

NDSU projects, regardless of source of funding or support, that meet regulatory definitions of 'research' involving 'human subjects' require prospective IRB review and ongoing oversight under the human research protection program. NDSU has provided a formal guarantee to the Office of Human Research Protections, that it will follow procedures which will assure the protection of all human participants involved in Federally-Funded research projects. To ensure equivalent protections to all human research participants, the NDSU IRB procedures also apply to all such research conducted by faculty, staff, or students, or other representatives of the University, whether or not the research is sponsored by agencies of the U.S. Government.

1.0 Research.

NDSU utilizes the US Dept. of Health and Human Services (HHS) definition of research, except when Food and Drug Administration (FDA) regulations apply (i.e. for research involving products regulated by the FDA).

'Research' is defined as:

- **HHS:** a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- **FDA:** any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA...or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. *Note: The FDA uses the term 'clinical investigation' to describe 'Research' activities.*

A research project may involve experimental or non-standard interventions, random assignment to compare outcomes, or activities not usually performed as part of standard operating procedures.

1.1 Generalizability.

A key characteristic of research, as defined by these regulations, includes an intention to contribute to generalizable knowledge. That is, the results or outcome from a study on one program, population, or situation will be broadly applied to draw conclusions, or make recommendations about other programs, populations or situations.

1.2 Dual- or multi-purpose projects.

Research may be conducted as part of a larger project, or as a secondary goal of a project performed primarily for other purposes (e.g., service, education, or program evaluation). Projects involving research, in whole or in part, are subject to policies for the protection of research subjects, including IRB review and oversight.

1.3 Internal evaluations, assessments, and customer polls.

Some projects are conducted for the sole purpose of evaluating or assessing a particular program or procedure to measure quality, or improve customer service, for example. Such projects may employ data collection procedures similar to those used in research (e.g., surveys or interviews). Projects conducted for the sole purpose of evaluating or measuring a particular program or procedure generally do not constitute 'research' as defined by HHS

and FDA regulations. However, such programs may sometimes include 'research' when the results are also intended to be used to contribute to generalizable knowledge. Prospective IRB review and oversight is required even when 'research' is a secondary goal of such projects.

1.4 Course assignments.

Course instructors may assign projects to their students that involve collection of information about individuals (e.g., a research methods course). When data and results of these assignments are not intended to be used outside of the classroom, they generally do not constitute 'research' as defined by HHS and FDA regulations. However, when the data and results are intended to be used for other purposes (e.g., an instructor's publication, or a student's thesis/dissertation), the project would constitute 'research' and require prospective IRB review and oversight.

2.0 Human subject.

NDSU utilizes the HHS definition of human subjects, except where FDA regulations apply (i.e. for research involving products regulated by the FDA). See Section 2.3 for more information.

2.1 Human subject (HHS):

A living individual, about whom, an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

2.1.1 Intervention.

A research project may involve human subjects when an investigator intervenes with individuals for research purposes.

2.1.1.1 Intervention may involve invasive or noninvasive procedures. This may include, but is 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

2.1.1.2 Intervention may occur through manipulation of the subject, or their environment. This may include, but is not limited to:

- controlling environmental light, sound, or temperature
- presenting sensory stimuli
- orchestrating environmental events or social interactions
- implementing an educational initiative
- redesigning a curriculum

2.1.2 Interaction.

A research project may involve human subjects when an investigator interacts with individuals for research purposes. This may include, but is 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

2.1.3 Identifiable private information or identifiable biospecimens.

A research project may involve human subjects when an investigator obtains private information or identifiable biospecimens for research purposes. This may or may not involve direct interaction or intervention with subjects. Examples would include, but are not limited to:

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

The IRB has final authority to determine whether use of private information or human specimens from living individuals constitutes human subjects research. A protocol form or other documentation is generally required; consult the Human Research Protection Program (HRPP) office for more information.

2.2 Applications.

2.2.1 Surveys.

Many research surveys meet the definition above as involving 'human subjects' because information is collected 'about' individuals. This includes anonymous surveys, when information 'about' an individual (e.g., their views, behavior, beliefs, cognition, etc.) is collected. This type of survey requires prospective IRB review and approval or determination of exemption before being conducted.

However, some research surveys do not meet this definition because they do not collect information 'about' an individual. Such surveys do not require IRB review and approval because they do not constitute the involvement of 'human subjects'. Examples would include surveys of businesses, schools or organizations to collect information on their policies, procedures, or curriculum programs.

2.2.2 Deceased individuals.

Research use of specimens or data from individuals who are deceased would not constitute the involvement of 'human subjects'. Research limited to use of only these specimens or data does not require IRB review or oversight.

2.2.3 Secondary use of data and biospecimens.

Research use of information or biospecimens would generally constitute involvement of 'human subjects' and require IRB review, with few exceptions. Refer to SOPs *11.1 Secondary Research Use of Identifiable Information* or *11.2 Human Biological Specimens*.

2.2.4 Research involving publicly available identifiable information or identifiable biospecimens.

Researchers may utilize some identifiable information or identifiable biospecimens that are publicly available. Research involving identifiable information or identifiable biospecimens from publicly available sources is considered to involve 'human subjects.' Examples of information which could be considered publicly available include:

- Secondary research use of archives in a public library,
- or government or other institutional records where public access is provided on request,
- or from a commercial entity if the information or biospecimens are provided to a member of the public on request or if the only requirement for obtaining the information is paying a user fee, registering or signing in as a visitor to an archive.

Refer to SOP *11.1 Secondary Analysis of Existing Data* for more information.

2.2.5 Third-party subjects.

When research collects identifiable private information about third parties, those individuals are also considered 'human subjects'. This may include projects such as research on married individuals' relationships with their spouse, a child's relationship with a grandparent, or genetic studies on family traits. When the research obtains private information that can be linked to the identity of a third party, these individuals are considered 'human subjects'. Therefore, informed consent must be obtained for their participation in research, unless the IRB otherwise waives the requirement.

2.3 Research subject to FDA regulations.

Research subject to FDA regulations includes clinical investigations (research) performed to determine efficacy and/or safety of a medical device, drug, biologic, or other article regulated by the FDA.

FDA regulations define a '**human subject**' as someone (a healthy individual or a patient) participating in research as:

- a recipient of a test article, or as a control
- an individual on whom, or on whose specimen an investigational device is used, or as a control

IRB review is required for all research subject to FDA regulations, including any use of private information or human specimens, whether identifiable or de-identified. Refer to *11.6 FDA-Regulated Research* for more information.

3.0 Examples.

Human subjects research may be conducted in various disciplines, and is not limited to the clinical, social, or behavioral sciences.

3.1 Human subjects research.

The following are some examples of projects that constitute 'human subjects research':

3.1.1 Studies that involve human subjects to test or develop devices, products, or materials that have been developed through research for human use.

3.1.2 Studies intended to contribute to generalizable knowledge that collect data through intervention or interaction with individuals. Examples of this type of research include: the evaluation of teaching methods and programs, internet surveys about alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors about family values in a foreign country.

3.1.3 Studies using private information or data that can be readily linked to individuals, even if the information was not collected specifically for the study in question.

3.1.4 Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials specifically for the study.

3.1.5 Studies that use human beings to evaluate environmental alterations, for example, weatherization options or habitat modifications.

3.2 Research not involving human subjects.

The following are some examples of projects that typically do NOT constitute 'human subjects research':

3.2.1. Data collection for internal departmental, school, or other Institutional administrative purposes is not human subjects research. Examples: teaching evaluations, customer service surveys.

3.2.2 Information-gathering interviews where questions focus on things, products, or policies rather than about people or their thoughts regarding themselves are not human subjects research. Example: canvassing librarians about interlibrary loan policies or rising journal costs.

3.2.3 Course-related activities designed specifically for educational or teaching purposes, where data is collected from and about individuals as part of a class exercise or assignment, but are not intended for use outside of the classroom are not human subjects research. Example: instruction on research methods and techniques where students will conduct 'research-like' activities for a course assignment.

3.2.4. Biography or oral history research involving a living individual that is not generalizable beyond that individual is not considered human subjects research.

3.2.5 Research involving cadavers, autopsy material or bio-specimens from deceased individuals is not human subjects research. *Note: Some research in this category, such as genetic studies providing private or medical information about living relatives, may need IRB review. Please contact the IRB for further information.*

3.2.6 Case histories which are published and/or presented at national or regional meetings are often not considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge.

4.0 IRB determination of Not Human Subjects Research.

An investigator may request a written determination regarding whether or not a particular project constitutes 'human subjects research'. Although not required, it may be beneficial when uncertainty exists as to the involvement of human subjects. Refer to SOP 11.1 *Secondary Research Use of Identifiable Information* or 11.2 *Human Biological Specimens* for more information.

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

- intended purpose and goals of the project
- how the information collected will be used
- the nature of any interaction or intervention with individuals
- what information, if any, will be obtained about living individuals
- a list of survey or interview questions, if applicable.

Information regarding a project's collection or use of identifiers, level of sensitivity or risks is usually not material to a determination of 'human subjects research'. Such information is useful, however, in determining the appropriate level of IRB review for a human subjects research project.

5.0 Cooperative research.

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

5.1 NDSU Principal Investigator (PI).

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*.

5.2 Non-NDSU Principal Investigator.

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. Refer to SOP 2.2 *NDSU Engagement in Human Subjects Research* for more information.

5.3 Single IRB (sIRB) Review of Cooperative Research.

NIH-funded cooperative research studies where each site will carry out the same research protocol must utilize a single IRB (sIRB) of record. Each research site will sign a reliance agreement ceding review to the sIRB of record (typically the prime awardee).

DEFINITIONS:

Human subject (HHS): a living individual, about whom, an investigator (whether professional or student) conducting research obtains 1) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human subject (FDA): an individual who is or becomes a participant in research either as a recipient of a test article or as a control. A subject may be either a healthy individual or a patient. For research involving medical devices, a human subject is someone who participates in a clinical investigation either as an individual on whom or on whose specimen an investigational device is used, or as a control.

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.

Private information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which they can reasonably expect will not be made public (e.g., a medical record).

Research (HHS): a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Clinical investigation (FDA): any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections, but results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. *(Note: Section 505(i) refers to any use of a drug other than the use of an approved drug in the course of medical practice; 520(g) refers to any use of a medical device other than the use of an approved medical device in the course of medical practice.) Note: The FDA uses the term 'clinical investigation' to describe 'Research' activities.*

Test article: any drug, biological product or medical device for human use, human food additive, color additive, electronic product, or other article subject to FDA regulations.

Investigational device: a medical device that is the subject of an investigation to determine safety and effectiveness

Medical device: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes

REFERENCES:

[45 CFR 46.101](#) To what does this policy apply? and [21 CFR 50.1](#) Scope

[45 CFR 46.102](#) , [21 CFR 50.3](#) and [21 CFR 812](#) Definitions

OHRP FAQs: [FWA](#)

[Terms of FederalWide Assurance](#)

OHRP Guidance on [Engagement of Institutions in Human Subjects Research](#)

[CITI](#) module 'Students in Research'

[Protection of Third-Party Information in Research](#), National Institutes of Health

RELATED HRPP SECTIONS:

2.2 NDSU Engagement in Human Subjects Research

2.3 Collaborative, Multi-site and Off-site Research

11.1 Secondary Use of Identifiable Information

11.2 Human Biological Specimens

11.6 Review of FDA Regulated Research