Institutional Review Board (IRB)

Documentation & Guidance

What Principal Investigators Need to Know

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Most of the guidance and documentation for the North Dakota Department of Health IRB protocols and guidelines can be found in the U.S. Department of Health and Human Services' “Protection of Human Subjects” Title 45 handout, Part 46. This document can be found in Appendix A of this document.

Additional information can be found at the U.S. Department of Health and Human Services' website, located at: www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

Date: 3-5-2020

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Authority of the IRB

The Office of Human Research Protections (OHRP) of the U.S. Department of Human Services has secured a commitment from the North Dakota Department of Health (NDDoH) that all human research will be subject to the oversight of this agency to ensure the protection of human subjects. In addition, the North Dakota Department of Health agrees to provide the same level of commitment and oversight to all human subject project requests received by the North Dakota Department of Human Services (DHS).

OHRP acts to guide and assist this agency to protect the rights of human research subjects. IRB authority extends to all research on living human subjects. Public health practice and public benefit services are not considered research and can be released from oversight; however, many projects have characteristics of both. **AN INVESTIGATOR MAY NOT DECIDE FOR THEMSELVES IF A PROJECT CAN BE RELEASED FROM IRB OVERSIGHT.**

Certain projects may be released from NDDoH IRB oversight and/or from federal oversight. However, a project may qualify for release from federal oversight yet remain under the oversight of NDDoH IRB at the discretion of the NDDoH IRB, or the project may be released from all oversight. The investigator may apply to the board for a release from IRB oversight; however, no investigator may self-determine that a project can be released. Even though a project may be released from oversight does not mean that the investigator is released from departmental expectations to follow the current protection standards for human subjects or from standards for high quality science and value to the agency.

Research conducted by another institution which is using NDDoH or DHS confidential data is not subject to the NDDoH IRB (as long as there is not an NDDoH/DHS employee as a co-investigator), but is subject to the IRB of the other institution. The NDDoH and DHS have data release procedures which may involve securing proof that the other institution has approved the research before confidential data is released. This is a privacy issue that must go through the NDDoH or DHS privacy officer(s).

Research funded by NDDoH/DHS, but does not have a participating investigator from the agency, must still have had an IRB review (approval or release), but not necessarily by this agency.

The NDDoH Institutional Review Board also agrees to cover local public health IRB needs.
Projects Not Needing to be Submitted to the IRB*

1. Projects not including human subjects
2. Survey or interviews where information collected is on protocols, opinions or best practices
3. Projects using existing data from public sources

*Projects on certain vulnerable groups may alter these criteria (e.g., children, pregnant women, etc.) and will need to be submitted to the IRB for review.

The best rule of thumb is to check with the IRB Administrator before implementing your project.

The following document, “Preview Questionnaire”, will help you begin your IRB process. (See appendix B)
Overview

The charge of the IRB is to weigh risks and benefits of participation in research/studies and to protect the rights and welfare of the participants.

All research or studies involving human participants conducted by NDDoH/DHS employees must be reviewed and approved by the NDDoH Institutional Review Board (IRB) prior to beginning the project. The IRB will review and classify the project into one of three categories: Administrative Review, Expedited Review, or Full Board Review.

Submitting to IRB Review

Preview Questionnaire

The IRB application process starts with the submission of the Preview Questionnaire (Appendix B). This form, which is submitted to the IRB Administrator, will help determine if the study will require an IRB review.

Once the IRB administrator receives the Preview Questionnaire from the principal investigator (PI), the administrator will determine:

1) An IRB application is not necessary (this is considered an Administrative Review)
2) The PI will need to submit the full IRB application package. The PI will be notified by email of this decision within 10 business days.

IRB Application Package

If the administrator determines that the project requires IRB review, the PI will need to submit the full application package. The IRB application package consists of:

- IRB request form v5.0 (fillable pdf)
- Project narrative
- Consent forms
- Survey tools/data collection forms/questionnaires
- Other required materials

The IRB administrator previews the application to make sure all of the necessary materials are there for IRB review.

Once the package is complete, the administrator will determine if the project can be classified as: 1) Expedited Review or 2) Full IRB review.
Project Classification Types

Administrative Review

Upon review of the Preview Questionnaire, if the IRB administrator has determined that the project does not meet the human subject’s regulations, the PI will not need to submit the full IRB application package.

Expedited Review

Upon review of the application package, if the IRB administrator determines a project may not need full board review (as defined by the federal regulations [www.hhs.gov/ohrp/policy/expedited98.html], the administrator will contact the IRB chair. If both the administrator and chair agree that the project meets the federal regulations and does not need full board review, the PI will receive a letter from the IRB administrator indicating the status of the requested project. The letter will contain any information required by the chair and administrator including any modifications or clarifications.

Expedited review waives only the need for full IRB review. However, any changes to the expedited project are required to be submitted to the IRB administrator. This update is to ensure that the scope of the expedited project has not changed so significantly that it may now require full board review.

The authority to determine and confirm expedited status rests with the IRB and not with the PI.

Full Board Review

If the administrator determines that the project is in need of full IRB review, the project information will be forwarded to the board members for an initial review.

An email will be sent to the investigator providing the IRB project number assigned to the project, along with the date, time, and location of the board review.

It is expected that the PI will be available (either in-person, via video, or phone) to participate in the board’s discussion of the project. This will allow the board to ask questions, receive clarification on topics, etc.

Only projects that are within the scope of the DoH/DHS, and are well planned and ethically sound, will be considered. At the conclusion of this meeting, the board will indicate:

- Modifications needed to the protocol
- If there is a need for resubmission of materials
- If needed, how often the PI will need to come before the board to provide updates
- Any additional Board requirements
If there is a need for resubmission of materials and a reconvening of the board on this project, this will be determined at the end of the meeting as well. Once the board feels that all areas of concern (whether it is just additional information, changes to methodology, need for clearer guidance on informed consent, etc.) have been addressed they will determine whether to approve or deny the request.

Within 10 business days after the final meeting, the PI will receive a letter from the NDDoH IRB administrator detailing the outcome of the IRB meeting in regard to the submitted project.

**Expedited and Full Board Review - Decisions and Outcomes**

1. **IRB Approval**: The IRB has reviewed the project proposal and has determined that the project is sound and ethical. The project is approved as written or approved subject to modifications required by the board.
   - One of two outcomes may occur:
     - Approved/Exempted: The project was reviewed and it was determined to not be research, and therefore was exempted from IRB oversight.
     - Approved/Oversight: The project was reviewed and determined to be/not to be research, but because of the nature of the project, the board has determined the need for IRB oversight.

2. **IRB Tabled**: The IRB has reviewed the project proposal and has determined that the project is poorly written, not all documents are available, ethical questions arose, or it appears to be scientifically unsound. The IRB will table the project until changes can be provided that bring the project in compliance with federal regulations. The application will be reviewed at the next IRB meeting once the PI has resubmitted the revisions.
   - Once documents are resubmitted for review, they will go through the same review process as all projects and will be subject to another board review.
     - The review outcomes and the need for IRB oversight for these projects will be the same as any other project.

3. **IRB Deny**: Applications will be disapproved if they are determined to be ethically or scientifically unsound and there are no possible solutions for improvements. Additionally, projects that fall outside the scope of the health department or the department of human services may also be denied. Investigators are not advised to resubmit denied projects without consulting the IRB administrator or chair.
   - This is a rare – but possible – outcome.

**Updates and Annual Project Reviews**

For those projects needing full board review, all projects must be reviewed annually. **It is the responsibility of the principal investigator to ensure that the annual review is scheduled with the board.** The IRB administrator will work with the PI to ensure follow-up reviews occur. If it has been more than a year since the last approval, the project is no longer approved and must stop until board re-approval is obtained.
The investigator will have to appear before the board to provide an update on the following areas:

- A brief review of the project, including its purpose, methods, and a full description of procedures or data collection which pose risk to the participants, whether risk to health or confidentiality;
- A review of project progress including the number of subjects enrolled;
- Adverse or unanticipated events which may alter the risk to participants, and any reasons for any person’s withdrawing from the project;
- Review of complaints received about the project;
- Proposed modifications to the protocol;
- Any new results from this project, or other studies, which may reflect upon the risk to the participants;
- Review of the current informed consent document which is in use;

Any other questions will be at the discretion of the board members present at that time.

For those projects which carry a greater weight of political, community, or personal stigma or shame, it is most likely that the investigator will be required to update the board more often than annually on the status of this project.

Appealing the Board Decision

An investigator who is unhappy with the decision of the board may request from the chair or administrator, information regarding how to request an appeal and re-hearing by the board.

Reporting Problems/Requesting Project Modifications

What if a problem is encountered during the project?

The PI must promptly report to the IRB administrator or chair any Serious Adverse Event (SAE). An SAE is considered a serious or continuing non-compliance with federal regulations or NDDoH policies, any injuries (including death) to subjects, or unanticipated problems. For more information about what needs to be reported, visit www.hhs.gov/ohrp/policy/advevntguid.html.

For questions about reporting, contact the IRB administrator (Tracy Miller, dohstateepi@nd.gov).

If your protocol deviation is not an SAE and has already occurred, or if it is a proposed deviation (has not yet occurred), you may wait and report it with the next continuing review or include it as a change in the project.
When does a problem/event report need to be submitted?

Prompt reporting of unanticipated problems/events should occur as soon as possible after the PI learns of the event. All cases, excluding unexpected deaths of the participant, should be reported within 10 working days of the PI receiving the report. If the death of the participant is unexpected, it must be reported to the IRB within three working days of when the PI receives the report of death. If the death is in no way related to the project, deaths can be reported at the annual review.

What if the investigator wants to modify the project?

Once the application is submitted and reviewed, the project team can read it, but not make any changes unless the application is returned to the IRB by the PI. To change a currently approved project, the PI must submit a Change in Project request to the IRB administrator. The Change in Project (Appendix C) must be reviewed and approved by the IRB administrator, and, if necessary, the chair and/or Board, before the change can take effect.

Important Things to Remember

Projects/studies are categorized into two broad risk categories – minimal risk and greater-than-minimal risk.

A project which is minimal risk, as many public health studies are, may not receive as much scientific scrutiny as one which is greater-than-minimal risk; however, no risk is justifiable for a poorly designed project.

- Minimal risk is defined as: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.¹
- Studies that have greater-than-minimal risk may include, but are not limited to, studies where there is any disclosure of illegal activity, sexual attitudes, genetics, or religious beliefs. Also, any disclosure of mental health that could place participants at risk of criminal or civil liability, be damaging to the participants financial standing, or employability, insurability, reputation, or be stigmatizing to the participant. Additionally, any study that includes a vulnerable population may be viewed as coercion (e.g. boss/employee). Deception or incomplete disclosure, or medically invasive studies may also be viewed as greater-than-minimal risk. ⁷

Informed Consent

Informed consent shall be obtained from all participants in all investigations unless the board determines that the project meets conditions for waiver and agrees to the waiver. The board may waive the requirement for informed consent (or alter some or all of the required elements of informed consent) if all of the following conditions are met:
1. The project involves no more than minimal risk; and
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
3. The project could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, subjects will be provided with additional pertinent information after participation.

The board may waive the requirement for written consent (i.e., a signed consent form from each participant) in any of the following circumstances:

1. Project does not involve greater-than-minimal risk and no procedure is being performed for which consent is normally required outside of project.
2. In projects in which breach of confidentiality is the primary risk and the only information linking the subject to the project is the consent form. In this case, each subject shall be offered the opportunity of signing consent (with the knowledge of possible risks due to the linkage) or of refusing consent and still participating in the research. The participant’s wishes will govern.

See attached examples of two informed consents 1) one that does not require a signature and 2) one that does require a signature. They can be found in Appendix D and Appendix E.

Informed consent shall be in writing, signed by the participant, and a copy shall be given to the participant or legal representative. Oral consent which does not involve obtaining the signature of the participant or their legal representative is not acceptable unless the board has determined that the project meets OHRP approved criteria for waiver of written consent, as noted above.

The investigator must ensure that the person fully understands the project and the nature of his or her consent and his or her right to withdraw at any time. An interpreter must be used if the participant lacks English proficiency.

Characteristics of the informed consent document are as follows:

1. Simple language explaining
   i. That consent means they are consenting to participate in the project;
   ii. The purpose of the project;
   iii. Duration of participation;
   iv. Procedures to be followed; and
   v. Identification of experimental procedures. 46.116(a)
2. Description of reasonably foreseeable risks or discomfort to the participant;
3. Potential benefits, to participant or to others, which may be expected from the project;
4. Any alternative procedures or treatments available to the participant;
5. Description of confidential information, which will be recorded and maintained regarding the subject;
6. If greater-than-minimal risk
   i. Availability of compensation if injury occurs, and
   ii. The nature of available treatments for any injury that occurs;
   iii. Contact persons for
      1. Reporting injury arising from the project, and
2. Obtaining answers about the project and participant rights;

7. Statement that
   i. Participation is voluntary; and
   ii. Refusal to participate or termination of participation will not result in penalty or loss of benefit (except that which might have arisen as a direct result in participation), and
   iii. Participation may be terminated at any time;

When appropriate, the consent shall also contain the following:
1. Possible occurrence of unforeseen risks which could potentially harm the participant (and fetus or embryo if participant is pregnant);
2. Circumstances which may result in the investigator terminating the project;
3. Any additional costs that may result from participation;
4. Potential consequences of participant’s early withdrawal from the project, and how termination will be conducted to minimize any risk to the participant;
5. Statement of the impact of new information or findings which could affect the participants willingness to participate;
6. The approximate number of persons to be enrolled in the project.

Language in Consent Forms

Consents may not include any statement which attempts to absolve the PI of liability. Consent forms may also not include language that is coercive, threatening or have undue influence over the voluntariness of consent or cloud someone’s appreciation of risks. Additionally, it must be clear that choosing not to participate will not adversely affect an individual’s relationship with the institution or its staff or the provision of services in any way (e.g., loss of credits or access to programs).

The purpose behind the consent form is to help prospective participants in the study to understand the purpose, the procedures, the potential risks and benefits of their involvement, and their alternatives to participation.

Protection of Information Under the Law

Unless a Certificate of Confidentiality has been obtained from the National Institutes of Health (NIH), consent forms should say that the confidential information will be protected “to the extent allowable by law” since the PI does not have the authority to protect the information from a court of law. In certain instances (e.g. projects involving drug abuse or other highly sensitive information), a Certificate of Confidentiality may be requested from NIH to protect the information from all disclosure. These certificates are infrequently granted.
Compensation

Compensation is the payment or non-monetary reward given to subjects as payment for time, travel and inconvenience of participation, as well as an incentive to participate. Compensation can include monetary (cash, gift cards, vouchers, etc.) and/or non-monetary (gifts/promotional items, course credit, extra credit, etc.) remuneration.

It is not permissible to offer compensation that is excessive or inappropriate in order to obtain compliance. If the level of compensation could persuade subjects to participate in the project against their better judgment, this would be considered undue influence.

Additionally, compensation must not be contingent upon completion of study procedures. Even if the subject decides to withdraw from the study, he/she must be compensated, prorated based on the study procedures he/she has completed.

If compensation is offered, the IRB will work with the PI to either accept the suggested compensation listed in the application, or aid in the development of more appropriate and reasonable compensation.

High Risk Groups:

Projects Involving Children
For projects enrolling children as participants, additional requirements must be met:
1. Investigators must clearly state to the board the extent to which children will be involved in the project.
2. The board will require a thorough review of projects including any survey, interview or observation.
3. Any child who is capable of understanding the nature of the project in which they are being asked to participate, must agree to participate (i.e., provide assent). The child's assent to participate shall be witnessed by the person granting permission (e.g., parent or guardian). In obtaining permission from the parent or guardian, the investigator must make sure the person granting permission is also documenting that either
   i. The child can give and has given assent, or
   ii. The child cannot reasonably provide such assent.

The PI must provide the procedure to be used for determining a child's capability/inability of providing assent.

Projects Involving Pregnant Women
Projects involving women who are, or may become pregnant, receives special attention from IRBs because of women's additional health concerns during pregnancy and to avoid unnecessary risk to the fetus. The IRB will also determine when the informed consent of the father is necessary. Additionally, because of fetal involvement, the IRB will consider the need to prevent harm or injury to the fetus.
However, the IRB will consider inclusion of pregnant women in studies if there is a clear reason that pregnant women are important to the findings and a clear benefit is outlined.

**Projects Involving Fetuses**
If the delivered fetus is likely to survive to the point of sustaining life independently, it is designated as an infant and is thus subject to federal regulations governing research with children. Because the fetus shares a unique relationship with its mother and cannot consent to be a participant, special federal regulations are in place to guide fetal research.

It is highly unlikely the NDDoH IRB will approve fetal projects.

**Projects Involving Prisoners**
Unique protections are required for review of projects involving prisoners. The investigator should review the federal requirements and discuss them with the board chair or administrator. Note that these requirements take affect even if an enrolled participant who was not a prisoner at the time of enrollment, becomes a prisoner while participating in the project.

**Projects Involving Persons with Cognitive Impairment**
A person who is cognitively impaired is defined as having either a psychiatric disorder, an organic impairment, or a developmental disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Additionally, persons under the influence of or dependence on drugs or alcohol, terminally ill patients, and persons who have severe physical disabilities, may also be compromised in their ability to make decisions in their best interests.

Also, these individuals may be residents of institutions responsible for their care and treatment and this factor may compromise the individual's ability to truly volunteer to participate in the project. It is for these reasons that special protections are in place to ensure their rights.

When individuals are deemed unable to consent, the investigator and the IRB must consider state and local laws governing the selection of an appropriate representative to consent on behalf of these individuals.

**Projects Involving Persons with Impaired English Language Skills**
When enrolling non-English speaking subjects, investigators must have a plan to manage communications with the person during all phases of study participation. This communications plan must be described in the IRB application as part of the procedure used to obtain consent.

**Responsibilities of Investigators**

Investigators must:

a. Submit to the IRB administrator documentation requesting IRB review.

b. Attest that they have read and understood the requirements and expectations of IRB oversight. (outlined in this document)
c. When needed, obtain the consent and complete understanding of all project participants. Consent must conform to federal requirements. For children, this may include assent depending on the child’s understanding.

d. Protect all personally identifiable health information;

e. Minimize risks to the full extent possible;

f. Provide special protections for vulnerable populations consistent with federal regulations (children, pregnant women, prisoners, persons with disabilities, and those with impaired English language skills);

g. Report all complications of the project or changes in protocol to the IRB;

h. Report to the board all actions taken by another IRB regarding the project in question;

i. Provide to the board for review, all of the following documents at least two weeks in advance of the scheduled board meeting:

   a. Complete protocol describing the project;
   b. All data collection instruments to be used;
   c. All consent forms;
   d. An approved grant application, if one exists;
   e. A completed IRB review request form (available from IRB administrator);
   f. Any documents used for participant recruitment;
   g. Any reviews by other IRBs.

j. Label all documents with date and revision number

k. Ensure that IRB approval is up-to-date, given that IRB approval cannot be longer than one year without a new review. Additionally, the approval period may also be shorter than one year.

l. When IRB oversight is needed, make note of when to schedule your oversight review to ensure they occur on time.
Resources

3. University of California, Berkeley. cphs.berkeley.edu/compensation.pdf
Appendix A: HHS Protection of Human Subjects Title 45, Part 46

This document is a hyperlink. The document can also be found at:
Appendix B: Preview Questionnaire

DO NOT USE: Please use document located on website

Preview questionnaire to determine if you need to submit a project to IRB?

<table>
<thead>
<tr>
<th>PI Name:</th>
<th>Phone and Email:</th>
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<tbody>
<tr>
<td>Project Name:</td>
<td>Agency:</td>
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</table>

Please answer the following questions about your ND Department of Health (DoH) or ND Department of Human Services (DHS) project.

1. (DoH/DHS Employees only) Will you be actively participating in the requested study?  
   - Yes  
   - No
2. Are you requesting only data from DoH/DHS with no DoH/DHS participation?  
   - Yes  
   - No
3. Does your data contain information on deceased persons only?  
   - Yes  
   - No
4. Does your study use existing data only?  
   - Yes  
   - No
5. Does the study require any individual participant level data?  
   - Yes  
   - No
6. Does the data being collected contain any individual health information?  
   - Yes  
   - No
7. Are confidential identifiers needed?  
   - Yes  
   - No
8. Are two data sets being linked?  
   - Yes  
   - No
9. Is the study looking at sensitive information (HIV, adoptions, WIC, etc.)?  
   - Yes  
   - No
10. Is the study being performed to improve or evaluate a program or service in ND only?  
    - Yes  
    - No
11. Is the study looking only at program or policy information, data improvement options, opinions, satisfaction on topics or study ideas?  
    - Yes  
    - No

Provide a brief summary (paragraph or two) of 1) What the study is about, 2) Who are the participants, 3) why you are doing it, 4) purpose or intent of study and 5) the health department or human services’ role?

Once completed, email this form to the NCDoH IRB Administrator, Tracy K. Miller, PhD, MPH at tkmiller@nd.gov

DO NOT FILL OUT. IRB ADMINISTRATOR USE ONLY

☐ Does not need to be submitted to IRB; project can proceed.
☐ Needs Data Agreement/Submit to HIPAA compliance officer
☐ Needs to be submitted to IRB. Please fill out the appropriate paperwork located at: www.ndhealth.gov/IRB/

Revised: 1-10-2018, tkm
Appendix C: Change in Project Request

**DO NOT USE:** Please use document located on website

### Change in Project Request

<table>
<thead>
<tr>
<th>PI Name: __________________________</th>
<th>Phone and Email: __________________________</th>
</tr>
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<tbody>
<tr>
<td>Project Name: ____________________</td>
<td></td>
</tr>
</tbody>
</table>

Please answer the following questions and submit form to the IRB administrator at: tkmiller@nd.gov:

1. Has minor (proposed or involuntary) changes been made to your study?  
   - [ ] Yes  
   - [ ] No

2. Has major (proposed or involuntary) changes been made to your study?  
   - [ ] Yes  
   - [ ] No
   - dates, name of PI, etc.
   - additional years needed for historical data, groups/agencies backed out, etc.

3. Have substantial (proposed or involuntary) changes been made to your study?  
   - [ ] Yes  
   - [ ] No
   - Need to include children in study, need to modify collection protocol, etc.

Provide an in-depth review of the proposed and involuntary project changes (please feel free to add attachments as needed.)

Once completed, email this form to the NDDoH IRB Administrator, Tracy K. Miller, PhD, MPH at tkmiller@nd.gov

**DO NOT FILL OUT. IRB ADMINISTRATOR USE ONLY**

- [ ] Changes do not need to be reviewed by IRB; project can proceed.
- [ ] Changes need to be reviewed by IRB; project cannot proceed.

Revised: 1-2018, tkm
Appendix D: Informed Consent Without Signature

Important Information About PRAMS

Please Read Before Starting the Survey

- The Pregnancy Risk Assessment Monitoring System (PRAMS) is a research project sponsored by the Centers for Disease Control and Prevention (CDC) and the North Dakota Department of Health.
- The purpose of the study is to find out why some babies are born healthy and others are not.
- We are asking one of every 10 mothers in North Dakota to answer the same questions. Your name and address were picked by a computer from recent birth certificates.
- You are free to do the survey or not. If you don’t want to participate at all, or if you don’t want to answer a particular question, that’s okay. There is no penalty or loss of benefits for not participating or answering all questions. If you wish to be removed from the study, you may call us at 1-800-XXX-XXXX or write to us at the address provided on the return envelope and ask to be removed from the study.
- It takes about 20 minutes to answer all questions. Some questions may be sensitive, such as questions about smoking or drinking during pregnancy.
- Your survey may be combined with information the health department has about you from other sources to evaluate other public health programs.
- If you choose to do the survey, your answers will be kept private to the extent allowed by law and will be used only for research.
- If you are currently in a correctional facility, your participation in the study will have no effect on parole or your legal status within the criminal justice system and you may not receive an incentive or reward depending on the rules of the facility. When mailing your questionnaire back to us, it may be subject to monitoring based on the facility’s normal monitoring or supervision policies.
- Your name will not be on any reports from PRAMS or any other evaluations conducted with PRAMS data. The booklet has a number so we will know when it is returned.
- Your answers will be grouped with those from other women. What we learn from PRAMS will be used to plan programs to help mothers and babies in North Dakota.
- Completing the survey means that you give your consent to participate in PRAMS.

If you have questions about PRAMS, or if you want to answer the questions by telephone, please call the North Dakota PRAMS Project at 1-800-XXX-XXXX. The call is free.

The PRAMS Project was reviewed and approved by four Institutional Review Boards for Research with Human Subjects: North Dakota Department of Health, Tribal Nations Research Group, North Dakota State University (NDSU) and the CDC. If you have any questions about your rights in the project, please call the NDSU Human Research Protection Program at 701-XXX-XXXX or toll-free at 1-855-XXX-XXXX.
Appendix E: Informed Consent With Signature

Consent to Participate in Research
North Dakota Department of Health Focus Groups

WHAT IS THE PURPOSE OF THIS STUDY?
You are invited to participate in a research study about the different ways women access health information (i.e., radio, TV, friends, relatives, newspapers, providers, educational materials) and the types of messages that encourage women to be screen for breast and cervical cancer.

HOW LONG WILL I BE IN THIS STUDY?
If you decide to take part, the focus group interview will last no more than two hours.

WHAT WILL HAPPEN DURING THIS STUDY?
You will be asked a series of questions in a group setting. We will ask about your thoughts, feelings, and experiences about sources of health information, women’s health information, and messages to promote cancer screening, in addition to your opinion of North Dakota Department of Health’s (NDDoH) educational material. You may choose whether or not to answer any of the questions posed, withdraw from the focus group, and leave at any time. The group interview will be audio recorded, however you have the right to ask that certain information not be recorded.

WHAT ARE THE RISKS OF THE STUDY?
There is a risk that your participation in this study may become known and the information you share could be seen or heard by someone other than the researcher. This may cause embarrassment or stress. However, many steps are taken to make sure your identity stays private. All data and identifiers will be stored and secured from unapproved access or disclosure.

Additionally, some of the questions I ask may cause worry, embarrassment, discomfort, or sadness. You may choose not to answer any question you do not want to. You can end the interview at any time. Referrals to counseling will be available should you experience bad feelings, but no money is available to pay for such services.

WHAT ARE THE BENEFITS OF THE STUDY?
There will be no immediate benefit to you for taking part in this study. Your help in this research may benefit you or other people in the future by helping us learn how women get their health information and how well they understand the information about cancer screening. This information may lead to changes in the NDDoH’s communication and outreach to the general public.

WILL I BE PAID FOR PARTICIPATING?
Participants who attend and remain until the group interview is finished will receive a $50 gift card. Participants who elect to leave prior to the end of the session will receive payment dependent on the amount of time spent in the group.
CONFIDENTIALITY
The records of this study will be kept private to the extent permitted by law. This means that any data containing information that can identify you will not be shared, disclosed, or accessed by anyone other than the researcher except if subpoenaed by a court of law. Any information collected during this study that can identify you will remain private. It will be disclosed only with your permission or as required by law.

The researcher will have sole access to private data. All other NDOH/research staff will only have access to data that cannot be linked to you.

No private information (information that can identify you) will be collected other than the audio recordings of the interview and the demographic form. Other than your zip code, no information regarding your location will be kept.

In any report about this study that might be published, you will not be identified. Information learned from this study will be used to improve the NDOH programs. Additionally, no information presented in scientific journal articles, oral presentations, or used to train NDOH employees will identify you personally.

If you choose to participate in the focus group session, you also have an obligation to respect the privacy of the other members of the group by not disclosing any personal information that they share during our discussion.

CONTACTS AND QUESTIONS
Contractor X is conducting these focus groups on behalf of the NDOH.

You may ask any questions you have now. If you later have questions, concerns, or complaints about the study, please contact Someone by phone at (701) 328-XXXX or email soone@nd.gov. You may also contact Someone Else, at (701) 328-XXXX or selse@nd.gov.

If you have questions about your rights as a research subject, you may contact the North Dakota Department of Health Institutional Review Board at (701) 328-XXXX.
- You may also call this number about any problems, complaints, or concerns you have about this research study.
- You may also call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.
Authorization to participate in the research study:

I give consent to be audiotaped during this study.
Please initial: ______ Yes ______ No

I give consent for my quotes to be used in the research; however I will not be identified.
Please initial: ______ Yes ______ No

Your signature indicates that you have read and understand the purpose, risk, and benefits of this research study, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

________________________________________
Participant’s Name (please print)

________________________________________
Signature of Participant

 ______ 
 Date

________________________________________
Signature of Person Obtaining Consent

 ______ 
 Date