

INFORMED CONSENT FORM

What is informed consent?

Informed consent is **the process of telling potential research participants about the key elements of a research study** and what their participation will involve.



What are informed consent forms?

Informed consent forms are written in plain language and provide adequate information about a clinical study. **The purpose of an informed consent form is to ensure the participant has everything they need to make a well-informed decision.**

Informed consent forms include:



1. A statement that participating in a research study is voluntary; refusal to participate will involve no penalty; and your ability to discontinue participation without penalty
2. A summary of the study including the purpose, duration, and list of procedures
3. Outline what participation will involve in order to comply with the study protocol (study objectives, design, methods, assessment types and collection schedules)
4. Description of any foreseeable risks or discomforts
5. Reasonable and expected benefits
6. Alternative procedures or course of treatment if any
7. Description describing how confidentiality of records are maintained
8. Contact information for whom can answer questions
9. Compensation and medical treatment in event of injury

Additional elements of informed consent forms may include:



1. Any additional costs that may result from participation in the research
2. Unforeseeable risks
3. Anticipated situations in which a subject may be terminated by the investigator
4. What happens if a subject withdraws from the study
5. Information of significant new findings that may develop during the course of the study which may relate to subjects' willingness to continue in the study
6. Number of subjects involved in the study

Important details



Take your time reviewing the informed consent form. **It is perfectly fine to ask as many questions as you have, and receive answers to your complete understanding, before signing an informed consent form.** Remember, even after signing an informed consent form, you can change your mind at any time.

Connect with resources to help guide you through this journey



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