



Informed Consent

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For CALGB Participants Only

Overview

- What is informed consent?
- Principles of informed consent
- Elements of a consent document
- Use of the CALGB "model consent form"
- Obtaining informed consent
- Documenting the consent process
- Resources

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What is Informed Consent?

Voluntary and documented confirmation of a subject's willingness to participate in a trial.

What Is Informed Consent? The Right To Say "No"

- Protection of subjects is the responsibility of the PI, IRB, and Sponsor.
- Lack of participation or withdrawal from the study will involve no loss of benefits or rights of care.

Principles of Informed Consent

- Descriptions are in the **Declaration of Helsinki**
- The primary principles are:
 - The form is written in a language they can understand
 - Information is given in both written and verbal form
 - The volunteer must personally sign and date the form

Principles of Informed Consent

The investigator is responsible to ensure informed consent is obtained and documented:

- Prior to registration on the study; and
- ***Before*** any protocol-related procedures or treatments are performed

Elements of Informed Consent

- Essential elements of informed consent can be found in the CFR § 46.116.
- These include descriptions of:
 - Study purpose, procedures, and duration
 - Risks and discomforts
 - Benefits
 - Treatment alternatives
 - Patient's rights
 - Confidentiality of records

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Use of the CALGB Model Consent Form

- The protocol provided model consent form is an NCI-approved written patient consent.
- IRB changes are acceptable as long as the major requirements/elements are not removed or changed dramatically (i.e., treatment, patient expectations, toxicities, benefits, etc.) Major changes require *CALGB Central Office approval*.

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Obtaining Informed Consent

- While the investigator is responsible for obtaining IC, s/he can delegate this responsibility to another, unless your IRB, sponsor, or state law prohibits this.
- Informed consent is a ***process*** that requires:
 - *Providing* adequate information so that the subject can make an “informed” decision.
 - Providing sufficient time for the subject to consider all options and receive answers to his/her questions.
 - Ensuring that the subject comprehends the information.
 - Obtaining the subject’s *voluntary* consent to participate.

Documenting the Informed Consent Process

- A properly completed and signed consent form serves to document the consent process.
- A progress note is not required, but does help to support the process...*include the study title, statement that the consent was discussed with an opportunity for Q&A, the subject appeared to comprehend, the consent was signed prior to enrollment and start of study treatment, and the subject received a copy of the consent form.*

General Resources

- Handouts
- www.fda.gov/oc/oha/faq
 - IRB regulations
 - Informed consent regulations
 - Clinical investigations
 - Other

