Screening Prior to Consent: VUMC HRPP Guidance

* Study screening procedures are frequently confused with study recruitment. The two activities may overlap but are distinctly different.
  + **Recruitment** includes all activities where information is provided to the prospective participant (e.g. flyers, advertisements, websites, etc.)
  + **Screening** includes obtaining information directly from prospective participants.
  + Recruitment does not require the consent of the prospective subject whereas screening may.

**Screening**

* Screening individuals to obtain and record information to determine eligibility involves obtaining identifiable private information and is considered human subjects research and is subject to 45 CFR 46.
* Per the regulations and VUMC HRPP policy, the VUMC IRB may approve screening procedures **without obtaining the prior informed consent** of the prospective subject or the subject’s legally authorized representative **only** if the solicited information is **limited to the minimum necessary for screening/determining eligibility** for the main study AND if these procedures are limited to obtaining information through oral or written communication with the prospective subject or legally authorized representative.

**Screening Procedures That May Occur Before Consent:**

* Screening procedures must be brief in duration and limited to information needed to determine eligibility for the research.
* **Example:** Asking individuals eligibility questions that may include medical history information

**Screening Procedures That Require Prior Consent:**

* Administration of questionnaires/surveys that increase the potential risk to subjects
  + **Examples**: Lengthy standardized questionnaires that make a new, or refute an existing, diagnosis; Surveys/questionnaires where subjects' responses may place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing)
* Collection of biospecimens solely for research purposes would also require prior informed consent.
* It is the responsibility of the IRB to determine whether the screening activities for a specific study requires prior consent.