SOP 401: RESEARCH EXEMPT FROM FEDERAL REGULATIONS

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 during or after their lifetimes shall be reviewed by the IRB. **An investigator may not make the determination of whether a research project is exempt from federal regulations (and therefore 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 the regulations. 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 exempt from federal regulations (and therefore IRB review) if:

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

Specific Policies

1.1 Classroom-Based Research Projects Conducted by OU Students

In addition to the federal regulations, the University considers research projects in which the involvement of human participants fall into the following category are exempt from IRB review:

1.1.1 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 because they are limited in scope and sample size, do not collect sensitive information, and are not intended to be publically disseminated as generalizable knowledge.

1.1.2 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 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.

1.2 Exempt Research Project Criteria

**NOTE:** Research projects that the IRB determined to be exempt prior to January 21, 2019, under the pre-2018 Common Rule will continue to be subject to the pre-2018 regulations until closure. Please refer to the pre-2018 Common Rule for the applicable federal
Projects subject to the 2018 Common Rule in which the involvement of human participants will be in one or more of the following categories may be exempt from IRB review:

1. Research conducted in established or commonly accepted educational settings and that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes:
   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.

2. Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), if at least one of the following criteria is met:
   a. Information obtained is recorded in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants;
   b. Any disclosure of the human participants’ responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, educational advancement, or reputation. (NOTE: The Department of Veterans Affairs (VA) also includes loss of insurability in this category); OR
   c. The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by 45 CFR46.111(a)(7).

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.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
   a. The information is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants; OR
   b. Any disclosure of the human participants’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to
the participants’ financial standing, employability, educational advancement, or reputation; OR

c. The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR§46.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on the participants, and give investigator no reason to think the participants will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having participants plan an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

a. The identifiable private information or identifiable biospecimens are publicly available;

b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human participants cannot be readily ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants;

c. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under HIPAA, 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); OR

d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
5. Research and demonstration projects that are conducted by or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

a. Each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

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.

1.2 Exempt Research Project Review

Protection of participants in exempt research includes determining 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 interests 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 no additional action is required by the IRB.

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 details, see SOP 405: Modifications.

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

2. SCOPE

This SOP applies to investigator requests to the IRB for exemption determinations.

3. RESPONSIBILITY

The IRB Chair or IRB designee is responsible for the review of exemption requests and making exempt determinations.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101, 104
21 CFR 56.104, 105
Pre-2018 Common Rule 45 CFR 46.101

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

7.1.1 IRB Staff makes sure all documents are reviewed for submission, per SOP 301: Research Submission Requirements.
7.1.2 The IRB Administrator assigns to the IRB Chair or IRB designee the item to be reviewed. The IRB Chair is provided a Reviewer Checklist in the IRB’s electronic information system to conduct the review.

7.1.3 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.

7.1.4 If the research project meets exempt criteria as described in Section 1.1 above, the IRB Chair will approve, indicate the exempt criteria number, and forward the research project to the IRB Administrator.

7.1.5 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.

7.1.6 The IRB Administrator will record the date of the exempt determination and category of exemption in the IRB’s electronic information system, generate the approval letter, and forward the approval letter to the investigator.

APPROVED BY:___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020