Identifying Screening Activities that Involve Human Subjects

Definitions:

HHS regulations define *human subject* at 45 CFR 46.102(f) as follows:

> ***Human subject*** **means a living individual about whom an investigator (whether professional or student) conducting research obtains**
>
> 1. **data through intervention or interaction with the individual, or**
> 2. **identifiable private information.**

Obtaining identifiable private information or identifiable specimens includes, but is not limited to using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that have been provided to investigators from any source or that were already in the possession of the investigator.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Individually identifiable means that the identity of the subject is or may readily be ascertained by the investigator or associated with the information (linked to specific individuals by the investigator(s) either directly or indirectly through coding systems).

Recruitment vs. Screening:

Recruitment activities involve giving potential subjects information about the study so that they can decide whether they are eligible. A consent process is not required.

Examples: posting flyers, websites, handing out consent forms, word of mouth solicitation

Screening activities involve obtaining information from/about a potential subject so that the study team can decide whether they are eligible.

When a screening activity involves human subjects, consent (and HIPAA) regulations apply.

1) Obtaining eligibility data through a research intervention

Examples: a blood test or scan for research purposes, a drug washout period before beginning a study, having a subject do a trial run of a study procedure, testing whether a subject can tolerate an environmental manipulation

2) Obtaining eligibility data through a research interaction (where data is recorded and kept by the study team or a measure is given that would not otherwise be given)

Examples; administering a psychological measure, giving an academic test, observations, recording and keeping data from a series of yes/no eligibility questions for analysis of non-qualifying participants

3) Obtaining (i.e. accessing or using) identifiable private information to determine eligibility

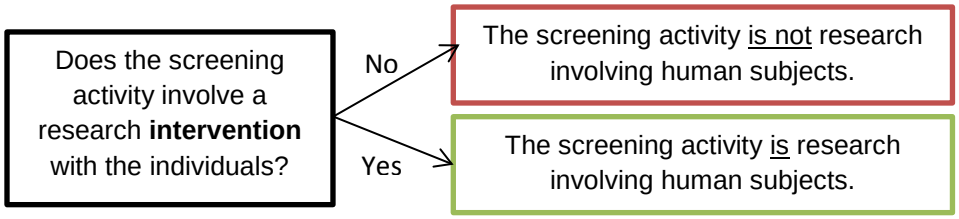
Examples: reviewing medical, educational, psychological records, obtaining data from a registry, obtaining data from another study

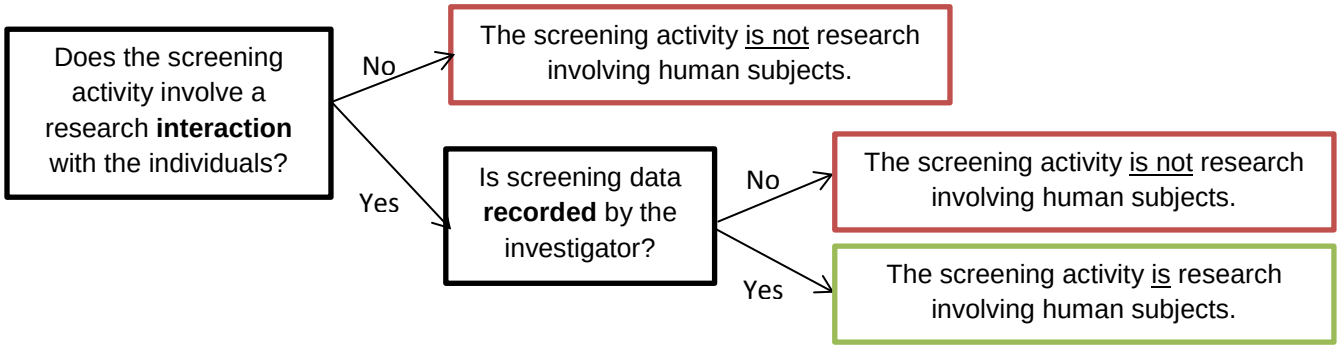
Sometimes studies provide screening measures that will be used as tools or guides, not for data collection

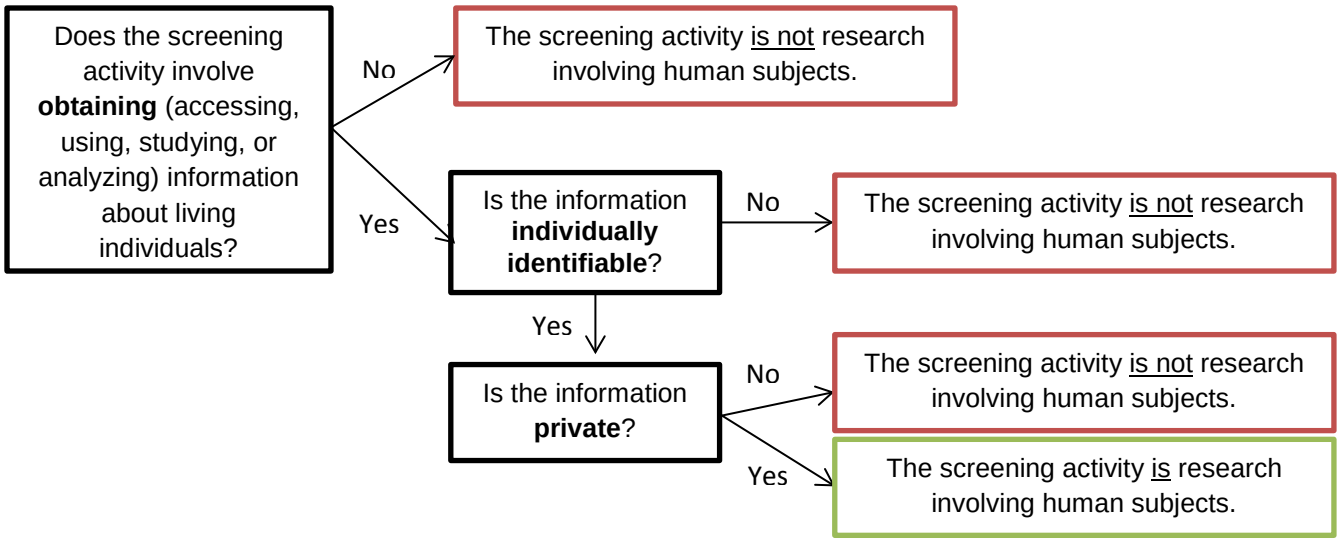
Examples of screening activities that do not involve human subjects:

- Asking a series of yes/no eligibility questions and not writing down responses
- Asking a series of yes/no eligibility questions and writing down responses but *immediately* destroying the information if the person is ineligible
- Searching a publicly available website to make a list of potential participants' names and contact information

When deciding whether screening involves human subjects, consider each screening activity separately.







For additional guidance, see OHRP's decision charts and "Guidance on Coded Private Information or Specimens Use in Research." The FDA also has guidance: "Screening Tests Prior to Study Enrollment"