Obtaining and Documenting Informed Consent

POLICY TITLE: Obtaining the Informed Consent and Documenting Informed Consent Process

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POLICY STATEMENT: The informed consent process will be conducted in compliance with all regulations, guidelines and policies applicable to the protection of human subjects.

SCOPE: This policy applies to all activities associated with the process of obtaining and documenting the informed consent process at the Center for Cancer Research, NCI.

CONSIDERATIONS/REFERENCES/DEFINITIONS:

The conduct of clinical investigations is based upon the voluntary consent of the subject who has been appropriately informed about a study’s risk and benefits. The ethical principle of respect for persons requires that subjects be given the opportunity to choose whether to participate in research.

Three elements are required for valid informed consent:

- Disclosure of relevant information to prospective subjects about the research
- Prospective subjects’ comprehension of the information
- Prospective subjects’ voluntary agreement, free of coercion and undue influence, to research participation.

Consent is an ongoing process. It starts well before any forms are signed and continues until the subject has completed participation. The informed consent process involves meeting with the potential subject, outlining the nature of the study, the risks and benefits of participating, alternatives to participation, and all other information necessary for the subject to make an informed decision whether or not to participate. The consent form formalizes the subject’s agreement to participate in the research study.

Obtaining the consent by telephone is prohibited on FDA (any IND, IDE) studies.

For a child to participate in research, permission must be obtained from the child’s parent(s), legal guardian(s), or other legally authorized representative. Additionally, assent must be obtained from the child, if capable of giving assent (as determined by the Institutional Review Board).

Obtaining consents for non-English speaking patients should be followed per the CCR Informed Consent SOP. Principal Investigators should consider the following when developing a protocol that may have multiple non-English speaking patients:

- If the population of a protocol will target a specific non-English speaking population, a translated version of the consent document should be included with the protocol submission to IRB
- The IRB will provide expedited approval of the Short Written Consent form in the subject’s native language for non-English speaking patients on a case per case basis. The IRB may require that the PI provide a translated full version of the consent if deemed appropriate.

Documentation of the informed consent process by the Principal Investigator or designee should be included in the medical record to establish that the subject was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent. The original consent should be filed in the medical record.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form. The informed consent process should be documented in the medical record.

Subject: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the clinical trial.

Adult: Anyone 18 years of age or older. For purposes of providing consent, a minor who is married, a parent, or an emancipated minor may also be considered an adult.

Assent: A child’s affirmative agreement to participate in a clinical investigation.

REGULATIONS/GUIDELINES:

FDA Regulations

21 CFR 50 Protection of Human Subjects:

- 50.3 Definitions
- 50.20 General Requirements for Informed Consent.
50.25 Elements of Informed Consent.
50.27 Documentation of Informed Consent.
50.55 Requirements for Permission by Parents or Guardians and for Assent by Children.

21 CFR 312 Investigational New Drug Application:
- 312.62 Investigator Record Keeping and Record Retention

DHHS Regulations

45 CFR 46 Protection of Human Subjects:
- 46.102 Definitions
- 46.116 General Requirements for Informed Consent
- 46.117 Documentation of Informed Consent
- 46.408 Requirements for Permission by Parents or Guardians and for Assent by Children

International Conference on Harmonisation-Good Clinical Practice (ICH-GCP)

E6 Good Clinical Practice (GCP) Consolidated Guidance:
- GCP 1. Glossary
- GCP 4.8 Informed Consent of Trial Subjects

NIH Medical Administrative Series

- MAS M77-2 (rev.) - Informed Consent
- MAS M92-5 (rev.) - Research Involving Children and Children's Assent to Research
- MAS M87-4 (rev.) - Research Involving Adults Who Are or May Be Unable to Consent

NCI Institutional Review Board

NIH Office of Human Subjects Research (OHSR)

RESPONSIBILITY: It is the responsibility of the staff of the Center for Cancer Research, NCI, involved in the conduct of clinical trials to ensure that the informed consent process is properly followed and that subjects’ rights are protected.