1. PURPOSE
   1. This procedure establishes the process for the review of Human Research and the expectations of IRB members in advance of a meeting or when serving as a Designated Reviewer.
   2. This procedure begins when the IRB member begins a review.
   3. This procedure ends when the IRB member completes a review.
2. POLICY
   1. For review using the expedited procedure, the Designated Reviewer fulfills the roles described for all IRB members, the primary presenter, and the scientific/scholarly reviewer, or obtains consultations for these roles.
   2. IRB members are to treat all oral and written information obtained as part of the review process as confidential and not disclose confidential information without prior authorization.
   3. IRB members are to know the definition of Conflicting Interest.
   4. IRB members are to review all agenda items for which they will be present with voting status.
   5. IRB members may not participate in any review (including discussion or voting) in which they have a Conflicting Interest, except to provide information requested by the IRB.
3. RESPONSIBILITY
   1. IRB members carry out these procedures.
4. PROCEDURE
   1. Evaluate whether you have a Conflicting Interest.
      1. When reviewing an item consider whether you have a Conflicting Interest and if so, self-identify that Conflicting Interest.
      2. When in doubt as to whether a Conflicting Interest exists, notify the IRB Executive Chair or Meeting Chair.
   2. Review Regulatory Review findings, if any.
   3. Consider the criteria in all applicable worksheets and checklists.
      1. If you are the primary presenter, in advance of the meeting:
         1. Review new or modified submitted materials for consistency with the materials reviewed by all IRB members, including the following when they exist:
            1. The complete protocol including any previously approved protocol modifications
            2. Investigator brochure
            3. HHS grant application
            4. HHS-approved protocol
            5. HHS-approved template consent document
         2. For initial review and for other reviews (review of a modification, continuing review, and/or new information[[1]](#footnote-2)) that affects the criteria in one or more applicable checklist, complete the checklist(s) with preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings justifying determinations.
         3. For review of a modification, continuing review, and/or new information that does not affect the criteria in an applicable checklist, do not complete the checklist.
      2. If you are not the primary presenter, you do not need to complete any checklists.
   4. For initial review: In advance of the meeting, review the following materials to a depth sufficient to determine whether the criteria in applicable worksheets and checklists are met:
      1. Initial application form(s)
      2. Sections of the protocol relevant to the criteria for approval
      3. Consent document(s) and script(s), when they exist
      4. Recruitment materials, when they exist
      5. Written reports of consultants, when they exist
   5. For review of a modification, continuing review, and/or new information:
      1. In advance of the meeting, review the modification, continuing review progress report, and/or new information.
      2. Review modified portions of the following materials, if any:
         1. Sections of the protocol relevant to the criteria for approval
         2. Consent document(s) and script(s), when they exist
         3. Recruitment materials, when they exist
      3. Determine which criteria in applicable worksheets and checklists are affected by the modification, continuing review progress report, and/or new information.
      4. If any criteria are affected, review the following materials as necessary to a depth sufficient to determine whether affected criteria are still met:
         1. Sections of the protocol relevant to the affected criteria for approval
         2. Sections of previously approved modifications relevant to the affected criteria for approval not reflected in the current protocol, when they exist
         3. Sections of previously approved consent document(s) and script(s) relevant to the affected criteria for approval, when they exist
         4. Recruitment materials, when they exist
         5. Written reports of consultants, when they exist
      5. If no criteria are affected, no other materials need to be reviewed.
   6. If you are an IRB member with scientific or scholarly expertise, review the submitted information in enough depth to answer the questions in “WORKSHEET: Scientific and Scholarly Review (HRP-401).”
   7. If the research involves prisoners as subjects and you are the prisoner representative, review the submitted information to determine whether the criteria in “CHECKLIST: Prisoners (HRP-308)” are met, be present when the research is reviewed[[2]](#footnote-3), and provide a review either orally or in writing.
   8. If you need to access minutes or other information in the IRB record, access that information directly or contact an HRPP staff member for assistance.
5. REFERENCES
   1. Defined terms are found in HRP 100 Policy:Definitions.

1. Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, and Termination of IRB Approval [↑](#footnote-ref-2)
2. The prisoner representative may attend the meeting by phone or video-conference, as long as the representative is able to participate in the meeting as if present in person. [↑](#footnote-ref-3)