


INVESTIGATOR GUIDANCE: Research Involving Vulnerable Populations

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- 3.2.4.3. Understand the risks and benefits of the research as it related to their own health condition.
- 3.2.4.4. The alternatives to participation.
- 3.2.4.5. Provide clear and effective consent or assent.
- 3.3. Research involving *persons with limited or non-English speaking individuals* is important to ensure the benefits of research are justly distributed and to address research topics that are specific to such populations. Regardless of the reasons for involving individuals with minimal or no English-language skills in research, researchers must design recruitment and consent processes to ensure prospective participants comprehend what is being asked of them and voluntarily agree to participate.
 - 3.3.1. A limited or non-English speaker is any person who, by reason of place of births or culture, speaks a language other than English and does not speak English with adequate ability to communicate.
 - 3.3.2. Researchers should be aware that there are cultural concerns and appropriateness for language that may need to be addressed. For example, certain words or phrases may not translate well (or at all) in each language.
 - 3.3.3. Federal regulations (45CFR46.116; 21CFR50.20) require consent documents to be in language understandable to the participant.
 - 3.3.3.1. For research posing greater than minimal risk, researchers must obtain legally effective signed consent from each participant in accordance with DHHS requirements for informed consent (at 45 CFR 46.116) and for documentation of informed consent (at §46.117), which includes use of a short form written consent document.
 - 3.3.3.2. For minimal risk research, researchers may use simplified information scripts/sheets and oral consent in lieu of a consent form, including a short form consent document. NOTE: For minimal risk research that is conducted or supported by federal funds, or that involves prisoners or incomplete disclosure/deception, the IRB must approve an alteration of informed consent (at §46.116(2)) and a waiver of the requirement to obtain a signed consent form (at §46.117(c)(1) or (2)).
 - 3.3.4. Ideally, the research team will include individuals fluent in the language spoken by prospective participants. If researchers and participants are not fluent in the same language, interpre.1 (t)-1.1 (er7a001 Tw 04 (t)-1.1 (i)3.1 (c)-20.1 (i)3.2 (pa)-12.3 Id(i)-8.9 (53upf.2 (pa

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