University Research
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

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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

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_ Choctaw.docx
MUSE_CONT Caregiver Over 18 Quant_Consent HIPAA_Whitesell_18-0109_ CSKT.docx
MUSE_CONT Caregiver Over 18 Quant_Consent HIPAA_Whitesell_18-0109_ EBCI.docx
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MUSE_CONT Caregiver Under 18 Quant_Consent HIPAA_Whitesell_18-0109_ White Earth.docx
MUSE_Family Resources Check-In_Whitesell_18-0109.pdf
MUSE_Home Visitor Interview Questions_Whitesell_18-0109.pdf
MUSE_Home Visitor Quant_Consent HIPAA_Whitesell_18-0109_ Choctaw.docx
MUSE_Home Visitor Quant_Consent HIPAA_Whitesell_18-0109_ CSKT.docx
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MUSE_Home Visitor Quant_Consent HIPAA_Whitesell_18-0109_ UIATF.docx
MUSE_Home Visitor Quant_Consent HIPAA_Whitesell_18-0109_ White Earth.docx
MUSE_Home Visitor Survey_Whitesell_18-0109.pdf
MUSE_Implementation Logs_Whitesell_18-0109.pdf
MUSE_IRB Authorization Agreement_Whitesell_18-0109_CSKT.pdf
MUSE_IRB Authorization Agreement_Whitesell_18-0109_Lake County.pdf
MUSE_IRB Authorization Agreement_Whitesell_18-0109_NAHC.pdf
MUSE_IRB Authorization Agreement_Whitesell_18-0109_Port Gamble.pdf
MUSE_IRB Authorization Agreement_Whitesell_18-0109_Riverside.pdf
MUSE_IRB Authorization Agreement_Whitesell_18-0109_SPIPA.pdf
MUSE_IRB Authorization Agreement_Whitesell_18-0109_UIATF.pdf
MUSE_Letter of Support_Whitesell_18-0109_Choctaw Nation of Oklahoma.pdf
MUSE_Letter of Support_Whitesell_18-0109_CSKT.pdf
MUSE_Letter of Support_Whitesell_18-0109_Eastern Band of Cherokee Indians.pdf
MUSE_Letter of Support_Whitesell_18-0109_Lake County.pdf
MUSE_Letter of Support_Whitesell_18-0109_NACHCI.pdf
MUSE_Letter of Support_Whitesell_18-0109_NAHC.pdf
MUSE_Letter of Support_Whitesell_18-0109_Navajo.pdf
MUSE_Letter of Support_Whitesell_18-0109_Port Gamble.pdf
MUSE_Letter of Support_Whitesell_18-0109_RSBCIHI.pdf
MUSE_Letter of Support_Whitesell_18-0109_Southcentral Foundation.pdf
MUSE_Letter of Support_Whitesell_18-0109_SPIPA.pdf
MUSE_Letter of Support_Whitesell_18-0109_Turtle Mountain.pdf
MUSE_Letter of Support_Whitesell_18-0109_UIATF.pdf
MUSE_Letter of Support_Whitesell_18-0109_White Earth.pdf
MUSE_Local Evaluator Interview_Whitesell_18-0109.pdf
MUSE_Local Program Evaluator_Whitesell_18-0109.pdf
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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_Qualitative_Professional_Consent HIPAA_Whitesell_18-0109_ White Earth.docx
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—Determinedto 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