questions at 303-724-1055 or [COMIRB@ucdenver.edu](mailto:COMIRB@ucdenver.edu).

As part of this review it was determined that for this research:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, §46.116.
5. Informed consent will be appropriately documented in accordance with, and to the extent required by, §46.117.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Appropriate safeguards are in place to protect potentially vulnerable populations from coercion and undue influence.

Sincerely,

UCD Panel S

## Amendment Approval

04-Jan-2019

**Title:** Multi-Site Implementation Evaluation of Tribal Home Visiting  
**Subject:** COMIRB Protocol 18-0109 Amendment  
**Investigator:** Nancy Whitesell  
**Sponsor(s):** Administration for Children and Families/DHHS~  
**Approval Date:** 26-Dec-2018

**Submission ID:** PAM001-1

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### **REQUESTED CHANGES:**

Description of change: We are requesting a waiver of parental consent for minor caregivers (ages 14-17) who enroll in the study. Attachment M is included with this Modification Request Form. Caregiver Under 18 Quant\_Consent+HIPAA forms (two versions, see Question 2 above) will no longer be necessary and will be removed from the study protocol. Caregiver Over 18 Quant\_Consent+HIPAA forms (two versions, see Question 2 above) will be revised to apply to all Caregivers (i.e., Caregiver Quant\_Consent+HIPAA).

Documents changed: Application and consent forms

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### **REVIEW DETAILS**– Please read carefully:

The following documents have been reviewed by the Chair as part of this approval:

1. 18-0109\_MUSE\_Application-for-Protocol-Review\_Amendment, v 12\_21\_18
2. Change Form, no date
3. CONT Caregiver Quant\_Consent HIPAA\_FINAL 12.20.18\_clean.docx
4. NEW Caregiver Quant\_Consent HIPAA\_FINAL 12.20.18\_clean.docx
5. Personnel eForm PAM 1-3-15, v 12.21.18

The Application for Protocol Review includes a Full Waiver of Consent for parental consent, which was reviewed and determined to meet criteria for full waiver of consent.

COMIRB only stamps the approved versions of consent documents and local advertisements in the top right hand corner. Approved copies of the study documents are available for download via eRA(InfoEd).

If red-line changes were made, the tracked changes and clean versions have been uploaded into eRA (InfoEd). If the PI disagrees with these changes, submit a change form to COMIRB with the revised documents.



**Click here to your submission: [Submission Page](#)**

Please reply to the email containing this letter, contact the COMIRB Help Desk at [COMIRB@ucdenver.edu](mailto:COMIRB@ucdenver.edu) or call 303-724-1055 if you have questions or concerns.

Sincerely,

UCD Panel S