Research ethics committees

Basic concepts for capacity-building

World Health Organization

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Glossary

Assent:
A variation on consent where a person who does not possess full competence to give informed consent gives affirmative agreement to participate in research. For instance, a child or person with dementia should give assent before being enrolled in research. However, it is important to note that assent does not eliminate the need for obtaining the permission of a parent or other legally authorized decision-maker.

Bioethics:
A field of ethical enquiry that examines ethical issues and dilemmas arising from health, health care and research involving humans.

Competence:
Refers to a potential or enrolled participant's mental capacity to provide informed consent.

Consent form:
An easily understandable written document that documents a potential participant's consent to be involved in research and describes the rights of an enrolled research participant. This form should communicate the following in a clear and respectful manner: research timeframe; title of research; researchers involved; purpose of research; description of research; potential harms and benefits; treatment alternatives; statement of confidentiality; information and data to be collected; how long the data will be kept, how it will be stored and who can access it; any conflicts of interest; a statement of the participant's right to withdraw from participation at any point; declarative statement of understanding that the potential participant agrees to and signs. The consent form should be in a language the potential participant understands. For potential participants with limited literacy, the verbal communication of the consent-document details should be provided along with proper documentation of consent, if it is given.

De-identification and data linkage:
The process of de-identification (anonymization) and linking of collected research trial data and identifiable private information. This process ensures that items of data are not individually identifiable, but provides a mechanism for appropriate access to identifiable information.

Ethical guidelines:
Guidance documents which assist with decisions relating to the responsibility to adhere to established and relevant standards of ethical principles and practice.

Personal data:
Data that relate to a living person and contain personally identifying information.

Principal investigator (PI):
The main researcher overseeing or conducting the research process.

Researcher:
A person who engages in the methodical and systematic investigation of hypotheses with the goal of contributing to new knowledge.

Research ethics committee (also known as ethical review board (ERB), ethical review committee (ERC), human research ethics committee (HREC), institutional review board (IRB)):
Group of individuals who undertake the ethical review of research proto-

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