

**Ohio University**  
**Office of Research Compliance**  
**Guidance on Screening Participants**

**Background**

Under the revised Common Rule (45 CFR 46.116(g)), an IRB may approve a proposal for the investigator to obtain information or access existing biospecimens to screen, recruit, or determine eligibility of prospective subjects for a research study without informed consent.

In order to utilize this flexibility, the IRB must determine that:

- (1) the information is obtained through oral or written communication with the subject or the subject's legally authorized representative, or
- (2) identifiable private information or identifiable biospecimens are obtained by accessing records or stored identifiable biospecimens.

Some instances when screening would not meet those determinations would be clinical interventions conducted specifically to determine eligibility, such as collecting biospecimens (as opposed to testing stored biospecimens), conducting physical assessments, or obtaining physical measurements or vital signs.

**Procedure**

The IRB must review and approve all screening and recruitment plans prior to implementation. If any changes need to be implemented, the PI will submit this amendment request to the IRB for review and approval prior to implementation.

The IRB prefers that, when possible, potential participants be consented prior to being screened. If screening occurs prior to the participant providing full informed consent, a study specific screening script should be used. The script describes 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.

Potential participants who are screened must be included in the maximum number of participants requested in the IRB application form and counted in the number of participants enrolled or that have been screened for the study in an amendment or periodic review submission.