review guide

|  |
| --- |
| Date:  Assigned Reviewer(s):  Investigator/Department:  Protocol #:       Title:  Review Category:  Due Date: |

**The research protocol noted above is:** Approved   
 Approved with conditions (see comments)   
 Deferred; protocol contains insufficient information   
 Refer for full board review

**Waiver or Alteration of Informed Consent:**

Not applicable

Approved

Not Approved (see comments)

**Waiver of Documentation of Informed Consent:**

Not applicable

Approved

Not Approved (see comments)

**Research with Children:**

Not applicable

Adequate provisions will be made for soliciting the assent of the children (unless a waiver is appropriate)

Adequate provisions will be made for soliciting the permission of each child’s parent or guardian (unless waived)

The research is approvable under the following category:

46 CFR 46.404 - Research not involving greater than minimal risk to children.

**Funding**:

Yes, the protocol has received external funding.

No external funding

If yes, the grant/funding proposal or report is consistent with the human subjects activities described on the IRB protocol:

Yes  No, additional approval or amendment will be required

**Review conducted by:** **Date:**

**Comments:**

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **Please check as applicable** | **Criteria for Approval**  **§\_\_\_.111** |
| Yes  No  N/A | 1. Risks to subjects are minimized: 2. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk; 3. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. |
| Yes  No  N/A | 1. 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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished form risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. |
| Yes  No  N/A | Categorize potential risk level:  no more than minimal risk  more than minimal risk:  minor increase over minimal risk, or  more than a minor increase over minimal risk  Categorize potential benefits:  no prospect of direct benefit to individuals, but is likely to yield generalizable knowledge.  prospect of direct benefit to individuals  Minimal risk: 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. |
| Yes  No  N/A | 1. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. |
| Yes  No  N/A | 1. 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 §\_\_\_.116. |
| Yes  No  N/A | The Informed consent contains the appropriate [required elements](https://www.ndsu.edu/research/integrity_compliance/irb/resources/consent_resources/):   1. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. 2. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate.   ([Click here for a list of Required Elements of Informed Consent](https://www.ndsu.edu/research/integrity_compliance/irb/resources/consent_resources/)). |
| Yes  No  N/A | (5) Documentation of Informed Consent. Informed consent will be appropriately documented or appropriately waived in accordance with §\_\_\_.117. |
| Yes  No  N/A | (6) Data Monitoring. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. |
| Yes  No  N/A | (7) Privacy and Confidentiality. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. |
| Yes  No  N/A | Coercion and Undue Influence. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. |

# Elements of Informed Consent

|  |  |
| --- | --- |
| **Please check as applicable** | **Basic Elements of Informed Consent**  **§\_\_\_.116(b)** |
| Yes  No  N/A | (1)   A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental; |
| Yes  No  N/A | (2)  A description of any reasonably foreseeable risks or discomforts to the subject; |
| Yes  No  N/A | (3)  A description of any benefits to the subject or to others that may reasonably be expected from the research; |
| Yes  No  N/A | (4)   A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; |
| Yes  No  N/A | (5)   A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; |
| Yes  No  N/A | (6)   For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; |
| Yes  No  N/A | (7)  An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject; |
| Yes  No  N/A | (8)  A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subjects is otherwise entitled; and |
| Yes  No  N/A | (9)  One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:  a.       A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for further research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or  b.       A statement that subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. |

|  |  |
| --- | --- |
| **Please check as applicable** | **Additional Elements of Informed Consent**  **§\_\_\_.116(c)** |
| Yes  No  N/A | (1)     A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable; |
| Yes  No  N/A | (2)     Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s or the legally authorized representative’s consent; |
| Yes  No  N/A | (3)     Any additional costs to the subject that may result from participation in the research; |
| Yes  No  N/A | (4)     The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject; |
| Yes  No  N/A | (5)     A statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject; |
| Yes  No  N/A | (6)     The approximate number of subjects involved in the study; |
| Yes  No  N/A | (7)     A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; |
| Yes  No  N/A | (8)     A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and |
| Yes  No  N/A | (9)     For research involving biospecimens, whether the research will (if known), or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen. |

# Waivers, Alterations and Exceptions to Informed Consent

|  |  |
| --- | --- |
| **Please check as applicable** | **Criteria for Waiver or Alteration of Consent**  **§\_\_\_.116(e)(3)**  **N/A** |
| Yes  No | (i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate or otherwise examine: |
| Yes  No | 1. Public benefit of service programs, |
| Yes  No | 1. Procedures for obtaining benefits or services under those programs, |
| Yes  No | 1. Possible changes in or alternatives to those programs and procedures, **or** |
| Yes  No | 1. Possible changes in method or levels of payment for benefits or services under those programs, AND |
| Yes  No | (ii) the research could not practicable be carried out without the waiver or alteration. |

|  |  |
| --- | --- |
| **Please check as applicable** | **Screening, recruiting, or determining eligibility**  **§\_\_\_.116(g)**  **N/A** |
| *An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:* | |
| Yes  No | 1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or |
| Yes  No | 1. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. |

|  |  |
| --- | --- |
|  | **Criteria for Waiver or Alteration of Consent**  **§\_\_\_.116(f)**  **N/A** |
| Yes  No | (i) The research involves no more than minimal risk to the subjects |
| Yes  No | (ii) The research could not practicably be carried out without the requested waiver or alteration; |
| Yes  No | (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; |
| Yes  No | (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and |
| Yes  No | (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. |

|  |  |
| --- | --- |
| **Check if applicable**  **(Select only 1)** | **Criteria for Waiver of Documentation**  **§\_\_\_.117**  **N/A** |
|  | (i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; |
|  | (ii) That the research presents no more than minimal risk of harm so subjects and involves no procedures for which written consent is normally required outside of the research context; or |
|  | (iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. |