UNIVERSITY OF SOUTH ALABAMA

IRB SOP 202
Ancillary Reviews

Purpose

This document outlines additional requirements for ancillary committee reviews. The USA IRB communicates between various offices, as appropriate and may rely upon oversight monitoring by these groups in lieu of monitoring at the study site conducted by the IRB.

Scope

The USA IRB, as well as appropriate University ancillary committees, must approve the research protocol and, when applicable, the consent form(s) to be used to obtain informed consent of subjects prior to the initiation of the research and enrollment of subjects. The decision of the USA IRB to disapprove a research protocol cannot be overruled by any other institutional body or individual(s)

Policy

Ancillary review assists the IRB with matters related to research feasibility, risk, regulatory requirements and research compliance. Not all studies require ancillary review. If ancillary review is required, documentation of IRB approval cannot be released until all ancillary reviews are completed.

The IRBNet system automatically routes submissions requiring an ancillary review to the appropriate departments or committees for approval.

Procedures

1.0 Institutional Biosafety Committee (IBC)

The IBC is responsible for ensuring that recombinant DNA activities comply with the NIH guidelines. Projects involving human gene therapy must be reviewed by the IBC. The IRB and the IBC communicates regarding committee deliberations.

2.0 Radiation Safety Committee

If a study requires radiation outside the standard of care, the Radiation Safety Committee must review the study prior to USA IRB granting final approval. This committee reviews any research that involves use of X-ray, radioisotopes or lasers. The committee provides expertise with regards to accepted radiation protection practices and regulations. The USA IRB allows concurrent review between both committees and defers the release of the study contingent upon the Radiation Safety Committee determinations.

3.0 Sponsored Projects Administration / Clinical Trials

The Director, Clinical Trials and Sponsored Projects Administration each provide additional oversight of human subject's research during their routine review of grants and contracts. These offices communicate with the IRB to resolve issues regarding IRB review of human subject's research, including conflict of interest issues. Sponsored Projects Administration processes all human research with external support which is funded from governmental agencies via Cayuse and requires the appropriate institutional office(s) review research proposals.

4.0 HIPAA Privacy and Security Office

The USA HIPAA Privacy and Security Office may be assigned to review IRB protocols, if needed for additional input. Additionally, a Business Associate Agreement may be required for data transactions of protected health information or a Limited Data Use Agreement.

5.0 Business Office

A W-9 is required to be issued to a study participant for completion before payments are made to participants. This W-9 form is completed and returned to the proper University Business Office. A 1099 will be issued to any subject that is paid $600 or more in a calendar year.

University Related Resources

Office of Research Compliance and Assurance
Office of Sponsored Projects Administration
Radiation and Laser Safety Office

HISTORY

Effective Date:
Revisions: November, 2018