

Reference:

SOP Current: Section 5

SOP Future: WVU OHRP SOP 007

Regulatory Criteria for IRB Approval

The text below indicates the regulatory criteria that an IRB will evaluate during the IRB review and approval process.

✓ **RISKS TO SUBJECTS ARE MINIMIZED AND REASONABLE**

Risks are minimized:

- Use procedures consistent with sound research design and do not unnecessarily expose subjects to risk.
- When appropriate, use procedures presently administered on subjects for diagnostic or treatment purposes.

Risks are reasonable relative to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.

- 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 without participating in the research).
- The IRB should not consider possible long-term effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as a risk that is within the scope of the research.

✓ **EQUITABLE SELECTION OF SUBJECTS**

Consider the purpose of the research and the setting in which the research will be conducted and should be particularly aware of the unique problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

✓ **INFORMED CONSENT IS LEGAL AND DOCUMENTED**

Informed Consent will be obtained from each prospective participant, or the participant's legally authorized representative, to the extent required by [§46.116](#) (unless waived by the IRB).

Informed Consent will be appropriately documented to the extent required by [§46.117](#) (unless waived by the IRB).

✓ **DATA MONITORING PLAN**

If required, adequate provisions are in place for monitoring the data collected to ensure the safety of participants.

✓ **DATA PRIVACY and CONFIDENTIALITY**

If required, adequate provisions are in place to protect the privacy of participants and to maintain the confidentiality of data.

✓ **VULNERABLE POPULATION SAFEGUARDS**

If participants are at risk to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards are in place to protect the rights and welfare of the vulnerable participants.