**REQUIREMENTS FOR SCREENING ACTIVITY AND MATERIALS**

**Screening Activities**

All screening procedures are part of the IRB review of proposed research. Although screening activities do not necessarily result in data that are used to evaluate study outcomes, such procedures occur because of the research reviewed by the IRB as part of the study application. Screening activities are reviewed as part of the overall recruitment and consent process and evaluated with respect to the protection of privacy and confidentiality of those who are screened.

**Screening procedures may include:**

• Any interaction or intervention with the participants to determine eligibility that would not otherwise have been performed if not for the study, or

 • Accessing the results of interventions that were performed for purposes other than the study.

 That is, collecting data directly from participants through written screening tools, oral responses to questionnaires, or accessing private information, i.e., grades, medical test results, legal records, or any other non-public information linked to a potential participant, for purposes of eligibility.

**Screening constitutes a research intervention or interaction that must be reviewed and approved by the IRB.**

The IRB application should include:

• All screening material(s) that may be used,

• Identification of data points, if any, that will be collected or acquired,

• Whether data will be retained from participants who are ineligible upon screening, and if so

why and how data collected during the screening procedures will be stored.

Additional Issues to Consider:

• **Protecting Privacy:** In order to protect the privacy of potential participants, collect only the minimal information necessary for screening purposes.

• **Keeping Information Confidential:** Often the greatest risk of obtaining information during the recruitment and/or screening process is the loss of confidentiality. The investigator must consider and describe how the confidentiality of this data will be maintained. Whenever possible, information obtained during this process should not be linked with subject identifiers. As noted above, the amount of data collected should be limited. Once collected it should be kept secure.

**Screening Procedures and Informed Consent**

• If screening procedures will take place prior to the participant providing informed consent for participation in the research, the investigator may request a waiver of signed informed consent or informed consent for screening activities in the IRB application.

• If an oral informed consent process is used, use of a screening script may be necessary.

• If screening activities will take place only after the subject has provided informed consent for participation in the research, then the waivers described above are unnecessary.

• HIPAA regulations apply to the screening process if it involves review of medical records. Investigators must obtain prospective HIPAA authorization or apply for a waiver of HIPAA authorization and informed consent.