

**SOP: 401**  
**RESEARCH EXEMPT FROM IRB REVIEW**

**1. POLICY**

All research involving the collection of data about living individuals through intervention or interaction with those living individuals or by collection of those individuals' private identifiable information shall be reviewed by the IRB. An investigator is **NOT** empowered to make the determination of whether a research project is exempt from IRB review. The investigator shall forward all human participant research projects to the IRB, and the IRB shall determine if the research project is exempt from review. The IRB Chair or Vice-Chair makes the determination of exemption based on regulatory and institutional criteria, except as specifically noted below.

When a research project is reviewed under exempt criteria, the reviewer shall take into consideration the level of risk involved as well as ethical concerns that may pose potential harm to a participant. If the reviewer finds that the ethical issues pose more than a minimal risk to the participant but the type of research falls within the exempt criteria, the reviewer shall determine whether the project will be reviewed as either expedited or by the convened IRB.

**Specific Policies**

**1.1 Exempt Research Project Criteria**

Research projects in which the involvement of human participants will be in one or more of the following categories are exempt from IRB review:

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

*Norman Campus IRB Note: Classroom evaluation activities do not require submission of an application to the IRB when assessment involves regular classroom activities and results of the evaluation process are intended to be used for the sole purpose of informing teaching practices of the classroom instructor.*

Additionally, the research must meet the following:

- The research is not FDA-regulated
- The research does not involve prisoners as participants.

- 1.1.2 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 participants can be identified, directly or through identifiers linked to the subjects; and

- b. Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. NOTE: The Department of Veterans Affairs (VA) also includes loss of insurability in this category.

Additionally, the research must meet the following:

- If the research involves children as participants, the procedures do not involve survey procedures, interview procedures, or observation of public behavior where the investigators participate in the activities being observed.
- The research is not FDA-regulated
- The research does not involve prisoners as participants.

1.1.3. 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 1.1.2 above if:

- a. The human participants 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.

Additionally, the research must meet the following:

- The research is not FDA-regulated
- The research does not involve prisoners as participants.

*Norman Campus IRB Note: Research activities that are requirements of a course, are being conducted for the purpose of learning research skills only, and do not meet the definition of "human subjects research" are not required to be submitted to the IRB for review.*

1.1.4. 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 participants cannot be identified, directly or through identifiers linked to the participants, and:

- Reviewed materials exist at the time the research is proposed
- The research is not FDA-regulated
- The research does not involve prisoners as participants.

1.1.5. 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:

- a. Public benefit or service programs;

- 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.

Additionally, the research must:

- Be conducted pursuant to specific federal statutory authority.
- Have no statutory requirements for IRB review.
- Not involve significant physical invasions or intrusions upon the privacy interests of the participant.
- Have authorization or concurrence by the funding agency.
- Not be FDA-regulated.
- Not involve prisoners as participants.

- 1.1.6. Taste and food quality evaluation and consumer acceptance studies:
- a. If 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Additionally, the research must not involve prisoners as participants.

## 1.2 Exempt Research Project Review

Protection of participants in exempt research includes:

- that the research involves no more than minimal risk to participants
- selection of participants is equitable
- if there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data
- if there are interactions with participants, there will be a consent process that will disclose such information as:
  - that the activity involves research
  - a description of the procedures
  - that participation is voluntary
  - name and contact information for the investigator
- there are adequate provisions to maintain the privacy interest of participants

The IRB Chair, Vice-Chair, or IRB member designee shall review research projects meeting exempt criteria; these projects do not require convened IRB review. The IRB Chair or Vice-Chair shall document the appropriate exempt criteria in the study file. The IRB staff will send written documentation to the investigator indicating the project meets exempt criteria and that the research may begin.

### **1.3 Exempt Research Annual Verification**

The status of research projects that qualified for exempt status shall be determined on an annual basis. The IRB will send a letter to the investigator to determine if the research project remains active and continues to meet the qualifications for exempt status.

## **2. SCOPE**

These policies and procedures apply to investigator requests for exemption from IRB review.

## **3. RESPONSIBILITY**

The IRB Chair or designee is responsible for the review of exemption requests and determination of whether the research project is exempt.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.101

21 CFR 56.104, 105

## **5. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 301, Research Submission Requirements

SOP 402, Expedited Review

SOP 501, Special Populations.

## **6. ATTACHMENTS**

203-C New Study Reviewer Checklist – Exempt (HSC)

203-C-1 New Study Reviewer Checklist – Exempt (NC)

203-CC Categories of Exemption Checklist (HSC)

203-CC-1 Categories of Exemption Checklist (NC)

203-D VA Research Reviewer Checklist (HSC)

601-J Protocol Exempt Status

## **7. PROCESS OVERVIEW**

### **7.1 Exempt Review / Determination Procedure**

IRB Staff makes sure all documents are reviewed for submission, per SOP 301, Research Submission Requirements.

The IRB Administrator provides to the IRB Chair or designee the item to be reviewed and the tools to conduct the review.

**7.1.1** Upon initial review of the research project, the IRB Chair may request verification and/or additional Information from the investigator in order to determine whether exemption is appropriate. The IRB will communicate this request to the investigator in writing.

- 7.1.2 If the research project meets exempt criteria as stated in Section 1.1 above, the IRB Chair will stamp it approved, indicate the exempt criteria number, and forward the research project to the IRB Administrator.
- 7.1.3 If the research project fails to meet the criteria for exemption, the IRB Chair will determine whether the project requires approval under expedited criteria as referenced in SOP 402, Expedited Review or by convened IRB review.
- 7.1.4 The IRB Administrator records the date of the exempt determination in the database, generates an anniversary date for renewal, generates the approval letter, and forwards the approval letter to the investigator.

## 7.2 Renewal of Exemption Procedure

The IRB shall send a letter to the investigator on an annual basis to determine if the research project remains active and continues to meet the qualifications for exempt status.

- 7.2.1 Within eleven months from the original approval date, the IRB staff will generate a notification letter to the investigator.
- 7.2.2 The investigator must respond to the IRB noting whether or not the project remains active and any changes that have occurred that could change the qualifications for exempt status.
- 7.2.3 Upon receipt of the letter from the investigator, the IRB processes the letter based upon the response given. If the investigator indicates the study is active, the letter is filed in the study file. If the investigator indicates the study is inactive, the IRB staff will present the file to the IRB Chair for inactivation.
- 7.2.4 If the investigator does not respond by the anniversary date of the original approval, the IRB staff will present the file to the IRB Chair for inactivation.
- 7.2.5 The IRB staff records the date of inactivation in the database, generates the inactivation letter, and forwards the letter to the investigator.
- 7.2.6 The termination is recorded in the next appropriate agenda/minutes for reporting to the IRB.

**APPROVED BY:** \_\_\_\_\_ **DATE:** 09/01/2009

**NEXT ESTABLISHED REVIEW DATE:** MAY 2012