Understanding Informed Consent for Investigational Products

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Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration

Objectives

- Describe the regulatory requirements for informed consent
- Outline the key information to help subjects to understand consent
- Provide an example of obtaining informed consent for a clinical study: dialogue between a patient with a rare disease and a physician

Key Words

You will hear us use these words. Here's what they mean:

1. Sponsor
2. Investigator
3. Sponsor-investigator
4. Clinical trial or study
5. Human subject/research participant
6. Institutional Review Board (IRB)

Elements of Informed Consent

a) Basic Elements

1. A statement that the study involves research
   - Explanation of the purpose / expected duration
   - Description of procedures/research interventions
2. Reasonably foreseeable risks or discomforts
3. Reasonably expected benefits to the subject or to others
4. Disclosure of appropriate alternatives
5. Confidentiality/FDA may inspect
6. Compensation and research-related injuries
7. Point of contact for questions
8. Participation is voluntary

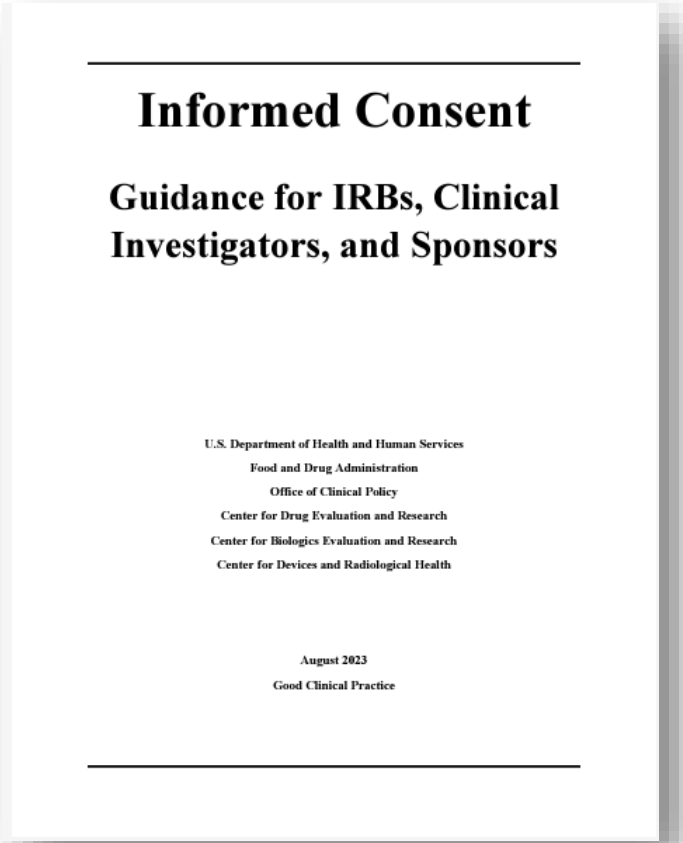
Elements of Informed Consent

b) Additional Elements (When Appropriate)

1. A statement that the particular treatment or procedure may involve unforeseeable risk to the subject (or embryo or fetus)
2. Circumstances of study termination
3. Costs to the subject
4. Consequences of withdrawal
5. A statement that significant new findings relating to the subject's willingness to continue will be communicated
6. Approximate number of subjects in the study

c) Mandatory verbatim statement related to posting on ClinicalTrials.gov

Informed Consent Guidance



Informed Consent

Guidance for IRBs, Clinical Investigators, and Sponsors

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Clinical Policy
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Center for Devices and Radiological Health

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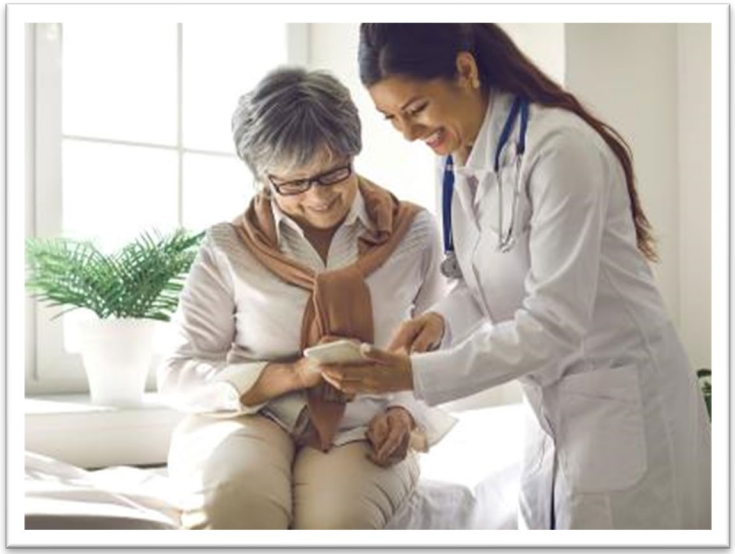
Good Clinical Practice

Improving Informed Consent with Key Information*

Informed consent must begin with:

- A concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative
- In understanding the reasons why one might or might not want to participate in the research
- This part of the informed consent must be organized and presented in a way that facilitates comprehension



*The revised Common Rule requires key information for federally funded research (see 45 CFR 46.116(a)(5)(i)). FDA's proposed rule would require the identical provision for FDA-regulated trials (see 21 CFR 50.20(e)(1); see 87 FR 58733).

Key Information Example

Key Information

This key information can help you learn more about this clinical trial and decide whether to take part in the trial.

Voluntary Participation and Right to Discontinue Participation

Your participation is voluntary and based on what is important to you.

You may leave at any time without penalty.

Purpose of the Research

This research is being conducted to find out if the product being studied is safe and effective in treating people like you with your health condition.

Key Information Example

Key Reasonably Foreseeable Risks and Discomforts

If you take the study product, you have a chance of side effects, such as fever or nausea.

We do not know if this product will help you.

There is a chance that it could worsen your condition.

Reasonably Expected Benefits

Researchers are studying this product to learn more about whether it will improve your condition.

If you are randomly assigned to take the product, it may improve your condition.

If you are randomly assigned to take the inactive pill (also called a placebo), you will not receive the product and will not benefit directly.

Key Information Example

Expected Duration and Procedures to Be Followed

To learn if the product is helpful, it is important that some people take a placebo (inactive pill). A computer will assign you randomly to take the product or the placebo.

The trial will take 6 months and each visit will take 2 hours. You will have blood drawn at each visit.

Compensation and Medical Treatments for Research-Related Injuries

If you are injured by participating in this research, the medical treatment of your injury will be paid for.

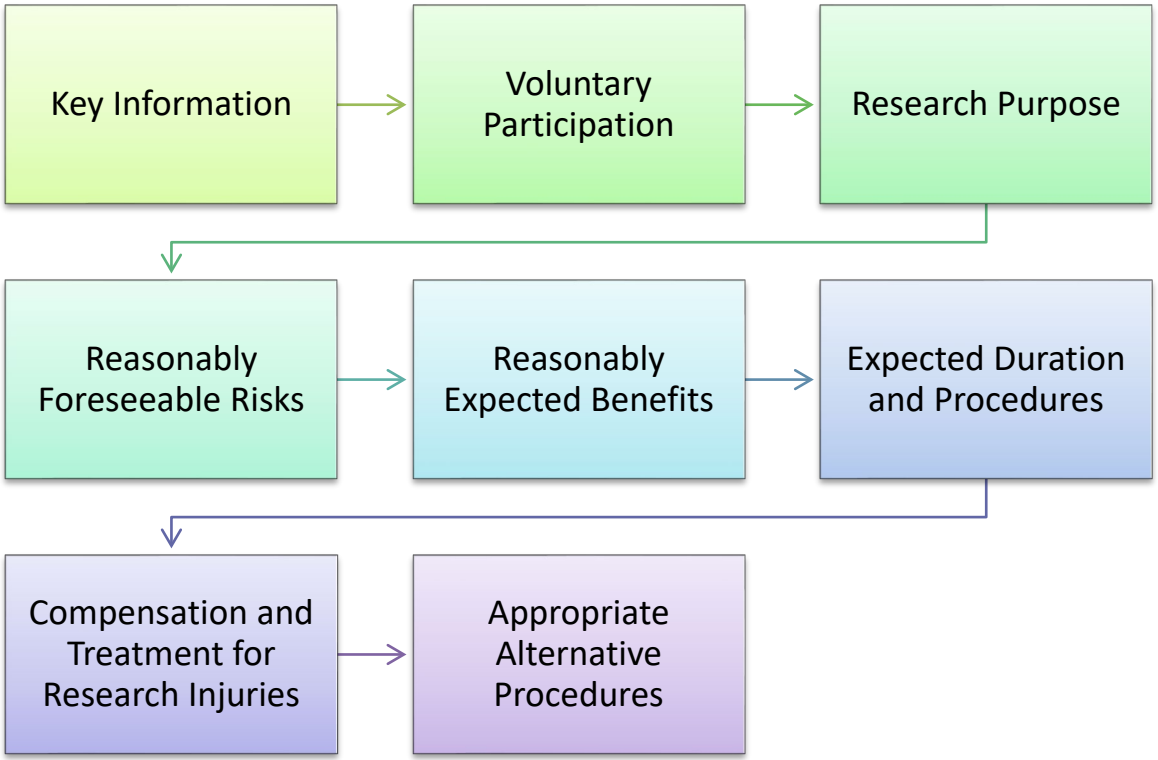
Appropriate Alternative Procedures

Before joining the trial, you should talk to your doctor about other approved options for your condition and whether this trial is a good choice for you.

Role Play

- Informed consent conversation with a patient with a rare disease and a physician using key information

Role Play with Key Information



Resources

- FDA Informed Consent Regulations – 21 CFR 50 (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50)
- Common Rule regulations – 45 CFR 46 (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46)
- FDA guidance on Informed Consent (https://www.fda.gov/media/88915/download)
- Clinical Trials Information (https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection)
- Clinical Trials: What Patients Need to Know (https://www.fda.gov/patients/clinical-trials-what-patients-need-know)
- FDA Information Sheet Guidance on Payment and Reimbursement to Research Subjects (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects)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