Informed Consent/Assent for Research Involving Vulnerable Populations

- The UK Institutional Review Board (IRB) gives special consideration to protecting the welfare of vulnerable subjects such as children, prisoners, fetuses/neonates, pregnant women, and individuals with impaired consent capacity. The IRB also recognizes that additional populations such as students may qualify as vulnerable populations and need safeguards in place for their protection during study participation.

- The IRB follows applicable federal and state regulations and IRB policy to assist in reviewing and approving proposed research that involves vulnerable subjects such as:
  - Pregnant Women, Human Fetuses and Neonates (45 CFR 46, Subpart B);
  - Research Involving Prisoners (45 CFR 46, Subpart C);
  - Research Involving Children (45 CFR 46, Subpart D, 21 CFR 50, Subpart D and U.S. Department of Education, Subpart D);
  - Research Involving Individuals with Impaired Consent Capacity (See UK Impaired Consent Capacity Policy);
  - Research involving UK students (See the IRB Guidance for Enrolling University Students as Subjects);
  - Research involving K-12 students (See the IRB Guidance for Enrolling K-12 Students as Subjects).

- One of the ethical concerns about the informed consent/assent process when recruiting vulnerable populations revolves around the Belmont Report principle of respect for persons:
  "Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied."  The Belmont Report (C.1.)

- The IRB application is designed to collect information from the PI which enables the IRB to determine whether additional safeguards and measures for the informed consent process need to be established (e.g., Form T, Form U, Form V, Form W).

- Application instructions [Med-Instructions]  [Nonmed-Instructions] offer tips on important verbiage to include as well as templates [Med-Template]  [Nonmed-Template] to use as a guide for developing the consent/assent/parental permission document. Also, for your convenience, the IRB/Office of Research Integrity (ORI) has provided a template of specific prisoner-related elements that should be included in the informed consent process and/or informed consent document: [WORD] [RTF].

- The IRB and ORI have standard operating procedures which describe additional measures to be taken and important references for obtaining and documenting informed consent/assent for vulnerable populations and for research involving sensitive issues (e.g., Research involving HIV screening and/or AIDS research; Research involving DNA banking, genetic research, or gene therapy). 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…
- Non-English Speaking Subjects or Subjects from a Foreign Culture
- 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.