

April 4, 2017

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95 Berkeley Street
Boston, MA 02116, United States

IRB#: 120170022

Sponsor Protocol Number: HHSP233201500040C

Study Title: Assessment of the Impact of Energy Development on Women's Behavioral Health in Eastern Montana and Western North Dakota

Notification of Approval

This is to inform you that New England Independent Review Board (NEIRB) has approved the following for the above referenced research.

Date of Review: 04/03/2017

Action Date (first day of study approval period): 04/03/2017

End Approval Date (last day that the study is approved): 04/02/2018

Approval Includes:

Investigator

Protocol (03-24-2017)

Consent Form NEIRB 1.0

Informed Consent Script - As Submitted #67728.0 - As Submitted

Intro letter for Key Informant Interviews - As Submitted #67726.0 - As Submitted

Stipend Receipt Form - As Submitted #67554.0 - As Submitted

Survey Instrument - #67727.0 - As Submitted

NEIRB's approval includes the following condition: The IRBs representing two tribal nations involved in the evaluation (Fort Peck and Fort Berthold) will also review this research and will have jurisdiction over participant recruitment, informed consent, data collection, and analysis components that will involve members of the tribal nations.

NEIRB has approved the following locations to be used in the research:

- Health Resources in Action, 95 Berkeley Street, Boston, Massachusetts 02116

Continued approval is conditional upon your compliance with the following requirements:

- Compliance with all aspects of NEIRB's Investigator Responsibilities (available at www.neirb.com).
- The study cannot continue after the End Approval Date unless re-approved by NEIRB. A Study Continuing Review Report must be completed and returned to NEIRB prior to the study end date of the approval period.
- Compliance with all federal, state and local laws pertaining to this research.
- Any and all necessary FDA approvals must be received prior to your initiation of the trial.

Please contact NEIRB with any questions about this determination.

Copy:

NEIRB study file

Enclosures

