



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 501
IRB Review

Purpose

This purpose of this document is to describe the review procedures followed by the University of South Alabama Institutional Review Board.

Scope

This policy and procedure applies to USA IRB members and Office of Research Compliance administrative staff, including the IRB Office.

Policy

1.0 IRB Review Requirement

IRB review and approval is required for all non-exempt human subject's research activities in which University of South Alabama is engaged, except when necessary to eliminate apparent immediate hazards to the human subjects. Review is required:

- 1.1 Before initiating a project (initial approval)
- 1.2 Before initiating any modifications to the project
- 1.3 At least once each calendar year (for applicable studies) or unless not required by the regulations governing a study
- 1.4 For any problems or relevant new information that develops during the research (i.e., adverse events)

2.0 Prospective approval

Review and approval must be obtained before implementing the activities, except for activities that are necessary to eliminate apparent immediate hazards to the subjects. Approval cannot be granted retrospectively, after a research activity has begun. This

applies to all activities, including modifications that may appear to investigators to be largely administrative in nature.

3.0 Materials reviewed

Investigators are expected to use the forms and guidance provided by the USA IRB to provide sufficient information to the research community and the IRB to make specific required determinations and to decide whether the criteria for IRB approval have been met.

3.1 When the research is conducted by a team of two or more individuals, the IRB requires the name and identifying information for only those individuals who will fulfill certain roles, as described in the IRB application forms.

4.0 Action of the IRB

Federal regulations give the USA IRBs the authority to take specific actions. USA policy grants additional authority to the USA IRB for some specific additional actions. See *SOP 303: Meeting Procedures and IRB Actions*. The IRBs are not authorized to take actions not specified in federal regulations, state law, or USA policy.

5.0 Approval periods and dates

With each review of an entire project (i.e., at initial and continuing review), the IRB may be required to specify the duration of the approval period depending upon the regulations that govern the study. This determines the date of the next continuing review (if required).

5.1 The approval date is the date when the research is approved

5.2 The expiration date of the approval period is at 11:59 pm on the last day of the approval period

5.3 The next report due date (annual check-in) is set one year from the date of initial approval. The annual check-in is required for studies that are exempt, where continuing review has been eliminated or approved by an external IRB.

5.4 The approval period of a study does not change when the IRB approves a modification or when the IRB suspends the IRB approval of a study

6.0 Communication of review outcomes

Outcomes of IRB review are communicated via IRBNet email notifications and published IRB board documents.

7.0 Investigator responses

Investigators are expected to respond to IRB reviews in a timely fashion and as described in the IRB board published document (i.e., modification request letter). Failure to respond may result in the administrative closure of the item. When the investigator fails to respond to the review of an initial application or a status report (i.e., expiration notice, annual-check in, etc.) the entire project may be administratively closed, unless there is an unresolved issue related to compliance or subject safety and rights. When this occurs, human subjects research activities must cease immediately (except as necessary to protect the safety of the subjects) and cannot resume until the investigator has fulfilled the requirements of the IRB.

7.0 Pre-review

The IRB review is preceded by a pre-review process performed by IRB staff or designee. This ensures that applicable regulatory requirements and determinations have been identified, and that the provided materials and information are complete.

Procedures

1.0 Materials reviewed

The IRB reviews the materials provided by the investigator, the IRB Office, and any other sources. See *SOP 302: Materials for Review*. As needed, the IRB asks the investigator for additional information, materials, or clarification. Consultants may also be obtained at any point during the review process.

2.0 Type of Review

The review may be conducted by the **full convened IRB** or by the **expedited process**.

Expedited review follows the procedures described in this document as well as the procedures described in *SOP 504: Expedited Research*. Eligibility for expedited review is determined by the IRB Office during the pre-review process.

3.0 Criteria for approval

The generic criteria for IRB approval are described in the *SOP: 506: Criteria for IRB Approval of Research*. Other criteria are specific to certain types of research or applicable regulations. The pre-review process identifies for the IRB which criteria of approval are applicable to an item being reviewed. The IRB may require changes, actions, and/or information in order to determine that the criteria for approval have been met. Section 5 lists examples.

4.0 General regulatory determinations

The IRB is required by federal regulations or USA policy to make the following Determinations for each initial review and continuing review. These determinations are noted in the IRB meeting minutes.

4.1 For reviews conducted by the full convened IRB, the IRB decides:

Whether the study meets the Expedited Category 9 criteria for conducting the next continuing review by the expedited review process. (A decision that the study does not meet the criteria does not need to be recorded in the meeting minutes.) Those criteria are:

The remaining research activities involve no more than minimal risk to subjects;

4.2 Study-specific regulatory determinations. The IRB is often required to make study-specific regulatory determinations as part of the review.

4.2.1 Which determinations. IRB staff identify the required study-specific determinations during the pre-review, to assist the IRB. The determinations may be:

4.2.1.1 Required by the regulations governing a study. For example, the IRB is required by federal regulations to specify which of four regulatory risk-and-benefit categories apply to a study involving children before it can approve the study.

4.2.1.2 Required by agencies providing funding or other involvement in the study. For example, the IRB is required to determine whether a medical monitor is necessary for studies in which the federal Department of Defense is involved.

4.2.1.3 Required by investigator request. Some determinations are required to respond to a request by an investigator. For example, the investigator may request a waiver of the requirement to obtain consent from the subjects.

4.2.2 IRB Actions

The *SOP 303: Meeting Procedures and IRB Actions* describes actions that may be taken by the IRB at the conclusion of a review. The actions are based on the IRB's assessment of whether the item met the applicable criteria for approval and whether the IRB was able to make the required determinations.

4.2 Communication of actions and determinations

The IRB communicates its actions and determinations, as required by federal regulations and as appropriate to the situation. Communication is in writing, using standardized templates. As appropriate, phone calls may communicate the outcomes in advance of a written communication.

- 4.2.1 To the investigator. The response letter is prepared by the IRB Office (with appropriate review provided by the IRB member, as applicable). The investigator receives IRB published board documents via IRBNet email notifications.
- 4.2.2 To the institution (USA). The outcomes are reported to the USA IRB via the meeting minutes, the Institutional Official has access to IRBNet.
- 4.2.3 To the IRB. The IRB members are advised via IRB meeting minutes of research proposals which have been approved by the expedited/exempt review process at the regular scheduled meetings of each IRB committee. to meeting minutes.
- 4.2.4 To other USA components or external entities (if applicable). A copy of the USA acknowledgment letter is provided to the investigator/research site.

4.0 Examples of IRB required actions, changes and information (not a complete list)

Examples of requirements for approval	
1	Require additional information from the researcher.
2	Require additional information or consultation from others.
3	Change the frequency of continuing review.
4	Require reports from the investigator after specific milestones (for example, after the first five subjects have completed the study intervention).
5	Obtain verification from sources other than the investigator that no material changes have occurred since the last IRB review. <i>However, the IRB is encouraged to rely upon the Human Subjects Protection Program to determine an appropriate and feasible way to obtain post-approval monitoring, auditing, or observation. Example: The IRB votes to require confirmation that subjects are not enrolled in a study unless they have met eligibility requirements, through independent review of the documentation for 10% of the subjects. The IRB requires HSD to determine an appropriate and feasible method of accomplishing this.</i>
6	Observe or have a third party observe the consent process and/or the research. <i>The IRB is encouraged to be as specific as possible about what it wishes to observe and, as necessary, how to do so. However, the IRB is encouraged to rely upon the Human Subjects Protection Program to help it determine an appropriate and feasible method for the observation.</i>
7	Require changes to parts of the research. Examples: add or drop procedures; changes in eligibility criteria; changes in recruitment approaches; changes in subject populations; enhanced confidentiality protections for data; etc.
8	Addition of safety monitoring procedures, such as additional lab tests for subjects or the additional of a medical monitor.

Examples of requirements for approval	
9	Enhanced confidentiality protections for data, such as data encryption on laptops.
10	Provision of a subject advocate.
11	Require re-consenting of subjects.
12	Require information to be provided to subjects (for example, new information about the risks of the study).
13	Require information to be provided to others – such as other entities involved in the research; subjects’ physicians; etc.
14	Require HSD and/or the researcher to report a problem or concern to funding agencies, sponsors, other UW offices, co-investigators, collaborators, and/or collaborating institutions.
15	Require training and education for the investigator or other individuals involved in the research.
16	Require the investigator to obtain permission from a site, to conduct the research.
17	Require that subject identifiers (or the link between data and identifiers) to be destroyed if those identifiers were collected (or relevant research procedures were performed) without prior IRB approval.
18	Require the investigator to submit a new (i.e., replacement) application for the study (especially if the existing file has become exceedingly large and complex).
19	Require the investigator to separate the existing study/application into two separate IRB applications, to facilitate IRB review and oversight. For example, a repository might be spun off of the main study.
20	Require the Director, Office of Research Compliance to forward to the appropriate institutional office (as discussed by the IRB) a request to consider the following actions (for which the IRB itself does not have the authority): <ul style="list-style-type: none"> • Require that data not be published or presented • Require that data not be used for a thesis or dissertation • Require that data be destroyed • Restrict the number of active studies for an investigator • Prohibit an investigator from engaging as the lead responsible party in human subjects research

University Related Documents

[SOP 302: Materials for Review](#)

[SOP 303: Meeting Procedures and IRB Actions](#)

[SOP: 506: Criteria for IRB Approval of Research](#)

HISTORY

Effective Date: November, 2018

Revisions:

Responsible Party:

Office of Research Compliance and Assurance