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Ethical framework for health research

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Ethical foundation is crucial for research, including health research

- Any research involving human participants should follow international standards of ethics
- Indian national standards are not less exacting and Indian ethical guidelines are on par with international guidelines
- Ethics review is also expected in situations involving no risk when available data are used or minimal risk such as when only questions are asked, no samples/ other specimens are collected

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Evolution of various guidance documents has greatly improved the practice of ethics in biomedical research

INTERNATIONAL	
1947, Nuremberg Code	Initiated discussion on rationale and justification of research risk benefit analysis, competence of investigators and voluntary consent in research
1964, Helsinki Declaration, Revised 1983, 1989, 1996, 2000, 2008, 2013	Commitment to individual rights to make informed decisions, investigators' duties, research participants' welfare, vulnerability
1978-79, Belmont report	Described the basic ethics principles of autonomy, justice and beneficence, emphasized informed consent and review by ethics committee
1992-93, CIOMS guidelines [Council for International organizations on Medical Sciences and WHO], Revised 2002	Reporting of adverse drug reactions and safety of research participants, benefit-risk balance, need and principles of pharmacovigilance,
1996, ICH [International Council on Harmonization]	Good Clinical Practice

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Indian Council of Medical Research introduced Ethical Guidelines for Research on Human Participants

NATIONAL GUIDELINES	
National Ethical Guidelines for Biomedical and Health Research Involving Human Participants; ICMR, 2017. Available from https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf	All institutions in the country which carry out any form of biomedical research involving human beings should follow these guidelines in letter and spirit to protect safety and well being of all individuals.
There are several other national guidelines available	Genome Policy and Genetic Research [2000], Indian GCP [2001], Amendment of Drugs and Cosmetics Act [2002], Assisted Reproductive Technology [2005], Stem Cell Research and Bio-banking [2006]

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Researchers must follow the following ethical principles

Respect for autonomy	• Autonomy is Latin for "self-rule" - We have an obligation to respect the decisions made by people concerning their own lives. This is respecting human dignity. • We must not interfere with the decisions of competent adults, and also actively empower others for whom we are responsible.
Justice	• We have an obligation to provide all with whatever they are deserve. Basically, we have an obligation to treat all people equally, fairly, and impartially. • All individuals should have an opportunity to participate in research unless contraindicated and we must not impose unfair burdens.
Beneficence	• We must be fair and correct in all our actions and must take positive steps to prevent harm. • Sometimes in our endeavor to pursue beneficence, we place ourselves in direct conflict with respecting the autonomy of people.
Non-maleficence	• We must not harm others: "First, do no harm", and wherever harm cannot be avoided, we must try to minimize the same. • It is wrong to waste resources that could be used for good.

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What is informed consent?

- Informed consent is the process of informing the potential participants about the proposed research in a systematic manner and empower them to take an informed decision to participate in the research study
  - Understand study procedures and risks and benefits
  - Get all questions and concerns answered
  - Take a learned and informed decision to [or not to] participate
- This process can be repeated several times during the research study if necessary
- Although group consent is desirable [e.g. tribal studies], it cannot replace individual consent

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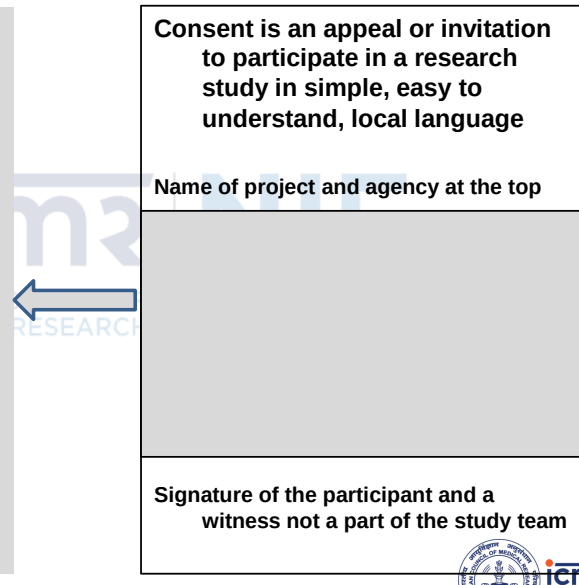
Informed consent document

- Research Description
- Risk
- Benefits
- Alternatives
- Confidentiality
- Compensation
- Contacts
- Voluntary participation and withdrawal



Stakeholders in informed consent process

- Researchers and institutions:
  - Information – discussion and explanation – comprehension – voluntary decision
- Participants:
  - Informed, free and independent consent without coercion or force
- Sponsors, monitors, regulators:
  - Assess fairness of consenting procedure
  - Verify consent documentation of research participants

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Issues related to informed consent

- **Whom does informed consent benefit?**
  - The research participant
  - The investigator
- **Is the research procedure adequately explained in the IC form?**
  - The language, simplicity and clarity
  - Translations and back-translations, certification of translations
  - Test of understanding
- **Issue of witness to consent procedure**
  - Impartial witness
- **Can there be different types of informed consents**
  - Traditional written IC form
  - Pictorial consent

Importance of scientific review

Explores the scientific novelty, rationality and relevance

1. Justification for conducting the trial in the context of national priorities
2. Scientific merits of the research project and feasibility: Review of toxicological studies, laboratory and animal data
3. Technology transfer and capacity building at sites

Soundness of the study design:

Inclusion-exclusion criteria,
Randomization/ blinding procedures
Study procedures and follow-up schedule
Sample size,
End-point assessment
Pharmacy plan

Scientifically well-planned research studies are more likely to correctly address human subjects and ethical issues

Objectives of regulatory review

- Evaluate pre-clinical trials data
- Assess in-country regulatory requirements for drug/ vaccine/ product import
- Ensure national requirements for special situations -genetically engineered products, stem cell research, research on reproductive technologies, organ transplantation etc.
- Sample shipment and transfers, transfer of raw data: IPR issues
- Exchange of scientists or visitors
- Budget: Foreign funding
- Research in border or high-security areas

Careful regulatory review results in answering some of the ethical concerns

Range of ethical issues that need to be addressed in health research

- Competence of the researchers and the research team
- Provisions for protection of human rights and ethical issues: vulnerable populations, women, children
- Measures for protecting confidentiality and non-discriminatory practices
- Appropriateness of Informed consent and study specific educational material
- Mechanisms for reporting and management of adverse events and serious adverse events
- Care and support for research participants: standard of care, long-term care, post-trial access to care and product
- Reimbursement and compensation
- Continuing review of progress of the study

Main responsibility of institutional ethics committees or institutional review board

- Does the study have real/ potential individual/ community benefit?
- Are the rights of research participants adequately protected?
- Does the potential benefit far overweigh the risks associated with research participation?
- Will the participants and communities have access to study findings and benefits of research?
- What is the mechanism for provision of safety, care and support to research participants?

Ethics influencing health research and practice of medicine ….

- Growing expectation about accountability:
  - Questioning of Government responsibility [local, state and national] and investigators' responsibility
  - Growing public awareness due to advocacy movement
- Collective demand for health benefits - Universal right to health care (health for all)
- Place for self responsibility (lifestyle) – should it always be researchers to be blamed for mishaps
- Need for including bioethics in medical curriculum being increasingly stressed

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There is hope	Ethics in practice of public health and health research is being increasingly addressed.
There are challenges	Public expectations and demands will continue to increase.
The search for solution should be an ongoing process	Public health system, policy makers, researchers and program managers should show enough sensitivity and realize that there is a scope for further improvement

Thank you

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