



## **POLICY: IRB Member Review Expectations**

Document No.:	Edition No.:	Effective Date:	Page:
<b>HRP-020</b>	<b>001</b>	<b>January 2, 2020</b>	<b>Page 1 of 4</b>

### **1. PURPOSE**

- 1.1. This policy establishes the expectations of IRB members for IRB reviews.
- 1.2. For convened IRB meetings, this policy applies to all members who will be present with voting status.
- 1.3. For review using the expedited procedure, this policy applies to the **Designated Reviewer** who fulfills the roles described for the primary presenter, and the scientific/scholarly reviewer, or obtains consultation for these roles.

### **2. POLICY**

- 2.1. Treat all oral and written information obtained as part of the review process as confidential, and do not disclose or use confidential information without prior authorization.
- 2.2. For each review consider whether you have a **Conflicting Interest**.
  - 2.2.1. Know the definition of **Conflicting Interest**.
  - 2.2.2. If you have a **Conflicting Interest**, do not participate in that review (including discussion or voting) except to provide information requested by the IRB.
- 2.3. Attend meetings you are committed to attend.
  - 2.3.1. If you cannot attend a meeting you previously committed to attend, immediately notify HRPP staff.
- 2.4. In advance of the meeting:
  - 2.4.1. Review the submitted materials as directed in (See Table 1 in REFERENCES).
  - 2.4.2. Consider the criteria in all applicable worksheets and checklists.
  - 2.4.3. If during your review, you:
    - 2.4.3.1. Need answers to questions about the submitted materials, ask **Meeting Chair** or HRPP staff.
    - 2.4.3.2. Need minutes or other information in the IRB record that you cannot access directly, ask the HRPP staff.
    - 2.4.3.3. Think one or more criteria are not met, consider what specific and directive changes would make the protocol approvable.
  - 2.4.4. If you are the primary presenter:
    - 2.4.4.1. Fill out applicable checklists with preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings justifying determinations marked with “Ⓢ.”
    - 2.4.4.2. Review all submitted materials for consistency, including the following when they exist:
      - 2.4.4.2.1. The complete protocol including any previously approved protocol modifications
      - 2.4.4.2.2. Investigator brochure



## **POLICY: IRB Member Review Expectations**

Document No.:	Edition No.:	Effective Date:	Page:
HRP-020	001	January 2, 2020	Page 2 of 4

- 2.4.4.2.3. HHS-approved protocol
- 2.4.4.2.4. HHS-approved template consent document
- 2.4.4.3. Prepare to lead the discussion at the meeting.
- 2.4.5. If you are the prisoner representative and the protocol involves prisoners as research subjects, determine whether the criteria in "[CHECKLIST: Prisoners \(HRP-308\)](#)" are met, be present when the protocol is reviewed, and provide a review either orally or in writing.
- 2.4.6. If you are an IRB member with scientific or scholarly expertise, additionally review the submitted materials in enough depth to evaluate whether the materials accurately describe the subject risks, subject benefits, and knowledge to result, whether alternative procedures could consistent with sound research design could reduce risk, and whether the research design is sound enough to yield the expected knowledge.
- 2.5. At meetings
  - 2.5.1. Share your unique input to get all the issues on the table.
    - 2.5.1.1. If you have a question, ask.
    - 2.5.1.2. If you have information that has not been discussed, share it.
  - 2.5.2. We think critically and use the criteria for approval to decide whether to approve research.
    - 2.5.2.1. If you have a concern, problem, or recommended change, be able to base it on the criteria for approval. If you are unsure of the basis, ask.
    - 2.5.2.2. If you think a criterion for approval is not met, say so.
    - 2.5.2.3. If you think the criteria for approval are not met, do not vote for approval.
  - 2.5.3. Make decisions by majority rule, not consensus.
    - 2.5.3.1. Listen and learn from the group, but think and vote independently
    - 2.5.3.2. Know that dissent is healthy and expected.
    - 2.5.3.3. Respect the opinions of others
- 2.6. Improve your knowledge over time.
  - 2.6.1. Participate in required and optional continuing education.
  - 2.6.2. Accept constructive feedback.
- 3. **REFERENCES** (*see next page*)



**POLICY: IRB Member Review Expectations**

Document No.:	Edition No.:	Effective Date:	Page:
HRP-020	001	January 2, 2020	Page 3 of 4

	<b>Initial Review</b>	<b>Review of a Modification</b>	<b>Continuing Review</b>	<b>Review of New Information</b>
3.1.	<ul style="list-style-type: none"> <li>Review the following materials to a depth sufficient to determine whether the criteria in applicable worksheets and checklists are met:</li> </ul>	<ul style="list-style-type: none"> <li>Review the summary of the modification.</li> <li>Determine which criteria in applicable worksheets and checklists are affected.</li> <li>Review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:</li> </ul>	<ul style="list-style-type: none"> <li>Review the continuing review progress report and attachments.</li> <li>Determine which criteria in applicable worksheets and checklists are affected.</li> <li>Review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:</li> </ul>	<ul style="list-style-type: none"> <li>Review the new information and attachments.</li> <li>Determine which criteria in applicable worksheets and checklists are affected.</li> <li>Review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:</li> </ul>
<b>Review of Research</b>	<ul style="list-style-type: none"> <li>Initial application form(s)</li> <li>Protocol</li> <li>Any consent document(s) and script(s)</li> <li>Any recruitment materials</li> <li>Any reports of consultants</li> <li>Any other information all IRB members were asked to review</li> </ul>	<ul style="list-style-type: none"> <li>Protocol</li> <li>Previously approved modifications not reflected in the current protocol, or a summary thereof</li> <li>Any consent document(s) and script(s)</li> <li>Any recruitment materials</li> <li>Any reports of consultants</li> <li>Any other information all IRB members were asked to review</li> </ul>	<ul style="list-style-type: none"> <li>Protocol</li> <li>Previously approved modifications not reflected in the current protocol, or a summary thereof</li> <li>Any consent document(s) and script(s)</li> <li>Any recruitment materials</li> <li>Any reports of consultants</li> <li>Any other information all IRB members were asked to review</li> </ul>	<ul style="list-style-type: none"> <li>Protocol</li> <li>Previously approved modifications not reflected in the current protocol, or a summary thereof</li> <li>Any consent document(s) and script(s)</li> <li>Any recruitment materials</li> <li>Any reports of consultants</li> <li>Any other information all IRB members were asked to review</li> </ul>



**POLICY: IRB Member Review Expectations**

Document No.:	Edition No.:	Effective Date:	Page:
HRP-020	001	January 2, 2020	Page 4 of 4

<b>Review of HUD Use</b>	<ul style="list-style-type: none"> <li>• HDE approval order</li> <li>• Description of the device</li> <li>• Product labeling</li> <li>• Any patient information packet</li> <li>• A summary of the proposed use of the device, including screening procedures, the HUD procedure, and patient follow-up visits, tests, or procedures.</li> </ul>	<ul style="list-style-type: none"> <li>• Description of the device</li> <li>• Product labeling</li> <li>• Any patient information packet</li> <li>• A summary of the proposed use of the device, including screening procedures, the HUD procedure, and patient follow-up visits, tests, or procedures</li> </ul>	<ul style="list-style-type: none"> <li>• Description of the device</li> <li>• Product labeling</li> <li>• Any patient information packet</li> <li>• A summary of the proposed use of the device, including screening procedures, the HUD procedure, and patient follow-up visits, tests, or procedures</li> </ul>	<ul style="list-style-type: none"> <li>• Description of the device</li> <li>• Product labeling</li> <li>• Any patient information packet</li> <li>• A summary of the proposed use of the device, including screening procedures, the HUD procedure, and patient follow-up visits, tests, or procedures</li> </ul>
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3.2. Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff  
Humanitarian Device Exemption (HDE) Regulation: Questions and Answers