UNIVERSITY OF SOUTH ALABAMA

IRB SOP 302
IRB Materials for Review

Purpose

This Standard Operating Procedure (SOP) describes the materials provided to the IRB for review purposes.

Policy

IRB review materials are provided to IRB members seven calendar days in advance of convened meetings, except in special circumstances described in *SOP 301: IRB Meeting Preparation*. IRB members may request additional information or supporting documents at any time.

Procedures

1.0 IRB Review Procedures

1.1 Primary/Secondary Reviewers

The primary and secondary reviewer (if applicable) for a given research protocol should make an evaluation of the protocol before the convened IRB meets and present the protocol during the meeting. A primary/secondary reviewer system is used for review of initial protocols which two members are assigned to lead the review and present the protocol for discussion at the convened meeting. Primary/secondary reviewers are assigned in advance of the meeting by the IRB chair or staff. This review/presentation should include an overview of the project and the identification of major issues arising in the project.

1.2 Other reviewers

All IRB members receive the IRB agenda, previous month's minutes for approval, appropriate IRB application(s), informed consent (or request to waiver informed consent) and surveys/questionnaires. Relevant materials are to be provided for all types of IRB review including initial review, continuing review and amendments for review at the convened meeting.

2.0 Materials Provided to IRB Members for Review

2.1 General
- 2.1.1 Meeting Agenda
- 2.1.2 Minutes for previous meetings
- 2.1.3 Report of completed expedited reviews
- 2.1.4 Educational materials

2.2 Initial Applications – Materials provided by the investigator (as applicable)
- 2.2.1 Application form(s)
- 2.2.2 Application supplements
- 2.2.3 Consent/assent
- 2.2.4 Recruiting materials
- 2.2.5 Data collection instruments
- 2.2.6 Investigator's drug brochure/package insert
- 2.2.7 Device brochure/other device information
- 2.2.8 Industry research: Protocol
- 2.2.9 Relevant grant applications/contracts
- 2.2.10 Financial Conflict of Interest disclosure/management plan
- 2.2.11 Other materials relevant to study or deemed useful by the IRB

2.3 Continuing Reviews
- 2.3.1 Continuing Review form
- 2.3.2 Updates to IRB Application Part A
- 2.3.3 Consent/assent documents
- 2.3.4 Relevant post-approval reports (e.g., Data Safety Monitoring reports)
- 2.3.5 Any other materials provided by the investigator
- 2.3.6 Other materials relevant to study or deemed useful by the IRB

2.4 Amendments
- 2.4.1 Amendment Review form
- 2.4.2 Modified protocol
- 2.4.3 Modified consent/assent
- 2.4.4 Modified recruitment materials
- 2.4.5 Modified investigator brochure/package insert
- 2.4.6 Other modified study documents

University Related Documents

SOP 301: IRB Meeting Preparation

History:

Effective Date:
Revisions: October, 2018

Responsible Office:

Office of Research Compliance and Assurance