The criteria for IRB approval, 45 CFR 46.111(a) and/or 21 CFR 56.111, requires an equitable selection of participants in the conduct of research. This requirement stems from the principal of justice which requires that no group is unduly burdened or will unfairly benefit from the research. As the Stanford community serves a highly diverse population, investigators must take into consideration the likelihood of encountering potential participants with limited English proficiency.

Investigators may not routinely exclude non-English speaking participants from research and should make appropriate provisions to include non-English speaking participants when the research is of therapeutic intent. If the research is limited to English speaking participants, there should be justification as to why non-English speaking populations are excluded. An investigator should consider the following when excluding non-English speaking populations:

- Does the research include validated questionnaires, surveys, or assessments that are only available in English?
- Does the research require situations where a translator may not be readily available (e.g., emergencies, external sites/clinics)?
- Does the research target a population that is highly likely to include only English speakers (e.g. Veterans)?
- Is the intent of the research outside of the therapeutic realm, with no prospect of direct benefit for the participants?

The regulatory requirements for informed consent (45 CFR 46.117(b)(1) and/or 21 CFR 50.27(b)(1)) state that information must be presented to participants "in a language understandable to the subject." When enrolling non-English speaking participants either the consent form document needs to be translated into the participant's native language or the use of the short form consent process should be requested. Any additional study materials such as questionnaires, surveys, diaries, etc. may also need to be translated into the participant's native language. The translated consent form or short form consent process, and translation of any other study materials require IRB approval prior to use.

Resources:

GUI-C39: Short Form Consent Process

GUI-33: General guidance on participant recruitment

HRPP Chapter 10: Participant Recruitment and Selection & HRPP Chapter 12: Informed Consent and Assent

Hospital translation services