



## SOP: IRB Meeting Conduct

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-041	Executive Director, IRB Office Northwestern University	05/20/2020	Page 1 of 4

### 1 PURPOSE

- 1.1 This procedure establishes the process to conduct convened 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 01/21/2019.

### 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 Meetings are conducted in person or via teleconference.
- 3.4 IRB attendance is captured by documenting in the minutes the IRB members (voting, alternates) in attendance, replacement of a voting member by an alternate, attendance of IRB members who participate through teleconference, and IRB members who are recused due to a conflicting interest.
- 3.5 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored. Even if quorum is restored, the IRB cannot take votes unless members with the appropriate expertise are also present per "WORKSHEET: Quorum and Expertise (HRP-305)".
- 3.6 Substantive changes and other issues related to the criteria for approval require review and approval by the convened IRB.
- 3.7 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.
- 3.8 The IRB will ensure review of Conflict of Interest (COI) during convened meetings as outlined below.
- 3.9 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 Call the meeting to order.
- 5.2 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 and verbally announce which IRB members present at the meeting are voting members. To further support ease of identification throughout the conduct of the meeting, an identification tool may be used that will plainly display the voting status of each member in attendance (e.g. a name tent card or other identification tool).
- 5.4 For each agenda item the following items will be completed:



## SOP: IRB Meeting Conduct

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-041	Executive Director, IRB Office Northwestern University	05/20/2020	Page 2 of 4

- 5.4.1 Table the item when notified by IRB Office staff that requirements for review of a specific item as defined in “WORKSHEET: Quorum and Expertise (HRP-305)” are not met.<sup>1</sup>
- 5.4.2 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 room for discussion and voting. If attending by teleconference, place the members with a Conflicting Interest on hold or disconnect for discussion and voting.
- 5.5 For each agenda item involving the initial review, modification, or continuing review of a protocol:
  - 5.5.1 If there is a consultant present, ask the consultant to present his or her review to the IRB.
  - 5.5.2 If a consultant provided written information to the IRB, ask the Primary reviewer to present that information to the IRB.
  - 5.5.3 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.
  - 5.5.4 Ask the primary reviewer to lead the IRB through a thorough and thoughtful discussion of the criteria for approval in the “WORKSHEET: Criteria for Approval (HRP-314)” and all checklists and worksheets as appropriate (listed below) to have the convened IRB 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.
  - 5.5.5 The Board will review COI status for each PI or Co-Investigator (previously determined by the COI Office or the University’s COI Committee) for all New Projects and Continuing Reviews to confirm that either: (1) There is no conflict for each PI or Co-Investigator, or (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. 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.
  - 5.5.6 Restate the IRB’s consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.
  - 5.5.7 Once the discussion of the agenda item has concluded, a motion for one of the following actions will be made:
    - 5.5.7.1 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.
    - 5.5.7.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review when applicable): Made when IRB members require specific modifications such that an IRB Office staff member can determine whether an investigator has made the required changes, 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

---

<sup>1</sup> “Tabled” is not an action of the IRB, but is a status based on the inability of the IRB to take an action because of reasons of quorum.



## SOP: IRB Meeting Conduct

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-041	Executive Director, IRB Office Northwestern University	05/20/2020	Page 3 of 4

- 5.5.7.3 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.
- 5.5.7.4 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 member's reasons for the decision.
- 5.5.7.5 Suspension or Termination: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use the "WORKSHEET: Review of 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.
- 5.5.8 Review any modifications required to secure approval to ensure that the IRB Office staff has recorded them.
  - 5.5.8.1 Ensure that the required modifications include any necessary review considerations in the Pre-Review activity.
  - 5.5.8.2 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 For each agenda item that is 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):
  - 5.6.1 Have the primary reviewer use the "WORKSHEET: Review of Information Items (HRP-321)" to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.
  - 5.6.2 Restate the IRB's consensus regarding any actions that need to be taken to protect subjects.
  - 5.6.3 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).
  - 5.6.4 Open the floor for additional discussion.
  - 5.6.5 Call for a vote.
    - 5.6.5.1 Only voting IRB members may vote in a meeting.
    - 5.6.5.2 Alternate members will only vote if their voting counterpart is not present when the vote is called.
    - 5.6.5.3 Consultants may not vote.
    - 5.6.5.4 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.)
    - 5.6.5.5 Re-invite IRB members with a Conflicting Interest back to the meeting
- 5.7 Adjourn the meeting when notified by IRB Office staff that quorum has been lost, or when there is no further business to conduct.



## SOP: IRB Meeting Conduct

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-041	Executive Director, IRB Office Northwestern University	05/20/2020	Page 4 of 4

### 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 SOP: IRB Meeting Preparation (HRP-040)
- 6.13 WORKSHEET: Review Materials (HRP-301)
- 6.14 WORKSHEET: Quorum and Expertise (HRP-305)
- 6.15 WORKSHEET: Pre-Review (HRP-308)
- 6.16 WORKSHEET: Criteria for Approval (HRP-314)
- 6.17 WORKSHEET: Advertisements (Recruitment Materials) (HRP-315)
- 6.18 WORKSHEET: Payments (HRP-316)
- 6.19 WORKSHEET: Short Form of Consent Documentation (HRP-317)
- 6.20 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- 6.21 WORKSHEET: Criteria for Approval for HUD (HRP-323)
- 6.22 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