



The Informed Consent Process

This is the third installment in a series devoted to familiarizing everyone committed to the protection of human research subjects at UB and its affiliated hospitals with the contents of the updated **Human Research Protection Program Policies and Procedures Manual**. The Manual devotes twenty pages to various aspects of the informed consent process (Section 14. The Informed Consent Process, pp. 120 –140).

Informed consent is one of the critical cornerstones of human subject protection. The informed consent process begins with the first contact between the research team and prospective subject and continues throughout the course of the study. The consent process must fully inform research subjects in language that they can understand about the study's risks and benefits and the subject's participation must be voluntary and not susceptible to any form of coercion. Special consideration must be given to vulnerable populations.

There is a great deal of useful information in this section concerned with the many aspects of the informed consent process. The subsection headings found below provide a general sense of the content. The first eight subsections deal with applicable federal regulations and best practices with respect to informed consent while final nine subsections treat the special considerations that must be given to various vulnerable populations. It is well worthwhile to peruse this important chapter. Access the Manual at www.research.buffalo.edu/forms/hs/ubsop.pdf.

14. The Informed Consent Process

- 14.1 Overview
- 14.2 IRB Requirements Regarding Individuals Who Will Obtain Consent
- 14.3 Presentation of Study Information
- 14.4 Use of IRB Approved Consent Documents
- 14.5 Providing Enrolled Subjects with Important New Information
- 14.6 Elements of Consent
- 14.7 Waiver of Consent Requirements
- 14.8 Documenting Consent
- 14.9 Use of Non-English Consent Forms
- 14.10 Consent of Illiterate English-Speaking Subjects
- 14.11 Consent of Physically Incapacitated Individuals
- 14.12 Consent Involving Adult Decisionally Incapacitated Individuals
- 14.13 Permission and Assent for Children
- 14.14 Wards of the State
- 14.15 Consent Guidelines for Genetic Research
- 14.16 Consent Guidelines for Research Involving Pregnant Women or Fetuses Prior to Delivery
- 14.17 Consent Guidelines for Research Involving Neonates