Criteria for IRB Approval of Research

1 Risks are reasonable relative to benefits

Anticipated benefits include the importance of the expected resulting knowledge to research subjects.

2 Risks to subjects are minimized

- Procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.
- If possible, the research uses procedures already being performed on subjects.

3 Protection of subject privacy & confidentiality

There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

4 Adequate safety monitoring plan

The research plan has adequate provisions for monitoring the data collected, to ensure the safety of subjects.

5 Written informed consent obtained

From each prospective subject or the subject's legally authorized representative, unless the IRB, per federal criteria:

- Waives the need for written consent.
- Waives the need for consent.

6 The consent process provides all required and appropriate information

Unless waived by the IRB per federal regulatory criteria.

7 Subject selection is equitable

Taking into account:

- The research purpose and setting, and
- Any special issues associated with vulnerable populations.

8 Additional safeguards for protected &vulnerable populations

- Additional safeguards are included to protect subjects who may be vulnerable to undue influence or coercion.
- Includes: children, prisoners, pregnant women, neonates.
- May also include decisionally-impaired, or economically or educationally disadvantaged subjects.

9 Other ethical & compliance issues

- Researcher conflict of interest.
- Involvement of non-UW institutions and individuals.
- Other compliance requirements.

45 CFR 46.111, OHRP & 21 CFR 56.111, FDA

Researcher Responsibilities

In Research with Human Subjects

The lead researcher / principal investigator (PI) is responsible for all aspects of the study.
Authority to perform aspects of the study may be delegated, but the PI retains full responsibility for all activities and obligations.

1 **Conduct** the research in accordance with the approved IRB application, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2 **Consent** is obtained (unless waived by the IRB) without coercion or undue influence, and the potential subjects are provided with sufficient opportunity to consider whether to participate.
- Use only the most current consent form, bearing the "APPROVED" stamp and date.
- Provide non-English speaking subjects with an IRB-approved translation of the consent form.

3 **Pre-approval** must be obtained from the IRB for any planned modifications or amendments, including new sources of funding and changes to recruiting materials.

4 **Report** promptly to the IRB any new information, unanticipated problems involving risks to subjects or others, or serious adverse events that may affect the welfare or safety of the subjects or the conduct of the research.

5 **Obtain Renewal** of IRB approval by providing required Status Reports at least 6 weeks before current IRB approval expires. IRB approval is not automatic and does not occur until the IRB has reviewed and approved the Status Report.

6 **Retain copies** of all IRB-related materials and correspondence, as described in the UW Record Retention Schedule.

7 **Ensure** that there is a system in place for promptly responding to letters, email or phone inquiries, and messages from subjects and from the IRB.

8 **Inform** the IRB when the research has been completed by completing a Status Report form and checking the box next to "Close IRB Application."

More Information: www.washington.edu/research/hsd
Assistance: hsdtrain@uw.edu

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