

## **WSIRB Member Responsibilities and Document Management**

### **Document Management: Setting up a Research Project File**

- The Primary Reviewer (PR) is responsible for setting up and maintaining an electronic file on the research project. The file will be complete and will parallel the central file in the HRRS office.
- Set up an electronic folder on your computer to store electronic records (i.e., PDFs). The highest level electronic folder should be named "WSIRB" with lower level folders for each project, named with the project code or name of the PI.
- HRRS staff are responsible for sending primary reviewers all documents needed to maintain a complete electronic project file.
- Primary reviewers will maintain an electronic project file on each research project they are assigned until the project is closed or cancelled, or until they leave the WSIRB.

### **Primary Reviewer Responsibilities: Full Board Review**

#### Initial Full Board Review

- Maggie or Mike will be assigned to each new application and will conduct a pre-review and send comments back to the PI. The PI will make revisions in the application based on pre-review comments and submit paper copies for distribution to WSIRB members.
- A WSIRB member will be asked to be primary reviewer and to present the application at the next WSIRB meeting. The PR will receive a paper copy of the new application in the package of materials for full Board review sent to all members.
- To conduct consistent and comprehensive reviews of applications, PRs are expected to use the Review Worksheet, and are encouraged to use the Consent Form Checklist and the Checklist for Research Involving Identifiable Records as needed.
- The PR will review the application, complete the Review Worksheet and send an electronic copy to the assigned HRRS staff at least one day prior to the meeting.
- PR and staff will confer prior to the meeting to discuss the review issues, regulatory determinations, waivers (if any), levels of risk, and review disposition recommendation. Staff will make copies of the Review Summary for distribution at the meeting.
- PR presents the new application at the meeting and makes the initial motion for disposition. After the motion is seconded, the Chair will open the discussion to comments from other members. The initial motion may be amended based on comments. Votes are taken until a motion is passed.
- Staff will draft the WSIRB letter based on the full Board review, and send a draft to the PR for comments. After hearing back from the PR, staff will send a signed letter in the form of a PDF to the PI and the PR. PI incorporates the response to the WSIRB letter into a revised application and sends it back to HRRS.

- If the application was conditionally approved, staff may review the revised application and extend approval if approval conditions have been met. If there are any questions about whether the approval conditions have been met, the revised application will be sent to the PR; staff and the PR will decide whether to request additional revisions to meet the WSIRB conditions, or to refer the application back to the full Board.
- If the application was deferred at the meeting, the revised application must be considered at the next available meeting. The PR will present the revised application following procedures outlined above.
- When the application has been approved, staff will send a PDF containing the approval letter, the approved application, confidentiality agreement (if any), and documentation of findings to the PI and to the PR for inclusion in the PR's electronic project folder.
- At this point, the PR can discard the original paper copy of the application that was reviewed at the meeting, and subsequently maintain only an electronic file for the research project.

### Expedited Study Amendments – Applications Approved by Full Board

- When a study amendment request is submitted, staff will determine whether the amendment is eligible for expedited review or requires full Board review. "Minor changes in previously approved research during the period for which approval is authorized" are eligible for expedited review.
- Study amendments eligible for expedited review are minimal risk and usually will be reviewed and approved by staff.
- Some study amendments eligible for expedited review may be sent to the PR for review with staff in a telephone conference.
- Whether reviewed by staff and the PR, or only by staff, a PDF containing the approval letter and approved study amendment will be sent to the PI and to the PR for inclusion in the PR's electronic project folder.

### Full Board Study Amendments and Continuation Approval Requests

- The PR will receive a paper copy of the study amendment or continuation approval request that requires full Board review. PR will review the study amendment or continuation approval request, complete the appropriate Worksheet and, if requested, send an electronic copy to the HRRS staff.
- As necessary, PR and staff will confer prior to the meeting to discuss review issues, new regulatory determinations, new waivers (if any), changes in levels of risk, and the review disposition recommendation. Staff may make copies of the Review Summary for distribution at the meeting.
- PR presents the study amendment or continuation approval request at the meeting using the same procedures used to present a new application.
- When approved, staff will send a PDF containing the approval letter, the approved study amendment or continuation approval request, and documentation of findings (if applicable) to the PI and to the PR for inclusion in the PR's electronic project folder.
- At this point, the PR can discard the original paper copy of the study amendment or continuation approval request that was reviewed at the meeting, and subsequently maintain only an electronic file for the research project.

## **Primary Reviewer Responsibilities: Expedited Review**

- WSIRB members will be asked to be primary reviewers on new applications eligible for expedited review several times a year. (Staff track primary reviewer assignments and attempt to maximize the intervals between assignments.)
- New applications for expedited review will be sent to primary reviewers in PDF format. PR sets up an electronic folder for the application and stores the PDF in that folder. The PR may review the application on the computer screen or print out a copy for review.
- A tentative date for a phone conference with HRRS staff will be set when the PDF is sent to the PR. If the PR has a conflict, or will be unavailable for review, the PR should notify HRRS and another member will be asked to review the application.
- To conduct consistent and comprehensive reviews of applications, PRs are encouraged to use the Review Worksheet and the Checklist for Research Involving Identifiable Records for expedited reviews.
- During the telephone conference, staff will encourage the PR to present their issues and questions first, followed by issues identified by staff. Staff will ask the PR for his/her disposition recommendation, and then prepare a letter based on the conference review.
- If the application was conditionally approved, staff will review the revised application and extend final approval if the conditions have been met.
- If the application has been deferred, staff will decide whether to send the revised application to the PR for re-review or to approve the response without further input from the PR.
- If the response does not support approval, staff will send the revised application to the PR to determine what course of action to take.
- When the application has been approved, staff will send a PDF containing the approval letter, the approved application, confidentiality agreement (if any), and documentation of findings to the PI and to the PR for inclusion in the PR's electronic project folder. At this point, the PR can delete the original PDF of the application that was reviewed with staff in the telephone conference. (See Disposition of Documents, below)
- Once the initial application has been approved, the PR is generally not expected to participate in study amendments and continuation approval requests. However, the PR should retain the electronic copy of the approved application, confidentiality agreement and documentation of findings until the project is completed or cancelled, or until the member leaves the WSIRB.

## **All Members: Full Board and Expedited Review**

### WSIRB Meeting Packets

- Members will receive paper copies of the following full Board agenda items:
  - A - new applications;
  - B - continuation approval requests;
  - C - study amendments.

- Members receive one or more PDFs (attached to an email from Lilly) which contain the following expedited agenda items:
  - D – Review correspondence and Research Abstracts for new applications;
  - E – Continuation Approval Requests and Research Abstracts for projects requiring annual review;
  - F – Review correspondence and Research Abstracts for study amendments.
- PDFs sent with the Meeting Packets also include: meeting minutes, lists of approved projects, lists of cancelled and completed projects, and lists of exempt reviews.
- Members are responsible for reviewing all full-Board agenda items prior to the meeting. Members are encouraged to raise issues and ask questions about any item on the meeting agenda when the Chair opens the meeting for discussion.
- Agenda items that are deferred will be resubmitted by the PI as a revised document for consideration at the next meeting; thus, it is not necessary to keep the original application or study amendment.
- Excluding primary reviewers, all paper documents distributed for the meeting may be discretely placed in recycle barrels, and all PDFs (except the meeting minutes) may be deleted from WSIRB member's computers after the meeting.
- Members are encouraged to retain a copy of the PDF containing meeting minutes in their electronic WSIRB folder.

## **Disposition of Documents**

### All Members

- Documents submitted for WSIRB review are generally not considered confidential, but are considered sensitive, i.e., their access and use is limited to WSIRB-related business.
- Paper documents may be discretely placed in recycle barrels and electronic files may be deleted from the PR's computer.
- Deleted folders on your computer should also be deleted at this time; backup files can be deleted on the schedule set by your IT support staff.

### Primary Reviewers

- When the research has been completed or cancelled, you may dispose of any paper records you have kept and delete electronic records per the guidelines above. Your responsibilities with respect to this research project are now completed.
- When you leave the WSIRB before a research project is complete, confer with HRRS staff before disposing of paper documents or deleting electronic documents.
- HRRS staff will check to make sure a complete electronic copy of the application exists so it can be transferred if necessary to Board member who will assume primary reviewer responsibilities.