

Washington State Institutional Review Board

REVIEW PROCESS

Applications

Research proposals are submitted to the DSHS Human Research Review Section (HRRS), which provides professional, technical, administrative and staff support to the WSIRB. Application forms are available on the HRRS/WSIRB website.

Researchers submit an electronic copy of their proposals requiring full-Board review by the due date for each scheduled Board meeting. Electronic files of research applications that qualify for expedited review may be submitted to the Review Section by email at any time.

WSIRB Review

Expedited Review

If a proposal meets the criteria for expedited review (*Washington State Agency Policy.... Section X*), Review Section staff ask one or more Board members to review the proposal. A telephone conference call is scheduled between the reviewer(s) and Review Section staff to discuss the proposal and reach a disposition decision.

Information about each proposal considered under expedited review procedures is placed on the agenda of the next Board meeting and is provided to all Board members as a PDF document attached to an email. The PDF file includes an abstract of the proposal and the Review Board's disposition correspondence to the researcher for each item reviewed under expedited review authority.

Full Board Review

All proposals requiring full Board review go through a **pre-review process**. Pre-review is intended to determine if the proposal is complete, responsive to instructions in the application forms, and ready for full Board review with a low chance of being deferred. Review Section staff conduct a pre-review of each proposal upon receipt. As needed, a list of pre-review issues is sent to each investigator, and he/she has one week to submit a signed original of the research application and sufficient copies of the proposal for distribution to Review Board members and consideration at the next WSIRB meeting.

Review Section staff ask one Board member to serve as the "primary reviewer" of each proposal. In some instances, a "secondary reviewer" also will be assigned. Reviewers must complete the *WSIRB Review Worksheet* to prepare for a pre-meeting telephone conference with staff. The Review Worksheet provides space for reviewers to note review questions or concerns and comments regarding requests for waivers, compliance with special protections, risks and benefits, and his/her disposition recommendation. During the pre-meeting telephone conference, staff and the reviewer(s) will discuss the proposal and identify key issues that need to be addressed in the application. At the meeting, reviewers are expected to distribute copies of the last page of the Review Worksheet which documents the recommended disposition of the application, including approval conditions or review issues. All WSIRB members are strongly encouraged to

complete their own Review Worksheet, which has been designed to provide a systematic overview of human subjects-related issues in each application.

Review Materials

Copies of research applications, study amendment requests, continuation approval requests that require full Board review, and an agenda are mailed to all Board members about ten days before each scheduled meeting. Copies of meeting minutes, correspondence with investigators, summary information about expedited reviews, and other Board materials are sent as PDF attachments to an email, unless Board members prefer paper copies. WSIRB members are expected to read all agenda items scheduled for full committee review and to note their scientific, ethical, legal, and other concerns for discussion at the Board meeting.

WSIRB Member Conflict of Interest

Before review business begins, the Chair will ask members if they have a conflict of interest with any item on the agenda for that meeting. WSIRB members who have a financial, personal, or professional “stake” in the research have a conflict of interest with their role as a reviewer. WSIRB members may also have a connection with an item on the agenda that falls short of producing a conflict of interest. An example would be a research project conducted by an investigator in the same organizational unit as the WSIRB member, but in which the WSIRB member has no significant involvement.

Members having a conflict of interest are expected to recuse themselves from the deliberation by leaving the room during consideration of that agenda item. Because recused members do not count toward the meeting quorum, a quorum could be lost and action could not be taken on that agenda item.

Members who have a connection that falls short of producing a conflict of interest may nevertheless prefer not to be involved in deliberations or voting on that agenda item. In this case, the member may remain in the room and count in the quorum, but would not participate in the deliberations and would vote to abstain. In such cases, the decision to leave the room is at the discretion of the individual. A member who abstains is counted in the quorum. Because a motion needs a simple majority of members present to pass, a vote to abstain has the same result as a vote against the motion. In practice, abstaining or recusing rarely has an effect on the quorum or on the outcome of the vote.

Meeting Protocol

The WSIRB Rules of Order for full committee meetings were adapted from Robert's Rules in Plain English. After presenting a research application, the primary reviewer makes a motion for disposition of the proposal. After a motion is made and seconded, other Board members may ask for the floor and make their comments without interruption. The Board Chair may then open the floor to general discussion.

After deliberation, the primary reviewer, with the assistance of staff, will restate the motion, including any additions and/or amendments, before a formal vote is taken. Disposition of each agenda item is determined by a simple majority vote of members

present. If a motion does not pass, the floor is open to disposition motions introduced by other Board members.

The Board may make any of the following decisions regarding a research application under review:

- **Approval:** The proposal can be approved as submitted or amended prior to the meeting.
- **Conditional Approval:** This should be moved when (1) the simple concurrence of the investigator to a specified set of conditions is all that is required for approval of the proposal, or (2) based upon the assumption that conditions are satisfied, the Board is able to make all the determinations required for approval. Final approval is delegated to a subcommittee; generally there is no need for review at another meeting.
- **Defer Consideration:** The number of issues, concerns and/or questions are too significant to be resolved by the simple concurrence of the investigator. The application must be re-reviewed at a subsequent WSIRB meeting.
- **Disapproval:** This should be moved only after the investigator has been invited to a meeting to resolve serious issues OR further attempts to negotiate required revisions would be fruitless. While this disposition puts an end to review of the research application, the investigator is free to submit a new application for consideration at a later meeting. .

Outside Consultation

If a proposal requires expertise beyond that of WSIRB members, Review Section staff may seek verbal or written consultation from outside professionals. Copies of the consultant's assessment will be distributed to all Board members. Consultation with outside experts is designed to preserve the anonymity of the researcher, or if this is not possible, is conducted in a confidential manner. If consultation is requested, however, the Review Board retains its responsibility for independent review of the scientific and ethical acceptability of the proposal. If a proposal is unusually complicated, or if considerable uncertainty or concerns exist about critical aspects of the research, the researcher may be invited to attend the Board meeting to provide additional information or to respond to specific issues or concerns. The researcher must leave the meeting prior to the disposition vote by the Board.

Correspondence with Investigators

The Board's disposition decision and any remaining review issues and/or required modifications are communicated in writing to the researcher by the Executive Secretary or the Associate Executive Secretary. Primary reviewers review and comment on draft Board correspondence to investigators whose proposals were reviewed at a full Board meeting. Primary reviewers may contact investigators in the course of preparation for the Board meeting. However, only the Executive Secretary, Associate Executive Secretary, or the Board Chair communicates with researchers following the Board's review at a convened meeting.

Continuation Approval Requests

As research may be approved for no longer than one year, researchers must submit a request for continuation approval if their research will continue beyond the one-year approval period. Review Section staff may notify researchers when a request is due for review by the WSIRB, but researchers have the responsibility for timely submission of continuation approval requests. A completed request should describe activities to date, study amendments, study participation, adverse events and unanticipated problems, remaining activities, and the anticipated study completion date.

Primary reviewers are expected to present the researcher's Continuation Approval Request at the Board meeting when he/she was primary reviewer in the initial full committee consideration of the research application.

Requests for continuation approval may be reviewed under expedited authority *if* the research initially underwent expedited review, or a project that underwent full-Board review has completed all contacts with subjects, or otherwise satisfies regulatory criteria for expedited review.

Study Amendment Requests

Primary reviewers may be asked to review and to present in a Board meeting Study Amendment Requests submitted by researchers after the research has been approved. The necessity for full committee review of a study amendment is determined by Review Section staff, based on the extent of proposed changes and possible risks to subjects. Study amendment requests for full Board consideration are included in the packets mailed to WSIRB members prior to the convened meeting.

Reports of Unanticipated Problems and/or Adverse Events

These reports are included on the WSIRB meeting agenda for Review Board members' information. Occasionally, issues described in a report are serious enough that it is placed on the timed agenda for discussion and feedback from the full Board. In this case, the primary reviewer or the Executive Secretary or the Associate Executive Secretary may be asked to provide a summary of the report and any proposed recommendations or WSIRB requirements for the investigator in order to address the issues or to decrease risks to subjects. Review Section staff will discuss the Unanticipated Problem/Adverse Event with primary reviewers prior to the meeting.