



Purpose

This document describes the procedures used to prepare for a meeting of the full convened IRB.

Definitions

Primary reviewer: The IRB member with the most appropriate expertise for reviewing a specific item. The primary reviewer:

- Provides a brief summary of the item to the IRB
- Leads a discussion of the criteria for approval with respect to the item, including the identification of any concerns
- Usually makes the first motion proposing specific IRB actions (for example, approval)
- May assist in writing or reviewing correspondence to the investigator that communicates the IRB's decisions, requirements, and questions

Secondary reviewer: An IRB member who fulfills the same responsibilities as the primary reviewer and who is chosen to ensure an appropriate balance of scientific and/or non-scientific expertise for a specific item. Secondary reviewers are not a routine part of the USA IRB review process.

A secondary review is NOT required for review of expedited studies that is reviewed outside an IRB convened meeting.

Quorum: Quorum consists of half plus one voting IRB members.

4.0 Prepare meeting materials. The IRB Office prepares the materials for IRB members, referring to the *SOP 302: Materials for Review* to ensure that all appropriate materials are provided, according to the individual's roles (i.e., primary review, other members, Chair, etc)

5.0 The IRB Office disseminates meeting materials via IRBNet online management system.

6.0 Urgent items. Items requiring urgent review may be provided to the IRB Office after an agenda has been completed and distributed with review materials. The IRB Office will use judgment (and may consult with the Chair, possible primary reviewer, or Office of Research Compliance and Assurance) to decide whether the urgent item can and should be placed on the already-distributed agenda for a pending IRB meeting. The following factors are considered:

6.1 Availability of an appropriate primary reviewer and/or consultant

6.2 Number of days prior to the IRB meeting

6.3 Size and complexity of the late materials

6.4 Urgency of the issue. Examples of urgent issues include but are not limited to:

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