EXEMPT REVIEW

SOP #:	**401**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**6/1/14**	**SUPERSEDES DOCUMENT:**	**5/1/09**
THIS POLICY PERTAINS TO:		**CLAIMS FOR EXEMPTION FOR IRB REVIEW**					
RESPONSIBILITY FOR EXECUTING POLICY:		**DEPARTMENT CHAIRPERSONS, IRB CHAIRPERSON, IRB VICE CHAIRPERSON, IRB COORDINATOR, INVESTIGATORS, IRB MEMBERS**					
LAST REVIEWED ON:		**/ /**		**RESULTS:**	**REVISED**		
APPROVAL AUTHORITY:		**Associate Vice President for Research and Economic Development**					
APPROVED BY:						**DATE:**	**3/1/14**

1. POLICY

The responsibility for determining whether an activity constitutes human subjects research rests with the investigator. Since the University will hold them responsible if the determination is not correct, investigators are urged to request a confirmation that an activity does not constitute human subjects research from the IRB. The University of North Dakota Institutional Review Board (IRB) requires all human subject research studies meeting or appearing to meet one of the exempt criteria to be submitted to the IRB for review and approval. No Investigator or department on campus shall have the authority to make this decision other than the IRB. All research, including that in the exempt categories, must meet at a minimum the principles outlined in the Belmont Report. The IRB Chairperson or designee may require additional protections to meet these principles, including a level of informed consent appropriate to the research, or review by the Full IRB.

Exempt research must be of minimal risk, have a sound research design, and be conducted ethically. No research involving, or potentially involving, prisoners as participants may be classified under the exempt categories listed below. UND IRB polices and procedures do not allow exemption of research involving audio, video, or digital recording.

2. SPECIFIC POLICY

2.1 Exempt Research Categories (45 CFR 46.101) (21 CFR 50)

Research activities in which the only involvement of human subjects will be in one or more of the following categories can be approved as exempt by the IRB:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

   NOTE: This category may be applied to research involving children.

   NOTE: This category may not be applied to FDA regulated research.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless**:
    a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
    b. 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 section of this category pertaining to standardized educational tests may be applied to research involving children. This category may also apply to research with children when the investigator observes public behavior but does not participate in that behavior or activity. This section is not applicable to survey or interview research involving children.

    NOTE: This category may not be applied to FDA regulated research.

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 category 2 above, if:
    a. The human subjects are elected or appointed public officials or candidates for public office; **or**
    b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

    NOTE: This category may not be applied to FDA regulated research.

4. Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or 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.
    a. To qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins. The Investigator must describe where the information exists.
    b. Under this exemption, an Investigator (with proper institutional authorization) may inspect identifiable records, but may only record information in a nonidentifiable manner. The Investigator must describe how information will be obtained, what data elements will be recorded, and whether any links to identifiers will be recorded.

    NOTE: Inclusion of fetal tissue in the pathological specimens category of exempt research is prohibited by regulation and requires additional IRB review.

    NOTE: This category may not be applied to FDA regulated research.

5. Research and demonstration projects which are conducted by or subject to the approval of federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
    a. Public benefit or service programs; this exemption is for federally supported

projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs."

i. 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)
ii. The research or demonstration project must be conducted pursuant to specific federal statutory authority.
iii. There must be no statutory requirement that an Institutional Review Board review the project.
iv. The project must not involve significant physical invasions or intrusions upon the privacy of participants.

b. Procedures for obtaining benefits or services under those programs;
c. Possible changes in or alternatives to those programs or procedures; or
d. Possible changes in methods or levels of payment for benefits or services under those programs.

Before invoking this exemption, the IRB will obtain concurrence of the funding agency that this exemption can be applied.

NOTE: This category may not be applied to FDA regulated research.

6. Taste and food quality evaluation and consumer acceptance studies if:
    a. wholesome foods without additives are consumed or
    b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE: This category may be applied to children.

NOTE: This category may be applied to FDA regulated research.

2.2 Additional Considerations

The IRB ensures that exempt research fulfills the organization’s ethical standards, such as:

- When exempt research involves interactions between the principal investigator and participants, the IRB should determine whether there should be a consent process that will disclose such information as:
    - That the activity involves research.
    - A description of the procedures.
    - That participation is voluntary.
    - The name and contact information for the principal investigator (and the advisor, if the investigator is a student or medical resident).
- The IRB should determine that there are adequate provisions to maintain the privacy interests of the participants.

2.3 Approval Period for Exempt Research

Research activities that meet the requirements for one or more of the exempt research categories must be reviewed by the IRB. The Principal Investigator must complete the appropriate Exempt Certification Form and submit it to the IRB for review. If the Principal Investigator proposes to do research that meets the requirements for exempt research, but for which there is no specific Exempt Certification Form, the Human Subjects Review Form must be filled out and submitted for review.

Studies receiving an exempt classification by the IRB will receive approval for the length of time specified by the Investigator, up to a maximum of three years. During the approval period, the Investigator must inform the IRB of any changes in the study scope or design prior to implementation of the changes to insure that the study continues to meet the exempt criteria. Annual continuing review is not required for research approved as exempt. Investigators must submit a Research Project Termination Form when the research and data analysis are completed.

2.4 Documentation of Exempt Review

If the study qualifies for exempt review, the IRB Coordinator, IRB Chairperson, or designee will document the review and category on the Report of Action Form along with his/her signature and the date.

2.5 Notification of the IRB

When the exempt review procedure is used, all regular members shall be informed of actions taken by the IRB at the next convened meeting.

3. RESPONSIBILITY

IRB Members and/or the IRB Coordinator are responsible for review of the project to determine if the research qualifies for exemption.

The IRB Chairperson, IRB Vice Chairperson, or IRB Coordinator is responsible for providing guidance to the reviewer as needed.

The IRB Secretary is responsible for sending out approval correspondence to Investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101
21 CFR 56. 104, 105

5. ATTACHMENTS

Exempt Certification Forms

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task

IRB Secretary	Maintain and make available submission information regarding exempt research.
IRB Coordinator, IRB Members	Review submitted projects to determine claims of exemption using the The Reviewers may: • Approve the request • Request revisions and/or additional documentation from PI • Disapprove claim of exemption and send for expedited or Full Board review. • Make a determination that the project is not human subjects research and does not require IRB review and approval. Approval: Document exemption category on Report of Action Form and confirm by signature and date. Disapprove claim of exemption: Inform PI that Human Subject Review Form must be filled out, and that the project must be sent to the IRB for expedited or Full Board review.
IRB Chairperson, IRB Vice Chairperson, IRB Members	Provide guidance to Investigators on claims of exemption as needed and requested. Review disapproved claims of exemption for expedited or Full Board review. If project falls under expedited or Full Board review, notify PI and request Human Subjects Review Form to be completed by Investigator.
IRB Secretary	Confirm by approval letter and Report of Action Form to the Investigator within 3 weeks of receiving complete exempt submission. If project falls under expedited or Full Board review, notify PI and request a Human Subjects Review Form to be completed by Investigator. Upon completion of the review, add the study to the List of Projects Reviewed and provide the list to IRB members at the next IRB meeting.