2 Applicability:
2.2 NDSU Engagement in Human Subjects Research

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Human subjects research projects, regardless of source of funding or support, in which NDSU employees or agents are 'engaged' require prospective IRB review and oversight under the human research protection program. Such projects may be under the direction of NDSU researchers, or researchers from another institution.

1.0 Engagement in human subjects research.

Based on federal guidance, NDSU has defined specific research activities and responsibilities which constitute 'engagement' on the part of an institution's employees or agents. Human subjects research projects in which NDSU is considered 'engaged' require NDSU IRB review, unless arrangements are made for cooperative review of collaborative projects.

1.1 Engaged in research.

An institution or entity is considered to be engaged in human subjects research when their employees or agents perform any of the following:

1.1.1 Receive a direct award, grant or contract for human subjects research.

1.1.2 Direct or supervise the human subjects research project.

1.1.3 Intervene with participants for research purposes by performing invasive or noninvasive procedures. *(Exceptions – when an institution's activities are limited to those described in 1.2.1 – 1.2.4 below, the institution is not engaged).* Examples may include, but are not limited to:

- administering counseling or psychotherapy
- drawing blood
- obtaining buccal mucosa cells using a cotton swab
- administering drugs or other treatment
- utilizing physical sensors, or other measurement procedures

1.1.4 Intervene with participants for research purposes by manipulating the environment. *(Exceptions – when an institution's activities are limited to those described in 1.2.1 – 1.2.4 below, the institution is not engaged).* Examples may include:

- controlling environmental light, sound, or temperature
- presenting sensory stimuli
- orchestrating environmental events or social interactions

1.1.5 Interact with participants for research purposes. *(Exceptions – when an institution's activities are limited to those described in 1.2.1 – 1.2.4 below, the institution is not engaged).* Examples may include, but are not limited to:

- engaging in protocol dictated communication or interpersonal contact

- asking someone to provide a specimen by voiding or spitting into a container
- conducting research interviews
- administering questionnaires

1.1.5 Obtain informed consent of human subjects for non-exempt research. *(Exceptions – when an institution's activities are limited to those described in 1.2.3 – 1.2.4 below, the institution is not engaged).*

1.1.6 Obtain for research purposes private information or identifiable specimens **from any source** for research purposes. It is important to note, that in general institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the institution's employees or agents do not directly interact or intervene with the human subjects. *(Exceptions – when an institution's activities are limited to those described in 1.2.1, 1.2.6, and 1.2.8 below, the institution is not engaged).* Examples may include, but are not limited to:

- observing or recording private behavior
- using, studying or analyzing private identifiable information or specimens provided by another institution
- using, studying or analyzing private identifiable information or specimens already in the possession of the investigator(s).

In general, private information or specimens are considered individually identifiable when they can be linked to specific individual by the investigator(s) either directly or indirectly through coding systems.

1.1.7 Utilize private information or human specimens (including de-identified materials) from any source for research subject to FDA regulations. This would include clinical investigations performed to assess the efficacy and/or safety of an FDA-regulated article (drug, biologic, medical device or other article regulated by the FDA). Refer to *11.5 FDA-Regulated Research* for more information.

1.2 Not engaged in research.

When the involvement of an institution's employees or agents is *limited* to one or more of the following activities, the institution is considered NOT engaged in human subjects research:

1.2.1 Perform commercial or other services for investigators, provided that:

- services do not merit professional recognition or publication privileges,
- services are typically performed for non-research purposes, and
- employees or agents do not administer any research intervention being evaluated under the protocol.

Some examples of services may include: an appropriately qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service, a transcription company whose employees transcribe research study interviews as a commercial service, a hospital whose employees obtain blood

through a blood draw or collect urine and provide such specimens to investigators as a service, data collection or analysis performed by a survey firm.

1.2.2 Institution's (e.g., schools, nursing homes, business) that permit use of facilities to allow another institution's investigators to intervene or interact with subjects by investigators from another institution.

1.2.3 Institution's whose employees or agents:

a) Inform prospective subjects about the availability of research,
b) Provide prospective subjects with information about research (may include a consent document or other IRB-approved materials) or contact information for investigators; provided they do not obtain consent or act as a representative for the research.
c) Provide prospective subjects with information about contacting investigators for information or enrollment,
d) Seek or obtain the prospective subjects' permission for investigators to contact them.

1.2.5 Release of identifiable private information or identifiable biological specimens pertaining to a research subject to an investigator at another institution.

Note that in some cases, releasing identifiable private information or identifiable biological specimens may have institutional requirements that would need to be satisfied before the information or specimens may be released, and/or may need to comply with other applicable regulations or laws, (e.g., HIPAA or FERPA). In addition, if the identifiable private information or identifiable biological specimens to be released were collected for another research study, the institution releasing the information/specimens should:

a) ensure that the release would not violate the informed consent provided by the subjects to whom the information or biological specimens pertain, or
b) if informed consent was waived by the IRB, ensure that the release would be consistent with the IRB's determinations that permitted a waiver of informed consent.

1.2.6 Access or utilize identifiable private information only while visiting an institution engaged in the research (provided that their IRB has approved the study).

1.2.7 Author a paper, journal article, or presentation describing a human subjects research study.

1.2.8 Obtain de-identified or coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information, and

- the NDSU investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
    - the NDSU investigator(s) and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances,

- the releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the key to the NDSU investigator(s) under any circumstances, or
- there are other legal requirements prohibiting the release of the key to the NDSU investigators.

The IRB has final authority to determine whether the use of private information or human biological specimens from living individuals constitutes NDSU engagement in human subjects research. A protocol form or other documentation is generally required; consult the IRB office for more information.

There may be additional scenarios that describe the types of involvement that would not engage NDSU in human subjects research. If a particular type of involvement is not described here, consult the IRB office to determine requirements for IRB review.

2.0 NDSU-directed research.

Human subjects research directed or supervised by an employee or agent of NDSU as PI constitutes engagement of the institution.

2.1 NDSU as primary awardee.

When NDSU receives a direct award to fund a human subjects research project, the institution is considered engaged in human subjects research. This is true even when the research is conducted elsewhere by non-NDSU employees or agents, or under the direct supervision of a non-NDSU employee.

2.2 Research initiated at another institution.

When research initiated at an NDSU employee's former institution will continue at NDSU, the institution may or may not be considered engaged in human subjects research. NDSU IRB review is required when NDSU employees or agents will perform activities constituting engagement, as described in Section 1. Cooperative IRB review arrangements may be possible; consult IRB staff for specific requirements.

2.3 NDSU faculty performing private consulting services

NDSU is not engaged in research when its employees or agents provide external consulting services that will not be used for any NDSU purpose or NDSU publication. Such activities do not require IRB review or oversight.

3.0 Cooperative research.

Human subjects research may involve the assistance or collaboration of multiple research institutions or other entities. The role of each entity in human subjects research will determine any requirements for training, IRB review, and signed agreements.

3.1 Projects directed or supervised by NDSU.

When a cooperative research project is under the direction and supervision of an NDSU employee or agent as PI, review by the NDSU IRB is required, unless cooperative review arrangements are made. For more information refer to SOP *2.3 Collaborative, Multi-site and Off-site Research.*

3.2 Project directed or supervised by a non-NDSU entity.

NDSU employees or agents may provide assistance or collaborate on research under the direction and supervision of a PI from another institution. When such involvement constitutes NDSU 'engagement' in human subjects research, NDSU IRB review is required, unless cooperative review arrangements are made.

4.0 IRB review.

Human subjects research projects involving the engagement of NDSU employees or agents are under the jurisdiction of the NDSU IRB. Refer to SOP *Section 7 IRB Review Process* for more information. NDSU IRB may enter into cooperative review arrangements (e.g. reliance agreements or IRB Authorization agreements) when research involves another institution. Refer to SOP *2.3 Collaborative, Multi-site, and Off-Site Research* for more information.

5.0 Investigator training.

NDSU employees and agents performing activities that constitute 'engagement' in research are required to complete appropriate human subjects protection training. Refer to SOP *5.3 Training, Education and Outreach: Research investigators and team members* for more information.

6.0 IRB determination of NDSU engagement.

An investigator may request a written determination from the IRB regarding whether or not a particular project constitutes the engagement of NDSU in human subjects research. A determination from the IRB is generally not required, with the exception of some uses of existing data or specimens. Refer to SOP *11.2 Human Biological Specimens* and *11.3 Secondary Analysis of Existing Data* for more information.

When requesting a determination from the IRB, submit a written description of the project including:

- a description of the intended purpose and goals of the project
- specific role of any NDSU faculty, staff, or student
- cite the section(s) concerning engagement (section 1.0) that may be relevant to NDSU's involvement in the project
- describe role(s) of any other entities

DEFINITIONS:

Employees or agents: an institution's employees or agents are individuals who: 1) act on behalf of the institution, 2) exercise institutional authority or responsibility, or 3) perform institutionally designated activities. Such individuals may be staff, students, contractors, or volunteers, among others, regardless of whether they are receiving compensation.

Cooperative research: research projects involving more than one institution (also known as collaborative research).

Performance site: physical location where research procedures are performed.

Anonymized (de-identified): identifiers were originally collected, but have been irreversibly removed from previously identified samples or data; an individual can no longer be identified or linked with their information

Anonymous: no identifiable information exists; individual identity cannot be known or deduced, no possibility of linkage with additional information or future data collection

Coded: 1) identifiable information has been replaced with a number, letter, symbol, or combination thereof (e.g., the code); and 2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens

Individually identifiable: the identity of the subject is or may be readily ascertained or associated with the information; data can be linked to specific individuals either directly or indirectly through coding systems. Would also include some demographic information, or other unique information or key details that would allow individual identification to be deduced (e.g., using internet search engines or other means).

Investigator: anyone involved in conducting the research; e.g., study design or supervision, data collection, obtaining informed consent, performing research procedures, obtaining coded private information or specimens, analyzing data (note that this would *not* include someone whose sole role is providing coded private information or specimens to an investigator).

Interaction: includes communication or interpersonal contact between investigator and subject.

Intervention: includes both physical procedures by which data are gathered, and manipulations of the subject or their environment that are performed for research purposes.

Obtaining: receiving or accessing identifiable private information for research purposes; includes an investigator's use, study, or analysis for research purposes of identifiable private information already in the possession of the investigator.

Private information: information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (e.g., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. *The IRB has the sole authority to determine whether or not a research project constitutes the involvement of human subjects.*

REFERENCES:

45 CFR 46.101 To what does this policy apply? and 21 CFR 50.1 Scope
45 CFR 46.102 and 21 CFR 50.3 Definitions
45 CFR 46.103 Assuring compliance with this policy
OHRP Correspondence: Determining When Institutions are Engaged in Research
OHRP FAQs: FWA
Terms of FederalWide Assurance
OHRP Guidance on Engagement of Institutions in Human Subjects Research

RELATED HRPP SECTIONS:

2.1 Human Subjects Research
2.3 Collaborative, Multi-site and Off-site Research
5.3 Training, Education and Outreach: Research investigators and research team
Section 7 IRB Review Process
11.1 Use of Confidential Records
11.2 Human Biological Specimens
11.3 Secondary Analysis of Existing Data