

Study recruitment and subject screening are related, but distinct, activities.

Recruitment involves information and activities designed to provide information to potential subjects.

Screening involves the collection of information from or about potential subjects to determine whether they are eligible to participate in the research. Because it is an activity that would not take place if not for the research, screening is a research activity that must be described in the IRB application, even if information collected in the screening process may not be included as research data used for analysis.

The IRB must evaluate screening procedures to protect the privacy of individuals being screened and the confidentiality of the data obtained.

In general, Information collected as part of the screening process should be limited to that necessary to determine eligibility, unless the investigator provides an acceptable justification.

In the description of the screening process, the investigator must indicate what information will be collected for screening purposes and why that information is necessary.

If the screening information will be recorded in such a way that individuals can be identified (directly or indirectly), the investigator must indicate why identifiers are necessary, and whose identifiable information will be recorded: (a) eligible individuals who agree to participate, (b) individuals who are eligible to participate but decline, and/or (c) ineligible individuals.

If the screening data will be retained, the investigator must indicate why, and for whom. If retained in identifiable form, the investigator must provide information about data security procedures and the retention period

If screening information will be linked to study data for research purposes, the investigator must indicate why the linking is necessary, how the link will be established, and for how long.

If the investigator wishes to retain contact information for screened individuals who might be interested in future studies, the investigator must describe the information to be retained (for example, contact information only, basic demographics, study specific screening responses, particularly sensitive information) and describe how confidentiality will be maintained.

If more than contact or basic demographic information for screened individuals who did not qualify for or enroll in the research, the investigator is creating a recruitment registry and must submit an IRB application to manage the procedures associated with the registry. Consent must be obtained to retain information in a recruitment registry.

Informed consent or waiver of consent may be necessary depending on the nature of the information being collected as part of the screening process. A script describing the screening process is recommended even if regulatory consent is not required. When the investigator obtains and/or records identifiable private information for screening purposes, the IRB must approve a consent waiver or consent process for the collection of that information.

U-MIC TRANSCRIPT

Screening and Recruitment

If potential subjects are asked questions to establish eligibility but *no* identifiable information is recorded, no informed consent or waiver of informed consent is required.

If the study team plans to record and retain information that is identifiable, but not sensitive, a consent script or information sheet with a waiver of documentation is appropriate.

If the study team plans to record and retain identifiable information, *only* for individuals who screen *in* a consent waiver for screening is appropriate if permission to retain screening data is granted in the study informed consent.

If the study team wishes to record and retain screening information that is identifiable and sensitive for eligible and/or ineligible, documented consent should be obtained prior to screening (see template that follows).

In summary, the screening process should be approvable as long as the screening data are:

- well-described and necessary to research
- consistent with the selection criteria and recruitment materials
- collected under an approved consent waiver or informed consent process where the requirement applies
- not sensitive, or not recorded, or sensitive but not identifiable or recorded with identifiers that are later destroyed.

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