

Vulnerable Domestic Populations

Who are considered vulnerable populations?

Vulnerable populations include: children (in some instances), prisoners, individuals with impaired decision-making ability, non-English speakers, English Language Learners, economically/educationally disadvantaged individuals

Why does my research with vulnerable populations require special consideration?

Conducting research with vulnerable populations raises important concerns about cultural sensitivity, possible coercion, and privacy/confidentiality.

What is different about an IRB application with vulnerable populations?

While the general criteria for exemption, expedited, and full review remain the same for studies with vulnerable populations, certain parts of your IRB application such as consent, privacy, data storage, and sample selection should be done with special attention regardless of review level.

How do I know if my IRB application will need exempt, expedited, or full review?

Check to make sure your research is not exempt ([link](#)). If it is not exempt, you will have to complete Form 1, which is the form used for both expedited and full reviews. The IRB Form 1 has a set of questions that will help you determine if your review will need expedited or full review based on if it presents more than minimal risk to the research participants. Ultimately, it will be up to the IRB to decide if your research will require full review.

Below are the relevant sections from The Code of Federal Regulations on research with vulnerable populations.

1. Specifically, Section 46.111 makes the following stipulations (underlined here for emphasis). “(a) (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(a) (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, §46.116.

(a) (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

2. In addition, Section 46.116 makes clear the requirements for informed consent, and in the context of research with these groups, special consideration must be given to (1) how informed consent is written in terms of understandability (Is it in the language understood by the

participant or the participant’s authorized representative?) and (2) special consideration should be paid to the method of obtaining consent.

Considerations for Researchers Conducting Research with Vulnerable Domestic Populations

The following must be carefully considered in the IRB protocol by the investigator where applicable:

Where information should appear in IRB Form	Additional Documentation or Explanation That May be Required of International Research
Part III: Study Population	Adequately describe the population you are studying so the IRB can determine the level of vulnerability.
Part II: Project Description	Demonstrate knowledge of the population through adequate background research and literature reviews.
Part II: Project Description Part III: Study Population	Consider the cultural norms of the group being studied and be sure to address any culturally sensitive matters in collecting data and obtaining consent.
Part III: Study Population Part VIII: Informed Consent Part V: Methods, Materials and Procedures	If the research subjects are non-English speakers or English language learners, the researcher should describe the methods for translation of documents (such as consent forms and recruitment scripts) and for in-person translation. Translated forms must be submitted after the researcher has received IRB approval but before starting data collection.
Part IV: Participant Identification/ Recruitment	The researcher should address the selection of subjects and explain how subjects were selected equitably.
Part VIII: Informed Consent	The researcher should explain any additional provisions required to protect the privacy of the subjects and confidentiality of data collected.

<p>Part VIII: Informed Consent</p>	<p>Your IRB application should clearly address how concerns about coercion are minimized during recruitment and consent. This is especially important when recruitment is tied to an organization that provides services or employment for vulnerable populations. For example, consider whether a subject who receives benefits from an organization or is employed by an organization might feel coerced if they believed their benefits/employment status could be impacted by participation or non-participation in the study.</p>
<p>Part V: Methods, Materials and Procedures</p>	<p>If your research provides rewards or incentives for participation, address how these incentives do not compel the participant to join the study despite the concerns they have for their well-being. For example, if you are providing financial rewards to economically disadvantaged populations, how will you ensure that participants are not participating against their better judgment or comfort level because they are poor and need the money?</p>
<p>Part VII: Risks and Benefits</p>	<p>The researcher should make sure to clearly and simply summarize all safeguards employed to protect the interests, rights, and welfare of vulnerable subjects.</p>
<p>Part IX: Outside Collaborations</p>	<p>If collaborating with an outside organization, a collaboration letter should acknowledge and make clear that no undue influence or coercion will be used in assisting any recruitment of subjects.</p>
<p>Part IX: Outside Collaborations</p>	<p>If there is a research collaborator at the outside organization, the researcher should provide that investigator's name and information about their qualifications.</p>