NORTH DAKOTA DEPARTMENT of HEALTH

Instructions for Completing the IRB REQUEST form.

Please read through these instructions prior to filling out the form so that you will have all necessary information gathered. Then use these instructions to help you fill out the IRB Request Form.

Please note: EVERY IRB Submission Packet MUST include the Request Form, a narrative of the project (please see the suggested narrative template), and any additional documents such as consent forms, survey tools, other institutions IRB determination, etc.

Log #: This is for administrative use only for tracking the request.
Orange Box: You must indicate in this box who your project is with
Name of Project: Provide a name that will uniquely identify the project.
Date of Application: Self-explanatory
Principal Investigator for Project: Name of the principal investigator who will be responsible for conduct or oversight of the project. Generally, this will be the person completing this form.
Email/Phone: email and phone number of principal investigator
Agency/Dept: Name of the agency or department where the principal investigator works.
Agency Involvement: Check the box marking how, if at all, is the ND Dept of Health (DoH) or ND Dept of Human Services (DHS) involved in this project.
Role of Employees: If the DoH/DHS is involved, explain how the Employee will be included. Roles may include one or more of the following:

- Primary investigator
- Contributory researcher
- Student Mentor
- Data provider
- Analyst
- Contractor (provider of pass-through money)

Not all roles will make the project subject to IRB oversight; however, this is a determination for the board to make.

Questions

1. The inclusion of persons who belong to a vulnerable population as research subjects affects how the IRB evaluates a program. For existing data sets, the researcher may not always know if the existing data includes persons belonging to one of these groups. In that case answer "Don't know" (DK) and provide an explanation in question box marked 1a.

   If the investigation involves the recruitment of subjects and these vulnerable categories are not specifically excluded, then it can be assumed that the study may include vulnerable persons in one or more of these categories. In that case answer "Yes" to any of the people populations that are not specifically excluded from your recruitment efforts.

   Of particular concern are children and prisoners. These categories have special protections in the regulations that must be met. Room is provided on the form for the investigator to provide additional detail, additionally, detail can be provided in the accompanying documentation.

2. Confidential identifiers include any information that uniquely identifiers a person or their personal residence (e.g., phone number, street address). For example, a person's name uniquely identifies a person but date of birth does not (although it may in a small population such as a classroom). The listed examples do not represent all possible confidential identifiers. For example, when using vital statistics, if certificate number is included, it would be a confidential identifier. If the investigator does not have the key (e.g., ability to identify a person from their unique number), still answer "Yes." The board will need to explore this issue in more detail.

3. Biological specimens include any material that contains a person's DNA regardless of how it is collected. Retention of any biological specimens after the study or testing for HIV require special considerations.

4. Pilot studies are small, preliminary studies done to consider feasibility and methodology for a larger study. For purposes of the IRB, pilot studies are treated like full studies.

5. Use of an investigational drug or device as part of the research automatically puts the study outside the bounds of research approved by DoH/DHS. This does not mean an investigational drug or device cannot be used for treatment in an emergency under FDA special provisions. However, it may not be used in DoH/DHS research.

6. The investigator may request that the project be released based on criteria set by the federal regulations. Multiple reasons can be selected for consideration. Only the board or its designee can determine whether the criteria for release are actually met. In addition, a project may meet criteria for release but still be retained under the authority of the board at the board's discretion.

   STEP 1:

   Mark this box if you feel this is not research and part of regular public health practice. However, the determination that an investigation is not research (that is, public health practice only) can be difficult and the criteria can be complex. The board has been trained and will make the final determination.

   STEP 2:

   i. If all persons are deceased, the project <u>may</u> be released. However, North Dakota considers identified death data to be confidential, whereas the federal government does not. The board may elect to have continued oversight even though it is released from federal oversight.
   ii. Some observational studies may be released under STEP 2, but no interaction with the research subjects may occur. The board does not require projects limited to analysis of a de-identified data set to be reviewed and approved by the board.

   STEP 3:

   i. The definition of a public benefit program is restrictive. See the footnote on the form for the working definition.
   ii. Data that is recorded from confidential records without collecting any identifiers <u>may</u> be released (e.g., results of immunization record review without recording any identifiers). If a coded identifier is recorded (e.g., a download of birth data including birth certificate number), the board will have to consider the potential for the code to be broken. If the code key resides in DoH/DHS, a determination that the code cannot be

broken will be difficult to justify. An MOU between DoH/DHS and an outside entity that the code will not be broken for the investigator is the strongest assurance of code security.

iii. Judgment of what may or may not be harmful if revealed is subjective. The final decision will be made by the board. Note that any interaction with children may prevent release of the project by the board.

iv. Although this is a common reason why IRB oversight is waived, these projects must still be submitted to the board for review. Note that any interaction with children may prevent release of the project by the board.

7. One of the core principles of human research protection is that participants have the right to consent or not consent to participate. If the board determines that the project is subject to federal human subject's regulation, the researcher has the option to request that the project not be required to obtain informed consent from participants. Release from consent requirements is not given lightly, even if the investigation only involves use of existing data. Detailed protocols are required for all projects that are subject to human subject's regulation and must justify a waiver of consent providing evidence that ALL four criteria have been met.

8. The standard practice for obtaining consent is to document it in writing. Occasionally this is impractical or the documentation poses a risk to the participant. The researcher may request that written consent be waived. Detailed protocols are required for all projects that are subject to human subject's regulation and must justify a waiver of written consent providing evidence that at least one of the two criteria has been met.

You are required to submit documentation with your request. If the documentation is incomplete, it will delay approval of your project. More detail is provided in the document "IRB Documentation and Guidance" which investigators are required to verify that they have read.

Completed submission packets should be submitted to the IRB administrator, Tracy K. Miller, PhD at tkmiller@nd.gov.