

ETHICAL GUIDELINES FOR OPERATIONAL RESEARCH ON HIV/AIDS

Version 2008



NATIONAL AIDS CONTROL ORGANISATION

Ministry of Health & Family Welfare,

Government of India

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1. INTRODUCTION

1.1 Preamble

NACO Ethics Committee for Research is constituted with responsibility to ensure that the ethical implications of any research undertaken are afforded serious consideration prior to the commencement of a project and that such research is consistent with legislative and statutory requirements.

The rationale for ethical approval is to ensure that the process of research is conducted 'ethically' and responsibly and ensures protection of privacy and not exploitative of participants. This mainly involves establishing procedures for the informed consent of those subjects involved in research, as well as appropriate handling of the research findings (e.g. secure storage of data) and material. The highest ethical standards must be upheld when collecting behavioral or biological data on HIV/AIDS, as due to stigma and human rights issues around HIV/AIDS, the study participants may experience psychological, social, physical or economic harm.

All the research activities involving human participants should be conducted in accordance with the four basic ethical principles, namely autonomy (respect for person/participant) beneficence, non-maleficence (do no harm) and justice. The guidelines laid down are directed at application of these basic principles to research involving human participants.

1.2 Basic Responsibility of the Committee

The basic responsibilities of NACO Ethics Committee are defined as follows:-

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

1.3 Composition of NACO Ethics Committee

The NACO Ethics Committee for Research consists of the experts in epidemiological, behavioral and social disciplines. In addition, a legal expert and a representative from the

community are also included. The Chairman of the Committee should not be appointed from the NACO so that independence of the committee can be maintained. The Member Secretary should be the officer in-charge for Operational Research in NACO who should organize the functioning of the Committee. The number of members in the ethics committee should be between 8 and 12.

Following will be the composition of the Ethics Committee:-

1. Chairperson [Eminent expert having vast experience in health or social sectors]
2. One - two evaluation and operational research scientist/experts from various Institutes
3. One legal expert or retired judge
4. One expert in bioethics or equivalent
5. One expert in epidemiological, social or behavioral scientist/ representative of non-governmental voluntary agency/philosopher/ ethicist/ theologian
6. One - two persons from basic medical science area
7. One representative of PLHA network (representative from the community) who have no affiliation with the institution or organisation, are not currently involved in medical, scientific, or legal work, and who are preferably from the community in which the institution or organisation is located.
8. Member Secretary [Ex-officio in-charge of Operational Research at NACO]

The Ethics Committee can have as its members, individuals from other institutions or communities with adequate representation of age and gender (minimum 25% members will be women) 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, pediatrician, statistician, epidemiologist, demographer, anthropologist, ethnographer, etc. It would be preferable to appoint person trained in bioethics or persons acquainted with ethical guidelines and laws of the country. One representative of PLHA network (representative from the community) who should be aware of local, social and cultural norms, as this is the most important social control mechanism.

1.4 Terms of Reference of Members

The Terms of References should include date of appointment, duration of the term, the policy for removal, replacement, resignation procedure, frequency of meetings, and payment of processing fee to the Ethics Committee for review, honorarium/consultancy to the members/invited experts *etc.* and these should be specified in the standard operating

procedures (SOP) which should be made available to each member. Committee should have its own written SOPs according to which committee should function. The SOPs should be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances. For this the criteria for number of missed meetings may be defined in the SOP.

2. PRINCIPLES FOR ETHICAL ISSUES:

Any research using the human beings as participants shall follow the principles given below.

2.1 General Principles:

The following 12 principles are common to all areas of research.

I. Principles of essentiality whereby the research entailing the use of human participants is considered to be absolutely essential after a due consideration of all alternatives in the light of the existing knowledge in the proposed area of research. After the careful consideration, the committee comes to the conclusion that the said research is necessary for the advancement of knowledge and for the benefit of well being.

II. Principles of voluntariness, informed consent and community agreement whereby research participants are fully informed of the research and the impact and risk of such research on the participant and others; and whereby the research participants retain the right to abstain from further participation in the research irrespective of any legal or other obligation.

Where any research entails treating any community or group of persons as a research participant, these principles of voluntariness and informed consent shall apply, *mutatis mutandis*, to the community as a whole and to each individual member who is the participant of the research.

Where the human participant is incapable of giving consent, it is considered to be essential that consent should be taken by someone who is empowered and under a duty to act on their behalf.

The principles of informed consent and voluntariness are fundamental principles to be observed throughout the research and experiment, including its consequences and applied

use so that research participants are continually kept informed of any and all developments in so far as they affect them and others.

The nature and form of the consent and the evidentiary requirements to prove that such consent was taken, shall depend upon the degree and seriousness of the invasiveness into the concerned human participant's person and privacy, health and life generally, and, the overall purpose and the importance of the research.

Ethics committee shall decide whether the consent to be taken in the particular research or its waiver based on the degree of risk that may be involved.

III. Principles of non-exploitation whereby as a general rule, research participants are remunerated/compensated for their involvement in the research or experiment; irrespective of the social and economic condition or status, or literacy or educational levels. Each research shall include an in-built mechanism for compensation for the human participants either through insurance cover or any other appropriate means to cover all foreseeable and unforeseeable risks by providing for remedial action and comprehensive aftercare, including treatment during and after the research or experiment, in respect of any effect that the conduct of research or experimentation may have on the human participant and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected, if and when necessary.

IV. Principles of privacy and confidentiality whereby the identity and records of the human participants of the research or experiment are as far as possible kept confidential; and that no details about identity of said human participants, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of interventions, without the specific consent in writing of the human participant concerned, or someone authorized on their behalf; and after ensuring that the said human participant does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the research or experiment.

The Supreme Court of India has rules on the issue of the right to confidentiality of subjects with HIV infection and the breach of confidentiality in order to protect the health of third parties. The opinion of the court is that the right to privacy and confidentiality is not absolute. The issues relating to confidentiality and partner notification within the context of HIV infection are complex. The right of the individual to confidentiality can

be conflict with the right of the partner to be protected from the risk of infection. Confidentiality is essential to prevent discrimination. On the other hand the seriousness of the threat to the health of unsuspecting third parties resulted in the debate on informing people at risk, also known as partner notification. NACO therefore encourages motivation of the HIV positive persons to disclose their status to the sex-partner.

V. Principles of precaution and risk minimization whereby due care and caution is taken at all stages of the research and experiment (from its inception as a research idea, its subsequent research design, the conduct of the research or experiment and its applicative use) to ensure that the research participant and those affected by it including community are put to the minimum risk, suffer from no known irreversible adverse effects, and generally, benefit from and by the research or experiment; and that requisite steps are taken to ensure that both professional and ethical reviews of the research are undertaken at appropriate stages so that further and specific guidelines are laid down, and necessary directions given, in respect of the conduct of the research or experiment.

VI. Principles of professional competence whereby the research is conducted at all times by competent and qualified persons who act with total integrity and impartiality and who have been made aware of preferably through training, the ethical considerations to be borne in mind in respect of such research or experiment.

VII. Principles of accountability and transparency whereby the research or experiment will be conducted in a fair, honest, impartial and transparent manner after full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research, and any conflict of interest that may exist; and whereby, subject to the principles of privacy and confidentiality and the rights of the researcher, full and complete records of the research inclusive of data and notes are retained for such reasonable period as may be prescribed or considered necessary for the purposes of post-research monitoring, evaluation of the research, conducting further research (whether by the initial researcher or otherwise) and in order to make such records available for scrutiny by the appropriate legal and administrative authority, if necessary.

VIII. Principles of the maximisation of the public interest and of distributive justice whereby the research and its subsequent applicative use are conducted and used to benefit all human kind and not just those who are socially better off but also the least

advantaged; and in particular, the research participants themselves and or the community from which they are drawn.

IX. Principles of institutional arrangements whereby there shall be a duty on all persons connected with the research to ensure that all the procedures required to be complied with and all institutional arrangements required to be made in respect of the research and its subsequent use or application are duly made in a bonafide and transparent manner; and to take all appropriate steps to ensure that research reports, materials and data connected with the research are duly preserved and archived.

X. Principles of public domain whereby the research and any further research, experimentation or evaluation in response to, and originating from such research is brought into the public domain so that its results are generally made known through scientific and other publications subject to such rights as are available to the researcher and those associated with the research under the law in force at that time.

XI. Principles of totality of responsibility whereby the professional and moral responsibility, for the due observance of all the principles, guidelines or prescriptions laid down generally or in respect of the research or experiment in question, devolves on all those directly or indirectly connected with the research or experiment including the researchers, those responsible for funding or contributing to the funding of the research, the institution or institutions where the research is conducted and the various persons, groups or undertakings who sponsor, use or derive benefit from the research, or prescribe its use so that, inter alia, the effect of the research or experiment is duly monitored and constantly subject to review and remedial action at all stages of the research and experiment and its future use.

XII. Principles of compliance whereby, there is a general and positive duty on all persons, conducting, associated or connected with any research entailing the use of a human participant to ensure that both the letter and the spirit of these guidelines, as well as any other norms, directions and guidelines which have been specifically laid down or prescribed and which are applicable for that area of research or experimentation, are scrupulously observed and duly complied with.

2.2 Specific Principles:

2.2.1. Informed Consent of Participants: For all evaluation and operational research involving human participants, the investigator must obtain the informed consent of the prospective participant or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. Informed consent protects the individual's freedom of choice and respect for individual's autonomy and is given voluntarily to participate in research or not.

The purpose and general objectives of the study has to be explained to the participants keeping in mind their level of understanding. Adequate information about the research is given in a simple and easily understandable unambiguous language in a document known as the Informed Consent Form with Participant Information Sheet. In the context of developing countries, obtaining informed consent has been considered many times as difficult/impractical / not meeting the purpose on various grounds such as incompetence to comprehend the meaning or relevance of the consent and culturally being dependent on the decision of the head of the family or village/community head. However, there is no alternative to obtaining individual's informed consent.

In this context, the role of investigator is crucial and s/he should remain vigilant and conscious of her/ his obligations towards the participants/ patients, all through the course of the studies.

The latter should have following components as may be applicable:

1. Nature and purpose of study stating it as research
2. Duration of participation with number of participants
3. Procedures to be followed
4. Investigations, if any, to be performed
5. Anticipated risks and discomforts adequately described and whether project involves more than minimal risk
6. Benefits to participant, community or medical profession as may be applicable
7. Policy on compensation
10. Steps taken for ensuring confidentiality
11. No loss of benefits on withdrawal
12. Benefit sharing in the event of commercialization

13. Contact details of PI or local PI/Co-PI in multicentric studies for asking more information related to the research.
14. Contact details of Chairman of the Ethics Committee for appeal against violation of rights
15. Voluntary participation
16. If test for HIV is to be done, counseling for consent for testing must be given as per national guidelines.
17. Storage period of data (biological sample as well) with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results

A copy of the participant information sheet should be given to the participant for her/ his record. The informed consent should be brief in content highlighting that it is given of free will or voluntarily after understanding the implications of risks and benefits and s/he could withdraw without loss of routine care benefits. Assurance is given that confidentiality would be maintained and all the investigations/interventions would be carried out only after consent is obtained. When the written consent as signature or thumb impression is not possible due to sensitive nature of the project or the participant is unable to write, then verbal consent can be taken after ensuring its documentation by an unrelated witness. In some cases ombudsman, a third party, can ensure total accountability for the process of obtaining the consent. Audio-visual methods could be adopted with prior consent and adequate precaution to ensure confidentiality, but approval of Ethics Committee is required for such procedures.

In most community based/ethnographic research it would be necessary to have the consent of the community, which can be done through the Village Leaders, the Panchayat head, the tribal leaders *etc.* who are considered to be gate keepers of the society/ community. Particularly in a country like India, with the level of poverty and ignorance that is prevalent, it is easy to use inducements, especially financial inducements, to get individuals and communities to consent. Such inducements are not permissible. However, it is necessary to provide for adequate compensation for loss of wages and travel/other expenses incurred for participating in the study.

Fresh or re-consent:

Re-consent is taken in following conditions:

1. When long term follow-up or study extension is planned later.
4. When there is a change in procedures and site visits.

5. Before dissemination/publication if there is possibility of disclosure of identity through data presentation or photographs.

2.2.2 Essential information for prospective research participants:

Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information in the language she or he is able to understand which should not only be scientifically accurate but should also be adaptive to their social and cultural context:

- Aims and methods of the research;
- Expected duration of the participation;
- Benefits that might reasonably be expected as an outcome of research to the participant or community or to others;
- Any alternative procedures or courses of treatment that might be as advantageous to the participant as the procedure or treatment to which s/he is being subjected;
- Any foreseeable risk or discomfort to the participant resulting from participation in the study;
- Right to prevent use of her/ his biological sample at any time during the conduct of the research;
- Extent to which confidentiality of records could be maintained ie., the limits to which the investigator would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality;
- Responsibility of investigators;
- Compensation of participants for participation in the study;
- Freedom of individual/family to participate and to withdraw from research any time without penalty or loss of benefits which the participant would otherwise be entitled to;
- Identity of the research teams and contact persons with address and phone numbers;
- Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same;
- Publication, if any, including photographs and charts.

The quality of the consent of certain social and marginalized groups requires careful consideration as their agreement to volunteer may be unduly influenced by the Investigator.

2.2.3 Confidentiality for Prospective research participants:

The investigator must safeguard the confidentiality of research data, which might lead to the identification of the individual participants. Data of individual participants can be disclosed under the following circumstances:

- only in a court of law under the orders of the presiding judge or
- there is threat to a person's life or
- if there is risk to public health it takes precedence over personal right to privacy and may have to be communicated to health authority.

Therefore, the limitations in maintaining the confidentiality of data should be anticipated and assessed and communicated to appropriate individuals or authorities as the case may be.

2.2.4 Conflict of Interest:

A set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain is termed as Conflict of Interest (COI). In all situations where there is likely to be conflicts of interest it must be ensured that the interest of the individuals involved in the study are protected at any cost. In cases where the NEC determines that a conflict of interest may damage the scientific integrity of a project or cause harm to research participants, the committee should advise accordingly.

Investigators should declare such conflicts of interest in the application submitted to NEC for review. NEC need self-regulatory processes to monitor, prevent and resolve such conflicts of interest. The NEC can determine the conditions for management of such conflicts in its SOP manual.

Prospective participants in research should also be informed of the sponsorship of research, so that they can be aware of the potential for conflicts of interest and commercial aspects of the research. Sponsorship of the research should also be informed to the audience when

presenting papers and should be mentioned when publishing in popular media or scientific journals.

Undue inducement through compensation for individual participants, families and populations should be prohibited. Undue compensation would include assistance to related person(s) for transport of body for cremation or burial, provision for insurance for unrelated conditions, free transportation to and fro for examination not included in the routine, free trip to town if the participants are from rural areas, free hot meals, freedom for prisoners, free medication which is generally not available, academic credits and disproportionate compensation to researcher / team/ institution. However, in remote and inaccessible areas some of the features mentioned above may be a necessity and culture specific.

Significant financial interest means anything of monetary value that would reasonably appear to be a significant consequence of such research including salary or other payments for services like consulting fees or honorarium per participant; equity interests in stocks, stock options or other ownership interests; and intellectual property rights from patents, copyrights and royalties from such rights. Therefore, the NEC should examine this on a case-by-case basis, as some of these elements may be justifiable for collecting vital data for national use or necessary to find if some interventions may significantly have direct impact on health policies.

2.2.5. International collaboration/assistance in Evaluation and Operational Research

Research in health areas has gained greater momentum only by the second half of the 20th Century, especially since the 1960s, the scope of international co-operation and collaboration assumed such proportions as to have exploitative connotations with commercial and human dimensions. Different levels of development in terms of infrastructure, expertise, social and cultural perceptions, laws relating to intellectual property rights etc., necessitate an ethical framework to guide such collaboration. The same concerns are applicable even when there is no formal collaboration between countries, but the research is undertaken with assistance from international organizations as sponsors (Governmental like National Institutes of Health, USA, non-Governmental like Bill & Melinda Gates Foundation, Ford Foundation or others like WHO, UNICEF, UNAIDS, etc.).

2.2.6. Special Concerns

1. Given the magnitude and severity of the health problems in different countries, capacity building to address ethical issues that arise out of collaborative research must be promoted on a priority basis. Strategies should be implemented so that various countries and communities can practice meaningful self-determination in health development and can ensure the scientific and ethical conduct of research.
2. The collaborating investigators, institutions and countries can function as equal partners with sponsors even when in a vulnerable position by building appropriate safeguards. Community representatives should be involved early enough while designing the protocol and in a sustained manner during the development, implementation, monitoring and dissemination of results of research.
3. Careful consideration should be given to protect the dignity, safety and welfare of the participants when the social contexts of the proposed research can create foreseeable conditions for exploitation of the participants or increase their vulnerability to harm. The steps to be taken to overcome these should be described and approval taken from concerned Ethics Committee.
4. Every adult participant in the research should voluntarily give informed consent. In case of children, guardian should give the consent.
5. As different kinds of research (epidemiological studies, behavioural and social science oriented research *etc.*) have their own particular scientific requirements and specific ethical challenges, the choice of study populations for each type of study should be justified in advance in scientific and ethical terms regardless of the place from where the study population is selected.
6. The nature, magnitude, and probability of all foreseeable harms resulting from participation in a collaborative research programme should be specified in the research protocol and explained to the participants as fully as can be reasonably done. Moreover, the modalities by which to address these, including provision for the best possible nationally available care to participants who experience adverse reactions to a vaccine or drug under study, compensation for injury related to the research, and referral for psychosocial and legal support if necessary, need to be described.
7. The research protocol should outline the benefits that persons/communities/countries participating in such research should experience as a result of their participation. Care should be taken so that these are not presented in a way that unduly influences freedom of choice in

participation. The burden and the benefit should be equally borne by the collaborating countries.

8. Guidelines, rules, regulations and cultural sensitivities of all countries participating in collaborative research projects should be respected, especially by researchers in the host country and the sponsor country. These could be with reference to intellectual property rights, exchange of biological materials (human, animal, plant or microbial), data transfer, security issues, and issues of socially or politically sensitive nature. In this context, it is essential for researchers to follow the GOI notification on “Exchange of Human Biological Material for Biomedical Research” issued on 19.11.97 and obtain appropriate regulatory clearances as prevalent in the country for international collaboration and EC approval from all trial sites before the initiation of research.

9. HIV testing was recognized as different from other blood tests because it presented serious, psychological risks such as family, discrimination in employment, and/or restricted or no access to health care, insurance and housing. Therefore, special protection for confidentiality of HIV test results should perform.

10. Vulnerability is particularly important in context of HIV related research. Those infected with HIV may be medically vulnerable because of their infection. In addition, homosexuals, injection drug users, minorities, and women, who, for various reasons, may be at higher risk of HIV infection, are more likely to be socially and economically vulnerable because of historical attitudes and discrimination. Accordingly, investigators conducting HIV related research must pay particular attention to vulnerability and take steps to protect potentially vulnerable research participants.

3. Researcher’s relations with the media and publication practices:

Researchers have a responsibility to make sure that the public is accurately informed about results without raising false hopes or expectations. It should also not unnecessarily scare the people. Researchers should take care to avoid talking with journalists or reporters about preliminary findings as seemingly promising research that subsequently cannot be validated or could lead to misconcepts if reported prematurely. Therefore, it is important to avoid premature reports and publicity stunts. The best safeguard against inaccurate reporting is for the researcher to talk to media on condition that the reporter submit a full written, rather than oral version, of what will be reported, so that it enables the researcher to make necessary corrections, if needed, prior to publication.

Investigator's publication plans should not threaten the privacy or confidentiality of participants. It is recommended that a clear consent for publication should be obtained besides the consent for participation in research such consent should preferably be obtained on two different occasions.

Maintenance of confidentiality while publishing data should be taken care of. In case there is need for publication/presentation of photographs/slides/videos of participant (s), prior consent to do so should be obtained. Identification features should be appropriately camouflaged. The same safeguard should be observed for video coverage.

With regard to authorship, the International Committee of Medical Journal Editors (ICJME) has laid down criteria based on credit and accountability. Only those who make substantial contribution to the article and take responsibility for the published matter can be co-authors. Plagiarism or falsification of data and authorship are important ethical issues in publications. The term 'misconduct in research' means fabrication, falsification, plagiarism, selective omission of data and claiming that some data are missing, ignoring outliers without declaring it, gift authorship, not citing others' work, not disclosing conflict of interest, redundant publication, and failure to adequately review existing research. The Commission on Research Integrity in US created by US Congress addresses the scientific, ethical, social and legal issues involving scientific misconduct in research.

4. Ethical Issues in Epidemiological Research

Epidemiology of HIV/AIDS and other infectious diseases are of prime importance in our country. Such studies are on large scale and assist in improving the public health, which includes both patients and healthy people and communities. Epidemiological studies cover research, programme evaluation and surveillance. Ethics in epidemiological studies is multidimensional covering clinical medicine, public health and the social milieu. In Epidemiological research if some mistakes or aberrations get detected during the course of conduct of such studies, repeating the whole exercise will be expensive, time consuming and may not even be feasible. Hence utmost care needs to be taken for various aspects - technical, practical and ethical.

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. The welfare of the individual has to be balanced against the welfare of the community and society at large. The C.I.O.M.S / 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. With large segments of our population, given their level of education, the full understanding in the sense of industrialised countries may not be achievable. How the principle of “do no harm” is ensured under such circumstances without being paternalistic is a major issue that has to be taken into consideration in ethical guidelines.

In cohort or survey techniques for incidence and prevalence of various diseases, a major issue that has to be considered is how much of intervention is justified and whether one is justified in withholding interventions. Health education or other interventions including non-health interventions can be quite expensive. An alternate strategy that may be followed is to make curative therapy available to the population at their own request. This usually involves running a clinic, which is readily accessible to the population without any other intervention. However, it is generally considered unethical to withhold intervention or services. Surveillance studies to obtain true HIV burden rates most likely give rise to ethical dilemmas regarding maintenance of confidentiality and prevention of stigmatization. Wherever applicable anonymisation could solve these problems when the information is required to be placed in public domain.

5. Distinction between research and programme evaluation:

It is difficult to make a distinction between epidemiological research and programme evaluation. Whenever a programme evaluation and surveillance is launched, the monitoring and evaluating mechanisms should clearly be planned and cleared by NEC (NACO Ethics Committee) before initiation as is done in all other studies. It is not always possible to know what will happen to the participants as unexpected results or undesirable events can sometimes occur. Very often the benefits and risks of the research pertain not only to the individual participants, but also the community from which they are drawn. Therefore, the participation of local community representatives in planning, conducting and monitoring

research is important to avert circumstances which may be detrimental to the participants' welfare. This also helps in improving the vision of the researcher regarding the objectives and the design of study. The inclusion of a community representative should be included in NEC act on behalf of all participants involved in a research study, Communities should be informed of the research, possible outcomes (positive and negative), and the results of the research. Community representatives and researchers can work together to make sure that research is conducted in the most appropriate way and the benefits if any, could be shared in a reasonable or workable manner.

6. Community Participation

A community can be defined as a group of people sharing the same location, beliefs, culture, ideals, goals, age, gender, profession, lifestyle, common interests, geographical locations or settings or disease. When research participants are drawn from a specific community, members of that community can be involved to discuss any concerns it may have regarding the research. In different ways such a dialogue can be facilitated. If an ethics committee does not have a member from the community, it may ask a local community representative to be the voice for all participants. On the other had, community representatives can formally join together to form a group termed as Community Working Group, or Community Advisory Group, which takes part in the research at all stages of the study. In international studies, particularly on issues involving communities, representation from this body ensures that the community's health needs and expectations are addressed, informed consent is appropriate, and access to research benefits is provided through research that is designed and implemented in the best interests of science and community. Community representation should be involved before, during and after the study. Before the study is initiated the community is informed to see if it agrees that the research addresses a need or problem relevant to that community and to confirm that the design is culture specific and brings some benefits to research participants or the community. Since some risk may be associated the community representation is needed to assist in developing appropriate ways to protect the participants. During the study, the association with community representatives continues to educate others about the research and to alert the researcher to ethical issues related to the research. After the study is completed, community representatives can help in making the results known to the entire community. However, application of research findings may take a long time, which the community representatives should be made to understand. The benefits

may be participants' and community's access to intervention. Person for intervention responsible and conditions under which this would be done, duration of availability of intervention, methods of improving the quality of health care in the community and any expected desirable behavioral change in the community should be clearly explained to community by the Ethics Committee or community representatives.

7. Ethical Issues in Questionnaire Based Research

A questionnaire is a common research methods used in the field of epidemiology, social sciences, psychology, etc. Success of research studies depends on the trust and cooperation the researcher gained from the participants. Therefore, in order to implement efficient and ethically appropriate questionnaire based research, it is essential to establish ethical standard that would govern this principle.

8. Ethical Issues in Focus Group Discussion

Ethical considerations for focus group discussion are the same as for most other methods of social research. For example, when selecting and involving participants, researchers must ensure that full information about the purpose and uses of participant's contributions is given. Being honest and keeping participants informed about the expectations of the group and topic, and not pressuring participants to speak is good practice. A particular ethical issue to consider in case of focus groups is the handling of sensitive material and confidentiality given that there will always be more than one participant in the group. Participants need to be encouraged to keep confidential what they hear during the meeting and researchers have the responsibility to anonymise data from the group.

9. Ethical Issues in Internet Based Research

The fundamental tenets governing the protection of human subjects in research studies apply to internet based research as well. The complexity of internet research through, for example, e-mail surveys, web based surveys or on-line discussion groups present different challenges that need to be addressed in accordance with the Ethics Committee. The general principles are applicable for internet based research as well. The specific guidelines/issues should also be followed while conducting internet based research.

1. Identification of who will have access to the data, how long the data will be protected (secure protection of information during the study, removal and storage of records following completion of the study, duration of storage is for a minimum of 3 years by primary investigator, faculty advisor, or department and accessible if review of the data is necessary).
2. Statement affirming that web surveys are password protected using a secure server without inclusion of identifying information.
3. Contact persons for questions about the research.
4. Statement that the participant has read the informed consent statement, all questions has been answered, and his/her willingness to complete the questionnaire or participate in the research implies consent.
5. Access to results whereby a summary or abstract may be posted or sent via e-mail.

The requirement for written documentation with participant's signature in studies involving minimal risk may be waived by the NEC. These procedures may not apply to research involving children or other vulnerable groups who are not, according to federal regulations, empowered to authorize consent for themselves. While the child may assent, the parents or guardians must provide consent. With internet use, the identity/age of the participant is not easily determined. In general, as risk level increases for participants, the use of the internet may not be advisable.

The use of the Web for recruitment of subjects, data collection, and data analysis may be advantageous in securing larger or more specific samples more efficiently and at a lower cost. Careful attention must be given to the treatment and protection of research participants and, specific to student research, research advisors must be vigilant about use of on-line data analysis.

10. Procedure for Ethical Review of Proposals

The Committee should review every research proposal before the research is initiated. The Committee should evaluate the possible risks to the participants with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and the justice issues. The NECs member-secretary shall screen all the proposals for their completeness and depending on the risk involved.

All research proposals/ protocols that involve vulnerable population and special groups shall be subjected to full review by all the members. While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick or venipuncture:

i. from healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;

ii. from other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week;

iii. from neonates depending on the haemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;

b. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

c. Collection of data from voice, video, digital, or image recordings made for research purposes.

d. Research on individual or group characteristics or behaviour not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

In the following situations, the Member- Secretary of the Committee may quickly review the protocols:

1. Revised proposal previously approved through full review by the committee
2. Continuing review of approved proposals where there is no additional risk or activity and is limited to data analysis.

11. Submission of Application

The researcher should submit an application in a prescribed format along with the study protocol. The protocol should include the following:

1. The title with signature of Principal Investigator (PI) and Co-investigators as attestation for conducting the study.
2. Clear rationale and objectives for undertaking the study/interventions in human participants in the light of existing knowledge.
3. Recent curriculum vitae of the Investigators indicating qualification and experience.
4. Participant recruitment procedures and brochures, if any.
5. Inclusion and exclusion criteria for entry of participants.
6. Precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, longitudinal, cohort, cross-sectional *etc.*), intended intervention.
7. Procedure for seeking and obtaining informed consent with sample of participant/patient information sheet and informed consent forms in English and local languages.
8. An account of storage and maintenance of all data collected during the research.
9. Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.
10. A statement on probable ethical issues and steps taken to tackle the situations.
11. All other relevant documents related to the study protocol.
12. Details of Funding agency/ Sponsors and fund allocation.
13. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/authority like Drug Controller General of India (DCGI).
14. A statement on conflict-of-interest (COI), if any.

12. Decision making process

The committee should be able to provide complete and adequate review of the research proposals submitted to them. It should meet periodically at frequent intervals to review new proposals, evaluate annual progress of ongoing ones, review serious adverse event (SAE) reports and assess final reports of all research activities involving human beings through a previously scheduled agenda and modified wherever appropriate. The following points should be considered while doing so:

1. The decision must be taken by a broad consensus after the quorum requirements are fulfilled to recommend/reject/suggest modification for a repeat review or advise appropriate

steps. The Member Secretary should communicate the decision in writing to the Principle Investigators.

2. If a member has conflict-of-interest (COI) involving a project then s/he should submit this in writing to the chairperson before the review meeting, and it should also be recorded in the minutes.
3. If one of the members has her/his own proposal for review or has any COI then s/he should withdraw from the NEC while the project is being discussed
4. A negative decision should always be supported by clearly defined reasons.
5. An NEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio.
6. In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.
7. Subject experts may be invited to offer their views, but should not take part in the decision making process. However, their opinion must be recorded.
8. Meetings are to be minuted which should be approved and signed by the Chairperson/ Vice Chairperson/designated member of the committee.

13. Review process

The method of review should be stated in the SOP. The ethical review should be done in formal meetings and EC should not take decisions through circulation of proposals. The committee should meet at regular intervals and should not keep a decision pending for more than 3 months, which may be defined in the SOP.

Periodic review

The ongoing research may be reviewed at regular intervals of six month as may be specified in the SOP of the ethics committee. The NEC also has the responsibility to review approved projects for continuation, new information, adverse event monitoring, follow-up and later after completion if need be.

Interim review

The NEC should decide the special circumstances and the mechanism when an interim review can be resorted to by a sub-committee instead of waiting for the scheduled time of the meeting like re-examination of a proposal already examined by the NEC or any other matter which should be brought to the attention of the NEC. However, decisions taken should be brought to the notice of the main committee.

Monitoring

Once NEC gives a certificate of approval it is the duty of the NEC to monitor the approved studies, for which an oversight mechanism should be in place. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights. Additionally, periodic status reports must be asked for at appropriate intervals based on the safety concerns and this should be specified in the SOP of the NEC.

Record keeping

All documentation and communication of an NEC are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval procedures. The following records should be maintained for the following:

- i. Constitution and composition of the NEC;
- ii. Signed and dated copies of the latest the curriculum vitae of all NEC members with records of training if any;
- iii. Standing operating procedures of the NEC;
- iv. National and International guidelines;
- v. Copies of protocols submitted for review;
- vi. All correspondence with NEC members and investigators regarding application, decision and follow up;
- vii. Agenda of all NEC meetings;
- viii. Minutes of all NEC meetings with signature of the Chairperson;
- ix. Copies of decisions communicated to the applicants;
- x. Record of all notification issued for premature termination of a study with a summary of the reasons;
- xi Final report of the study including microfilms, CDs and Video recordings.

It is recommended that all records must be safely maintained after the completion/termination of the study for a period of at-least 3 years.

Administration

A full time secretariat and space for keeping records is required for a well functioning of NEC.

Special Consideration:

While all the above requirements are applicable to research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards / protection and specific considerations for the NEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of NEC should be given in writing in unambiguous terms in such instances.

The procedure for obtaining ethical clearance will involve:

- Being familiar with the NACP policy on research ethics.
- Submission of request form for ethical clearance in the prescribed format for approval to the Chair of the Committee.
- Along with the request form, Research/Project Information Sheet and Informed Consent Form (where applicable) should be submitted.
- Informed Consent Process and Research/Project Information Sheet: This has been described in detail earlier.

An application for approval should be submitted to Evaluation and Research Division at NACO. Received application will then be reviewed by the concerned officer of the Division, who will, if necessary, seek clarifications from the applicant before making a recommendation to the NACO Ethics Committee for Research.

The Committee shall determine whether or not the proposed project is acceptable on ethical grounds.

- If the project is ethically acceptable, the Committee shall issue a written ethical clearance which shall include a 'Project Identification Number' and details of those methods of observation to ensure that the project continues to conform to approve ethical standards.
- If the project is ethically acceptable with revision, the Principal Investigator of the project should re-submit an application for approval.

- If the project is ethically unacceptable, the Committee shall advise the application in writing of its concerns.

The project shall not commence until such time as these concerns are addressed to Committee's satisfaction. The Committee shall maintain a record of all proposed research projects which shall include the following items:

- Project Identification Number
- Name/s of Principal Investigator/s
- Title of the Project
- Ethical approval/non-approval with date

NATIONAL AIDS CONTROL ORGANISATION
(Monitoring, Evaluation and Research Division)
APPLICATION FORM FOR ETHICAL CLEARANCE

SECTION 1: DETAILS OF APPLICANT

NAME: Prof/Dr/Mr/Mrs/Miss/Ms	
Professional status	
IF STUDENT/FELLOW (Tick the appropriate code)	YES/NO
Degree Applicable (Masters/M.Phil/PhD)	
Principal Investigator (Name, Designation, Organisation, Contact details)	
Co-Investigators (Name, Designation, Organisation, Contact details)	
Institution/Organization where applicant registered/employed and full address	
Whether member of NIIHAR	YES/NO
If yes Quote ID No	

Please attach detailed Curriculum Vitae of all Investigators (with subject specific publication limited to previous 5 years)

SECTION 2: PROJECT DETAILS

1. TITLE OF PROJECT in full (do not abbreviate)			
2.Type of Study :		Biomedical & Clinical Research=1 Social Science Research=2 Epidemiological Study=3 Policy Management Study=4	
3. Status of Review:		New <input type="checkbox"/>	Revised <input type="checkbox"/>
4. Sponsor Information :			
1. Indian		a) Government <input type="checkbox"/>	Central <input type="checkbox"/> State <input type="checkbox"/> Institutional <input type="checkbox"/>
		b) Private <input type="checkbox"/>	Specify details
2. International		Government <input type="checkbox"/>	Private <input type="checkbox"/> UN agencies <input type="checkbox"/>
		Specify details	
3. Industry		National <input type="checkbox"/>	Multinational <input type="checkbox"/>
		Specify details	
5. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?		Yes/No	
6. Contact Address of Sponsor:			
7. Total Budget (INR):			
8. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):			
9. Subject selection:			
i. Number of Subjects :			
ii. Duration of study :			
iii. Will subjects from both sexes be recruited		Yes	No
iv. Inclusion / exclusion criteria given		Yes	No
v. Type of subjects		Volunteers <input type="checkbox"/>	Patients <input type="checkbox"/>

vi. Vulnerable subjects (Tick the appropriate response)		
PLHA Pregnant women Children HRG Orphan Illiterate any other (specify)		
10. Privacy and confidentiality		
i. Study involves -	Direct Identifiers	<input type="checkbox"/>
	Indirect Identifiers/coded	<input type="checkbox"/>
	Anonymous/delinked	<input type="checkbox"/>
ii. Confidential handling of data by staff	Yes	No
11. Use of biological/ hazardous materials		
	Yes	No
i. Use of blood	Yes	No
ii. Use of body fluids	Yes	No
12. Consent :		
	*Written <input type="checkbox"/>	Oral <input type="checkbox"/>
		Audio-visual <input type="checkbox"/>
i. Consent form : (tick the <input type="checkbox"/> included elements)		
Understandable language	<input type="checkbox"/>	Alternatives to participation
Statement that study involves research	<input type="checkbox"/>	Confidentiality of records
Sponsor of study	<input type="checkbox"/>	Contact information
Purpose and procedures	<input type="checkbox"/>	Statement that consent is voluntary
Risks & Discomforts	<input type="checkbox"/>	Right to withdraw
Benefits	<input type="checkbox"/>	Consent for future use of biological material
Compensation for participation	<input type="checkbox"/>	Benefits if any on future commercialization
Compensation for study related injury	<input type="checkbox"/>	eg. genetic basis for drug development
	<input type="checkbox"/>	
*If written consent is not obtained, give reasons:		
ii. Who will obtain consent ?		
	PI/Co-PI <input type="checkbox"/>	Nurse/Counsellor <input type="checkbox"/>
	Research staff <input type="checkbox"/>	
Any other (specify)		
13. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)		
	Yes	No
14. Risks & Benefits:		
i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No

ii. Is there physical / social / psychological risk / discomfort? If Yes, Minimal or no risk <input type="checkbox"/> More than minimum risk <input type="checkbox"/> High risk <input type="checkbox"/>	Yes	No
Iii. Is there a benefit a) to the subject ? Direct <input type="checkbox"/> Indirect <input type="checkbox"/> b) Benefit to society <input type="checkbox"/>		
15. Data Monitoring	Yes	No
i. Has provision been made for data monitoring and security?		
ii. Is there a plan for interim analysis of data?	Yes	No
iii. Is there a plan for reporting of adverse events?	Yes	No
16. Is there compensation for participation?	Yes	No
If Yes, Monetary <input type="checkbox"/> In kind <input type="checkbox"/> Specify amount and purpose:		
17. Is there compensation for medical care?	Yes	No
If Yes, by Sponsor <input type="checkbox"/> by Investigator <input type="checkbox"/> by insurance <input type="checkbox"/> by any other company <input type="checkbox"/>		
18. Do you have conflict of interest? (financial/nonfinancial)	Yes	No
If Yes, specify :		

Checklist for attached documents:	
Project proposal – 10 Copies	<input type="checkbox"/>
Curriculum Vitae of Investigators	<input type="checkbox"/>
Brief description of proposal	<input type="checkbox"/>
Participant information sheet	<input type="checkbox"/>
Informed Consent form	<input type="checkbox"/>
Investigator’s brochure for recruiting subjects	<input type="checkbox"/>
Copy of advertisements/Information brochures	<input type="checkbox"/>
Copy of questionnaire	<input type="checkbox"/>
HMSC/DCGI/DBT/BARC clearance if obtained	<input type="checkbox"/>

Signature of Applicant

Countersignature of PI/HOD

(incase of student/fellow)

Place:

Date: