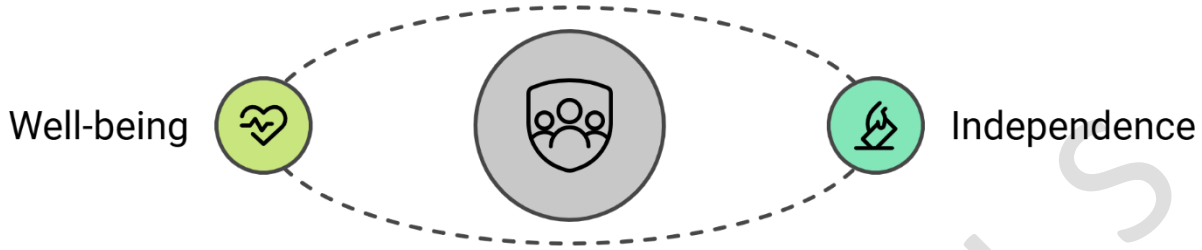
INFORMED CONSENT FORM IN CLINICAL TRIALS

Informed consent protects individuals who participate in clinical research. Its primary purpose is to promote independence and protect the well-being of participants.



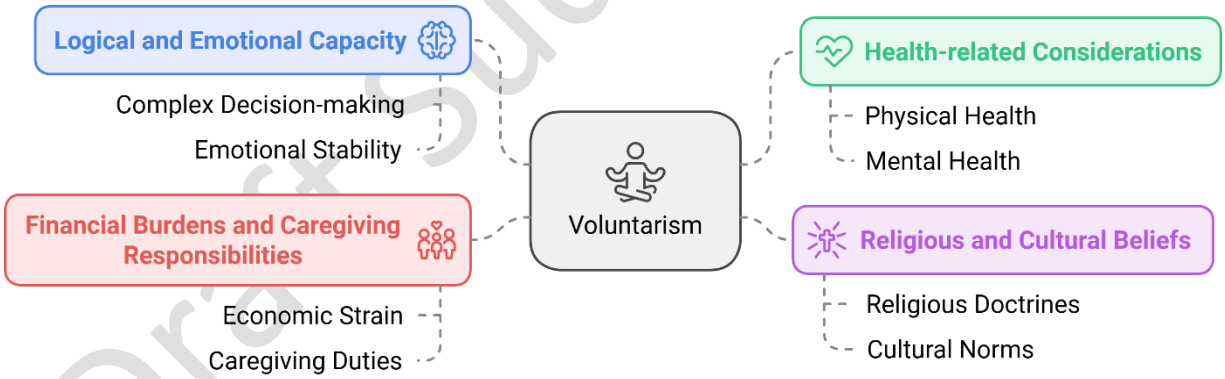
FUNDAMENTALS OF INFORMED CONSENT

1. Voluntarism

Voluntarism is a person's ability to make independent, unforced decisions that are compatible with their goals, circumstances, and prior experiences.

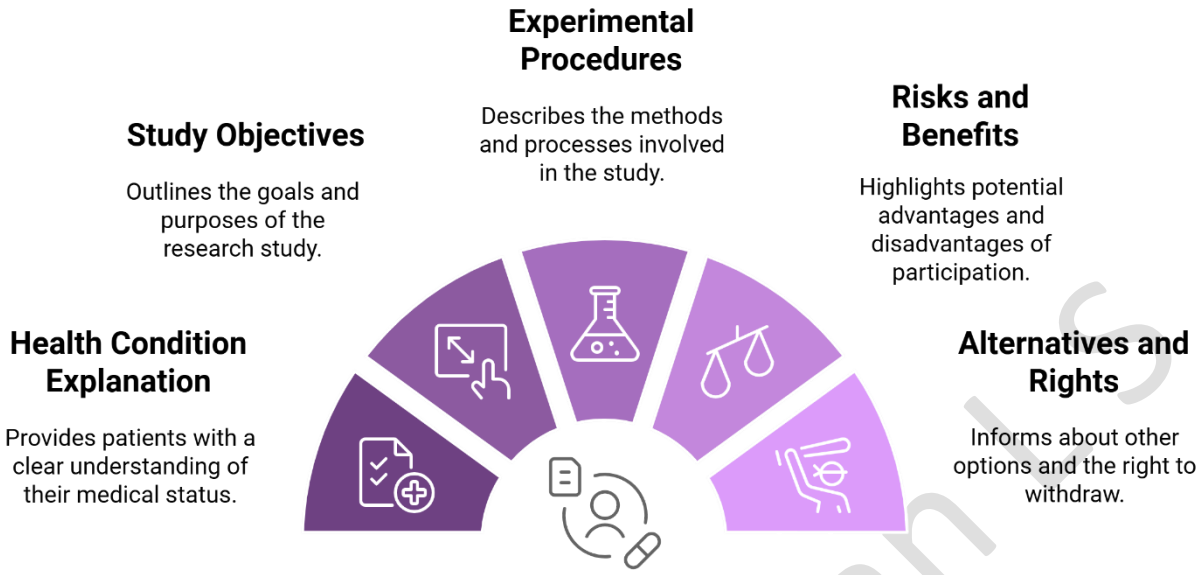
Factors that may impact voluntarism include:

- Logical and emotional capacity to make complex decisions
- Health-related considerations
- Religious and cultural beliefs
- Financial burdens and caregiving responsibilities



2. Information Disclosure

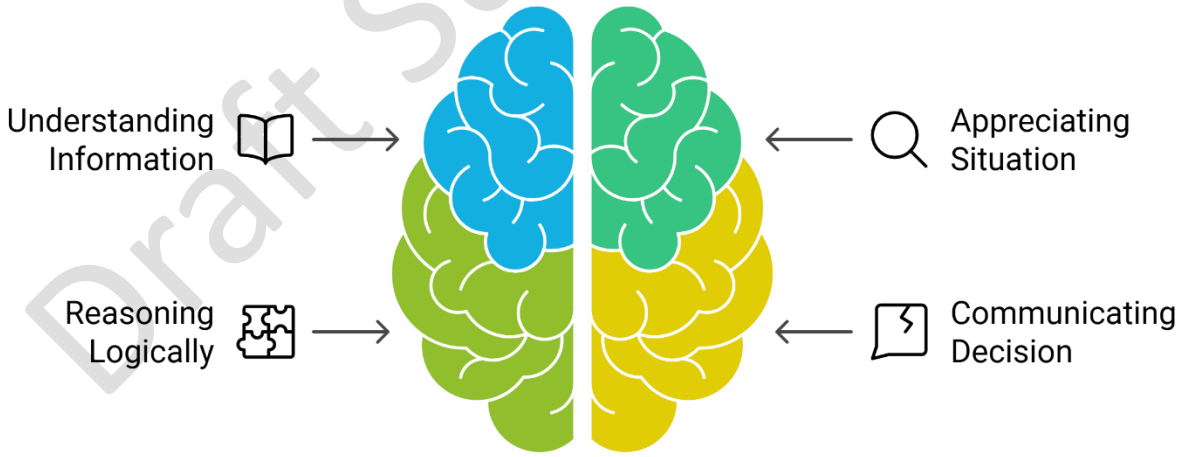
Information disclosure means providing patients with all of the information they need to make an informed decision. This should contain an explanation of their health condition, the study's objective, any experimental procedures used, potential risks and benefits, the nature of the problem, and the likely outcomes without treatment. It should also detail viable alternatives, related risks and advantages, the right to withdraw at any time, and any other information necessary for making an informed decision.



3. Decision-Making Capacity

This refers to the participant's ability to understand and consider health-related decisions, as well as successfully convey their choices. Decision-making capacity is based on both mental talents and voluntarism and is made up of four components:

- Understanding the information provided
- Appreciating the specifics of their situation
- Reasoning through the information logically
- Clearly communicating a decision



Researchers are encouraged to ensure that participants understand the study's aim, risks, obligations, potential outcomes, and the opportunity to withdraw at any time.

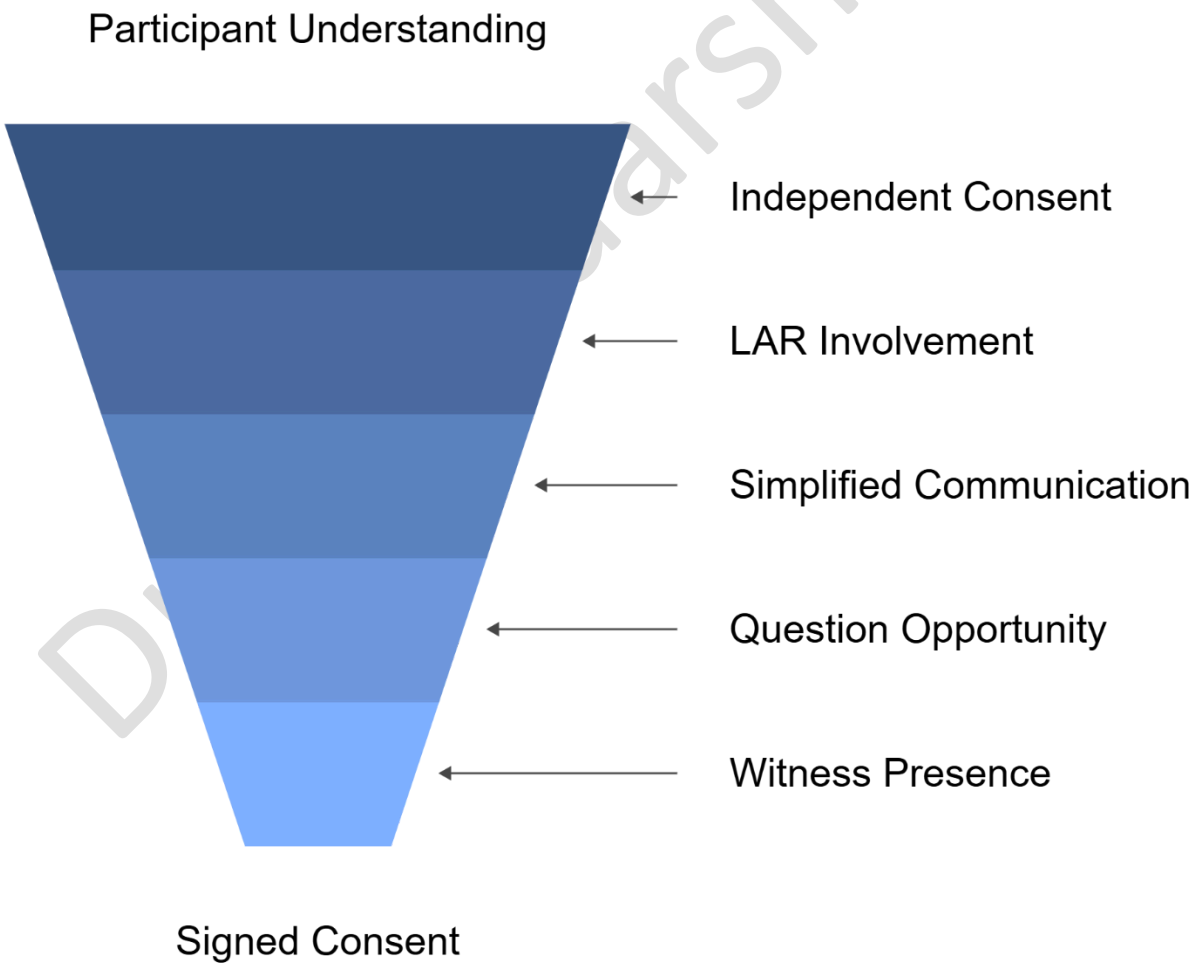
OBTAINING INFORMED CONSENT

Individuals who understand the research information should personally consent to their participation.
In circumstances when participants are unable to consent independently, such as minors or those with serious cognitive impairment, a legally authorized representative (LAR) or guardian may do so on their behalf.

Where feasible, the subject should offer written consent in addition to that of their LAR. Effective communication tactics, such as employing simplified language, breaking down material into smaller chunks, and repeating crucial elements, can aid comprehension. Participants should also have the opportunity to ask questions and explain any doubts.

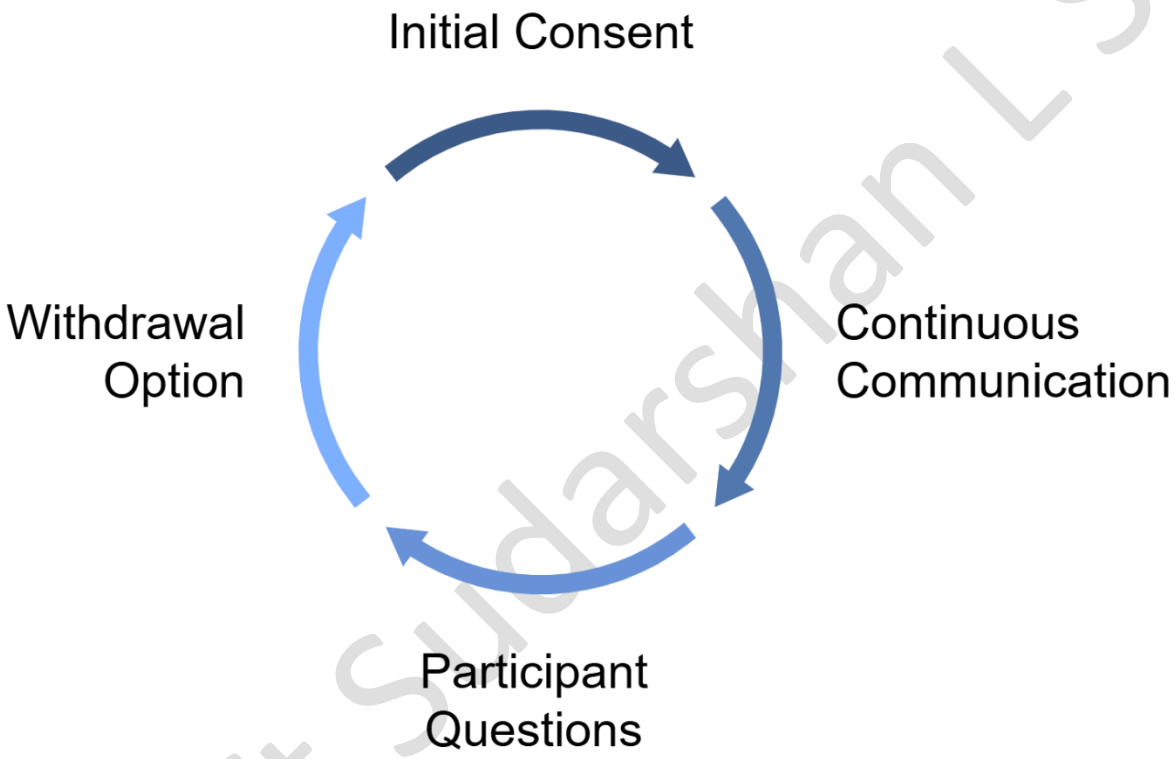
When participants or LARs are unable to read the consent document, an impartial witness should remain present during the conversation.

The investigator must answer all questions to the participant's satisfaction. Once satisfied, the participant acknowledges consent by signing the ICF, confirming informed and willing participation.



INFORMED CONSENT: AN ONGOING PROCESS

Consent does not compel subjects to stay in the study until it is completed. Participants can withdraw their participation at any time. "Ongoing consent" refers to gaining further consent as needed throughout the study. This is an important ethical practice in clinical research, with the researcher accountable for informing participants of any new developments. Participants may continue to ask questions, express concerns, or withdraw consent.



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EXCLUSIONS TO INFORMED CONSENT

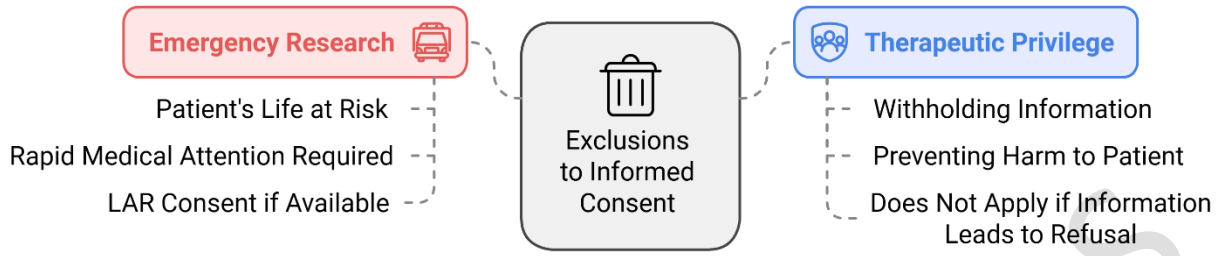
1. Emergency Research

In cases where the patient's life is at risk, rapid medical attention may be required, and any delay could be detrimental to the patient. In such circumstances, if the LAR is available, their consent should be sought.

2. Therapeutic Privilege

Therapeutic privilege occurs when an investigator withholds medical information that could jeopardize a patient's physical, mental, or social well-being. This does not, however, apply to

circumstances in which withholding information causes the patient to decline treatment or refuse participation in a potentially helpful study.



REFERENCE

1. Informed consent in clinical research: Revisiting few concepts and areas
2. Informed Consent for Clinical Trials - USFDA
3. Informed Consent form template