

Ohio University

Office of Research Compliance guidance on screening participants

After seeking input from IRB members and reviewing other guidance and resources, the Office of Research Compliance has determined the following.

Individuals who are screened or “pre-screened” qualify as human subjects when the criteria defining a human subject have been met, based on the definition at 45 CFR 46.102(e)(1).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Screening activities include:

- Any interaction or intervention with an individual to determine eligibility that would not otherwise have occurred if not for the study, regardless of whether or not data is recorded, or
- Accessing identifiable private information.

The following activities would be considered screening.

- Interacting directly with prospective participants such as through written screening tools, or oral conversations about the study.
- Accessing identifiable private information, i.e., medical, legal, or academic records, for purposes of determining eligibility for a research study.

Whenever activities occur that qualify as “screening,” those individuals who are screened should be counted and included in the **maximum number of participants** in the IRB application form and included in the **number of participants currently enrolled or that have been screened for the study** in an amendment or periodic review submission.

When possible, potential participants should be consented prior to being screened. If screening occurs prior to the participant providing consent for full study participation, a screening consent should be developed that is specific to the screening process and should include how the information collected will be kept confidential and what will happen to the data if the individual does / does not qualify for the study. The IRB can utilize the flexibility in the regulations such as approving a screening consent procedure, which alters some or all of the required elements and / or waiving the requirement for documentation of informed consent for this consenting process, e.g., the IRB may approve an oral consent script to occur prior to screening potential participants.