

# Oklahoma State University Institutional Review Board Standard Operating Procedures

<b>Exempt Review</b>	SOP #	RR 401
	Effective Date	1/1/2012
	Revision Date	08/12/2019
	Revision #	3
	Approval: IRB	10/17/2019

## 1. POLICY

Oklahoma State University policy 4-0115, Policy for the Protection of Human Subjects in Research, requires that, prior to initiation of any human subjects research related activities (i.e. prior to recruitment of subjects and data collection), all research involving human beings as subjects of research, including research with human material (e.g., pathological and diagnostic specimens) obtained from living individuals, be reviewed and approved by the IRB.

Research activities in which the only involvement of human subjects will be in one or more specific categories, which are listed in section 1.1 of this policy, may be deemed exempt. Determination of exempt status must be based upon regulatory and institutional criteria and the exemption decision must be documented. Determination of exempt status must be conducted by the IRB Manager, the IRB Coordinator, or the IRB Chair (or his/her designee). No investigator or department shall have the authority to make this decision.

Exempt research must be of [minimal risk](#) to the subjects, have a sound research design, and be conducted ethically, meaning that at a minimum the principles of respect of persons, beneficence and justice must be met. The individual making the exemption determination may require protections to meet these principles, including informed consent appropriate to the research, or review at a convened meeting of the IRB.

No research involving **prisoners** as the subject population may be classified as exempt.. Note that studies that are aimed at involving a broader subject population that only incidentally includes prisoners may be deemed exempt.

### Specific Procedures

#### 1.1 Determining Exempt Status

The IRB makes the final determination regarding whether an application qualifies for exempt status. Research activities in which the only involvement of human subjects will be in one or more of the exempt categories listed in 45 CFR 46.104 may be deemed exempt by the IRB. For reference, a description of exempt categories is included at the end of this document.

#### 1.2 Submission

##### 1.2.1

The investigator submits an electronic copy via IRBManager of a completed IRB application form to the IRB in the Office of University Research Compliance (URC).

**1.2.2** Upon receipt of the application in IRBManager tracking begins and a protocol number is assigned upon assignment to a reviewer.

#### 1.3 Review

**1.3.1** Research applications submitted by investigators will be evaluated by the IRB Coordinator, the IRB Manager, or the IRB Chair (or his/her designee), the exempt review determination is made by the IRB personnel and is assigned to a reviewer.

**1.3.2** If the reviewer feels that the protocol does not meet the criteria for exemption, the review level will be changed and the application will be processed at that level.

**1.3.3** IRB members assigned as reviewers of exempt protocols are responsible for notifying the OSU IRB staff if they are not able or available to conduct the review and of any conflict of interest she/he may have in regards to the assigned review.

**1.3.4** The reviewer makes one of the following determinations or recommendations by completing the IRB Review form:

- i. **Approved:** The research procedures and associated documents meet the criteria for exempt determination with no further revision needed.
- ii. **Approved with Conditions:** The research procedures and associated documents meet the criteria for exempt determination with no further revision needed. However, final approval is contingent upon receiving external documentation as specified (i.e., school permissions, other committee approvals, second IRB approval documentation, etc.).
- iii. **Pending Revision:** Minor revisions that do not involve substantive issues must be made before the research can be approved. The investigator must submit the revisions for review.
- iv. **Designated for expedited review or full board review:** The reviewer determines that the application should be reviewed at a convened meeting of the IRB or *via* expedited review.
- v. **Not research involving human subjects:** The proposed activity does not meeting the federal definition of research involving human subjects per 45 CFR 46.

**1.3.5** When an application is placed in pending revision status, the approval status and any suggested revisions will be communicated in IRBManager.

**1.3.6** Investigators are responsible for submitting any requested revisions. The IRB Manager or IRB Coordinator reviews the response to the request for revisions to determine if the investigator's response is appropriate. If the response is deemed appropriate, the protocol is approved in IRBManager.

**1.3.7** If the IRB Manager or IRB Coordinator determines that the revisions are inappropriate or insufficient, the investigator will be asked to make further revisions. This review and revision process will continue until the application is approved or reassigned to a different review level (e.g., expedited or full board).

**1.3.8** When an application is approved with conditions, the IRB office will generate a "conditionally approved" letter that will be sent to the investigator stipulating the documents that are needed prior to final approval. Upon receipt of the requested documentation, an exempt determination letter will be issued as described in 1.3.9.

**1.3.9** When an application is approved, the IRB office will generate the exempt determination letter, along with all recruiting, consent and debriefing documents with the IRB approval stamp affixed with the date of IRB approval. Stamped recruitment, consent documents, etc. will be found in the attached documents of the study in the electronic system, IRBManager.

**1.3.10** A report of all exempt determinations made since the previously convened meeting of the IRB will be posted to the IRB members' secure website prior to the next convened meeting of the IRB. The report will also contain lists of applications approved under expedited review procedures and continuing review procedures, as well as those applications for which modifications were approved since the previously convened meeting of the IRB.

**1.3.11** The Institutional Official (IO) will be informed of IRB actions.

## **1.4 Approval Period**

**1.4.1** Applications deemed exempt do not need annual review.

## 1.5 Modifications to Exempt Studies

Modifications that increase risk to subjects must be submitted via IRBManager to the IRB for review. Researchers can make *minor* changes to an exempt study without notifying the IRB. Minor changes are changes that do not increase risk to subjects. [Examples of minor changes that do not require submission to the IRB:](#)

- Editorial or administrative revisions to consent documents or other study documents
- Adding non-sensitive questions to a survey or interview or revising current questions in a way that does NOT increase risk to participants
- Adding sensitive questions to a survey if no direct or indirect subject identifiers are collected
- Adding a new [recruitment material](#) that follows IRB guidelines
- Increasing or decreasing the number of subjects, unless you are adding a new subject population
- Study team/personnel changes (except a change in PI)

## 1.6 Notification of the IRB

IRB applications that undergo exempt review are documented and a list is made available to all members *via* IRBManager and presented to the Board at the next convened meeting.

## 1.7 Exempt studies approved prior to January 21, 2019 (date of implementation of the Revised Common Rule)

Studies that received an exempt determination prior to the implementation of the Revised Common Rule are “grandfathered in” under the previous regulations. No action is required on the part of the investigator.

## 2. Applicable Regulations and Guidelines

45 CFR 46 subpart A

OSU Policy 4-0115, Policy for the Protection of Human Subjects in Research

## **Exempt Categories from 45 CFR 46.104**

1. Research conducted in established or commonly accepted educational settings, 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 most research on regular and special education instructional strategies, and 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. However, this category does not apply to Food and Drug Administration (FDA) regulated research.*

2 Research that only includes 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:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects 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).

**Note:** *Research activities which qualify for (i) and (ii) involving children that qualify for exempt status in this category are those involving educational tests and observation of public behavior where the investigator does not participate in the activity being observed; surveys and/or interviews involving minors do not qualify for this exemption. Paragraph (iii) of this section may not be applied to children as participants.*

3 Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject 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:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects 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 a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play 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 the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Research involving minors is not eligible for this category of exemption.

**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:

- i. The identifiable private information or identifiable biospecimens are publicly available;
- ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 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
- iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch 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.

**Note:** *This category may be applied to research involving children however, this fourth criteria is unlikely to be used. **Please contact the IRB office if you feel that this category is applicable to your study.** Also, this category may not be applied to research involving primary collection from subjects; collection must be performed for a non-related purpose. Collection can be either prospective or retrospective.*

**5** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the 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.

- i. 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.

**Note:** *This category may be applied to research involving children.*

**6** Taste and food quality evaluation and consumer acceptance studies if:

- i. Wholesome foods without additives are consumed, **or**
- ii. 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.

**Note:** *This category may be applied to research involving children.*

**1.1.7** Storage or maintenance for secondary research for which broad consent is required:

- i. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

**1.1.8** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);
- ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;
- iii. An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph 1.1.8(i) of this section; and
- iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

**Note:** *At this time OSU-Stillwater will not implement new Exempt categories 7 & 8 due to a possible increase in researcher's burden to track and store broad consents. This may change after additional guidance is provided by the Office of Human Research Protections (OHRP).*