

4 IRB Structure and Administration:

4.2 IRB Meeting Procedures

Effective Date: 6/11/2010
Revised: 12/09/2011,
6/12/2015

The Institutional Review Board (IRB) holds convened meetings on a regular basis to review proposed and ongoing human research projects, and conduct other business related to human subject protections at NDSU.

1.0 Meeting schedule.

IRB meetings are scheduled as frequently as necessary to conduct required protocol reviews; additional meetings may be called at the discretion of the Chair. HRPP staff schedule monthly meetings for each fiscal year, and make the schedule available to IRB members, the campus community, and general public via the website.

2.0 Agenda.

Under the direction of the IRB Chair, HRPP staff draft the meeting agenda. The IRB Vice Chair, other members, and the IO may also provide input. The agenda may include the following as applicable:

- Call to order
- Conflict of interest disclosure (refer to SOP 7.4 *Full Board Review*)
- Announcements
- Old business:
 - Approval of previous meeting minutes
 - Status of previously reviewed protocols
 - Attachment of other IRB actions since last meeting
- New business:
 - Review of new protocols
 - Review of protocols for continuation
 - Review of protocol amendments
 - Review of reports of noncompliance or unanticipated problems
- Discussion items:
 - Review of proposed revisions to policy or procedures
 - Other discussion items related to human research protections
- Continuing education

HRPP staff distribute agenda and meeting materials to IRB members approximately one week in advance of the meeting date to allow sufficient time for review. IRB actions taken outside of a convened meeting, including expedited reviews and exempt determinations, are reported via an attachment as described in *4.3 IRB Records*.

3.0 Quorum.

A **quorum**, consisting of a simple majority of the members, including at least one **nonscientist** member, is required to conduct IRB review and take official actions. Should quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests, early

departures, or absence of a nonscientist member), no further votes or actions may be taken by the IRB.

3.1 Participation by conference call.

Members not available to physically attend a meeting may participate by another means (e.g., by telephone conference call). Applicable meeting materials must be received sufficiently in advance, and provisions made for their equal and active participation in real-time discussions during the meeting.

3.2 Alternate members.

Designated alternate members may vote in the absence or recusal of a regular member in order to achieve or maintain quorum; the substitution is noted in meeting minutes. Alternate members are also encouraged to attend convened meetings in a non-voting capacity to gain and maintain familiarity with the review process and current IRB issues. Refer to SOP 4.1 *IRB Membership* for more information.

3.3 Recusal for conflict of interest.

Quorum is affected when a member is recused for a **conflict of interest**. No member may participate in IRB review of new or continuing research in which they have a conflict of interest, except to provide information requested by the IRB, as described in 7.4 *Full Board Review*. The conflicted member may provide information regarding the project, but must leave the room prior to IRB discussion and voting. The recusal, including its justification, and the absence of the conflicted member is documented in meeting minutes.

3.4 Abstentions.

A member may choose to abstain from voting on a particular protocol for any reason. The abstention is documented in the meeting minutes, but does not affect quorum.

4.0 Call to order.

The IRB Chair calls the meeting to order and directs it according to the agenda. In the absence of the Chair, the Vice Chair (or substitute Vice Chair) shall convene and direct the meeting.

4.1 Review and Consideration of Protocols.

The IRB conducts initial and continuing reviews of research, as described in 7.4 *Full Board Review*. After preliminary discussion with investigators and/or reviewers, the IRB Chair/designee calls for a 'motion to consider' from the board members. After further discussion and deliberation, the motion may be put to a vote. Approval of the motion requires a simple majority of those voting members present and contributing to the quorum. The IRB Chair is considered a voting member, except in the case of a recusal or abstention, as described above.

4.2 Other action items.

The IRB may discuss and take action on other items, such as new procedures or guidance, or issues of non-compliance or complaints. After preliminary discussion, the IRB Chair calls for a 'motion to consider' from the board members. After further discussion and deliberation, the motion may be put to a vote. Approval of the motion requires a simple majority of those voting members present and contributing to the quorum.

5.0 Meeting minutes.

HRPP staff document the proceedings of the meeting, as described in *4.3 IRB Records*. Draft minutes are reviewed for approval at the next convened meeting.

DEFINITIONS:

Nonscientist member: someone whose primary concerns are in nonscientific areas.

Quorum: the presence of a majority of IRB members, including one nonscientist member.

Conflict of interest: an interest (financial or other) in the outcome of the research that conflicts with, or has the potential to create a bias in, consideration for the protection of the safety and welfare of research participants.

REFERENCES:

[45 CFR 46.115\(a\)\(2\)](#) and [21 CFR 56.115\(a\)\(2\)](#) IRB records
[45 CFR 46.108\(b\)](#) and [21 CFR 56.108\(c\)](#) IRB functions and operations
[OHRP guidance on Written Procedures](#)

RELATED HRPP SECTIONS:

- 4.1 IRB Membership
- 4.3 IRB Records
- 6.1 Conflicts of Interest – IRB Members
- 7.2 Criteria for IRB Approval
- 7.4 Full Board Review