

Washington State University Institutional Review Board
Application Instructions

Application Instructions:

The Principal Investigator (PI) must be WSU faculty or staff, and will be the study supervisor at WSU. Students, post-doctoral researchers, and visiting faculty may not serve as PI, but may be listed as co-investigators. All correspondence will be directed to the PI.

- *Do NOT begin data collection prior to IRB approval.*
- *All materials must be typed; handwritten materials will be returned.*
- *DO NOT leave a question blank; write "n/a" if a question does not apply to the application.*
- *WSU researchers (faculty and staff) conducting research in Deaconess Medical Center, Holy Family Hospital, Sacred Heart Medical Center, St. Luke's Rehabilitation Institute, and Valley Hospital & Medical Center should contact WSU IRB at 335-3668 prior to filing this application.*
- *WSU researchers (faculty and staff) using DSHS records or facilities should contact WSU IRB at 335-3668 prior to filling this application.*
- *If necessary, complete the addendums on the website and submit them along with the application.*

Research Staff include all individuals who will be involved in this proposed research including, but not limited to, staff that will recruit participants, obtain informed consent, administer surveys/questionnaires, and perform data analysis. The PI is required to receive training in the ethical use of human participants in research, and other research staff is encouraged to receive training in the ethical use of human participants in research. **Beginning August 1, 2008 WSU IRB will only accept CITI training.**

Types of IRB Review:

An IRB application submitted for review will fall into one of the following categories listed below. The categories reflect the risks for the human subjects participating in the study.

Full board Review- Research that involves more than minimal risk are recommended for review by a full board. Approval for these studies requires that the proposed research be reviewed at a convened meeting with a quorum of IRB members present. IRB approvals are valid for up to one year and require submission of annual renewals and approval for amendments.

- *Full Board applications* are reviewed at monthly IRB meetings, if and only if the packets are received at ORA at least 10 working days prior to the meeting date.
- Submit original application (single sided, not stapled) and 20 copies (double sided, stapled).

Expedited Review- Research that involves no more than minimal risk and for minor amendments in approved research. These will be reviewed by one or two members designated by the IRB chair rather than by the entire convened IRB. Approvals are valid for up to one year and require submission of annual renewals and approval for amendments.

- *Expedited applications* take approximately 12 working days for review once they arrive at ORA.
- Submit original application (single sided, not stapled) and 2 copies (double sided, stapled).

Exempt Certification- Research considered as minimal risk to human subjects can be exempt under federal regulations; however the exempt application must be submitted to the IRB for determination. The

exempt categories include certain educational practices and tests, study of archived or existing data, public service programs and *food evaluation*. No renewals are required for a certified exempt activity, although amendments are required to be submitted to the IRB.

- *Exempt Certification applications* take approximately 10 working days for review once they arrive at ORA.

Exemption Review Checklist:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - i. research on regular and special educational instructional strategies, **or**
 - ii. research on the effectiveness of **or** the comparison among instructional techniques, curricula, **or** classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - i. information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
 - ii. any disclosure of the human participants ' responses outside the research could reasonably place the participants at risk of criminal or civil liability; or
 - iii. be damaging to the participants ' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2) of this section, if:
 - i. the human participants are elected or appointed public officials or candidates for public office; or
 - ii. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the participants. PLEASE NOTE: According to the Office for Human Research Protections (OHRP), "to qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins. The principle behind this policy is that the rights of individuals should be respected; participants must consent to participation in research."
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - i. public benefit or service programs;
 - ii. procedures for obtaining benefits or services under those programs;
 - iii. possible changes in or alternatives to those programs or procedures;
 - iv. possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies:

- i. if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Review Checklist:

Applicability

- Research activities that (1) present no more than minimal risk to human participants, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.
 - The categories in this list apply regardless of the age of participants, except as noted.
 - The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' 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.
 - The expedited review procedure may not be used for classified research involving human participants.
 - 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.
 - Categories one (1) through seven (7) pertain to both initial and continuing IRB review.
 - Categories eight (8) and (9) pertain to continuing review of research previously approved by the convened IRB. See complete guidance below.
1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. **Note:** *Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.*
 - b) Research on medical devices for which
 - (i) an investigational device exemption application (21 CFR Part 812) is not required; **or**
 - (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a) From healthy, non pregnant adults who weigh at least 110 pounds. For these participants, 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 children¹ considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml

or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples:
 - (a) Hair and nail clippings in a non-disfiguring manner
 - (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
 - (c) Permanent teeth if routine patient care indicates a need for extraction
 - (d) Excreta and external secretions (including sweat)
 - (e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
 - (f) Placenta removed at delivery
 - (g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
 - (h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
 - (i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
 - (j) Sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non research 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. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
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 Where no subjects have been enrolled and no additional risks have been identified; or Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

If your study DOES NOT meet exemption or expedited review criteria, then it qualifies for full board review.

Packet Checklist:

- 1. Completed and signed IRB Application _____
- 2. Documentation of consent procedures (**ONLY FOR EXPEDITED AND FULL BOARD**): _____
 - a. Consent Form _____
 - b. Assent Form _____
 - c. Parent Permission Form _____
 - d. Verbal Consent Script _____
 - e. Cover letter _____
 - f. Waiver Request _____
- 3. All survey instruments or questionnaires to be used _____
- 4. All interview questions or topics, in as much detail as possible _____
- 5. All advertisement or recruiting materials _____
- 6. If applicable, HIPAA Authorization Form & HIPAA Appendix A _____
- 7. Number of applications **and** additional materials: _____
 - a. **Exempt** **original** application and additional materials listed in 3-5.
 - b. **Expedited** **original** application and additional materials listed in 2-6
2 additional **copies** of application and materials listed in 2-6.
 - c. **Full Board** **original** application and additional materials listed in 2-6
20 additional **copies** of application and materials listed in 2-6.

Original must be single-sided and not stapled. Copies may be stapled and double-sided.

Top 5 Mistakes To Avoid When Submitting an Application:

- 1. Indicating that data is anonymous when it is actually confidential (check definitions).
- 2. Not providing enough information as to who will have access to the data.
- 3. Stating there are no risks involved in the activity. Even though the risks may be low, they need to be listed on the application.
- 4. The signature page does not have all the required signatures.
- 5. Consent forms, survey, or interview instruments are not attached for review.

IRB Contact Information:

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