

ATTACHMENT I: INFORMED CONSENT TO TAKE PART IN AN ASSESSMENT

TITLE OF ASSESSMENT: Assessment of the Impact of Energy Development on the Behavioral Health of Women in Western North Dakota and Eastern Montana

INVESTIGATOR: Heather Nelson, PhD, MPH
Director, Research and Evaluation
Health Resources in Action

PHONE NUMBER: (617) 279-2126

SPONSOR: U.S. Department of Health and Human Services, Office on Women's Health, Region VIII

What is the purpose of this form?

You are being asked to participate in a community assessment. It is important that you read the following explanation of the proposed procedures. This form describes the purpose, activities, benefits, and risks, of the assessment. It also describes your right to withdraw from the assessment at any time. A member of the assessment staff will read through the consent with you and discuss all the information. When you think you understand the assessment, you will then be asked if you agree to take part. If you agree, you will be asked to sign this consent form. Once you sign it, we will give you a signed and dated copy to keep.

Why is this assessment being done?

This assessment is being done to better understand women's behavioral health issues in Western North Dakota and Eastern Montana from the perspective of women and key community leaders.

What is being studied?

- What is known about:
 - the impact of rapid economic changes in rural and frontier communities on the behavioral health of women
 - the impact of the change in environment due to energy development on women's health
- What the current status is of women's behavioral health and what the existing data sources and gaps are related to women's behavioral health
- What behavioral health services are currently available to address the needs of women
- What the current concerns, needs and issues of women, providers, tribal, state, and local government officials and service agencies are related to women's behavioral health

You are being asked to be in this assessment because you are a woman living and/or working in the assessment geography.

What do you need to know about this assessment?

We will be holding 20 focus groups with 8-12 participants per group. About a total of 240 subjects will take part in this assessment across the assessment geography. The assessment will last for about 6 months. Your participation in the assessment will be about 90 minutes.

What will happen during this assessment?

During this assessment, you will:

- Participate in a 90-minute discussion about community and behavioral health issues
- The conversation in the focus group will be audio recorded and transcribed, but you will not be identified individually on the transcripts.

What are the potential risks of being in the assessment?

There are no anticipated possible risks of your involvement in this assessment. You may withdraw from this assessment at any time without penalty. Your name will not be on the transcripts of the focus group.

There is a potential risk of breach of confidentiality of focus group responses and assessment data; however, special precautions are taken to ensure confidentiality and voluntary participation.

Does being in this assessment provide any benefit?

You may or may not benefit from participating in this assessment.

Will it cost me anything to be in this assessment?

The only cost is to travel to the facility where the focus group is being held.

Will you be paid for being in this assessment?

You will receive \$25 for participating in this assessment.

Do you have to be in this assessment?

Your participation in this assessment is voluntary. You may stop your participation at any time.

Can you be removed from the assessment without your permission?

The investigator, sponsor, or New England IRB may decide at any time that you should no longer participate in this assessment.

Who will have access to your assessment information?

Records of your participation in this assessment will be held confidential so far as permitted by law. Any publication or presentation of the data will not identify you. Audio recordings, transcripts, and survey data will be stored for 7 years after the assessment is completed and then destroyed.

Who do you contact if I have questions about the assessment?

If you have questions or concerns about the assessment, you can contact Heather Nelson, PhD, MPH, Managing Director of Research and Evaluation, Health Resources in Action at (617) 279-2126.

If you have questions about your rights as a research subject, or other concerns about the research, you can contact NEIRB at 1-800-232-9570.

VOLUNTEER'S STATEMENT

You agree that you have been given a chance to ask questions about this research assessment. These questions have been answered to your satisfaction. You may contact **Heather Nelson, PhD, Director of Research and Evaluation, Health Resources in Action** if you have any more questions about taking part in this assessment. The company she is employed by is being paid by the sponsor for your participation in this assessment.

Your participation in this research project is voluntary. You may quit the assessment at any time. The investigator in charge of this assessment may decide at any time that you should no longer participate in this assessment.

By signing this form, you have not waived any of your legal rights.

You agree to participate in this assessment. You will be given a copy of this signed and dated form for your own records.

_____ Date
Assessment Participant (signature)

Print Participant's Name

_____ Date
Person who explained this assessment (signature)