

WSIRB In-Service Training:

Using the WSIRB Review Worksheet

In accordance with Chapter 5, Section 5.3 of the WSIRB Procedures Manual, the WSIRB Review Worksheet (“Worksheet”) provides a comprehensive checklist of issues relevant to WSIRB human subjects protection review.

WSIRB primary reviewers complete the Worksheet for their assigned studies, and turn in the Worksheet to the WSIRB Executive Secretary (ES) (Stone) or the Associate Executive Secretary (AES) (Frederick), as applicable, prior to the primary reviewers’ study consultation/review conference. Completion of the Worksheet serves to:

- Document reviewers’ findings for key study features (46.115(a), (b)).
- Identify issues that require clarification or additional information (46.109(a)).
- Document reviewers’ recommendations to the WSIRB for required regulatory determinations on studies undergoing full WSIRB board review (convened meeting) (e.g., risk level; benefits greater than risks; additional protections; waivers) (e.g., 46.111(a); 46.116(d); 46.403)).
- Serve as a key source of information for HRRS staff for preparing notifications to investigators of WSIRB decisions (46.109(d)) and for advising all WSIRB members of expedited review approvals (46.110(c)).

After completion and consultation:

- For studies subject to review at convened (full WSIRB) meetings, the primary reviewer and/or ES/AES will make copies and distribute the last page (“Review Summary”) of the Worksheet to members at the meeting.
- For studies reviewed through the expedited review procedure, a copy of the expedited review determination is provided in the WSIRB packet.
- The Worksheet is available online in MS Word format at the HRRS Website; go to <http://www.dshs.wa.gov/rda/hrrs/handbook.shtm> in order to access a Word-format version. WSIRB members are encouraged to utilize the Worksheet when reviewing studies subject to review at convened meetings
- The Worksheet includes checkboxes and fields to enter free-form text. *To enter free-form text in other fields,* select “Review” from the pull-down menu, select “Protect Document,” select “Restrict Formatting and Editing,” and select “Stop Protection” (note that the location of this document protection feature may vary by Word version).
- Copies of completed worksheets are not provided to investigators, their institutions or agencies, study sponsors, other regulatory agencies, and are not routinely maintained in the official WSIRB files; completed worksheets are usually maintained in the HRRS staffers’

working files at least until final WSIRB approvals are granted.

- Each worksheet reflects findings by individual reviewers; findings rendered through conference between expedited reviewers and full convened meetings are reflected in review letters and the Documentation of Findings that are provided to PIs pursuant to WSIRB review and/or approval.
- Worksheets (and other HRRS and WSIRB records and documents) may constitute a “public record” under Washington law (RCW 42.56 et seq.), and may therefore be subject to public disclosure (“research data” or “intellectual property” may be exempt from public disclosure if doing so may result in private gain and public loss).

WSIRB Review Worksheet

Reviewer Name:

Project #:

Board Meeting Date:

Application

- Is the application complete (including the appropriate appendices)?

Yes

No

Points for discussion on application:

Consider completing this section last as a way to summarize key observations and findings below, and enumerate observations and findings as needed (e.g., (1) The consent form lacks an adequate description of the range of possible harms and discomforts; (2) Appendix D must be completed and submitted since children may be included as study subjects)

Investigator(s)

- Are the investigators appropriately trained and qualified to conduct/manage this research?

Yes

No

Points for discussion on investigator(s):

Key study staff (PI, co-investigators) are expected to have the requisite experience and background to execute the study, and to provide sufficient documentation to demonstrate their qualifications. For example, study staff may be expected to have medical or health-related qualifications (MDs, nursing) to conduct medical or health-related activities (blood draws, clinical interventions), and social science qualifications to conduct sociological, anthropological, political science or related activities (focus groups, in-depth interviews). Study staff CVs, resumes and/or biographical sketches should be used by reviewers to make these observations and findings. Consider, for example, education, training, post-doctoral experience, past and current research, grantsmanship and publications.

Collective experience and background among study staff may be sufficient, such as having statisticians, epidemiologists, named as study staff in the event other investigators lack this qualification. In some cases, junior Principal Investigators (PIs) may need to have senior co-investigators or supervisors/mentors to meet this qualification; students are expected to have supervisors/mentors or faculty as co-investigators.

There is no need to review investigators' human subjects protection, HIPAA Privacy Rule or Financial Conflicts of Interest-related training; this documentation is routinely not included in reviewers' study or the WSIRB packets, and will be separately reviewed and documented by HRRS staff. Any deficiencies will be noted during consultation, as needed during the convened meeting or expedited review, and in the notifications to investigators, as applicable.

Funding

- Is the funding source clear?

- Yes
 No

Points for discussion on funding:

If applicable, PIs should identify study sponsors, amount of extramural funding and period of support (e.g., Centers for Disease Control and Prevention; National Institutes of Health). Evidence of extramural and intramural support is used to characterize WSIRB activity and volume

Additionally, extramural support provided pursuant to peer review suggests robust scientific review and superior scientific design, innovation, approach, methods, analyses, as well as acceptable human subject protection. Such

extramural support may be accepted by the WSIRB as evidence of sound research design. Consider requesting copies of peer review findings (e.g., NIH summary statements) to supplement the Application for WSIRB Review and confirm the acceptability of the proposed study design and analyses.

Conflict of Interest

- Is there a potential conflict of interest?

No

Yes

Points for discussion on conflict of interest:

Conflicts of interest may be financial and non-financial in nature. Investigators are expected to disclose any possible conflicts of interest, which is documented primarily through Appendix N. Appendix N is routinely not included in reviewers' study or the WSIRB packets, and will be separately reviewed and documented by HRRS staff. Any Appendix N deficiencies will be noted during consultation, as needed during the convened meeting or expedited review, and in the notifications to investigators, as applicable.

However, other aspects of proposed studies may suggest possible conflicts of interest (e.g., instructors as investigators who involve their students as subjects; clinicians as investigators who will consent their patients as subjects; case workers as investigators who will randomize their wards or clients). Reviewers should consider whether investigators have described procedures that are sufficient to effectively manage such possible conflicts of interest (e.g., proctors administer surveys to students; clinicians or case workers have no direct role in recruiting or consenting patients/wards/clients who may be prospective subjects).

Study Design and Analysis

- Is the purpose of the research clear, and the study design sound enough to produce valid results related to the research objectives?

Yes
 No

- Are study procedures and instruments clearly described and appropriate for the aims of the study? (Who, what, when, where, how?)

Yes
 No

- Is there a clear differentiation between research procedures and standard/routine care?

Yes
 No

- Is the proposed data analysis sufficient to address the research questions and/or hypothesis?

Yes
 No

Points for discussion on study design and analysis:

Investigators are expected to provide an unambiguous statement of their study purpose and goals, hypotheses and research questions, as well as a detailed and thorough description of their research design, methods and analyses. A primary objective of the WSIRB is to ensure that prospective subjects, including their identifiable private information, are not needlessly used or involved in studies that are unlikely to have sufficient scientific merit, as the involvement of subjects in such studies is unethical (i.e., exposing subjects to risks to examine questions that have already been answered)

As observed above, some extramural support (NSF, NIH, AHA, Robert Wood Johnson Foundation) provided pursuant to peer review suggests robust and stringent scientific review and studies' superior scientific design, innovation, approach, methods, analyses, as well as acceptable human subject

protection. Such extramural support may be accepted by the WSIRB as strong evidence of sound research design.

The relevant scientific literature, including literature about similar research or research upon which the proposed study is built or intended to replicate, should be fully cited and annotated. The lack of relevant scientific literature should be noted, as applicable. Consider here whether the proposed study will meaningfully add to or advance the existing knowledge base, as the involvement of subjects in studies that have no such prospect are ethically suspect.

The study sample and the nature of their involvement in the study should be thoroughly described (population groups, geography, age range, other qualifying or disqualifying characteristics and inclusion/exclusion criteria). Consider whether the study sample is appropriate to the research design, methods and analyses, including for example in terms of size, power, representation, accrual and retention, and whether the investigators have acknowledged limitations in the sample.

All study procedures, including use of data collection instruments, should be carefully described, including whether these procedures are experimental (e.g., first in human use of drugs, devices or intervention) or part of standard of care or practice (e.g., research use of data generated during routine or typical social or health services). Standard of care or practice should be distinguished from experimental activities. Copies of all instruments should be provided; draft instruments may be conditionally approved, but must be finalized and approved in advance by the WSIRB before being deployed.

***END OF FEBRUARY 21, 2013 WSIRB TRAINING;
WSIRB TRAINING FOR SUBSEQUENT SECTIONS
TO BE CONTINUED AT THE NEXT SCHEDULED WSIRB MEETING.***