When NDSU research use of confidential records (e.g., education or medical records) constitutes the engagement of the institution in human subjects research, policies for protecting the rights, safety and welfare of research participants apply. Such records 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 confidential records constitutes NDSU engagement in human subjects research, IRB oversight is required. Requirements for IRB review or certification of exempt status 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 he/she 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 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 subject to IRB oversight. 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).

2.2 Coded records.
When an investigator obtains only coded records, the research is not applicable 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.

2.3 Records in the public domain.
When an investigator uses only publicly available records for research, IRB review or certification of exempt status is not required. For example, student ‘directory information’ is that portion of the education record that is not considered confidential and commonly published by the institution.

IRB review or certification of exempt status 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 review
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 for exemption, category #4, when the records are currently in existence, were collected for a purpose other than the proposed research, and the investigator accesses but does not record (even temporarily) direct or indirect identifiers or links to identifiers. Refer to SOP 7.1 Exemption Determinations for more information.

3.2 Expedited review.
The IRB may determine that research is eligible for expedited review, category #5 when 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 determine that research is not eligible for exempt status or expedited review, and full board review is required. The IRB may also elect to review a project at a convened meeting in order to ensure that the rights and welfare of subjects will be adequately protected. Refer to SOP 7.4 Full Board Review for more information.

3.4 Collaborative research.
Collaborative research involving confidential records may or may not constitute the engagement of NDSU in human subjects research. For example, when the role of NDSU in the research is limited to analysis of de-identified information, it is not applicable to NDSU IRB oversight. Refer to SOP 2.3 Collaborative, Multi-site and Off-site Research for more information.

4.0 Research applicable to additional regulations.
Research use of some confidential records 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 General Counsel. Access to education 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 also require compliance with Health Insurance Portability & Accountability Act of 1996 (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 IRB 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.

4.2.2 IRB waiver of written authorization.
PHI held by an NDSU healthcare provider may be used for research without authorization when the IRB documents the following determinations:

- the PHI requested is the minimum necessary information needed to accomplish the objectives of the research
- use of PHI involves no more than minimal risk to the privacy of individuals whose records will be used because the following is in place:
  - an adequate plan to protect identifiers from improper use and disclosure
  - a plan to destroy identifiers at the earliest opportunity, unless retention is required by law, or justified for health or research purposes
  - PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research which the use or disclosure of PHI would be permitted by the Privacy Rule
- the research could not practically be conducted without the waiver, and
the research could not practicably be conducted without access to and use of the PHI.

For access to medical records held by a healthcare component of NDSU, direct questions regarding policy and procedures to the Privacy Officer in the Office of General Counsel. Access to medical records held by an unaffiliated entity requires the investigator to comply with that entity’s HIPAA policy and procedures, which may include applicable training regarding data confidentiality and security, as well as review by their IRB.

5.0 Risks.
Use of confidential records for research may pose significant 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.
Research involving confidential records that constitutes the involvement of human subjects requires consent of the subject, or their legally authorized representative. The IRB may waive the requirement to obtain, and/or document informed consent under certain conditions.

To approve a waiver or alteration of informed consent, the IRB makes the following determinations:

- the research involves no more than minimal risk
- the waiver would not adversely affect the rights and welfare of participants
- the research could not practicably be conducted with the waiver, and
- when appropriate, subjects will be provided with information after participation

As part of the determination, the IRB may consider other applicable laws (such as FERPA or HIPAA) that afford individuals certain rights with respect to their records. Debriefing is typically not considered appropriate for research involving use of confidential records. Refer to SOP 9.3 Waiver or Alteration of Informed Consent Requirements for more information.
7.0 IRB determination of applicability.
An investigator may request a written determination regarding whether IRB oversight is required. 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 constitutes the involvement of human subjects. Human subjects research conducted without IRB review or determination of exempt status is considered non-compliant 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: (HHS) a living individual, about whom, an investigator (whether professional or student) conducting research obtains:
- Data through intervention or interaction with the individual, or
- Identifiable private information

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.

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; 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

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:
21CFR50.3(g) (FDA) Definition – human subject
45CFR46.102(f) Definition – human subject
45CFR46.111(a)(7) IRB Criteria for Approval
45CFR46.116 General requirements for informed consent
NDSU Office of General Counsel
HIPAA Privacy Rule Information for Researchers (NIH)
FERPA Family Educational Rights and Privacy Act
OHRP Informed Consent FAQs
OHRP Guidance on Research involving Coded Private Information or Biological Specimens
OHRP Guidance on Data or Tissue Repositories
Expedited Review Categories
Exemption Categories (45CFR46.101)
RELATED FORMS:
IRB Protocol Form
IRB Protocol Form: Exempt Categories
Informed Consent Waiver or Alteration Request
Use of Medical Records Attachment

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