ETHICS REVIEW BOARD RESOURCES
A GUIDEBOOK FOR MEMBERS OF ETHICS REVIEW BOARDS

COMPILED BY

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2005

PREFACE

We compiled this guidebook as a resource for new institutional review boards/institutional ethics committees that we have been involved in establishing in India. This guidebook provides an overview of the functioning of IRBs/IECs as well as a few relevant guidelines and references. We hope that other groups will expand, revise and edit this guidebook, and support the institutionalization of the protection of human participants in biomedical and social science research on health in India.

We are grateful for the support and contributions of numerous individuals and organizations, including Samuha/Samraksha, Amar Jesani (Centre for Studies in Ethics and Rights), Mala Ramanathan (Achutha Menon Centre for Health Science Studies), Arthur L Reingold (University of California, Berkeley) and others. We welcome comments and suggestions (email to suneeta.krishnan@gmail.com).

This work has been supported by a grant from the NIH Fogarty International Center (The University of California, Berkeley – San Francisco AIDS International Training and Research Program Grant number TW00003-15).

Suneeta Krishnan
Bangalore, 2005

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Indian Council of Medical Research
http://icmr.nic.in/ethical_guidelines.pdf

The Belmont Report
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
http://ohsr.od.nih.gov/guidelines/belmont.html

Declaration of Helsinki
World Medical Association
http://www.wma.net/e/ethicsunit/helsinki.htm

Ethical Guidelines for Social Science Research in Health
National Committee for Ethics in Social Science Research in Health

The Nuffield Council on Bioethics
Report on: The ethics of research related to healthcare in developing countries
http://www.nuffieldbioethics.org/fileLibrary/pdf/HRRDC_Follow-up_Discussion_Paper001.pdf

Operational Guidelines for Ethics Committees that Review Biomedical Research,
World Health Organization
http://www.searo.who.int/LinkFiles/RPC_Operational_Guidlines_Ethics.pdf

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Ethics Theories Principles & Laws

Prepared by: Amar Jesani, MD
Centre for Studies in Ethics and Rights, Mumbai

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Presentation covers ....

- Morality
- Ethics
  - Three practical uses of ethics; Ethics for others and self
  - Normative and Non-normative ethics,
  - Theories
  - Principles
- Ethics and law

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Do we make moral judgments?

- The statements like:
  - He is a cheat
  - We should not kill
- The statements like:
  - Public buses are painted red in Mumbai
  - She is very good singer
- Both describe certain qualities, but there is a difference

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Moral Judgments

- Any judgement that consists of approving or disapproving of an action in such a way that we state our (dis)approval.
- It is about judging an action as good or bad.
- Such judgments are based on the standard one uses for approving or disapproving an action.
- Morality and ethics are often used interchangeably, but they could be looked at separately in order to distinguish moral judgments based on considered reasoning from those based on first order beliefs.

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Morality - 1

- Morality refers to the first-order beliefs and practices about good and evil by means of which we guide our behaviour.
- Morality is made up of a lot of values and duties based on beliefs that people take for granted most of the time.
- Values describe certain qualities that constitute “a good life”.
- Duties describe actions in response to claims that are either self-imposed or imposed by others.

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Morality - 2

- Personal morality is made up of values and duties adopted by individual as relevant.
- Large component of personal morality represents a common denominator of shared belief about values and duties called societal morality. They are culturally, ethnically, class or geographically generated.
- Morality of a strata/group of society is group morality.

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Ethics - 1

- Ethics is a second-order, systematic, reflective consideration of our moral beliefs & practices.
- The explicit and philosophical reflection on our moral beliefs and practices. In other words, it is a conscious stepping back and reflecting on morality.
- It is “systematic” reflection because it is a discipline that uses special methods and approaches to examine moral situations.
- It is a “reflection” because it consciously calls into question assumptions about existing components of morality – habits, customs, traditions, beliefs, etc.

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Ethics - 2

- (1) Requires a human 'agent' doing the acting, if not always also a human as the recipient of the action;
- (2) Moral action requires the capacity in the agent to reason about their action and understand it as moral or immoral; and
- (3) The agent must be responsible for their action and have the freedom to act otherwise.

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Three practical uses of Ethics

- Analysis of morality allows you to stand back and identify categories of issues and problems as well as to delineate which of the aspects of morality are involved in any situation.
- Resolution of the moral conflict, i.e. the knowledge base of analysis is complemented by a process that works towards resolution.
- Action – purposive action can stem from analysis and successful resolution.

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Ethics: For others and for self

Ethics for evaluating other people's conduct

- May become an instrument to beat others
- Demanding something that you do not do yourself in that field - hypocrisy
- Knowing others, having right to judge and intervene in the works of others
- Caring and judging

Ethics for evaluating and improving conduct of self

- For positive self development
- Search for good values – rising above personal morality
- Personal responsibility for values and judgments

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Ethics Discourse

- Two Types
  - Normative
  - Non-Normative

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Normative & Non-Normative Ethics

Normative Ethics

- Attempts to provide prescriptive actions – guides.
- Revolves around principles, which are used as foundation for resolving specific moral dilemmas.

Non-Normative Ethics

- Attempts to establish what factually or conceptually is the case, not what ethically ought to be the case.
- Descriptive: Factual investigation of moral behaviour and beliefs.
- Meta-ethics: Analysis of meanings of 'rights', 'virtue', 'responsibility" etc.

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Four levels of ethical analysis

- 1. Micro-ethical: How one person treats another.
- 2. Macro-ethical: How one group of persons such as members of a community collectively treats other communities and individuals such as members of the group itself and non-members.
- 3. Meso-ethical: Somewhere between micro & macro. Concerns of govt, institutions & private-sector resources for resource allocation in face of competing demands.
- 4. Mega-ethical: Transcends national health issues. Environment/ecology and health, international health issues

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Ethics Theories

A complete theory is
a general overview or statement
that begins with an assumption about
the very nature of doing right and wrongdoing,
of virtuous and vicious character,
and includes how humans go about
achieving and avoiding the other.

It has systematic bodies of rules and principles.

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Deontological Theories

- (deon = duty) Immanuel Kant (18th C)
- Diverse origin (e.g. religion) – divine revelation, intuition, common sense, hypothetical contract
- Concept of duty is independent of concept of good, and right actions are not determined exclusively by production of non-moral goods. One is acting rightly when one acts according to duties and rights.
- Kant's categorical imperatives - categorical because they are true in themselves and not based on any hypothetical conditions: Act in such a way that if a general rule was made based upon your actions it would be a rule applicable to all people at all times.

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Utilitarian Theories

- Consequentialist (rightness or wrongness of actions depend upon their consequences), Teleological (telos=end)
- David Hume, Jeremy Bentham, JS Mill (18-19th C)
- Morally right actions are determined by the non-moral value, such as pleasure (hedonistic), happiness (eudaimonistic) knowledge, health, etc.
- Utilitarianism: In all circumstance we ought to produce the greatest possible balance of value over disvalue for all persons affected (or the least possible balance of disvalue if only bad result can be brought about)

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Virtue Theory

- Describes character traits
- A character trait is a disposition or readiness to act in certain ways.
- Over time, importance attached to various character traits has varied. It could also vary according to culture.

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Feminist approaches or framework

- Based on the understanding that (a) there is systematic oppression of and discrimination against women, (b) such oppression is morally wrong and unjust.
- There are different streams of feminism, each having different approaches.
- More eclectic than having coherent bioethics theory.
- Instead of separation, bringing women's concerns into the mainstream

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Principles as a guide

- Serious shortcoming in using deontological or teleological theories as the sole tools.
- Hence, some useful norms or elements developed that could guide action expressing respect for the dignity of human being.
- They are called principles.
- There are many principles – four of them have been popularised and more often used.

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Non-maleficence and Beneficence

Non-maleficence

Primum non nocere: above all or first, do no harm

Beneficence

All actions only for prevention of harm, removal of harm and for the provision of benefits

Cost/Risk-Benefit Analysis

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Autonomy

- The ability to freely determine one's own course in life
- Assumption: An autonomous person determines his/her course of action in accordance with a plan chosen by him/herself.
- Informed consent
  - Who is autonomous?
  - Constraints in autonomy?
  - Refusal of treatment, Autonomy to commit suicide

Autonomy v/s Paternalism

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Justice

- How social burden and benefits ought to be allocated
  - Meaning & Types of Justice
  - Fairness
  - Equity
  - Distributive justice
- Resource allocation

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Confidentiality

- Confidentiality of information received from patient, client, participant.
- Absolute and partial confidentiality
- Is breach of confidentiality justified?

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Fidelity and Veracity

- Fidelity
- Latin fides means faithfulness
- Being faithful to patient entails meeting patient's reasonable expectations.
- What can be counted as reasonable expectations?
  - Respect, competency, commitment to ethics, follow laws, honour whatever is agreed, etc.
- Veracity
- Veracity means that you will tell the truth
- Also includes honesty

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Bioethics as a discipline

- Bioethics is a subdivision of the body of ethics, with a multi-disciplinary field of enquiry, both academic and professional, that addresses ethical issues in clinical practice and health care, biomedical research involving humans and animals, health policy and environment.
- The term bioethics emerged in 1960s in the USA, coined by Van Rensselaer Potter, a biochemist and researcher at Univ. of Wisconsin, by combining "bio" – biological knowledge or science of living, with "ethics" – knowledge of value system.
- However, medical ethics is centuries old – "decorum", "duty" and "plolitic" ethics

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Sources of development of bioethics – 1960s

- 1. Opening up of once-closed professions to public scrutiny
- 2. Development of liberal individualism – focus on rights and autonomy – forcing paternalism to recede
- 3. Development of new biomedical technologies that brought new ethical problems.
- 4. Renewed interest of philosopher in applied/ normative ethics.
- 5. Concerns about research with humans
- 6. Turning away from religious debates – to secular space

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Ethics and law - 1

- Ethics and law are different systems of rule-making and rule-application, but they constantly interact
- Ethics and law may coincide or overlap, they may also come in conflict or contradict each other
- Exercise of legal choice is not necessarily ethical OR to exercise legal power or right should be based on ethics.
- On the other hand, an ethical choice of conduct may not be permitted by law.
- General ethical expectation – laws should be observed, but unethical, oppressive laws may be ethically challenged.

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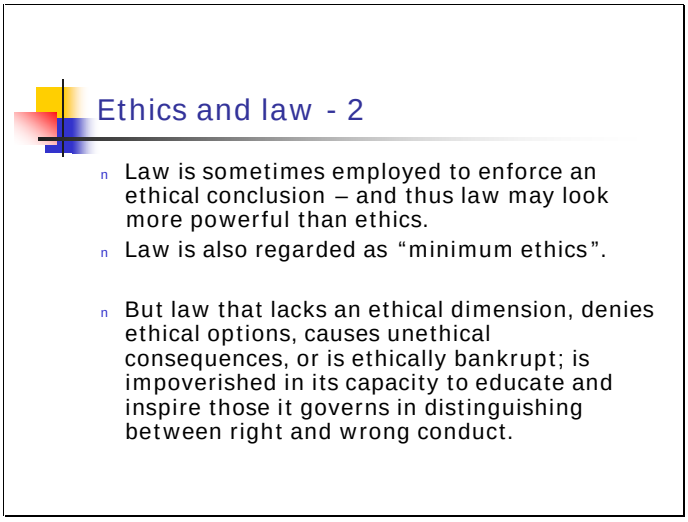

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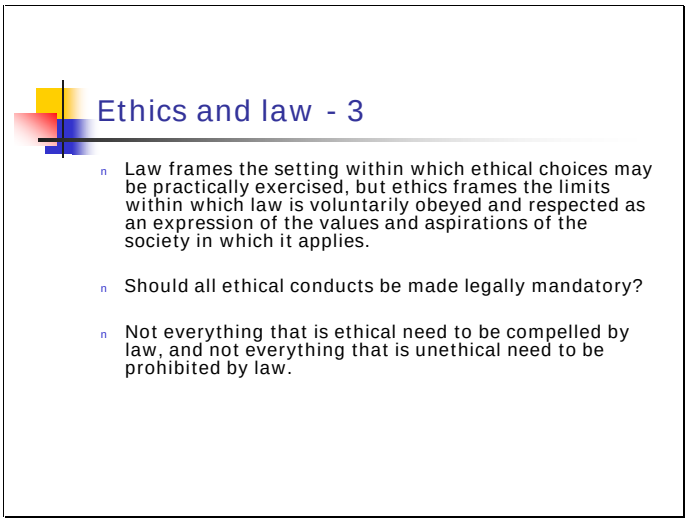

ETHICAL GUIDELINES FOR SOCIAL SCIENCE RESEARCH IN HEALTH

By
National Committee for Ethics in Social Science Research in Health (NCESSRH)

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Section I
Preamble

I.1. There has been a steady growth of research in the social sciences and in social science research in health in India. A wide range of research topics and issues including those that have the potential to seriously invade the privacy and security of individuals are being studied. Methodologies employed for such research have also expanded in range and depth. There is a considerable increase in the types and numbers of individuals and institutions[1] undertaking such research and those sponsoring and funding it.

I.2. While it is encouraging that social science research and social science research in health are getting the attention they deserve, the growth of research without social and ethical commitment could adversely affect the credibility of research, the autonomy of researchers,[2] the quality of research and the rights of participants[3]. In fact, there is a growing concern about indifference to ethics in some the social science research in the field of health in India.

I.3. Social and ethical commitment and self-regulation are, therefore, imperative for all parties in research, namely, institutions undertaking research, researchers, funders/sponsors[4] and those who publish material generated from research. Their individual and joint efforts are needed in order to achieve consensus on a common framework for research, and to improve and strengthen the system and environment in which research is conducted. Enunciation of ethical principles and formulation of necessary guidelines for research are, therefore, a part of such a process, and also a necessary and desirable step.

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[1] Institution is any organisation (public, private or voluntary) undertaking research.
[2] Researcher is any individual directly involved in research or a research project.
[3] Participants are individuals or groups from and/or on whom the researchers collect information for research.
[4] Funders/Sponsors are individuals and organisations (public, private or voluntary) providing full or part funding and/or sponsorship for the research.

I.4. This document contains ethical principles and guidelines formulated by a national committee with the additional inputs of individuals from different institutions and disciplines. While it has immediate specific applicability for social science research in health, it is relevant for social science research in other fields as well. For medical and clinical research some of the ethical guidelines may be different.

I.5. The ethical principles and guidelines for social science research in health, given in this document, are developed for the follow purpose:

(i) To sensitise and protect researchers who are often under pressures from various quarters/forces while undertaking research.

(ii) To preserve and promote the autonomy of research through the observance of ethics, ethical values and ethical self-regulation.

(iii) To protect and promote the human rights of participants and to sensitise and encourage researchers and organisations to respect participants' rights and needs.

(iv) To improve quality, legitimacy and credibility of social science research in health.

(v) To make ethics an integral part of the planning and methodology of research, and to enable organisations and individuals to develop appropriate mechanisms for ethical self-regulation.

I.6. The ethical principles and the guidelines given in this document do not, by themselves, resolve all ethical problems and dilemmas, which may confront researchers. For each dilemma and conflict they face, researchers may be required to balance the demands made by moral principles of research. The resolution of the dilemma may best be arrived at in concrete relation to the context and circumstance(s); it may involve a decision privileging one principle over another.

I.7. The experiences in using this document may be shared. Keeping in mind the immediate and long-term interests of the larger sections of people and the autonomy of researchers, the ethical guidelines given in this document may be refined through periodic reviews.

Section II
Ethical Principles for Research

II.1. Four well-known moral principles constitute the basis for ethics in research. They are:

(i) The Principle of Non-maleficence: Research must not cause harm to the participants in particular and to people in general.

(ii) The Principle of Beneficence: Research should also make a positive contribution towards the welfare of people**.**

(iii) The Principle of Autonomy: Research must respect and protect the rights and dignity of participants.

(iv) The Principle of Justice: The benefits and risks of research should be fairly distributed among people.

II.2. Ten general ethical principles, presently relevant for social science research in health in India, are as follows:

(i) Essentiality: For undertaking research it is necessary to make all possible efforts to get and give adequate consideration to existing literature/knowledge and its relevance, and the alternatives available on the subject/issue under the study.

(ii) Maximisation of public interest and of social justice: Research is a social activity, carried out for the benefit of society. It should be undertaken with the motive of maximisation of public interest and social justice.

(iii) Knowledge, ability and commitment to do research: Sincere commitment to research in general and to the relevant subject in particular, and readiness to acquire adequate knowledge, ability and skill for undertaking particular research are essential prerequisites for good and ethical research.

(iv) Respect and protection of autonomy, rights and dignity of participants: Research involving participation of individual(s) must not only respect, but also protect the autonomy, the rights and the dignity of participants. The participation of individual(s) must be voluntary and based on informed consent.

(v) Privacy, anonymity and confidentiality: All information and records provided by participants or obtained directly or indirectly on/about the participants are confidential. For revealing or sharing any information that may identify participants, permission of the participants is essential.

(vi) Precaution and risk minimisation: All research carries some risk to the participants and to society. Taking adequate precautions and minimising and mitigating risks is, therefore, essential.

(vii) Non-exploitation: Research must not unnecessarily consume the time of participants or make them incur undue loss of resources and income. It should not expose them to risks due to participation in the research. The relationship within the research team, including student and junior members, should be based on the principle of non-exploitation. Contribution of each member of the research team should be properly acknowledged and recognised.

(viii) Public domain: All persons and organisations connected to research should make adequate efforts to make public in appropriate manner and form, and at appropriate time, information on the research undertaken, and the relevant results and implications of completed research.

(ix) Accountability and transparency: The conduct of research must be fair, honest and transparent. It is desirable that institutions and researchers are amenable to social and

financial review of their research by an appropriate and responsible social body. They should also make appropriate arrangements for the preservation of research records for a reasonable period of time.

(x) Totality of responsibility: The responsibility for due observance of all principles of ethics and guidelines devolves on all those directly or indirectly connected with the research. They include institution(s) where the research is conducted, researcher(s), sponsors/funders and those who publish material generated from research.

Section III
Rights and Responsibilities of Researchers and Institutions

III.1. Relationship between researchers and institution

III.1.1. Institutions have a responsibility to respect the autonomy of researchers and the ethical guidelines for research.

III.1.2. Institutions should create and maintain an environment with adequate support systems to enable researchers to follow ethical guidelines.

III.1.3. Institutions have a responsibility to take appropriate and adequate steps for protection against pressures inimical to the observance of ethical guidelines for research.

III.2. Protection and promotion of integrity in research

III.2.1. Researchers have a right, as well as a responsibility, to refrain from undertaking or continue undertaking any research that contravenes ethical guidelines, violates the integrity of research and/or compromises their autonomy in research, including design methodology, analysis and interpretation of findings and publication. If they feel that their rights are being violated, or that the study is unethical, they should make all possible efforts at making corrections. In the event of failure of remedial measures they should exercise their right to terminate the study or to opt out of it.

III.2.2. Researchers should undertake only such research that according to their understanding will be useful to society or for the furtherance of knowledge on the subject.

III.2.3. Researchers should not undertake secret or classified research, any secret assignment under the garb of research nor research whose findings are to be kept confidential. Researchers have a right as well as responsibility to make all necessary efforts to bring the research and its findings to the public domain in an appropriate manner.

III.2.4. Researchers have a responsibility towards the interests of those involved in or affected by their own work. They should make reasonable efforts to anticipate and to guard against possible misuse and undesirable or harmful consequences of research. Researchers should take reasonable corrective steps when they come across misuse or misrepresentation of their work.

III.2.5. Researchers should ensure that there is honesty and transparency at every stage of research as these are indispensable for good and ethical research.

III.2.6. Researchers should ensure that there is no fabrication, falsification, plagiarism or other unethical practices at any stage of the research; and that the findings of research are reported accurately and truthfully. They should also ensure protection of historical records and preservation of study material.

III.2.7. All parties involved in research and dissemination of its findings should inculcate and practice sensitivity and respect for culture and other aspects of the group or community studied.

III.2.8. Researchers must ensure respect, protection and promotion of rights of participants. Criteria for the selection of participants of research should be fair, besides being scientific.

III.2.9. Peer review should be an essential part of every research endeavour or initiative, and should be sought at various stages of research.

III.3. Relationship among researchers

III.3.1. Principal researchers are responsible for the ethical conduct of research by all juniors, assistants, students and trainees. At the same time juniors, assistants, students and trainees have an equal responsibility for ethical conduct and observance of ethical guidelines.

III.3.2. The juniors, assistants, students and trainees have a right to receive, and principal researchers have a responsibility to provide/impart, proper training and guidance regarding all aspects of research, including ethical conduct. The principal researchers should delegate to the juniors, assistants, students and trainees only those responsibilities that they are reasonably capable of performing on the basis of their education, training or experience, either independently or under supervision.

III.3.3. No researcher should engage, personally or professionally, in discriminatory, harmful or exploitative practices, or any perceived form of harassment. Nor should the researcher impose views/beliefs on or try to seek personal, sexual or economic gain from anybody, including other researchers, juniors, assistants, trainees and students.

III.3.4. Researchers should not deceive or coerce other researchers, including juniors, assistants, trainees and students into serving as research subjects/participants, nor use them as cheap labour.

III.3.5. Researchers should be co-operative, responsive, honest and respectful about the interest, opinion/view, capability and work of other researchers, including juniors, assistants, trainees and students.

III.3.6. While working in the team on a research project, at the outset, all members of the team have a right to know and document all aspects of research including ownership of the data. This procedure also applies to the participation of students doing their own research in a project team. Students should have the right to opt out of a research project without having to face adverse consequences.

III.3.7. In addition to researchers, other individuals such as administrative staff of the organisation conducting research or that of the research setting, etc may be associated, in some way, with the research. All of them should be briefed on ethical issues and the guidelines, including the need to protect the rights of participants and the confidentiality of identifiable data.

III.4. Data sharing

III.4.1. Sharing of data should be done in a form, which is in consonance with the interests and rights of the participants. Researchers who have conducted the study and the institution where the study is conducted are fully responsible for ensuring the protection and promotion of the interests and rights of participants while sharing or making public available data in any form.

III.4.2. The researchers involved in a particular research and the institution where the research is conducted, have a joint right over and ownership of all raw data, including those identifying the participants. Along with this right, they are fully responsible for ensuring that when such data, including those that identify participants, are shared with other researchers, all necessary measures are taken and followed to maintain confidentiality, by those researchers with whom data are shared.

III.4.3. Data that do not identify participants and their whereabouts, in the form of anonymous or abstracted facts, may be commonly shared, if necessary even before the publication of the study, among researchers, peer reviewers, or may even be made available to the public.

III.4.4. As far as possible, researchers and institutions should ensure that relevant summary findings of the research are taken back to the research participants in a form and manner that they can understand. In this process they should take into consideration the possible social harm that such information might cause to the research participants.

III.5. Reporting and publication of research

III.5.1. Reporting of research and its results is the right as well as duty of every researcher and institution that conducted the study. When they agree to delegate this responsibility to funder(s)/sponsor(s) or any other individual(s)/organisation(s), they should do it only if they have received mutually agreed and expressed commitment to publish/disseminate the results/report within a stipulated period.

III.5.2. The results should be reported irrespective of whether they support or contradict the expected outcome(s). Researchers should also disclose in their publications, the source(s) of funding and sponsors, if any, unless there is a compelling reason not to do so. The findings should also explain the methodology used, as well as how, in actual practice the ethical guidelines were followed, ethical dilemmas encountered and resolved, etc.

III.5.3. *Authorship credit*: The following guidelines should be followed for giving authorship credit while reporting the research in any form:

(i) Authorship, and its sequence in case of more than one author, should be based on the quantum of contribution made in terms of ideas, conceptualisation, actual performance of the

research, analysis and writing of the report or any publication based on the research. Authorship and its sequence should not be based on the status of the individual in the institution or elsewhere.

(ii) All other individuals not satisfying the criteria for authorship but whose contribution made the conduct and completion of research or publication possible should be properly acknowledged.

(iii) A student should be listed as principal or first author on any multiple authored publication that substantially derives from the student's dissertation or thesis.

(iv) Appropriate credits should be given where data or information from other studies or publications is quoted or otherwise included.

III.5.4. Researchers should avoid dissemination of the results of research before they are peer-reviewed or published in appropriate journals. When such results are disseminated through the popular media, extra care should be taken to ensure that even those media persons not specifically trained in social science and health issues and research, are able to comprehend the limitations and implications of research results. Journalists and the media that publish these research results have a responsibility to do so truthfully and honestly.

III.5.5. When institutions and/or researchers publish a report or any other documents based on research, they should make adequate efforts to ensure their easy availability and accessibility.

Section IV
Rights of Participants

IV.1. Relationship with the participants

IV.1.1. Participants should be seen as indispensable and worthy partners in research. Researchers should recognise and ensure that respect, protection and promotion of the rights of participants are made intrinsic to every stage and level of research undertaken by them.

IV.1.2. Research undertaken should not adversely affect the physical, social and/or psychological well being of the participants. The risks and benefits of the research to the prospective participants must be fully considered; research that could lead to unnecessary physical harm or mental distress should not be undertaken. Researchers should make adequate provision for the comfort of the participants as well as for protection against all possible and potential risks.

IV.1.3. The criteria for selecting research participants should be fair. The easy accessibility of the participants alone does not constitute a fair criterion for their inclusion in research as that will make them bear an unfair share of the direct burden of participation. At the same time, it should be borne in mind that no particular group or groups should be unfairly excluded from research, as that could well exclude them from the social understanding of their situation, and can also unfairly exclude them from direct, indirect or potential benefits of research.

IV.1.4. Unless consent on mutually beneficial arrangement is obtained, institution and student should not use community or research setting as a constant and long-term resource for data collection for curricular research or training in an institution.

IV.1.5. The relevant social, cultural and historical background of the participants should be taken into consideration and given appropriate importance in the planning and conduct of research.

IV.1.6. Researchers should not impede the autonomy of participants by resorting to coercion, promise of unrealistic benefits or inducement. Participants and communities should not be exploited and the time taken for data collection from these sources should not be inordinately long.

IV.1.7. Participants are autonomous agents and must have the right to choose whether or not to be part of the research. They also have the right to change their decision or withdraw the informed consent given earlier, at any stage of the research without assigning any reason.

IV.2. Informed consent

IV.2.1. Voluntary and informed participation of individuals or communities is necessary for research. Their participation should be based on informed consent; the greater the risk to participants, the greater is the need for it. Informed consent is essential to protect the participants, not the researchers and institutions.

IV.2.2. Consent for participation in research is voluntary and informed only if it is given without any direct/indirect coercion and inducement, and is based on adequate briefing given to the participants about the details of the project. The briefing should be given both verbally and in writing in a manner and language that the participants know and understand. In the prevailing circumstances in India, often, it may not be possible to obtain signed informed consent of the participants in social science research in health. It is however essential that the participants are furnished with written information giving adequate details of the research. Researchers have a duty to ensure that the participants comprehend the information given.

IV.2.3. The verbal and written briefing of the participants, in the manner and language they understand, should include the following details:

(i) *Purpose of research*: The goal and objective of research should be presented in simple local language.

(ii) *Identity of the researchers*: Name and address of researcher(s), the institution(s) and the main person of the ethics committee/ethical review board or any such ethics group of the institution.

(iii) *Identity of others associated with the research*: Name(s) and address of chief consultant(s), funder(s) or sponsor(s), etc., if any.

(iv) *Why selected*: Reasons or method for selecting the particular locality, community and/or any other setting; and individual(s) or group(s) within that, for participation in the study.

(v) *Harms and benefits*: The possible, anticipated and potential benefits and/or harms (direct/indirect, immediate/long term) of research and their participation.

(vi) *Privacy, anonymity and confidentiality*: Information on the extent of privacy, anonymity and confidentiality that will be provided to participant(s). This must include, at least, the firm commitment that privacy, anonymity and confidentiality of data identifying participants will be strictly maintained. In case the data identifying participants is to be shared with or made available to individuals/organisations not in the research team, information about them (their names, addresses etc.) should be provided.

(vii) *Future use of information*: The future possible use of the information and data obtained, including use as a database, archival research or recordings for educational purposes, as well as possible use in unanticipated circumstances, like its use as secondary data should be made known to participants. Such use should be only of anonymous or abstracted information and data, and should in no way conflict with or violate the maintenance of privacy, anonymity and confidentiality of information identifying participants.

(viii) *Right not to participate and withdraw*: Participants should also be informed about their right to decline participation outright, or to withdraw consent given at any stage of the research, without undesirable consequences, penalty and so on. The participants should be informed that they are free to object to and refuse to allow the use of data gathering devices, such as camera, tape recorder, etc.

(ix) *Right to get help*: The researcher should try and get all the possible help that the participants might require. The researcher also has a responsibility to help the participant(s) in cases of adverse consequence or retaliation against the participant(s) by any agency due to their participation in the research. Information, which may contribute to the improvement of quality of life of the participants, should be passed on to concerned person(s), official(s) or the agencies.

IV.2.4. If the data collection from the participant(s) is done in more than one sitting or contact and there is a long time period between the sittings/contacts, informed consent should be sought each time.

IV.2.5. In some cases, revealing the identity of the group of participants, groups, village(s), neighbourhood(s), etc, in the report could have an adverse effect on members/residents there. Sometimes the researchers are not able to anticipate the possibility of adverse effect at the time of conducting research and publishing reports. Researchers should take care that the study communities and/or localities are not identified or made identifiable in the report unless there are strong reasons for doing so. If the researcher(s) and institution intend to identify them in the report, participants' informed consent allowing such disclosure should be obtained.

IV.2.6. *Non-disclosure of all information*: In some specific situations and research issues, it is not practically possible to carry out research if all the details of the study are revealed to participants. This may be due to genuine difficulties in accessing participants, possibility of

affecting change in behaviour or responses, etc., when the details are revealed. Thus, it is not possible to obtain the informed consent in the same way as described above. In such cases, the following should be done:

(i) A detailed justification for not revealing all necessary information must be provided in the research proposal and methodology and should be subject to peer and ethical reviews. Only on approval in peer review, should such research be undertaken.

(ii) The participants' right to privacy, anonymity and confidentiality gains additional importance in such cases as they do not know fully the real purpose or objective for which they provide information.

(iii) Even if through a peer review process it is accepted that some of the information about the study need not be revealed, participants must be provided the rest of the information. Under no circumstance should the researchers withhold the information regarding physical risks, discomfort, unpleasant emotional experiences, or any such aspect that would be a major factor in taking the decision to participate.

(iv) As far as possible, debriefing should be done with the participants after completion of the research, giving reasons for not providing full information. As a part of the debriefing process, it might often be necessary to provide services such as counselling and referral.

IV.2.7. *Consent where gatekeepers*[5] *are involved*: In some situations there may be a need to obtain permission of the 'gatekeeper' to access the participants for research. The following care must be taken in such situation:

(i) Permission obtained from the gatekeeper must not be substituted for the need to take separate and full informed consent of the participants. The rights of participants in such situation are the same as in all other cases and need determined protection.

(ii) For obtaining permission of the gatekeeper, no pre-condition demanding sharing of information or data obtained should be accepted.

(iii) In the process of research or data collection, adequate care should be taken to ensure that the relationship between the gatekeeper and the participants is not jeopardised.

(iv) Greater care should also be exercised in protecting participants and their interest while publishing and disseminating results of research.

IV.2.8. Informed consent in the case of research with children (below the age of fourteen years) should be sought from the parents/guardians as well as the children themselves. Where the parents/guardians consent to participate, and the children have declined, the rights of the children should be respected. The consent from parents/guardians should be waived only in special cases

[5] Gatekeepers are those who control researchers' access to participants. They could be persons in-charge of research setting, a community leader whose advise or instruction the participants follow, or any other without whose consent the researchers are unable to obtain access to participants.

such as child abuse. Peer review is indispensable and the protection of children especially from the immediate consequences of research gains prime importance.

IV.3. Privacy, anonymity and confidentiality

IV.3.1. Anonymity and confidentiality are the inherent rights of all participants. The right whether to remain anonymous or to be identified lies with the participant. It becomes all the more important in research projects dealing with stigmatised, sensitive or personal issues and information.

IV.3.2. Possibility of the breach of confidentiality and anonymity should be anticipated, addressed and explained to the participants.

IV.3.3. Appropriate methods should be devised to ensure privacy at the time of data collection. These methods are also essential to ensure the validity of data.

IV.3.4. The obligation to maintain privacy, anonymity and confidentiality extends to the entire research team, other researchers in the institution, the administrative staff, and all those (from or outside the institution) not directly associated with the research who may possibly have access to the information.

IV.3.5. While deciding on what information should be regarded as private or confidential, the perspective of the participant(s) on the matter should also be given adequate importance.

IV.3.6. Researchers should maintain appropriate anonymity and confidentiality of information in creating, storing, accessing, transferring and disposing of records under their control, whether these are written, automated or in any other medium.

Section V
Rights and Responsibilities of Peer Reviewers/Referees

V.1. The purpose of peer review and refereeing is to improve and advance research, and facilitate observance of ethics. Researchers should be encouraged to make themselves available for such work and subject their own work to such a process.

V.2. Researchers should accept the role and duties of peer reviewer and referee only for the research in the fields they have adequate knowledge and expertise. They must also be fully aware of the ethical aspects of research and publication.

V.3. When called upon to act as peer reviewer and referee, researchers have an ethical duty to undertake it objectively, impartially and constructively.

V.4. If the peer reviewers/referees have any actual or potential conflicts of personal or professional interest with the work under review, they should either disclose the same or decline to review the work concerned. In such situations, their role should be decided on the basis of the type and severity of the conflict of interest.

V.5. When malpractice in research or violation of ethics are discovered, the researcher/peer reviewer has the ethical responsibility to take appropriate steps to report it.

Section VI
Rights and Responsibilities of Editors and Publishers

VI.1. Before accepting the research based articles for publication, editors and publishers have the right and duty to ensure that such material is, duly reviewed by referees deemed by the publication to have the relevant expertise and knowledge in the particular field.

VI.2. As social scientists and as journalists, editors are responsible for ensuring that the editorial policy and instructions to authors reflect the ethical concerns and the guidelines for research. Referees and editorial staff should be made aware of the editorial policy including the need for articles/papers to adhere to prescribed ethical norms. Contributors should be informed that the material submitted for publication should carry appropriate credits. Fabricated, falsified or plagiarised information should not be entertained.

VI.3. If, after the publication of material, any doubt is raised about its ethical status or ethical conduct of the study on which the said material is based, editors should take appropriate corrective steps.

Section VII
Rights and Responsibilities of Funders and Sponsors

VII.1. Funders and sponsors have the right to expect that researchers and institutions report the progress of their work and submit a copy of the final report on results of research as per the schedule agreed in advance.

VII.2. Funders and sponsors have a right to get a copy, if any, of the ethical guidelines for research followed by the researchers and institutions. They also have a right to expect that the research proposal submitted for funding or sponsorship by researchers and institution contains necessary information on ethical issues in and ethical conduct of the particular research proposed.

VII.3. The funders and sponsors of research should respect the ethical guidelines for research and should not expect researchers and institutions to undertake research or conduct it in any way contrary to the ethical guidelines.

VII.4. Where sponsors and funders also act, directly or indirectly, as gatekeepers and control access to the participants, researchers should not devolve onto the gatekeeper their responsibility to obtain separate and full informed consent from participants and protect all rights of the participants.

Section VIII
Organisational Mechanism for Ethics

While ethical guidelines are not administrative rules and the conscience of researchers may be the best guide for ensuring that ethics are followed in research and for resolving ethical dilemmas, conduct of research cannot be completely left to the discretion of individual researchers. Institutions and researchers involved in social science research in health should create appropriate institutional or research project based mechanisms to ensure ethical conduct of research and implementation of guidelines.

ERB OPERATIONAL GUIDELINES:

Overviews and Functions of Ethics Review Boards
PowerPoint Presentation

Basic Terms and Information on Ethics Review Boards

Composition and Responsibilities of Ethics Review Boards

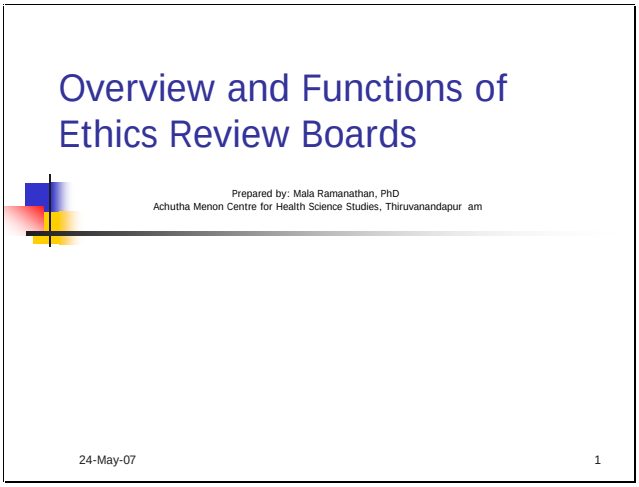
Protocols and Procedures

Approval Categories

Operational Guidelines for Ethics Committees that Review Biomedical Research
World Health Organization

Overviews and Functions of Ethics Review Boards
PowerPoint Presentation

Slide 1



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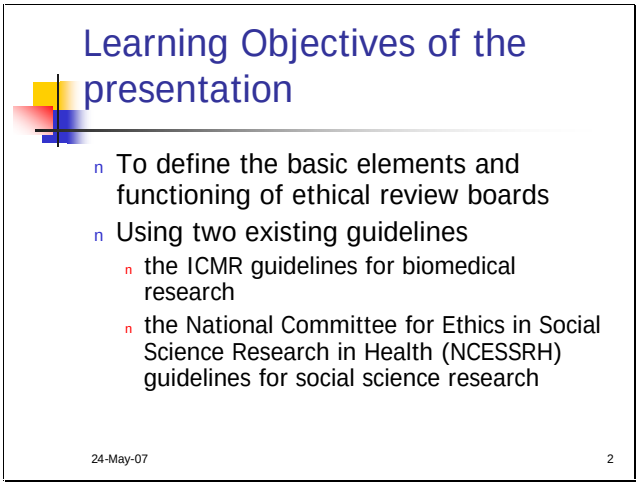

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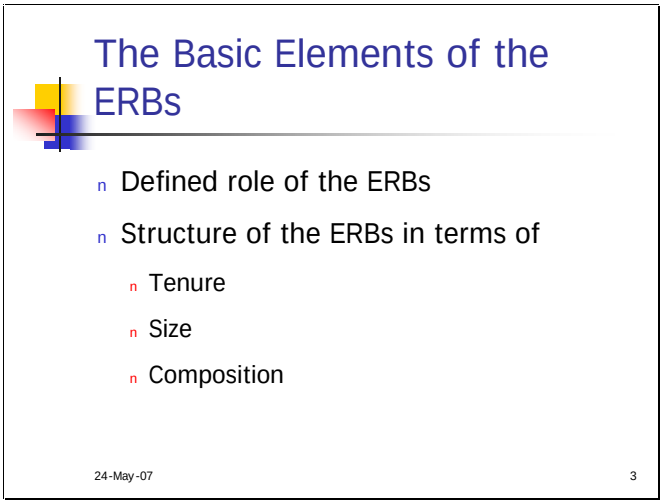

Slide 4

Role of the ERB – ICMR Guidelines

- All proposals on biomedical research involving human subjects be cleared by the ERB
- The purpose is to safeguard the welfare and the rights of the participants
- The ERB has responsibility for initial review of project and of regular monitoring for compliance of the ethics of approved projects till they are completed

Slide 5

Role of the ERB – ICMR Guidelines

- To protect the dignity, rights and well being of research participants
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs
- To assist in the development and education of a research community responsive to local health care requirements

Slide 6

Role of the ERB– NCESSRH guidelines

- The NCESSR guidelines do not provide a mechanism for operationalising the institutionalisation of ethical review in social science research
- Mechanisms of operationalising it – taken from the report of the ERB, CEHAT (Feb 2001 – June 2002)

Slide 7

Role of the ERB – NCESSRH guidelines

- Functions of the ERB
  - Protection: to contribute to the dignity, rights, safety and well being of all groups and persons related to the concerned project activity. This would include participants in the research, community at large, researchers, research community and institution
  - Advice: useful resource for commenting on project
  - Education: of project staff
  - Analysis and documentation: for self learning and educating others

Slide 8

Structure of ERB – ICMR Guidelines

- Tenure: not mentioned specifically but this needs to be specified in the TOR
- Composition:
  - Multidisciplinary and multisectorial in composition
  - Number of persons – 5/7 – 12/15

Slide 9

Specific members of ERBs - ICMR Guidelines

- Chair should preferably be from outside the Institution and not head of the same Institution to maintain the independence of the Committee.
- Member secretary, from same institution should conduct the business of the Committee

Slide 10

Structure of ERB– NCESSRH guidelines

- Tenure: 2 years
- Structure:
  - Comprise of external as well as internal members
  - External members – a majority
  - Internal members – adequate to fulfill role of the secretariat

Slide 11

Specific members of ERBs - NCESSRH guidelines

- One external member will be appointed Chair
- Internal members of a sufficient number to run the Secretariat.

Slide 12

Members of ERB – ICMR Guidelines

- Chair
- 1-2 basic medical scientists
- 1-2 clinicians from various institutes
- One legal expert or retired judge
- One social scientist/representative of NG voluntary agency
- One philosopher/ethicist/theologian
- One lay person
- Member Secretary
- If required, subject experts could be invited to offer views

Slide 13

Members of the ERB – NCESSRH guidelines

- At least one external member who represents interests of lay people, one Chairperson
- In case one or more members leave the IEC during its tenure, the institution will fill the gap in consultation with the existing IEC

Slide 14

Functioning of ERBs

- Described in terms of;
  - Review procedures
  - Decision making processes
  - Documentation requirements

Slide 15

Review Procedures – ICMR Guidelines

- Scientific evaluation should be completed before ethical evaluation
- Evaluated possible risks to the subjects with proper justification
- Expected benefits

Slide 16

Review Procedures – ICMR Guidelines

- Adequacy of documentation for ensuring privacy, confidentiality and justice issues
- The ethical review should be done through formal meetings and should not resort to decisions through circulation of proposals

Slide 17

Review procedures – NCESSRH Guidelines

- Process
  - Stages of review: three stages, prior to sending for funding, finalizing methodology, prior to report dissemination
  - Conducting of review through meeting
- Reporting format
- Documentation and dissemination of ethical reviews

Slide 18

Decision making process – ICMR Guidelines

- ERB should meet periodically
- Evaluate annual progress of ongoing projects, assess final reports of all research activities
- Decision making by building broad consensus
  - After fulfilling quorum requirements
  - Member must voluntarily withdraw during conflict of interest
  - Non-participation in review of own proposals
  - Negative decision should be supported by defined reasons

Slide 19

Decision making process –ICMR Guidelines

- Decision making
  - ERB can reverse its decision on study after receiving information that will adversely affect risk-benefit ratio
  - Discontinuation should be ordered if ERB finds that goals of trial have already been achieved midway or unequivocal results are obtained
  - Notification needs to be issued with reasons along with summary of results conducted to date in case of premature termination of study

Slide 20

Decision making process – ICMR Guidelines

- The ERB should be cognisant of:
  - Any amendment to the protocol from the originally approved protocol with proper justification
  - Serious and unexpected adverse events and remedial steps taken to tackle them
  - Any new information that may influence conduct of the study

Slide 21

Decision making process – ICMR Guidelines

- If necessary the PI may be invited to present the protocol or offer clarifications
- Representatives of patient groups or interest groups can be invited during deliberations to offer their viewpoint
- Subject experts views can be invited, but they should not form a part of the decision making process. Their opinions must be recorded

Slide 22

Decision making process – NCESSRH guidelines

- PI not required to be physically present, but available on telephone for consultation
- Internal members can abstain after providing explanation for the same
- Decision making should be majority of external members
- Certification is done only by external members
- Policing and monitoring of field activities not desirable nor expected

Slide 23

Documentation requirements – ICMR Guidelines

- Record Keeping Requirements
  - Meetings must be minuted and approved and signed by chair
  - Strict confidentiality
  - All documentation, including final reports of the study, microfilms, CDs and video recordings
  - Duration: if not permanently, at least for 15 years

Slide 24

Documentary requirements – NCESSRH guidelines

- Reporting of Review
- Documentation
  - Maintaining minutes of IEC meetings
  - Maintaining confidentiality
- Record keeping requirements in terms of duration: not mentioned.

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Summary

ICMR Guidelines

- Tenure-as per TOR
- No. of members: 5/7-12/15
- External chair
- Scientific evaluation precedes ethical evaluation
- Review through formal meetings
- Decision by broad consensus

NCESSRH guidelines

- 2 years
- No. of members: not specified (majority external members)
- External chair
- Review in three stages- prior to funding, methodology, prior to dissemination
- Review through meetings
- Decision by majority of external members

Reference material for Institutional Ethics Committee (IEC)/Insitutional Review Board (IRB) review[6]

I. Basic Definitions

Research: systematic investigation designed to develop or contribute to generalized knowledge

Human subject[7] (participant): living individual with whom a researcher obtains data.

Informed consent: the process during which individuals are educated about the nature of research and make a knowledgeable and voluntary decision regarding participation. NIH & US federal regulations require eight types of information that must be included in the informed consent procedure while ICMR requires 15[8].

Benefit: a valued or desired outcome.

Minimal Risk: when the probability and magnitude of anticipated harm or discomfort is not greater than that ordinarily encountered in daily life/during routine physical or psychological exams/ tests.

Privacy: the extent to which an individual has control over the timing, extent and circumstances under which they interact with others (pertains to methods used to collect information).

Confidentiality: the way in which information that is disclosed in a relationship of trust is treated – the understanding that this information will not be divulged to others in ways that are contrary to the agreement at the time of disclosure (pertains to how collected information is treated/shared).

Monitoring: On-going collection and analysis of data to ensure that the research design and protection of participants is sufficient.

Review: Oversight of research by IEC/IRB on a periodic (at least an annual) basis.

II. Underlying principles of the IEC/IRB

Ethical principle as described in Belmont Report	**Meaning**	**Aspects for IRB review**
Respect	Respect for individual autonomy Protection of individuals with reduced autonomy	Informed consent Protect confidentiality
Beneficence & non-maleficence	Maximize benefits & minimize harms	Risk/benefit analysis Scientific merit
Justice	Equitable distribution of research burdens & benefits	Review of participant selection

[6] Based on informational found at the NIH website (www.nih.gov); ICMR; and CEHAT guidelines.
[7] "subject" is the term used by US Federal Agencies such as the Office for Human Research Protections. "Participant" is the term preferred by some. We have chosen to do use the latter term here.
[8] NIH requires description of (1) study purpose, duration, procedures; (2) risks or discomforts; (3) anticipated benefits; (4) disclosure of alternatives; (5) extent of confidentiality; (6) procedures in the event of injury; (7) contact information; (8) implications of participation and non-participation. For ICMR requirements, please see p. 18 & p. 36 of ICMR guidelines.

III. IEC minimum functioning requirements

1. Should be comprised of epidemiologists, clinicians, statisticians, social scientists, philosophers, legal experts and representatives form community/voluntary groups, who are aware of local social and cultural norms.
2. Should have a: chairperson (NIH&ICMR). ICMR also recommends a member secretary.
3. Majority of members are present at a meeting and at least one non-scientist is present.
4. If required number are not present, no action is taken.
5. For approval and certification, majority of those present must approve the protocol.
6. Minutes of meetings should be prepared and should include the following:
    a. Attendance
    b. Actions taken including vote (number in favor, against & abstaining)
    c. Description of review findings
    d. Basis for requiring protocol modifications
    e. Summary of discussion

IV. Basic criteria for IEC review & approval

1. Informed consent is being sought.
    a. Content
    b. Expression
    c. Process
2. Informed consent is appropriately documented.
3. Data collection will be monitored to ensure safety of participants.
4. Privacy & confidentiality of participants is protected.
5. Risks to participants are minimized.
    a. Physical harm
    b. Psychological harm
    c. Social and economic harm
6. Risks are reasonable in relation to anticipated benefits.
    a. Benefits to participants
    b. Benefits to society
7. Selection of participants is equitable.

V. Questions to consider during review of protocols

Informed consent:

- Ø Does the study involve a vulnerable population?
- Ø Are the risks and anticipated benefits clearly explained?
- Ø Is the language and presentation of information appropriate for the study population? Is translation from English required?
- Ø Can individuals make decisions about consent under the described conditions?
- Ø Who will ascertain consent? Is the presence of a third party necessary?
- Ø Should consent be ascertained periodically over the course of the study?
- Ø Should the IRB monitor the information provided to potential participants to determine its sufficiency? Who will facilitate this?
- Ø Is a waiver of consent requirements justified? Does the study pose a greater than minimal risk? Will additional information be provided at completion?

"The IRB may waive the regulatory requirement for written documentation of consent in cases where: (1) the principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research (e.g., studies on sensitive topics such as drug abuse or sexual deviance); and (2) the consent document is the only record linking the subject with the research [Federal Policy §___.117(c)(1)]. Written documentation of consent may also be waived when the research presents no more than minimal risk and involves procedures that do not require written consent when they are performed outside of a research setting [Federal Policy §___.117(c)(2); FDA regulations on IRB review, 21 CFR 56.109(c)]. Source: [IRB Guidebook Chapter III]

Monitoring and observation:

- Ø How will data be recorded and mainitained?
- Ø Will researchers be monitoring the research? Is their plan adequate? Is the principal investigator full time on the project (or is there an appropriate individual for oversight)?
- Ø Is there a mechanism for researchers to update the IRB in the event of unexpected developments?

Privacy and confidentiality:

- Ø Would the research be considered an intrusion and would individuals be offended? Are there ways to reduce this? Does the aim of the study justify this intrusion?
- Ø Will sensitive information (e.g. information regarding alcohol or drug use; illegal conduct; or issue that could lead to social stigmatization) be collected?
- Ø Are there sufficient provisions for protection of confidentiality? Who will have access to data?
- Ø Are researcher's statements to participants regarding confidentiality sufficient?

Risk-benefit analysis:

- Ø Are risks and anticipated benefits accurately identified, evaluated, and described?
- Ø Are risks greater than minimal risk?
- Ø Has attention been paid to minimizing risk and maximizing likelihood of benefits?
- Ø Are there adequate provisions for monitoring risks and benefits? Is a data safety monitoring committee required?

Selection of participants:

- Ø Do participants belong to group that is most likely to benefit from the research?
- Ø Is participant selection justified?
- Ø Will the research pose an unfair burden for potential participants?
- Ø Are there procedures to minimize the pressures on potential participants?

Recruitment and Incentives:

- Ø Will informed consent be possible given the recruitment strategies employed?
- Ø Are incentives required – given the demands of participation and the study population?

- Ø Are incentives offered reasonable? Will they pose an undue influence for participation?

Brief description of responsibilities of an Independent Ethics Committee (IEC)*

The primary responsibility of the IEC is to review and oversee the ethical aspects of the research, that is, to ensure that research is conducted in an ethical fashion. Specifically:

1. The IEC shall ensure that research complies with accepted and established standards for human research such as those set forth in the 2000 Indian Council of Medical Research Ethical Guidelines for Research Involving Humans and by the US National Institutes of Health (for US NIH funded research and described further below).
2. The IEC shall review the research and continue oversight of the research including an annual review.
3. The IEC shall ensure that all research obtain informed consent (ascertained using plain language understandable to the subject) in a culturally appropriate fashion (US NIH (or other federal agency)-funded projects typically require written informed consent, but this requirement may be waived if culturally inappropriate).
4. The IEC shall establish written procedures for a) verifying whether proposed activities qualify for exemption from or waiver for IEC review; b) conducting initial and continuing IEC review, approving research, and reporting IEC findings to the investigator and the institution conducting the research; c) determining appropriate intervals for continuing review of projects and oversight mechanisms for all approved research; d) ensuring that changes in the approved research are not initiated without IEC approval, except when necessary to eliminate apparent immediate hazards to the subject; and e) ensuring prompt reporting to the IEC, institutional officials, the relevant US Agency Head, any applicable regulatory body, and the US Office for Human Research Protection of any i) serious or continuing noncompliance with US, institutional, or IEC requirements; ii) unanticipated problems involving risks to subjects or others in any covered research; and iii) suspension or termination of IEC approval for US-supported research.
5. The IEC should acknowledge that special protections are needed for vulnerable populations of subjects.
6. The IEC should ensure the existence of adequate education and oversight mechanisms (appropriate to the nature and volume of the research being conducted) to verify that research investigators maintain continuing knowledge of and comply with relevant policies and procedures for the protection of human subjects.

*Based on NIH guidelines.

Guidelines for composition and qualifications of IEC members*

1. At least five members with varying backgrounds and qualified through sufficient experience and expertise.
2. Diverse in terms of ethnicity and gender.
3. Include individuals able to ascertain the acceptability of research in terms of institutional commitments and regulations, applicable law and standards of professional conduct and practice.
4. If reviewing research on vulnerable populations such as pregnant women and children, should include members with knowledge about and experience in working with these populations.
5. Not all members should be either men or women, or belong to a single profession.
6. At least one member whose primary concerns are in scientific areas and at least one whose primary concerns are in nonscientific areas.
7. At least one member who is not otherwise affiliated with the entity and who is not part of the immediate family of a person who is affiliated with the entity.
8. No member should participate in initial or continuing review of any project in which the member has a conflicting interest, except to provide information if requested.
9. May invite individuals with competence in special areas to assist in review if they require additional expertise.
10. All members and staff shall complete appropriate education and training before reviewing research such as the training available at the OHRP website or some other appropriate training source.

*Based on NIH guidelines.

Procedures and protocols to be developed

Protocols and procedures to be developed by the Institutional Ethics Committee
As part of the establishment of the IEC, members are responsible for the development of specific protocols and procedures for the functioning of the IEC. The following is a summary of procedures for which the WHO *recommends* the IEC establish protocols:

1. Selection/appointment of officers in the IEC (i.e. chair person, secretary, etc.)[9]
2. Quorum requirements[10]
3. Terms of reference for independent consultants[11]
4. Documentation and archive process for recording IEC meeting minutes, discussions with researchers, and communication with involved groups.[12]
5. Requirements for submission of proposals from researchers involved with Samuha/Samraksha (includes development of application forms, requests for specific information, number of copies required for review, time frame for review, and procedures for acknowledgement of receipt of necessary information, terms for conditional approval and amendments).
6. Procedures for expedited review
7. Decision-making procedures and methods (member vote, committee consensus, conflict resolution, time frame for decision-making once proposals have been reviewed, etc.)
8. Protocol for communicating decisions (written documentation, time frame for communication with researchers and organizations, etc.).
9. Requirements for progress reports, frequency and number of reviews, level and type of monitoring during research phases, etc.[13]

Protocols and procedures to be developed by the researchers and participating organizations
Researchers and participating organizations are responsible for the development of roles and responsibilities and certain procedures for the operations of the IEC. These include:

1. Identification, recruitment, and appointment of IEC members
2. Term and conditions of appointment (including duration, renewal, disqualification, resignation and replacement of appointment)
3. Training programs for both introductory training and continuing education to build capacity of the IEC
4. Expectations for annual review of project protocols and proposals
5. Procedures for expenditures and reimbursements for IEC related costs.

[9] NIH (USA) only requires the IEC to appoint a Chairperson. Appointment of additional officers, such as a secretary or note-taker, is left open to the discretion of the IEC.
[10] Currently, the NIH requires a minimum of at least 5 members to be present to reach quorum. WHO guidelines recommend at least more than half of the total number of members on the IEC.
[11] The decision to invite and involve independent consultants is open to the members of the IEC.
[12] Currently, WHO recommends that all communication and information used for decision-making be kept on record for a minimum of three years following completion of the project.
[13] Currently, NIH requires an annual review by the IEC (with reports submitted annually by research project staff)

CATEGORIES OF APPROVAL

Ethics Review by the IEC would have ONE of the TWO following outcomes:

(A) The investigators can begin the study without submitting additional information to the IEC,

Or

(B) The investigators may not begin the study until additional information is provided. Based on the discussion during the review process, one of the following **five categories of approval** is applied to each application:

In the case of (B), ONE of the following FIVE categories are applied (including denial):

(a) Study can begin and approval letter is issued:

1. STRAIGHT APPROVAL OR APPROVAL WITH COMMENT:

- Granted when the Committee has no questions about the application.
- The members may, however, make comments about this approval or recommendations for future submissions. Such comments will be included in the approval letter itself.

2. CONDITIONAL APPROVAL:

- Granted when the Committee approves an application with conditions and the members recommend, but do not require, a response to those conditions.
- Such conditions usually involve changes in the consent form; however, the members are willing to allow the study to be conducted even if no changes are made.
- Conditional approval can also be given, for example, if an investigator is asked to submit a finalized version of a questionnaire or letters of support from others including institution's departments cooperating in the research.
- Conditional approval may not be given if government/legal requirements are not met.
- Conditions will be explained in the approval letter. Once the investigator responds to the conditions, a letter is sent out that indicates the conditions have been removed; however, no new approval letter is generated

(b) Study cannot begin until committee's concerns or required changes are communicated in writing, the investigators respond to the concerns or requested changes, and the response is approved:

3. CONTINGENT APPROVAL:

- The Committee approves the study in principle.
- However, the members require a written response from the investigator regarding particular items of concern. The members may ask the investigator to: (a) clarify a point, (b) provide further information, (c) make revisions in, for example, the protocol, recruitment, and/or consent form.

- Normally, only Chairperson reviews the response from investigator. The Chair has the option of sending the response to the Full Committee or a Subcommittee. At this stage as far as possible, no new or additional issues should be raised unless (a) it is found that some aspects of government/legal requirements were overlooked during the Committee review and/or (b) in the opinion of the Chair, the new or additional issue is of high importance and was inadvertently overlooked during the Committee review.
- No approval number is given until the questions and/or concerns of the Committee have been satisfactorily addressed and approved by the Chair.

4. RETURNED FOR ADDITIONAL INFORMATION:

- Committee is not prepared to approve the study without additional information and review.
- Requested when serious concerns are raised about the risk/benefit ratio or other issues of participants' protection and the members agree that additional information, justification, or changes are needed before approval can be reconsidered.
- The Committee members have explicitly asked that the study be returned to them for additional review.
- The investigator must respond to this request in writing and then the Full Committee or the Subcommittee reviews this response depending on the decision of the members or Chair.
- If the revised proposal meets the requirements, it is granted contingent, conditional, or straight approval at the time of the second review. However, the study may be returned again if the members request it.

3. DENIAL OF APPROVAL:

- Committee disapproves the study in principle.
- Denied approval because members' concerns for the protection of the participants have not been satisfactorily addressed even after the revision.
- Before the proposal/project is denied approval, the Committee must invite the investigator to present his/her views/justification and the same are discussed by the members of the Committee with the investigators and among themselves.