Did You Know…?

- The federal regulations establish a mandate for the inclusion of eight basic elements of informed consent [e.g., 21 CFR 50, 45 CFR 46.116, 117, and 38 CFR 16.116, 117]. Six additional elements may be required, depending on the nature of the research. The University of Kentucky (UK) Institutional Review Board (IRB) also asks for more site-specific elements of informed consent to be included. All elements of informed consent are in the informed consent form (ICF) template to be used as a guide [Medical] [Nonmedical].

- The informed consent process is one of the primary ethical considerations underlying research with human subjects and reflects the basic principle of “Respect for Persons” as outlined in the Belmont Report.

- The informed consent process is an ongoing exchange of information between the investigator and the research participant. Once the subject agrees to participate and/or signs the informed consent document, the lines of communication between researcher and participant should remain open throughout the study.

- Studies designed to test research participant’s actual versus perceived understanding of the clinical trials in which they participated suggests the presence of therapeutic misconception. ¹, ²

- The purpose of the study and potential benefits to society are among the elements of informed consent reported to be the least understood. Alternatives to participation was also among the least understood elements of informed consent.¹

- 24% of research participants do not know who to contact with a problem³.

³as reported from post-consent interviews conducted by Education and Compliance Coordinators at the University of Pittsburgh.

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- Informed Consent/Assent Process Resources at your Fingertips
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