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 University criteria, except as specifically noted below.

When a research project is reviewed under exempt criteria, the IRB 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 IRB 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 IRB reviewer shall determine whether the project will be reviewed either as expedited or by the convened IRB.

Research projects cannot be exempted from IRB Review if:

- The research is FDA-regulated
- The research involves prisoners as participants.

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 is 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.

1.1.2 Classroom-Based Research Projects Conducted by OU Students: Many OU courses include instruction on research design and methods and feature an experiential learning component requiring data collection from humans. The majority of these projects do not require IRB review since they are limited in scope and sample size, do not collect sensitive information and are not intended to be publically disseminated as generalizable knowledge.

There are three types of classroom-based research projects that have an elevated level of risk and require IRB review to determine they if are human research. These include:

1. Projects that include deception or that may elicit a strong

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emotional response from the participant and require referrals to a mental health professional.

2. Projects that include a physical testing procedure such as large volume blood draws or exposure to radiation.

3. Projects that gather data from protected or special populations such as children, cognitively impaired persons, prisoners, or the elderly.

1.1.3 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 participants; 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.

1.1.4 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.

1.1.5 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

1.1.6 Research and demonstration projects that are conducted by or subject to the approval of department or agency heads and that 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.

1.1.7 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.

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 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 research project file. The IRB staff will send written documentation to the investigator indicating the project meets exempt criteria and that the research may begin.

The Investigator is responsible for notifying the IRB of any proposed changes to the research. Investigators requesting approval of revisions to previously approved research projects must submit a protocol modification for approval prior to implementation. For specific policy details, see SOP 405: Modifications.

The Investigator is responsible for notifying the IRB of the completion of the research project. For specific policy details, see SOP 408: Research Project Completion.

2. SCOPE

This SOP applies to investigator requests for exemption from IRB review.

3. RESPONSIBILITY

The IRB Chair or IRB 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 405: Modifications

SOP 408: Research Project Completion

SOP 501: Special Populations

6. ATTACHMENTS

Reviewer Checklist (HSC)

Reviewer Checklist (NC)

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 assigns to the IRB Chair or IRB designee the item to be reviewed. The Reviewer Checklist is provided in the IRB's electronic information system 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.

7.1.2 If the research project meets exempt criteria as stated in Section 1.1 above, the IRB Chair will approve, 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 and category of exemption in the IRB's electronic information system, generates the approval letter, and forwards the approval letter to the investigator.

APPROVED BY:_____ **DATE: 08/31/2014**

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016