



Informed Consent

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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.
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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
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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
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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.
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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, etc.)

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.
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Documenting the IC 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.*
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General Resources

- handouts
 - www.fda.gov/oc/oha/faq
 - IRB regulations
 - Informed consent regulations
 - Clinical investigations
 - other
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