	SOP: Member Review Expectations		
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1 PURPOSE

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

2 REVISIONS FROM PREVIOUS VERSION

2.1 Revised from 5/30/2017 version

2.2 Revised from 6/30/2019 version

3 SOP Statement

3.1 In this SOP, “all IRB members” refers to all members of the committee who will be present with voting status.

3.1.1 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.

3.2 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.

3.3 All IRB members are to know the definition of Conflicting Interest.

3.3.1 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.

3.3.2 When reviewing an item each IRB member is to consider whether he or she has a Conflicting Interest and if so, to disclose that Conflicting Interest.

3.4 All IRB members are provided a user account in the electronic IRB submission system for access to review materials.

3.4.1 All IRB members are to access review materials through the electronic system.

3.4.2 IRB members attending by video or teleconference are to access review materials through the electronic system.

3.4.3 Any IRB member may request review materials be delivered outside the electronic system by contacting the IRB/HRPP staff.

3.5 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 HRP-051 - SOP - Consultation. Sufficient expertise includes as applicable for the research:

3.5.1 Scientific or scholarly expertise

3.5.2 Knowledge of or experience working with vulnerable populations

3.5.3 Qualifications as a prisoner representative

3.5.4 Knowledge of the country in which the research is conducted

3.5.5 Medical licensure for FDA-regulated test articles

3.5.6 Knowledge of community base participatory research

3.6 IRB members have access to review the Pre-Review stipulations for each submission, if any.


3.7 IRB members consider the applicable criteria for each submission and use the worksheets and checklists, as needed.

3.7.1 Worksheets and checklists are available through the HRPP/IRB website or the electronic system or can be available outside the electronic system by contacting the IRB/HRPP staff.


3.7.2 The primary presenter for each submission may use applicable worksheets and checklists as needed to support preliminary judgments as to whether each criterion is met along with the rationale for the determination.

3.7.3 The primary presenter leads the discussion.

3.7.4 IRB members who are not the primary presenter for a submission do not need to use any worksheets or checklists.

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- 3.7.5 HRP-314 - WORKSHEET - Criteria for Approval is appropriate for all non-exempt research.
- 3.7.1 IRB/HRPP staff may assist IRB members with the use or completion of worksheets and checklist as requested.
- 3.8 For initial review: In advance of the meeting, all IRB members review the following materials, as applicable, to a depth sufficient to determine whether the criteria are met using applicable worksheets and checklists as needed:
 - 3.8.1 Protocol application form with local context
 - 3.8.2 Sponsor Protocol
 - 3.8.3 Consent/Assent document(s) and script(s)
 - 3.8.4 Survey Instruments
 - 3.8.5 HIPAA Authorization
 - 3.8.6 Recruitment materials
- 3.9 For review of a modification: In advance of the meeting, all IRB members review the modification and the following materials, as applicable, to determine which criteria are affected using applicable worksheets and checklists, as needed:
 - 3.9.1 Protocol Application form
 - 3.9.2 Sponsor Protocol
 - 3.9.3 Consent document(s) and script(s)
 - 3.9.4 Survey Instruments
 - 3.9.5 HIPAA Authorization
 - 3.9.6 Recruitment materials
- 3.10 For continuing review: In advance of the meeting, all IRB members review continuing review progress report and attachments, determine which criteria are affected and use applicable worksheets and checklists, as needed, and review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:
 - 3.10.1 Protocol
 - 3.10.2 Current consent document(s) and surveys or script(s), when they exist
 - 3.10.3 Recruitment materials, when they exist
- 3.11 For review of new information: In advance of the meeting, all IRB members review the new information and attachments, determine which criteria are affected, using applicable worksheets and checklists, as needed, and review the relevant sections of the following materials to a depth sufficient to determine as necessary whether affected criteria are met:
 - 3.11.1 Protocol application and/or sponsor protocol
 - 3.11.2 Previously submitted modifications or a summary thereof
 - 3.11.3 Consent document(s) and surveys or script(s), when they exist
 - 3.11.4 Written reports of consultants or auditors, when they exist
- 3.12 The primary presenter reviews the submitted materials for consistency with the materials reviewed by all IRB members, including the following additional documents when they exist:
 - 3.12.1 The complete research protocol
 - 3.12.2 Investigator brochure for investigational drugs
 - 3.12.3 Model template consent document
 - 3.12.4 New Information reported during the current period of approval for continuing review submissions.
- 3.13 If the HHS supported research involves prisoners as subjects, the prisoner representative reviews the submitted information to determine whether the criteria for approval is met using HRP-415 - CHECKLIST - Prisoners as needed, be present when the research is reviewed², and provide a review either orally or in writing.

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- 3.14 IRB members or consultants with scientific or scholarly expertise review the submitted information in enough depth to answer questions and using HRP-320 - WORKSHEET - Scientific or Scholarly Review, as needed.
- 3.15 All IRB members review written reports of consultants, if any.
- 3.16 Any IRB member who needs to access additional information in the IRB records can contact an IRB/HRPP staff member for assistance.
- 3.17 A subset of materials that are to be made available for members as needed, include (see: HRP-301 - WORKSHEET - Review Materials)
 - 3.17.1 Information for Other Business items to be discussed
 - 3.17.2 Educational Materials when applicable

4 Materials:

- 4.1 HRP-051 - SOP - Consultation
- 4.2 HRP-301 - WORKSHEET - Review Materials
- 4.3 HRP-314 - WORKSHEET - Criteria for Approval
- 4.4 HRP-318 - WORKSHEET - Additional Federal Agency Criteria
- 4.5 HRP-320 - WORKSHEET - Scientific or Scholarly Review
- 4.6 HRP-321 - WORKSHEET - Review of Information Items
- 4.7 HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
- 4.8 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
- 4.9 HRP-412 - CHECKLIST - Pregnant Women
- 4.10 HRP-415 - CHECKLIST - Prisoners
- 4.11 HRP-416 - CHECKLIST - Children
- 4.12 HRP-417 - CHECKLIST - Cognitively Impaired Adults
- 4.13 HRP-418 - CHECKLIST - Non-Significant Risk Device
- 4.14 HRP-441 - CHECKLIST - HIPAA Waiver of Authorization
- 4.15 Electronic Protocol Application

5 References:

- 5.1 AAHRPP II.2.D, II.2.E, II.2.F