



SOP: IRB Meeting Conduct

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1 PURPOSE

- 1.1 This procedure establishes the process for conducting convened Institutional Review Board (IRB) meetings.
- 1.2 The process begins when the IRB members gather for a convened meeting.
- 1.3 The process ends when the meeting is adjourned.

2 PREVIOUS VERSION

- 2.1 Revised from previous version 05/20/2020.

3 POLICY

- 3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
- 3.2 The IRB chair (and vice chair, when applicable) votes as a regular member.
- 3.3 IRB attendance is captured by documenting in the minutes the IRB members and alternates (voting and non-voting alternates) in attendance as listed on the IRB roster, the substitution of a voting member by an alternate, and IRB members who are recused due to a conflicting interest. Staff and guest attendance are also recorded in the minutes.
- 3.4 If the quorum is lost during a meeting, the IRB cannot discuss or take votes until the quorum is restored. Even if the quorum is restored, the IRB cannot take votes unless members with the appropriate expertise are also present per "WORKSHEET: Quorum and Expertise (HRP-305)."
- 3.5 Substantive changes and other issues related to the criteria for approval require review and approval by the convened IRB.
- 3.6 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual).
- 3.7 The IRB will ensure the review of Conflicts of Interest (COI) during convened meetings as outlined below.
- 3.8 The worksheets and checklists described in "WORKSHEET: Review Materials (HRP-301)" and listed below in "Section 6: MATERIALS" are made available to IRB members in advance of meetings per "SOP: IRB Meeting Preparation (HRP-040)" to conduct meetings and fulfill regulatory requirements.

4 RESPONSIBILITIES

- 4.1 The IRB chair carries out these procedures, unless otherwise noted.
- 4.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.

5 PROCEDURE

- 5.1 The agenda will list the quorum for the meeting. IRB Office staff in attendance will ensure that the meeting attendance is properly constituted and that the quorum calculation for the meeting is correct and met (see "WORKSHEET IRB Composition -HRP-304" and "WORKSHEET: Quorum and Expertise -HRP-305").
- 5.2 The Chair will call the meeting to order when 5.1 is met. The Chair will ask IRB members whether anyone has a stake in the outcome or a Conflicting Interest for any item on the agenda and document the responses.
- 5.3 IRB Chair and/or IRB Office staff will identify which IRB members present at the meeting are voting members.
- 5.4 To further support ease of identification throughout the meeting, an identification tool may be used that will identify the voting status of each member in attendance .
- 5.5 For each agenda item, the following items will be completed:



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- 5.5.1 If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of those members and then ask the members to leave the meeting for discussion and voting.
- 5.6 For each agenda item involving the initial review, modification, or continuing review of a protocol, the Chair will:
- 5.6.1 If a consultant is present, ask the consultant to present their review to the IRB. If they are not present, the review will be read.
- 5.6.2 Ask the assigned reviewer(s) to present their review to the IRB. If the member is not present, ask another member to read the review.
- 5.6.3 For initial and continuing reviews, ask the primary reviewer to lead the IRB through a thorough and thoughtful discussion of the criteria for approval [see "WORKSHEET: Criteria for Approval (HRP-314)"] and all checklists and worksheets as appropriate (listed below).
- 5.6.4 For modifications, ask the assigned reviewer to summarize the changes or information. Ask the convened IRB to discuss and determine which regulatory criteria are met (or continue to be met), which are not met (or no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.
- 5.6.5 The panel will review the COI status for each PI or Co-Investigator (previously determined by the COI Office or the University's COI Committee) for all Initial Reviews and Continuing Reviews to confirm that either:
- 5.6.5.1 There is no conflict for each PI or Co-Investigator, or
- 5.6.5.2 If there is a conflict identified for a PI and/or Co-I, the Board will review the respective management plans that have been executed and uploaded by the COI Office to ensure that the consent and protocol documents align with the COI management plan requirements.
- 5.6.5.3 If the COI review status is pending at the conclusion of the meeting, the IRB Chair or IRB Office Staff will consider if it requires convened review at a future meeting. New Studies may not be approved when the COI status for the PI or Co-I is pending.
- 5.6.5.4 For a pending COI review, if there is a COI management plan that includes anything more involved than simple disclosure of the financial interest or other conflict in the consent document, consider whether it must return to the convened IRB for review.
- 5.6.6 The Chair or staff will restate the IRB's consensus regarding any protocol specific findings justifying a determination when the determination is required by a checklist (and not previously determined and documented).
- 5.6.6.1 For a pending COI review, if there is a COI management plan that includes anything more involved than simple disclosure of the financial interest or other conflict in the consent document, consider whether it must return to the convened IRB for review.
- 5.6.7 Once the discussion of the agenda item has concluded, a motion for one of the following actions will be made:
- 5.6.7.1 Approve: (with a specific continuing review interval for initial or continuing review when applicable): Made when all criteria for approval are met. Include in the motions for initial and continuing review the period of approval and the level of risk.
- 5.6.7.2 Modifications Required to Secure Approval: (with a specific continuing review interval for initial or continuing review when applicable): Made when all criteria for approval are met and the IRB members require specific modifications, such that an IRB Office staff member, Chair, or IRB member can determine whether an investigator has made the required changes,



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without needing to judge whether a change meets the regulatory criteria for approval. When making this motion, the assigned primary reviewer restates the modifications required by the IRB members and the IRB member's reasons for those changes. Include in the motions for initial and continuing review the period of approval and the level of risk.

5.6.7.3 **Defer:** Made when the research does not qualify for Approval or Modifications Required to Secure Approval, and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision and describes recommendation to make the research approvable. All deferred submissions must go back to the same IRB panel that conducted the initial review.

5.6.7.4 **Disapprove:** Made when the research does not qualify for Approval or Modifications Required to Secure Approval, and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB members' reasons for the decision.

5.6.7.5 **Suspension or Termination of IRB Approval:** Made for some or all of the research activities when the panel determines that either the previously approved research is not being conducted in accordance with the NU IRB requirements, and/or that the research has been associated with unexpected serious harm to participants. When making this motion, have the primary reviewer use the "WORKSHEET: Reportable New Information Items (HRP-321)" to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member's reasons for the decision.

5.7 For each agenda item that is Reportable New Information (Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, or Terminations of IRB Approval) the Chair will:

5.7.1 Ask the primary reviewer to use the "WORKSHEET: Reportable New Information Items (HRP-321)" to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

5.7.2 Restate the IRB's consensus regarding any actions that need to be taken to protect subjects.

5.7.3 Make a motion for the IRB's determination(s) regarding the action items (e.g., "the motion is for the Principal Investigator to provide the IRB additional information regarding the status of currently enrolled subjects").

5.7.4 Open the floor for additional discussion.

5.7.5 Call for a vote.

5.7.5.1 Only voting IRB members may vote in a meeting.

5.7.5.2 Alternate members will only vote if their voting counterpart is not present when the vote is called.

5.7.5.3 Consultants and those with a COI may not vote.

5.7.5.4 For a motion to be approved, it needs the approval of more than half of the members present at the meeting. If there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5, respectively.

5.7.5.5 Re-invite IRB members with a Conflicting Interest back to the meeting.

5.8 Adjourn the meeting when notified by IRB Office staff that quorum has been lost, or the meeting is not properly constituted, or when there is no further business to conduct.



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6 MATERIALS

- 6.1 CHECKLIST: Pre-Review (HRP-401)
- 6.2 CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
- 6.3 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
- 6.4 CHECKLIST: Pregnant Women (HRP-412)
- 6.5 CHECKLIST: Non-Viable Neonates (HRP-413)
- 6.6 CHECKLIST: Neonates of Uncertain Viability (HRP-414)
- 6.7 CHECKLIST: Prisoners (HRP-415)
- 6.8 CHECKLIST: Children (HRP-416)
- 6.9 CHECKLIST: Cognitively Impaired Adults (HRP-417)
- 6.10 CHECKLIST: Non-Significant Risk Device (HRP-418)
- 6.11 CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
- 6.12 CHECKLIST: Waiver of HIPAA Authorization (HRP-441)
- 6.13 WORKSHEET: Genetic Biobanking Studies (HRP-442)
- 6.14 CHECKLIST Principal Investigator (PI) Transfer of Responsibilities (HRP-1408)
- 6.15 SOP: IRB Meeting Preparation (HRP-040)
- 6.16 WORKSHEET: Review Materials (HRP-301)
- 6.17 WORKSHEET IRB Composition (HRP-304)
- 6.18 WORKSHEET: Quorum and Expertise (HRP-305)
- 6.19 WORKSHEET: Pre-Review (HRP-308)
- 6.20 WORKSHEET: Criteria for Approval (HRP-314)
- 6.21 WORKSHEET: Advertisements (Recruitment Materials) (HRP-315)
- 6.22 WORKSHEET: Payments (HRP-316)
- 6.23 WORKSHEET: Short Form of Consent Documentation (HRP-317)
- 6.24 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- 6.25 WORKSHEET: Criteria for Approval for HUD (HRP-323)
- 6.26 WORKSHEET: Reportable New Information Items (HRP-321)

7 REFERENCES

- 7.1 21 CFR §50.20, §50.25, §56.109, §56.111
- 7.2 45 CFR §46.109, §46.111, §46.116, §46.117
- 7.3 34 CFR 356.3
- 7.4 ICH-GCP 2.4, 2.5, 2.13, 3.2.6