Eligibility Assessment Prior to Consent: VUMC HRPP Guidance

* Eligibility Assessment 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.)
  + **Eligibility Assessment** includes obtaining information directly from prospective participants via oral, written, or electronic means to assess whether they meet the study’s inclusion/exclusion criteria.
  + Recruitment does not require the consent of the prospective subject whereas Eligibility Assessment may or may not.

**Eligibility Assessment That May Occur Before Consent:**

* Per the regulations and VUMC HRPP policy, the VUMC IRB may approve the conduct of Eligibility Assessment procedures **without obtaining the prior informed consent** of the prospective participant **only if ALL of the following criteria are met:**
  + The solicited information is limited to the minimum necessary for determining eligibility for the main study
  + The Eligibility Assessment is limited to obtaining information through oral, written, or electronic communication with the prospective participant
  + The Eligibility Assessment does not increase the potential risk to the participant
  + The information collected during the Eligibility Assessment will not be utilized for any purposes other than determining eligibility for the study.
* **Example:** *Asking individuals eligibility questions that may include medical history information that is not expected to incur risk to the participant*

**Eligibility Assessments That CANNOT Occur Before Consent:**

* Administration of Eligibility Assessments 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)*

**It is the responsibility of the IRB to determine whether the Eligibility Assessment procedures for a specific study require prior consent from the participant.**