

BEST PRACTICES: HEALTH LITERACY AND ELECTRONIC CONSENT (eCONSENT) FOR RESEARCH

Informed consent is based on the ethical principles of respect for autonomy, and requires adequate information, comprehension, and voluntariness. With widespread use of technology, many research studies are using electronic consent (eConsent).

Increasing use of technology in the consent process requires translation of key elements of informed consent to eConsent procedures. Use of technology may be a barrier for some potential participants – incorporating best practices can ensure adequate understanding and reduce the barrier(s) to consent for your research participants.

At Vanderbilt University Medical Center, all research studies are closely monitored by the Institutional Review Board (IRB) Office of Research. The IRB requires the following from studies using eConsent:

- The consent form must be prepared in REDCap, which is HIPAA compliant. The template REDCap data dictionary for a standard health sciences eConsent can be downloaded [here](#) and uploaded into your REDCap project to add eConsent functionality.
- Investigators should provide a pdf and a link to their REDCap eConsent survey for IRB approval.
- A signature with a date stamp for each enrolled participant. Participants can sign by typing in their name, typing in a personalized PIN, or using their stylus/fingertip on a touch-screen.
- For studies following Good Clinical Practice or using PHI: Participants are provided a copy of the signed consent (e.g. hard copy in clinic or via mail or a link to download the pdf). Soon, participants may be able to receive a text and receive a link to the ICD.

Best Practice for Informed Consent	Application to eConsent	Resources
Using language appropriate for all health literacy levels	Write <u>at or below</u> an 8th grade reading level, depending on your population of interest Avoid jargon and multisyllabic words when possible	Flesh-Kinkaid Grade Level and SMOG Index <ul style="list-style-type: none"> • Both available for free online here • Flesh-Kinkaid Grade Level also available in Microsoft Word EHC Core services can assist you to: <ul style="list-style-type: none"> • Improve readability of consent materials according to effective communication techniques • Provide in-text suggestions to improve understanding
Using teach-back and teach-to-goal techniques when reviewing the ICD with patients	Incorporate comprehension questions online to confirm understanding of the ICD Summarize key elements	EHC Core services can assist you to: <ul style="list-style-type: none"> • Identify key elements of understanding • Determine processes for handling missed comprehension questions
Being able to describe both research processes and relevant medical terms to patients	Use hover-over definitions in REDCap; clearly instruct participants how to use this feature in your ICD Incorporate educational videos	REDCap team <ul style="list-style-type: none"> • Request permission from REDCap administrators to access hover-over definition functionality EHC Core services can assist you to: <ul style="list-style-type: none"> • Translate medical and research terms into lay language • Reduce/Identify text in need of hover-over definitions

The EHC Core has experience with eConsent and can assist – please reach out to us!

Website: https://www.vumc.org/cehc/consultingservices_home

EHC Core Contact: lindsay.mayberry@vumc.org