

Washington State Agency Policy on Protection of Human Research Subjects

July 1, 2020

Human Research Review Section
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FOREWORD

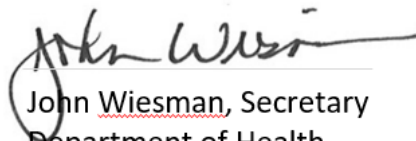
July 1, 2020

The Washington State Agency Policy on Protection of Human Research Subjects applies to all research conducted under the terms of Federalwide Assurances that the Washington State Department of Social and Health Services (DSHS), Department of Health (DOH), Department of Corrections (DOC), Health Care Authority (HCA), Office of Financial Management (OFM), Department of Children, Youth, and Families (DCYF) and the Department of Labor and Industries (L&I) have established with the U.S. Department of Health and Human Services. This Policy is based on current federal regulations (45 Code of Federal Regulations (CFR), Part 46) and on applicable Washington State statutes, regulations, and Agency policies. Under this Policy, all research involving human subjects in the jurisdiction of the State Agencies subject to RCW 42.48 must be reviewed and approved by their designated institutional review board, the Washington State Institutional Review Board (WSIRB).

This Policy has been revised and updated to reflect current federal requirements in 45 CFR, Part 46 Protection of Human Subjects. This Policy has been adopted by these Washington State Agencies, and shall become effective immediately. Should additional Washington State Agencies come under the jurisdiction of WSIRB, those Agencies will adopt this Policy as well.



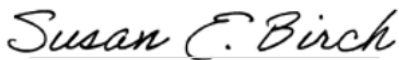
Cheryl Strange, Secretary
Department of Social and
Health Services



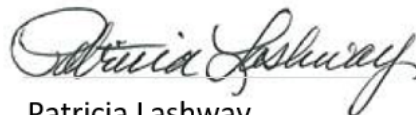
John Wiesman, Secretary
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Susan E. Birch, Director
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**Washington State
Department of Social and Health Services
Department of Health
Department of Corrections
Health Care Authority
Office of Financial Management
Department of Children, Youth, and Families
and
Department of Labor and Industries**

**WASHINGTON STATE AGENCY POLICY ON
PROTECTION OF HUMAN RESEARCH SUBJECTS**

I. POLICY

Washington State Agencies have adopted this policy by selecting the Washington State Institutional Review Board (WSIRB) as their institutional review board of record. These agencies are responsible for safeguarding the rights and welfare of persons who serve as human subjects in research and related activities sponsored, conducted by these agencies, or whose employees' records or the personal records held by the agencies are disclosed for research purposes. Research procedures must comply with federal regulations for the protection of human subjects (e.g. 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). WSIRB will apply the Common Rule regulations to all studies, including studies that are not federally funded and/or those that are Food and Drug Administration (FDA) regulated research. FDA-regulated research will be reviewed in accordance with both 45 and 21 CFR.

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), 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.
2. Whenever these Washington State Agencies become involved in human subject research.

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 and other submissions 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 advise 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 coordination and communication with federal regulatory agencies, with other research organizations that maintain federally mandated review procedures, and with Washington State Agency management.

IV. BASIC DEFINITIONS

"Agency(ies)" means any Washington State Agency that has adopted this policy.

"Agents" means individuals acting on behalf of an agency (or other institution), exercising institutional authority or responsibility, or performing institutionally designated activities. Agents may include employees, contractors, sub-contractors, collaborators, etc.

"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.

"Children" are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

“Clinical Trial” refers to a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

“Conduct” means the carrying out of activities involved in human subjects research. Investigators are responsible for ongoing requirements in the conduct of approved research including, but not limited to:

- Obtaining and documenting informed consent of subjects or subjects’ legally authorized representatives prior to the subjects’ participation in the research, unless these requirements have been waived by the WSIRB;
- Obtaining prior approval from the WSIRB for any modifications of the previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects;
- Ensuring that progress reports and requests for continuing review and approval are submitted to the WSIRB in accordance with the policies, procedures, and actions of the WSIRB;
- When applicable, providing to the WSIRB prompt reports of any unanticipated problems involving risks to subjects or others;
- Providing to the WSIRB prompt reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the WSIRB; and
- Notifying the WSIRB of study closure.

“Consent” means the active process beginning with the initial approach of an investigator to the potential subject (e.g., through a flyer, brochure, or any advertisement regarding the research study) and continuing until the completion of the research study. Informed consent must be legally effective and prospectively obtained.

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

“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.

“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: 1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

“Identifiable biospecimen” is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

“Identifiable private information” is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the 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.

“Institution” means any public or private entity, department, or agency (including federal, state, or other agencies)

“Interaction” includes communication or interpersonal contact between investigator and human subject.

“Intervention” includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

“Investigator” means a research professional, student, or consultant involved in the design, conduct, or reporting of research.

“Involvement” refers to a set of criteria based on Washington State law and used to identify research that must obtain WSIRB review. An agency becomes involved in research whenever:

- the employees or agents of the agency intervene or interact with living individuals for purposes of research;
- the employees or agents of the agency obtain, release, disclose, or access individually identifiable private information for the purposes of research per RCW 42.48.020;
- the agency receives a direct federal award through a grant, contract, or cooperative agreement to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor, collaborator, or an agent; or
- subjects are recruited from a Washington State Agency facility, or when any research activities involve Washington State Agency clients, beneficiaries, patients, wards, or employees as human subjects, except for research aimed at a broader subject population that only incidentally includes these populations.
- Determinations regarding involvement will be made at the discretion of the WSIRB in consultation with the applicable Agency.

“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. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research.

“Limited review” refers to a category of exempt review which applies only to certain types of exempted studies and focuses on privacy and confidentiality protections.

“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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

“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.

“Public Health Authority” refers to an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

“Research” means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that 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).

“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. EXEMPT RESEARCH AND OTHER ACTIVITIES

Research activities in which the only involvement of human subjects will be in one or more of the categories below in this subsection, are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

The DSHS Human Research Review Section is responsible for reviewing preliminary determinations of exemptions under the policy and activities that are determined not to be human subject research made by investigators and supervisors via submission of an Exempt Determination Request. The Review Staff will make the final determination and convey the determination in writing to the investigator. All research that is ineligible for an exempt determination or a determination of not human subjects research covered by this policy will be forwarded to the Review Board when the investigator submits an Initial Research Application.

Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

Subpart B. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

Subpart C. The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Subpart D. The exemptions at paragraphs 1, 4, 5, 6, 7, and 8 of this Section of this policy (below) may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs 2(a) and (b) of this Section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph 2(c) of this Section may not be applied to research subject to subpart D.

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, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or

observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and WSIRB conducts a limited IRB review.
3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
- (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and WSIRB conducts a limited IRB review.

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - (a) The identifiable private information or identifiable biospecimens are publicly available;
 - (b) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - (c) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 - (d) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information it is subject to Federal privacy laws.
5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of Federal department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs. Including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
 - (a) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
6. Taste and food quality evaluation and consumer acceptance studies.
7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable

biospecimens for potential secondary research use if WSIRB conducts a limited IRB review.

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use if the following criteria are met:
 - (a) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with Section XIII of this policy;
 - (b) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with Section XIV of this policy;
 - (c) WSIRB must conduct limited IRB review and make the determination required by Section IX of this policy and makes the determination that the research to be conducted is within the scope of the broad consent; and
 - (d) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

For categories 7 and 8 to be considered by the WSIRB, the investigator must provide documentation from the applicable state agency(ies) that the agency(ies) has/have appropriate policies and procedures in place to manage the requirements of broad consent, i.e. to maintain the list of subjects who have refused to participate and not contact those individuals again for similar studies. WSIRB cannot grant a waiver of consent for use of identifiable material for any individual who has refused participation.

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

The DSHS Human Research Review Section reviews projects that may not meet the definition of human subjects research. Among the wide variety of projects that may not involve human subjects research, the following specific activities are considered not research:

- Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship) including the collection and use of information, that focus directly on the specific individuals about whom the information is collected;
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or

conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes; and
- Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

VI. REVIEW BOARD COMPOSITION

The 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 (professional competence), and the diversity of its members, including 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.

The Review Board shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The Review Board shall therefore include or obtain consultation from persons knowledgeable in these areas as appropriate. The Review Board shall also include persons who are knowledgeable about and experienced in working with subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

The 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. The 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.

The Review Board may not 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 that require expertise beyond or in addition to that available on the Review Board. These individuals may not vote with the Review Board.

VII. 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), accept, decline, or disapprove all research activities covered by this policy including exempt research and other activities under this policy.

The Review Board shall require that information given to subjects or their legally authorized representatives, when appropriate, as part of informed consent is in accordance with Section XIII of this policy. The Review Board may require that information, in addition to that specifically mentioned in Section XIII, 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 XIII of this policy.

The Review Board shall notify investigators 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 may conduct continuing review of research at intervals appropriate to the degree of risk, not less than once per year. Revised Code of Washington 42.48.020 requires ongoing monitoring of studies within WSIRB's jurisdiction to ensure confidentiality and security of State data for research. The State requirements include "...specific safeguards to assure the continued confidentiality and security of individually identifiable records or record information..." as a condition for allowing research professionals access to State records. This language is also in existing Confidentiality Agreements. If no agency included in RCW 42.48 is involved in the research, WSIRB has the option to determine that continuing review of the research is not required.

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, or continued compliance with regulations.

VIII. EXPEDITED REVIEW PROCEDURES FOR CERTAIN KINDS OF RESEARCH INVOLVING NO MORE THAN MINIMAL RISK, AND FOR MINOR CHANGES IN APPROVED RESEARCH

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 Review Board. The following is a list of categories of research that may be reviewed by the WSIRB through this expedited review procedure. The list may be updated in the future to align with updates to the expedited review categories found in the Common Rule. The WSIRB staff will advise the Review Board of all submitted proposals that have been reviewed under the expedited procedure at the next regularly scheduled convened meeting.

Applicability

Research activities that:

- present no more than minimal risk to human subjects;
- Present minor changes in previously approved research during the period (of one year or less) for which approval is authorized;
- for which limited IRB review is a condition of exemption under Section V of this policy.

Expedited Categories

1. 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.

2. 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.
3. 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.
4. 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 subject's 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.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. 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 behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
8. 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.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) 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.

Full Board Review

Any proposal that in a reviewer's judgment exceeds the criteria for expedited review or proposals not eligible for expedited review under the foregoing categories shall be subject to review and approval at a convened meeting of the Review Board.

IX. CRITERIA FOR REVIEW BOARD APPROVAL OF RESEARCH

1. To approve research covered by this policy, the Washington State Institutional Review Board shall determine that all of the following requirements are satisfied:
 - a. Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - b. 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 (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
 - c. 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. The Review Board should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
 - d. 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 XIII of this policy.
 - e. Informed consent will be appropriately documented in accordance with, and to the extent required by Section XIII of this policy.
 - f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 - h. For purposes of conducting the limited IRB review required by Section V of this policy, the IRB need not make the determinations at paragraphs (a) through (g) of this Section (above), and may make the following determinations:

- Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained;
 - Broad consent is appropriately documented or waiver of documentation is appropriate; and
 - If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
2. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
3. Investigator Qualification Requirements
- a. Investigators must provide evidence of competence and experience in the proposed research area. Investigators must also provide documentation of any conflicts of interest and documentation of current human subjects protection training. Research applications will be considered only if they include adequate documentation of the applicant's professional training and experience.
 - b. The only exception to this policy is in the case of student projects, i.e., projects serving professional research training purposes for graduate students currently enrolled in an academic degree curriculum. Research proposals submitted by students must name the chair of their academic department or the chair of their thesis/dissertation committee.
4. 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.
- a. 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.
 - b. Investigators who submit to WSIRB and intend to involve human research subjects will not make the final determination of exemption from applicable federal regulations from this policy.

- c. Investigators will initiate study activities only after certification of study approval has been received from the Review Board and all requirements have been met.
 - d. 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.
 - e. Investigators will promptly request 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.
 - f. Investigators are responsible for reporting progress of approved research to the WSIRB, as often as and in the manner prescribed by the Review Board on the basis of risks to subjects.
 - g. Investigators will promptly report to the Review Board any instances of non-compliance, serious adverse events, or unanticipated problems, involving risks to subjects or others.
 - h. 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.
5. 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 with WSIRB. Investigators shall provide documentation of their completion of appropriate education and training in the protection of human research subjects with their application for initial review of their research by the Review Board. Investigators that are added to a study after initial approval is granted must submit documentation of their completion of appropriate education and training in the protection of human research subjects at the time that the proposed change in staffing is submitted to the Review Board. . Information about how this requirement may be satisfied is posted on the DSHS Human Research Review Section website..

X. 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 involved Washington State Agency(ies). Washington State Agency administrative officials may decline to allow Agency involvement in 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. The Executive Secretary of the Review Board, or their designee, and by the approving Washington State Agency administrative official shall jointly indicate final approval to the investigator.

XI. 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.

XII. COOPERATIVE RESEARCH

Cooperative research projects involve more than one institution. If a Washington State Agency subject to RCW 42.48 is one of the institutions involved in a cooperative research project, the agency's standing human research review board is required to review the research proposal in accordance with RCW 42.48.020. Therefore, Washington State Institutional Review Board does not cede review of proposals in its jurisdiction to another IRB. However, other IRBs can enter into a reliance agreement with WSIRB to avoid duplication of effort. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

XIII. GENERAL REQUIREMENTS FOR INFORMED CONSENT

Participation of subjects in research must be voluntary. Before involving a human subject in research covered by this policy an investigator shall obtain 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 legally authorized representative sufficient opportunity to discuss and 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 legally authorized representative shall be in language understandable to the subject or legally authorized representative.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitate comprehension.

Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

No informed consent may include any exculpatory language through which the subjects or the legally authorized 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, the sponsor, the institution, or its agents from liability for negligence.

Basic Elements of Informed Consent

Except as provided in the General Waiver or Alteration of Consent in this Section, in seeking informed consent the following information shall be provided to each subject or subject's legally authorized representative:

1. 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;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. 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;

7. 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
8. 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.
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements of Informed Consent

The Review Board may require one or more of the following additional elements of information to be provided to each subject:

1. 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) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;

7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Elements of Broad Consent

The Review Board may approve a consent procedure for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) as an alternative to the informed consent requirements above, also known as "broad consent" provided that the broad consent procedure contains:

1. The information required in sections 2, 3, 5, and 8 of Basic Elements of Informed Consent, and, when appropriate, the information required in sections 7 and 9 of Additional Elements of Informed Consent of this policy;
2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens;
3. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
4. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained, and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes;
5. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

6. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
7. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

General Waiver or Alteration of Consent

Waiver

WSIRB may waive the requirement of informed consent for research within General Requirements for Informed Consent; Basic Elements of Informed consent, or Additional Elements of Informed Consent (above), provided that WSIRB satisfies the criteria listed in the Requirements for Waiver or Alteration (below). If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements in Elements of Broad Consent, and refused to consent, the WSIRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

Alteration

WSIRB may approve a consent procedure that omits some, or alters, some or all, of the elements of informed consent set forth in Basic Elements of Informed consent, or Additional Elements of Informed Consent (above), provided the WSIRB satisfies the criteria listed in the Requirements for Waiver or Alteration (below). If a broad consent procedure is used, WSIRB may not omit or alter any of the elements required under Elements of Broad Consent.

Requirements for waiver and alteration

In order for WSIRB to waive or alter consent as described in this subsection, the WSIRB must find and document that:

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials

In order for the WSIRB to waive or alter consent for these specific programs, the WSIRB must find and document that:

1. 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: (a.) Public benefit or service programs; (b.) Procedures for obtaining benefits or services under those programs; (c.) Possible changes in or alternatives to those programs or procedures; or (d.) Possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

Posting of clinical trial consent form

For each clinical trial conducted or supported by a Federal department or agency, one WSIRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal website that will be established as a repository for such informed consent forms.

If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

The informed consent form must be posted on the Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

XIV. Documentation of informed consent

Except as provided below in this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

Except as provided below in this section, the informed consent form may be either of the following:

1. A written informed consent form that meets the requirements Section XIII of this policy. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.
2. A short form written informed consent form stating that the elements of informed consent required by Section XIII of this policy have been presented orally to the subject or the subject's legally authorized representative, and that the key information required was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

Exception to Documentation of Consent

WSIRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds: any of the following:

1. That the only record linking the subject and the research would be the informed consent form document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
2. 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 of the research context; or
3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the WSIRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

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

Unless the WSIRB 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 disclosure;
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.

XVI. 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;
2. The waiver of authorization will not adversely affect the rights and welfare of the subjects;
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;
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;
5. An adequate plan to protect the identifiers from improper use and/or disclosure and to protect identifiable information from redisclosure has been described;
6. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research has been described;
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;
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; and
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.

XVII. WAIVER OF AUTHORIZATION OR CONSENT FOR SCREENING, RECRUITING, OR DETERMINING ELIGIBILITY

The Review Board may waive authorization or consent for use and/or disclosure of protected health information and other individually identifiable personal records **for the**

purposes of screening, recruiting, or determining eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

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

In addition to the requirements in Section XVI, above, the Review Board may approve research use and/or disclosure of Washington State Agency personal records 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;
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.

XIX. FINAL PROJECT REPORT REQUIREMENT AND PUBLICATION RIGHTS

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 their completed project.

Prior to publication or report of findings, the investigator must first contact the State Agency(ies) involved in the research to determine the Agency's policy regarding publication. Any publication must be at the investigator's own expense. Any such publication must acknowledge that the inclusion of a Washington State Agency does not imply endorsement of the publication or the research. Upon request, the investigator shall furnish a copy of any such publication to the Washington State Agency.

XX. 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.

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 nonresearch activities.

Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects, as revised July 19, 2018

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

HCA Policy 1-12, Human Research Review Policy

DOC Policy 260.050

OFM Policy 1.14, Human Research Review Policy

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