

Research involving human subjects or participants may qualify as exempt from federally required IRB review, providing the involvement of subjects is limited to certain categories defined by federal regulations. However, such projects must be conducted according to established ethical principles; and, in accordance with the terms of NDSU's FederalWide Assurance, the IRB must certify the project as eligible for exemption before the research is initiated.

1.0 Categories of research exempt from further IRB review:

Research activities involving human participants in which there is minimal or no risk and in which the IRB determines that the only involvement of human subjects will be in one or more of the following 6 categories are eligible for exemption. The following restrictions apply:

- research involving prisoners is not eligible for exemption
- FDA-regulated research is not eligible for categories #1, 2, 3, 4 or 5
- research with children is not eligible for category #2 when it will involve surveys, interviews, or observations of public behavior where the investigator will participate in the activities being observed (the other categories may apply to research with children)
- research involving an intervention where the investigator attempts to influence or change participants' behavior, perception, or cognition is not eligible for exemption

Note that investigators must file a protocol with the IRB for a formal determination of exempt status prior to initiation of the research.

1.1 Category #1.

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

- (i) research on regular and special education instructional strategies, or
- (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

1.2 Category #2.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- (i) information obtained is recorded in such a manner that human subjects can be identified, directly or indirectly through identifiers linked to the subjects; and
- (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

NOTE: *The data would be considered identifiable if a participant's identity may be deduced using any research data, or in combination with other information. This category has limited applicability where children will be involved: research involving educational tests, or public*

observation where the investigator does not take part in the activities being observed. Surveys or interviews of children are not applicable to this category.

1.3 Category #3.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

- (i) the human subjects are elected or appointed public officials or candidates for public office; or
- (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

1.4 Category #4.

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if

- (i) these sources are publicly available or
- (ii) if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

NOTE: *To qualify under this category, all of the following must apply:*

- *all records/data/specimens currently existed (were 'on the shelf') before this research was proposed*
- *the research will not involve prospective collections (use of 'left-over' or 'extra' specimens, or information that will be added to a record or dataset)*
- *materials are publicly available; or investigators will not record or retain access to identifiers*

1.5 Category #5.

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- (i) public benefit or service programs;
- (ii) procedures for obtaining benefits or services under those programs;
- (iii) possible changes in or alternatives to those programs or procedures; or
- (iv) possible changes in methods or levels of payment for benefits or services under those programs.

NOTE: *Guidance from OHRP indicates that institutions should consult the HHS funding agency before invoking this exemption. In addition, it clarifies that:*

- 1) *The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).*
- 2) *The research or demonstration project must be conducted pursuant to specific federal statutory authority.*
- 3) *There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).*

- 4) *The project must not involve significant physical invasions or intrusions upon the privacy of participants.*

1.6 Category #6.

Taste and food quality evaluation and consumer acceptance studies,

- (i) if wholesome foods without additives are consumed, or
- (ii) if a food is consumed that contains a:
 - food ingredient or additive at or below the level and for a use found to be safe by the Food and Drug Administration, or
 - agricultural chemical or environmental contaminant at or below the level found to be safe, approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

2.0 Ethical principles:

When NDSU employees or agents will be engaged in research involving human subjects, (including research that qualifies for exempt status) the research is to be conducted in accordance with the Belmont ethical principles of respect for persons, beneficence and justice. Although such projects would involve little, if any risk, research participants are to be afforded basic rights and protections, which include:

- the right to choose for themselves, in an environment free of coercion or undue influence, whether or not to take part in research
- the right to information about the research purpose, procedures, confidentiality limits, and any risks that may be involved
- the right to decline participation, or withdraw from research at any time without penalty
- the right to respect for their privacy and the confidentiality of their information
- the right to receive contact information for questions about the research (investigator or co-investigator's contact information)
- the right to receive contact information to express concerns or report a problem about a research project (NDSU IRB office contact information)

The basic elements of informed consent are to be communicated to each prospective subject, unless adequate justification has been provided for a waiver of this requirement. This may be accomplished by informing participants with printed information (a consent form, cover letter, handout), oral information (via a script), or electronic information in an email or online posting. When the elements of informed consent are to be given orally, the investigator must develop a written script (oral script) of the oral presentation; participants' signature is not typically required for most projects eligible for exemption, although it may be appropriate for some projects. The IRB reserves the right to require signed consent for where applicable.

3.0 Certification of new projects:

In accordance with federal regulations, investigators must obtain a written determination of exempt status from the IRB prior to the initiation of a research project that will involve human participants.

3.1 Application materials and submission process.

Investigators complete the protocol forms and applicable attachments, utilizing the most recent versions from the IRB web site. Protocol applications must be completed thoroughly, containing sufficient information for the IRB to determine eligibility for a claim of exemption, and to verify that the conduct of the research will follow Belmont principles. A checklist (also available on the IRB website) may be utilized to ensure the application is complete.

3.2 IRB determination.

Upon receipt of a signed protocol, HRPP staff verify training documentation, and ensure the application is complete. A qualified HRPP staff member, IRB chair or designee who is well acquainted with interpretation of the regulations and categories of exemption, will verify, using a checklist form, that the research meets the criteria under 1 or more of the exempt categories, and conforms to basic ethical requirements. Processing of the application requires a minimum of 5 business days, unless the submission is incomplete, contains conflicting or insufficient information, or the project is found to be ineligible for exemption. The project may not be initiated prior to receipt of an approval letter from the IRB.

IRB actions may include any of the following:

3.2.1 Revisions required.

The IRB may determine that additional information and/or revisions are needed in order to verify eligibility for exemption, and/or meet Belmont ethical principles. A qualified HRPP staff member notifies the investigator in writing to request the missing information or revisions. Once the revisions and/or additional information are received, qualified HRPP staff ensure that the standards are met, and the investigator is notified of the exempt certification in writing. If the investigator fails to respond within a reasonable period of time (ie, 60-90days) the project will be considered inactive and the protocol withdrawn. All communication is documented in the protocol file.

3.2.2 Project not eligible for exemption.

The IRB may determine that the proposed project is not eligible for one or more allowable categories of exemption. Qualified HRPP staff notify the investigator in writing, citing the reason for the ineligibility; and may request additional materials for review by the expedited method or full board. In some instances, the investigator may elect to submit a revised protocol, with changes in the research methods, subject population, and/or collection of identifiable information in order to qualify the project for exemption.

The IRB retains the final authority in determining project eligibility for exempt status, and may err on the side of caution to require expedited or full review to ensure adequate protection of subjects, and full compliance with the terms of NDSU's assurance. Refer to 7.3 Expedited Review and 7.4 Full Board Review for more information.

3.2.3 Project eligible for exemption.

The IRB may determine that the project, as submitted, is eligible for exemption, and Belmont ethical principles will be utilized in the conduct of the research. Qualified HRPP staff notify the investigator in writing with a letter of exempt certification; the research may then be initiated. The letter will specify the applicable exempt category, and the date of expiration of IRB approval.

3.3 Approval period.

The determination of exempt status expires after a maximum of 3 years. If the project will continue beyond that time period, a new protocol submission is required to avoid a lapse in IRB approval. The IRB office will typically send a notice approximately 2 months prior to the expiration date; however, the investigator is responsible for submission of a new protocol to maintain current approval for ongoing research.

3.4 Notification of exempt determinations to IRB.

Each month prior to the meeting, IRB members are provided with an attachment listing protocols certified as exempt, and new and continuing protocols reviewed by the expedited method. All members have an opportunity to review the list and ask questions about the actions performed outside of full board deliberations.

3.5 Other institutional approval.

Some projects may be subject to further review and approval or disapproval by officials of the institution. These officials may not approve the research, however, if it has not been approved by the IRB.

4.0 Post-approval procedures:

4.1 Protocol amendments.

Prior IRB approval is required for proposed changes to a protocol to ensure that the project remains eligible for exemption, and the conduct of the project will continue to follow Belmont ethical principles. These changes may include, but are not limited to changes in: subject population, recruitment procedures, informed consent process, research procedures, type of information collected, or research setting. If a proposed change would alter the eligibility for exempt status, the project will require review by either the expedited method, or by the full board at a convened meeting. Refer to *7.5 Protocol Amendments* for more information.

4.2 Unanticipated problems.

A report is required to the IRB in the event of unanticipated problems involving risks to participants or others. A research-related injury, or loss of confidential research data are several examples of unanticipated events that would place participants at risk. Refer to *7.8 Unanticipated Problems and Serious Adverse Events* for more information.

4.3 Quality assurance and research compliance:

Research eligible for exempt status is also subject to random (not-for-cause) or directed (for-cause) audits to ensure compliance with federal regulations and institutional policies. Refer to *Section 12 Quality Assurance and Research Compliance* for more information.

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

Disclosure: would include both intended (ie, publication) and unintended release of information (ie, breach of confidential data)

Existing data (documents, records or specimens): data or information that was already in existence ('on-the-shelf') prior to, and was collected for purposes other than, the currently proposed research

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.

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).

Interaction: includes communication or interpersonal contact between the investigator and participant

Intervention: includes both physical procedures by which data are gathered and manipulations of the subject or their environment that are performed for research purposes

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

Obtained: received or accessed

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:

[Exempt categories \(45CFR46.101\(b\)\)](#)

[FederalWideAssurance Terms](#)

[Human subject definition 45CFR46.102\(f\)](#)

[Belmont Report](#)

[OHRP guidance: Public Benefit and Service Programs](#)

RELATED FORMS:

Exemption Protocol Form

Participant informed consent/info sheet template and instructions

Protocol Submission Checklist

Protocol Amendment Form

Unanticipated Event Report Form

Exempt Determination Checklist

RELATED HRPP SECTIONS:

- 2 Applicability
- 7.3 Expedited Review
- 7.4 Full Board Review
- 7.5 Protocol Amendments
- 7.7 Unanticipated Problems and Serious Adverse Events
- 11.1 Use of Confidential Records
- 11.2 Human Biological Specimens
- 11.3 Secondary Analysis of Existing Data
- 12 Quality Assurance and Research Compliance