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Medical Ethics in research proposal

Edited and picked by Dr Homayoun Nobarani

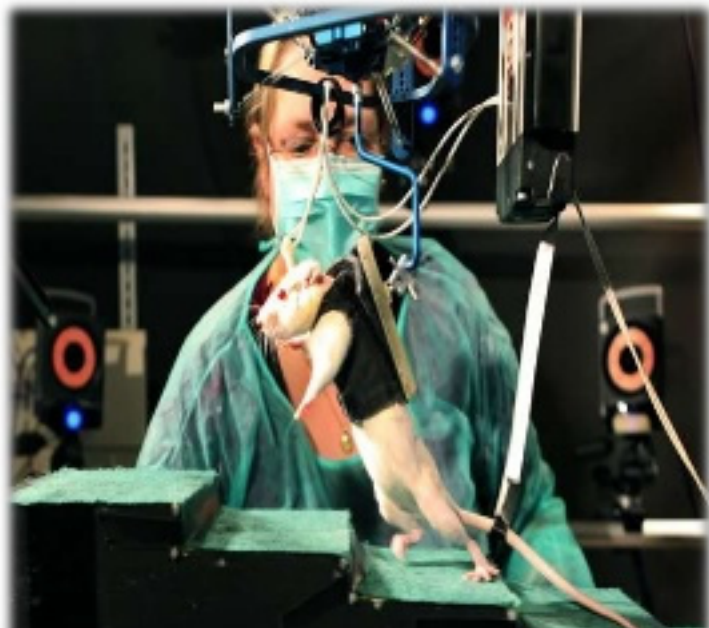
MEDICAL ETHICS IN RESEARCH PROPOSALS

Thanks to Dr.T.V.Rao MD



Research Ethics and Integrity

- Research, in all domains, is an important activity of every human society and represents a major commitment on the part of the various people involved, whether in the public or private sector. Research results constitute the basis for political and technical decisions, it is essential that the research itself be conducted with integrity, in a responsible manner and in accordance with high ethical standards.



History of Ethical Codes in Human Research

- The first International Statement on the ethics of medical research using human subjects namely, the Nuremberg Code was formulated in 1947. Although informed consent for participation in research was recorded in 1900, the **Nuremberg Code** highlighted the essentiality of voluntariness of this consent.

Ethics incorporate Human rights

- Declaration of Human Rights (adopted by the General Assembly of the United Nations) expressed concern about rights of human beings being subjected to involuntary maltreatment



Rights of Humans Redefined



In 1966, the International Covenant on Civil and Political
As states -

Rights specifically stated,
'No one shall be subjected
to **torture or to cruel,
inhuman or degrading
treatment or punishment.**

In particular, no one shall be
subjected without his
consent to medical

Helsinki Declaration

- Based on the preliminary efforts of the Council for International Organizations of Medical Sciences (CIOMS) in 1964 at **Helsinki, the World Medical Association formulated general principles and specific guidelines on use of human subjects in medical research**, known as the Helsinki Declaration, which was revised from time to time.



NEW EDITION OF THE DECLARATION OF HELSINKI

WORLD MEDICAL
ASSOCIATION'S

**Declaration
of Helsinki**

7TH REVISION, 2013

- In June 1964, the World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

Proposed guidelines by WHO

- In 1982, the World Health Organisation (WHO) and the CIOMS issued the 'Proposed International Guidelines for Biomedical Research involving Human Subjects.'
- B - Subsequently the CIOMS brought out the 'International Guidelines for Ethical Review in Epidemiological studies' in 1991 and 'International Ethical Guidelines for Biomedical Research involving Human Subjects

Most recent guidelines on Human Research

The most recent documents on ethics are

- Those of UNESCO's "**The Universal Declaration on Human Genome and Human Rights**" (1997), "The International Declaration on Human Gene Data" (2003) and "**Universal Declaration on Bioethics and Human Rights**" (2005).



Purpose of Research to be Defined

- The **PURPOSE**, of such research is that it should be directed towards the increase of knowledge about the human condition in relation to its social and natural environment, mindful that the human species is one of the many species in a planet in which the well being of all species is under threat, no less from the human species as any other, and and that such research is for the **betterment of all, especially the least advantaged.**

GENERAL ETHICAL PRINCIPLES

- **General ethical principles of respect for persons, duty to maximize possible benefits and minimise possible harm are important considerations in ethical guidelines. At the same time it is essential that all individuals in an epidemiological research are treated alike keeping in mind the rules of distributive justice**

GENERAL PRINCIPLES

- The welfare of the individual has to be balanced against the welfare of the community and society at large.

W.H.O

**Guidelines for Epidemiological Research
assume that the individuals or populations**

being studied are capable of giving informed consent understanding the implications of the study.

Regime of EVALUATION

- Such research must be subjected to a regime of **EVALUATION** at all stages of the proposal i.e., research design and experimentation, declaration of results and use of the results thereof, and that each such evaluation shall bear in mind the objects to be achieved, the means by which they are sought to be achieved, the anticipated **benefits and dangers, the potential uses and abuses of the experiment** and its results, and above all, the premium that civilised society places on saving and ensuring the safety of each human life as an end in itself.

STATEMENT OF GENERAL PRINCIPLES IN BIOMEDICAL RESEARCH INVOLVING HUMAN PARTICIPANTS

- **Statement of Ethical Guidelines for Biomedical Research on Human Participants**
shall consist of the following:-
 - (a) **Statement of General Principles on Research using Human Participants in Biomedical Research**
 - (b) **Statement of Specific Principles on Research using Human Participants in specific areas of Biomedical Research**

BASIC RESPONSIBILITIES of Ethical Committee

- The basic responsibility of an Institutional Ethics Committee (IEC) is to ensure a **competent review of all ethical aspects of the project proposals** received by it in an objective manner. IECs should provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committee

Always assess the Technical Appropriateness

- The scientific evaluation should ensure technical appropriateness of the proposed study.



COMPOSITION of Ethical Committee



- The IECs should be multidisciplinary and multi sectorial in composition. Independence and competence are the two hallmarks of an IEC. The number of persons in an ethics committee should be kept fairly small (**8 - 12 members**).

Ethical Committee is composed of mixed group of people

- Other members should be a mix of medical/ non-medical, scientific and non-scientific persons including lay persons to represent the differed points of view.



The Members can from other Institutes too

- **The Ethics Committee (EC) can have as its members, individuals from other institutions or communities with adequate representation of age and gender to safeguard the interests and welfare of all sections of the community/society. If required, subject experts could be invited to offer their views, for instance, a paediatrician for paediatric conditions, a cardiologist for cardiac disorders etc. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. it is desirable to include a member from specific patient groups in the Committee.**

Training Ethical Committee Members

- The EC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body(ies), so that they become aware of their role and responsibilities



Members to be trained on Good Clinical Practice



- For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. .

**All participants to be educated
and oriented on Ethics
before Starting the Research
Work**



Have knowledge on Trails going on in the Community

Clinical Trials

Three sequential phases of evaluation



Access to benefits of therapy IT IS THE PART OF THE ETHICS

- **The Helsinki Declaration of the World Medical Assembly, 2008(2), states that “at the conclusion of the study, patients entered in to the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.”**



guidelines



- “After the clinical trial is over, if indeed the drug is found effective, it should be made mandatory that the sponsoring agency should provide the drug to the patient till it is marketed in the country and thereafter at a reduced rate for the participants whenever possible. A suitable a priori agreement should be reached on post-trial benefits

Informed Consent means

- Informed consent is a process for getting permission before conducting a healthcare intervention on a person. A health care provider may ask a patient to consent to receive therapy before providing it, or a clinical researcher may ask a research participant before enrolling that person into a clinical trial. Informed consent is collected according to guidelines from the fields of medical ethics and research ethics.



Getting Informed consent can be challenging



Sometimes getting
"informed" consent
can be a
futile task



Dean V. Scott

Consent and assent for epidemiological studies on minors and school children

- ICMR guidelines also say: "the assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years."



Right of Participants to withdraw from the Research assessments



The right of participants in research to decline to participate, or withdraw, or abstain from further participation, has been repeatedly emphasised by the ICMR guidelines. It has been clearly stated that the patients can **“withdraw without penalty or loss of benefits which the participant would otherwise be entitled to.”**

In-house monitoring and ongoing review process

- The greatest problem with the working of the IEC in any institute is the lack of an ongoing monitoring process to ensure that the guidelines have been followed, that there is no deviation from the protocol, and that any adverse effects are reported. In actual practice,



Cohort Studies

- **These are longitudinal or prospective studies of a group of individuals with differing exposure levels to suspected risk factors. They are observed over a long period usually several years. The rate of occurrence of the condition of interest is measured and compared in relation to identified risk factors.**
- **It requires a study of large number of participants for a long time and involves asking questions, checking of records, routine medical examination and sometimes laboratory investigations. Individuals are being followed up as the cohort and it is essential to identify precisely every individual to be studied.**

Follow the Principals of Cohort Studies

Cohort Studies



Research on archived (retrospective } specimens

- The guidelines permit an expedited review on “research involving clinical materials (data, documents, records or specimens) that have been collected for non-research (clinical) purposes.” No further instructions are provided as to how this information is to be dealt

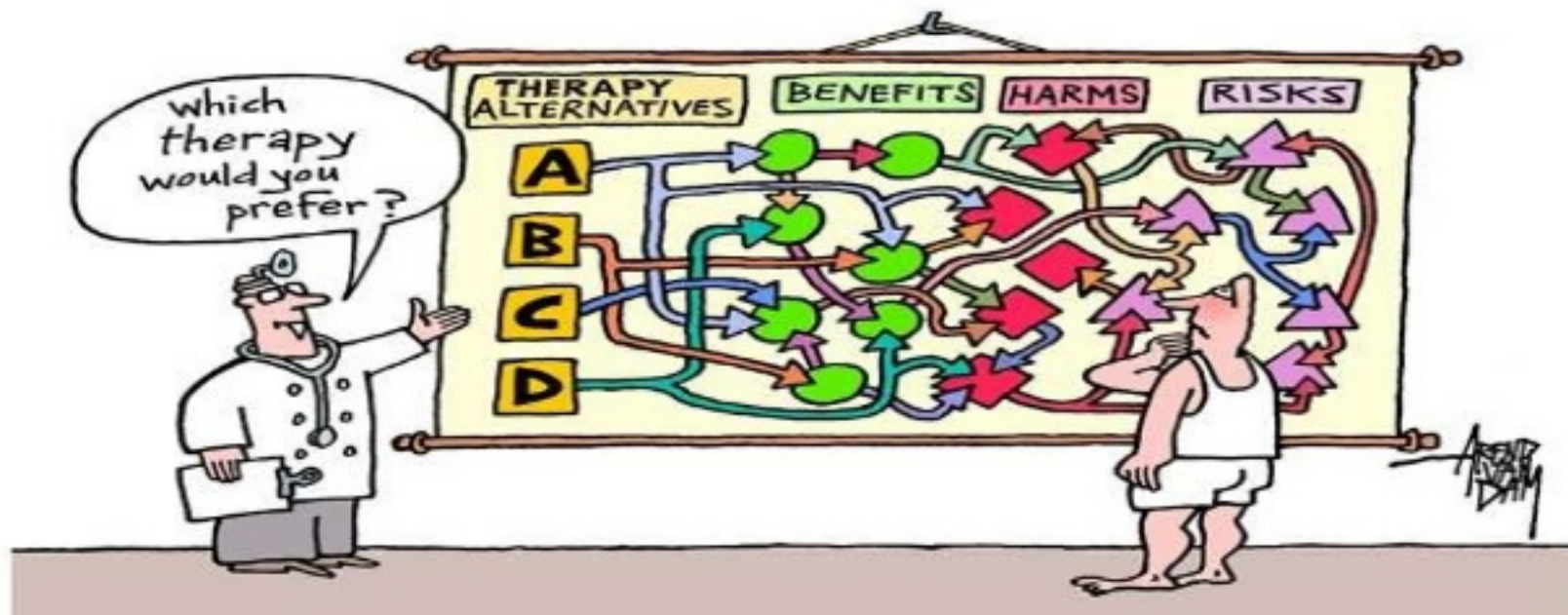


Waiver of consent

voluntary informed consent ... “can be waived if it is justified that the research **involves not more than minimal** risk or when the participant and the researcher do not come into contact **or when it is necessitated in emergency situations.**”



Consent Forms to be Simple and Understandable in local language and familiar to the participants



Trial on non-allopathic drugs and herbal remedies

- These have become more numerous in recent times, particularly in medical colleges. The guidelines are quite clear on this issue: “when clinical trials of herbal drugs used in recognised Indian Systems of Medicine and Homeopathy are to be undertaken in Allopathic hospitals, association of physicians from the concerned system as co-investigators/collaborators / members of the expert group is desirable

Ethics of live operative workshops

- Operative workshops call for a situation where a visiting surgeon performs a procedure, which may be major, on a patient whom s/he has not seen before, or perhaps not interacted with in any detail or any length of time before. It also involves circumstances where s/he has no responsibility for preoperative or postoperative care; this is left to the parent institution conducting the workshop.

Support, guidance and reporting

We the Committee members have responsibility

- **Providing information, support and guidance to staff and students;**
- **Administrative support for the Animal Research and Human Research Ethics Committees;**
- **liaising between Committees and applicants;**
- **preliminary reviews of applications and provision of feedback to applicants;**
- **monitoring approved research projects;**
- **developing, implementing, reviewing and updating policies and procedures; and**
- **reporting to the University, the National Health and Medical Research Council, and other organisations.**

Look at the Matters with Human perception and just for pure Research



WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:

- 29th WMA General Assembly, Tokyo, Japan, October 1975
- 35th WMA General Assembly, Venice, Italy, October 1983
- 41st WMA General Assembly, Hong Kong, September 1989
- 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
- 52nd WMA General Assembly, Edinburgh, Scotland, October 2000
- 53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
- 55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
- 59th WMA General Assembly, Seoul, Republic of Korea, October 2008
- 64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient’s best interest when providing medical care.”

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician’s knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises possible harm to the environment.
12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.
13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.
14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

What Is Ethics in Research & Why Is It Important?

by David B. Resnik, J.D., Ph.D.

December 1, 2015

The ideas and opinions expressed in this essay are the author's own and do not necessarily represent those of the NIH, NIEHS, or US government.

When most people think of ethics (or morals), they think of rules for distinguishing between right and wrong, such as the Golden Rule ("Do unto others as you would have them do unto you"), a code of professional conduct like the Hippocratic Oath ("First of all, do no harm"), a religious creed like the Ten Commandments ("Thou Shalt not kill..."), or a wise aphorisms like the sayings of Confucius. This is the most common way of defining "ethics": norms for conduct that distinguish between acceptable and unacceptable behavior.

Most people learn ethical norms at home, at school, in church, or in other social settings. Although most people acquire their sense of right and wrong during childhood, moral development occurs throughout life and human beings pass through different stages of growth as they mature. Ethical norms are so ubiquitous that one might be tempted to regard them as simple commonsense. On the other hand, if morality were nothing more than commonsense, then why are there so many ethical disputes and issues in our society?

Alternatives to Animal Testing

test tubes on a tray decorative image

Alternative test methods are methods that replace, reduce, or refine animal use in research and testing

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One plausible explanation of these disagreements is that all people recognize some common ethical norms but interpret, apply, and balance them in different ways in light of their own values and life experiences. For example, two people could agree that murder is wrong but disagree about the morality of abortion because they have different understandings of what it means to be a human being.

Most societies also have legal rules that govern behavior, but ethical norms tend to be broader and more informal than laws. Although most societies use laws to enforce widely accepted moral standards and ethical and legal rules use similar concepts, ethics and law are not the same. An action may be legal but unethical or illegal but ethical. We can also use ethical concepts and principles to criticize, evaluate, propose, or interpret laws. Indeed, in the last century, many social reformers have urged citizens to disobey laws they regarded as immoral or unjust laws. Peaceful civil disobedience is an ethical way of protesting laws or expressing political viewpoints.

Another way of defining 'ethics' focuses on the disciplines that study standards of conduct, such as philosophy, theology, law, psychology, or sociology. For example, a "medical ethicist" is someone who studies ethical standards in medicine. One may also define ethics as a method, procedure, or perspective for deciding how to act and for analyzing complex problems and issues. For instance, in considering a complex issue like global warming, one may take an economic, ecological, political, or ethical perspective on the problem. While an economist might examine the cost and benefits of various policies related to global warming, an environmental ethicist could examine the ethical values and principles at stake.

Many different disciplines, institutions, and professions have standards for behavior that suit their particular aims and goals. These standards also help members of the discipline to coordinate their actions or activities and to establish the public's trust of the discipline. For instance, ethical standards govern conduct in medicine, law, engineering, and business. Ethical norms also serve the aims or goals of research and apply to people who conduct scientific research or other scholarly or creative activities. There is even a specialized discipline, research ethics, which studies these norms. See Glossary of Commonly Used Terms in Research Ethics.

There are several reasons why it is important to adhere to ethical norms in research. First, norms promote the aims of research, such as knowledge, truth, and avoidance of error. For example, prohibitions against fabricating, falsifying, or misrepresenting research data promote the truth and minimize error.

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Second, since research often involves a great deal of cooperation and coordination among many different people in different disciplines and institutions, ethical standards promote the values that are essential to collaborative work, such as trust, accountability, mutual respect, and fairness. For example, many ethical norms in research, such as guidelines for authorship, copyright and patenting policies, data sharing policies, and confidentiality rules in peer review, are designed to protect intellectual property interests while encouraging collaboration. Most researchers want to receive credit for their contributions and do not want to have their ideas stolen or disclosed prematurely.

Third, many of the ethical norms help to ensure that researchers can be held accountable to the public. For instance, federal policies on research misconduct, conflicts of interest, the human subjects protections, and animal care and use are necessary in order to make sure that researchers who are funded by public money can be held accountable to the public.

Fourth, ethical norms in research also help to build public support for research. People are more likely to fund a research project if they can trust the quality and integrity of research.

Finally, many of the norms of research promote a variety of other important moral and social values, such as social responsibility, human rights, animal welfare, compliance with the law, and public health and safety. Ethical lapses in research can significantly harm human and animal subjects, students, and the public. For example, a researcher who fabricates data in a clinical trial may harm or even kill patients, and a researcher who fails to abide by regulations and guidelines relating to radiation or biological safety may jeopardize his health and safety or the health and safety of staff and students.

Codes and Policies for Research Ethics

Given the importance of ethics for the conduct of research, it should come as no surprise that many different professional associations, government agencies, and universities have adopted specific codes, rules, and policies relating to research ethics. Many government agencies have ethics rules for funded researchers.

National Institutes of Health (NIH)

<https://ethics.od.nih.gov/default.htm>

National Science Foundation (NSF) > pdf

Food and Drug Administration (FDA) <https://www.fda.gov/about-fda/jobs-and-training-fda/ethics>

Environmental Protection Agency (EPA) pdf environment

US Department of Agriculture (USDA) <https://www.ethics.usda.gov/>

Singapore Statement on Research Integrity <https://wcrif.org/singapore-statement>

American Chemical Society, The Chemist Professional's Code of Conduct

<https://www.acs.org/content/acs/en/careers/career-services/ethics/the-chemical-professionals-code-of-conduct.html>

Code of Ethics (American Society for Clinical Laboratory Science) <https://www.ascls.org/about-us/code-of-ethics>

American Psychological Association, Ethical Principles of Psychologists and Code of Conduct

<https://www.apa.org/ethics/code/index>

Statement on Professional Ethics (American Association of University Professors)

<https://www.aaup.org/report/statement-professional-ethics>

Nuremberg Code <https://history.nih.gov/display/history/Niremberg+Code>

World Medical Association's Declaration of Helsinki

<https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/>