Exempt Status Initial Review Procedures

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Policy Statement

All proposed projects that involve regulated research with human subjects must be reviewed prior to the activity beginning. Three types of review of proposed studies are conducted: exempt status review, expedited review, and full Board review.

To assure protection of human research subjects, institutional policy requires that all protocols believed by the investigator to be "exempt" must be reviewed by the Office of Research and Sponsored Projects Operations to certify whether the research in fact qualifies for exempt status. While most research activities in this category do not undergo IRB review, the ORSPO requires review to confirm exempt status and to determine that the research meets the ethical standards of UIW.

Description and Procedures

A. Qualifications for Exempt Status Review

In order to qualify for exempt status, research must be no more than minimal risk, and must fit into one or more of the categories listed below.

Minimal risk is defined in 45 CFR 46.102(j): "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

B. Exempt Categories

Category 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 or special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 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:

1. 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; and/or

2. 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.

This exemption DOES NOT apply to research involving minors, except for research involving only educational tests or the observation of public behavior when the investigator does not participate in the activities being observed.

Category 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:

1. 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; and/or

2. 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.

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.

Category 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:

1. the identifiable private information or identifiable biospecimens are publicly available;

2. information 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;

3. the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under the HIPAA Privacy Rule for the purposes of health care operations, research, or public health activities; and/or

4. research that is conducted by, or on behalf of, a Federal department/agency or using government-generated or government-collected information obtained for non-research activities.

Category 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, 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.

Category 6: Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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.

These exemptions do not apply to research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Effective Date

August 24, 2020

Revision History

References

45 CFR 46