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)**

University Research
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
Aurora, Colorado 80045

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comirb@ucdenver.edu [E-Mail]
FWA00005070 [FWA]

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

SUBMISSION DESCRIPTION:

Initial expedited submission

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.

REVIEW DETAILS:

COMIRB staff has redlined in the COMIRB contact information in your verbal script parental consents.
The following documents have been reviewed as part of this approval:
18-0109 Signed IAAs
Application Form v. 3.26.18 with attachments A,F, G,H, J, M
Community Flyer v7 Design.pdf
Cover letter_v5.docx
Family Flyer v7 Design.pdf
MUSE Data Flow Diagram_v4.pptx
MUSE Email Templates_Staff Survey_Whitesell_18-0109.docx
MUSE Study Sites_Whitesell_18-0109_.pdf
MUSE Study Sites_Whitesell_18-0109_.pdf
MUSE VerbalParentalConsentScript_CONTINUING_v2 CLEAN.docx
MUSE VerbalParentalConsentScript_CONTINUING_v2 REDLINED.docx
MUSE VerbalParentalConsentScript_CONTINUING_v2 STAMPED.docx
MUSE VerbalParentalConsentScript_CONTINUING_v2.docx
MUSE VerbalParentalConsentScript_NEW_v2 CLEAN.docx
MUSE VerbalParentalConsentScript_NEW_v2 REDLINED.docx
MUSE VerbalParentalConsentScript_NEW_v2 STAMPED.docx
MUSE VerbalParentalConsentScript_NEW_v2.docx
MUSE_Ad Components Form_Whitesell_18-0109.docx
MUSE_Administrative Data Elements_Whitesell_18-0109.pdf
MUSE_CONT Caregiver Over 18 Quant_Consent HIPAA_Whitesell_18-0109_
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MUSE_Family Resources Check-In_Whitesell_18-0109.pdf
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MUSE_Implementation Logs_Whitesell_18-0109.pdf
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MUSE_Local Program Evaluator_Whitesell_18-0109.pdf
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MUSE_Participant 6 12 Month Follow-up Survey_Whitesell_18-0109.pdf
MUSE_Participant Baseline Survey_Whitesell_18-0109.pdf
MUSE_Participant Interview Questions_Whitesell_18-0109.pdf
MUSE_PI Oversight Plan_Whitesell (COMIRB #18-0109).pdf
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MUSE_Program Coordinator and Program Director Interview Questions_Whitesell_18-0109.pdf
MUSE_Program Coordinator-Manager Survey_Whitesell_18-0109.pdf
MUSE_Program Director Survey_Whitesell_18-0109.pdf
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MUSE_Qualitative_Professional_Consent HIPAA_Whitesell_18-0109_
MUSE_Rapid Reflect Caregiver Self-Completed Questionnaire_Whitesell_18-0109.pdf
MUSE_Rapid Reflect Home Visitor Self-Completed Questionnaire_Whitesell_18-0109.pdf
MUSE_Site Logos_Whitesell_18-0109.docx
MUSE_Study Protocol_Whitesell_18-0109.docx
Personnel Form (eForm) 1-3-15 v. 3.22.18
Staff Flyer v7 Design.pdf
Volume I Technical Proposal-MUSE 7-29-2016.pdf
Application for Protocol Review includes Attachment M: Waiver of Documentation of Consent—Determined to meet criteria for waiver of documentation of consent
Affiliated Site(s):
UCD Anschutz Medical Campus
Non-Affiliated Sites: 17

If this protocol requires full-board review and includes attachment C and/or D, the PI will be required to complete GCP training. COMIRB will begin enforcing this new requirement on 9/1/15. It is highly recommended that you complete this training as soon as possible to prevent delays on approvals after the 9/1/15 deadline.

For the duration of this research the investigator must:

- Submit any change in the research design, personnel, and any new or changed study documents (including new/changed consent forms, questionnaires, advertisements, ect.) to COMIRB and receive approval before implementing the changes.
- Use only a copy of the COMIRB-approved, stamped Consent and/or Assent Form. The investigator bears the responsibility for obtaining from all subjects "Informed Consent" as required by COMIRB. COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form after it is signed.
- Provide non-English speaking subjects with a certified translation of the approved Consent and/or Assent Form in

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.

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

University Research
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
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University of Colorado Hospital | Denver Health Medical Center | Colorado Prevention Center | Children's Hospital Colorado | Denver Health and Hospital Authority | VA Eastern Colorado Health Care System (Denver VAMC)

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

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

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 or call 303-724-1055 if you have questions or concerns.

Sincerely,

UCD Panel S