

## WSIRB Board Members: Responsibilities and Expectations

### Talking Points

#### Structure of WSIRB

- Federal IRB member and quorum requirements:
  - An IRB must have no fewer than 5 members (quorum=3).
  - The Board must have 1 scientist; 1 non-scientist, 1 unaffiliated; sufficient expertise to review research at every convened meeting (one member can fill more than 1 role: i.e., unaffiliated, non-scientist).
  - Members cannot all be from one profession.
  - Members should not be all the same gender.
- WSIRB membership: currently 16 members (quorum=9), plus alternate members and ad hoc members.
- Non-agency WSIRB Members are appointed as official volunteers with DSHS to ensure services of Attorney General if legal representation required.

#### Role and authority of WSIRB

- The role of WSIRB is to advocate for the rights and welfare of human research subjects, and to promote ethical and meaningful research.
- WSIRB has the authority to review; approve; request modifications to; disapprove; suspend; or terminate research involving human subjects within its jurisdiction.
- Washington State Agency administrative officials may disapprove research approved by WSIRB, but they may not approve research that has not been approved by WSIRB.
- WSIRB is not a:
  - Scientific review committee (scientific merit is evaluated only in relation to risk/benefit analysis)
  - Risk management committee
  - Editorial committee

#### Member training requirements

All WSIRB Members are required to:

- Participate in an initial in-person one-on-one orientation/training session with WSIRB staff.

- Complete the CITI web-based training in human subjects protection prior to serving as a voting WSIRB Member.
- Attend a WSIRB meeting as a non-voting observer; complete *Review Worksheets* for new proposals for the meeting.
- Attend a follow-up in-person one-on-one training session with WSIRB staff to discuss meeting observation and completed *Review Worksheets*.
- Attend in-service training modules presented at WSIRB meetings.
- Complete the CITI refresher course every three years.

### Preparation for meetings

- Board Members should expect to spend approximately 4-6 hours preparing for meeting (more if serving as Primary Reviewer).
- Board Members should expect to be assigned as Primary Reviewer once or twice per year—assigned on expertise and rotation.
- All Board Members are expected to review all Board materials prior to meetings, with special emphasis on new proposals and modifications.
- All Members should complete the *Review Worksheet* for new proposals and significant modifications. The Primary Reviewer distributes the last page of *Review Worksheet*, “Regulatory Determinations and Disposition Recommendation” to the Board prior to their presentation.

### Meetings

- Board meetings are conducted according to WSIRB Rules of Order, adapted from Robert’s Rules of Order.
- WSIRB Members are asked to disclose any conflict of interest with any item on the meeting agenda prior to review business:
  - Does a Board Member have a financial, personal or professional “stake” in the research?
  - Is the research in competition with a Board Member’s research?
  - Could there be a perception of impropriety?
- Voting:
  - A simple majority of quorum determines vote outcome.
  - Abstention vs. recusal:
    - Abstaining members count towards quorum, recused members do not count towards quorum.

- Abstention is not appropriate in situations of conflict of interest; abstention counts as a “no” vote in a functional sense since a majority present must vote in favor. If a Board Member wishes to remain neutral, he/she should recuse themselves.
- Board Members are asked not to miss more than 2 meetings/year, if possible. Contact WSIRB staff as soon absence is known so quorum and other federal requirements for meeting attendance are ensured.
- Non-DSHS/DOH Board Members receive reimbursement for travel to and from meetings. DSHS/DOH employee Board Members may request reimbursement from their organizational unit.

### **Confidentiality of Board materials/proceedings and document retention**

- All WSIRB Board materials and proceedings are considered confidential.
- Document retention guidelines are distributed to Board Members and posted on the WSIRB website under Board Member Handbook.