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 an
Executive 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 Executive Reviewer fulfills the roles
described for all IRB members, the primary reviewer, and the scientific/scholarly
reviewer, or obtains consultation for these roles.

2.2. All IRB members have access to the Pre-review findings for each submission, if any.

2.3. All IRB members may reference the criteria in IRB REGULATORY GUIDANCE: Criteria for
Approval HUD (HRP-450).

2.3.1. The primary reviewer leads the discussion.

2.4. For initial review: In advance of the meeting, all IRB members have access to the myIRB
submission which includes all materials to a depth sufficient to determine whether the criteria
for IRB approval of an HUD are met. The myIRB submission will include:

2.4.1. A copy of the FDA HDE approval letter
2.4.2. A description of the device
2.4.3. The product labeling
2.4.4. The patient information packet
2.4.5. A summary of how the physician proposes to use the device, including a
description of any screening procedures, the HUD procedure, storage security of
the device, and any patient follow-up visits, tests or procedures
2.4.6. If the HUD is being used in research, then the protocol must be submitted as a
research protocol and not under an HUD review type.

2.5. All continuing reviews or revisions are reviewed by an Executive reviewer. If the HUD is
being used for research, then in advance of the meeting, all IRB members have access to
myIRB continuing review form or revision with any attachments. Information in myIRB will include:

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, or
2.5.5. A description of the requested revisions; and all relevant revised documents.

2.6. 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 have access to
myIRB which includes all information regarding this protocol in addition to new information
and attachments; this information will include:

2.6.1. A description of the compliance issue
2.6.2. A description of the impact if any to study subjects
2.6.3. A description of the corrective action plan proposed.
3. REFERENCES

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