WHITWORTH
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Whitworth University Policy for the Protection of Human Subjects in Research

Contents

Introduction

Whitworth University upholds the highest ethical standards in protecting human subjects in research. In pursuit of this goal, all research involving human subjects is required to be reviewed in order to ensure that it complies with the standards set forth in 45 CFR Part 46, also known as the Revised Common Rule. This document adopts the Revised Common Rule as the standard for the protection of human subjects in research on a line-by-line basis. Equivalent lines in the Revised Common Rule are noted in square brackets, e.g., [= §46.101(a)]. Where lines of the Revised Common Rule are administrative in nature and do not apply to the review of human-subjects research, they are omitted, but the omissions are noted in square brackets, e.g., [§46.101(b) omitted]. Where Whitworth University extends additional protections, the extension follows the appropriate line, and is introduced in bold type: **Whitworth University extension**. Where Whitworth University seeks to abide by a consistent interpretation, the interpretation follows the appropriate line, and is introduced in bold type: **Whitworth University interpretation**. Where Whitworth University completes a section by specification, the specification follows the appropriate line, and is introduced in bold type: **Whitworth University specification**. Cross-references to sections of the Revised Common Rule are introduced with the section sign in the pattern §46.101(a). Cross-references to sections of this document are introduced with the double section sign in the pattern §§1(a).

Policy

Subpart A

1 To what does this policy apply? [= §46.101]

(a) Except as detailed in IV, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. [= §46.101(a), administrative language omitted]
Whitworth University extension: This policy applies to all research involving human subjects conducted, supported, or otherwise subject to oversight by Whitworth University.

(b) [§46.101(b) omitted]

(c) [§46.101(c) omitted]

(d) [§46.101(d) omitted]

(e) [§46.101(e) omitted]

(f) This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects. [= §46.101(f)]

(g) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research. [= §46.101(g)]

(h) [§46.101(h) omitted]

(i) [§46.101(i) omitted]

(j) [§46.101(j) omitted]

(k) [§46.101(k) omitted]

(l) [§46.101(l) omitted]

(m) [§46.101(m) omitted]

2 Definitions for purposes of this policy [= §46.102]

(a) *Certification* means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance. [= §46.102(a)]

(b) *Clinical trial* means 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. [= §46.102(b)]

(c) [§46.102(c) omitted]

(d) *Federal department or agency* refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency). [= §46.102(d)]

(e)

(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and, uses studies, or analyzes the information or biospecimens;
or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [= §46.102(e)(1)]

(2) *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. [= §46.102(e)(2)]

(3) *Interaction* includes communication or interpersonal contract between investigator and subject. [= §46.102(e)(3)]

(4) *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). [= §46.102(e)(4)]

(5) *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. [= §46.102(e)(5)]

Whitworth University interpretation: Any information that is posted online and associated with a user profile (e.g., on a social media platform) is considered identifiable private information, whether or not the hosting platform indicates there is an expectation of privacy.

(6) *Identifiable private 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. [= §46.102(e)(6)]

(7) [§46.102(e)(7) omitted]

(f) *Institution* means any public or private entity, or department or agency (including federal, state, and other agencies). [= §46.102(f)]

Whitworth University specification: In this policy the *institution* refers to Whitworth University.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy. [= §46.102(g)]

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements. [= §46.102(h)]

(i) *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. [= §46.102(i)]

(j) *Minimal risk* means that the probability and magnitude of harm or discomfort 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. [= §46.102(j)]

(k) *Public health authority* means 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. [= §46.102(k)]

(l) *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 service programs may include research activities. For purposes of this part, the following activities are deemed not to be research: [= §46.102(l)]

(1) 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. [= §46.102(l)(1)]

Whitworth University interpretation: Studies that employ a recognized experimental method, but have a very small sample size are not deemed to be research, as not being designed to lead to generalizable knowledge, and in the spirit of §§2(l)(1). A sample size of one is "very small", but there is no set upper limit; investigators should consult with the IRB chairperson.

(2) [§46.102(l)(2) omitted]

(3) [§46.102(l)(3) omitted]

(4) [§46.102(l)(4) omitted]

(m) *Written* or *in writing*, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format. [= §46.102(m)]

3 Assuring compliance with this policy—research conducted or supported by any Federal department or agency [= §46.103]

(a) Each institution engaged in research that is covered by this policy, with the exception of research that is eligible for exemption under 4, and that is conducted or supported by a Federal department or agency, shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of this policy. In lieu of requiring submission of an assurance, individual department heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for Federal-wide use by that office. [= §46.103(a), administrative language omitted]

(b) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes. [= §46.103(b)]
Whitworth University specification: The Provost and Executive Vice President is the authorized individual.

(c) [§46.103(c) omitted]

(d) Certification is required when the research is supported by a Federal department or agency and not otherwise waived under §46.101(i) or exempted under 4. For such research, institutions shall certify that each proposed research study covered by the assurance and this section has been reviewed and approved by the IRB. Such certification must be submitted as prescribed by the Federal department or agency component supporting the research. Under no condition shall research covered by this section be initiated prior to receipt of the certification that the research has been reviewed and approved by the IRB. [= §46.103(d)]

(e) For nonexempt research involving human subjects covered by this policy (or exempt research for which limited IRB review takes place pursuant to §§4(d)(2)(ii), §§4(d)(2)(iii)(C), §§4(d)(7), or §§4(d)(8) that takes place at an institution in which the IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol). [= §46.106(e)]
Whitworth University interpretation: Research approved by an IRB outside of Whitworth must be submitted to the Whitworth IRB by an individual associated with Whitworth (typically a faculty member, or the Assistant Vice President, Research & Innovation). The Whitworth IRB reserves the right to request additional protections. See the Policy on Outside Applications.

4 Exempt research [= §46.104]

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section 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. [= §46.104(a)]

(b) *Use of the exemption categories for research subject to the requirements of subparts B, C, and D:* Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows: [= §46.104(b)]
   (1) *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. [= §46.104(b)(1)]
   (2) *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. [= §46.104(b)(2)]
   (3) *Subpart D*. The exemptions at paragraphs §§(d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs §§(d)(2)(i) and (ii) 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 (d)(2)(iii) of this section may not be applied to research subject to subpart D. [= §46.104(b)(3)]
   Whitworth University extension: Whitworth University also considers the following protected populations, and the exemptions do not apply to these groups:
      (i) Individuals with impaired decision-making abilities.
      (ii) Protected minority classes, except for research aimed at involving a broader subject population that only incidentally includes members of the protected minority classes; protected minority classes include but are not limited to:
         (A) Racial, ethnic, and religious minorities
         (B) Unhoused persons
         (C) LGTBQ community
         (D) Veterans
      (iii) Fetuses *in utero*.
      (iv) Students or employees of the investigator.
      Whitworth University extension: Whitworth University considers that the exemptions do not apply to research when the research involves:
         (A) Federally funded research.
         (B) Use of alcohol, marijuana, prescription drugs, or OTC drugs.

(c) [§46.104(c) omitted]

(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy: [= §46.104(d)]
   (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 instruction strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [= §46.104(d)(1)]
   (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: [= §46.104(d)(2)]

(i) 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; [= §46.104(d)(2)(i)]

(ii) 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; [= §46.104(d)(2)(ii)]

OR

(iii) 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 an IRB conducts a limited IRB review to make the determination required by §§11(a)(7). [= §46.104(d)(2)(iii)]

Whitworth University extension: Whitworth does not consider research that allows the identity of human subjects to be ascertained directly to be exempt (i.e., the identity of subjects in the data must be coded).

(3)

(i) 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: [= §46.104(d)(3)(i)

(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; [= §46.104(d)(3)(i)(A)]

(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; [= §46.104(d)(3)(i)(B)]

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 an IRB conducts a limited IRB review to make the determination required by 11(a)(vii). [= §46.104(d)(3)(i)(C)]

Whitworth University extension: Whitworth does not consider research that allows the identity of human subjects to be ascertained directly to be exempt (i.e., the identity of subjects in the data must be coded).

(ii) For the purposes of this provision, 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. [= §46.104(d)(3)(ii)]

(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: [= §46.104(d)(4)]
   (i) The identifiable private information or identifiable biospecimens are publicly available; [= §46.104(d)(4)(i)]
   (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects; [= §46.104(d)(4)(ii)]
   (iii) 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 [= §46.104(d)(4)(iii)]
   (iv) 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 that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. [= §46.104(d)(4)(iv)]

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contacts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act as amended. [= §46.104(d)(5)]
   (i) [§46.104(d)(5)(i) omitted]
   (ii) [§46.104(d)(5)(ii) omitted]

(6) Taste and food quality evaluation and consumer acceptance studies: [= §46.104(d)(6)]
   (i) If wholesome foods without additives are consumed, or [= §46.104(d)(6)(i)]
   (ii) 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. [= §46.104(d)(6)(ii)]

(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 an IRB conducts a limited IRB review and makes the determinations required by 11.a.viii [= §46.104(d)(7)]
Whitworth University interpretation: It is not expected that research at Whitworth will appeal to this exemption; investigators should consult with the IRB chairperson.

(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 [= §46.104(d)(8)]
Whitworth University interpretation: It is not expected that research at Whitworth will appeal to this exemption; investigators should consult with the IRB chairperson.

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §§16(a)(1) – (4), §§16(a)(6), and §§16(d); [= §46.104(d)(8)(i)]

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §§17; [= §46.104(d)(8)(ii)]

(iii) An IRB conducts a limited IRB review and makes the determination required by §§11(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph d.viii.1 of this section; and [= §46.104(d)(8)(iii)]

(iv) 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. [= §46.104(d)(8)(iv)]

5 [§46.105 omitted]

6 [§46.106 omitted]

7 IRB Membership [= §46.107]

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB 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 IRB 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 IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects. [= §46.107(a)]
Whitworth University interpretation: Each academic department whose members submit at

least eight applications per year for expedited or full-board review will have a member of their faculty on the IRB (see Faculty Handbook 2.2.4.6.1.1).

Whitworth University interpretation: Members-at-large are appointed by Faculty Executive in consultation with the provost; department members are nominated by their departments and approved by Faculty Executive. Members serve for three-year terms. Departments may rotate their members yearly. Members, with the exception of the community member, must be regular faculty (see Faculty Handbook 2.2.4.6.1.1).

Whitworth University interpretation: The IRB administrator is appointed by the provost and serves on the IRB ex officio; the IRB administrator serves as the member familiar with institutional commitments and regulations, applicable law, and standards of professional conduct and practice (see Faculty Handbook 2.2.4.6.1.1). The IRB administrator maintains the application software system and is responsible for communications with investigators.

Whitworth University interpretation: The IRB will elect from its members a chairperson, who will be approved by the provost; the IRB will elect from its members a vice chairperson and a secretary (see Faculty Handbook 2.2.4.6.1.1). The IRB chairperson calls meetings of the IRB, sets meeting agendas, and conducts the meetings; the IRB chairperson is responsible for communications with other organs of the university (e.g., the Provost, Faculty Executive, Faculty Research and Development Committee, Faculty Assembly). The IRB vice chairperson conducts meetings of the IRB if the chairperson is unavailable. The IRB secretary compiles the meeting minutes.

(b) Each IRB 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.

Whitworth University interpretation: "Scientific areas" is understood to be biology, chemistry, mathematics, and physics; it is preferred that this member is on the biology faculty as that helps provide background for applications from students in the animal physiology course, but that is only a preference. [= §46.107(b)]

(c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. [= §46.107(c)]

(d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member as a conflicting interest, except to provide information requested by the IRB. [= §46.107(d)]

(e) An IRB 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 IRB. These individuals may not vote on the IRB. [= §46.107(e)]

8 IRB functions and operations [= §46.108]

(a) In order to fulfill the requirements of this policy each IRB shall: [= §46.108(a)]

(1) Have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties; [= §46.108(a)(1)]

(2) Prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for

example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant; [= §46.108(a)(2)]

(3) Establish and follow written procedures for: [= §46.108(a)(3)]
   (i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; [= §46.108(a)(3)(i)]
   (ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and [= §46.108(a)(3)(ii)]
   (iii) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject. [= §46.108(a)(3)(iii)]

(4) Establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of [= §46.108(a)(4)]
   (i) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and [= §46.108(a)(4)(i)]
   (ii) Any suspension or termination of IRB approval. [= §46.108(a)(4)(ii)]

(b) Except when an expedited review procedure is used (as described in §§10), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. [= §46.108(b)]

Whitworth University interpretation: When changes to the protocol are required by the IRB, the IRB may vote "to approve the research once the indicated changes have been made". The IRB administrator then reviews the amended protocol, judges that the indicated changes have been made, and informs the investigator of the approval. Alternatively, the IRB may indicate that the revisions should be reviewed by the full board before being approved. The IRB administrator may always return revisions to the full board.

9 IRB review of research [= §46.109]

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under 4 for which limited IRB review is a condition of exemption (under §§4(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8). [= §46.109(a)]

(b) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with §§16. The IRB may require that information, in addition to that specifically mentioned in §§16, be given to the subjects when in the IRB's judgment this information would meaningfully add to the protection of the rights and welfare of subjects. [= §46.109(b)]

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §§17. [= §46.109(c)]

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. [= §46.109(d)]

(e) An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in §§9(f). [= §46.109(e)]

(f)

(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances: [= §46.109(f)(1)]

(i) Research eligible for expedited review in accordance with 10; [= §46.109(f)(1)(i)]

(ii) Research reviewed by the IRB in accordance with the limited IRB review described in §§4(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8); [= §46.109(f)(1)(ii)]

(iii) Research that has progressed to the point that it involves only one or both of the following which are part of the IRB-approved study: [= §46.109(f)(1)(iii)]

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or [= §46.109(f)(1)(iii)(A)]

(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. [= §46.109(f)(1)(iii)(B)]

(2) [§46.109(f)(2) omitted]

(g) An IRB shall have authority to observe or have a third party observe the consent process and the research. [= §46.109(g)]

10 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. [= §46.110]

(a) [§46.110(a) omitted]

Applicability and categories of research for expedited review procedure from HHS (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html):

(1) Applicability

(i) 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 by 45 CFR 26.110 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.

Whitworth University extension: Research involving deceit is not eligible for review through the expedited review procedure.

(ii) The categories in this list apply regardless of the age of subjects, except as noted.

(iii) 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.

(iv) The expedited review procedure may not be used for classified research involving human subjects.

(v) IRBs are reminded that 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.

(vi) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

(2) Research Categories

(i) Clinical studies of drugs and medical devices only when condition (a) or (b) is met. **Whitworth University extension**: It is expected that research at Whitworth will typically use over-the-counter medications or medical devices; investigators should consult with the IRB chairperson if interventions use prescription medications; see also interpretation of minimizing risks associated with medications at §§11(a)(1);

(A) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.

(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.

(ii) 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 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.

(iii) 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 was 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.

(iv) 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.

(v) 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 (see §§1(b)(4)). This listing refers only to research that is not exempt.)

(vi) Collection of data from voice, video, digital, or image recordings made for research purposes.

(vii) 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 (see §§1(b)(2) and (3)). This listing refers only to research that is not exempt.)

(viii) 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.

(ix) 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.

(b)

(1) An IRB may use the expedited review procedure to review the following: [= §46.110(b)(1)]

(i) Some or all of the research appearing on the list in paragraph (a) of this section, unless the reviewer determines that the study involves more than minimal risk; [= §46.110(b)(1)(i) slightly modified]

(ii) Minor changes in previously approved research during the period for which approval is authorized; or [= §46.110(b)(1)(ii)]

Whitworth University interpretation: "Minor changes" is understood to include, but not be limited to: changes in the dates of the study and addition of sites.

Whitworth University interpretation: For minor changes, the IRB administrator is understood to be the sole designated reviewer; the IRB administrator may refer minor changes to the IRB chairperson or to the convened board if it is deemed appropriate.

(iii) Research for which limited IRB review is a condition of exemption under §§4(d)(2)(iii), (3)(i)(A), (7), and (8). [= §46.110(b)(1)(iii)]

Whitworth University interpretation: For limited review, the IRB administrator is understood to be the sole designated reviewer.

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in §§8(b). [= §46.110(b)(2)]

Whitworth University interpretation: Expedited review is carried out by two members of the IRB, the first member will be from the same department as the investigator, if practicable; the second reviewer will be selected at random from the remaining members of the IRB, excluding the IRB administrator and community member. A third reviewer may be assigned for training purposes.

(3) Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure. [= §46.110(c)]

(4) [§46.110(d) omitted]

11 Criteria for IRB approval of research [= §46.111]

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied: [= §46.111(a)]

(1) Risks to subjects are minimized: [= §46.111(a)(1)]

Whitworth University interpretation: It is expected that research at Whitworth using FDA-approved medication (over-the-counter or prescription) as an intervention will have a licensed healthcare provider with appropriate prescribing privileges as a co-investigator. However, studies of subjects who are already prescribed a medication, where the medication use is used as an outcome measure, will not be subject to this requirement, for example: when using a non-pharmacological intervention to reduce pain after surgery, it would be appropriate to track opioid use in subjects as an outcome measure.

(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and [= §46.111(a)(1)(i)]
(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. [= §46.111(a)(1)(ii)]

(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 IRB 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 IRB 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. [= §46.111(a)(2)]

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB 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. [= §46.111(a)(3)]

(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 §§16. [= §46.111(a)(4)]

(5) Informed consent will be appropriately documented or appropriately waived in accordance with §§17. [= §46.111(a)(5)]

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. [= §46.111(a)(6)]

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. [= §46.111(a)(7)]
(i) [§46.111(a)(7)(i) omitted]
(ii) [§46.111(a)(7)(ii) omitted]

(8) For purposes of conducting the limited IRB review required by §§4(d)(7), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations: [= §46.111(a)(8)]
(i) Broad consent for storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §§16(a)(1) – (4), (a)(6), and (d). [= §46.111(a)(8)(i)]
(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §§17; and [= §46.111(a)(8)(ii)]
(iii) 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. [= §46.111(a)(8)(iii)]

(b) 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. [= §46.111(b)]

12 Review by institution [= §46.112]

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

13 Suspension or termination of IRB approval of research [= §46.113]

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB'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 IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

14 Cooperative research [= §46.114]

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. 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. [= §46.114(a)]

(b)

(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research. [= §46.114(b)(1)]

(2) The following research is not subject to this provision: [§46.114(b)(2)]

(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or [= §46.114(b)(2)(i)]

(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context. [= §46.114(b)(2)(ii)]

(c) For research subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort. [= §46.114(c)]

Whitworth University interpretation: The Whitworth IRB will generally accept the determination of the IRB of the originating institution, but reserves the right to extend additional protections consistent with local practice. The IRB administrator is understood to be the IRB chairperson's designee authorized to accept the determination of the IRB of the originating institution and to identify additional protections. The IRB administrator may consult with the IRB chairperson or convened IRB as appropriate. The Institutional Official (i.e. the Provost) will ratify the IRB's reliance and guarantee compliance with the determination of the IRB of the originating institution.

15 IRB records [= §46.115]

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following: [= §46.115(a)]
  (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects. [= §46.115(a)(1)]
  (2) Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. [= §46.115(a)(2)]
  (3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §§9(f)(1). [= §46.115(a)(3)]
  (4) Copies of all correspondence between the IRB and the investigators. [= §46.115(a)(4)]
  (5) A list of IRB members in the same detail as described in §§8(a)(2). [= §46.115(a)(5)]
  (6) Written procedures for the IRB in the same detail as described in §§8(a)(3) and (4). [= §46.115(a)(6)]
  (7) Statements of significant new findings provided to subjects, as required by §§16(c)(5). [= §46.115(a)(7)]
  (8) The rational for an expedited reviewer's determination under §§10(b)(1)(i) that research appearing on the expedited review list described in §§10(a) is more than minimal risk. [= §46.115(a)(8)]
  (9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §§3(e). [= §46.115(a)(9)]
(b) The records required by this policy shall be retained for at least 3 years, and records relating to research that is concluded shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner. [= §46.115(b)]

16 General requirements for informed consent

(a) *General*. General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy: [= §46.116(a), altered]
  (1) 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. [= §46.116(a)(1)]

(2) 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. [= §46.116(a)(2)]

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative. [= §46.116(a)(3)]

Whitworth interpretation: If the investigator can reasonably ascertain that prospective subjects are non-native English speakers, consent documents will be provided in the prospective subjects' native languages. For general adult audiences consent documents will be at an eighth-grade reading level. Technical language should be avoided, or preceded by a non-technical overview.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. [= §46.116(a)(4)]

(5) Except for broad consent obtained in accordance with paragraph (d) of this section: [= §46.116(a)(5)]

(i) 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 facilitates comprehension. [= §46.116(a)(5)(i)]

(ii) 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. [= §46.116(a)(5)(ii)]

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. [= §46.116(a)(6)]

(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative: [= §46.116(b)]

(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 that are experimental; [= §46.116(b)(1)]

(2) A description of any foreseeable risks or discomforts to the subject; [= §46.116(b)(2)]

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research; [= §46.116(b)(3)]

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; [= §46.116(b)(4)]

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; [= §46.116(b)(5)]
(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; [= §46.116(b)(6)]
(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; [= §46.116(b)(7)]
(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and [= §46.116(b)(8)]
(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: [= §46.116(b)(9)]
    (i) 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 [= §46.116(b)(9)(i)]
    (ii) 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. [= §46.116(b)(9)(ii)]

(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative: [= §46.116(c)]
(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; [= §46.116(c)(1)]
(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; [= §46.116(c)(2)]
(3) Any additional costs to the subject that may result from participation in the research; [= §46.116(c)(3)
(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; [= §46.116(c)(4)]
(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; [§46.116(c)(5)]
(6) The approximate number of subjects involved in the study; [§46.116(c)(6)]
(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; [§46.116(c)(7)]

(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 [= §46.116(c)(8)]

(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). [= §46.116(c)(9)]

(d) *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information of identifiable biospecimens.* Broad consent 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) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative: [= §46.116(d)]

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section; [= §46.116(d)(1)]

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted; [= §46.116(d)(2)]

(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; [= §46.116(d)(3)]

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite); [= §46.116(d)(4)]

(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 purpose of the research, and that they might have chosen not to consent to some of those specific research studies; [= §46.116(d)(5)]

(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 [= §46.116(d)(6)]

(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. [= §46.116(d)(7)]

(e) *Waiver or alteration of consent in research involving public benefit and services programs conducted by or subject to the approval of state or local officials.* [= §46.116(e)]

(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. 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 at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens. [= §46.116(e)(1)]

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set for thin paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section. [= §46.116(e)(2)]

(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that: [= §46.116(e)(3)]

(i) 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: [= §46.116(e)(3)(i)]

(A) Public benefit or service programs; [= §46.116(e)(3)(i)(A)]

(B) Procedures for obtaining benefits or services under those programs; [= §46.116(e)(3)(i)(B)]

(C) Possible changes in or alternatives to those programs or procedures; or [= §46.116(e)(3)(i)(C)]

(D) Possible changes in methods or levels of payment for benefits or services under those programs; and [= §46.116(e)(3)(i)(D)]

(ii) The research could not practicably be carried out without the waiver or alteration. [= §46.116(e)(3)(ii)]

(f) *General waiver or alteration of consent.* [= §46.116(f)]

Whitworth interpretation: It is expected that research at Whitworth will rarely require the waivers or alterations provided for in this section; investigators should consult with the IRB chairperson. Research involving deceit requires an alteration of consent, to be accompanied by a plan to debrief subjects noted in §§16(f)(3)(v).

(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. 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 at paragraph (d) of this section, and refused to consent, and IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens. [= §46.116(f)(1)]

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If a broad consent procedure is used, and IRB may not omit or alter any of the elements required under paragraph (d) of this section. [= §46.116(f)(2)]

(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that: [= §46.116(f)(3)]

(i) The research involves no more than minimal risk to the subjects; [= §46.116(f)(3)(i)]

(ii) The research could not practicably be carried out without the requested waiver or alteration; [= §46.116(f)(3)(ii)]

(iii) 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; [= §46.116(f)(3)(iii)]

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and [= §46.116(f)(3)(iv)]

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. [= §46.116(f)(3)(v)]

(g) *Screening, recruiting or determining eligibility*. An IRB may approve a research proposal in which an investigator will obtain information of biospecimens for the purpose of screening, recruiting, or determining the 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: [= §46.116(g)]

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or [= §46.116(g)(1)]

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. [= §46.116(g)(2)]

(h) *Posting of clinical trial consent form.* [= §46.116(h)]

(1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-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 Web site that will be established as a repository for such informed consent forms. [= §46.116(h)(1)]

(2) 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 Web site (e.g., confidential commercial information), such Federal department or agency may permit or require redactions to the information posted. [= §46.116(h)(2)]

(3) The informed consent form must be posted on the Federal Web site 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. [= §46.116(h)(3)]

(i) *Preemption.* The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective. [= §46.116(i)]

(j) *Emergency medical care.* Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe). [= §46.116(j)]

17 Documentation of informed consent [= §46.117]

(a) Except as provided in paragraph (c) of 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. [= §46.117(a)]

(b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following: [= §46.117(b)]

(1) A written informed consent form that meets the requirements of §§16. 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. [= §46.117(b)(1)]

(2) A short form written informed consent form stating that the elements of informed consent required by §§16 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §§16(a)(5)(i) 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. [= §46.117(b)(2)]

(c)

(1) An IRB 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: [= §46.117(c)(1)]

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked wither the subject wants documentation linking the subject with the research, and the subject's wishes will govern; [= §46.117(c)(1)(i)]

(ii) 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 [= §46.117(c)(1)(ii)]

(iii) 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. [= §46.117(c)(1)(iii)]

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research. [= §46.117(c)(2)]

18 Applications and proposals lacking definite plans for involvement of human subjects. [= §46.118]

Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under 1(i) or exempted under 4, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research.

19 Research undertaken without the intention of involving human subjects. [= §46.119]

Except for research waived under §§1(i) or exempted under §§4, in the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted by the institution to the Federal department or agency component supporting the research, and final approval given to the proposed change by the Federal department or agency component.

20 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency. [= §46.120]

(a) [§46.120(a) omitted]
(b) [§46.120(b) omitted]

21 [§46.121 omitted]

22 Use of Federal funds. [= §46.122]

Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

23 Early termination of research support: Evaluation of applications and proposals. [= §46.123]

(a) [§46.123(a) omitted]
(b) [§46.123(b) omitted]

24 Conditions. [= §46.124]

With respect to any research project or any class of research projects the department or agency head of either the conducting or the supporting Federal department or agency may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Subpart B

201 To what do these regulations apply? [= §46.201]

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees. [= §46.201(a)]
Whitworth University extension: This subpart applies to the research involving the classes of persons described above conducted, supported, or otherwise subject to oversight by Whitworth University.

(b) The exemptions at §§1(b)(1) through (6) are applicable to this subpart. [= §46.201(b)]

(c) The provisions of §§1(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in §§1(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments. [= §46.201(c)]

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part. [= §46.201(d)]

202 Definitions [= §46.202]

The definitions in §§2 shall be applicable to this subpart as well, in addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord. [= §46.202(a)]

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means. [= §46.202(b)]

(c) Fetus means the product of conception from implantation until delivery. [= §46.202(c)]

(d) Neonate means a newborn. [= §46.202(d)]

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable. [= §46.202(e)]

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. [= §46.202(f)]

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated. [= §46.202(g)]

(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part. [= §46.202(h)]

203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates [= §46.203]

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

204 Research involving pregnant women or fetuses [= §46.204]

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses; [= §46.204(a)]
(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means; [= §46.204(b)]
(c) Any risk is the least possible for achieving the objectives of the research; [= §46.204(c)]
(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part; [= §46.204(d)]
(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. [= §46.204(e)]
(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate; [= §46.204(f)]
(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part; [= §46.204(g)]
(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy; [= §46.204(h)]
(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and [= §46.204(i)]
(j) Individuals engaged in the research will have no part in determining the viability of a neonate. [= §46.204(j)]

205 Research involving neonates [= §46.205]

(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met: [= §46.205(a)]
    (1) When scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. [= §46.205(a)(1)]

(2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate. [= §46.205(a)(2)]
(3) Individuals engaged in the research will have no part in determining the viability of a neonate. [= §46.205(a)(3)]
(4) The requirements of paragraph (b) or (c) of this section have been met as applicable. [= §46.205(a)(4)]

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met: [= §46.205(b)]
(1) The IRB determines that: [= §46.205(b)(1)]
(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or [= §46.205(b)(1)(i)]
(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and [= §46.205(b)(1)(ii)]
(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. [= §46.205(b)(2)]

(c) Nonviable neonates. After delivery nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met: [= §46.205(c)]
(1) Vital functions of the neonate will not be artificially maintained; [= §46.205(c)(1)]
(2) The research will not terminate the heartbeat or respiration of the neonate; [= §46.205(c)(2)]
(3) There will be no added risk to the neonate resulting from the research [= §46.205(c)(3)]
(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and [= §46.205(c)(4)]
(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of §§16(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5). [= §46.205(c)(5)]

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part. [= §46.205(d)]

206 Research involving, after delivery, the placenta, the dead fetus, or fetal material [= § 46.206]

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities. [= §46.206(a)]

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable. [= §46.206(b)]

207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates. [§46.207 omitted]

Subpart C

301 Applicability [= §46.301]

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects. [= §46.301(a)]
Whitworth University extension: This subpart applies to the research involving prisoners as subjects conducted, supported, or otherwise subject to oversight by Whitworth University.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law. [= §46.301(b)]

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part. [= §46.301(c)]

302 Purpose [= §46.302]

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

303 Definitions [= §46.303]

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services and any other office or employee of the Department of Health and Human Services to whom authority has been delegated. [= §46.303(a)]

(b) *DHHS* means Department of Health and Human Services. [= §46.303(b)]

(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures

which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. [= §46.303(c)]

(d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. [= §46.303(d)]

304 Composition of Institutional Review Boards where prisoners are involved [= §46.304]

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board. [= §46.304(a)]

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement. [= §46.304(b)]

305 Additional duties of the Institutional Review Boards where prisoners are involved [= §46.305]

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that: [= §46.305(a)]

(1) The research under review represents one of the categories of research permissible under 306(a)(2); [= §46.305(a)(1)]

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weight the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired; [= §46.305(a)(2)]

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers; [= §46.305(a)(3)]

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project; [= §46.305(a)(4)]

(5) The information is presented in language which is understandable to the subject population; [= §46.305(a)(5)]

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and [= §46.305(a)(6)]

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact. [= §46.305(a)(7)]

(b) The Board shall carry out such other duties as may be assigned by the Secretary. [= §46.305(b)]

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled. [= §46.305(c)]

306 Permitted research involving prisoners [= §46.306]

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if: [= §46.306(a)]

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under 305 of this subpart; and [= §46.306(a)(1)]

(2) In the judgment of the Secretary the proposed research involves solely the following: [= §46.306(a)(2)]

(i) Studies of possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects; [= §46.306(a)(2)(i)]

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects; [= §46.306(a)(2)(ii)]

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or [= §46.306(a)(2)(iii)]

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research. [= §46.306(a)(2)(iv)]

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects. [= §46.306(b)]

Subpart D

401 To what do these regulations apply? [= §46.401]

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services. [= §46.401(a)]

Whitworth University extension: This subpart applies to the research involving children as subjects conducted, supported, or otherwise subject to oversight by Whitworth University.
(1) [§46.401(a)(1) omitted]
(2) [§46.401(a)(2) omitted]

(b) Exemptions at §§1(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §§1(b)(2) regarding education tests is also applicable to this subpart. However, the exemption at §§1(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed. [= §46.401(b)]

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of subpart A are applicable to this subpart. [= §46.401(c)]

402 Definitions [= §46.402]

The definitions in §46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Children* are 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. [= §46.402(a)]
Whitworth University interpretation: Individuals 17 and under are considered "children"; individuals 18 and over are considered "adults".

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. [= §46.402(b)]

(c) *Permission* means the agreement of parent(s) or guardians to the participation of their child or ward in research. [= §46.402(c)]

(d) *Parent* means a child's biological or adoptive parent. [= §46.402(d)]

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. [= §46.402(e)]

403 IRB Duties [= §46.403]

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

404 Research not involving greater than minimal risk [= §46.404]

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as set forth in §46.408.

405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects [= §46.405]

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the

individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects; [= §46.405(a)]
(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, and [= §46.405(b)]
(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408. [= §46.405(c)]

406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition [= §46.406]

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or a procedure that does not hold out prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk; [= §46.406(a)]
(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; [= §46.406(b)]
(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and [= §46.406(c)]
(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians as set forth in §46.408. [= §46.406(d)]

407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. [§46.407 omitted]

408 Requirement for permission by parents or guardians and for assent by children [= §46.408]

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the RIB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out the prospect of a direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under

circumstances in which consent may be waived in accord with §46.116 of Subpart A. [= §46.408(a)]

Whitworth University interpretation: Assent is generally required for children ages 7 and older, but the IRB may adjust that threshold depending of the maturity and psychological states of the anticipated subjects. Investigators working with special populations are encouraged to consult the IRB chairperson.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §46.406 and §46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. [= §46.408(b)]

(c) In addition to the provisions for waiver contained in §46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subjects population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section , provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition. [= §46.408(c)]

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A. [= §46.408(d)]

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented. [= §46.408(e)]

Whitworth University interpretation: Normally child assent is required for children ages 7 and older, and a signed child assent form provides documentation; please contact the IRB chairperson for guidance if these guidelines do not appear appropriate for a specific project.

409 Wards [= §46.409]

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research in: [= §46.409(a)]
   (1) Related to their status as wards; or [= §46.409(a)(1)]
   (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children in involved as subjects are not wards. [= §46.409(a)(2)]

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of

the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization. [= §46.409(b)]