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Review Article

Informed Consent Standards in Research

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Abstract

Research is a carefully planned, systematic, and organized process aimed at finding solutions to unanswered questions. The researcher must always consider fundamental ethical principles such as beneficence, non-maleficence, justice, and respect for persons. All research studies involving human participants must obtain Informed consent. The informed consent must have four essentials: relevant information about the research study, competence of the participants, understanding of the study, and voluntariness for participation. Informed consent can be waived in situations of minimal risk and impracticability of obtaining consent. Re-consent should be taken following revisions or modifications of study procedures. Special groups, the community and vulnerable populations must be carefully contacted and included in the study. Thus, Informed consent is not only a legal requirement but also a vital pillar of ethical practice in research.

Keywords: Informed consent, Re-consent, Consent process, Research ethics.

Introduction

Research is a carefully planned, systematic, and organized process aimed at finding solutions to unanswered questions. When research involves human participants, it requires additional caution at every stage—from planning to implementation and utilization of the findings. The researcher must always consider fundamental ethical principles such as beneficence, non-maleficence, justice, and respect for persons. It is essential to follow established protocols and standard operating guidelines throughout the study.

The responsibility of safeguarding participants' rights, safety, and well-being lies with the researcher. This includes addressing legal, ethical, and social concerns associated with the research. Participants may choose to take part for various reasons—such as the desire to help others, contribute to a noble cause, or receive monetary benefits. However, participation must always be completely voluntary. Participants should be fully informed about the study's purpose, methodology, interventions, potential benefits to themselves and society, possible risks or adverse effects, as well as policies on data privacy, data sharing, and confidentiality.

All research studies involving human participants must obtain Informed consent. Informed consent is a process of complete and accurate disclosure of the study protocol, ensuring comprehension and voluntary participation by the subjects. The informed consent must have four essentials-relevant information about the research study, competence of the participants, understanding of the study and voluntariness for participation.

Requirements for Informed Consent

- It is mandatory to obtain informed consent from participants before the study.
- The participants must have the capacity to understand the proposed study.
- If the participant is not able to give consent, the legally acceptable/authorized representative (LAR) may give consent.
- If the participant or LAR is illiterate, a literate impartial witness should also be present during the informed consent process.
- Audio -video recorded consent can be obtained, but displayed only after taking the participant's permission

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Essential information to be provided in Informed Consent

- Detailed information about the study- Purpose, sampling, intervention, direct or indirect benefits, risks, compensation, confidentiality, reimbursement of expenses incurred (in terms of loss of wages or food supplies, travel expenses, compensation for research-related harm -physical, psychological, social, legal or economic harm) in a language they can understand. The language should be scientifically accurate and simple. It should be cultural and socially sensitive.
- The Informed Consent has two parts – the Patient/ participant information sheet (PIS) and the informed consent form (ICF).
- Sufficient time must be given to the participants to read the information, discuss with friends and family members and clarify doubts, if any.
- Informed consent must be translated into the local language.

The following are the essential elements of an informed consent

- Statement of research.
- Purpose of research.
- Expected duration and frequency of contact with the participant.
- Type of data to be collected and method of data collection
- Benefits to participant or community.
- Any foreseeable risks, discomfort or inconvenience.
- Confidentiality of the information shared.
- Anonymity of the participant.
- Payment /reimbursement for any economic losses.
- Free treatment for research related injury/harm.
- Freedom to participate or withdraw from the study any time without any penalty or loss of benefit.
- Contact details of Principal Investigator like address, phone numbers, email id, place of work.
- Contact details or helpline numbers for appeal against violation of human or ethical rights.

Additionally following information can also be included

- Any alternated procedure to be done
- Insurance coverage if any, in case of research related harm.
- Duration of data storage.
- Third party involvement.
- Post research plan, benefit sharing.
- Publication plan, utilizing photographs and pedigree charts.

Responsibilities of a researcher

Use of Approved Consent Forms

The researcher must always use the ethically approved version of the informed consent document. Any changes must also receive prior approval.

Special Considerations for Differently-Abled Participants

When participants have physical, mental, or visual impairment, the researcher should use additional supportive methods to ensure comprehension—for example, providing information in Braille for visually impaired individuals, or simplified formats for those with cognitive difficulties.

Opportunity to Ask Questions

Participants must be given full freedom to ask questions, seek clarifications, and understand all aspects of the study before agreeing.

- ***Signature or Thumb Impression***

If a participant cannot sign, a thumb impression should be obtained as valid documentation of consent.

- ***Oral Consent When Signing Is Refused***

If a participant is willing to participate but is not comfortable signing:

- Oral consent may be taken only after ethical committee approval.
- An impartial witness must certify the process by signing the document.
- The entire oral consent process should be audio–video recorded, clearly showing the principal investigator, participant, and impartial witness.

- ***Right to Withdraw Without Penalty***

The researcher must reassure participants that withdrawal at any point will not affect their routine care, services, or rights.

- ***Spousal/Partner Consent in Specific Studies***

Certain research areas also require consent from spouse/ partner, especially those involving:

- Infertility
- Contraception
- Assisted reproductive technologies (ART)

- ***Family Consent in Genetic Research***

Genetic studies may have implications for biologically related individuals; therefore, other family members may need to be involved, and their consent should also be obtained.

Conditions where the consent may be waived off-

Retrospective Studies Where Participants Cannot Be Contacted

- These studies use past records, case files, or existing databases.
- If participants cannot be traced and data is not identifiable, ethics committees may waive consent.

Example

- Review of 5 years of hospital records to study antibiotic resistance patterns

Research on Anonymous Biological Samples

- Samples that do not carry any personal identifiers (e.g., name, ID, phone number).
- Since identity cannot be linked, consent is not needed.

Example

- Testing stored tissue samples labelled only with serial numbers.
- DNA extraction from anonymized blood samples in a biobank.

Information Available in the Public Domain

Consent is not needed when the data is publicly accessible to everyone.

Examples

- Analyzing newspaper reports on road traffic accidents.
- Studying trends in suicide reporting using published news articles.
- Content analysis of health messages broadcast on TV channels.
- Review of posts on government public websites or open health dashboards.

Surveillance and Programme Evaluation Studies

Routine public health surveillance done for disease monitoring, not for individual research. Consent is typically waived because:

- Data is collected under government mandate.
- Individual participants cannot be approached every time.

Examples

- Surveillance of malaria cases in endemic blocks.
- Monitoring dengue outbreak trends from health department data.
- Evaluation of immunization programme coverage using routine HMIS records

Conditions where re consent should be obtained

When New Information Changes the Risk–Benefit Ratio

If new findings emerge that increase risk or alter potential benefits, participants must be informed again. **Example:** discovery of a newly reported serious side effect of a drug being tested.

When an Unconscious Participant Regains Consciousness

If consent was taken from an LAR (Legally Acceptable Representative) because the participant was unconscious:

- Once the participant regains consciousness and is able to understand the study
- Fresh informed consent must be obtained directly from the participant**.**

When a Child Participant Becomes an Adult During the Study

Consent originally taken from parents/guardians becomes invalid once the participant turns 18 years.

- The participant must give fresh adult consent to continue in the study.

For Publication of Facts, Figures, or Photographs

Even if consent for participation was taken earlier,

- Additional consent is required for publishing identifiable information, such as:
- Photographs
- Case details
- Video clips
- Sensitive personal data

When There Are Changes in the Research Protocol

Any modification that affects participants requires fresh consent. Such as:

- Change in treatment procedure
- Change in data collection method
- Additional blood samples
- Increased or decreased number of follow-up visits
- Introduction of new equipment or tests

Informed consent in special situations

- Consent of gatekeepers, head or group leader, should be obtained on behalf of the group that should be audio or video recorded.
- In certain cases, the individuals may not participate in the study until the consent of the community is obtained. In such cases organization that represents the community, consent is obtained after a minimum quorum is achieved.
- Researchers should justify the inclusion of the vulnerable population. In no case should the dignity, rights, safety, confidentiality, and privacy be hampered.

Vulnerable population or groups

- Economically and socially disadvantaged (orphans, unemployed, minorities, ethnic minorities, persons below poverty line. LGBTs, gay/lesbian, prisoners, refugees, migrants)
- Children up to 18yrs
- Tribal communities
- Person suffering from rare disease
- Pregnant or lactating women
- Cognitively impaired or physically impaired
- People with diminished authority (students, subordinates, defense service personnel, institutionalized individuals)

Informed consent is not only a legal requirement, but it stands as a vital pillar for ethical practice. Strengthening consent practices helps to foster trust, shared decision making, transparency and patient-centered communication. Continuous evaluation and improvement of consent processes will remain vital for building trust in healthcare and research environments.

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