

**Vanderbilt Center for Effective Health Communication (CEHC)
BEST PRACTICES: HEALTH LITERACY AND ELECTRONIC CONSENT (eCONSENT)**

Informed consent is historically based on the ethical principles of respect for autonomy, and an individual's right to be left alone. While informed consent evolved separately in the medical and research domains, they now use similar consenting procedures. Informed consent currently focuses on **patient-centeredness, patient empowerment, and meaningful consent**. In addition, informed consent is increasingly shifting to technology that streamlines consent processes and increases patient understanding.

At Vanderbilt University Medical Center, all research studies are closely monitored by the Institutional Review Board (IRB) Office of Research. As such, VUMC is committed to obtaining legally effective informed consent prior to initiating research activities. Consent may be given by either the research participants themselves, or by legally authorized representatives.

Best practices for **approaching patients** about research opportunities include:

1. Positioning patients to make a voluntary choice about participating
2. Presenting research opportunities to patients at appropriate times
3. Viewing other individuals as part of the decision-making process
4. Considering cultural and language differences

Best practices for the **informed consent document (ICD)** include:

1. Writing at or below an 8th grade reading level
2. Using teachback and teach-to-goal techniques when reviewing the ICD with patients
3. Being able to describe both research processes and relevant medical terms to patients
4. Providing a copy of the consent form to patient

Informed consent document necessities:

- Details about what will happen for the duration of the study
- Summary of risks, benefits, and alternatives for study participants
- Summary of procedures to be followed
- Who to call if something goes wrong
- Who to call for information about participant rights and interests
- Confidentiality provisions

Consent documents should be drafted so they meet a variety of possible health literacy levels.