Guidance on Vulnerable Populations in Research

Office of Research Integrity & Compliance | Version 2
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This document is intended to help educate investigators and IRB members on vulnerable populations used in research, as well as outline certain populations that the WVU IRB considers to be vulnerable. If further assistance or clarification is required, please contact the ORIC at 304-293-7073, or at IRB@mail.wvu.edu.

Vulnerable Populations

The question in the IRB application is intended to help determine whether the targeted study population is vulnerable. To be considered a vulnerable population (i.e. pregnant women, fetuses, children, prisoner, or cognitively impaired persons) must be the focus of the research. If the target is the general population, and one of these groups (except prisoners), participates there is no need to list them on the Questionnaire of the KC submission.

Note: If prisoners are the targeted study population, the study must be reviewed via full board and a prisoner representative must be consulted by the IRB.

Diminished Capacity

The PI should identify the intent to enroll vulnerable subjects in the proposed research at initial review and provide justification for their inclusion in the study. This should include a description of how mental capacity will be assessed.

1. If the research involves adults unable to consent, the IRB evaluates the proposed plan for consent of legally authorized representatives
2. The IRB evaluates and approves the proposed plan for the assent of participants. If mental capacity is over 7 years of age, an assent is needed with a guardian consent.
3. Be aware that the IRB evaluates the research to determine the need for additional protections and consider the use of a data and safety monitoring board or data monitoring committee as appropriate
4. The PI should provide appropriate safeguards to protect the subject's rights and welfare, which may include the addition of an independent monitor. The independent monitor is a qualified individual not involved in the research study who will determine the subject's capacity to provide voluntary informed consent

An example of study that warrants independent monitoring include:

- Those involving schizophrenic patients who will be exposed to placebo, and/or drug washout, and/or treatment with agents that are not approved by the Food and Drug Administration (FDA).

Examples of populations requiring independent monitoring would include:

- Individuals with schizophrenia, other psychotic disorders or conditions characterized by lack of reality testing (i.e., psychosis).
- Populations not usually requiring independent monitoring would include those with substance use disorders.

WVU Students & Employees as Participants

WVU students and employees are considered a vulnerable population, if the intent is to enroll current students or employees that are being taught by the research team or are employees under someone on the research team. The main concern is perceived coercion.

- If students are targeted, the PI must state that students are informed in the cover letter or consent that the study is voluntary and their grades will not be affected.
- If employees, the consent should say that the study is voluntary and their employed status is not affected.

Coercion

There are methods that can be used to alleviate the concern of coercion. Some suggestions are:

1. Making participation completely anonymous
2. Recruiting by a person who is not giving the class or is not the employer
3. The faculty or employer can recruit, but make it very clear that the class status, grades or employee status will not be affected by non-participation or withdrawal
4. Conducting the research after class grades have already been given
5. You may develop other methods, such as having someone not involved with the study de-identifying the data