

## Section 11 Special Research Topics

### 11.1 Secondary Research Use of Identifiable Information

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When NDSU faculty, staff or student researchers utilize identifiable information obtained for another primary purpose for research purpose, NDSU is engaged in human subjects research; therefore, policies for protecting the rights, safety and welfare of research participants apply. Such identifiable information may originate from NDSU or other entities, and their use for research requires compliance with additional federal regulations to protect privacy and confidentiality.

#### 1.0 Research subject to IRB oversight.

When research use of identifiable information constitutes NDSU engagement in human subjects research, IRB oversight is required. Requirements for IRB review or a determination of exemption are dependent on the source of these materials, intended use, and the investigator's access to individually identifiable information.

#### 1.1 NDSU-directed projects.

NDSU is engaged in human subjects research when the institution receives funding for, or an NDSU investigator directs or supervises a project that involves human subjects. This would include projects in which the human subjects activities are carried out by NDSU investigators, or by other entities under the direction of an NDSU investigator.

#### 1.2 NDSU interaction with participants.

NDSU is engaged in human subjects research when an NDSU investigator interacts or intervenes with participants for research purposes. Refer to SOP 2.1 *Human Subjects Research* for more information.

#### 1.3 Identifiable records.

NDSU is engaged in human subjects research when an investigator obtains (receives or accesses) identifiable information in which s/he may be able to readily ascertain the identity of individuals to whom the records pertain or which includes any of the eighteen (18) HIPAA identifiers.

#### 1.4 Coded records.

NDSU is engaged in human subjects research when an investigator obtains (receives or accesses) coded information about individuals that is not directly identifiable, and the investigator:

- is able to access the key with linkage to individual identities
- attempts to contact individuals, or
- unexpectedly learns the identity of one or more individuals

Refer to SOP 2.1 *Human Subjects Research* for more information. Should an investigator discover the identity of one or more research participants inadvertently, contact the HRPP office to file a protocol as soon as possible to bring the research into compliance.

### 1.5 Research subject to FDA regulations.

NDSU is engaged in human subjects research when an investigator obtains confidential records (identifiable, coded, or de-identified) for clinical investigations involving a test article subject to FDA regulations. Refer to SOP 11.6 *Review of FDA-Regulated Research* for more information.

### 2.0 Research not subject to IRB oversight.

Research use of private records that does not constitute involvement of human subjects is outside the purview of the IRB. The following examples assume the NDSU investigator's role in the research is limited to that described below, and does not include any other involvement in the project that would constitute engagement in human subject research as described in 1.0 above.

#### 2.1 Information from or about deceased individuals.

When research uses data that is composed entirely of information about deceased individuals, it does not constitute human subjects research and does not require IRB oversight.

#### 2.2 De-identified records.

When an investigator obtains (receives or accesses) only de-identified information (has been stripped of identifiers and linkage to identifiers), the project is not human subjects research; therefore IRB oversight is not required. This may apply to medical and education records that are stripped of identifiers and codes prior to release to, or access by the researcher. Additional regulations specify the de-identification process for medical records (see 4.2.1 below).

#### 2.3 Coded records.

When an investigator obtains only coded records, the research is not subject to IRB oversight provided that the investigator cannot readily ascertain the identity of the individual(s) to whom the information pertains because:

- the NDSU investigator(s) and the holder of the key enter into an agreement prohibiting the release of the key to the investigators
- there are IRB-approved written policies and operating procedures for a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased; or
- there are other legal requirements prohibiting the release of the key to the investigators.

IRB review or an exempt determination is not required for research meeting these criteria. An investigator may voluntarily request a written determination from the IRB regarding whether IRB oversight is required, as described in 8.0 below. Refer to SOP 2.2 *NDSU Engagement in Human Subjects Research* for more information.

### 3.0 IRB oversight

IRB oversight is required for those projects that constitute NDSU engagement in human subjects research.

### 3.1 Exempt determination.

The IRB may determine that research is eligible under:

Exemption Category #4: Secondary research for which consent is not required: user of identifiable private information or identifiable biospecimens; if at least one of the following criteria is met:

- (i) Information or biospecimens are publicly available – Examples of information which would be considered publicly available include: Secondary research use of archives in a public library, or to government or other institutional records where public access is provided on request, or from a commercial entity if the information is provided to members 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.
- (ii) Recorded information cannot readily be identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects.
- (iii) Information collection and analysis involving identifiable health information when use is regulated by HIPAA for “health care operations” or “research” or “public health activities and purposes.”
- (iv) Research by or on behalf of a federal department/agency using government-generated or collected information. Must be compliant with relevant privacy protections such as:
  - a. E-government Act of 2002, 44 USC 3501
  - b. Privacy Act of 1974
  - c. Paper Reduction Act of 1995

Exemption Category 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a **limited IRB review** and makes the determinations required by §\_\_\_\_.111(a)(8).

- **Due to the robust, institutional systems needed to ensure valid broad consent has been obtained in order to track or flag records or specimens for which broad consent was refused, the IRB will refrain from utilizing this exemption category.**

Exemption Category 8: Secondary research for which broad consent is required: Research involving the use of identifiable private information for secondary research use, if the following criteria are met:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information was obtained.
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained.
- (iii) An IRB conducts a limited IRB review and makes the determination required by §\_\_\_\_.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent.
- (iv) The investigator does not include returning individual research results to subjects as part of the study plan. (This does not prevent an investigator from abiding by any legal requirements to return individual research results).

- **Due to the robust, institutional systems needed to ensure valid broad consent has been obtained in order to track or flag records or specimens for which broad consent was refused, the IRB will refrain from utilizing this exemption category.**

### 3.2 Expedited review.

The IRB may determine that research is eligible for expedited review under category #5 when the information is not publicly available, and direct or indirect identifiers are recorded by the investigator, and data safeguarding procedures are sufficient to involve no more than minimal risk. Refer to SOP 7.3 *Expedited Review* for more information.

### 3.3 Full board review.

The IRB may require review at a full convened meeting if the research is not eligible under an exempt category and during expedited review, a reviewer determines that the study would involve greater than minimal risk. The IRB documents the rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.

Refer to SOP 7.4 *Full Board Review* for more information.

### 3.4 Collaborative research.

Collaborative research involving the use of identifiable information by NDSU would constitute the engagement of NDSU in human subjects research. Refer to SOP 2.3 *Collaborative, Multi-site and Off-site Research* for more information.

## 4.0 Research subject to additional regulations.

Research use of some identifiable information requires compliance with additional federal regulations to protect privacy and confidentiality.

### 4.1 Education records and FERPA.

Use of student educational records for research also requires compliance with Family Educational Rights and Privacy Act (FERPA) regulations. With limited exceptions, written consent is required for access to such records, unless de-identified or designated as 'directory information' that is published by the institution. FERPA contains no provision for a waiver of written consent. For access to education records held by NDSU, questions regarding policy and procedures should be directed to the Office of Registration and Records. Access to educational records held by an unaffiliated entity requires the investigator to comply with that entity's FERPA policy and procedures.

### 4.2 Medical records and HIPAA.

Research use of protected health information (PHI) from records created in the process of providing healthcare requires compliance with Health Insurance Portability & Accountability Act (HIPAA) regulations. Access to such records generally requires written authorization from the patient(s), unless the record is de-identified prior to research access, or the Covered Entity's Privacy Board approves a waiver of the requirement to obtain authorization.

#### 4.2.1 De-identification.

Medical records are considered de-identified when all of the following are removed prior to access by the investigator:

1. Names;
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
  - a. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
  - b. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Telephone numbers;
5. Fax numbers;
6. E-mail addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators; (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code, except as otherwise permitted.

## 5.0 Risks.

Use of identifiable information for research may pose privacy and confidentiality risks when the identity of individuals may be readily ascertained either directly, or in combination with other information.

### 5.1 Social, economic and legal risks.

Unauthorized disclosure or access to individually identifiable information for research may place individuals at risk of civil or criminal liability, damage their financial standing, reputation, or employability. Robust safeguarding procedures are required in order to minimize risks for participants. Refer to *8.2 Privacy and Confidentiality* for more information.

### 5.2 Group harms.

Identified groups or communities, especially those subject to discrimination and/or of low socio-economic status may also be vulnerable to harms as a result of research. When research results are stigmatizing or support harmful stereotypes about a group, the community as a whole suffers, even when individual participants are not identified in results. To minimize these risks, the investigator should consult the community in advance to obtain approval, ensure potential harms are understood by all parties, and ensure the study will be beneficial to the group.

## 6.0 Informed Consent.

### 6.1 Consent not required.

Secondary research with identifiable information does not typically require informed consent if it is eligible for exemption under exemption Category 4.

### 6.2 Broad Consent is required.

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the typical informed consent requirements. Research utilizing broad consent is subject to *limited IRB* review under Exemption Categories 7 and 8. If the subject or legally authorized representative is asked to provide broad consent, the broad consent must contain the required elements as required in §\_\_\_\_.116(d).

### 6.3 Waiver of Informed Consent.

Secondary research requiring review under Expedited Category 5, *Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)* may be eligible for a waiver of informed consent.

An IRB may waive the requirement to obtain informed consent for research, provided the IRB satisfies the requirements listed below. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

Criteria for waiver or alteration of informed consent:

- (i) the research involves no more than minimal risk to subjects;
- (ii) the research could not practicably be carried out without the requested waiver or alteration;
- (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;
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (v) Whenever appropriate, subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Refer to SOP 9.3 *Waiver or Alteration of Informed Consent Requirements* for more information.

## 7.0 IRB determination of Not Human Subjects Research.

An investigator may request a written determination regarding whether the research being conducted involves human subjects as defined in §\_\_\_\_.102(e)(1). Although not required, it may be beneficial when uncertainty exists as to the involvement of human subjects.

To obtain a written determination from the IRB, submit a written description of the project including descriptions of:

- intended purpose and goals of the project
- source and content of the records
- existence of, and access of investigator to any identifiers or codes
- role of NDSU faculty, staff, or student, as well as another entity
- any applicable agreement, contract, privacy or confidentiality policy or usage restrictions.

In accordance with guidance from the Health and Human Services Office of Human Research Protections (OHRP), the IRB has final authority to determine whether or not a research project involves human subjects. Human subjects research conducted without IRB review or an Exempt determination is considered noncompliant and subject to procedures as outlined in SOP *12.3 Complaints and Noncompliance*.

#### **DEFINITIONS:**

De-identified: identifiers were originally collected, but have been irreversibly removed from previously identified samples; 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 (i.e., the code); and 2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Confidentiality: pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission

Directory information (FERPA): information contained in an education record of a student that would not generally be considered harmful or an invasion of privacy if disclosed. Directory information includes, but is not limited to: the student's name, address; telephone listing; electronic mail address, photograph, date and place of birth, major field of study, grade level, enrollment status, dates of attendance, participation in officially recognized activities and sports, weight and height of members of athletic teams, degrees, honors and awards received, and the most recent educational agency or institution attended.

Education record: means those records that are directly related to a student; and maintained by an educational agency or institution, or by a party acting for the agency or institution.

Human Subject: (Common Rule) a living individual, about whom, an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

- 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 the test article or as a control. A subject may be either a healthy human or a patient. This would include individuals whose private information is used to test the safety or efficacy of a diagnostic device, even if the information is not individually identifiable, and was obtained in a retrospective fashion.

Identifiable private information: private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Investigator: anyone involved in conducting the research; i.e., 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)

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: 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Protected health information (PHI): Individually identifiable health information held or transmitted by a covered entity or its business associate. Individually identifiable health information includes written records or oral information about past, present, or future mental or physical health, including payment for health care that is created or received by a covered entity, and can identify an individual.

Test article: any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to the Federal Food, Drug and Cosmetic Act.

## **REFERENCES:**

21 CFR §50.3(g) (FDA) Definition – human subject  
§ \_\_\_\_.102(e)(1) Definition – human subject  
§ \_\_\_\_.111 IRB Criteria for Approval  
§ \_\_\_\_.104 Exempt Research  
§ \_\_\_\_.116 General requirements for informed consent  
[HIPAA](#) Privacy Rule Information for Researchers (NIH)  
[FERPA](#) Family Educational Rights and Privacy Act  
[OHRP Informed Consent FAQs](#)  
[Expedited Review Categories](#)

## **RELATED FORMS:**

IRB Protocol Form

IRB Protocol Form: Secondary research for which consent is not required  
Informed Consent Waiver or Alteration Request

**RELATED HRPP SECTIONS AND STANDARD OPERATING PROCEDURES:**

- 2.1 Human Subjects Research
- 2.2 NDSU Engagement in Human Subjects Research
- 2.3 Collaborative, Multi-site and Off-site Research
- Section 7 - IRB Review Process
- 8.2 Privacy and Confidentiality
- 9.3 Waiver or Alteration of Informed Consent Requirements
- 11.2 Human Biological Specimens