Washington State University Institutional Review Board

Application Instructions

Application Checklist:

1. Completed IRB Application ___
2. Documentation of consent procedures **(ONLY FOR EXPEDITED AND FULL BOARD):** ___

a. Consent Form ___
b. Assent Form ___
c. Parent Permission/guardian Form ___
d. Verbal Consent Script ___
e. Cover letter ___

3. Addendums

___Addendum 1: Expedited Categories and Determination (**ONLY FOR EXPEDITED REVIEW**)
___Addendum 2: Research with Children
___Addendum 3: Research with Prisoners
___Addendum 3a: Research with Prisoner Data Sets Collected for Purposes Other than Research
___Addendum 4: Alteration or omission of elements from Consent, Permission or Assent Process
___Addendum 5: Waiver of Documentation (Signature for participant) of Informed Consent, Permission or Assent Process
___Addendum 6: Waiver of Informed Consent, Permission or Assent Process
___Addendum 7: HIPAA Authorization Form and Appendix A
___Addendum 8: Investigational Drugs, Other Drugs, and Devices
___Addendum 9: Blood, Tissue, Bodily fluids, or Other Biological Specimens or Samples
___Addendum 10: Confidentiality Agreement

4. All survey instruments or questionnaires to be used ___
5. All interview questions or topics, in as much detail as possible ___
6. All advertisement or recruiting materials ___

a. **Exempt original** application and additional materials listed in 4-6
b. **Expedited original** application and additional materials listed in 2-6
c. **Full Board original** application and additional materials listed in 2-6

How to Submit:

1. ***All submissions (application and the supporting materials) should be emailed to irb@wsu.edu. Subject line: "Human Subject Application, for expedited or full board review submission'. If someone else (example: graduate student, post doc, Co-PI or staff) is submitting the application on behalf of PI, the submission should be copied to PI. The e-mail should come from WSU e-mail id.***

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.

Human Participants Training: WSU IRB ***requires all the personnel*** *involved in the research to complete CITI training in the ethical use of human participants in research. The principal investigator (PI) is responsible for the training and the documentation of the personnel listed on the application. Section 1, question 2 requires the CITI training record of PI.* ***Re-training is required every five years****. For CITI training details visit the CITI website at http://www.citiprogram.org or http://www.irb.wsu.edu/citi.asp If you have any further questions, you can also contact the IRB coordinator at 335-3668 or irb@wsu.edu.*

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 application is received at least 10 working days prior to the meeting date.
- Submit original application and the additional materials

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.

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

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.

Common 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. Consent forms, survey, or interview instruments are not attached for review.

IRB Contact Information:

Institutional Review Board (IRB)
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