

Washington State Agency Policy on Protection of Human Research Subjects

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Human Research Review Section
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FOREWORD


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The Washington State Agency Policy on Protection of Human Research Subjects applies to all research conducted under the terms of Federalwide Assurances that the Department of Social and Health Services (DSHS), the Department of Health (DOH), and the Department of Labor and Industries (L&I) have established with the U.S. Department of Health and Human Services. Formerly known as the *DSHS/DOH Policy on Protection of Human Research Subjects*, the Policy is based on current federal regulations (45 CFR, Part 46) and on applicable Washington State statutes, regulations and state agency policies. Under the Policy, all research involving human subjects in the jurisdiction of these state agencies must be reviewed and approved by the Washington State Institutional Review Board (formerly, the DSHS/DOH Human Research Review Board), or by another institutional review board designated on these agencies' Federalwide Assurances.

The Policy has been revised and updated to reflect new federal requirements in the HIPAA Privacy Rule (45 CFR, Part 164). This Policy has been adopted by these three Washington State Agencies, and shall become effective immediately.



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**Washington State
Department of Social and Health Services
Department of Health
and
Department of Labor and Industries**

**POLICY ON
PROTECTION OF HUMAN RESEARCH SUBJECTS**

I. POLICY

Washington State Agencies that have adopted this policy¹ are responsible for safeguarding the rights and welfare of persons who serve as human subjects in research and related activities sponsored or conducted by these agencies, or whose personal records held by the agencies are disclosed for research purposes. Research procedures must comply with federal regulations for the protection of human subjects (45 CFR, Part 46), with state law on the release of records for research (e.g., Chapter 42.48, Revised Code of Washington), and with rules for the protection of human research subjects codified in the Washington Administrative Code (e.g., Chapter 388-04 WAC).

No service unit or administrative unit in these Washington State Agencies shall permit, or shall participate in, the conduct of research and related activities until the plans or protocols for such activities have been reviewed and approved by the Washington State Institutional Review Board (WSIRB, or Review Board), or by another institutional review board designated on these agencies' Federalwide Assurances, unless the research has been specifically exempted from this review requirement by this policy.

Review of research and related activities by the Review Board shall determine that the rights and welfare of human subjects are adequately protected; that risks to individuals are minimized, are not unreasonable, and are outweighed by the potential benefits to them or by the knowledge to be gained; and that the proposed project design and methods are adequate and appropriate in the light of stated project purposes.

II. APPLICABILITY

This policy applies:

1. Whenever the Washington State Institutional Review Board provides review and oversight of human subject research, regardless of where the research takes place or by whom it is conducted.

¹ Department of Social and Health Services (DSHS), Department of Health (DOH), and Department of Labor and Industries (L&I).

2. Whenever these Washington State Agencies become engaged in human subject research. An agency becomes engaged in research whenever (a) the employees or agents² of the agency intervene or interact with living individuals for purposes of research; (b) the employees or agents of the agency obtain, release, or access individually identifiable private information for purposes of research³; or (c) the agency receives a direct federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

III. POLICY IMPLEMENTATION AND COORDINATION

The Human Research Review Section (HRRS) in the Department of Social and Health Services (DSHS) shall be responsible for providing administrative support to the Review Board, and for the receipt, processing and disposition of all research proposals that require review under the Washington State Agency Policy on Protection of Human Research Subjects. The HRRS shall develop and publish written procedures which implement this policy. Staff in the HRRS shall assist researchers in the preparation of their proposals for review by the Review Board. The administrator of the HRRS shall serve as the Executive Secretary of the Review Board, and shall also be responsible for human research review liaison and coordination with federal regulatory agencies, with other research organizations that maintain federally mandated review procedures, and with Washington State Agency management.

IV. BASIC DEFINITIONS

"Certification" means the official notification by the Executive Secretary of the Washington State Institutional Review Board, or his/her designee, to the investigator, the department, and any agency or organization requiring such certification for regulatory, cooperative research, or funding purposes that the proposed human research activity has been reviewed and approved in accordance with the Washington State Agency Policy on Protection of Human Research Subjects and the Federalwide Assurances of the Washington State Agencies that have adopted this policy.

"Common rule" means the federal regulation for the protection of human subjects currently adopted by seventeen federal agencies. The rule is codified for the Department of Health and Human Services in Title 45 CFR Part 46.

"Disclosure" means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

² Agents include individuals who have contracts or other formal relationships with a Washington State Agency.

³ When individually identifiable records held by a Washington State Agency are disclosed for research purposes per RCW 42.48020(2), or when subjects are recruited from a Washington State Agency facility, the Washington State Agency is engaged in the research and the research requires approval by the WSIRB.

"Federalwide Assurance (FWA)" means the written assurance of compliance with the federal regulations for the protection of human subjects which institutions must provide as a condition for the receipt of federal research funds. Each institution must renew its FWA every three years.

"Health information" means any information created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse that relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual.

"Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

"Individually identifiable" means that a record contains information which reveals or can likely be associated with the identity of the person or persons to whom the information pertains.

"Interaction" includes communication or interpersonal contact between investigator and subject.

"Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

"Investigator" means a research professional or student engaged in the conduct of research under this policy.

"Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Personal records" means any information obtained or maintained by a state agency which refers to a person and which is declared exempt from public disclosure, confidential, or privileged under state or federal law.

"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical

record). Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.

“Protected health information (PHI)” means individually identifiable health information created or received by a health care provider, health plan or health care clearinghouse that is transmitted or maintained in any form or medium.

“Research” means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and services programs may include research activities.

“Review Board” means the Washington State Institutional Review Board (WSIRB), which is the designated institutional review board (IRB) for the Department of Social and Health Services, the Department of Health, and the Department of Labor and Industries. The Washington State Institutional Review Board is comprised of Review Board A and Review Board B.

“Use” means, with respect to individually identifiable information, the sharing, employment, application, utilization, examination, or analysis of such information within the entity that maintains the information.

V. REVIEW BOARD COMPOSITION

Each Review Board shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted within the jurisdiction of these Washington State Agencies. The Review Board shall be 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 human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the Review Board shall be able 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 shall therefore include persons knowledgeable in these areas. The Review Board shall also include persons who are knowledgeable about and experienced in working with vulnerable populations such as children, prisoners, pregnant women, and handicapped or mentally disabled persons.

No Review Board shall consist entirely of men or entirely of women, nor shall it consist entirely of members of one profession. Each Review Board shall include at least one member whose primary concerns are in scientific areas, and at least one member whose

primary concerns are in nonscientific areas. Each Review Board shall include at least one member who is not otherwise affiliated with these Washington State Agencies, and who is not part of the immediate family of a person who is affiliated with these Washington State Agencies.

No Review Board may have a member 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. Review Board members shall disclose any potential conflicts of interest they may have to the Review Board prior to discussion of a research proposal.

The Review Board may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the Review Board. These individuals may not vote with the Review Board.

VI. REVIEW OF RESEARCH BY THE REVIEW BOARD

The Washington State Institutional Review Board shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

The Review Board shall require that information given to subjects as part of informed consent is in accordance with Section XVII of this policy. The Review Board may require that information, in addition to that specifically mentioned in Section XVII, be given to the subjects when in the Review Board's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

The Review Board shall require documentation of informed consent or may waive documentation in accordance with Section XVII of this policy.

The Review Board shall notify investigators and the Washington State Agency program sponsoring the research in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure Review Board approval of the research activity. If the Review Board decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for the decision and give the investigator an opportunity to respond in person or in writing.

The Review Board shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. The Review Board shall have authority to observe or have a third party observe the consent process and the research, and to conduct site visits and interviews to audit the research for compliance with Board-approved procedures.

VII. CRITERIA FOR REVIEW BOARD APPROVAL OF RESEARCH

To approve research covered by this policy, the Washington State Institutional Review Board shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the Review Board should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The Review Board should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects must be equitable. In making this assessment, the Review Board should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section XVI of this policy.
5. Informed consent will be appropriately documented in accordance with, and to the extent required by Section XVI of this policy.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

VIII. ADMINISTRATIVE REVIEW AND APPROVAL

Research covered by this policy that has been approved by the Review Board is also subject to further administrative review and approval by the Washington State Agency program in whose jurisdiction the research is being conducted. Washington State Agency administrative officials may disapprove research that has been approved by the Review Board; however, Washington State Agency administrative officials may not approve the research if it has not been approved by the Review Board. Final approval letters to investigators shall be signed both by the Executive Secretary of the Review Board, or his or her designee, and by the approving Washington State Agency administrative official.

IX. SUSPENSION OR TERMINATION OF REVIEW BOARD APPROVAL OF RESEARCH

The Review Board shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the Review Board's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the Review Board's action and shall be reported promptly to the investigator, to appropriate Washington State Agency officials, and to the DHHS Office for Human Research Protections.

X. EXPEDITED VERSUS FULL BOARD REVIEW

Following initial screening of research proposals by the DSHS Human Research Review Section, research proposals are assigned to one of the following two review categories:

Expedited Review

Under an expedited review procedure, the review may be carried out by the Chair of the Review Board, or by one or more experienced reviewers designated by the Chair from among members of the Review Board. In reviewing the research, the reviewers may exercise all the authorities of the Review Board, except that reviewers may not disapprove the research. A research activity may be disapproved only after review at a convened meeting of the full Review Board.

Applicability

1. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through

the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

2. The categories in this list apply regardless of the age of subjects, except as noted.
3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
4. The expedited review procedure may not be used for classified (i.e., secret) research involving human subjects.
5. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
6. Categories two (2) through eleven (11) pertain to both initial and continuing IRB review.

Research Categories

1. Minor changes in previously approved research during the period for which approval is authorized.
2. Research involving access to identifiable materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis), and which does not involve direct contacts with human subjects. Use or disclosure of identifiable personal information obtained or maintained by a state agency is subject to requirements specified in Chapter 42.48, Revised Code of Washington.
3. Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, provided that:
 - a. The research does not involve use or disclosure of an agency's non-public information for purposes of contacting human research subjects or prospective subjects, and
 - b. The information obtained does not deal with sensitive aspects of the subject's own behavior or experiences, such as illegal conduct, drug use, sexual behavior, or physical, sexual, or emotional abuse, and is not likely to cause the subject undue stress, fatigue, or other psychological or emotional reactions, and either

- c. The information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to subjects, or
 - d. Any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation.
- 4. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviors), where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- 5. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 6. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 7. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for

extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

8. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

9. Collection of data from voice, video, digital, or image recordings made for research purposes.
10. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
11. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

12. Continuing review of research previously approved by the convened IRB as follows:
 - a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. Where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.
13. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through four (4) or categories six (6) through twelve (12) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Any proposal that in a reviewer's judgment exceeds the criteria for expedited review shall be subject to full-Board review and approval.

Full Board Review

All research and related proposals not eligible for expedited review under the foregoing categories are subject to full Board review and certification at a scheduled meeting at which a majority of the members of the Review Board are present, including at least one member whose primary concerns are in a nonscientific area. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

In special circumstances, unscheduled reviews may be conducted by teleconference. Teleconference reviews shall be subject to the same quorum requirements that apply to meetings of the Review Board. Unscheduled review shall be limited to the review of investigator responses to Board-required research clarifications or modifications, to proposals in which delay until a 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, and to Review Board consideration of any reported unanticipated problems or adverse events.

XI. ACTIVITIES EXEMPT FROM POLICY

The DSHS Human Research Review Section is responsible for reviewing preliminary determinations of exemption made by investigators and supervisors, and for making the final determination. Notice of concurrence for all exempt research will be conveyed in

writing to the investigator. All nonexempt research covered by this policy will be forwarded to the Review Board.

Research activities in which the only involvement of human subjects is in one or more of the following categories are exempt from this policy:

1. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs, or procedures for obtaining benefits under those programs, possible changes to or alternatives to those programs, or possible changes in methods or levels of payment for benefits or services under those programs, provided that:
 - a. The research relies entirely on information obtained routinely for program management purposes in the course of, and as part of, the ongoing public benefit or service program; and
 - b. Access to identifiable data used in the research is limited to staff of the agency that manages the program.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, provided that:
 - a. The research does not involve use or disclosure of an agency's non-public information for purposes in contacting human research subjects or prospective subjects; and
 - b. The information obtained does not deal with sensitive aspects of the subject's own behavior or experiences, such as illegal conduct, drug use, sexual behavior, or physical, sexual, or emotional abuse, and is not likely to cause the subjects undue stress, fatigue, or other psychological or emotional reactions; and
 - c. The information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to subjects; and
 - d. Any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; and
 - e. The research does not involve collecting information from subjects who are unable to provide legal consent for their own participation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 3 of this section, if the human subjects are elected or appointed public officials or candidates for public office.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is used by or disclosed to the researchers in such a manner that it is not identifiable, e.g., it does not contain information which reveals or can likely be associated with the identity of the person or persons to whom the information pertains.

All human subjects research which is exempt as specified in 1-4 of this section, must be conducted in accordance with: (1) The Belmont Report⁴; (2) Washington State Agency administrative procedures to ensure valid claims of exemption; and (3) orderly accounting for such activities.

XII. PROPOSAL SUBMISSION REQUIREMENTS

Investigators are urged to consult the DSHS Human Research Review Section regarding application and review requirements before completing and submitting their proposals. The Washington State Institutional Review Board has Cooperative Agreements with the University of Washington and the Fred Hutchinson Cancer Research Center IRBs which may affect the review of research in the joint jurisdiction of these institutions. All proposals must be submitted to the Review Board on the official application forms available on the Review Section's website: <http://www1.dshs.wa.gov/rda/hrrs/>. Project narratives developed for applications to a federal, public, or private funding source will be accepted in lieu of Form E (Project Description) of the application if they provide all the required information. Applicants are urged to note the instructions in the application forms and to provide in an addendum any required information not included in their project narrative.

Proposals found incomplete or otherwise not in compliance with the instructions in the application forms may be returned to the applicant upon initial screening in the Human Research Review Section.

Investigators whose agency of affiliation (e.g., university) maintains an accredited human research review process must submit their proposals to their institution's human research review office prior to submitting the proposal to the Washington State Institutional Review Board. However, the investigator is not required to obtain final institutional review board approval from his or her home institution prior to submitting the proposal to the Review Board.

XIII. APPLICATIONS FOR FEDERAL FUNDING

Under the Common Rule, federal agencies require review and approval of research proposals involving human subjects by the designated institutional review board (IRB) of

⁴ The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.

the applicant's institution prior to the initiation of research involving human subjects. Investigators applying for federal funding are responsible for confirming the specific review requirements with their federal project officer, and for submitting certification of IRB approval for all activities involving human subjects to the funding agency prior to commencement of research activities.

Under "just-in-time" procedures adopted by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), certification of IRB approval is not required at the time of application, but may be deferred until just prior to funding and before contact with human subjects. For NIH and CDC applications, investigators should submit their proposal to the Review Board when they are informed that the proposal has received a score in the fundable range or otherwise learn that the proposal may be funded.

Applications for funding to all other federal agencies for activities involving research with human subjects must be reviewed and approved by the Review Board no later than 60 days following submission of the application to the funding agency.

Certain types of applications for funding may be submitted to federal agencies with the knowledge that human subjects may be involved within the period of support, but definite plans for research are not described in the application. These include institutional-type grants when selection of specific projects is the responsibility of the applicable Washington State agency; research training grants in which activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, or the prior completion of other, defined activities. Such proposals will be approved by the Review Board on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated. Investigators will submit certification of all subsequent approvals to the funding agency prior to initiating activities involving human subjects.

XIV. INVESTIGATOR QUALIFICATION REQUIREMENTS

Investigators must provide evidence of competence and experience in the proposed research area. Professional research applications will be considered only if they include adequate documentation of the applicant's professional training and experience.

The only exception to this policy is in the case of student projects, i.e., projects serving professional research training purposes for graduate students (up to and including candidates for the Master degree) currently enrolled in an academic degree curriculum. Research proposals submitted by students must be signed by the chair of their academic department or the chair of their thesis/dissertation committee, and by the director of the university's or college's institutional review board office. Research applications by candidates for a doctoral degree (dissertation research) and by post-doctoral trainees are considered professional applications and are subject to all departmental application and review standards that apply to professional research activities in general.

XV. INVESTIGATOR'S RESPONSIBILITY

Investigators who conduct research under this policy have the following responsibilities. Failure to fulfill these responsibilities may result in suspension or termination of Review Board approval to conduct research.

1. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all the provisions of this policy.
2. Investigators who intend to involve human research subjects will not make the final determination of exemption from applicable federal regulations from this policy.
3. Investigators will initiate study activities only after written certification of study approval from the Review Board has been received.
4. Investigators are responsible for adherence to contact and consent procedures approved by the Review Board and for providing a copy of the Board-approved consent document to each subject at the time of consent, unless the Review Board has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the Review Board.
5. Investigators will promptly report proposed changes in previously approved human subject research activities to the Review Board. The proposed changes will not be initiated without Review Board review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
6. Investigators are responsible for reporting progress of approved research to the DSHS Human Research Review Section, as often as and in the manner prescribed by the approving Review Board on the basis of risks to subjects, but no less than once per year.
7. Investigators will promptly report to the Review Board any serious adverse events or unanticipated problems involving risks to subjects or others.
8. Investigators are responsible for disclosing to the Review Board whether they have a significant financial interest in the research, including information on the nature and/or monetary value of the interest.
9. Investigators who are not employees or agents of the Washington State Agencies that have adopted this policy must sign a formal written agreement of commitment to the relevant human subject protection policies and IRB oversight of these Washington State Agencies.

XVI. EDUCATION AND TRAINING IN THE PROTECTION OF HUMAN SUBJECTS

Members and staff of the Review Board, and investigators who are subject to this policy, shall complete specified education and training in the protection of human research subjects. Review Board members and staff shall complete this educational requirement within three months of their initial appointment to the Review Board or employment in the Review Section. Investigators shall provide documentation of their completion of appropriate education and training in the protection of human research subjects with their application for initial or continuing review of their research by the Review Board. Washington State Agency investigators must complete appropriate re-training in the protection of human research subjects every three years. Information about how this requirement may be satisfied is posted on the DSHS Human Research Review Section website at: <http://www1.dshs.wa.gov/rda/hrrs/>.

XVII. GENERAL REQUIREMENTS FOR INFORMED CONSENT

Participation of subjects in research must be voluntary. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless this investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

An investigator shall seek informed consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence. The information that is given to the subject or to the representative shall be in language understandable to the subject or representative. No informed consent, whether oral or written, may include any exculpatory language through which the subjects or the representative is made to waive or appear to waive any of the subject's legal rights, or which releases or appears to release the investigator or Washington State Agencies from liability for negligence.

1. Basic Elements of Informed Consent

Except as provided in subsections 3 or 4 of this Section, in seeking informed consent the following information shall be provided to each subject or subject's representative:

- a. 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;
- b. A description of any reasonably foreseeable risks or discomforts to the subject;
- c. A description of any benefits to the subject or to others which may reasonably be expected from the research;

- d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 - e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - f. For research involving more than minimal risk, an explanation as to whether any compensation and medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
 - g. An explanation of whom to contact for answers to questions about the research and subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
 - h. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at anytime without penalty or loss of benefits to which the subject is otherwise entitled.
2. When appropriate, one or more of the following additional elements of information shall also be provided to each subject:
- a. A statement that, regardless of other provisions for protecting confidentiality of information obtained during the research, professionals conducting research under the state agencies' jurisdiction are required to report suspected abuse or neglect of children and dependent adults;
 - b. 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;
 - c. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - d. Any additional costs to the subject that may result from participation in the research;
 - e. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
 - f. 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
 - g. The approximate number of subjects involved in the study.
3. The Review Board may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or

waive the requirement to obtain informed consent, provided the Review Board finds and documents that:

- a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - i. programs under the Social Security Act, or other public benefit or service programs;
 - ii. procedures for obtaining benefits or services under those programs;
 - iii. possible changes in or alternatives to those programs or procedures;
or
 - iv. possible changes in methods or levels of payment for benefits or services under those programs; and
 - b. The research could not practicably be carried out without the waiver or alteration.
4. The Review Board may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the Review Board finds and documents that:
- a. The research involves no more than minimal risk to the subjects;
 - b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c. The research could not practicably be carried out without the waiver or alteration;
 - d. Whenever appropriate, the subjects will be provided with additional information after participation.
5. Except as provided in subsection 6 of this Section, informed consent shall be documented by the use of a written consent form approved by the Review Board and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. The consent form may be either:
- a. A written consent document that embodies the elements of informed consent required by subsection 1 of this Section. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

- b. A "short form" written consent document stating that the elements of informed consent required by subsection 1 of this Section have been presented orally to the subject or to the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the Review Board shall require a written summary of what is to be said to the subject or the representative. Only the short form itself need be signed by the subject or representative. However, both the investigator and the witness shall sign both the short form and the summary, and the person actually obtaining consent shall sign the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
6. The Review Board may waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if it finds either:
 - a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject would be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - b. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

In cases where the documentation requirement is waived, the Review Board may require the investigator to provide the subjects with a written statement regarding the research.

XVIII. AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH

Unless an institutional review board approves a waiver of authorization, use and/or disclosure of protected health information for research in Washington State is subject to submission of a signed authorization to the entity that maintains the information. A valid authorization must include the following elements:

1. A specific description of the information to be used or disclosed;
2. The name of the person or class of persons authorized to approve the requested use or to make the requested disclosure;
3. The name of the person or class of persons for whom the requested use is approved or to whom the requested disclosure is made;
4. A description of each purpose of the use or disclosure;

5. A statement of the ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization;
6. A statement explaining the extent to which information disclosed is subject to redisclosure by the recipient and no longer protected under state and/or federal laws;
7. A statement that the individual may revoke the authorization in writing, except to the extent that the entity has taken action in reliance on the authorization;
8. An expiration date or expiration event that relates to the individual or the purpose of the use or the disclosure⁵;
9. The signature of the individual granting the authorization and the date.

In addition, the authorization must be written in plain language. A copy of the signed authorization must be retained by the entity that approves the requested use or makes the requested disclosure, and a copy must be provided to the individual.

An authorization for the use and/or disclosure of protected health information for research may be combined with any other type of written permission for the same research study; e.g., the required elements of a valid authorization may be combined with the required elements for informed consent for study participation in one consent document. Alternatively, authorizations for use and/or disclosure of PHI may be prepared on a document separate from the research consent form.

XIX. WAIVER OF AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION AND/OR INDIVIDUALLY IDENTIFIABLE PERSONAL RECORDS FOR RESEARCH

The Review Board may waive authorization or consent for use and/or disclosure of protected health information and other individually identifiable personal records only if the Review Board documents that the following criteria have been met:

1. The research involves no more than minimal risk to subjects ([45 CFR 46.116\(d\)\(1\)](#) and [45 CFR 164.512\(i\)\(2\)\(ii\)\(A\)](#));
2. The waiver of authorization will not adversely affect the rights and welfare of the subjects ([45 CFR 46.116\(d\)\(2\)](#));

⁵ Washington State law (RCW 70.02.030) prohibits an authorization from permitting the disclosure of health care information relating to future health care that the patient receives more than ninety days after the authorization was signed. Thus, by Washington law, the authorization expires ninety days after it is signed; after that date, a researcher must either obtain another authorization from the subject, or request a waiver of authorization from the institutional review board.

3. The research could not practicably be carried out without the waiver of authorization and without access to and use of the protected health information and/or individually identifiable personal records ([45 CFR 46.116\(d\)\(3\)](#), [45 CFR 164.512\(i\)\(2\)\(ii\)\(B\)\(C\)](#), [RCW 70.02.050\(g\)\(ii\)](#), and [RCW 42.48.020\(2\)\(a\)](#));
4. Whenever it is appropriate, subjects will be provided with additional pertinent information about the research and/or waiver of authorization for use and/or disclosure after the information is disclosed ([45 CFR 46.116\(d\)\(4\)](#));
5. An adequate plan to protect the identifiers from improper use and/or disclosure and to protect identifiable information from redisclosure has been described ([45 CFR 164.512\(i\)\(2\)\(ii\)\(A\)\(1\)](#), [RCW 70.02.050\(g\)\(iii\)](#) and [RCW 42.48.020\(2\)\(c\)\(i\)](#));
6. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research has been described ([45 CFR 164.512\(i\)\(2\)\(ii\)\(A\)\(2\)](#), [RCW 70.02.050\(g\)\(v\)](#), and [RCW 42.48.020\(2\)\(c\)\(iii\)](#));
7. The research is of sufficient importance to outweigh the intrusion into the privacy of the individual that would result from disclosure of his/her protected health information and/or identifiable personal records ([RCW 70.02.050\(g\)\(i\)](#) and [RCW 42.48.020\(2\)\(c\)\(i\)](#));
8. Written assurance is provided that the protected health information and/or individually identifiable personal records will not be reused for other purposes or disclosed to any other person or entity, except as specifically required or permitted by law and approved by the Review Board ([45 CFR 164.512\(i\)\(2\)\(ii\)\(A\)\(3\)](#) and [RCW 42.48.020\(2\)\(c\)\(iv\)](#));
9. Written assurance is provided that no individual whose protected health information and/or individually identifiable personal records is used in the research will be identified in any written report resulting from the research ([RCW 70.02.050\(g\)\(iv\)](#) and [RCW 42.48.020\(2\)\(c\)\(ii\)](#)).

XX. USE AND DISCLOSURE OF WASHINGTON STATE AGENCY PERSONAL RECORDS FOR RESEARCH

In addition to the requirements in Section XIX, above, the Review Board may approve research use and/or disclosure of Washington State Agency personal records⁶ without the authorization or consent of the persons to whom the records pertain only when all the following conditions have been met:

1. The disclosure does not violate federal law or regulation;

⁶ Protected health information is included in the definition of personal records.

2. The recipient of the individually identifiable records or record information will not use the information to contact or attempt to contact any person identified in the record or record information, unless and until the state agency obtains prior consent from the person to whom the record pertains, or at a minimum, provides prior written notification to the person to whom the record pertains, and allows a reasonable amount of time for the person to deny the state agency permission to disclose the information for purposes of being contacted;
3. Provision of the individually identifiable records or record information would not be unacceptably burdensome to ongoing departmental operations; and
4. The applicable Washington State Agency negotiates with the research professional receiving the records or record information a written and legally binding Confidentiality Agreement prior to disclosure. The Agreement shall:
 - a. Specify the information sought and the conditions under which the researcher will have access to or copies of individually identifiable records or record information;
 - b. Establish specific safeguards to assure the continued confidentiality and security of the records or record information;
 - c. Ensure that the research professional will report or publish research findings and conclusions in a manner that does not permit identification of the person whose record was used, and that research reports and publications will not include photographs or other visual representations contained in personal records;
 - d. Establish that the research professional will destroy the individual identifiers associated with the records or record information as soon as the purposes of the research project have been accomplished and notify the applicable Washington State Agency to this effect in writing;
 - e. Prohibit any subsequent disclosure of the records or record information in individually identifiable form except as provided by law;
 - f. Provide for the signature of the research professional, of any of the research professional's team members who require access to the information in identified form, and of the appropriate Washington State Agency official authorized to approve disclosure of identifiable records or record information for research purposes.

XXI. FINAL PROJECT REPORT REQUIREMENT

Approval of research and related proposals is contingent on the investigator's agreement to submit to the DSHS Human Research Review Section a report on his/her completed project for distribution and/or publication by Washington State Agencies at their discretion.

Distribution and/or publication by a Washington State Agency does not preclude the author's publication of the research in a professional journal. Most professional journals permit duplicate publication when research is conducted in cooperation or under contract with a governmental agency and requires publication in that agency's bulletin series.

XXII. PUBLICATION RIGHTS

Unless otherwise mutually agreed to, a non-state agency employed investigator may publish at his or her own expense the results of his or her research without prior review by the Washington State Agency, provided that such publication acknowledges Washington State Agency participation or cooperation, and provided further that such participation or cooperation does not imply endorsement of the publication. Upon request, the investigator shall furnish ten copies of any such publication to the Washington State Agency.

XXIII. COMPLIANCE WITH FUTURE CHANGES IN DHHS REGULATIONS (45 CFR 46)

The administrator of the DSHS Human Research Review Section shall be responsible for advising Washington State Agencies of future changes in federal human research review policy and regulations. If Washington State Agencies find that changed federal regulations fail to meet minimum requirements for the adequate protection of its clients, they will adopt a more restrictive version of the regulations and inform the DHHS Office for Human Research Protections of this action.

CITATIONS

The Policy on Protection of Human Research Subjects is based on federal regulations and guidelines, state statutes and regulations, departmental administrative policies, and the departments' Federalwide Assurance with the Department of Health and Human Services. These documents are cited below, along with guidelines for distinguishing between public health research and public health non-research activities. Most of these documents are on the DSHS Human Research Review Section website at <http://www1.dshs.wa.gov/rda/hrrs/>.

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

Guidelines for Defining Public Health Research and Public Health Non-Research, Centers for Disease Control and Prevention, 1999.

