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| SOP: IRB Member Review Expectations |          |             |
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## 1 PURPOSE

- 1.1 This policy establishes for the review of Human Research the expectations of IRB members in advance of a meeting or when serving as a Designated Reviewer.

## 2 POLICY

- 2.1 In this policy, "all IRB members" refers to all members of the committee who will be present with voting status.
- 2.1.1 For review using the expedited (non-committee) procedure, the Designated Reviewer fulfills the roles described for the primary reviewer, and the scientific/scholarly reviewer, or obtains consultation for these roles.
- 2.2 All IRB members are to treat all oral, written and electronic information obtained as part of the review process as confidential. IRB members must not disclose, use, share or duplicate review documents or confidential information without prior authorization.
- 2.3 All IRB members are to know the definition of Conflicting Interest.
- 2.3.1 No IRB member may participate in any review (including discussion or voting) in which he or she has a Conflicting Interest, except to provide information requested by the IRB.
- 2.3.2 When reviewing an item each IRB member is to consider whether he or she has a Conflicting Interest and if so, self-identify that Conflicting Interest.
- 2.4 All IRB members are provided a user account in the electronic IRB submission system for access to review materials.
- 2.4.1 All IRB members are to access all review materials through the electronic system.
- 2.4.2 IRB members attending by video or teleconference are to access all review materials through the electronic system.
- 2.4.3 Any IRB member may request review materials be delivered outside the electronic system by contacting the IRB staff.
- 2.5 All members assigned as a primary reviewer or scientific/scholarly reviewers are to consider whether they have sufficient expertise to review the submission. If additional expertise is required, follow SOP Consultation (HRP-051). Sufficient expertise includes as applicable for the research:
- 2.5.1 Scientific or scholarly expertise
- 2.5.2 Knowledge of or experience working with vulnerable populations
- 2.5.3 Qualifications as a prisoner representative
- 2.5.4 Knowledge of the country in which the research is conducted
- 2.5.5 Medical licensure for FDA-regulated test articles
- 2.6 All IRB members review the Pre-Review findings for each submission, if any.
- 2.7 All IRB members consider the criteria in all applicable worksheets and checklists.
- 2.7.1 Worksheets and checklists are available in the IRB Library through the electronic system or can be available outside the electronic system by contacting the IRB staff.
- 2.7.2 The primary presenter for each submission is expected to use applicable worksheets and checklists for preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings justifying determinations.
- 2.7.3 The primary presenter leads the discussion.
- 2.7.4 IRB members who are not the primary presenter for a submission do not need to complete any checklists.
- 2.7.5 "WORKSHEET: Criteria for Approval (HRP-314)" applies to all non-exempt research.
- 2.8 For initial review: In advance of the meeting, all IRB members review the following materials to a depth sufficient to determine whether the criteria in applicable worksheets and checklists are met:
- 2.8.1 Application form with local context (TEMPLATE PROTOCOL - HRP-503)

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- 2.8.2 Study Protocol
- 2.8.3 Consent/Assent document(s) and script(s), when applicable
- 2.8.4 HIPAA Authorization
- 2.8.5 Recruitment materials, when applicable
- 2.9 For review of a modification: In advance of the meeting, all IRB members review the modification, determine which criteria in applicable worksheets and checklists are affected, and criteria are met:
  - 2.9.1 Protocol
  - 2.9.2 Consent document(s) and script(s), when they exist
  - 2.9.3 HIPAA Authorization
  - 2.9.4 Recruitment materials, when they exist
- 2.10 For continuing review: In advance of the meeting, all IRB members review continuing review progress report and attachments, determine which criteria in applicable worksheets and checklists are affected, and review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:
  - 2.10.1 Protocol
  - 2.10.2 Current consent document(s) and script(s), when they exist
  - 2.10.3 Recruitment materials, when they exist
- 2.11 For review of new information<sup>1</sup>: In advance of the meeting, all IRB members review the new information and attachments, determine which criteria in applicable worksheets and checklists are affected, and review the relevant sections of the following materials to a depth sufficient to determine as necessary whether affected criteria are met:
  - 2.11.1 Protocol
  - 2.11.2 Previously submitted modifications or a summary thereof
  - 2.11.3 Consent document(s) and script(s), when they exist
  - 2.11.4 Written reports of consultants or auditors, when they exist
- 2.12 The primary presenter reviews all submitted materials for consistency with the materials reviewed by all IRB members, including the following additional documents when they exist:
  - 2.12.1 The complete research protocol including any previously approved protocol modifications
  - 2.12.2 Investigator brochure
  - 2.12.3 Contract or grant application
  - 2.12.4 Model template consent document
  - 2.12.5 New Information reported during the current period of approval for continuing review submissions.
- 2.13 If the HHS supported research involves prisoners as subjects, the prisoner representative reviews the submitted information to determine whether the criteria in “CHECKLIST: Prisoners (HRP-415)” are met, be present when the research is reviewed<sup>2</sup>, and provide a review either orally or in writing.
- 2.14 IRB members or consultants with scientific or scholarly expertise review the submitted information in enough depth to answer the questions in “WORKSHEET: Scientific and Scholarly Review (HRP-320).”
- 2.15 All IRB members review written reports of consultants, if any.
- 2.16 Any IRB member who needs to access additional information in the IRB records can contact an IRB staff member for assistance.
- 2.17 A subset of materials that are to be made available for review include (see: WORKSHEET: Review Materials (HRP-301)
  - 2.17.1 List of protocols approved using the expedited procedure (For Veterans Administration (VA) Research, include the review category.)

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2.17.2 List of protocols approved after verification of Modifications Required to Secure Approval for VA Research.

2.17.3 Information for Other Business items

2.17.4 Educational Materials when applicable

### 3 Materials:

- 3.1 WORKSHEET: Review Materials (HRP-301)
- 3.2 WORKSHEET: Criteria for Approval (HRP-314)
- 3.3 WORKSHEET: Short Form of Consent Documentation (HRP-317)
- 3.4 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- 3.5 WORKSHEET: Scientific or Scholarly Review (HRP-320)
- 3.6 WORKSHEET: Review of Information Items (HRP-321)
- 3.7 WORKSHEET: Criteria for Approval for HUD (HRP-323)
- 3.8 CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
- 3.9 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
- 3.10 CHECKLIST: Pregnant Women (HRP-412)
- 3.11 CHECKLIST: Non-Viable Neonates (HRP-413)
- 3.12 CHECKLIST: Neonates of Uncertain Viability (HRP-414)
- 3.13 CHECKLIST: Prisoners (HRP-415)
- 3.14 CHECKLIST: Children (HRP-416)
- 3.15 CHECKLIST: Cognitively Impaired Adults (HRP-417)
- 3.16 CHECKLIST: Non-Significant Risk Device (FDA) (HRP-418)
- 3.17 CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
- 3.18 CHECKLIST: HIPAA Waiver of Authorization HRP-441
- 3.19 TEMPLATE PROTOCOL - HRP-503

### 4 References:

- 4.1 AAHRPP II.2.C, II.2.D, II.2.E