

POLICY: IRB Member Review Expectations HUD

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1. PURPOSE

- 1.1. This policy establishes for the review of the use of device that is FDA-approved under an HDE 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 procedure, the <Designated Reviewer> fulfills the roles described for all IRB members, the primary presenter, and the scientific/scholarly reviewer, or obtain consultation for these roles.
- 2.2. All IRB members review the <Pre-Review> findings for each submission, if any.
- 2.3. All IRB members consider the criteria in “WORKSHEET: Criteria for Approval HUD (HRP-450).”
 - 2.3.1. The primary presenter for each submission is expected to fill out applicable checklists with preliminary judgments as to whether each criterion is met .
 - 2.3.2. The primary presenter leads the discussion.
 - 2.3.3. IRB members who are not the primary presenter for a submission do not need to complete any checklists.
 - 2.3.4. The area marked with “Ⓢ” is optional and may be used for protocol identification information.
 - 2.3.5. The area marked with “Notes” is optional and may be used to document notes.
- 2.4. 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:
 - 2.4.1. A copy of the HDE approval order
 - 2.4.2. A description of the device
 - 2.4.3. The product labeling
 - 2.4.4. The patient information packet, if any
 - 2.4.5. A summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures
- 2.5. For review of a modification: In advance of the meeting, all IRB members review the modification form, 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:
 - 2.5.1. A description of the device
 - 2.5.2. The product labeling
 - 2.5.3. The patient information packet, if any
 - 2.5.4. A summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures
- 2.6. For continuing review: In advance of the meeting, all IRB members review continuing review form 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:
 - 2.6.1. A description of the device
 - 2.6.2. The product labeling

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- 2.6.3. The patient information packet, if any
- 2.6.4. A summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures
- 2.7. For a review related to an <Unanticipated Problem Involving Risks to Subjects or Others>, <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IRB Approval>, or <Termination of IRB Approval>: 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:
 - 2.7.1. A description of the device
 - 2.7.2. The product labeling
 - 2.7.3. The patient information packet, if any
 - 2.7.4. A summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures
- 2.8. The primary presenter reviews all submitted materials for consistency with the materials reviewed by all IRB members.
- 2.9. All IRB members review written reports of consultants, if any.
- 2.10. Any IRB member who needs to access minutes or other information in the IRB record access that information directly or contact an HRPP staff member for assistance.

3. REFERENCES

- 3.1. Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff Humanitarian Device Exemption (HDE) Regulation: Questions and Answers