Informed Consent versus Documentation of Informed Consent – What’s the Difference?

- Informed consent is an ongoing educational process that takes place between the investigator and prospective subject, allowing the investigator and the participant to exchange information and ask questions. It may occur verbally, and does not necessarily involve acquiring signatures on an informed consent or assent document.

- In most cases, federal regulations require informed consent AND documentation that the informed consent process took place. Documentation that the informed consent process took place is typically in the form of an informed consent or assent document signed by the subject or the subject’s legally authorized representative.

- In certain circumstances, the federal regulations allow a:
  - waiver of the requirement for documentation of informed consent (which means the informed consent process still takes place, but there is nothing the subject signs to document it occurred), or
  - waiver of the requirement for the informed consent process (e.g., deception research requires this waiver; some record-review research may justify this waiver).

- If the requirement for documentation of informed consent has been waived, the IRB may still ask the PI to develop documents like phone scripts, or cover letter templates (e.g., for survey/questionnaire research), which include all the required elements of informed consent per federal and institutional regulations. Visit Section 2 of any of the online IRB applications to download a copy of the Cover Letter Template (associated with “Form F: Request for Waiver of Documentation of Informed Consent Process”).

- Best Practice Tip: Include notes in the subjects’ charts or study records describing the informed consent process. The Office of Research Integrity (ORI) offers key elements and sample notes on its Quality Improvement Resources web page, topic “Key Elements for Notes Describing the Informed Consent Process”.

- The Institutional Review Board (IRB) and ORI have standard operating procedures which describe policies and procedures for obtaining and documenting informed consent/assent, and for requesting waiver of informed consent or waiver of documentation of informed consent for non-exempt human research. For a copy, go to the “Special Requirements” section of ORI’s Standard Operating Procedures web page.

Next, in the Informed Consent Process Educational Series…
- Informed Consent/Assent for Research Involving Vulnerable Populations
- Informed Consent/Assent Process Resources at your Fingertips
- and more…!

Have ideas for other Informed Consent Process Educational Series topics? Contact Judi Kuhl at Judi.Kuhl@uky.edu with suggestions.