UNIVERSITY OF SOUTH ALABAMA

IRB SOP 502
Exempt Research

Purpose

Research activities in which the only involvement of human subjects will be in one or more specific categories (45 CFR 46.101(b)) may be exempt from IRB review. The determination by the IRB of exemption must be based on regulatory, institutional and ethical criteria, and be appropriately documented. In addition, the IRB, must determine whether research that qualifies for an exemption requires consideration under the HIPAA regulations for the use and/or disclosure of protected health information.

Scope

This Standard Operating Procedure applies to all Investigators submitting exempt research for IRB review, and the IRB Office/designee when reviewing exempt request.

Definitions

Exempt Review Categories: The following six exemption categories are outlined by federal regulations as follows:

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 and 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:

a) The information obtained is recorded by the investigator in such a manner that the identity of the human participant's 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;

- or -

c) 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 §46.111(a)(7)

NOTE: Projects involving oral histories are not considered research unless the projects (a) utilize a "systematic investigation" with analysis of data to answer a scientific question and (b) are designed to develop or contribute to generalizable knowledge.

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:

a) The information obtained 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 subjects; 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 participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7)

For the purposes of this provision, benign behavioral interventions are brief, 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 purpose 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.

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 are met:

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

b) Information, which may include information about biospecimens, 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, the investigator does not contact the participants, and the investigator will not re-identify participants; or

c) 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 options" 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

Category 5 Research and demonstration projects which are conducted by or subject to the approval of (Federal) department or agency heads and which are designed to study, evaluate or otherwise examined

Category 6 Taste and food quality evaluation and consumer acceptance studies

NOTE: Research which involves photographing, audiotaping, or videotaping of participants during the research may be granted an exemption with some discretion as it relates to identifiability or sensitivity of the research. Projects involving photographing, audiotaping, or videotaping will be reviewed on a case by case basis to determine the risk in relation to the identifiability of the photographs, audios, and/or videos along with the sensitivity of the questions being asked. The use of scrambling technologies, such as voice alteration or blurring/masking, also will be taken into consideration.

Category 7 and 8 The USA IRB does not utilize these categories for review/approval of exempt research.

Policy

Research initially submitted as exempt before January 21, 2019, shall comply with the Common Rule pre-2018 requirements. Exempt research submitted approved after January 21, 2019 will comply with the Common Rule 2018 requirements.

Research activities in which the only involvement of human subjects are in one or more of the categories listed 45 CFR 46.101(b) may be exempted from IRB review. Studies that qualify for exemption are only required to adhere to certain federal regulations and must also follow state laws and University policies applicable to research. Studies that qualify for exemption must adhere to principles of sound research design and ethics. Participant rights and welfare must also be protected in a manner appropriate for research that poses minimal risk.

Submissions of exempt research will be reviewed by the IRB Office, or member of the Office of Research Compliance and Assurance. The reviewer may request the assistance of other individuals in the consideration of exempt status. Investigators do not have the authority to make an independent determination that research involving human subjects qualifies for an exemption.

1.0 Exempt Research Involving Minors

Research involving minor children may be exempt only as it applies to categories 1, 4, 5, 6, 7 and 8. Research involving minors which falls under category 2 may be exempt for educational tests and observation (when the investigator does not participate in the activities being observed). **Research involving survey or interview procedures may not be exempted for minors.** Research involving prisoners may not be exempted, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Procedures

1.0 If an Investigator believes that his/her research study meets the federal regulations, and institutional and ethical criteria for an exemption from IRB review, he/she will complete the appropriate USA IRB Application dependent on the nature of the research study. (i.e., Exempt Application, Retrospective Request for Review of Medical Records, Use/Storage of Biological Specimens)

2.0 HIPAA Compliance

2.1 The reviewer will determine whether the proposed research involves the use and/or disclosure of Protected Health Information and that such use and/or disclosure complies with USA IRB and USA Health Systems policies.

2.2 If PHI is to be used/disclosed in the research, the investigator may request that a HIPAA waiver or alteration of authorization to be approved by the IRB. Alternatively, the investigator may obtain authorization from each subject.

2.3 Any time the IRB grants a waiver or alteration of Authorization, the IRB office will indicate that a waiver or alteration has been granted to the investigator in the approval letter.

2.4 Investigators must account for any disclosures under a waiver of authorization

3.0 Obtaining Informed Consent in Exempt Research

Informed consent is a practice that helps to ensure that the rights and welfare of participants are protected. The IRB requires that informed consent from participants be obtained when it is reasonable and practicable to do so. The process of informed consent process must still be upheld (with the exception of obtaining signatures). The IRB requires an information sheet to be used to disclose the required basic elements of consent, such as (i) that the activity involves research (ii) a description of the procedure(s), (iii) that participating is voluntary, (iv) name and contact information for the investigator, and (v) other information may be provided to the potential participants as appropriate in order for participants to make an informed decision. The IRB provides an Information Sheet template to be used as a guide in creating a consent document.

Consent documents processed for exempt research are marked with an IRB approval stamp in the footer; however, because the project does not expire or require continuing review, no expiration date will appear with the stamp. The document is considered “approved”, however, requires an annual check-in with the IRB. An automated generated email via IRBNet will be disseminated to prompt Investigators of the requirement to complete and submit the annual check-in form.

4.0 Changes to Exempt Research

3.1 Investigators should consult with the IRB or submit an amendment if they wish to make changes to an exempt study.

3.2 Investigators shall document revisions to the research on an IRB Amendment Form and submit to the IRB Office via IRBNet online management system.

3.3 The IRB will evaluate revisions according to 45 CFR 46.101(b) to determine if the revised research meets the exempt criteria.

3.4 The IRB Office will notify investigators of the determination.

3.4.1 If the revisions alter the research such that the study is no longer exempt from IRB review, the investigator shall submit the study to the IRB on the IRB Expedited Application form and IRB approval must be secured prior to implementation of the changes.

3.4.2 If the revised research study continues to meet the exempt from IRB review criteria, the IRB Office will document the exempt category on the IRB Approval Letter.

5.0 Annual Check-In

In the absence of continuing review for exempt studies, USA IRB has implemented an automated email notification via IRBNet requesting an annual check-in to report on status of project and remind the study team of their responsibilities. IRBNet will generate 60 and 30 day notice of reminders prior to the anniversary approval date for the study.

IRB Responsibilities Related to Exempt Research

The IRB ensures valid claims of exemption by reviewing the proposed research via an IRB application. A designated IRB member determines that the study is exempt from further IRB review and from applicable federal regulations governing human research, under 45 CFR 46.101(b) or according to University of South Alabama IRB policy. All research involving human subjects must be approved or exempted by the IRB before the research is conducted.

The IRB determines that the study is in compliance with applicable laws and regulations, including the HIPAA Privacy Rule, state law, and institutional policy.

The IRB determines that the study conforms to the principles of sound research ethics, in accordance with principles of the Belmont Report, as follows:

1.0 The research holds out no more than minimal risk to participants

2.0 The selection of subjects is equitable

3.0 If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data

4.0 If there are interactions with participants, there is a consent process that will disclose such information as:

4.1 That the activity involves research

4.2 A description of the procedures

4.3 That participating is voluntary

4.4 Name and contact information for the investigator

5.0 There are adequate provisions to maintain the privacy interest of participants
6.0 The research is conducted in an ethical manner which does not adversely affect the rights and welfare of the participants

Limited Review Requirements

1.0 Exempt categories 2, 3, 7, and 8 include a provision for limited IRB review.

For **exempt categories 2 and 3,** the requirement for limited IRB review is triggered when:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subject can readily be ascertained, directly or through identifiers linked to the subjects, AND

- Any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, education advancement, or reputation.

2.0 For **exempt categories 7 and 8,** limited review is always required. It is also important to remember that exempt categories 7 and 8 are only available for use when board consent will be (or has been) obtained. *The USA IRB has not implemented utilization for exempt categories 7 and 8.*

3.0 The IRB Chair or a member of the IRB designated by the IRB Office will review exempt declarations and studies requiring **limited review**.

4.0 The status and protocol will be updated in IRBNet to reflect the reviewer's determination.

Investigator Responsibilities Related to Exempt Research

1.0 The investigator submits proposed research to the IRB for review using the IRBNet online management system
2.0 The investigator begins research activities after documentation of IRB approval or exemption is received
3.0 The investigator ensures that the study is conducted in compliance with applicable laws and regulations, including the HIPAA Privacy Rule, state law, and institutional policy
4.0 The investigator ensures that the study conforms to the principles of sound research ethics, in accordance with principles of the Belmont Report, including but not limited to:
  4.1 Ensuring the research presents no more than minimal risk to participants
  4.2 Selecting subjects equitably
  4.3 If there is recording of identifiable information, maintaining the confidentiality of the data

4.4 If there are interactions with participants, conducting a consent process that will disclose such information as:
- 4.4.1 That the activity involves research
- 4.4.2 A description of the procedures
- 4.4.3 That participating is voluntary
- 4.4.4 Name and contact information for the investigator
- 4.4.5 Maintaining the privacy interest of participants
- 4.4.6 Conducting the research in an ethical manner which does not adversely affect the rights and welfare of the participants

5.0 The investigator conducts the research in compliance with the protocol as submitted to and exempted by the IRB

6.0 The investigator obtains approval for all changes to the protocol prior to implementing the changes

7.0 The investigator adheres to IRB policy for reporting unanticipated problems and deviation

Regulated Documentation

45 CFR 46.101(b) – Categories of Exempt Human Subjects Research

References

45 CFR 46.101(b) Categories of Exempt Human Subject Research
USA IRB: Getting Started- Determine Which Type of IRB Review Applies to Your Research
DHHS Office of Human Research Protections FAQS: Exempt Research Determinations

HISTORY

Effective Date:
Revisions: January 2019, February 2022