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

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 invee ms (a)10 pt afuldil14 (l14 ()14 (te)3 (d)t[le(al)]T0 r)TJ0.33 0.13 w 7.2 7 9.0 16 d0 ( )Td( )TJ Artifact 0.002 Tc 0 Tw 4.23 4.

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 review [illegible]

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.

However, the IRB is encouraged to rely upon the Human Subjects Protection P

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

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