HRP-334 | 3/29/2024

WORKSHEET: Vulnerable Populations

The purpose of this worksheet is to provide support for IRB members reviewing research in evaluating whether potential research participants could be vulnerable to coercion or exploitation that might influence their consent to research or their decision to continue in research. This worksheet is to be used. This worksheet does not need to be completed or retained.

1. Is the research likely to enroll participants to which any of the following would apply?

Difficulty understanding information about the research due to the complexity of the study (e.g. gene transfer research)

Non-English speakers

Unable to read (illiterate)

Approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.

Employees of researcher

Students

Members of the military

Serious health condition for which there are no satisfactory standard treatments

Fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior)

Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research: Click or tap here to enter text.

1. Research Review/Design/Conduct Considerations: Inclusion of vulnerable individuals or groups requires the investigator to develop additional safeguards proportional to the degree of vulnerability and proportional to the degree of risk and benefit of the research.

Engage consultant in IRB review of the study

Use of an independent clinical monitor

Use of a consent monitor

Independent capacity to consent to research assessment

Translation of consent form and/or use of interpreter during consent process

Use of short-form consent form and process

Modify timing of consent process if possible (before or after stressful situation)

Alternative to participation in research to fulfill course requirement

Additional information in the informed consent form

When appropriate:

Use of [Participant Contact Card Template](https://research.umn.edu/units/hrpp/education-training/order-print-participant-materials).

Use of [participant-facing brochures.](https://research.umn.edu/units/hrpp/research-participants/resources-research-participants)

Exclusion of the population if not required to achieve study objectives

Researcher should not have any role in decisions impacting participants’ status (e.g. institutionalization, judicial determination of competence)

Treating physician (if member of the research team) should not participate in the consent process

Apply for Certificate of Confidentiality (CoC) if unfunded or not funded by NIH

Other: Click or tap here to enter text.