

11 Special Research Topics

11.3 Secondary Analysis of Existing Data

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Research involving secondary analysis of existing data, documents or records that contain information about living individuals may or may not require IRB oversight. Such materials were in existence prior to, and collected for purposes other than, the currently proposed research. When NDSU research use of existing data, documents or records constitutes the engagement of the institution in human subjects research, policies for protecting the rights, safety and welfare of research participants apply.

1.0 Research subject to IRB oversight.

Research use of existing data that constitutes NDSU engagement in human subjects research requires IRB oversight. Requirements for IRB review or certification of exempt status are dependent on the source of these materials 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 includes 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 Identifiable information.

NDSU is engaged in human subjects research when an investigator obtains (receives or accesses) **individually identifiable** information.

1.3 Coded information.

NDSU is engaged in human subjects research when an investigator obtains only **coded** information from any source, 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.

1.4 FDA-regulated research.

NDSU is engaged in human subjects research when an investigator conducts a clinical investigation to evaluate the safety and efficacy of FDA-regulated test articles (drugs, devices, biologics, etc.). This may include use of existing, **de-identified** data to evaluate an in-vitro diagnostic assay or instrument. Refer to *SOP 11.6 FDA-Regulated Research* for more information.

2.0 Research not subject to IRB oversight.

Use of existing data that does not constitute the engagement of NDSU in human subjects research 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 subjects 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 information.

When an investigator obtains (receives or accesses) information for which identifiers or coded links to identifiers no longer exist, the project is not subject to IRB oversight. De-identified information is that in which an individual can no longer be identified directly or indirectly through a linkage to identifiable information held by any party.

2.3 Coded information.

When an investigator obtains coded information, the research is not subject to IRB oversight provided that the investigator cannot readily ascertain the identity of the individual(s) 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.

2.4 Information in the public domain.

Research involving **public information** does not require IRB oversight, even when the data is individually identifiable. This may include information published in a journal, newspaper, or public website, as well as Census records or police records. In accessing such information, researchers have had no interactions or interventions with living individuals, the information is not restricted to certain uses, or protected by privacy or confidentiality policies.

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 stating that the research does not involve human subjects, as described in 6.0 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 data is currently in existence, was collected for a purpose other than the proposed research, and the investigator does not record (even temporarily) any direct 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 will be recorded and/or the records do not currently exist but will be collected solely for non-research purposes, 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 existing data, documents or 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 data, it is not subject to NDSU IRB oversight. When collaborative projects involving use of human specimens are under the purview of multiple IRBs, arrangements for cooperative review are permitted under certain conditions. Refer to *SOP 2.3 Collaborative, Multi-site and Off-site Research* for more information.

4.0 Risks.

Secondary use of existing data, documents or records for research may pose significant privacy and confidentiality concerns when the identity of individuals may be readily ascertained either directly, or in combination with other information.

4.1 Social, economic and legal risks.

Unauthorized disclosure or access to individually identifiable information 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.

4.2 Group harms.

Identified groups or communities, especially those subject to discrimination and/or of low socioeconomic 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.

5.0 Informed consent.

Research involving human subjects requires informed consent, unless the requirement is waived by the IRB. To approve a waiver or alteration of informed consent, the IRB must make 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.

The requirement to obtain informed consent of participants or their legal representatives may be waived by the IRB for research limited to use of existing data, particularly when de-identified. As part of the determination, the IRB may consider terms of any original contract or agreement (if available) under which individuals originally provided their information. Debriefing is typically not considered appropriate for research involving secondary use of existing data. Refer to SOP *9.3 Waiver or Alteration of Informed Consent Requirements* for more information.

6.0 IRB determination of applicability.

An investigator may voluntarily request a written determination from the IRB regarding applicability of a particular project to IRB oversight. Although not required, it may be beneficial when uncertainty exists regarding 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 existing data or documents,
- 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 (HHS) 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 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.

Human Subject: (as defined by 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.

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. This would also include some demographic information, or other unique information or key details that would allow individual identification to be deduced (i.e., 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)

Public information: information that has been collected by a government agency (such as the federal Bureau of the Census or a state Office of the Secretary of State) or a private organization (such as a newspaper or a journal) and made available for consumption by the general public without restrictions or limitations.

REFERENCES:

45CFR46.101 Exemption Categories

Expedited Review Categories

45CFR46.102(f) Definition of human subject

45CFR46.111(a)(7) Criteria for IRB approval – privacy and confidentiality protections

45CFR46.116 General requirements for informed consent

[OHRP Guidance on Research Involving Coded Private Information or Biological Specimens](#)

OHRP Guidance on Data or Tissue Repositories

RELATED FORMS:

IRB Protocol Form

IRB Protocol Form: Exempt Categories

Expedited Categories Attachment

Additional Materials Attachment

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
- 11.1 Use of Confidential Records