



## Initial Full Board Review

### I. Purpose

To define policies and procedures for initial review by a fully convened IRB.

### II. Revisions from Previous Version

None.

### III. Definitions

None.

### IV. Policy

The Institutional Review Board (IRB) conducts an initial review for research that is greater than minimal risk at convened meetings regardless of the funding source. See the procedures and requirements for conducting a convened meeting and the definition of *quorum* in the IRB Meeting Conduct SOP. The IRB only approves research that meets the federal criteria for approval as specified in 45 CFR 46.111 and/or 21 CFR 56.111. During the initial full board review, the IRB reviews the informed consent process and documentation.

### V. Procedure

#### *Submission and Screening*

1. After having completed the Intake in WRG, the Principal Investigator (PI) will submit a complete submission (initial application and other project documents) to the IRB via WRG-HS. Instructions for preparing the application are available on the IRB website. The researcher may contact the IRB office with questions.
2. The IRB staff will make an initial assessment to determine whether the project is greater than minimal risk and direct the submission to the appropriate review process. If greater than minimal risk, the protocol will be assigned to either the Cancer or General board as applicable.
3. Once assigned, the IRB staff will conduct pre-review activities according to the Staff Processing of Submissions SOP.
4. After the pre-review is complete and if the project is greater than minimal risk and/or does not meet exempt or expedited review criteria, it is scheduled on the agenda for the next available meeting. There are eight IRB meetings a month, four meetings for General and four meetings for Cancer. The IRB staff will schedule protocols for review on a "first-come, first-serve" basis, limiting the number of reviews as appropriate in order to permit adequate time for discussion and deliberation of agenda items. Submission deadlines are posted on the IRB website. Please note, protocols must be ready for assignment to the board agenda by the published meeting due date in order to be reviewed at the scheduled meeting.
5. The IRB staff will review the protocol to determine whether additional expertise is necessary to conduct the review. The IRB staff will assign a primary reviewer based on the IRB member's background and expertise, as necessary. If no IRB member has the appropriate expertise, the IRB staff may ask a consultant to review the protocol.
6. Consultant reviews are conducted as described in the IRB Meeting Conduct SOP.
7. If the researcher indicates that the project involves an investigational new drug (IND) or investigational device exemption (IDE), the IRB staff will confirm the validity of the IND or IDE number by ensuring that the researcher has included a copy of the detailed protocol from the sponsor (containing the IND or IDE number) and/or verification statement from the sponsor or the Food and Drug Administration (FDA). In situations where

a device does not have an IDE, the IRB staff will inform the reviewers that a nonsignificant risk (NSR) determination is needed.

8. The IRB staff will confirm that any applicable auxiliary reviews (e.g. Institutional Biosafety, Conflict of Interest Committee approvals, etc.) are necessary. If applicable approvals are necessary, the IRB staff request the appropriate information from the PI. A submission may not be assigned to an agenda until auxiliary reviews are completed and appropriate documents submitted to the IRB.
9. The IRB staff will also ensure that all listed researchers have completed the required training (see Researcher Training SOP). If the researchers have not completed the required training, the IRB staff will notify the PI in writing. The researcher must remove the individuals from the personnel list or submit the appropriate certifications of training before the IRB can issue approval.

#### *Assignment of Reviews to the IRB*

1. Approximately two weeks prior to each convened meeting, the IRB staff will provide the meeting agenda and all review materials to IRB members in WRG-HS. The documentation provided to IRB members includes all applicable sections of the application. Reviewers are expected to return completed reviews five calendar days prior to the meeting, including review of the:
  - Research protocol;
  - Consent/assent process and forms including waiver requests;
  - HIPAA forms, including waiver requests;
  - COI Management plans, if applicable;
  - Device risk determination, if applicable;
  - Investigational new drug and INDs, if applicable;
  - Other committee reviews or final approval materials;
  - Additional documents, including recruitment materials, proposed data instruments (e.g. surveys, interview questions, etc.), materials/letters of support for off-site research.
2. All IRB members will review all information in the agenda packet in advance of the meeting (including those protocols for which the IRB member is not the primary reviewer) in enough depth to be familiar with the protocol, to be prepared to discuss the protocol at the meeting, and to be prepared to determine whether the research meets the regulatory criteria for approval. The reviewers will ensure that the research meets ethical principles and standards for protecting research participants.
3. Consultants may provide comments or recommendations in writing to the IRB prior to the meeting or may be asked to attend the convened meeting to participate in the review. The IRB staff will maintain documentation of written comments or reports in the project file. In cases when the consultant participates in the meeting, the minutes of the meeting will document the information provided by the consultant.

#### *IRB Review*

1. All IRB members attending the meeting will receive materials listed in the *Assignment of Reviews to the IRB* section above prior to the convened meeting and have the opportunity to discuss each research protocol during the convened meeting and participating in the determination of whether the research meets the regulatory criteria for approval. IRB review will occur as detailed in the IRB Meeting Conduct SOP.
2. When the IRB reviews research that involves categories of individuals vulnerable to coercion or undue influence, the IRB staff will ensure that adequate representation or consultation for that population is present for discussions of the project.
3. When conducting the review of the proposed research, the IRB will utilize the appropriate Reviewer Checklists.
4. A member or consultant with a COI must leave the room during the deliberation and vote and only participate in the review by providing information.
5. During the convened meeting, the IRB will determine the approval period, as appropriate to the degree of risk but not less frequently than once per year (unless the IRB determines that the research is minimal risk and meets exempt or expedited review criteria). The IRB may set a shorter approval period for high-risk protocols or protocols with high risk/low potential benefit ratios.
6. For research involving a device where the PI or the sponsor has not obtained an IDE, the IRB will determine what action(s) is needed (whether the PI needs to obtain an IDE or whether the device meets criteria for abbreviated requirements at 21 CFR 812.2(b)). The IRB will review relevant information including, but not limited to, a description of the device, the proposed investigational plan and participant selection criteria. The

IRB will also confirm the process described in the Device Form to ensure investigational devices are used only in approved research protocols and under the direction of approved researchers. If the IRB determines the device does not meet the definition of significant risk (also called NSR), the project may be approved using criteria at 21 CFR 56.111. The determination will be documented in the IRB meeting minutes.

7. For research involving an investigational drug, biologic, therapeutic dietary supplement, substance affecting structure or function of the body, or product intended to diagnose, cure, mitigate, treat, or prevent disease, the IRB will confirm that an IND has been secured and the process described in the Drug Form to ensure investigational drugs are used in approved research protocols and under the direction of approved researchers.
8. When a protocol receives final approval, approval periods will be assigned as described in the IRB Meeting Conduct SOP.
9. If the research involves prisoners, the IRB staff will check to determine whether the PI submitted the protocol for funding to any DHHS agency. The IRB staff will prepare and submit a prisoner certification report to the Office for Human Research Protection (OHRP) in accordance with OHRP requirements. The IRB will not issue a final approval letter under the IRB has received final prisoner certification from OHRP.
10. Once the IRB approves a protocol, the IRB staff will send an approval letter to the PI, which includes the approval period, a reminder to use only the approved and stamped consent/assent form(s), and a reminder that the IRB must approve any changes to the protocol prior to initiation of the changes.
11. If the PI has concerns regarding the IRB decision/recommendations for changes in the project, he/she/they may submit them to the IRB for consideration via WRG-HS that includes a justification for changing the IRB decision, in writing.

## **VI. References**

21 CFR 50.25  
21 CFR 56.111  
21 CFR 312  
21 CFR 812  
45 CFR 46.108  
45 CFR 46.111  
45 CFR 46.116  
45 CFR 46.117  
45 CFR 46 Subparts B, C, D