WASHINGTON STATE INSTITUTIONAL REVIEW BOARD
PROCEDURES MANUAL

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Human Research Review Section
Research and Data Analysis
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WASHINGTON STATE INSTITUTIONAL REVIEW BOARD
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1.0 PURPOSE AND AUTHORITY OF THE REVIEW BOARD

1.1 Purpose of the Review Board

The Washington State Institutional Review Board (WSIRB) protects the rights and welfare of individuals who participate in research under the jurisdiction of three Washington State Agencies: the Department of Social and Health Services (DSHS), the Department of Health (DOH), and the Department of Labor and Industries (L&I). In fulfillment of these State Agencies' Federalwide Assurances with 45 CFR Part 46 and the *Washington State Agency Policy on the Protection of Human Research Subjects,* the Review Board works to ensure that the rights and welfare of research participants are adequately protected; that the risks to individuals are minimized, are not unreasonable, and are outweighed by the potential benefits to the individual or by the knowledge to be gained; and that the proposed research design and methods are adequate in light of the stated research objectives.

1.2 Authority of the Review Board

The Washington State Institutional Review Board (WSIRB or the Review Board) is established under the general statutory authority of the Secretary of the Washington State Department of Social and Health Services. (RCW 43.20A.050 and RCW 43.20A.110). The WSIRB is registered with the federal Office of Human Research Protections (OHRP) in the Department of Health and Human Services; the three state agencies, DSHS, DOH, and L&I, have Federalwide Assurances (FWAs) on file at OHRP. All three state agencies have adopted the *Washington State Agency Policy on Protection of Human Research Subjects.*

The operation of the WSIRB is subject to the human subjects protection rules, policies, and guidelines contained in the following documents:

- Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects, as revised June 18, 1991

- Title 45, Code of Federal Regulations, Part 164, Privacy Rule – Security and Privacy

- The Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979

- Chapter 42.48, Revised Code of Washington, Release of Records for Research

- Chapter 70.02, Revised Code of Washington, Medical Records – Health Care Information Access and Disclosure

- Chapter 388-04, Washington Administrative Code, Protection of Human Research Subjects

- DSHS Administrative Policy 12.01, Human Research Review

- DOH Policy/Procedure 03.001, Human Research Review

- L&I Policy 9.43, Human Research Review Process

As provided in these documents, the Washington State Institutional Review Board has the following powers:

- Research in the jurisdiction of these state agencies may not proceed until the protocol has been reviewed and approved by the Review Board[1]. In the course of its deliberations, the Review Board may approve proposals, disapprove proposals, or defer final approval until review issues have been resolved.

- The Review Board may prescribe scientific and ethical restrictions or conditions under which a project may be conducted, require substantive changes in project plans, and determine the nature and frequency of interim review procedures necessary to ensure continued acceptable conduct of the project and the protection of human subjects.

- Negative Review Board decisions (disapprovals, restrictions, or approval conditions) are binding, are not subject to administrative override, and may be rescinded only by action of the Board. Projects approved by the Board are subject to further review, disapproval, or restrictions by departmental officials.

- The Review Board may suspend or terminate approval of research that is not being conducted in accordance with its requirements or that has been associated with unexpected serious harm to participants.

[1] At the discretion of the Human Protections Administrator of these Washington State Agencies, research in the jurisdiction of that agency may be forwarded for review by an alternate institutional review board designated on that agency's Federalwide Assurance. Reliance on the IRB of another FWA institution requires documentation on an IRB Authorization Agreement signed by the Institutional Official of the respective FWA institutions and filed with the DSHS Human Research Review Section.

2.0 MANAGEMENT AND SUPPORT OF THE REVIEW BOARD

2.1 Human Research Review Section

The Human Research Review Section (HRRS) in the Department of Social and Health Services, Research and Data Analysis Division, provides administrative and staff support to the Washington State Institutional Review Board, and is responsible for the receipt, processing, and disposition of all research proposals that require review by the Review Board.

The Review Section staff:

- Provide consultation to researchers;
- Determine whether a proposed activity is research or not research, and if research, whether the activity is exempt from WSIRB review and approval;
- Receive and process research proposals that require review;
- Communicate Review Board decisions to researchers;
- Solicit Continuation Approval Requests from researchers;
- Advise researchers and agency program managers regarding human research review policies and procedures;
- Maintain and update the Review Section's website which contains the State Agency and Review Board policies and procedures, application forms, and other information related to the review process;
- Facilitate required training and provide training resources on human subjects protection to researchers, research staff, and Review Board members.

2.2 IRB Administrator

The IRB Administrator is responsible for implementing and directing the operations of the Washington State Institutional Review Board and for ensuring compliance with applicable federal and state laws and regulations and departmental policies and procedures. The IRB Administrator also serves as the Executive Secretary (ES) and the Human Protections Administrator for the Department of Social and Health Services and the Department of Health. The IRB Administrator is responsible for the human subject protections programs in those state agencies, and provides technical consultation, educational resources and guidance to the Human Protection Administrator at the Department of Labor and Industries. In these multiple roles, the IRB Administrator has the following responsibilities:

- Assigns review workload to HRRS staff and WSIRB members and provides technical consultation to WSIRB members during review of research proposals;

- Ensures that Review Board decisions are enforced and monitors ongoing human research projects under the review by the Review Board;

- Maintains the credibility of the review process through constructive contacts with investigators, agency managers, and administrators;

- Provides professional liaison with federal and state agencies;

- Coordinates the WSIRB human research review process with the University of Washington Human Subjects Division, Fred Hutchinson Cancer Research Center Institutional Review Office and other institutions;

- Plans, develops, and proposes policies and procedures concerning the review and approval of human subjects research and the confidentiality of personal records;

- Hires and supervises HRRS staff; manages HRRS fiscal and computer resources to optimize research review objectives..

WSIRB Executive Secretary:

- Is a permanent voting member of the WSIRB;

- Provides technical support, training, and guidance to the WSIRB Chair; assists the WSIRB Chair to efficiently and effectively run the WSIRB meetings;

- Reviews research proposals for compliance with scientific, ethical, and legal standards for conducting research;

- Consults with investigators and primary reviewers regarding scientific, legal, ethical, and programmatic implications of proposed research design and protocols;

- With delegated authority from the WSIRB Chair, conducts expedited reviews of new proposals with at least one other member of the Review Board, and conducts expedited reviews of "minor changes in previously approved research during the period for which approval is authorized," with or without participation of another member of the Review Board, at his or her discretion.

As the DSHS and DOH Human Protections Administrator:

- Implements and maintains the human subjects protection program in the Department of Social and Health Services and the Department of Health;

- Provides technical consultation and support for the maintenance of the human subjects protection programs in the Department of Labor and Industries and in other state agencies;

- Determines which DSHS and DOH activities constitute research that is subject to WSIRB review and approval;

- Advises researchers and the Human Protections Administrator for the Department of Labor and Industries regarding which activities are subject to IRB review and approval.

2.3 HRRS Review Coordinators

In consultation with the IRB Administrator, HRRS Review Coordinators provide professional staff support to the Review Board and are permanent voting members of the WSIRB. One of the HRRS Review Coordinators may serve as the Associate Executive Secretary (AES). The HRRS Review Coordinators have the following duties:

- Review research proposals for compliance with scientific, ethical, and legal standards for conducting research;

- Consult with investigators and primary reviewers regarding scientific, legal, ethical, and programmatic implications of proposed research design and protocols;

- With delegated authority from the WSIRB Chair, conduct expedited reviews of new proposals with at least one other member of the Review Board, and conduct expedited reviews of "minor changes in previously approved research during the period for which approval is authorized," with or without participation of another member of the Review Board, at his or her discretion;

- Conduct outreach and educational activities with research professionals and program managers across state agencies;

- Develop and conduct workshops for researchers on the requirements for research involving human subjects;

- Conduct site visits and audit research procedures to ensure compliance with Review Board requirements for conducting approved research and to investigate suspected or reported noncompliance;

- Analyze policy manuals, application forms, instructions to researchers, review worksheets, etc., to identify and recommend ways to improve the quality of reviews of research proposals and to accommodate increasing workloads.

2.4 HRRS Compliance & Training Coordinator

The HRRS Compliance & Training Coordinator provides administrative and technical staff support to the Review Board and has the following duties:

- Coordinates continuing review of active research by screening project files at least annually to ensure compliance with Board-approved methods and procedures;

- Organizes and coordinates the Review Board workload of active research projects using the HRRS Access Database and maintaining project files;

- Screens and directs all telephone inquiries and mail;

- Arranges for meeting rooms and travel arrangements;

- Prepares meeting agendas, meeting minutes, and distributes Review Board materials to Review Board members;

- Prepares minutes of Review Board meetings based on correspondence to investigators and meeting notes;

- Works with the web coordinator to maintain the HRRS website and ensure that information on the website is current;

- Facilitates and monitors required training in the protection of human subjects for HRRS staff, Review Board members, and researchers.

3.0 REVIEW BOARD ORGANIZATION AND MEMBERSHIP

3.1 Composition of the Review Board

The Washington State Institutional Review Board has approximately 14 to 16 full members with additional alternate and ad hoc members who participate in reviews under specified circumstances. Members have diverse backgrounds to promote complete and adequate review of research activities conducted within the jurisdiction of the Washington State Agencies, DSHS, DOH, L&I, HCA, OFM, and DEL. The Review Board is sufficiently qualified through the experience and expertise of its members, and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of research participants.

In addition to possessing the professional competence necessary to review specific research activities, the Review Board is qualified to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The Review Board therefore includes persons knowledgeable in these areas. The Review Board also includes persons who are knowledgeable about and experienced in working with vulnerable populations such as children, prisoners, pregnant women, and physically or mentally disabled persons.

The Review Board includes several members whose primary concerns are in scientific areas, and at least one member whose primary concerns are in nonscientific areas. The Review Board includes several members who are not otherwise affiliated with Washington State agencies, and who are not part of the immediate family of a person who is affiliated with the Washington State agencies. The Review Board has at least one member who is a physician licensed to prescribe drugs in the State of Washington. Every effort is made to include members who mirror the ethnic and racial composition of subjects who volunteer for research under review. The Review Board maintains at least one member who serves as a prisoner representative during the review of research involving prisoners.

3.2 Board Members

3.2.1 Appointment

Recommendations for Review Board membership are solicited by the Executive Secretary from departmental administrators, Board members, and non-departmental professional and human service agencies and organizations. Candidates for Review Board membership are submitted for consideration and formal appointment by the Secretary of DSHS. The Secretary of DSHS appoints candidates to the Board who are DOH, L&I, HCA, OFM, and DEL employees with the concurrence of the candidate's management. Board members who are not employees of a state agency are appointed as official volunteers with DSHS. Volunteer status provides

members with the services of the Office of the Attorney General in the event that legal representation is required as a result of participation in Review Board business.

3.2.2 Length of Service

Board members serve a term of one year upon their first appointment. To assure continuity of Board operations, members may be appointed for terms of one, two, or three years following expiration of their first term. Members who exceed ten years of service on the Review Board are recognized as Distinguished Members.

3.2.3 Duties

Members of the Washington State Institutional Review Board are expected to contribute time necessary to complete Review Board business. The Review Board meets 12 times per year at monthly intervals. Board members are expected to attend at least seven meetings per year. Depending on the workload, members spend approximately four to eight hours reviewing proposals prior to a Board meeting. State agency employees appointed to the Board are authorized by their agency to set aside time from their regular duties for review preparation, meeting attendance, and other Board business.

During the review of research proposals, members do not participate as representatives of the agency or organization with which they may be affiliated or employed. Rather, each member brings to the review task his/her own expertise, principles, and points of view based on his/her own unique experiences and background. Members are expected to indicate if they have a conflict of interest with any research proposal under consideration.

During the review of each research proposal under consideration, whether the review is conducted through the expedited or full-Board review process, the duties of Board members include, but are not limited to, determining that:

- Risks to subjects are minimized, and are reasonable in relation to anticipated benefits to subjects, if any, and the importance of the knowledge that may reasonably be expected to result;

- Taking into account the purposes of the research and the setting in which the research will be conducted, selection of subjects is equitable;

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, and that it is

appropriately documented, in accordance with and to the extent required by state and federal statute and regulation;

- Approval of a waiver of consent or waiver of authorization is extended only when all criteria in state and federal statute and regulation have been satisfied;

- When appropriate, adequate plans are in place to monitor study procedures to ensure the safety of subjects;

- Adequate plans are in place to protect the privacy of subjects and to maintain the confidentiality of identifiable personal records;

- Additional safeguards are in place to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically and/or educationally disadvantaged persons;

3.2.4 Severance

Review Board members may resign from the Review Board upon written notification to the Executive Secretary.

If a member fails to attend more than three consecutive meetings, violates the confidentiality rules specified under Section 4.4 of this document, or otherwise behaves in a manner that is inconsistent with the mission of the Review Board, the Executive Secretary may recommend the member's severance from Board membership at a meeting of the full Board. The matter is decided by a vote of the Board.

3.3 Chairperson

3.3.1 Appointment

Candidates under consideration for the position of Chair must have been a member of the Review Board for not less than one year and should be affiliated with DSHS, DOH, L&I, HCA, OFM, DEL or a county public health department. Affiliation is defined as being a current or previous employee of one of these agencies.

Candidates for Chair of the Review Board are selected by the Executive Secretary and the outgoing Chair based on demonstrated commitment to the mission of the Review Board and on the ability to command the respect of members of the Review Board. Candidates are also sought on the basis of their ability to run meetings in an efficient and effective manner, and to provide leadership and facilitate problem solving during meeting deliberations. The Review Board Chair is appointed by the Secretary of the

Department of Social and Health Services based on the recommendation of the Executive Secretary.

3.3.2 Length of Service

The Chair is appointed to an initial term of one year. Upon successful completion of an initial term, the Executive Secretary will invite the Chair to accept reappointment for up to two consecutive terms of two years each. The total time a person may serve as Chair of the Review Board is five years. At the conclusion of a five year term as Chair of the Review Board, a Chairperson may elect to remain as a member of the Board.

3.3.3 Duties

In addition to the duties of a member, the Chair's duties include, but are not limited to, the following:

- Conduct Board meetings following a prepared timed agenda in accord with the *WSIRB Rules of Order;*

- Direct Board deliberations to focus on essential review concerns; probe Board consensus on critical review issues by eliciting individual votes; lead the Board to develop clear disposition instructions for correspondence to investigators by the Executive Secretary and Associate Executive Secretary;

- Serve as a voting member for the purpose of 1) breaking a tie vote; 2) satisfying quorum requirements if meeting attendance falls short by one Board member; and 3) participating in the expedited review of proposals;

- Share with the Executive Secretary in assuring Review Board compliance with *Washington State Agency Policy on Protection of Human Research Subjects* and *WSIRB Procedures Manual*;

- Share with the Executive Secretary in making recommendations for appointment of new Board members and in selecting candidates for Chair;

- Share with the Executive Secretary in representing the Review Board administratively within the three state agencies;

- Sign meeting minutes prepared by the Associate Executive Secretary.

The Review Board Chair delegates to the Executive Secretary and Associate Executive Secretary authority to carry out the following duties (per 45 CFR 46.110):

- Conducting expedited reviews of new proposals with or without participation of another qualified member of the Review Board, at his or her discretion.

- Conducting expedited reviews of minor changes in previously approved research during the period for which approval is authorized, with or without participation of another member of the Review Board, at his or her discretion.

- Signing all official Review Board correspondence.

3.3.4 Appointment of Vice Chair and Chair Pro Tem

The Vice Chair exercises all the duties of the Chair in the Chair's absence, and at all other times exercises the duties of a Board member. Appointment, length of service, and severance of the Vice Chair follow the WSIRB Procedures Manual section 3.3 applicable to the Chair, with the exception that candidates for Vice Chair are selected by the Executive Secretary and the current Chair.

If unable to attend a meeting, the Chair or Vice Chair should inform the Executive Secretary, if possible, at least three weeks prior to the scheduled meeting date. If neither the Chair nor Vice Chair is able to attend a meeting, the Executive Secretary has the authority to appoint another qualified member of the Review Board to serve as Chair Pro Tem for that meeting.

3.3.5 Severance

The Chair may resign from his/her duties as Chair upon written notification to the Executive Secretary.

If a Chair fails to attend more than two consecutive meetings, violates the confidentiality rules specified under Sec. 4.4 of this document, or otherwise behaves in a manner that is inconsistent with the mission of the Review Board, the Executive Secretary may recommend the Chair's severance from Board membership at a meeting of the full Board. The matter is decided by a vote of the Board.

3.4 Use of Consultants

If a proposal requires expertise beyond those represented on the Review Board, the Chairperson and/or the Executive Secretary may seek verbal advice or written consultation from outside professionals. When consultation is obtained, however, the Board remains responsible for independently determining the scientific and ethical acceptability of the proposal. Consultation with outside experts shall preserve the anonymity of the researcher, or, if this is not possible, shall be conducted in a confidential manner. Consultants may participate in the discussion

of a proposal at the meeting, but may not be present during or participate in the voting process. Copies of the consultant's viewpoint are distributed to all Board members prior to the meeting.

3.5 Board Member Education/Training

Under the *Washington State Agency Policy on Protection of Human Research Subjects*, members of the Washington State Institutional Review Board are required to complete training in the protection of human subjects. Review Board members must complete the training requirement before they participate as voting members.

Review Board members may satisfy this education and training requirement by:

- Completing a course in the protection of human research subjects at their home institution and submitting to the HRRS written documentation of the content of the training and the date it was completed.

- Completing the web-based training in the Protection of Human Research Subjects provided by CITI/University of Miami. There is no charge to members if they access this training through the HRRS website. Members must complete all required modules and the quizzes for these modules and review the *Washington State Government Agencies Institutional Page* and links to receive credit for training.

The cost of providing required Board member training is included in the HRRS budget. Links to the web-based training listed above may be accessed through the HRRS website. A list of individuals who completed the required training, along with the date of their training, is maintained on the HRRS website.

In addition to the required member training, in-service training in a variety of applied topics relevant to reviewing human subject research is provided in each Board meeting as time allows. The Executive Secretary's Report at the beginning of each Board meeting also provides timely information on topics relevant to the work of the Review Board. Topics covered include regulatory updates, state legislative and policy developments, and current or future WSIRB quality improvement initiatives.

A *Board Member Handbook* which includes additional resource materials useful for reviewing research proposals is available on the HRRS website.

3.6 Reimbursement

As allowed DSHS, DOH, L&I, HCA, OFM, and DEL employees appointed to the Review Board receive mileage reimbursement from their own organizational units.

3.7 Conflict of Interest

No Review Board member may participate in the Review Board's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the Review Board. Conflicts of interest may arise for either financial or personal reasons. At the beginning of each WSIRB meeting the Chair shall ask Review Board members to disclose any potential conflicts of interest they may have with any item on the agenda, and this shall be noted in the meeting minutes.

Members who have a significant conflict of interest (e.g., being the PI or Co-PI, a contributor to the design of the research, or a member of the research staff) must recuse themselves from consideration of the research proposal. Members who recuse themselves must leave the meeting room during discussion of and voting on the research proposal, and are not counted in the quorum for consideration of that agenda item. Members who have a less significant conflict of interest (e.g., the proposal was developed by a researcher in the same organizational unit, but the member did not make a direct contribution to the research) may remain in the room during consideration of the proposal, but should not participate in the discussion except to answer questions, and must abstain from the vote. Members who abstain from voting are counted in the quorum for consideration of that item.

The Chair of the Review Board shall be the final arbitrator regarding whether a member's conflict is significant enough to require recusal from consideration of an agenda item. If the Chair has a conflict of interest, the Executive Secretary shall decide if the conflict is significant enough to require recusal. If recusal of the Chair is required, the Executive Secretary shall chair the meeting until the Chair is able to return to the meeting.

3.8 Liability Coverage

State law (RCW 4.92.060) provides that state officers, employees, and volunteers may request representation by the Attorney General in any action or proceeding for damages in which the officer, employee, or volunteer has been named a defendant. Representation from the Office of the Attorney General applies to legal claims arising from acts or omissions which occurred while performing, or in good faith purporting to perform, official duties.

Representation from the Office of the Attorney General is available to all Board members who are state employees or volunteers of state agencies for their acts or omissions, if such acts/omissions are determined to be in good faith and within the scope of their official duties and responsibilities as member of the Washington State Institutional Review Board. Where representation from the Office of the Attorney General is provided, Board members are protected from judgments against the State of Washington.

To provide representation from the Office of the Attorney General, Review Board members who are not state agency employees are officially appointed as volunteers of the Department of Social and Health Services for purposes of performing their official Review Board duties.

4.0 REVIEW BOARD OPERATIONS

4.1 Meeting Schedule and Venue

The Review Board meets on the third Thursday morning of each month. Meetings commence at 8:30 am and are generally completed by 12:00 pm. To accommodate Board members who live in Seattle as well as in the Tacoma and Olympia areas, meetings generally are held at the Tacoma Rhodes Center in downtown Tacoma. Meetings in July and December tend to be teleconferences. A calendar of future Board meetings is posted on the WSIRB website.

4.2 Distribution of Materials

Review materials and information are mailed to all Board members approximately one week before each scheduled meeting. Review materials distributed prior to each meeting may include:

- A Detailed and a Timed Meeting Agenda
- Minutes from the previous Review Board meeting (PDF)
- *Research Applications* for full-Board review
- *Continuation Approval Requests* for full-Board review
- *Study Amendment Requests* for full-Board review
- The list of items reviewed under expedited review authority, including new applications; Continuation Approval Requests; and Study Amendment Requests
- *Unanticipated Problems and/or Adverse Events Reports*, if any
- *Miscellaneous Board actions*, if any
- Final study approvals
- Canceled and Completed Projects
- Exempt Determination Requests reviewed

Materials pertaining to Review Board actions taken under expedited review authority are distributed to all Board members for informational purposes. Either at or before the meeting, Review Board members may ask questions, raise issues, and/or ask for full-Board consideration regarding any actions taken under expedited review authority.

4.3 WSIRB Rules of Order

WSIRB Rules of Order, adapted from *Robert's Rules in Plain English,* by Doris P. Zimmerman, are used as a guide for conducting business during full-Board meetings. The *WSIRB Rules of Order* are intended to provide a mechanism to keep Board meeting deliberations focused on relevant topics, to promote efficient use of meeting time, and to allow all members to participate in the review process, while not unduly inhibiting discussion and/or debate among Board members. The Chair has the authority to implement the *WSIRB Rules of Order* to the extent that he/she believes this intent is being met, or to suspend the *WSIRB Rules of Order* if he/she believes they are acting as an impediment to running the meeting in an efficient and effective manner. The *WSIRB Rules of Order* are also used to settle disagreements about procedural matters.

4.3.1 Basic Rules

A. All members are equal and their rights are equal. Those rights are:
- To attend meetings
- To make motions
- To speak in debate
- To vote

B. A quorum must be present to do business:
- A quorum is a simple majority of full members of the WSIRB, except as modified below; at least one member whose primary concerns are in non-scientific areas must be present.
- Alternate members of the WSIRB are counted in the quorum when they are attending a meeting on behalf of the full members for whom they are alternates.
- Ad hoc members of the WSIRB are counted in the quorum when they participate in deliberations related to their specified area of expertise.
- Members who do not vote (abstain) are counted toward the quorum.
- Members who recuse themselves from consideration of a proposal due to conflict of interest must leave the room and are not counted in the quorum.

C. The majority rules:
- A majority means the majority of members present.

- The minority has the right to be heard.
- Once a decision has been made by the majority, the minority must then respect and abide by the decision.

D. Silence is consent:
- Members who do not vote (abstain) agree to go along with the decision of the majority by their silence.

E. A two-thirds vote is required whenever:
- The rights of members are limited or taken away.
- Something that has already been decided is being changed.

F. One question at a time and one speaker at a time:
- No motion is in order which does not directly relate to the question under consideration.
- Once a member has been recognized by the Chair, he/she has the floor and may not be interrupted.

G. Debatable motions must receive full debate:
- Debatable motions may not be voted on as long as members wish to debate it.
- Exception: debate can be suspended by a two-thirds vote of members present.

4.3.2 Duties of Chairperson during Board Meetings

A. Arrive on time and start on time.

B. Follow the timed agenda and keep on schedule.

C. Be in control of the floor:
- "Assign" the floor by recognizing members who wish to speak.
- Remind those who interrupt that the floor has been assigned to another.
- Discourage private conversations during the meeting.
- Be impartial when calling on members to speak.

D. Direct deliberations to focus on essential review concerns.

E. Facilitate consensus on critical issues by eliciting individual votes.

F. Restate the main motion before taking a vote.

G. Lead the Board to develop clear instructions on review issues for correspondence to the researcher.

H. Use general consent when possible (e.g., "If there are no objections...").

I. Allow the withdrawal of motions using general consent.

4.3.3 Types of Motions

A. Main motions:

- Cannot interrupt a member who has been assigned the floor.
- Require a second, unless the motion is from a committee.
- Can be debated.
- Can be amended.
- Require a majority vote.

B. Secondary motions:

- Can be made while the main motion is on the floor and before it has been decided.
- Three classes: subsidiary motions; privileged motions; incidental motions.

C. Subsidiary Motions:

- Subsidiary motions relate directly to the main motion on the floor.
- They have rank among each other: a motion of higher rank can be made at the time when a motion of lower rank is on the floor or pending; the motion of higher rank takes precedence:
  1. Previous Question (call for the vote) – Highest Rank
  2. Limit or Extend Limits of Debate
  3. Amend
  4. Main Motion – Lowest Rank

Amend: Changes the wording of a motion to make it clearer, more complete or more acceptable *before* the motion is voted upon.

- An amendment must be germane to the motion on the floor.
- A member must obtain the floor to offer an amendment.
- An amendment must be seconded.
- An amendment is debatable if it is made to a debatable motion.
- A primary amendment can be amended; the secondary amendment cannot.
- An amendment requires a majority vote even when applied to a motion that requires a two-thirds vote.
- Adopting an amendment does not adopt the motion.
- Amendments that are the same as a negative vote on the motion are out of order.

Limit Debate: Exercises special control over the debate by reducing the number and length of speeches allowed or by requiring that

debate be limited to a period of time after which the vote must be taken.

- Can be used with any motion.
- Must be seconded.
- Is not debatable.
- Can be amended but only regarding the number and/or length of speeches or when the vote will be taken.
- Requires a two-thirds vote.

Previous Question:

- Can be applied to any pending question.
- It is out of order when a member has the floor.
- It cannot be debated.
- Requires a two-thirds vote.

D. Privileged Motions:

- Privileged motions are not related to the business on the floor but to the rights of members and the organization.
- The Chair can move for recess or adjournment by using general consent.

Recess: Proposes a short intermission in the meeting.

- It must be seconded.
- It cannot be debated.
- It can be amended only as to the length of time or recess.
- It requires a majority vote.

Adjourn: Closes the meeting.

- It must be seconded.
- It cannot be debated.
- It cannot be amended.
- It requires a majority vote.

E. Incidental Motions:

- Have no rank among themselves and may be applied to any main motion; usually decided as they arise, they are usually not debatable and can only rarely be amended.

Point of Order: To raise the possibility that rules of order are not being followed.

Point of Information: To obtain additional information on the subject being considered.

Division of Question: Used when a motion contains several parts, and the group wishes to vote on each part separately:

- It requires a second.
- It requires a majority vote.

F. Restorative Motions:

- Allows the group to change its mind on previously adopted motions.

Rescind: Used to quash or nullify a previously adopted motion:

- It requires a second.
- It requires a two-thirds vote.
- It is not in order if action has already been taken as a result of adoption of the motion.

Reconsider: Used to reconsider the vote on a previously adopted motion:

- Can only be made by someone who voted on the prevailing side.
- Must be made on the same day that the vote to be reconsidered was taken.
- It requires a second.
- It may be debated, and it opens up to debate the motion to which it is applied.
- It requires only a majority vote.

4.3.4 Process

A. The floor is assigned to the primary reviewer.

B. The primary reviewer presents the proposal and the issues, and makes a motion for disposition of the proposal.

C. A motion is seconded.

D. The Chair states the motion (the motion is pending).

E. Debate is held “one speaker at a time.”

F. The Chair may open the floor to general discussion.

G. The Chair puts the question to vote.

H. Votes are taken by a show of hands.

I. The Chair announces the vote.

J. If the motion fails to pass, the floor is open to alternative motions from any member of the Review Board.

4.3.5 Other Points

A. The maker of a motion has the first right to speak about it.

B. A member can vote against his/her own motion, but cannot speak against it.

C. A member can modify his/her own motion *before* it is stated by the Chair.

D. A member can amend his/her own motion *after* it has been stated by the Chair.

E. A member can withdraw his/her own motion up to the time it is stated by the Chair, and after that with the group's permission (e.g., with general consent).

F. Motions that repeat the same question on the same day, or that conflict with an already adopted motion, are out of order.

4.3.6 Voting and Disposition Decisions

A. All votes on motions for disposition are taken by a show of hands; the number in favor, opposed, and abstaining are recorded.

B. To be adopted, a majority of members present at the meeting must vote in favor.

C. In a full-Board review, the Chair may vote only to break a tie vote.

D. For proposals being reviewed under expedited review authority, or by subcommittee, the majority also prevails.

E. Disposition Decisions:

- **Approve:** The proposal can be approved as submitted or amended prior to the Review Board meeting.

- **Conditionally Approve:** Simple concurrence of the researcher to a specified set of revisions is all that is required for approval of the proposal. Review of the revised proposal is delegated to a subcommittee; if approval conditions have been met, the proposal is approved. If approval conditions have not been met, or if new issues surface in the revised proposal, the proposal is referred back to the full Board for further consideration at the next scheduled meeting.

- **Defer Consideration:** The number of issues, concerns and/or questions is too great to be resolved by the simple

concurrence of the researcher. The issues must be addressed in a revised proposal which is considered in a subsequent Review Board meeting.

- **Disapprove:** This is moved only after the investigator has been given an opportunity to resolve serious issues, and further attempts to negotiate required revisions would be unproductive. While this disposition effectively terminates the proposal, the investigator is free to submit a new proposal for consideration at a later Board meeting.

- **Suspend Approval:** This action is taken by the Executive Secretary/Associate Executive Secretary (ES/AES) when investigators fail to submit information required for continuation review prior to expiration of study approval. This action is also taken by the ES/AES in concurrence with the Chair when adverse events or unanticipated problems involving risks to subjects or others requires temporary suspension of study activities, except to the extent that suspension would pose additional risks to subjects.

- **Terminate Approval:** This action is taken by ES/AES with the concurrence of the Chair in instances in which the investigator fails to submit information required for continuation review within 30 days of expiration of study approval. This action is taken by the full Board when serious and continuing non-compliance with federal, state, institutional, or WSIRB requirements have occurred which the investigator has failed to resolve to the satisfaction of the Review Board.

4.3.7 Appeals of WSIRB Decisions

Investigators have the right to appeal Review Board decisions, including disapprovals, terminations of approval, restrictions on study design and/or study procedures, and approval conditions. Appeals must be submitted in writing to the Review Board within 60 days of the written notice to the investigator of the Review Board decision. Appeals should provide a rationale for why the Review Board's decision is in error, is not consistent with the *Washington State Agency Policy on Protection of Human Research Subjects* and/or the *WSIRB Procedures Manual*, or is not inconsistent with these policies and procedures but is unreasonable given the circumstances and constraints of the proposed research.

All written appeals, including those of decisions made through the expedited review process, will be placed on the agenda of the next meeting

of the Review Board. Investigators may request to be present at the meeting during consideration of the appeal to answer questions from Review Board members and/or to clarify aspects of the proposed research they believe the Review Board has not adequately taken into consideration. The investigator must leave the meeting prior to final Review Board consideration of the appeal.

A motion for disposition of the appeal, and the rationale for that disposition, is made by the primary reviewer of the proposal. After the motion is seconded, the Chair opens the floor to debate on the motion. After debate, the Chair puts the question to vote. Votes are taken by a show of hands and a simple majority is needed for the motion to pass.

If unsatisfied with the Board's decision on the appeal, the investigator may, within 30 days of the appeal decision, request in writing that the appeal be re-considered by an ad hoc WSIRB Appeals Committee. The WSIRB Appeals Committee shall be comprised of the Chair of the WSIRB and four randomly selected members from the Review Board to exclude the ES/AES. The Chair of the WSIRB Appeals Committee shall have a vote on the final decision. The ES/AES will form the WSIRB Appeals Committee and schedule the meeting, which may be conducted by teleconference, if necessary, to ensure timely consideration of the appeal. Decisions made by the WSIRB Appeals Committee are final and are not subject to further review or appeal.

4.4 Confidentiality of Review Board Materials

All materials listed below are considered sensitive information and shall not be disclosed to or discussed with any individual who is not a WSIRB member. The only exception to this rule is that the Chair, the primary reviewer of the proposal, and the staff reviewer may discuss the proposal with the principal investigator and his/her staff prior to the meeting. Only the staff reviewer may discuss the disposition of the proposal with the principal investigator and his/her staff after the meeting.

4.4.1 Sensitive Information

The following materials are classified as sensitive information:

- Proposals submitted to the Review Board, unless and until they have been approved by the Board. Disapproved proposals and proposals canceled before approval shall remain classified as sensitive information.

- Oral and written arguments, opinions, and decisions (votes) by individual Board members during the review process. Meeting minutes summarize discussion and votes in anonymous form, except for recusals.

- Written reviews of proposals by outside consultants.

- Correspondence between the Review Board and the investigator prior to approval of the proposal. Correspondence with investigators of disapproved proposals shall remain classified as sensitive information.

- Any identifiable personal records and/or information pertaining to agency clients, employees, or members of the general public made available to the Review Board in the process of review are classified as confidential information and shall be treated as such under applicable laws.

Board members should keep review documents and correspondence classified as sensitive information in a secure location at all times. Review documents and correspondence transmitted as email attachments to Board members are accompanied with a statement that the materials contain sensitive information and should be opened only by the intended recipient.

4.4.2 Retention of Sensitive Information

To minimize storage of paperwork related to Review Board business, members may destroy all review materials (except identifiable personal records) by discreet recycling when the meeting is completed, except for materials related to proposals for which a member is the primary reviewer, which should be retained until the project is completed or canceled.

All other Board-related paperwork (correspondence, agendas, cover memos, proposals, continuation approval requests, etc.) may be discreetly recycled after the meeting to which they pertain has been completed.

4.5 Record Keeping

4.5.1 Research Project Files

The Review Section maintains separate project files for each research proposal. Upon submission, proposals are assigned a project code. The project code appears as "X-mmddyy-X" and consists of a single letter prefix assigning the project to type of review (D=WSIRB review; C=cooperative review; E=exempt review) , followed by the date the application is received by the Review Section, and ending with a single letter suffix indicating the agency in whose jurisdiction the research would be conducted ("S" for DSHS; "H" for DOH; "L" for L&I; "A" for HCA; "F" for OFM, "E" for DEL or "U" for unaffiliated or other).

Each project file contains, in order from front to back:

- A *Face Sheet* created by the Access database
- A copy of the *Project Identification from the Research Application*
- The original signed and executed Confidentiality Agreement, if identifiable personal records maintained by these Washington State Agencies are used or disclosed for the research.
- WSIRB approval letter, and an approved proposal, with addendums as applicable, which reflects Board-negotiated revisions in the original proposal, and which officially represents how the research will be conducted. Documentation of Training in the Protection of Human Subjects completed by the principal investigator, unless such documentation is included in the Review Section's Training Database. A *Documentation of Findings* based on the WSIRB review of the proposal.
- All other correspondence and documentation related to the project, in reverse chronological order.
- The Summary of Pre-Review Issues completed prior to the initial full- Board review of the proposal.

The Review Section also maintains electronic files of all proposals submitted for review. Hard copies of outdated versions of proposals are discarded from the paper file.

4.5.2 Record Storage and Retention

Proposals reviewed by the Board and all materials and documents related to the Board review are maintained in individual project files stored in

locked file cabinets in the DSHS Human Research Review Section. Only staff in the Review Section have direct access to materials in the locked file cabinets.

Project files may be retained in the Review Section for 12 months after the project is completed or canceled. The files are then moved to the Washington State Records Center where they are retained for seven years. Within these retention parameters, all project files are accessible for inspection and copying by authorized representatives of the U.S. Department of Health and Human Services at reasonable times and in a reasonable manner.

Materials which have historical value may be selected and retained in the Washington State Archives indefinitely.

4.5.3 Review Board Correspondence

Review Board correspondence is prepared by the staff reviewer assigned to the proposal and has attended the meeting in which the proposal was considered. Correspondence is written to represent the consensus view of the Review Board. However if a strong minority viewpoint is expressed in the meeting it will be included in the correspondence. Draft correspondence must be reviewed for accuracy and tone by the primary reviewer before it is transmitted to the investigator. Other Review Board members may request that they also review and comment on draft correspondence. Review Board correspondence is signed by the staff reviewer on behalf of the Review Board.

Review Board correspondence in response to expedited reviews is prepared by the staff reviewer who participated in the review of the proposal. The primary reviewer may request to review and comment on draft correspondence prepared by the staff reviewer; however, under normal circumstances this review may not be necessary.

Correspondence is sent to investigators via PDF and/or first class, or campus mail. Copies of all written correspondence and email correspondence related to Board reviews are included in the project file maintained in the Review Section.

4.5.4 Review Board Meeting Minutes

Meeting minutes are drafted by the Associate Executive Secretary after all Review Board disposition letters have been conveyed to investigators. The review of a proposal is described in the minutes based on Board correspondence to investigators. The meeting minutes include:

- The time the meeting was called to order;

- Attendance and quorum verification;
- Documentation of the acceptance of the minutes of the previous Board meeting,
- Executive Secretary's report;
- In-Service Training Module, if applicable;
- Documentation of whether any member in attendance has a personal or financial conflict of interest with respect to any item on the meeting agenda;
- A brief description of the proposal, continuation approval requests, study amendment requests, or unanticipated problems and/or adverse event reports submitted for full-Board review, along with a description of the Review Board's deliberations, actions, and votes on each item. The minutes document the basis for requiring changes or for disapproving research and include a summary of controverted issues, if applicable;
- A list of new proposals, continuation approval requests, and study amendment requests reviewed under expedited procedures, and any Board member comments and questions;
- Other Review Board actions;
- The time the meeting was adjourned.

4.5.5 Review Board Member List

The HRRS maintains a current Review Board membership list, including names; earned degrees; relevant experience such as board certifications, licenses, etc., sufficient to describe each member's principal anticipated contributions to Review Board deliberations; and any employment or other relationship between each member and the institution. Changes to Board membership are reported promptly to the federal Office of Human Research Protections.

4.5.6 Written Procedures

HRRS staff maintain current written procedures for the WSIRB. Written procedures are codified in the *WSIRB Procedures Manual*, which is available on the WSIRB website. Proposed revisions and/or additions to procedures are prepared by HRRS staff and distributed in mark-up format to the Review Board. Review and comments on revisions and/or additions to procedures are solicited from Board members prior to adoption. Formal adoption of the *WSIRB Procedures Manual* is by vote at a convened Review

Board meeting. The date of the current version of the *WSIRB Procedures Manual* is listed in the footer on each page.

4.5.7 Research Tracking System

The Review Section maintains an Access Database to manage and track active as well as completed research protocols. The Access Database serves as a historical record of all proposals reviewed by the Board. It is also used to produce a list of projects due for continuation review before each review cycle; to evaluate Review Board and Review Section workload; and to prepare the workload reports.

4.6 Methods of Documentation

4.6.1 Education and Training

Principal investigators and research staff who have contacts with human subjects or access to identifiable records must document completion of training in protection of human research subjects before their proposals can be approved. The Review Section will accept certificates of completion of such training from recognized institutions including the National Institutes of Health. Investigators who complete the CITI training offered through these Washington State Agencies are included on reports sent to the Review Section by the University of Miami, the CITI host institution.

The Review Section maintains a training database of all persons who have completed the requirements for education and training in the protection of human research subjects and who are involved in research under Washington State Agency jurisdiction. The Training Coordinator is responsible for updating and maintaining the Training Database from the sources listed above. The Training Coordinator ensures that a current list of training participants is posted on the Review Section website.

4.6.2 Informal Review and Consultation

The staff reviewers provide consultation to researchers, students, program managers, and Washington State Agency employees on a wide variety of topics related to the human subjects protection program. Many consultations involve inquiries about whether a specific activity constitutes research under the *Washington State Agency Policy on Protection of Human Research Subjects* (See Section 5.1, *WSIRB Procedures Manual*, to determine if an Activity Requires WSIRB Review and Approval).

A written determination about whether an activity constitutes research must be based on submission of information in an *Exempt Determination Request*. Files documenting each exempt review are maintained in a central file cabinet in the Review Section. At a minimum, the file includes the name and affiliation of the person submitting the *Exempt*

Determination Request, a written description of the activity in question, a written determination about whether the activity constitutes research, and the date the determination was made. Each activity described in an *Exempt Determination Request* is entered into the Access Database maintained by the Review Section.

4.6.3 Exemptions from Review Policy

Activities described in the *Exempt Determination Request* that are found to be research may still be exempt from WSIRB review and approval if they fall into one of the exempt categories in the *Washington State Agency Policy on Protection of Human Research Subjects.* Exempt research activities are entered into the Access Database, but are not subject to annual review. However, the investigator is notified at the time of the initial exempt determination that if the activity changes in a manner such that it may no longer be exempt, he/she must update the Exempt Determination Request and submit it to the Review Section prior to implementing changes. If information on the form indicates the study is no longer exempt, the investigator must submit a Research Application for expedited or full-Board review.

4.6.4 Findings Required by Regulation

Upon approval of a project reviewed by either expedited or full-Board procedures, the staff reviewer will complete a *Documentation of Findings* form. This form includes information abstracted from the proposal submitted by the investigator as well as the results of the review of the proposal. The form meets requirements in 45 CFR 46 and 45 CFR 164.512(i) for documenting the findings and actions of the Review Board, including:

- Project title, principal investigator, and primary reviewer.
- Type of review conducted and approval date.
- Justification for expedited review, if applicable.
- Period of Review Board approval.
- Level of risk to subjects.
- Additional protections for pregnant women and human fetuses involved in research, if applicable. (45 CFR 46, Subpart B)
- Additional protections for prisoners involved in research, if applicable. (45 CFR 46, Subpart C)

- Additional protections for children involved in research, if applicable. (45 CFR 46, Subpart D)

- Waiver of some/all elements of consent for study participation, if applicable. (45 CFR 46.116(d))

- Waiver of written documentation of consent; oral consent will be obtained, if applicable. (45 CFR 46.117(c))

- Waiver of parental permission for study participation of a child, if applicable. (45 CFR 46.408(c))

- Waiver of authorization for disclosure of individually identifiable private information and/or protected health information, if applicable. (45 CFR 46.116(d)); 45 CFR 164.512(i); RCW 70.02.050(g); RCW 42.48.020)

The completed *Documentation of Findings* form is signed by the staff reviewer, a copy is provided to the investigator with the WSIRB approval letter, and the original is filed in the project file.

4.6.5 Review by another IRB

In the course of review, the Review Board may request documentation of study approval by the funding agency's IRB, from the IRB of the investigator's home institution, or from other IRBs which retain jurisdiction over the research. Such documentation is included in the project file maintained in the Review Section. An Institutional Review Board Authorization Agreement (IAA) may be required.

5.0 REVIEW PROCESS

5.1 Determining if an Activity Requires WSIRB Review and Approval

Activities that include many of the features of research may not necessarily require review and approval by the WSIRB. Some activities resemble research but are not research as defined in the federal regulations. Other activities meet the definition of research but are exempt from needing WSIRB review and approval.

5.1.1 Research versus Non-Research Activities[2]

Research is defined in the federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." There are a variety of activities that employ many of the features of research, such as rigorous design, systematic data collection, and statistical analyses, which are nevertheless not considered research under this definition. The key to distinguishing between research and non-research activities is to determine the primary intent of the activity. The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of similar activities that are not research may be to prevent or control disease in a population or to identify methods of improving services for a group of clients or customers.

Some activities conducted by or on behalf of institutions which involve systematically collecting and analyzing data are not research. Included in this category are audit activities, resource and/or drug utilization studies using institutional records, and client outcome monitoring in which individual level data are routinely collected and analyzed to determine the extent to which clients are experiencing the intended outcomes of a program. Client satisfaction and needs assessment surveys which only collect information from clients who are eligible to receive program services are also included in this category. <u>If the primary intent of these activities is to support the administration of the program, and if data collection is limited to information needed to administer the program, these activities are not considered research</u>. The HIPAA Privacy Rule classifies such activities as part of "health care operations" and not research. However, data collected through such activities could be used secondarily for research, in which case WSIRB review and approval would be required.

Program evaluation, surveillance activities, disease investigation and/or emergency response activities, and quality assurance and/or quality improvement are activities that may or may not constitute research that requires IRB review. The WSIRB uses the following guidelines to determine

[2] This section draws heavily on the "Distinguishing Public Health Research and Public Health Non-Research," published by the Centers for Disease Control and Prevention, July 2010.

when activities in these categories constitute research that requires IRB review and approval:

Program evaluation activities in which the primary intent is to assess the success of an *established* program or intervention in achieving its objectives in a specific population, and in which the information gained will be used only to provide feedback to the program, to ensure service quality, or to make improvements in the program, are not considered research. However, when the primary intent is to test a new, modified, or previously untested intervention, service, or program in a defined population to determine whether it is effective, the evaluation is research. The systematic comparison of standard or non-standard interventions in an experimental-type design is also research.

Surveillance activities which involve the regular, ongoing collection and analysis of health-related data conducted to monitor the frequency of occurrence and distribution of disease or a health condition in a population and which are authorized by state statute or regulation which specify the intent of the activity, its purpose, and uses of the data are not considered research. Quality control activities that assess, for example, completeness of reporting of surveillance data by matching case records with records from other databases are not considered research. However, when health-related data are collected in surveillance systems and analyzed with the primary intent to produce knowledge applicable to other populations and settings from which the data were collected, or to contribute to new knowledge about the health condition, the activities are likely to be research. Surveillance systems that involve longitudinal data collection systems (e.g., follow-up surveys and registries) that allow hypotheses testing, which collect more information than the occurrence of a health-related problem, in which etiologic analyses can be conducted, or in which cases may be identified to be included in subsequent studies, are likely to be research.

Disease investigation and/or emergency response activities authorized under state statute or regulation which are undertaken to identify, characterize, and solve an immediate health problem, and in which the information gained will directly benefit those participants involved in the investigation or their communities, are not considered research. However, when biological samples are stored for future use intended to produce generalizable knowledge, or when additional analyses are conducted beyond those needed to solve the immediate health problem, the activity may have a research component. When investigational new drugs or devices are used, or when drugs are used off-label, the activity is almost always considered research. Whenever a systematic investigation of a non-standard intervention or a systematic comparison of standard interventions occurs, the activity is research.

Quality assurance and/or quality improvement activities[3] in which existing individual-level data are collected and analyzed and in which there is a formal commitment in advance of data collection to a corrective action plan related to any of a number of possible outcomes of the analyses are not considered research. However, prospective interventional activities which may involve systematic comparison of standard or non-standard therapies are considered research even when conducted by the entity responsible for quality assurance and/or quality improvement.

Activities conducted for educational purposes may fall into a category that would not be considered research if the activity was not conducted primarily for educational purposes. For example, the design of a thesis or dissertation project might be classified as program evaluation or a quality improvement activity rather than research if it was being conducted primarily to support the administration of a program or to develop a corrective action plan. However, as the primary intent of the activity is related to training in research methods in partial fulfillment of requirements for an advanced degree, the educational activity is considered research.

Investigators should consult with staff in the Human Research Review Section (HRRS) if they have questions about whether a specific activity is considered research. The IRB Administrator is responsible for making the determination of whether or not an activity is considered research. If the investigator disagrees with the determination made by the IRB Administrator, he/she may provide additional information for consideration. The Human Protection Administrator of the state agency that has jurisdiction over the activity in question shall make the final determination.

5.1.2 Research Exempt from Review

Once an activity is determined to be research, a determination should be made as to whether the activity involves human subjects as defined in the federal regulations. Human subject means "a living individual *about whom* an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

If the activity is determined to be research that involves human subjects, a determination should be made about whether the research falls into a category of research that is exempt from needing review and approval by the WSIRB. To qualify for exemption from WSIRB review, a research proposal must fall into one of the categories that are listed in Section XI of the *Washington State Agency Policy on Protection of Human Research Subjects*. These categories are more restrictive than the federally-approved exemption categories, and reflect a higher local standard for what can be excluded from WSIRB review.

[3] Based on "The Quality Improvement-Research Divide and the Need for External Oversight," Eran Bellin and Nancy N. Dubler, American Journal of Public Health, Sept 2001, Vol 91, Issue 9, p1512

5.1.3 Procedures for Determining if an Activity Requires WSIRB Review and Approval

Washington State Agency staff and outside investigators are expected to contact the HRRS to inquire about whether a planned activity constitutes research which requires review and approval by the WSIRB. Contact should be made at least 60 days prior to any planned contact with potential subjects or access to individually identifiable personal records. After discussion with the HRRS staff, the agency employee or outside investigator will be advised whether to submit an *Exempt Determination Request* to the HRRS. The *Exempt Determination Request* and supporting information and documents about the planned activity may be submitted electronically to wsirb@dshs.wa.gov. Washington State Agency staff and outside investigators will be informed in writing about whether the planned activity requires submission of an application for review and approval by the WSIRB.

5.2 Research Application Submission Procedures

Investigators planning to submit a proposal to the Washington State Institutional Review Board should contact the HRRS to discuss their proposed research before completing and submitting their application for review. Investigators are encouraged to notify the HRRS of their intent prior to submitting an application. Only an electronic copy of the application in Word format is required when the investigator's proposal is initially submitted to the HRRS. After the application has been screened or pre-reviewed, investigators will be instructed to obtain all needed signatures and submit paper copies for WSIRB review.

The investigator is not required to obtain final IRB approval from his or her home institution prior to submitting the proposal to the WSIRB. The investigator's home institution may be willing to rely on the WSIRB if it has an IRB Authorization Agreement with these Washington State Agencies.

5.2.1 Research Application Forms

Research proposals must be submitted on the latest version of the official WSIRB Research Application available on the Review Section's website. Investigators may cut and paste relevant information from project narratives developed for applications to a federal, public, or private funding source into the WSIRB Research Application. However, investigators must follow the instructions in the application forms and provide all the required information. In general, the narrative sections of the application should be no more than several pages in length. However, the Research Application must be complete, and must include all relevant appendices and data collection instruments. If research is supported by a federal grant or contract to these Washington State Agencies, one copy of the original grant application should be included with the signed original of the application.

5.2.2 Submission Timelines

- Full Board Review: Research applications requiring full Board review must be submitted as Word files to wsirb@dshs.wa.gov by the published deadline date for each scheduled Board meeting, which is posted on the HRRS website.

- Expedited Review: Research applications that qualify for expedited review may be submitted to HRRS at any time. Research applications eligible for expedited review must be submitted as Word files to wsirb@dshs.wa.gov.

5.2.3 Non-Scheduled Review

Under special circumstances, and at the discretion of HRRS staff, non-scheduled reviews of proposals that do not qualify for expedited review may be conducted by teleconference. Reviews conducted by teleconference are subject to the same quorum requirements that apply to regularly scheduled meetings of the Review Board.

Non-scheduled reviews are limited to the following:

- Initial review of a proposal, or review of an investigator's response to the Board's review issues when consideration of the proposal has been deferred at a scheduled meeting, and when delay until the next regularly scheduled Board meeting would make the conduct of the proposed research impossible or would unacceptably affect the soundness and integrity of the ongoing research;

- Review Board consideration of any unanticipated problems and/or adverse events involving risks to subjects or others, or serious and continuing noncompliance with Board-approved procedures.

Investigators who believe their circumstances justify WSIRB consideration through a non-scheduled review process may contact the HRRS staff to request a non-scheduled review.

5.2.4 Cooperative Review

The Department of Social and Health Services has established multiple project IRB Authorization Agreements with the University of Washington, Washington State University, Eastern Washington University, and the Fred Hutchinson Cancer Research Center. These agreements are intended to reduce the number of proposals that require review by both IRBs when the research is in the joint jurisdiction of both institutions. These IRB Authorization Agreements are posted on the HRRS website.

5.2.5 Reliance on the Review of another IRB

Procedures are available for the home institution of an investigator who is submitting an application to the WSIRB to rely on the WSIRB review rather than to conduct its own IRB review of the research. These procedures are intended to minimize redundant reviews and to conserve time and resources when research is in the jurisdictions of two or more IRBs. Establishing an *IRB Authorization Agreement* documents an arrangement in which one institution relies on the review of an IRB at another institution for a single research proposal or group of research proposals. This Agreement must be signed by the signatory official of each institution and kept on file at the IRB offices of the respective institutions.

In some instances, these Washington State Agencies will rely on the review of an IRB at another institution. An example would be a situation in which IRB review is required for the use of a non-approved device or drug in a surveillance activity or an emergency disease investigation. If a central IRB has authority to conduct such a review on behalf of local study sites, these Washington State Agencies may elect to rely on that review to expedite early implementation of the protocol in the field. Another example would be the interview of one subject in an ongoing research project who has been placed in a DSHS institution subsequent to enrollment in the study. Washington State Agency administrators and/or investigators who believe a research activity meets these circumstances should discuss this option with the IRB Administrator, who will make the initial determination about whether to rely on the review of another IRB. Final decisions about relying on the review of an IRB at another institution will be made by the Human Protection Administrator of the state agency that has jurisdiction over the research in question.

If a decision is made to rely on the review of another IRB, the application submitted to the reviewing IRB must be submitted to the HRRS, along with documentation of IRB approval and of any restrictions or conditions on the research imposed by the reviewing IRB. If the ES/AES is satisfied with the review done by the home institution, the HRRS will initiate establishment of an IRB Authorization Agreement between the researcher's home institution and the Washington State Agency in whose jurisdiction the research would be conducted. If the ES/AES is not satisfied with the home institution IRB review, the proposal will be referred to the WSIRB for independent review. If relying on the home institution IRB review, the research may not commence in the Washington State Agency until the IRB Authorization Agreement has been signed by the respective Institutional Officials. The HRRS will open a project file for the research reviewed by another IRB. Progress reports submitted for continuation review and documentation of continuation approval will be requested from the reviewing IRB by the HRRS.

5.2.6 "Just-In-Time" Review Procedures

Applications for federal funding for research may qualify for "just-in-time" review procedures. Under these procedures certification of IRB approval is not required at the time of application for federal funding, but may be deferred until just prior to an award being made, but at least 60 days prior to contacts with potential human subjects. Investigators should inquire with their federal project officer to verify that "just-in-time" procedures will apply to their grant application. If so, investigators should submit their proposal for WSIRB review when they are informed that the application for federal funding has received a score in the fundable range, or when they learn that the proposal may be funded.

5.2.7 Human Subjects Protection Training Requirements

The Washington State Agency training requirements are grounded in federal recommendations and reflect a belief that appropriate education and training is an important component of an effective system of human subject protections.

All principal investigators and co-principal investigators submitting new research proposals to the WSIRB must have completed training in human subjects protection before their research will be approved. All research staff responsible for the design of the study and all those in contact with human subjects and/or who will have access to identifiable records (e.g., interviewers, and data analysts) are also required to complete the training before they will be authorized to have contact with human subjects or identifiable records.

Investigators may satisfy this education and training requirement by:

- Completing a course in the protection of human research subjects at their home institution and submitting to the HRRS written documentation of the content of the training and the date it was completed;

- Completing the web-based National Institutes of Health human subject protections training;

- Completing the web-based training in the Protection of Human Research Subjects provided by CITI/University of Miami. There is no charge to investigators if they access this training through the HRRS website. Investigators must complete all required modules and the quizzes for these modules and review the *Washington State Government Agencies Institutional Page* and links to receive credit for training. Investigators who complete CITI training through their home institution must submit their certificate of completion to the HRRS.

The HRRS maintains a Training Database to track completion of training, and provides a current training participant list on the HRRS website.

5.2.8 Applications that Request Use or Disclosure of Identifiable Confidential Records

WSIRB has adopted the HIPAA "safe harbor" provisions for defining what constitutes an identifiable confidential record. An individual record must meet all the requirements in 45 CFR 164.514(b)(2) to be considered not individually identifiable. At a minimum, all 18 data elements listed in 164.514(b)(2)(i) must be removed from the record before the WSIRB will consider the record to be de-identified.

Use and/or disclosure of individually identifiable confidential records and/or protected health information for research purposes requires the written consent or authorization of the person to whom the information pertains. In some situations, however, it may be impractical to obtain written consent or authorization for the research use or disclosure. In this case, the investigator may ask the WSIRB to approve a waiver of the consent or authorization requirement. The WSIRB can approve such a waiver only if requirements in applicable statutes and regulations are satisfied.

The state laws and federal regulations which define the requirements that must be met for the WSIRB to approve a waiver of consent or authorization depend on the information that is being requested. The most common applicable laws and regulations that must be satisfied are:

- All requests for research use and/or disclosure of identifiable personal record information and/or protected health information must satisfy the requirements in 45 CFR 46.116(d).

- All requests for research use and/or disclosure of protected health information must satisfy the requirements in 45 CFR 164.512(i).

- All requests for research disclosure of identifiable personal record information (including protected health information) from DSHS and DOH must satisfy the requirements in RCW 42.48.020.

- All requests for research use and/or disclosure of health care information from a health care provider must satisfy the requirements in RCW 70.02.050(g).

The unduplicated criteria that must be satisfied in two laws and two regulations are listed in Appendix I, Section 4, of the *WSIRB Research Application*.

Depending on the information being sought, other laws and regulations must be satisfied for the WSIRB to approve a waiver of consent or authorization for use and/or disclosure of the information. A partial list of record information and the applicable law or regulation that pertains to its use and/or disclosure follows:

- *Aging and disability client services information* is subject to requirements in RCW 74.04.060.

- *Arrest records* held by the Washington State Patrol are subject to requirements in RCW 10.97.050.

- *Child abuse and/or child welfare* record information is subject to requirements in 45 CFR 1340 §14.

- *Child support enforcement* records are subject to requirements in RCW 74.20.280 and RCW 26.23.120.

- *Criminal history information for juveniles* is subject to requirements in RCW 13.50.010 and RCW 13.50.050.

- *Criminal history information for adults* is subject to requirements in RCW 10.97.050.

- *Department of Health registries* are subject to requirements in the following statutes and regulations:

  Cancer -- WAC 246-102-070
  CHARS -- WAC 246-455-080
  HIV/AIDS/STD -- RCW 70.24.105 and WAC 246-101-635
  Lead -- WAC 246-101-610 and RCW 42.48
  Newborn screening – RCW 70.83.020, WAC 246-650-030
  Trauma -- RCW 70.168.090 and WAC 246-976-420
  Vital records -- RCW 70.58.104, RCW 70.58.082 and WAC 246-490-030

- *Driver's license information* held by the Department of Licensing is subject to requirements in WAC 308-10-050 and 18 USC 2721(b)(5).

- *Education/school records* are subject to requirements in Title 20, USC, Chapter 1232h, Protection of Pupil Rights, 34 CFR Part 98, Student Rights in Research, Experimental Programs, and Testing, and 34 CFR Part 99, Subpart D.

- *Food stamp information* is subject to requirements in RCW 74.04.060.

- *Medicaid record information* is subject to requirements in 42 CFR 431.300 and RCW 74.04.060.

- *Mental health treatment information* is subject to requirements in RCW 71.05.390, RCW 71.05.630, and RCW 71.05.620.

- *Minor's record information* for various programs is subject to requirements in the following statutes:

  STD testing/treatment -- RCW 70.24.110.
  Mental health treatment -- RCW 71.34.340.
  Substance abuse treatment -- RCW 70.96A.095, RCW 70.96A.235, and RCW 70.96A.250.

- *Nursing home patient assessment information* in the Minimum Data Set is subject to requirements in 42 CFR 483.315.

- *Public assistance record information* is subject to requirements in RCW 74.04.060.

- *Substance abuse treatment information* is subject to requirements in 42 CFR Part 2 §52, RCW 70.96A.095, RCW 70.96A.150, and RCW 70.96A.235.

- *Unemployment insurance records* held by the Department of Employment Security are subject to requirements in RCW 50.13.015 and RCW 50.13.020.

- *Vital records* are subject to requirements in RCW 70.58.104.

- *Vocational rehabilitation records* are subject to requirements in 34 CFR Part 361 §38 and WAC 490-500-555.

- *Wage and income records* held by the Department of Employment Security are subject to requirements in RCW 50.13.060.

- *Worker's Compensation records* held by the Department of Labor and Industries are subject to requirements in RCW 51.36.060.

Appendix I, Section 4, in the *Research Application* asks investigators to provide information needed by the WSIRB to determine whether requirements for the waivers can be satisfied. Investigators requesting information subject to other requirements in law or regulation are advised to provide information to allow the WSIRB to determine that those requirements have been met.

Per RCW 42.48.020(c), disclosure of identifiable personal record information held by DSHS and/or DOH for research purposes is subject to the

establishment of a legally-binding confidentiality agreement. This agreement is prepared by WSIRB staff and sent to the investigator for signature with the WSIRB letter approving the research proposal. After signing the agreement, the investigator must return it to the HRRS, and it will then be sent for signature by the DSHS and/or DOH administrator authorized to disclose the information for research purposes. When signed by the agency administrator the agreement authorizes disclosure of the confidential record information needed for the research. A copy of the signed agreement is sent to the investigator and to the program manager responsible for disclosing the data to the investigator. The agreement remains in effect until all terms of the agreement, including permanent destruction of the ability to identify the records disclosed, have been satisfied.

Identifiable personal record information may be used only for purposes that are described in the confidentiality agreement. Investigators are not authorized to re-disclose or provide access to the record information to other individuals without the prior written approval of the WSIRB. Investigators are not allowed to attempt to de-identify identifiable personal record information for the purpose of re-disclosing or providing access to the record information to any other party without the prior written approval of the WSIRB.

Use of record information for thesis, dissertation, or other educational purposes not described in the original proposal approved by the WSIRB must be submitted for review and must receive prior approval before student use of the personal records will be authorized. Any such unauthorized use or disclosure of personal records is a violation of terms of the confidentiality agreement. The principal investigator will be held accountable under RCW 42.48.050 for each violation.

5.2.8.1 Research Registry

5.2.8.1a. Definition

The term “Research Registry” means a database or a collection of databases that have been created or organized to facilitate the conduct of multiple research studies, including future studies not yet envisioned. The terms “Research Registry” and “Research Data Repository” have the same meaning. A Research Registry may also have been created for other purposes in addition to research, such as administrative and clinical purposes. Generally, Washington State agency databases comprised of information collected during the course of regular services, care or treatment provided to individuals, clients or patients are not considered research registries. For example, collections of Medicaid eligibility, birth, workers compensation claims, State mental health services, jail booking, public health surveillance, primary education and hospitalization

records routinely collected by state agencies would not generally be considered research registries. However, extracts of these collections intended for use for multiple research studies may be deemed research registries.

5.2.8.1b. Review

All research registries require review and approval by the WSIRB. Review considerations will include, but not be limited to:

- Purpose of the research registry;
- Data to be included in the research registry;
- Consent, assent, parental permission and authorization, including related waivers;
- Data security, including location and housing of research registry data, access to the research registry data and data transfer protocol;
- Confidentiality, including federal Certificates of Confidentiality;
- Disclosure and use of research registry data, including transfer procedures and documentation of IRB and research registry review and approval;
- Research registry operating procedures or data management plan, including research registry governance, documentation of IRB approval for all source data, limitations on future use, and documentation of data sharing agreements, as applicable;
- Termination of a research registry

5.2.8.1c. Other Review Requirements

All other review requirements under Section 5, including Section 5.2.8 apply to review of research registries.

5.2.9 Review Fees

Fees are charged for the review of studies according to a fee schedule. The schedule is posted on the HRRS website. These fees defray costs that are associated with review and oversight of studies, including meetings, documentation and administrative and professional staffing. Fees are non-refundable regardless of the outcome of the human subjects review or if the research is suspended, canceled, or terminated before research objectives have been achieved. Because considerable time, effort and resources are committed to all reviews, fees are due in full in advance of review and before a study is placed on the agenda for full Board review or scheduled for expedited review.

NOT subject to this section are studies for which the following Washington State agencies are the sole sponsors or the PI's employer:

Department of Health
Department of Labor & Industries
Department of Social and Health Services
Health Care Authority
Office of Financial Management

5.3 Review and Approval Considerations

The Review Board is guided by federal regulations, the Belmont Report, institutional policies, and applicable state laws and regulations. The *Washington State Agency Policy on Protection of Human Research Subjects* is based on the federal regulation for the protection of human participants (45 CFR 46), but is more restrictive. Review also must include consideration of local laws, regulations, and policies that may apply to the research activity. In Washington, laws that may apply to research include abuse reporting, mandatory disease reporting, and disclosure of information about HIV testing or treatment for STDs.

The *WSIRB Presentation Guide* provides a comprehensive checklist of issues relevant to human subjects protection review. Primary reviewers are required to complete the *Presentation Guide* for their assigned proposal and turn it in to the staff reviewer during the last consultation before the meeting. The staff reviewer will make copies and distribute the last page of the Presentation Guide to members at the meeting. Other Review Board members are encouraged to use the *Presentation Guide* as a worksheet for reviewing proposals.

The following review criteria are carefully considered in the WSIRB review of research proposals:

5.3.1 Study Design and Scientific Merit

The review of research begins with an assessment of the overall scientific merit and the logical and technical soundness of the proposal. The proposal should discuss the relevant literature or describe the context in which the study will occur to provide an adequate conceptual framework. The objectives, research questions, and/or hypotheses of the study should be clearly stated, and the proposed methods and study instruments should produce data relevant to the study objectives. Plans for data analysis should be well-defined and likely to produce results related to the study purposes, objectives, and hypotheses. The researcher should have appropriate qualifications to conduct the project, or adequate supervision by a qualified professional if the researcher is a student.

5.3.2 Benefits and Risks

A fundamental task in the Board's review of proposals is to balance the anticipated benefits and risks of the research activity. Benefits accruing from research may include direct, personal benefits to the participants, such as increased medical oversight of a condition or disease, or the opportunity to obtain treatments, assessments, and/or services not otherwise available. Benefits also include general societal benefits in the form of new scientific or applied knowledge. Compensation to participants is not considered a benefit in the risk/benefit analysis, nor is the fact that participants may find it rewarding to participate. Risks include any research activities that potentially may harm the research participant psychologically, physically, socially, economically, legally, or otherwise. Risks may range from physical injury from biomedical or pharmaceutical research, to mere inconvenience from participation in survey research. In assessing risks inherent in a proposal, reviewers will consider both the magnitude and probability of the harm occurring. If the balance between risks and benefits is unfavorable, the Review Board will explore options for reducing risks and/or increasing benefits.

5.3.3 Selection of Participants

Research proposals should clearly define who will be enrolled as subjects in the research and explain why these subjects are being selected. Justification for inclusion and exclusion criteria are reviewed carefully to determine if subject selection is equitable and appropriate for study objectives. Justification must be provided for limiting subject population to an ethnic group, gender, or age. The Review Board will consider whether participants will share benefits in proportion to burdens imposed by the research.

5.3.4 Vulnerable Participants

If vulnerable populations are included, the Review Board will consider whether the research could be done with a non-vulnerable population or whether additional safeguards are necessary to protect vulnerable subjects. Federal regulations for the protection of human subjects (45 CFR 46) require additional protections for the inclusion of pregnant women and fetuses (Subpart B), prisoners (Subpart C), and children (Subpart D) in research. Other vulnerable populations that may require additional safeguards include persons who are decisionally-impaired, disabled, institutionalized, and/or socially or economically disadvantaged.

5.3.5 Participant Recruitment

The Review Board will examine the procedures for identifying, contacting, and recruiting potential participants. Generally, researchers should not

make first contact with potential participants. If the researcher proposes to identify and sample the study population from confidential state agency records, contact must first be made by agency employees and individuals must be provided, at a minimum, the option of refusing further contact regarding the research. Recruitment procedures must be free of coercion or undue influence and must present information in a format and language that the intended population can understand.

See Section 6 for additional information about research involving DSHS clients and special issues related to research with vulnerable groups.

5.3.6 Informed Consent

The informed consent process must ensure 1) that adequate information is provided, 2) that comprehension is verified, and 3) that participation is voluntary. The review will consider the appropriateness of the individual(s) who will obtain consent, as well as the location and timing of the consent process. The researcher must provide complete information about the proposed research and the individual's role in the research in an environment and manner that is free of coercion or undue influence and in a format and language that potential subjects can understand. Consent/assent documents must contain all required consent elements, and be written at an appropriate reading level and language for the intended study population.

Research proposals involving vulnerable populations merit special consideration to determine whether subjects are capable of understanding the research and providing informed consent, and to minimize the potential for coercion or undue influence in the consent process. The Review Board must ensure that there are adequate safeguards in place to protect the interests of vulnerable subjects, i.e., requiring a consent witness or subject advocate. Assent to participate in research generally is required from persons who are decisionally-impaired and/or legally incompetent, as well as children less than 18 years of age. In addition, permission must be obtained from parents, legal guardians, or family members who may legally provide consent, and, in some cases, from the social worker assigned to potential subjects.

Waivers or alterations of consent requirements may be approved by the Review Board provided the conditions delineated in 45 CFR 46, the HIPAA Privacy Rule, and other relevant federal regulations, state statutes and rules, when applicable, have been documented to the satisfaction of the WSIRB. The general requirement for written (i.e., signed) consent may be waived if conditions in 45 CFR 46.117(c) are satisfied. If signed consent is waived, verbal consent (e.g., in the case of telephone surveys) or implicit consent (e.g., in the case of mailed surveys) must be obtained. State laws which allow minors to obtain family planning services, treatment for STDs, outpatient substance abuse treatment and outpatient mental health

treatment without parental permission, may help justify waiver of parental permission for participation in research related to these services. However, requirements for waiver of parental permission in 45 CFR 46.408(c) must also be satisfied.

5.3.7 Privacy and Confidentiality

The Review Board will carefully consider possible risks to participant privacy and confidentiality in all phases of the proposed research: sampling, recruitment, consent procedures, proposed methods and setting for data collection, etc. The Review Board may require alterations in the proposed study to minimize privacy and confidentiality risks. Research which may pose special concerns may include surveys or interviews in which sensitive information regarding the subject's personal experiences or behavior is collected, genetics research, and/or research which collects personal information or physical specimens for possible future use in unspecified research may be retained.

5.4 Procedures: Initial Full Board Review of Research

5.4.1 Pre-review Procedures

Research proposals requiring full Board review may be pre-reviewed before being placed on the agenda of a convened meeting of the Review Board. 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 relatively low chance of approval being deferred. Pre-review is conducted by HRRS staff using the electronic application initially submitted by the investigator. HRRS staff may request that an investigator submit, in advance of a convened meeting of the Review Board, additional explanations, documents or other materials that may be necessary to facilitate the proposal's review.

Pre-review is an administrative review process and does not represent an official review by the IRB. However, the intent of pre-review is to alert the principal investigator to issues which are likely to be raised in the IRB review, and failure to respond to the request for additional explanations, documents or other materials before the Board meeting could delay approval of the proposed research.

Investigators are asked to be available by telephone during the time their proposal is discussed in the meeting. If questions arise that cannot be answered, the ES/AES may contact the investigator and patch him/her into the meeting by conference call.

If a proposal is unusually complicated, or if considerable uncertainty or concerns exist about critical aspects of the research, the investigator may be invited to attend a subsequent Board meeting to provide additional information or to respond to specific review concerns. Investigators may

request to attend initial or subsequent meetings to provide information about their proposal. The investigator must leave the meeting prior to the discussion and disposition vote by the Board.

5.4.2 Board Meeting Review Procedures

WSIRB Rules of Order are followed during full Board meetings. Board members with any conflict of interest with the proposal under review will be expected to abstain from voting. If the conflict is significant (e.g., the Board member is the principal investigator or a member of the research team), the member will be expected to recuse himself/herself from the discussion of the proposal and leave the room.

The primary reviewer uses the *WSIRB Review Worksheet* to present the proposal to the Review Board at the convened meeting. While the *Review Worksheet* provides a comprehensive list of topics to be considered in reviewing human subjects research, only those issues that raise concerns need to be presented by the primary reviewer. After summarizing the risks to subjects in relation to the benefits of the research, the primary reviewer will make a motion for disposition of the proposal. When the motion is for approval or conditional approval, the primary reviewer also will recommend the length of the approval period based on criteria discussed in Section 5.6.

After a motion is made and seconded, the Chair will recognize other Board members who wish to make comments about the risk/benefit ratio of the proposed research. (Note: consideration of risk/benefit ratios implicitly involves consideration of issues related to the integrity of the study design.) Other members who wish to speak to the same question will be recognized by the Chair in turn. When comments about risk/benefit ratios are concluded, the Chair will ask if any members wish to speak to issues related to recruitment, consent and/or waiver of consent, and will recognize members in turn. Finally, the Chair will ask if any members wish to speak to issues related to general study methods and procedures, data collection instruments and procedures, and language in consent documents. The Chair may then open the floor to general discussion.

After deliberation, the Chair will ask the primary reviewer if he/she wishes to amend or withdraw the motion on the floor. If the primary reviewer withdraws the motion on the floor, he/she will be asked if he/she wishes to introduce a new motion. The Chair will then ask any other members if they wish to amend the motion on the floor. With the assistance of the ES/AES, the Chair will then restate the motion, including any amendments, before the formal vote is taken. Disposition options are listed in Section 4.3.6. Disposition of the proposal is determined by a simple majority vote of members present. The Chair votes only to break a tie. If the motion does not pass, the floor is open to disposition motions introduced by other Board members. The process continues until the Board has approved a disposition motion by a simple majority of members present at the meeting.

5.4.3 Procedures for Reporting Review Findings to Investigators and to Agency Administrators

Following the meeting, the staff reviewer will prepare in writing the Board's disposition decision and any remaining review issues and/or required revisions for transmission to the investigator. The primary reviewer, and any other member in attendance at the meeting who asks, will review and comment on draft Board correspondence before it is mailed to the investigator.

If a proposal is granted approval, the staff reviewer proceeds with the approval process as documented below.

If a proposal is not approved at the meeting, investigators must submit a revised application which provides a substantive response to the stipulated approval conditions or to the review issues raised during review of his/her proposal within 90 days of the review.

If a proposal is conditionally approved at the meeting, the investigator's response to the Review Board will be generally reviewed within two weeks of receipt by a Board subcommittee consisting of the primary reviewer, the staff reviewer, and sometimes the Board Chair. Board members with special expertise in the subject area of the research may be asked to join the subcommittee, and any member in attendance at the meeting may volunteer to participate on the subcommittee. The WSIRB subcommittee generally communicates via conference call.

If the subcommittee documents that the investigator's response satisfies the approval conditions stipulated by the Review Board, an approval letter is drafted for signature by the staff reviewer and by the agency administrator in whose jurisdiction the research will be conducted. The agency administrator will receive copies of the approved proposal, and the *Documentation of Findings* which documents that all statutory and regulatory requirements for conducting the research have been met. The agency administrator provides final departmental approval for the commitment of staff and organizational resources needed for the study to be conducted. When the approval letter has been signed by the agency administrator it is returned to the HRRS. A PDF of the approval documents is emailed to the investigator: original documents are sent by surface mail only upon request. Copies are sent to agency program managers in units affected by the research, and are filed in the project file.

The final approval letter informs the investigator of the following:

- The approval/anniversary date, determined by the date of the Review Board meeting at which the proposal was granted approval or conditional approval;

- The approval period determined by the Review Board at the time of approval. A *Continuation Approval Request* is required before the anniversary date if the project extends past the approval period;

- That no changes in study purposes, design or methods may be initiated prior to review and approval by the Review Board, except when necessary to eliminate apparent immediate hazards to the subject;

- That adverse events and unanticipated problems involving risks to subjects or others must be reported promptly to the Review Board;

- That study completion requires submission of a final report.

Included with the approval letter will be the following:

- Copies of all Board-approved consent and assent forms, recruitment and consent scripts, and contact letters, stamped as approved;

- The *Documentation of Findings* form, which specifies the Board's findings with respect to level of risk, length of approval period, special protections for vulnerable populations, and the approved rationale for waiver of consent or authorization, if applicable;

- A Confidentiality Agreement per requirements in RCW 42.48, if the research involves disclosure of state agency record information without the consent or authorization of the persons to whom the records pertain.

If action on a proposal is deferred during the meeting due to unresolved issues and concerns or incomplete information, the investigator will be instructed to address the review issues and incorporate them into a revised *Research Application* for review at the next convened meeting of the Review Board. An electronic copy of the revised application may undergo pre-review to determine if it is ready for resubmission to the full Board.

5.5 Procedures: Initial Expedited Review of Research

To qualify for expedited review, a research proposal must incur no more than minimal risk to subjects and must involve only one or more of the activities that are listed in Section X of the *Washington State Agency Policy on Protection of Human Research Subjects*. These activities are more restrictive than the federally-approved activities for expedited review, and reflect a higher local standard for what can be reviewed through the expedited process.

When discussing research plans with investigators prior to submission of the application for review, HRRS staff generally will be able to determine whether the proposal qualifies for expedited review. Incoming proposals are screened to ensure they meet expedited criteria and that they are reasonably complete,

responsive to instructions in the application forms, and ready for review, before they are sent out for review.

If a proposal is eligible for expedited review, the staff reviewer will assign one or more Board members to review the proposal. An electronic copy of the proposal is emailed to the primary reviewer and a telephone review conference is generally scheduled within five working days of receipt of the proposal. Expedited reviewers may use the *WSIRB Presentation Guide* and should apply the same review criteria to proposals as in a full-Board review. Expedited reviewers may exercise all the authorities of the Review Board, and review disposition options are the same as in full Board reviews (See Section 4.3.6), except that proposals may not be disapproved through the expedited process. If expedited reviewers believe that a proposal should be disapproved, it will be placed on the agenda for consideration at the next convened meeting of the Review Board.

Disposition decisions in an expedited review are generally achieved through consensus. If two reviewers disagree over the disposition of a proposal, the Chair will become a third reviewer and the majority decision will prevail.

Following the review, the HRRS staff will prepare in writing the Board's disposition decision, including approval conditions, any remaining review issues, and/or required revisions, for transmission to the investigator. Investigators may expect to receive Board correspondence within one week of the expedited review. If the proposal is granted approval during the initial expedited review, the HRRS staff completes the *Documentation of Findings* and includes it in the project file.

If a proposal is conditionally approved at the expedited review conference, the investigator must incorporate a response to the Review Board's approval conditions in a revised application and submit the revised application with all required signatures and paper copies to the HRRS. The HRRS staff will review the revised application generally within 14 days of its receipt by the HRRS. If the HRRS staff documents that the investigator's response satisfies the approval conditions stipulated by the Review Board, an approval letter is drafted for signature by the HRRS staff and by the agency administrator in whose jurisdiction the research will be conducted. The approval date for the study is the date of the initial expedited review. Procedures for reporting Review Board findings to investigators and to agency administrators are the same as for full Board reviews.

If a decision regarding an application is deferred during the expedited review conference due to unresolved issues and concerns or incomplete information, the investigator will be instructed to address the review issues and incorporate them into a revised application submitted electronically for review at another expedited review conference. If instructed, the investigator should submit an original revised application with all required signatures and paper copies to the HRRS. The revised application will then be scheduled for another telephone review conference. The approval date for the study is the date of the expedited review conference at which the proposal is either approved or conditionally approved.

If a proposal is not approved at the expedited review conference, investigators must submit a substantive response to the approval conditions stipulated or review issues raised within 90 days of the review. If no response is received, the project file will be canceled, the investigator notified, and the investigator will be required to submit a new research application for subsequent expedited review.

5.6 Criteria for Determining Frequency of Continuing Review

During the initial review of the research proposal, the Review Board considers a number of factors in establishing the period of approval for the study. The length of approval in turn establishes the frequency of continuing review. Criteria that are used in making this determination include, but are not limited to, the following:

- The nature of the study;
- The degree of risk involved;
- The vulnerability of the study population;
- Evidence of noncompliance with Review Board requirements and/or any applicable policies, laws, or regulations.

Investigators are informed of the study approval period for their research in their original approval letter, and in their continuation approval letters, from the Review Board.

5.7 Continuing Review of Research

Principal investigators of ongoing research projects are required to submit a Continuation Approval Request (CAR) for continuing review at intervals commensurate with the degree of risk posed by the research, but not less than once per year, as determined by the Review Board. Continuing review of research is conducted by the convened Review Board, with recorded vote on the disposition, unless the research is eligible for expedited review. Research eligible for expedited review is considered by a sub-committee.

5.7.1 Submission of Continuation Approval Requests

The HRRS Compliance & Training Coordinator notifies investigators by email of the need to submit a CAR for review and Board approval. The CAR is due approximately three weeks in advance of the submission due date for the next meeting. Generally projects eligible for expedited review have their CARs reviewed under expedited review authority and are placed on the agenda of the convened meeting for information only.

Each project has a fixed anniversary date. The anniversary date is calculated from the date at which a study was conditionally approved. CARs are submitted for review at the meeting before the anniversary date

of individual projects, to ensure as much as possible that study approval does not expire.

Continuation requests must be submitted via email.

Investigators are required to submit the following information in their *CAR:*

1. The current status of the project in terms of whether recruitment and enrollment is ongoing, whether contacts with subjects is completed, or whether the study involves only use of existing records;

2. The number of subjects targeted for enrollment during the entire study; the number approached for participation since the last review, the number of subjects who declined, were ineligible, currently enrolled, and the cumulative total of subjects enrolled to date;

3. A general overview of study activities to date;

4. Study amendments implemented during the last approval period;

5. A summary of any new literature, findings, or other relevant information that may affect study goals, objectives, procedures, and/or risks to subjects;

6. A description of any adverse events or unanticipated problems, including problems with recruitment, retention, field activities, complaints about research, etc.;

7. A description of changes to risk or benefits to subjects ;

8. A description of any new funding sources and activities;

9. An Appendix N: Conflict of Interest Reporting form *if* a new or updated potential conflict of interest has been identified;

10. A summary of remaining study activities to be conducted;

11. The estimated study completion date;

12. Information on who has access to confidential records released under a Confidentiality Agreement for the research;

13. Copies of recruitment and consent documents, if ongoing contact with subjects.

14. List of staff having contact with human subjects or access to identifiable records.

Research involving only the secondary use of identifiable records in which no subjects were directly recruited and enrolled are not required to provide information on the numbers of subjects.

If a study has been completed, researchers also must submit a copy of a final report. If the study required a Confidentiality Agreement for disclosure of identifiable records, investigators must provide written assurance that all terms of the Agreement have been satisfied. Usually this requires written certification that all data elements that could directly or indirectly identify individuals have been permanently removed and destroyed. The *Certification that Research Records have been De-Identified* is available on the HRRS website.

When a CAR arrives in the HRRS, staff review the corresponding project file and evaluate the project's conformity with Board approved procedures. Consent forms and other materials submitted with the CAR are compared to Board approved forms and deviations from the approved forms are noted. Any deviations from Board approved procedures are noted and investigators may be contacted to submit information necessary for continuation review.

Full Board Continuing Review: CARs for research subject to full Board review are reviewed by the full Board for continuing review, unless the research is eligible for expedited review. Full Board continuing review generally is conducted by the original primary reviewer (if available) and/or by the staff reviewer. As necessary, the staff reviewer consults with the primary reviewer prior to the WSIRB meeting to provide feedback regarding recruitment and consent documents, any issues that arose during review of the project file, and/or discussions with the investigator. The primary reviewer and all Review Board members are notified about full Board CARs requiring the Board's review. The staff reviewer and primary reviewers have access to the project file, and have copies of all recruitment and consent documents and published articles submitted with the CAR. Review staff bring the entire paper project file to the convened WSIRB meeting.

The primary reviewer presents the continuation request to the WSIRB at a convened meeting prior to the anniversary date. The primary reviewer provides a brief overview of the research and progress made over the past year, the number of subjects accrued, any changes in risks or benefits to subjects, a summary of any recent literature, any interim findings, and amendments or modifications to the research since the last review. Unanticipated problems and/or adverse events or concerns regarding conduct of the research are discussed, as are changes to subject risks or

benefits, new funding sources, and changes in research staff conflict of interest; remaining study activities are noted. Following the presentation, the primary reviewer makes a motion regarding continuation approval and the Review Board votes on disposition. The motion may include recommendations for revising the consent form based on changes in risks, and changes in the period of approval, as applicable.

Expedited Continuing Review: CARs for research subject to expedited review are reviewed under an expedited review procedure, provided there have been no serious or unanticipated events, or changes in procedures that could increase risk to subjects. Certain categories of research originally reviewed by the full Board are eligible for expedited review if they meet criteria in the *Washington State Agency Policy*..., Section X, Research Categories 12 and 13. Expedited continuing review may be conducted by the staff or primary reviewer. CARs reviewed under expedited review are listed on the meeting agenda for informational purposes. Any Review Board member who has questions about a continuation request eligible for expedited review should contact the staff reviewer.

No Evidence of Progress: If a CAR includes no evidence of progress toward completion of the research the WSIRB may extend continuation approval for three months instead of one year, and will ask the investigator to submit a *Study Amendment Request* describing detailed plans to complete the research and a firm date for completion. If the *Study Amendment Request* is approved, the investigator will be expected to complete the research by the specified date, with extensions beyond that date subject to approval by the Review Board. If the *Study Amendment Request* is not approved before expiration of continuation approval, study approval will expire.

Continuing Review Dispositions: Disposition options for continuing review of research parallel the disposition options for initial review, listed in Section 4.3.6. However, as research undergoing continuing review already has an approval period established with an anniversary date at which approval expires, the implications of various dispositions are different than during initial review, as follows:

- Projects that receive conditional continuation approval must receive final continuation approval prior to expiration of the approval period. If a project fails to receive final continuation approval before the expiration of the approval period, all study activities involving human subjects and/or use of confidential records must cease immediately. The only exception is if continued subject participation in the research is necessary for the subject's safety. The Review Board may suspend or terminate study activities due to non-compliance with federal regulations and Washington State Agency Policy.

- Projects in which continuation approval is deferred must receive final continuation approval prior to expiration of the approval period. All study activities for which continuation approval is deferred must cease immediately. The only exception is if continued subject participation in the research is necessary for the subject's safety. The Review Board may terminate study activities due to non-compliance with federal regulations and Washington State Agency Policy.

- In rare instances, approval for conducting the research may be disapproved during the continuation review process. If disapproved the study will be suspended and/or terminated. While approval may be suspended under expedited authority, approval can be terminated only by action of the full Review Board. While this disposition results in the research approval being permanently canceled, the investigator may submit a new proposal for consideration at a later date.

Reporting Continuing Review Findings to Investigators: Investigators are informed of the Review Board's decision regarding continuation prior to the project's anniversary date. Once continuation approval conditions or review issues have been resolved, researchers will receive a continuation approval letter.

5.7.3 Resubmission Requirements

Research initially reviewed and approved by the full Board that continues to have active contacts with subjects for enrollment and/or data collection purposes may require submission as a new application for full Board review after five years.

5.7.4 Study Suspension or Termination for Serious or Continuing Non-Compliance

If the investigator fails to submit a *CAR*, fails to respond to conditions or review issues required by the Board or review staff during the continuation review, the study will be referred to Board for suspension. If the study is suspended, all research activities, including contact with human subjects and/or use of any identifiable records, must stop. Although the research is suspended the regulations allow for continued subject participation in research if necessary for the subjects' safety. In that event, the Board must be immediately notified by the investigator.

The Board will consider suspending the study due to serious or continuing non-compliance with federal regulations and Washington State Agency Policy. If the Board suspends research approval the following may then occur:

- The Review Board will notify the head of the investigator's department or division, the IRB at the investigator's home institution, and the investigator's funding agency of this action;

- The federal Office of Human Research Protections will be notified of this action; and

- The investigator will be required to submit a Corrective and Preventive Action plan, request that suspension be lifted, and submit other documentation as required by the Review Board.

The Board may consider terminating IRB approval of the study due to serious or continuing non-compliance with federal regulations and Washington State Agency Policy. If the Board terminates research approval, the following may then occur:

- The Review Board will notify the head of the investigator's department or division, the IRB at the investigator's home institution, and the investigator's funding agency of this action;

- The federal Office of Human Research Protections will be notified of this action;

- The investigator will be required to immediately return all identifiable personal record information disclosed for research purposes. Failure to immediately return identifiable personal record

information is a violation of Washington State law (RCW 42.48) and will be reported to the Attorney General's Office for further action; and

- Approval to continue the canceled research will require submission of a new application for review and approval by the WSIRB.

5.7.5 Independent Verification that No Material Changes Have Occurred Since the Previous Review

The Review Board may determine that a project needs verification from sources other than the investigator that the project is being conducted in compliance with procedures approved by the Review Board and that no material changes have occurred since the previous review. Factors considered by the Review Board in determining the need for such verification include, but are not limited to:

- Projects conducted by researchers who previously have failed to comply with the requirements or determinations of the Review Board and/or applicable laws and regulations.

- Complex projects involving unusual levels or types of risks to subjects.

- Projects where concern about possible material changes occurring without Review Board approval have been raised based upon information provided in continuation requests or from other sources.

Outside verification may be obtained 1) by conducting inquiries or site visits with or without formal audits of study procedures, to collect information to report back to the Review Board; or 2) by having third parties observe the consent process and conduct of the research. As necessary and/or appropriate, this determination will be made by the Review Board at any time during the approval period of a project, or prior to extending continuation approval for the research. Written notice of intent to conduct a site visit which may include an audit of study activities, or to have third parties observe the consent process, will be provided to the investigator no less than 48 hours before the planned site visit. Such written notice will include an explanation of the reasons for the site visit and an outline of the study procedures and materials that will be reviewed.

5.8 Study Amendment Requests

Investigators must request WSIRB review and approval of all proposed changes in approved research. Such Study Amendment Requests (SAR) are submitted for review via email. Changes to an approved protocol may not be initiated without

prior approval of the Review Board, except when necessary to eliminate immediate hazards to participants.

5.8.1 What Requires Review

SARs requiring review include, but are not limited to:

- Revisions to study methodology, including study eligibility;
- Addition of new study sites;
- Revisions to recruitment materials or methods;
- Revisions to contact and consent procedures;
- Revisions to consent forms;
- Implementation of additional instruments, or revisions to approved instruments;
- Requests for additional department records;
- Contact with subjects for research purposes when all previous study activities were restricted to records and datasets;
- Requests to link study datasets to additional datasets not previously approved by the Review Board.

5.8.2 Submission of Study Amendment Requests

SARs must be submitted via email.

A SAR should clearly indicate the proposed revision(s) and provide a rationale indicating how the proposed amendment relates to overall study objectives and the research questions under analysis. The investigator also should describe any problems with current approved procedures, study recruitment, or other issues that may necessitate the proposed revision(s). Any proposed instruments, protocols, and other documents to be used if the amendment is approved should also be submitted.

5.8.3 Procedures for Reviewing Study Amendment Requests

Upon receipt of a SAR, the staff reviewer will screen the proposed revision(s) and determine the appropriate level of review. Minor changes in previously approved research during the period for which approval is authorized qualify for expedited review. Examples include minor revisions

to consent forms, minor changes in study incentives, requests for additional identifiable records, or minor changes to study instruments. In general, SARs are reviewed under expedited review procedures if the proposal was eligible for expedited review at initial review. Expedited reviews are conducted by the staff reviewer, who may request the involvement of the primary reviewer or Board Chair, as appropriate.

SARs for projects that were reviewed by the full Board at initial review may require full Board review. If a proposed amendment introduces procedures or methods that may increase risks to participants, if it involves a significant change to currently approved procedures, or if it incorporates a vulnerable study population, the SAR will be forwarded to the full Board for review at a convened meeting. SARs reviewed by the full Board are presented by the primary reviewer or by the staff reviewer if the primary reviewer is not available. Voting on SAR dispositions follows the same procedures as for the initial and continuing review of research.

Investigators are informed by letter of the Review Board's decision regarding review of a SAR. Once approval conditions or review issues have been resolved, the investigator will receive a SAR approval letter. If the study amendment requires changes in consent documents, the newly approved consent documents stamped with the period of approval will be enclosed with the approval letter. If the study amendment requires changes in the Confidentiality Agreement which authorizes disclosure of individually identifiable personal record information, an addendum to the agreement for signature by the investigator will be enclosed with the approval letter. When signed by the appropriate agency administrator, the addendum authorizes disclosure of the additional confidential record information needed for the research. A copy of the signed addendum is sent to the investigator and to the program manager responsible for disclosing the records to the investigator.

5.8.4 Procedures for Ensuring Prompt Reporting to the WSIRB of Proposed Changes in a Research Activity

Investigators are informed at multiple points during the ongoing review process of the importance of promptly reporting proposed changes to approved research activities to the WSIRB:

- Investigators are informed in the initial approval letter that changes in study purposes, design, or methods may not be initiated prior to review and approval by the Review Board, except when necessary to eliminate apparent immediate hazards to subjects.

- Investigators not affiliated with these Washington State Agencies are required to complete and sign an *Unaffiliated Investigator Agreement* which stipulates in part that investigators will report

promptly any proposed changes in the research conducted under the Agreement;

- The WSIRB *Continuation Approval Request form* and the *Study Amendment Request form* include a statement which documents the investigator's responsibility to report to the Review Board any study modifications and that no modifications will be put into effect without prior WSIRB approval;

- During CAR reviews and SAR reviews, HRRS staff routinely compare submitted forms to approved versions in the project file to determine that changes in approved study activities have not occurred without prior review and approval by the WSIRB.

5.9 Unanticipated Problems, Adverse Events, and/or Protocol Deviations

An unanticipated problem is an incident, experience, or outcome affecting subjects or others that 1) is unexpected given the approved research procedures and the characteristics of study subjects; 2) is related or possibly related to participation in the research; an 3) may place subjects or others at a greater risk of physical, psychological, economic, or social harm.

An adverse event is an untoward or unfavorable *medical* occurrence in a human subject (e.g., abnormal sign, symptom, or disease) that 1) is unexpected in nature, severity, or frequency; 2) is related or possibly related to participation in the research; and 3) may place subjects at a greater risk of physical or psychological harm.

A protocol deviation is a departure from the approved study plan.

All unanticipated problems, reportable adverse events, and protocol deviations must be reported to the WSIRB. The promptness of the report and the level of review depend on a number of factors which include, but are not limited to, the following:

- Whether the unanticipated problem, adverse event, or protocol deviation increases risks to subjects or others; and,

- Whether the unanticipated problem or adverse event is possibly related to study procedures.

5.9.1 Procedures for Reporting Unanticipated Problems, Adverse Events, and/or Protocol Deviation

Reports of unanticipated problems and/or adverse events, or protocol deviation must be submitted via email.

Unanticipated problems need to be immediately reported to the Review Board. The incidence and a description of these unexpected problems must also be included in the Continuation Approval Request submitted at least annually.

Adverse events that may *reasonably be expected* to arise as a result of research procedures must be described in the consent form and do not need to be immediately reported to the Review Board on an individual basis. However, the incidence and a description of these expected adverse events must be included in the Continuation Approval Request submitted at least annually.

Unexpected adverse reactions to drugs and/or medical procedures or to the administration of psychological assessments or instruments designed to collect personal or sensitive information from subjects, that are possibly related to the research must be promptly reported to the WSIRB. Unanticipated problems possibly related to any aspect of the research that involve risks to subjects or others must be promptly reported to the WSIRB.

For adverse events and unanticipated problems involving risks to subjects and others that are possibly related to the research, the following reporting guidelines should be used:

- Adverse events occurring with greater frequency or at a higher level of severity than anticipated: Investigators must report via email within 48 hours of the event.

- Other adverse events, unanticipated problems, or protocol deviations that involve risks to subjects or others: Investigators <u>must</u> report via email within five working days of the event.

5.9.2 Procedures for Reviewing Unanticipated Problems, Adverse Events, and/or Protocol Deviations

The staff reviewer reviews all *Unanticipated Problems/Adverse Events and Protocol Deviation reports* as they are submitted to determine if the problem and/or event is of sufficient importance to require review by a subcommittee comprised of the ES/AES or staff reviewer, primary reviewer, and Board Chair. If so, and if the reported event appears to be related to study procedures, this subcommittee reviews the consent form language describing the risks to evaluate possible revisions and whether subjects

already enrolled in the research should be appropriately advised. The subcommittee may request reports by the coordinating institution's Data and Safety Monitoring Board (for multi-site clinical research), or request additional information from the investigator.

Unanticipated problems and adverse events involving risks to subjects or others are reported to the full Board and documented in the minutes of the meeting. The full Board may determine that additional action needs to be taken in response to the report. Additional action could include, but is not limited to, requiring additional revisions in the consent form, advising or requiring that the study be modified to reduce risks to subjects, or rescinding study approval if the risks are determined to outweigh anticipated benefits of the research.

Documentation of all reports of unanticipated problems and/or adverse events and protocol deviations, and any action taken by the Review Board are placed in the project file. If the Review Board has serious concerns about the research, and/or the safety and welfare of subjects, the staff reviewer will inform the investigator, his/her home institution IRB, the coordinating center IRB and/or the funding agency, and OHRP, in writing.

5.9.3 Procedures for Ensuring Prompt Reporting to the WSIRB of any Unanticipated Problems and/or Adverse Events

Investigators are informed at multiple points during the ongoing review process of the importance of promptly reporting any unanticipated problems and/or adverse events to the WSIRB:

- Investigators are informed in the initial approval letter that unanticipated problems and/or adverse events must be reported to the WSIRB;

- Investigators not affiliated with these Washington State Agencies are required to complete and sign an *Unaffiliated Investigator Agreement* which stipulates in part that investigators will report immediately to the WSIRB any unanticipated problems involving risks to subjects or others in the research conducted under the Agreement;

- The WSIRB *Continuation Approval Request form* and *Study Amendment Request form* include a statement documenting the investigator's responsibility to report to the Review Board any unanticipated problems and/or adverse events that may increase risks to subjects and that are related or possibly related to participation in the research.

5.10 Noncompliance Procedures

WSIRB procedures for responding to investigator noncompliance are based on the seriousness of the violation, the frequency of the violations, and any history of violations the investigator may have. Noncompliance that is discovered by the principal investigator or study team must be reported to the WSIRB promptly.

5.10.1 Noncompliance

Noncompliance is a failure of the investigator or the research team to follow the applicable regulations or the requirements/determinations of the IRB. Every instance that meets this definition is noncompliance, regardless of the magnitude of the issue. Failure to follow the approved study application(s) or protocol (except where necessary to protect the subject from an apparent immediate hazard) are also noncompliance, unless it is outside the control of the investigator.

At the discretion of the reviewer(s), in consultation with the ES/AES, if the noncompliance is not serious, appears to be inadvertent, and/or if the investigator does not have a history of noncompliance, the reviewer will respond to the noncompliance by communicating with the investigator and attempting to correct the situation through a corrective and preventative action plan. Noncompliance that is neither serious nor continuing can be handled administratively and does not require evaluation by the convened Review Board to protect subjects. The appropriate authorities may be informed at the reviewer's discretion.

5.10.2 Serious Noncompliance

Serious noncompliance is noncompliance that adversely affects the rights and welfare of subjects or involves violations of state or federal laws. The term "welfare" refers to placing subjects at risk of harm. Subjects can be placed at increased risk of harm without experiencing actual harm. If the noncompliance places one or more subjects at a materially-increased risk of harm, then the noncompliance is serious, even if no harm resulted.

5.10.3 Continuing Noncompliance

Continuing noncompliance can be either a pattern of noncompliance that is likely to continue without intervention or a failure of the principal investigator and/or study team to work with WSIRB to resolve noncompliance. Repeated instances of noncompliance that are detected once do not necessarily constitute continuing noncompliance. Continuing noncompliance may involve repeated instances of noncompliance around the same issue or may involve more than one noncompliance issue. If the investigator has multiple instances of noncompliance on different issues or with different studies, a finding of continued non-compliance may be appropriate and should be considered. If WSIRB is repeatedly evaluating

episodes of noncompliance at a site, and concludes that the investigator is unable to properly conduct research, WSIRB can reasonably find that this pattern constitutes continuing noncompliance.

5.10.4 Procedures for Serious and/or Continuing Noncompliance

If an investigator exhibits serious and/or continuing noncompliance with Board-approved procedures, the following steps will occur:

1. The staff reviewer in consultation with the ES/AES, will clarify with the investigator the nature of the noncompliance and any steps already taken to correct the noncompliance. If appropriate, the WSIRB Chair will be consulted;

2. The noncompliance will be placed on the agenda of the next Review Board meeting. The staff reviewer will present a report to the full Board with a recommendation of appropriate action;

3. The Board will evaluate whether additional corrective and preventative actions are appropriate, which may include, but are not limited to, submission of additional documentation explaining how and why the noncompliance occurred, steps to remediate the noncompliance, and how similar noncompliance will be prevented in the future;

4. As part of the review of serious and/or continuing noncompliance, the Board can require clarifications and place the review item on the next appropriate agenda for further review. If the Board does not believe further clarifications are necessary, the verification of any required follow-up actions may be delegated to a Board subcommittee. If the Board is ready to make a decision, the following determinations must be made:

    i. If the matter is serious noncompliance, continuing noncompliance, or serious and continuing noncompliance.

    ii. Whether the noncompliance requires:

        a. no further action,

        b. further steps and/or additional corrective and preventive actions,

        c. suspension of some study activities such as the enrollment of new subjects or the disclosure of additional Washington State Agency records. If some study activities are suspended, the Review Board will stipulate the review issues

the investigator must respond to before reinstatement will be considered by the Review Board,

d. suspension of all study activities (with the exception of continuing review reporting). If project approval is suspended, the Review Board will stipulate the conditions for reinstatement of WSIRB approval or the review issues the investigator must respond to before reinstatement will be considered by the Review Board, and/or

e. termination of study approval (cessation of all study activities).

iii. Whether the investigator may keep all of the data collected or obtained for the study, or whether some or all of the data must be returned, de-identified, or destroyed. As part of this determination, the Board may consult with any applicable Washington State agencies.

5.10.5 Reporting Procedures for Serious and/or Continuing Noncompliance

If the WSIRB makes a finding of serious and/or continuing noncompliance, the determination will include a description of the noncompliance, the WSIRB's determinations, and any required actions. The following individuals/institutions will be notified regarding the serious and/or continuing noncompliance:

- the investigator's immediate supervisor,
- the IRB in the investigator's home institution,
- appropriate institutional officials,
- the investigator's funding agency, and
- the Office for Human Research Protections, HHS, or the equivalent office within the appropriate Federal department or agency.

The Attorney General's Office may be informed, at the Board's discretion, depending on the seriousness of the noncompliance and whether any contract, state, or federal laws have been violated.

If the Board terminates the project approval, the investigator will be required to immediately return or destroy all identifiable personal record information disclosed for research purposes. Failure to immediately return or destroy identifiable personal record information may be reported to the Attorney General's Office for further action.

5.10.6 Noncompliance Prior to Initial Study Approval

In some instances, serious noncompliance with Washington State Agency Policy... and/or violations of state or federal law may be detected during the initial review of a research proposal. Detection of serious noncompliance or violation of law during the initial review of a research proposal is sufficient grounds for disapproval of the research proposal. If serious noncompliance or violation of law is discovered during the initial expedited review of a proposal, the ES/AES, staff reviewer, Board Chair, or primary reviewer may make a motion for disapproval of the proposal at the next scheduled meeting of the Review Board. (*5.10 revised 06/18/2020*)

5.11 Study Completion/Cancellation

Upon completion of a research project the Principal Investigator is required to submit a final project report. The following documents will be accepted as the required final report: a published article based on the research; a report prepared for the institution that funded or sponsored the research; a thesis or dissertation based on the research. Final reports may be submitted as electronic documents. The investigator should consult with HRRS staff if there is a question about what will be accepted as the final project report.

If the project required a Confidentiality Agreement for the disclosure of individually identifiable personal record information, the investigator must meet all requirements in the Agreement before the study file can be closed. At a minimum, this requires the investigator to certify in writing the destruction of all data elements that could directly or indirectly identify individuals whose records were disclosed for the research as soon as the purposes of the research have been accomplished. The investigator should use the *Certification that Research Records have been De-Identified* form to document that this requirement has been met.

For research that involves collecting primary research data from subjects, the investigator will be asked to certify that all terms and conditions in the study consent and/or assent forms have been fulfilled, including that identifiers have been permanently removed from study records and destroyed.

When the final report and written assurance that identifiers have been destroyed are received by HRRS, the principal investigator is informed by letter that the requirements to the WSIRB have been completed and the project file is closed.

6.0 RESEARCH WITH AGENCY CLIENTS

6.1 STATE HOSPITAL PATIENTS

6.1.1 State Hospital Patients

Researchers may request access to patients in the state psychiatric hospitals for purposes of study recruitment. In general, patients eligible for the research are first identified by ward staff, based on their day-to-day interaction with patients and knowledge of their clinical conditions. On occasion, researchers may require access to medical record information in order to identify potential subjects. In such cases, the WSIRB may consider a waiver of authorization for access to and disclosure of protected health information for subject identification and selection only. Actual contact with patients for research purposes is always conducted according to the procedures outlined in section 6.1.4 below.

Although the federal human subjects protection regulations do not include special protections for persons with mental disorders, individuals with these conditions are considered a vulnerable group by the WSIRB. In addition, many patients on forensic services wards meet the definition of prisoners under 45 CFR 46 Subpart C. If a researcher proposes to enroll children from the Child Study and Treatment Center, special protections for children would also apply.

6.1.2 Concurrence of Treating Physician

Research procedures may include interventions, assessments, and/or administration of investigational new drugs which may pose risks to individual subjects. In most cases, researchers will be expected to obtain concurrence from each patient's treating physician that the individual patient would be an appropriate subject and that the proposed research would not jeopardize or interfere with his/her treatment or pose any undue stress or adverse effects. If the researcher is also the treating physician, this assessment should be made by clinical staff unaffiliated with the research and independent of the researcher.

6.1.3 Contacting Hospital Patients

The WSIRB does not permit researchers direct access to psychiatric inpatients for subject recruitment purposes. In the event the researcher is affiliated with the hospital or DSHS Integrated Health Systems, initial research contact must be made by hospital staff unaffiliated with the study--even when the researcher may normally have direct contact with patients for purposes of health care or service delivery. This procedure helps to minimize the possibility of undue influence to participate.

6.1.4 Recruitment of Hospital Patients

A two-stage process for recruitment of state hospital patients is generally required. In the first stage, patients are informed by hospital staff, either individually or as a group (ward, medical diagnosis, treatment group, etc.), that the researcher wishes to talk to them about the proposed study. The role of hospital staff is limited to providing information and asking whether patients are interested in being contacted by the researcher—hospital staff should not recruit, market the research, or otherwise encourage research participation. If a patient refuses researcher contact, he/she should not be contacted further regarding the research.

If the patient is interested in hearing more about the study, his/her contact information is provided to the researcher. At a minimum, the patients' positive oral consent for disclosure of their contact information must be obtained by hospital staff. In some instances, the patient may be asked to sign a simple release form to document that the hospital has been given permission to allow the researcher to talk with the patient.

In the second stage, the researcher contacts patients to provide additional information about the study and, if the individual is interested, to request assent or consent to research participation. At the time of proposed contact by the researcher, the patient is free to change his/her mind and to decline actual contact. A patient's agreement to allow contact by the researcher *does not* mean that the individual has agreed to research participation.

6.1.5 Capacity to Provide Informed Consent

Hospital patients may lack capacity to provide informed consent, although this should not be assumed. Capacity refers to a clinical judgment about whether the individual can understand information presented to him/her and can make his/her own independent decisions. *Incapacity* (lack of competence), on the other hand, is "a legal not a medical decision, based upon a demonstration of management insufficiencies over time in the area of person or estate. Age, eccentricity, poverty, or medical diagnosis alone shall not be sufficient to justify a finding of incapacity" (RCW 11.88.010)(c)).

Individuals with mental disorders may be fully capable of informed decision-making regarding participation in research. Capacity to provide informed consent may also fluctuate over time, in severity, or in certain circumstances. Researchers must describe plans to assess capacity in their proposal to the WSIRB and provide information to support their approach. The human subjects review will evaluate *when* and the *manner* in which persons with mental disorders may be vulnerable to coercion or exploitation, the possible risks of research participation, and level of risk(s), in order to ensure that appropriate protections are in place. In some cases, the WSIRB may require changes to study eligibility criteria.

Researchers should develop proposed recruitment and consent procedures in light of these potential vulnerabilities, and develop plans to verify that potential subjects have the capacity to make an informed decision regarding participation in the research. The setting in which recruitment and consent procedures would occur, as well as who obtains consent and the manner in which it would be obtained, must also be explained in the proposal. Depending on the specifics of the research, researchers also may need to develop appropriate procedures for subjects whose capacity for full informed consent may diminish during the course of the research.

6.1.6 Legal Guardian Permission

The WSIRB may require permission of the inpatient's legal guardian for participation in research. If no legal guardian has been appointed, it may be acceptable to follow the hierarchy of substitute decision makers for health care of persons who are not competent, as specified in RCW 7.70.065.

Hospital staff may be asked to contact legal guardians/decision makers to inform them of the researcher's request to include the patient in research. Contact is usually by letter, although telephone contact also may be acceptable. The WSIRB may require signed guardian permission to include the patient in the research. Researchers should discuss study plans with hospital staff, to ensure that research procedures would not be overly burdensome or disruptive to daily operations.

In some cases, the WSIRB would consider a process in which guardians are notified in advance of the hospital's intent to disclose information about the patient (name, address, etc.) for purposes of contact by the researcher. In this "prior notification" procedure, a waiver of guardian authorization must be approved by the WSIRB, but guardians do have the opportunity to "opt out" or refuse involvement of the inpatient. Notification procedures are always carried out by hospital staff. If guardians do not actively opt out or refuse, the procedures in item 6.1.4 above would be followed to recruit the patient for the research.

Patients are not required to participate in the research, even when a guardian has given written permission.

6.1.7 Witness to the Assent/Consent Process

The WSIRB may require a witness to the consent/assent process, to ensure the subject's understanding of and voluntary participation in the research. The witness should be affiliated with the hospital, such that he/she normally has interaction with inpatients, but should not be in a position of authority over individuals recruited for the research. For example, a member of the clergy, case manager, ward nurse, or other health care provider from a different unit of the hospital could reasonably fill this role. Direct care providers or staff who oversee the patient's treatment may not be appropriate, as involvement of these staff could increase the possibility of undue influence.

The witness should have sufficient information and an understanding of the proposed research to advocate for patients. He/she must be able to assess whether patients are fully informed, whether in his/her judgment they understand what they are asked to do, and he/she must be able to verify that individual decisions regarding research participation were voluntary. It is the *researcher's* obligation to fully explain the study and to carry out the informed assent/consent process. The witness serves to protect the rights of vulnerable human subjects. If the WSIRB requires a witness, the Review Board may also require his/her certification on assent/consent forms attesting that the patient's decision was fully informed and voluntary.

If the witness believes that patients are not fully informed, that they are not given the opportunity to ask questions regarding the research, that procedures are not carried out appropriately or cause undue stress to potential participants, he/she should report this information to hospital staff and to the researcher. Such concerns may be addressed through additional training of research staff, alterations in assent/consent procedures, a change in timing of the assent/consent process, etc. Concerns regarding research procedures may also be referred to the WSIRB, which may request additional information, conduct a site visit, and/or take additional action, as appropriate.

6.1.8 Administration of Medications for Research Purposes

Under state statute (RCW 71.05.215) a "person found to be gravely disabled or presents a likelihood of serious harm as a result of a mental disorder" retains the right to refuse antipsychotic medication unless certain conditions are met.

When researchers propose clinical trials of antipsychotic medications, or any other psychotropic drug, inpatient participation and consent is always voluntary, even when the medication could be prescribed against his/her objections in a clinical setting per state statute.

If the research involves an investigational medication, researchers should provide a detailed protocol for tapering or a “wash-out” period of current medications and plans for phase-in of the investigational drug (where applicable), including necessary psychological assessments, physical exams, clinical procedures, and laboratory tests. The research protocol should describe how adverse events would be handled (see Procedures Manual, Section 5.9), and specify criteria for withdrawing a subject from the research. Researchers should also provide a plan for continued clinical follow-up of subjects in the event they withdraw or are withdrawn from the research and for aftercare when they complete all research procedures. Transition back to regular clinical care and collaboration with the individual subject’s treating physician should be described in the human subjects application.

If the clinical trial would potentially increase length of stay, patients and their guardians/legally authorized representatives must be informed during the consent process. As increased length of stay would result in increased cost of care within the institution, the researcher should obtain approval from any third-party payers or work out financial arrangements with hospital administration prior to submitting the human subjects application. If the research will assume all or partial costs of participation, the researcher should specify this in the application.

6.1.9 Reporting of Abuse/Neglect of Vulnerable Adults

Investigators generally must submit a protocol for reporting suspected abuse/neglect of vulnerable adults as part of the human subjects application. Training of research staff in identifying and reporting suspected abuse should also be described. Departmental and WSIRB policy require researchers to report *all*

suspected abuse/neglect, even if the researcher may not be a mandatory reporter under state statute. However, researchers should not assume an investigatory role: researchers should simply report to the hospital's administration (or any supervisor) what they know that lead them to suspect abuse. Investigatory functions are conducted by the appropriate authorities. For more information regarding abuse reporting of state hospital patients, see RCW 70.124 and Section 6.7 of the Procedures Manual.

6.1.10 Reporting Threats of Harm

The WSIRB also may require researchers to report threats of harm to self or others made by research subjects, particularly when the research involves sensitive issues, psychological assessments, clinical trials, or other research methods which may elicit such responses or cause distress to patients and/or other research participants. Reporting of threats of harm is based on a California court decision that a mental health provider has an ethical obligation to break client confidentiality if he/she has reasonable cause to believe "that the patient is in such mental or emotional condition as to be dangerous to himself or to the person or property of another and that disclosure of the communication is necessary to prevent the threatened danger". (see Tarasoff v. Regents of University of California, 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976). This legal obligation also applies to the hospital's treatment team members, to whom the researcher should report such threats (see RCW 71.05.120(2).

Researchers should keep in mind that threats of harm may be expressed by family members of inpatients, care providers, or other parties, not just patients themselves. Researchers should submit a protocol for reporting threats of harm, including plans to handle imminent threats, with the human subjects application.

6.1.11 Research Participant Rights

The WSIRB requires language in the consent form to inform state hospital patients and their guardians, where applicable, that they may call the WSIRB if they have questions about their rights. Consent form language should read substantially as follows: "You might have questions about your rights as someone who takes part in this study. You can make a free call to the Washington State Institutional Review Board at 1 (800) 583-8488. The Board oversees this study to protect the rights of people who take part. You don't have to give your name if you call."

6.1.12 Resources

Investigators and research staff who wish additional information related to research involving persons with mental disorders may review the National Bioethics Advisory Commission report, *Research Involving Persons with Mental Disorders which May Affect Decision-making Capacity*, December 1998, at http://bioethics.georgetown.edu/nbac/capacity/TOC.htm

6.2 JUVENILE OFFENDERS

6.2.1 Definitions

"*Prisoner*" is defined in 45 CFR Part 46.303(c) as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."

"*Minimal Risk*" in prisoner research (45 CFR 46.303(d)) is defined as "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons". This definition differs from the definition of minimal risk in 45 CFR46.102(i), in that it refers to physical or psychological harm and uses healthy persons as the reference for assessment of risk.

6.2.2 Applicability

Subpart C applies when the research involves individuals who are prisoners at the time of enrollment in the research *and* to active research subjects who become incarcerated during their involvement in the research. The exemptions in 45 CFR 46.101(b) do not apply to research involving prisoners.

6.2.3 Identifying Juvenile Offenders for Research

Researchers may request access to juvenile offenders in JRA institutions for purposes of study recruitment. In general, youth eligible for the research are first identified and sampled by JRA program staff, based on review of case files, electronic records, or program information.

Juvenile offenders may be considered vulnerable due to age, substance abuse, mental health issues, family circumstances, educational and literacy levels, and other factors, in addition to their status as prisoners. Researchers should plan research procedures and prepare recruitment and assent/consent materials with these vulnerabilities in mind.

6.2.4 Contacting Juvenile Offenders

The WSIRB does not permit researchers direct access to juvenile offenders for research purposes. If the researcher is affiliated with the JRA institution, initial research contact must be made by JRA staff unaffiliated with the study--even when the researcher may normally have direct contact with youth for purposes of service delivery. This procedure helps to ensure that the possibility of undue influence or coercion is minimized.

6.2.5 Recruitment of Juvenile Offenders

The WSIRB requires a two-stage process for recruitment of juvenile offenders, as with other DSHS clients. In the first stage, youth are informed by JRA staff, either individually or as a group (by cottage, type of offender, treatment group, etc.), that the researcher wishes to talk to them about the proposed study. The role of JRA staff is limited to providing information and asking whether the youth are interested in being contacted by the researcher—they do not recruit, market the research, or otherwise encourage research participation. If the youth refuses researcher contact, he/she is not contacted further regarding the research. If the youth is interested in hearing more about the study, his/her contact information is provided to the researcher. The youth's agreement to contact *does not* mean that the individual has agreed to research participation.

In the second stage, the researcher contacts youth to provide additional information about the study and, if he/she is interested, to request assent or consent to research participation. The youth, at the time of proposed contact by the researcher, is free to change his/her mind and to decline actual contact. The researcher's initial contact with youth is for the purpose of providing information; assent/consent to participate in the study should not be assumed.

6.2.6 Parent Permission

The WSIRB requires parent permission for participation of children in research, unless the researcher can justify a waiver under Subpart D (see Section 5.3.6). Youth as young as 10 years of age may be placed in JRA institutions, therefore the researcher should submit plans for requesting permission from parents of youth aged 10-17 years. Juvenile offenders aged 18-20 may provide their own consent for research participation. If the researcher proposes to include parents in research procedures, parental permission for participation of the child would be required in almost all cases. If parental rights have been terminated, the WSIRB may require consent of the court-appointed guardian, legal guardian, or, in some cases, the child's social worker (*not* the JRA caseworker).

JRA staff would contact parents to inform them of the researcher's request to include the child in research. Contact is usually by letter, although telephone contact also may be acceptable. The WSIRB may require signed parent permission to include a child in the research. Researchers should discuss study plans with JRA institutional staff, to ensure that research procedures would not be overly burdensome or disruptive to daily operations.

In some cases, the WSIRB would consider a process in which parents are notified in advance of JRA's intent to disclose information about the child (name, address, etc.) for purposes of contact by the researcher. In this "prior notification" procedure, a waiver of parent permission has been approved by the WSIRB, but parents have the opportunity to "opt out" or refuse involvement of their child. Parental notification procedures are always carried out by JRA staff. If parents do

not actively opt out or refuse, the procedures in section 6.2.5 are followed to inform the youth of the research.

Whether parental consent is required or waived by the WSIRB, the two-stage procedure described in Section 6.2.5 above is always followed for contact with and recruitment of youth offenders. Juvenile offenders are not required to participate in the research, even when a parent has given permission for the child's participation.

6.2.7 Youth Assent

Youth assent (agreement) is always required if research involves interaction or intervention with juvenile offenders, regardless of whether parent permission is required or waived by the WSIRB. The form of assent is usually written, although the WSIRB may approve a verbal consent procedure, if the study meets requirements in 45 CFR46.117(c) for a waiver of signed consent. The WSIRB evaluates all assent and consent documents to ensure that reading levels are appropriate for the intended study population. Assent forms should be written in lay language, avoiding technical terminology as much as possible.

The WSIRB also considers the age of potential participants, capacity to provide informed assent, and other factors during human subjects review. As juvenile offenders may be multiply vulnerable, particular attention will be paid to the assent process: who requests assent; how, where, and when it would occur; and procedures to ensure the youth fully understands what he/she is asked to do. Juvenile offenders may have diminished capacity due to developmental delay, substance abuse, medications, or mental health issues. In such cases the WSIRB may require a process in which the researcher verifies that information in the assent form has been understood, or a process in which the researcher asks youth to explain the study in his/her own words.

The youth's decision regarding continued research participation must be honored in all cases.

6.2.8 Witness to the Assent Process

The WSIRB may require a witness to the youth assent process, to ensure the youth's understanding of and voluntary participation in the research. The witness should be affiliated with the JRA institution, such that he/she normally has interaction with offenders, but should not be in a position of authority over youth recruited for the research. For example, a member of the clergy, a public defender, case manager, nurse, or other health care provider could reasonably fill this role. JRA staff who are direct care providers or who oversee the youths' detention and treatment decisions may not be appropriate, as involvement of these staff could increase the possibility of undue influence for the youth to agree to participate.

The witness should have sufficient information and an understanding of the proposed research to advocate for youth. He/she must be able to assess whether youth are fully informed, whether in his/her judgment offenders understand what they are asked to do, and he/she must be able to verify that individual decisions regarding research participation were voluntary. It is the *researcher's* obligation to fully explain the study and to carry out the informed assent/consent process. The witness serves to protect the rights of vulnerable human subjects. If the WSIRB requires a witness to the assent process, the Review Board may also require his/her certification on assent/consent forms attesting that the offenders' decision was fully informed and voluntary.

If the witness believes that youth are not fully informed, that they are not given the opportunity to ask questions regarding the research, or that procedures are not carried out appropriately or cause undue stress to potential participants, he/she should report this information to JRA staff assigned to coordinate the research within the institution and to the researcher. Such concerns may be addressed through additional training of research staff, alterations in assent and consent procedures, a change in timing of the assent/consent process, etc. Concerns regarding research procedures may also be referred to the WSIRB, which may request additional information, conduct a site visit, and/or take additional action, as appropriate.

6.2.9 Review of Research Involving Juvenile Offenders

Research involving intervention or interaction with juvenile offenders and their family members requires full committee review at a convened meeting of the WSIRB with the WSIRB prisoner representative present, to ensure that the rights and welfare of offenders are protected and that the research does not pose undue burdens on or undue influence for potential subjects. WSIRB review ensures that the requirements in 45 CFR 46.305 and §306(a) have been met. The Review Board may require alterations in study procedures and methods, recruitment and consent procedures, or changes in other aspects of the research to satisfy these regulatory requirements.

6.2.10 Permissible Research Involving Prisoners

The human subjects protection regulations in 45 CFR 46.306(a)(2) list four categories of permissible research involving prisoners:

"(A) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

"(B) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

"(C) research on conditions particularly affecting prisoners as a class (for example,

vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

"(D) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research."

The WSIRB must determine that research involving juvenile offenders meets one of these categories of permissible research. The WSIRB applies the special protections in Subpart C to *all* research involving contact with juvenile offenders, regardless of funding source.

6.2.11 Waiver of Applicability of Certain Provisions of Subpart C

In June 2003, the federal Department of Health and Human Services granted a waiver of 45 CFR 46.305(a)(1) and 46.306(a)(2) for epidemiologic research on prisoners. The waiver applies *only* to epidemiologic research conducted or supported by HHS in which the sole purposes are "to describe the prevalence or incidence of disease by identifying all cases, or to study potential risk factor associations for disease, and where the institution responsible for the conduct of the research certifies to the Office of Human Research Protections...that the IRB approved the research and ...determined and documented that the research poses no more than minimal risk and no more than inconvenience to prisoner-subjects, and prisoners are not a particular focus of the research." (Federal Register, Vol 68, No. 119, Friday, June 20, 2003).

The WSIRB will consider whether a research proposal meets the requirements for this waiver of some of the requirements in Subpart C.

6.2.12 Active Study Participants Who Become Incarcerated

Periodically, studies normally outside WSIRB jurisdiction may include occasional study participants who become incarcerated in JRA institutions during ongoing research procedures. In such cases, DSHS may consider establishing an IRB Authorization Agreement (IAA), in which the agency accepts the review and continuing oversight by the researcher's home IRB or another designated IRB. In order to consider an IAA, the WSIRB requires the researcher to submit the following for review:

- A copy of a current protocol approved by the home institution;

- A copy of each current IRB-approved parent permission and/or youth assent/consent form utilized for the research;

- Documentation from the investigator's home institution that the specific findings required under in 45 CFR 46.305(a) have been satisfied. This must include designation of the category of permissible research involving prisoners, and a description of the rationale for the determination;

- If the research is funded by HHS, documentation that the researcher's home institution has certified to OHRP that the research meets the requirements in 45 CFR 46.305;

- Documentation of support from each JRA institution in which research procedures would occur.

A subcommittee of the WSIRB will review the above materials to ensure that research procedures are appropriate and consistent with departmental policy, relevant statutes and regulations, and that they would not pose a burden on either the JRA institution or the individual subject. The subcommittee may require revisions to parent permission and/or youth assent documents or other aspects of the research to comply with WSIRB requirements. Researchers may not contact or involve juvenile offenders in JRA custody in the research until such time as an IAA has been established or the protocol has been reviewed and approved by the WSIRB. The WSIRB retains the right to require full committee review of the research.

The above procedure will be followed when it is expected that only a small number of study participants may become incarcerated during the course of a study. Once an IAA is established, the researcher need only inform the WSIRB of additional JRA sites in which they propose to interview study subjects who have become prisoners. Approval to actually contact the youth offender in the institution remains at the discretion of the Superintendent or his/her designee.

Occasionally, a previously enrolled research participant becomes incarcerated, but the research protocol was *not* reviewed and approved by the WSIRB or the researcher's home IRB for compliance with the requirements in 45 CFR Part 46, Subpart C. In such cases, the principal investigator should promptly notify the relevant IRB(s) of this event and cease *all* research activities involving the incarcerated study subject until the IRB(s) determine that the requirements of Subpart C have been satisfied. Temporary cessation of the research means halting all interventions or interactions with the individual and halting access to and disclosure of identifiable private information regarding the subject.

If an IAA is not established as described above, the researcher should submit an application to the WSIRB for review and approval. The WSIRB will review the protocol for compliance with the requirements of Subpart C if the Principal

Investigator wishes to retain the prisoner subject in the research. The investigator may also choose to forgo involvement of the incarcerated subject until such time as he/she is released from JRA custody. In this case, review by the WSIRB would not be required.

6.3 FAMILIES IN THE CHILD WELFARE SYSTEM

6.3.1 Identifying Division of Children and Family Services Clients for Research

Researchers may request access to families involved with the Children's Administration for purposes of study recruitment. This may include children in foster care or therapeutic child care; street youth in temporary residential placement; sexually aggressive youth; children in residential behavioral rehabilitation programs; families investigated for abuse/neglect; foster parents; or families which have received family preservation or family reconciliation services. Potentially eligible children or families are most often identified in one of two ways:

- For small-scale studies or studies in which the researchers conduct local interventions with agency staff/families, the social workers would be asked to identify children on their caseload who meet eligibility criteria. They may be asked to use a checklist of eligibility criteria provided by the researchers or use information in standard assessments of the child/family (CBCL, CHET, etc.) conducted for program purposes.

- Families may also be sampled from Children's Administration electronic records of department clients (e.g., FamLink). Actual contact with these clients for research purposes must be conducted according to the procedures outlined in Sections 6.3.3 through 6.3.5 below.

6.3.2 Contacting Parents, Caregivers, and Children

The WSIRB requires that agency staff make first contact with children in the child welfare system, their parents, or foster parents, to protect their privacy and to provide an opportunity for them to opt out of any contact by the researcher.

In the event the researcher is an employee or contractor of the DSHS Children's Administration, initial research contact must be made by DSHS staff unaffiliated with the study--even when the researcher normally may have direct contact with clients for purposes of service delivery. This procedure helps to ensure that the possibility of undue influence is minimized.

6.3.3 Recruitment of Parent Subjects

The WSIRB requires a two-stage process for recruitment of parents involved with the child welfare system, as with other DSHS clients. In the first stage, parents

are informed by DSHS staff, usually the family's social worker, that the researcher wishes to talk to them about the proposed study. Social workers are limited to providing information and asking whether parents are interested in being contacted by the researcher—they should not recruit, market the research, or otherwise encourage research participation. If a parent refuses researcher contact, he/she would not be contacted further regarding the research, and the child should not be approached. If the parent is interested in hearing more about the study, the social worker obtains written or verbal consent to release his/her contact information to the researcher. The parent's agreement to contact *does not* mean that the parents or their child have agreed to research participation.

In the second stage, the researcher contacts parents to provide additional information about the study and, if they are interested, to request permission for the child to participate in the research. The parent, at the time of proposed contact by the researcher, is free to change his/her mind and to decline actual contact. The researcher's initial contact with parents is for purposes of providing information; consent to participate, or permission for the child to participate in the study, should not be assumed.

6.3.4 Recruitment of Children in Out-of-Home Placement

If a potential research subject is a child in out-of-home placement, permission of the child's *social worker* is required. Social workers have legal authority to consent to release of information about or interventions or decisions regarding children on their caseload. A *three-stage* recruitment procedure is generally required:

1. If a child's social worker determines that the child may be eligible and gives permission for the child to participate in the research, he/she would contact the caretaker/foster parent to inform him/her of study eligibility.

2. Foster parents would be asked for permission to disclose their identity and contact information to the researchers. The foster parent/caregiver would also be asked to discuss the study with the child to assess whether he/she may be interested in participation.

3. If the foster parent and child agree to researcher contact, the social worker would give identifiers of the child and foster parent to the researcher, so that the researcher may begin recruitment procedures.

These procedures may require adjustment, depending on the specifics of the research, the age of the child/ren sampled for the research, and individual child or family circumstances.

Permission of a social worker does not mean that the child is required to participate in the research--the child's assent regarding research participation must be requested. The child retains the right to refuse participation, even when the social worker (or a birth parent) has given permission.

Parental notification or permission to include the child in research is required by the Children's Administration, even though children in out-of-home placement may be dependent and in the legal custody of DSHS. The WSIRB may require signed parent permission for a child's participation, depending on the specifics of the research, number of subjects, and other factors.

As described in 6.3.2 above, the notification or request for permission must be made by the child's social worker. Research involvement of children in out-of-home placement due to Voluntary Placement Agreements or the need for shelter care typically requires parental consent. Researchers should develop recruitment and consent procedures that take into account these requirements.

6.3.5 Recruitment of Foster Parents or Caregivers

Similar to consent for involvement of the child, social worker permission is required when a researcher wishes to contact the child's caregiver or foster parent. Caregivers may be subjects of the research (see definition in 5.1.2), in which case they would provide consent for their own participation in the research. If a caregiver will be disclosing information about a child, social worker consent is required in order for the caregiver to disclose the information.

6.3.6 Assent of a Child Subject

"Assent" refers to a minor's agreement or concurrence to participate in research, as opposed to a parent or other adult's *permission* for the child to participate. Assent procedures must be appropriate to the age and developmental level of the child. In general:

- Children aged 5-7 should be verbally informed of the research and asked if they agree to be in the study. Researchers should submit a script to be used for recruitment of children in this age range.

- Children aged 8-17 should read a written assent form, written in lay terms that they can readily understand. Many researchers read the form aloud with the child, as some children may not read at grade level and may be too embarrassed to say so.

- If the research involves children in a wide range of ages, separate assent forms should be written for ages 8-12 and 13-17.

Any minor who does not understand what he/she is being asked to do should not be enrolled in the study.

6.3.7 Capacity to Provide Informed Assent/Consent

Children and/or their parents may lack capacity to provide informed consent/assent, although this should not be assumed. Capacity refers to a clinical

judgment that the individual can understand information presented to him/her and can make his/her own independent decisions. *Incapacity* (lack of competence), on the other hand, is "a legal not a medical decision, based upon a demonstration of management insufficiencies over time in the area of person or estate. Age, eccentricity, poverty, or medical diagnosis alone shall not be sufficient to justify a finding of incapacity" (RCW 11.88.010(c)).

Children in out-of-home care may be fully capable of informed decision-making regarding participation in research. Foster children may have mental health issues, substance abuse, or other vulnerabilities which warrant special protections during the assent process. During human subjects review, the WSIRB will evaluate *when* and the *manner* in which children may be vulnerable to undue influence or exploitation, the possible risks of research participation, and the level of risk(s), to ensure that appropriate protections are in place. In some cases, the WSIRB may require changes to study eligibility criteria.

Researchers should develop recruitment and consent procedures in light of these potential vulnerabilities. Researchers should explain plans to verify that potential subjects have the capacity to make an informed decision regarding the research in their proposal submitted to the WSIRB. Researchers should also describe the setting in which recruitment and consent procedures would occur and specify who would request consent/assent.

6.3.8 Witness to the Assent Process

The WSIRB may require a witness to or youth advocate for the assent process, to ensure the youth's understanding of and voluntary participation in the research. Advocates should be individuals who are not in a position of authority over the youth. For example, a member of the clergy, trusted neighbor, teacher, or health care provider could reasonably fill this role. Direct care providers or staff who oversee the family's case may not be appropriate, as involvement of these staff could increase the possibility of undue influence.

The witness should have sufficient information and an understanding of the proposed research to advocate for the child. He/she must be able to assess whether the child is fully informed, whether in his/her judgment the child understands what the study involves, and he/she must be able to verify the child's decision regarding research participation was voluntary. It is the *researcher's* obligation to fully explain the study and to carry out the informed assent process. The witness serves to protect the rights of vulnerable child subjects. If the WSIRB requires a witness to the assent process, the Review Board may also require his/her certification on assent forms attesting that the youth's decision was fully informed and voluntary.

If a witness believes that a child is not fully informed, is not given the opportunity to ask questions regarding the research, or is concerned that procedures are not carried out appropriately or cause undue stress, the advocate should report this to the researcher. Such concerns may be addressed through additional training of

research staff, alterations in assent procedures, a change in timing of the assent process, etc. Concerns regarding research procedures may also be referred to the WSIRB, which may request additional information, conduct a site visit, and/or take additional action, as appropriate.

6.3.9 Reporting Child Abuse/Neglect

Departmental and Review Board policy require reporting of *all* suspected abuse/neglect of children, even when the researcher is not a mandatory reporter under state statute. In RCW 26.44, a child is defined as anyone under the age of 18. Poverty, homelessness, or exposure to domestic violence as defined in RCW 26.50.010 that is perpetrated against someone other than the child does not constitute negligent treatment or maltreatment in and of itself. Researchers who in good faith make a report of alleged child abuse or neglect are immune from any liability arising out of such reporting.

Investigators should submit a protocol for reporting suspected abuse/neglect of children as part of the human subjects application. Training of research staff in identifying and reporting suspected abuse should also be described. Researchers should not assume an investigatory role: researchers should simply report what they were told, observed, or special situations which lead them to suspect abuse. Researchers should not probe into the situation, nor attempt to identify the perpetrator. Investigatory functions would be carried out by Child Protective Services. For more information regarding child abuse/neglect reporting requirements, see RCW 26.44 and the DSHS Children's Administration website.

6.3.10 Reporting Threats of Harm

The WSIRB also may require researchers to report threats of harm to self or others, particularly when the research involves sensitive issues, psychological assessments, or other research methods which may elicit such responses or cause distress to children and/or other research participants. Reporting of threats of harm is based on a court determination that mental health providers have an ethical obligation to break client confidentiality if they have reasonable cause to believe “that the patient is in such mental or emotional condition as to be dangerous to himself or to the person or property of another and that disclosure of the communication is necessary to prevent the threatened danger” (see Tarasoff v. Regents of University of California, 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976).

Researchers should keep in mind that threats of harm may be expressed by family members, foster parents, care providers, siblings, or the child subjects themselves. Child subjects, and their social workers and caregivers, must be informed of this limit to confidentiality protections during the informed consent process, and language to that effect must be included in the consent and assent forms. Researchers should submit a protocol for reporting threats of harm, including plans to handle imminent threats. The protocol should be submitted with the human subjects application, along with a plan for training research staff in this issue.

6.3.11 Research Participant Rights

When research involves particularly vulnerable groups, the WSIRB requires language in consent and assent forms to inform children and their social worker and caregiver that they may call the WSIRB if they have questions about rights of research subjects. Consent/assent form language should read substantially as follows: "You might have questions about your rights as someone who takes part in this study. You can make a free call to the Washington State Institutional Review Board at 1 (800) 583-8488. The Review Board oversees this study and works to protect the rights of study volunteers. You don't have to give your name if you call."

6.4 STANDARDS FOR TRANSLATORS AND INTERPRETERS

6.4.1 Definitions

Interpreter: A person who orally transfers a message from one spoken language to another.

Certified/Authorized interpreter: A person who has passed the required DSHS language interpreter examination, or has passed the language interpreter examination offered by the State of Washington Administrator for the Courts or the Federal Court.

Translator: A person who transfers a message in writing from one language to another.

Certified Translator: A person who has passed the required DSHS written translation examination, or has passed the American Translators Association written translation examination.

6.4.2 Requirement for certified translators and interpreters

DSHS is committed to providing equal access to services for all department clients, including persons with limited English proficiency. The DSHS standards for translators and interpreters help to ensure consistent quality of interpreter services provided to its clients. Quality is assured through administration of a standardized test.

Similarly, researchers must ensure equity in the benefits and burdens of research. The WSIRB does not consider lack of proficiency in English , in and of itself, as sufficient grounds to exclude subject populations from research projects. Researchers must provide a justification in their proposal to the WSIRB if they plan to exclude non-English speaking persons. Feasibility studies that are relatively small in scope or studies in which validated instruments are not available in

languages other than English may warrant exclusion of these potential subjects on scientific or methodological grounds. Conversely, if research will take place within a population that includes significant numbers of persons who are not proficient in English, exclusion of these potential subjects would be difficult to justify.

Researchers should have sufficient information at the planning stage of their research to assess whether translation and interpretation services will be necessary, and to budget accordingly. Using certified translators and interpreters will ensure that all documents and methods used for contact and interaction with potential subjects is appropriate and respectful of their particular cultural and linguistic heritage.

In general, the WSIRB does not approve procedures in which family members or friends of potential subjects would be used as interpreters. Such a procedure could cause embarrassment or discomfort to subjects--particularly if the research involves sensitive topics--and could infringe on their right to privacy. The quality and consistency of translation and interpretation cannot be assured, nor would the researcher be able to ensure that the full informed consent of subjects was obtained. Such “ad hoc” interpretation may also jeopardize the integrity of research data.

6.4.3 Certification Standards

The WSIRB accepts the DSHS certification exam, the certification exam offered by the American Translators Association, and comparable professional exams. The exams developed by DSHS aim to measure both language proficiency in English and a second language and interpreting/translation skills. DSHS language certification is currently available in Spanish, Vietnamese, Russian, Cambodian, Laotian, Mandarin Chinese, Cantonese Chinese, and Korean. Qualification screening tests are also available in all other languages.

DSHS policies regarding certification of translators and interpreters can be found at on their website.

The WSIRB would also accept certification by the American Translators Association Certification Program. All candidates for this certification exam must meet education and experience prerequisites prior to registering for the exam. They must provide proof of a combination of education and work experience in order to qualify to take the examination. All applicants must sign a statement that they have read and understood ATA's Code of Professional Conduct and Business Practices and that they pledge to abide by it.

6.4.4 American Sign Language certification

Similar to foreign language interpretation, any interpreters who facilitate communication with the deaf or hard of hearing should also be certified in ASL. The DSHS Office for the Deaf and Hard of Hearing provides technical assistance regarding deafness and TTY usage to DSHS staff and other interested agencies.

ODHH can help researchers identify local, regional, and state services which are available for the deaf and hard of hearing populations, and provide resources for interpreting, captioning, and amplification services for DSHS clients.

6.4.5 Other professional standards

In addition to training in human subjects protection and ethical conduct of human subjects research, interpreters and translators must adhere to the DSHS Interpreter Code of Professional Conduct or an equivalent Code developed by other professional associations such as the American Translators Association. The DSHS Code follows:

> State of Washington Department of Social and Health Services
>
> Language Interpreter and Translator Code of Professional Conduct
>
> Accuracy
>
> Interpreters/translators shall always thoroughly and faithfully render the source language message, omitting or adding nothing, giving consideration to linguistic variations in both source and target languages, conserving the tone and spirit of the source language message.
>
> Cultural Sensitivity - Courtesy
>
> Interpreters/translators shall be culturally competent, sensitive, and respectful of the individual(s) they serve.
>
> Confidentiality
>
> Interpreters/translators shall not divulge any information obtained through their assignments, including but not limited to information gained through access to documents or other written material.
>
> Disclosure
>
> Interpreters/translators shall not publicly discuss, report, or offer an opinion concerning matters in which they are or have been engaged, even when that information is not privileged by law to be confidential.
>
> Proficiency
>
> Interpreters/translators shall meet the minimum proficiency standard set by DSHS by passing the required certification examination or screening evaluation.

Compensation

The fee schedule agreed to between the contracted language service providers and the department shall be the maximum compensation accepted. Interpreters/translators shall not accept additional money, compensation, or favor for services reimbursed by the department. Interpreters/translators shall not use for private or others gain or advantage, the department's time, facilities, equipment, or supplies, nor shall they use or attempt to use their position to secure privileges or exemptions.

Nondiscrimination

Interpreters/translators shall always be neutral, impartial, and unbiased. Interpreters/translators shall not discriminate on the basis of gender, disability, race, color, national origin, age, socioeconomic or educational status, or religious or political beliefs.

Self-evaluation

Interpreters/translators shall accurately and completely represent their certifications, training, and experience.

Impartiality - Conflict of Interest

Interpreters/translators shall disclose any real or perceived conflict of interest which would affect their objectivity in the delivery of service. Providing interpreting or translation services for family members or friends may violate the individual's right to confidentiality, or constitute a conflict of interest.

Professional Demeanor

Interpreters and translators shall be punctual, prepared, and dressed in a manner appropriate and not distracting for the situation.

Scope of Practice

Interpreters/translators shall not counsel, refer, give advice, or express personal opinions, to individuals for whom they are interpreting/translating, or engage in any other activities which may be construed to constitute a service other than interpreting/translating. Interpreters/translators are prohibited to have unsupervised access to clients, including, but not limited to, phoning clients directly.

Reporting Obstacles to Practice

Interpreters/translators shall assess at all times their ability to interpret/translate. Should interpreters/translators have any reservations about their competency, they must immediately notify the parties and offer to withdraw without threat of retaliation. The interpreter/translator may remain until more appropriate interpreters/translators can be secured.

Ethical Violations

Interpreters/translators shall immediately withdraw from encounters they perceive as violations of this Code. Any violation of the Code of Professional Conduct may cause termination of the contract.

Professional Development

Interpreters/translators shall develop their skills and knowledge through professional training, continuing education, and interaction with colleagues and specialists in related fields.

6.5 REPORTING THREATS OF HARM TO SELF OR OTHERS

6.5.1 What is the Duty to Report Threats of Harm?

The WSIRB holds researchers to the requirement to protect persons from imminent harm, similar to the requirement to report suspected abuse/neglect of children or vulnerable adults. In the course of research interviews or interactions, a study subject may make statements, respond to questions, or make overt threats of suicide or to harm a third party. A particular situation may raise concern that an individual may be in danger. In such cases, the WSIRB believes that researchers are ethically bound to report such incidents.

The duty to protect others supersedes the obligation to protect subject confidentiality in a research setting. A duty to protect others exists when:

- risk to an identifiable person or group is determined, *or*
- the risk of harm includes severe injury, death, or serious psychological harm, *or*
- the threat appears imminent.

6.5.2 Ethical Framework for the Duty to Protect: The Tarasoff Decisions

Although there is no legal mandate in Washington State to report threats of harm, the WSIRB has adopted the standard set by the Tarasoff decisions. In a 1976 California Supreme Court case, a therapist was sued because a client had threatened his girlfriend. The therapist did not intervene on behalf of the

potential victim, who was later murdered by the client. The court held that the clinician had a duty to warn the intended victim, even if that meant breaking client confidentiality. The court held:

"When a therapist determines, or pursuant to the standards of his profession, should determine, that his patient presents a serious danger of violence to another, he incurs an obligation to use reasonable care to protect the intended victim against such danger. The discharge of this duty may require the therapist to take one or more of various steps, depending upon the nature of the case. Thus, it may call for him to warn the intended victim or others likely to apprise the victim of the danger, to notify the police or to take whatever other steps are reasonably necessary under the circumstances." Tarasoff v. Regents of the Univ. of Cal., 118 Cal. Rptr. 129 (Cal. 1974) (*Tarasoff I*), *modified by* Tarasoff v. Regents of the Univ. of Cal., 551 P.2d 334 (Cal. 1976) (*Tarasoff II*).

The WSIRB requires researchers to report *all* threats of harm to self or others -- even when the researcher and his/her research staff may not be mental health professionals.

6.5.3 How Should a Report be Made?

Researchers should ***only*** report what they know, have observed, or issues that cause them to suspect a threat of suicide or harm to others. Researchers may report concerns regarding suicidal ideation to the County Designated Mental Health Provider or the local crisis line. It may be appropriate to make the report to the client's case manager, legal guardian, or parent (in the case of minors), if the research subject is a DSHS client.

In most cases, concerns about an imminent threat should be reported to the police.

As part of the consent process, research subjects must be told of this *limit to confidentiality*. The consent/assent form(s) should include information about the requirement to report threats of harm, such as the following: "If we are concerned that you may hurt yourself, we will call the Crisis Line or the County Designated Mental Health Provider. If you threaten to hurt someone else, we will report it to the police".

Researchers may wish to develop a resource list of crisis lines and social service agencies for study subjects. Resource lists would be appropriate if the research involves psychological assessments or interview items which may elicit information regarding depression, substance abuse, domestic violence, service needs, etc.

6.5.4 What are Possible Risk Factors for Suicide?

- Previous suicide attempts
- Talking about death or suicide, either directly or indirectly. Individuals may make references to saying goodbye or going away, or that others would be "better off without me".
- Planning for suicide. People may give away items they value or put their affairs in order.
- Depression: Most depressed people are not suicidal, however, most suicidal people are depressed. Serious depression is expressed as a loss of pleasure or withdrawal from activities that had once been enjoyable.

6.6 REPORTING CHILD ABUSE OR NEGLECT

6.6.1 Who Is Required to Report Child Abuse or Neglect?

Mandatory Reporters

Mandatory reporters are professionals who *by law* must make a report if they have reason to believe that the abuse or neglect of a child has occurred. Mandatory reporters include:

- Practitioners of the healing arts
- Registered/licensed nurses
- Dentists
- Social service counselors/therapists
- Psychologists, therapists
- Medical examiners and county coroners
- Pharmacists
- Professional school personnel
- Child care providers/employees
- Law enforcement officers
- Juvenile probation officers
- Corrections employees
- DSHS and DEL employees
- Placement and liaison specialists
- Responsible Living Skills Program staff
- HOPE center staff
- State family and children's ombudsman
- Any volunteer in the ombudsman's office
- Adults residing with a child suspected to have been severely abused
- Supervisors in non-profit and for-profit agencies

The WSIRB requires researchers to report *all* suspected child abuse/neglect to CPS -- even when the researcher and his/her research staff may not be "mandatory reporters" under Washington State statute.

6.6.2 How Should a Report Be Made?

RCW 26.44.040 requires that "an immediate oral report must be made by telephone or otherwise to the proper law enforcement agency or the department of social and health services and, upon request, must be followed by a report in writing". DSHS Child Protective Services (CPS) Offices within local communities are responsible for receiving and investigating reports of suspected child abuse and neglect. There are several ways to report abuse:

Hotline - call 1-866-ENDHARM (1-866-363-4276), Washington State's toll-free, 24 hour, 7 day-a-week hotline that will connect you directly to the appropriate local CPS office to report suspected child abuse or neglect.

TTY Callers - call 1-800-624-6186 to place a direct TTY call.

CPS will ask questions to determine whether the report meets the legal definition of abuse or neglect and how dangerous the situation is.

6.6.3 What Information Should Be Included in a Report of Suspected Child Abuse/Neglect?

Researchers should ***only*** report what they know, have observed, or issues that cause them to suspect child abuse or neglect. They should not "investigate" their suspicions or ask questions of the child or parent/caregiver regarding suspected abuse/neglect. The requirement to report suspected abuse/neglect must be described in research consent forms so that parents and children are informed of this potential limit to assurances of confidentiality.

Reports of suspected child abuse or neglect must contain the following information, **if known**:

- The name, address, and age of the child;
- The name and address of the child's parents, stepparents, guardians, or other persons having custody of the child;
- The nature and extent of the alleged injury or injuries;
- The nature and extent of the alleged neglect;
- The nature and extent of the alleged sexual abuse;
- Any evidence of previous injuries, including their nature and extent; and
- Any other information that may be helpful in establishing the cause of the child's death, injury, or injuries and the identity of the alleged perpetrator or perpetrators.

6.6.4 What is Child Abuse and Neglect?

RCW 26.44.020 defines child abuse or neglect as "sexual abuse, sexual exploitation, or injury of a child by any person under circumstances which cause harm to the child's health, welfare, or safety, excluding conduct permitted under

RCW 9A.16.100; or the negligent treatment or maltreatment of a child by a person responsible for or providing care to the child".

Sexual exploitation includes: allowing, permitting, or encouraging a child to engage in prostitution by any person; or allowing, permitting, encouraging, or engaging in the obscene or pornographic photographing, filming, or depicting of a child by any person.

Negligent treatment or maltreatment is defined as "an act or a failure to act, or the cumulative effects of a pattern of conduct, behavior, or inaction that evidences a serious disregard of consequences of such magnitude as to constitute a clear and present danger to a child's health, welfare, or safety". Evidence of parental substance abuse should be given great weight as a contributing factor to negligent treatment or maltreatment. The fact that siblings share a bedroom is not, in and of itself, negligent treatment or maltreatment. The statute also states that "poverty, homelessness, or exposure to domestic violence as defined in RCW 26.050.010 that is perpetrated against someone other than the child do not constitute negligent treatment or maltreatment in and of itself".

6.6.5 Recognizing Child Abuse and Neglect: Signs and Symptoms [4]

The presence of a single sign does not prove child abuse is occurring in a family; however, when these signs appear repeatedly or in combination researchers should take a closer look at the situation and consider the possibility of child abuse. The following signs may signal the presence of child abuse or neglect.

The Child:

- Shows sudden changes in behavior or school performance.
- Has not received help for physical or medical problems brought to the parents' attention.
- Has learning problems (or difficulty concentrating) that cannot be attributed to specific physical or psychological causes.
- Is always watchful, as though preparing for something bad to happen.
- Lacks adult supervision.
- Is overly compliant, passive, or withdrawn.
- Comes to school or other activities early, stays late, and does not want to go home.

The Parent or Caregiver:

- Shows little concern for the child.
- Denies the existence of—or blames the child for—the child's problems in school or at home.
- Asks teachers or other caretakers to use harsh physical discipline if the child misbehaves.
- Sees the child as entirely bad, worthless, or burdensome.
- Demands a level of physical or academic performance the child cannot achieve.

[4] *Child Welfare Information Gateway, U.S. Department of Health and Human Services (DHHS). This should not be considered as an exhaustive list of signs of child abuse and neglect.*

- Looks primarily to the child for care, attention, and satisfaction of emotional needs.

The Parent /Caregiver and Child:

- Rarely touch or look at each other.
- Consider their relationship entirely negative.
- State that they do not like each other.

6.6.5.1 Common Indicators of Physical Abuse

Consider the possibility of physical abuse when the **child**:

- Has unexplained burns, bites, bruises, broken bones, or black eyes.
- Has fading bruises or other marks noticeable after an absence from school.
- Appears frightened of the parents and protests or cries when it is time to go home.
- Shrinks at the approach of adults.
- Reports injury by a parent or another adult caregiver.

Consider the possibility of physical abuse when the **parent or other adult caregiver**:

- Offers conflicting, unconvincing, or no explanation for the child's injury.
- Describes the child as "evil," or in some other very negative way.
- Uses harsh physical discipline with the child.
- Has a history of abuse as a child.

6.6.5.2 Common Indicators of Neglect:

Consider the possibility of neglect when the **child**:

- Is frequently absent from school.
- Begs or steals food or money.
- Lacks needed medical or dental care, immunizations, or glasses.
- Is consistently dirty and has severe body odor.
- Lacks sufficient clothing for the weather.
- Abuses alcohol or other drugs.
- States that there is no one at home to provide care.

Consider the possibility of neglect when the **parent or other adult caregiver**:

- Appears to be indifferent to the child.
- Seems apathetic or depressed.
- Behaves irrationally or in a bizarre manner.
- Is abusing alcohol or other drugs.

6.6.5.3 Common Indicators of Sexual Abuse:

Consider the possibility of sexual abuse when the **child**:

- Has difficulty walking or sitting.
- Suddenly refuses to change for gym or to participate in physical activities.
- Reports nightmares or bedwetting.
- Experiences a sudden change in appetite.
- Demonstrates bizarre, sophisticated, or unusual sexual knowledge or behavior.
- Becomes pregnant or contracts a venereal disease, particularly if under age 14.
- Runs away.
- Reports sexual abuse by a parent or another adult caregiver.

Consider the possibility of sexual abuse when the **parent or other adult caregiver**:

- Is unduly protective of the child or severely limits the child's contact with other children, especially of the opposite sex.
- Is secretive and isolated.
- Is jealous or controlling with family members.

6.6.5.4 Common Indicators of Emotional Abuse:

Consider the possibility of emotional maltreatment when the **child**:

- Shows extremes in behavior, such as overly compliant or demanding behavior, extreme passivity, or aggression.
- Is either inappropriately adult (parenting other children, for example) or inappropriately infantile (frequently rocking or head-banging, for example).
- Is delayed in physical or emotional development.
- Has attempted suicide.
- Reports a lack of attachment to the parent.

Consider the possibility of emotional maltreatment when the **parent or other adult caregiver**:

- Constantly blames, belittles, or berates the child.
- Is unconcerned about the child and refuses to consider offers of help for the child's problems.
- Overtly rejects the child.

6.6.6 Resources

The Mandatory Reporter's video is available for download on the DSHS Children's Administration website..

Sources: Child Welfare Information Gateway (DHHS, Administration for Children and Families); Washington State Department of Social and Health Services Children's Administration; Revised Code of Washington, as of April 2010.

6.7 REPORTING ABUSE OR NEGLECT OF ELDERLY OR VULNERABLE ADULTS

6.7.1 Who Is Required to Report Abuse or Neglect of Vulnerable Adults?

Mandatory Reporters

Mandatory reporters are professionals identified *by law* who *must* make a report if they have reason to believe that the abuse, abandonment, neglect, or financial exploitation of a vulnerable adult has occurred. Mandatory reporters include:

- DSHS employees
- Law enforcement
- Social workers
- Professional school personnel
- Contracted individual providers caring for a DSHS client
- Employees of a social service, welfare, mental health, home care, hospice, home health, adult day care, and adult day health agency
- Owners or employees of nursing homes, boarding homes, or adult family homes
- Health care providers subject to Title 18 RCW
- Christian Science practitioners
- Financial institutions

Mandatory reporters must also make a report to law enforcement if they suspect a vulnerable adult has been sexually or physically assaulted, or if they have reasonable cause to believe that an act has caused fear of imminent harm. Mandatory reporters may not have to report some types of physical assault between two vulnerable adults RCW 74.34.035(4).

The WSIRB requires researchers to report *all* suspected abuse/neglect of vulnerable adults -- even when the researcher and his/her research staff may not be "mandatory reporters" under Washington State statute.

6.7.2 How Should a Report of Abuse/Neglect Be Made?

There are several ways to report suspicions of abuse or neglect of a vulnerable adult:

Call the DSHS toll-free hotline: 1-866-ENDHARM (voice/TTY). The person answering your call will transfer you to the correct office to report abuse or neglect.

If the vulnerable adult lives in a long-term care facility (nursing home, boarding home, assisted living, or adult family home), call the DSHS Complaint Resolution Unit toll-free hotline at 1-800-562-6078 to report (dedicated TTY: 1-800-624-6186).

If the vulnerable adult lives in their own home or somewhere other than a long-term care facility, call the DSHS Adult Protective Services Office for

your county. APS is located within the DSHS Aging and Disability Services Administration, Home and Community Services Division.

6.7.3 What Information Should Be Included in a Report?

Researchers should ***only*** report what they know, have observed, or issues that cause them to suspect abuse or neglect. They should not "investigate" their suspicions or ask questions of the adult regarding suspected abuse/neglect. The requirement to report suspected abuse/neglect must be described in research consent forms so that study subjects are informed of this potential limit to confidentiality.

Proof of harm is not required in order to make a report. A person who makes a report in good faith is immune from any liability. As soon as a researcher has reason to believe that abuse is occurring, he/she should report as much as possible of the following information, **if known**:

- Name and address of the vulnerable adult;
- Name and address of the legal guardian or alternate decision maker;
- Name of the facility or agency providing care for the vulnerable adult, if any;
- Nature and extent of the abandonment, abuse, exploitation, or neglect;
- Any history of previous abandonment, abuse, financial exploitation, neglect, or self-neglect;
- Identity of the alleged perpetrator, if known;
- Any other information that may be helpful in establishing the extent of the abuse, abandonment, neglect, self-neglect, or financial exploitation of the deceased vulnerable adult.
- Name and address of the person making the report.

6.7.4 Who Would be Considered a Vulnerable Adult?

A vulnerable adult is defined by law as a person:

- 60 years of age or older who has the functional, mental, or physical inability to care for himself or herself; or
- Found incapacitated under chapter 11.88 RCW; or
- Who has a developmental disability as defined under RCW 71A.10.020; or
- Who has been admitted to any facility; or
- who receives services from home health, hospice, or home care agencies licensed or required to be licensed under chapter 70.127 RCW; or
- Receives services from an individual provider.

6.7.5 What is Abuse of Elderly or Vulnerable Adults?

Abuse can happen to a vulnerable adult in their own home, in an adult family home, in a boarding home, or in a nursing facility. It can happen to an adult who is low-income or wealthy, mentally ill or mentally competent, alone or surrounded by family and friends. Abuse, abandonment, exploitation, or neglect may be criminal activity known by a different name under criminal law. For example, exploitation may involve forgery or theft; abuse may be called assault; sexual abuse may be called indecent liberties;

and neglect may be called criminal mistreatment. Adult Protective Services investigators report suspected criminal activity to law enforcement and may work with law enforcement during the investigation.

Physical abuse is intentional bodily injury or physical maltreatment. Some examples include slapping, pinching, choking, kicking, shoving, or inappropriately using drugs or physical restraints.

Sexual abuse is any nonconsensual sexual contact. Any sexual contact between a facility staff person--such as staff in a nursing home, adult family home, boarding home, or supportive living--and a vulnerable adult is considered nonconsensual. Sexual abuse includes unwanted touching, rape, sodomy, coerced nudity, sexually explicit photographing.

Mental mistreatment is deliberately causing mental or emotional pain. Examples include intimidation, coercion, ridiculing; harassment; treating an adult like a child; isolating an adult from family, friends, or regular activity; use of silence to control behavior; and yelling or swearing which results in mental distress.

Neglect occurs when someone, either through action or inaction, deprives a vulnerable adult of care necessary to maintain physical or mental health.

Self-neglect occurs when a vulnerable adult fails to provide adequately for self. A competent person who decides to live his/her life in a manner which may threaten the person's safety or well-being does not come under this definition.

Exploitation occurs when a vulnerable adult or the resources or income of a vulnerable adult are illegally or improperly used for the benefit of someone other than the vulnerable adult.

Abandonment occurs when a vulnerable adult is left without the ability to obtain necessary food, clothing, shelter, or health care.

See RCW 74.34.020 for more detailed definitions.

6.7.6 Abuse and Neglect of Vulnerable Adults: Signs and Symptoms [5]

6.7.6.1 Signs of physical abuse

- bruises, black eyes, welts, lacerations, and rope marks
- broken bones
- open wounds, cuts, punctures, untreated injuries in various stages of healing
- broken eyeglasses/frames, physical signs of being subjected to punishment, and signs of being restrained
- laboratory findings of either an overdose or under-dose of medications
- individual's report of being hit slapped, kicked, or mistreated
- vulnerable adult's sudden change in behavior
- the caregiver's refusal to allow visitors to see vulnerable adult alone

6.7.6.2 Signs of sexual abuse

- bruises around the breasts or genital area
- unexplained venereal disease or genital infections
- unexplained vaginal or anal bleeding
- torn, stained, or bloody underclothing
- an individual’s report of being sexually assaulted or raped

6.7.6.3 Signs of mental mistreatment or emotional abuse

- being emotionally upset or agitated
- being extremely withdrawn and non-communicative or non-responsive
- unusual behavior usually attributed to dementia (e.g., sucking, biting, rocking)
- an individual's report of being verbally or mentally mistreated

6.7.6.4 Indicators of neglect

- dehydration, malnutrition, untreated bed sores, and poor personal hygiene
- unattended or untreated health problems
- hazardous or unsafe living condition or arrangements (e.g., improper wiring, no heat, or no running water)
- unsanitary and unclean living conditions (e.g., dirt, fleas, lice on person, soiled bedding, fecal/urine smell, inadequate clothing)
- an individual’s report of being mistreated

6.7.6.5 Indicators of self-neglect

- dehydration, malnutrition, untreated or improperly attended medical conditions, and poor personal hygiene
- hazardous or unsafe living conditions or arrangements

[5] This should not be considered an exhaustive list of signs of abuse and neglect.

- unsanitary or unclean living quarters (e.g., animal/insect infestation, no functioning toilet, fecal or urine smell)
- inappropriate and/or inadequate clothing, lack of the necessary medical aids
- grossly inadequate housing or homelessness
- inadequate medical care, not taking prescribed medications properly

6.7.6.6 Signs of exploitation

- sudden changes in bank account or banking practice, including an unexplained withdrawal of large sums of money by a person accompanying the individual
- the inclusion of additional names on bank signature card
- unauthorized withdrawal of funds using ATM card
- abrupt changes in a will or other financial documents
- unexplained disappearance of funds or valuable possessions
- bills unpaid despite the availability of adequate financial resources
- forged signature for financial transaction and for the titles of possessions
- sudden appearance of previously uninvolved relatives claiming rights to affairs and possessions
- unexplained sudden transfer of assets to a family member or someone outside the family
- the provision of services that are not necessary
- individual's report of exploitation

6.7.6.7 Signs of abandonment

- desertion of an individual in public place
- desertion of an individual in own home
- individual's report of being abandoned

6.8 CONSENT FORM REQUIREMENTS

Consent and assent forms are only part of the *process* of informed consent. The process of informed consent should be an ongoing, give-and-take discussion during which potential subjects are informed of the research, questions are answered, and voluntary participation is requested. Consent must be requested in an atmosphere and manner that is free of coercion and undue influence, and the process of informed consent must ensure that potential subjects or their legally authorized representatives have sufficient knowledge and time to evaluate whether to participate. Consent forms serve as documentation of the basis for consent and a readily available reference for subjects of what they have agreed to do.

Researchers must use the WSIRB format for all consent and assent forms.

6.8.1 Content

The federal human subjects protection regulations set minimum standards for consent form content (45 CFR 46.116). The WSIRB may require additional information beyond this minimum standard, depending on the research protocol, subject population, or requirements of agency policy or state statute.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The following items are required elements of informed consent, unless the WSIRB approves a waiver of one or more required elements.

Basic elements of informed consent:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

- A description of any reasonably foreseeable risks or discomforts to the subject;

- A description of any benefits to the subject or to others which may reasonably be expected from the research;

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

One or more of the following elements of information should also be provided to each subject, depending on the specifics of the study:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

- Any additional costs to the subject that may result from participation in the research;

- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

- The approximate number of subjects involved in the study.

6.8.2 Reading Levels

Information in consent and assent forms must be "in language understandable to the subject or representative" (45CFR46.116). In general, lay language should be used, and the reading level should be appropriate to the subject population's expected cognitive ability and level of literacy. All recruitment and consent materials should be written in clear, short, declarative sentences. Technical terms should be avoided; if they cannot be avoided, definitions should be provided.

Documents intended for adults should be written at *no higher* than an 8th grade reading level. Documents intended for children should be written at a level appropriate for the lowest age or developmental level of potential research subjects. If the subject population includes individuals with developmental delays, dementia or Alzheimer's disease or other cognitive

difficulties, reading levels should be appropriate to the subjects' expected ability to comprehend.

Researchers should assume that translation of study documents will be required by the WSIRB when a subject population may not be proficient in English. Translations of study documents should be submitted for review only after English versions have been approved by the WSIRB.

6.8.3 Avoiding Undue Influence: Appropriate Consent Form Language

Consent documents should contain objective, factual information about the research. Researchers are advised to avoid terms such as "new" or "novel" when describing research interventions. They should avoid the first person and statements such as "I understand..." which may imply comprehension or undue influence to participate. [What the researcher intends to convey and what the potential subject actually "understands" may be completely different.]

Some examples:

Unacceptable: "Some foster parents will be enrolled in a special program of supportive services and respite care".
Acceptable: "This research will compare a pilot program of support services and respite care to the usual services foster parents can get in their communities."

Unacceptable: "This new medication offers an alternative to the harmful side effects of chemotherapy. It will revolutionize the standard of care for cancer patients."
Acceptable: "The study is testing a drug for cancer to see if it improves patient outcomes and quality of life. We don't know if the study drug will work better or have less side-effects than other drugs used routinely for cancer".

Unacceptable: "If he/she participates in this study, your child's reading level will improve."
Acceptable: "This study will compare two teaching methods for kids in the first through fourth grades. We want to know if these methods improve reading and comprehension".

Unacceptable: "We don't anticipate any risks to you if you participate in this research".
Acceptable: "Interviews take over 3 hours, so you may get bored or restless. You may feel that some of the questions we ask are too personal. You may be concerned that your parents will find out that you had an STD."

Unacceptable: "I understand that if I participate in this research, I waive my right to get compensation for any research-related injuries. The

researchers may use my blood and tissue samples to develop commercial products or tests. By agreeing to participate in this research, I hereby and forever waive my right to financially benefit from any such products or tests."
Acceptable: "I have been told that the researchers have not set aside funds to pay for care if I am injured in this study. I have been told that the researchers don't plan to pay me any money if they use my tissue sample or blood to develop a commercial product".

6.8.4 Format

Consent and assent documents need not be prepared in a more formal consent form template. Depending on the subject population, it may be appropriate to utilize lists or bulleted outlines of study procedures, etc. The format should be user-friendly from the *subject's* point of view.

Depending on the subject population, it may be important to utilize larger font sizes, increase line spacing, and/or incorporate additional "white space", for ease of reading.

Consent documents should be as clear and concise as possible, describing the study, potential risks, procedures, etc. in a straightforward manner. Researchers are required to ensure that subjects read the written consent document (or have it read to them) and that they understand what they are asked to do if they participate in the research.

6.8.5 Sample Language

Researchers often ask the WSIRB for sample consent form language which would meet WSIRB requirements. The following are *examples only*, and may require editing to be consistent with a given research protocol, subject population, etc.

Reporting abuse/neglect of a child: "If we are concerned about child abuse or neglect, we will report it to Child Protective Services".

Reporting abuse/neglect of a vulnerable adult: "If we are concerned about abuse or neglect of a vulnerable adult, we will notify Adult Protective Services".

Handling threats of harm (homicide, suicidal ideation): "If we are concerned that you are a danger to yourself or other people, we will notify the county-designated mental health provider. If there is an imminent threat of harm, we will call the police". OR "If you tell us that you are thinking about hurting yourself or someone else, we will take steps to make sure you or the other person is safe, such as calling the Crisis Line or 911".

Disease reporting: "If your tests/exams reveal X, we are required to report it to the local or state health department. We would report your name, address, test results, diagnosis, and other required information". OR "We will report positive tests for X, along with your name, address, and other required health information to the local or state health department".

Note that the above situations comprise *limits to promises of confidentiality*. In consent and assent documents, such statements should follow text which explains how confidentiality of research data would be maintained. Researchers may wish to use a transition phrase such as, "…There are X exceptions to this promise of confidentiality…"

WSIRB contact: "If you have questions about your rights as a research subject, you may call the Washington State Institutional Review Board at 1-800-583-8488. The Board works to protect the rights of people who take part in research. You do not have to give your name."