

STANDARD OPERATING PROCEDURE ADDENDUM
Facilitated Review Procedures for the
National Cancer Institute Central Institutional Review Boards

1. After determining that he/she wants to participate in a CIRB-reviewed Oncology Group trial, the Penn State College of Medicine (COM) principal investigator (PI) or designee downloads the protocol, consent form and CIRB application form from the CIRB website. PI or designee revises the consent form to comply with local requirements and creates a separate HIPAA authorization form. PI completes COM application form (Parts 1 to 5) and abstract.
 - a. Consent form: The CIRB does not allow CIRB-approved language to be deleted but does allow the local institution to comply with local requirements in terms of required consent language. To comply with COM requirements, the PI or designee inserts the following elements into the CIRB-approved consent form and parental permission form:
 - i. Standard COM consent form header (i.e., COM/PSMSHMC header, protocol title, PI name, other investigator names, participant name). The CIRB header should remain above the COM header;
 - ii. Local contact information paragraphs (see section 12 of the COM consent form template);
 - iii. COM language regarding research-related injury (see section 8 of the COM consent form template); and
 - iv. COM consent form signature statements and lines.
 - b. HIPAA Authorization form: Use the current COM template for a separate HIPAA authorization form.
 - c. The COM application form (Parts 1 to 5) provides the names of the local PI and other investigators who will be involved in the study as well as contact information for the local coordinator. Signature pages certify understanding of research responsibilities
 - d. The abstract provides a brief summary of the research.
2. PI or designee submits the following materials to the Human Subjects Protection Office (HSPO):
 - a. Oncology group protocol
 - b. CIRB application form
 - c. CIRB model consent form
 - d. Consent form(s) revised to include COM required elements
 - e. HIPAA authorization form
 - f. COM application form (Parts 1 to 5) with signature pages
 - g. Abstract form
 - h. Any other supporting materials
3. IRB coordinator enters the study in PRAMS and notes CIRB on the comments section of the first screen and selects expedited folder. The IRB protocol number is emailed to the PI or designee.
4. IRB coordinator creates new electronic and paper file for the study.

- a. The electronic file is found under E-Forms on HSPO folder
 - b. The paper file uses a green folder and follows the standard filing procedures
5. IRB coordinator reviews the application materials and consent and authorization forms to ensure that the forms have all necessary elements and agrees with the protocol. If revisions are required the IRB coordinator notes the changes on the forms.
6. IRB coordinator prints copies of the CIRB review paperwork from the CIRB website.
7. IRB coordinator assigns protocol to two designated IRB members for facilitated review of the material.
 - a. One of the facilitated reviewers will be a physician while the other reviewer is a non-physician. The HSPO will maintain a list of facilitated reviewers who have been approved by the executive committee for this function.
 - b. Each facilitated reviewer will receive copies of all application materials and CIRB review materials:
 - i. Application materials:
 1. HMC application form
 2. CIRB application form
 3. HMC abstract
 4. ONCOLOGY GROUP Protocol
 5. CIRB model consent form(s)
 6. HMC Consent form(s)
 7. Authorization form(s)
 8. Supporting materials if applicable
 - ii. Review materials:
 1. CIRB reviewer form(s)
 2. Minutes of CIRB meeting(s)
 3. Memo(s) to PI listing stipulations and changes to the consent form
 4. Approval memo(s) to PI
 5. Memo(s) to local IRBs
 6. Other relevant materials
8. The facilitated reviewers determine if there are any local context issues that must be addressed by the local IRB. Based on this review, the reviewers decide whether to accept the CIRB review, accept with minor modifications, or not accept the CIRB review. Each facilitated reviewer is asked to complete a Facilitated Review form and indicate the following:
 - a. Accept the CIRB review with no modifications
 - b. Accept the CIRB review with minor modifications to the CIRB application materials.
 - c. Submit to a convened PSU/HMC IRB due to local context issues.
9. Both reviewers must accept the CIRB review with or without modification in order to rely on the CIRB. If one reviewer accepts the CIRB and the other does not accept the CIRB review, the study will go to a convened PSU/HMC IRB for review.
10. If accepting the CIRB review with no modifications,
 - a. The IRB coordinator notifies CIRB via internet.
 - b. CIRB sends a confirmation email to IRB coordinator. CIRB review date becomes official review date. This email is saved to the E-Forms sub-file for this protocol.
 - c. The IRB coordinator notifies the PI via written memo of acceptance of the CIRB review and approval of HIPAA authorization. Consent form(s) is stamped with CIRB approval/expiration dates and date of facilitated review as the "released for accrual" date. The stamped consent form(s) is sent with memo and CIRB confirmation.

- d. A convened IRB is notified of the facilitated review via IRB meeting agendas and a copy of the abstract is included in the board packet.
11. If accepting the CIRB review with minor modifications to the CIRB application materials,
 - a. The IRB coordinator notifies the CIRB to confirm that required modifications are minor.
 - b. The IRB coordinator compiles changes and requests changes from PI or designee in a written memo or email.
 - c. After receiving modifications and reviewing them for completeness, the IRB coordinator notifies the CIRB via email to accept the CIRB.
 - d. CIRB sends a confirmation email to HSPO. CIRB review data becomes official review date. This email is saved to the E-Forms sub-file for this protocol.
 - e. The HSPO notifies the PI via written memo of acceptance of the CIRB review and approval of HIPAA authorization. Consent form(s) is stamped with CIRB approval/expiration dates and date of facilitated review as the "released for accrual" date. The stamped consent form(s) is sent with memo and the CIRB confirmation.
 - f. A convened IRB is notified of the facilitated review via IRB meeting agendas and a copy of the abstract is included in the board packet.
12. If not accepting the CIRB review,
 - a. The IRB coordinator notifies the PI via written memo that the CIRB review was not accepted and that the studies requires review by the PSU IRB.
 - b. The PI must submit the protocol to the HSPO for convened board review as per standard operating procedures.
13. If facilitated review is accepted, the protocol is approved in PRAMS.
 - a. "FR" is added to the protocol number on the protocol page.
 - b. The total subject number is entered in PRAMS.
 - c. Facilitated reviewers are listed as the reviewers. Type of review is listed as expedited.
 - d. On the final approval page "facilitated review" is added to the comment section.
 - e. The PRAMS expiration date is modified to the CIRB expiration date.
14. The paper file is organized following standard procedures and using the same document flags.
15. IRB coordinator notifies IRB staff assistant that the study needs to be added to the next IRB agenda by placing the folder in a designated bin. The study is added to the agenda as receiving facilitated review. A copy of the abstract is included in the board packet. The folder is then filed with the other active studies.
16. For studies with CIRB oversight,
 - a. CIRB notifies HSPO and PI (via email) of any actions on the protocol. All actions will be entered into PRAMS. All information is filed in the study folders (electronic and paper).
 - b. At time of continuing review and any consent form modifications, PI must submit a clean copy of the current or revised consent form(s) for new consent form stamp. It will be the PI's responsibility to track this and confirm completion.
 - c. All events following the initial review (i.e., renewals, revisions/amendments, data monitoring progress reports, etc) must be submitted to the HSPO in accordance with the process described below.
 - d. PI reports the following to the HSPO for IRB review according to standard operating procedures:
 - i. Local unanticipated problems according to local policies and procedures; and
 - ii. Protocol violations/deviations.
 - e. COM IRB is responsible for the following:
 - i. Reviewing local problems and protocol violations/deviations;

- ii. Monitoring protocol compliance at COM;
- iii. Reporting to CIRB any actions taken as a result of problems that are identified in the conduct of the study at COM; and
- iv. Notifying the CIRB immediately if there is a suspension or restriction of a local investigator.

17. Modifications

- a. PI or designee submits the following materials to the Human Subjects Protection Office (HSPO):
 - i. Revised ONCOLOGY GROUP protocol
 - ii. Revised consent form(s) if applicable (1 marked copy and 2 clean copies)
 - iii. Revised abstract form if applicable
 - iv. Modification Request Form
- b. IRB coordinator enters the modification in PRAMS and notes CIRB on the comments section of the first screen.
- c. IRB coordinator prints the CIRB review paperwork from the CIRB website.
- d. IRB coordinator assigns protocol modification to one designated IRB member for facilitated review of the material. If the modification qualifies for expedited review, an IRB coordinator in the HSPO will perform the facilitated review; otherwise, a physician IRB member will do the review.
 - i. The facilitated reviewer receives copies of all modification materials and CIRB review materials.
 - ii. The reviewer reviews the modification materials to ensure that there are no local context issues and that all forms have all necessary elements.
 - iii. This facilitated review is documented using the Facilitated Review form.
- e. IRB coordinator stamps consent forms and returns one copy to the PI or designee if applicable.

18. Continuing Review

- a. PI or designee submits the following materials to the Human Subjects Protection Office (HSPO)
 - i. Completed progress report for the study; and
 - ii. Two copies of current consent form(s) for stamping if applicable.
- b. IRB coordinator enters the continuing review event in PRAMS and notes CIRB on the comments section of the first screen.
- c. IRB coordinator prints the CIRB review paperwork from the CIRB website.
- d. An IRB Coordinator in the HSPO performs the facilitated review.
 - i. The reviewer reviews the materials to ensure that there are no local context issues and that all forms have all necessary elements.
 - ii. This facilitated review is documented using the Facilitated Review form.
 - iii. If any issues are identified, the progress report and all other materials are sent to an IRB chair for facilitated review.
- e. IRB coordinator stamps consent forms and returns one copy to the PI or designee

19. Safety Reports

- a. Reports from other sites – the COM IRB will rely on the CIRB for the review of SAEs that occur at other sites
- b. Reports at this site – the PSU policy for reporting unanticipated problems will be followed

- 20. For existing protocols that have COM approval, the COM will rely on CIRB as the IRB of record at the next continuing renewal if requested by the PI. At the time of renewal, the PI/coordinator will follow the procedure outlined above for initial facilitated review.

- a. The protocol must be closed at COM and opened through the CIRB simultaneously. This ensures that the protocol will not be opened under two different IRB's concurrently and that there are no gaps in the protocol's history.
- b. The IRB coordinator must provide the CIRB with a copy of the termination/closure documentation.
- c. Patients currently on the study at COM need to be re-consented using the CIRB approved informed consent. This can be done as they come in for treatment or the consent could be mailed to them.

Institutional Review Board The Pennsylvania State University Penn State College of Medicine Penn State Milton S. Hershey Medical Center	PENNSTATE 
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