Washington State University Institutional Review Board

Points to consider While Submitting the Non-Exempt Application

DESIGN:

The proposed research design is scientifically sound & will not unnecessarily expose subjects to risk.- *Is hypothesis or purpose clear & clearly stated?- Is the study design appropriate to the hypothesis/purpose?- Will the research contribute to generalizable knowledge & is it worth exposing subjects to risk?*

SUBJECT SELECTION:

Subject selection is equitable.- *Who is enrolled? Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)?- Are these subjects appropriate for the protocol?*

RISKS:

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and, the importance of knowledge that may reasonably be expected to result.- *What is the level of risk? (See assessment guide)- What does the PI consider the level of risk/discomfort to be?- Is there prospect of direct benefit to subjects?*

RISKS MINIMIZED:

Risks to subjects are minimized.- *Does the research design minimize risks to subjects?- Would use of a data & safety monitoring board or other research oversight process enhance subject safety?*

VULNERABLE SUBJECTS:

Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.- *Are appropriate protections in place for vulnerable subjects, e.g., pregnant women, fetuses, socially- or economically-disadvantaged, decisionally-impaired?*

CONFIDENTIALITY/PRIVACY:

Subject privacy & confidentiality are maximized.- *Will personally-identifiable research data be protected to the extent possible from access or use?- Are any special privacy & confidentiality issues properly addressed, e.g., use of genetic information?*

INFORMED CONSENT:

Informed consent is obtained from research subjects or their legally authorized representative(s).- *Does the consent form document include the 8 required elements?- Is the consent document understandable to subjects?- Who will obtain informed consent (PI, nurse, other?) & in what setting?- If appropriate, is there a children's assent?- Is the IRB requested to waive or alter any informed consent requirement*

Other Considerations

HIPAA:

Health information- *Is any health data, subject to HIPPA, used in this research?- If so, what measures are in place to comply with the Privacy Rule?- Are the measures adequate? Is a special Informed Consent required?*

RISK LEVEL:

Does not involve greater than minimal risk

a. **Explanation of risk level for CHILDREN:**
b. **Explanation of risk level for OTHER:**

Risk/Benefit Assessment Risk Regulatory definition of minimal risk

Risk Definition: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(i)).

Researchers need to assess the risk as given below:

- The research involves no more than minimal risk to subjects.
- The research involves more than minimal risk to subjects
- The risk(s) represents a minor increase over minimal risk
- The risk(s) represents more than a minor increase over minimal risk

Benefit Definition: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Researchers need to assess the benefits as given below:

- No prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition
- No prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition
- No prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge to further society's understanding of the disorder or condition under study
- The research involves the prospect of direct benefit to individual subjects

Risk Benefit Ratio:

Potential risks to subjects are reasonable in relation to potential benefits to subjects or society.