

Section 11 Special Research Topics

11.1 Use of Confidential Records

Effective Date: **07/11/2008**

Revised:

When the research use of private information from confidential records (ie, academic or medical records) constitutes the involvement of human subjects, in whole or in part, the project is subject to policies for protecting the rights, safety and welfare of research participants. In accordance with OHRP guidance, the IRB retains the final authority to determine the involvement of human subjects in such projects.

1.0 Prospective collection:

Research that plans to obtain future private information from confidential records constitutes involvement of human subjects, and requires IRB review as well as informed consent, unless the IRB approves a waiver of the requirement. However, the prospective nature of the collection would usually involve an opportunity to seek consent from the individuals whose records will be utilized. If the research would involve no more than minimal risk, it may qualify for review by expedited procedures; otherwise full review would be required.

2.0 Retrospective collection:

Research use of private information that is already in existence ('on-the-shelf'), and was collected for a purpose other than the proposed research may or may not constitute involvement of human subjects. *As the IRB has the final authority to make this determination, a protocol is required for any research use of private information.*

2.1 No human subjects involved. Obtaining coded or identified pre-existing information for research use **would not** constitute involvement of human subjects if:

- the research only involves the coded or identified information, AND
- the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
 - the key to decipher the code is destroyed before the research begins;
 - the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased;
 - 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, until the individuals are deceased.

2.2 Human subjects involved. Obtaining coded or identified pre-existing information for research use **would** constitute involvement of human subjects if:

- other associated information about the individual(s) will be obtained by the researchers
- The investigators will have access to the code or key, or unexpectedly learn the identity of one or more individuals

If the research would involve no more than minimal risk, it may qualify for expedited review and a waiver of informed consent; otherwise it would be reviewed at a convened meeting of the IRB.

2.3 No human subjects involved. Obtaining anonymous or anonymized (de-identified) pre-existing information for research **would not** constitute involvement of human subjects if the research is limited to use of this information. *As the IRB has the final authority to make this determination, a protocol is required for any research use of private information.*

2.4 Human subjects involved. Obtaining anonymous or anonymized (de-identified) pre-existing information for research **would** constitute involvement of human subjects if other associated medical, health, or other information will also be obtained. The research may qualify for exemption or review by the expedited method. The IRB may also approve a waiver of the requirement to obtain informed consent.

3.0 Potential risks and harms to research subjects:

Use of private confidential information for research may pose significant privacy and confidentiality concerns. If informed consent will not be sought from individuals for permission to use their information for research, the IRB must consider whether or not this would violate their rights, or be inconsistent with any previous agreement or terms under which that original specimen was obtained. There may be situations where certain policies, terms or agreements would preclude use of the information for research purposes, even if de-identified.

Harm to groups or communities may also result, even where data or information is individually de-identified, but the group or community is named in the research results. Refer to *8.2 Privacy and Confidentiality* for more information.

Private, identifiable information may place individuals at risk in the event of an unintended breach of confidentiality; such data requires robust safeguarding procedures. Potential risks may be related to civil or criminal liability, damage to financial standing or reputation, or employability. A breach of confidential data is considered to be an unanticipated event involving risks to subjects, and requires a report to the IRB. It may also be necessary to notify participants, so they can take appropriate measures to protect themselves. Consult the ITS Security Officer for appropriate current data security procedures for access, transfer, use and storage of data in electronic format; also refer to *8.2 Privacy and Confidentiality* for more information.

4.0 Data Repositories:

Prospective collection of private information with the intention to create a data bank or repository for future research purposes would constitute the involvement of human subjects and requires prospective IRB review and approval. The research may qualify for expedited review, or require a review by the convened IRB; informed consent would also be required, unless the criteria for a waiver of the requirement can be met. When research will involve utilization of data from a bank or repository, it may or may not constitute the involvement of human subjects; a protocol is required to the IRB for a determination.

5.0 Academic Records and FERPA

Use of individual academic records (identifiable or de-identified) for research may constitute the involvement of human subjects, requiring IRB review. In addition, the investigator is responsible for complying with Family Educational Rights and Privacy Act (FERPA) policies of the entity providing the records. Consult the Office of the General Counsel with any questions about the use of NDSU academic records for research. In many instances, a signature is required from the student or parent to access or release identifiable academic records; there is no provision for waiver of this requirement. Research involving academic records may qualify for an exemption, or review by expedited procedures; informed consent is required, unless the IRB approves a waiver of the requirement.

6.0 Medical records and HIPAA

Use of medical records (identifiable or de-identified) for research may constitute the involvement of human subjects, requiring IRB review. In addition, when the records are considered Protected Health Information (PHI), the investigator is responsible for compliance with any applicable Health Insurance Portability & Accountability Act (HIPAA) policies, and must complete the CITI HIPAA module or other equivalent training. Consult the NDSU Privacy Officer for any questions regarding use of NDSU PHI for research, and specific training requirements. If the PHI to be studied are held by an unaffiliated entity, the investigator would be responsible for compliance with that entity's HIPAA policy.

Research involving medical records may qualify for an exemption, or review by expedited procedures. Informed consent and authorization is required, unless the IRB approves a waiver of the requirement, or access will be limited to de-identified information. Note that PHI is considered to be de-identified only when all of the following are removed prior to access by researchers:

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.

Requests for a waiver of authorization will be reviewed by a Privacy Board or IRB using the following criteria: 1) the use of PHI involves no more than minimal risk to the privacy of individuals, 2) the research could not practicably be conducted without the waiver, and 3) the research could not practicably be conducted without access to and use of the PHI.

Research records containing PHI require strict data safeguarding procedures, in accordance with HIPAA policy. Consult the NDSU IT Security Officer for the required procedures to maintain confidentiality in the access, use, transfer and storage of hard-copy and electronic records.

7.0 Use of Private Information to Recruit Participants

If an investigator wishes to utilize confidential records to identify potential participants for a prospective study, any initial contact with participants must be made by an individual with legitimate access to the records (e.g., subject's dentist, pharmacist, nurse, lawyer, social worker, etc.). The researcher may not obtain any information from the records prior to IRB review. The research may be eligible for expedited review, or require full board review; informed consent would also be required.

DEFINITIONS:

Anonymized (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 (ie, 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

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 (ie, using internet search engines or other means).

Investigator: anyone involved in conducting the research; ie, 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: information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (ie, 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.*

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 HIPAA policy](#)
[NDSU FERPA policy](#)
[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

Exemption Protocol Form
Expedited Categories Attachment
Additional Materials Attachment
Informed Consent Waiver or Alteration Request Form
PHI and HIPAA Attachment Form

RELATED HRPP SECTIONS:

- 2 Applicability
- 7 IRB Review Process
- 8.2 Privacy and Confidentiality
- 9.3 Waiver or Alteration of Informed Consent Requirements
- 11.2 Human Biological Specimens
- 11.3 Secondary Analysis of Existing Data