



Elements of a Successful Consent

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Topic: Informed Consent

Problem/Issue Statement

To train investigators, research staff and clinicians on how to conduct an appropriate, effective and successful consent process.

Description of Program

Under the auspices of the NIMH Office of the Clinical Director, the Human Subject Protections Unit (HSPU) developed a course that provides training to investigators on how to ensure informed consent of research participants. This program includes the following elements:

- Element 1: Awareness & Understanding of Process Defines informed consent, who may obtain informed consent, who may give consent and assent, who may be surrogate decision makers, and identifying the concept of therapeutic misconception.
- Element 2: Subject's Capacity To Give Informed Consent Differentiates between competency vs. consent capacity and reviews facets of capacity, the elements of a capacity assessment, and what can impair capacity.
- Element 3: Structure & Format Reviews the required elements of the informed consent document and special processes for the blind, non-English speaking and telephone consents. Presents informed consent as an ongoing dialogue between researchers and subjects.
- Element 4: Scaffolding & Context – Provides guidance for conducting the consent process: consent preview, document preparation, differentiating research vs. clinical care, presentation style and language, body language, consenting one subject to one consent at a time, and the consent environment and timeline.

Program Evaluation: This program is evaluated by pre-and post-course tests to determine if educational goals have been met; Feedback is solicited from attendees

Future Use: A consent training videotape is nearing completion The course is being offered to other NIH intramural institutes.

Suggestions for implementation at other sites: This best practice serves as a guide for other research venues and can easily be implemented with existing resources.