



NATIONAL GUIDELINES ON ETHICS FOR RESEARCH ON HIV/AIDS



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NATIONAL AIDS CONTROL
ORGANISATION
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A large, abstract graphic at the bottom of the page consists of several overlapping, semi-transparent geometric shapes in shades of blue, purple, and grey. The shapes are arranged in a way that creates a sense of depth and movement, with some shapes appearing to recede into the background while others come forward.

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1. INTRODUCTION

1.1 Preamble

In 2007 India had an estimated 1.8 – 2.9 million HIV positive persons with an estimated adult HIV prevalence of 0.34% (0.25%–0.43%), which being very high among the high risk groups (HRG) makes India continue in the category of concentrated epidemic. The vision of National AIDS Control Organisation (NACO) is endeavouring to make it possible for every HIV affected individual in India have access to treatment, and respect for human rights by being treated with dignity through its network of public and private organizations and civil society groups at state, district and grassroot level. For this it requires careful management systems and focused research to achieve that end. The National AIDS Control Programme (NACP) Phase-III (2007-2012) has the overall goal of halting and reversing the epidemic in India over the five-year period and places the highest priority on preventive efforts. This involves clinical trials, social and behavioural studies, epidemiological studies including data collection and maintaining of services through a chain of organizations like Blood Banks, STI/RTI Clinic Services, Integrated Counselling and Testing Centers (ICTCs), Anti Retroviral Therapy (ART) Centers, Community Care Centers (CCCs), research on high risk groups (HRG), HIV Sentinel Surveillance Program *etc.* The key activities of NACO for research during NACP Phase III are given below:

1. Establish a Research Wing/ Division at NACO with strong linkages developed with research/academic institutions at regional/ state level;
2. Multi-disciplinary Research Advisory Committee to guide implementation of research agenda;
3. Identify critical gaps in existing knowledge through a commissioned comprehensive research review in relevant disciplines to develop an appropriate research agenda for filling in gaps at various levels;
4. Identify key areas of research in bio-medical, clinical, epidemiological, behavioural and social fields which have a direct bearing on the HIV epidemic;
5. Support ongoing applied research programmes for better understanding of the epidemic – its spread and impact and filling critical gaps in existing knowledge;
6. Strengthen operations research and evaluation studies on the design, strategies, implementation and testing of HIV intervention programmes and measure their impact related to risk/vulnerability reduction, behaviour change, stigma reduction, HIV prevalence rate *etc.*;
7. Build and improve capacity of researchers in the country for undertaking HIV research including inter-disciplinary, multi-site, action, intervention and operations research, and to increase skills in communicating research findings for impacting policy and programme;
8. Build capacity for developing innovative methods to carry out studies on “hard to reach” and marginalized populations, mobile and migratory groups, stigmatized populations and other vulnerable groups like youth, adolescents, children, housewives, MSM (men having sex with men) and transgender groups;
9. Build capacity for monitoring and evaluating community based interventions, school based adolescent education programmes and support groups of positive people;
10. Build networks, alliances and partnerships with national, state and district level research organizations, universities, UGC, CSIR, ICMR, ICSSR, AIU, individual researchers, NGOs, PLHA networks and others, around key research themes (*i.e.*

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stigma, discrimination etc.) to produce contextualized knowledge for local initiatives; and

11. Identify and promote a national research agency/ consortium to organize national conference on HIV/AIDS research once in every two years to share new developments on HIV/AIDS research

As is evident from the type of research areas listed above being conducted by NACO both quantitative and qualitative research methodologies are used. Such a large scale undertaking requires good research governance which harmonises with established international standards and national/ local customs and culture against the background of existing knowledge for decision-making, and evaluating the expectations against the effectiveness of policies, structures and services. The research participants are highly vulnerable group comprising different affected communities with specific problems of more marginalized groups such as FSW (female sex workers), MSMs and IDUs (intravenous drug users) which are even more marginalized than the other HIV affected groups. Against such background the 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 while harmonizing with international universal ethical principles is consistent with national legislative and statutory requirements.

The rationale for ethics approval is to ensure that the process of research is conducted 'ethically' and responsibly and ensures protection of privacy and is not exploitative in nature. This mainly involves establishing procedures for the informed consent of those participants involved in research, as well as appropriate handling of the research findings *e.g.* secure storage of data and biological 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 based on the universal ethical principle of 'do no harm' which has been enunciated in classical texts of Indian systems of medicine centuries ago and later emphasized by Hippocrates down. In modern times all international and national guidelines that have followed have been in accordance with the basic ethical principles of autonomy (respect for person/participant) beneficence, and justice as clearly explained in the Belmont Report of 1979. The guidelines laid down are directed at application of these basic principles to research involving human participants with slight modification to western principles of autonomy on account of the variation in concept of individualism in social terms and local cultural context as is prevalent in most of the developing countries.

This document will serve as a guide to address ethical challenges faced in research on HIV/AIDS and describe responsibilities of stakeholders involved in it for ethical decision-making. Relevant issues need to be identified but sometimes short-term solutions may not be available for long term complex situations since some ethical principles can be obligatory, and some desirable. Depending upon the circumstances, obligatory principles may be deviated but justifiable, for example, waiver of consent *etc.* The obligatory principles are generally universal in nature, applicable for any type of research.

2. ETHICAL PRINCIPLES

2.1 General Principles:

Any type of research or experiment using human beings as participants shall be bound by the following 12 obligatory principles which are common to all areas of research:

I. PRINCIPLES OF ESSENTIALITY

1. The research or experiment entailing the use of human being is considered necessary after thorough review of all alternatives in the light of best available existing knowledge in the proposed area.¹
2. The proposed research is carefully examined and passed by an external appropriate and responsible body of persons, and after having careful considerations come to the conclusion that the said research is necessary for the advancement of knowledge for the benefit of all human beings and for the ecological and environmental well being of all.

II. PRINCIPLES OF VOLUNTARINESS, INFORMED CONSENT AND COMMUNITY AGREEMENT

1. The research participants are fully apprised of the research or experiment, its impact and possible risks of such research on them and others.
2. The research participants shall retain the right to abstain from further participation in the research or experiment, irrespective of any legal or other obligation that might have been entertained by such human participants or some one on their behalf, subject to only minimal compensatory obligations of any advance consideration received and outstanding if applicable.
3. The aforesaid principles shall apply *mutatis mutandis* (by changing those things which need to be changed) to the community as a whole and to each individual member, depending on whether it is a community or a person involved in the research or experiment.²
4. In the case of the participant incapable of giving consent which is necessary for any research, it shall be obtained and exercised on her/ his behalf by a person authorised and under duty to act so as legally authorised representative (LAR).³

¹ Research design with placebo control should be justified. The design of the study should address local health priorities and community values and not be instrumental in increasing social inequalities. At earlier stages of research design the investigator could consult experts, local community leaders to discuss the ethical aspects, if felt necessary.

² Obtaining the community's assent before initiating the research, wherever applicable, would be appropriate as this shows respect for its values. However, this may be limited where human rights violation exist with gender inequalities and discrimination against a group.

³ LAR could be next of kin, legally acceptable relative/ caregiver/ acceptable companion/ peer educators.

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5. The research participants shall be kept informed throughout the research about all developments in so far as they affect them, including its consequences and applied use.
6. 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 or experiment.

III. PRINCIPLES OF NON-EXPLOITATION

1. Research participants will be reasonably remunerated for their involvement in the research or experiment, and irrespective of the social and economic condition or status, or literacy, they shall be kept fully apprised of all the dangers arising in and out of the research so that they can appreciate all the physical and psychological risks and other implications of the research, whether to themselves or others, including those yet to be born.
2. The human participants shall be selected in such a manner that the burdens and benefits of the research or experiment are distributed without arbitrariness or discrimination.
3. Each research or experiment shall include an in-built mechanism for compensation to 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 after-care, including treatment during and after the research or experiment irrespective of its causality, in respect of any effect that the conduct of research may have on the human participant and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected as and when necessary.

IV. PRINCIPLES OF PRIVACY AND CONFIDENTIALITY

1. The identity and records of the research participants shall, as far as possible, be kept confidential.
2. No details about identity of said human participants, which will result in the disclosure of their identity, be disclosed without valid scientific and legal reasons to do so if it is essential for the purpose of therapeutics or other interventions. In such instances the specific consent in writing is not required from the participants concerned, or the LAR.⁴ It must also be ensured that in doing so, the research

⁴ The Supreme Court of India has rules on the issue of the right to confidentiality of participants 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.

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participant does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the research or experiment.

V. PRINCIPLES OF PRECAUTION AND RISK MINIMISATION

1. Due care and caution shall be taken at all stages of the research or 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 are put to the minimum risk, suffer from no irreversible adverse effects and generally, benefit from and by the research or experiment.
2. Requisite steps are taken to ensure that both scientific and ethical reviews of the research are undertaken at appropriate stages so that further and specific guidelines are laid down by the institutions concerned, and necessary directions given, in respect of the conduct of the research or experiment.

VI. PRINCIPLE OF PROFESSIONAL COMPETENCE

The research or experiment shall be conducted at all times by competent and qualified persons who act with integrity and impartiality and who have been made aware of, and are mindful of, the ethical considerations to be borne in mind in respect of such research or experiment.

VII. PRINCIPLES OF ACCOUNTABILITY AND TRANSPARENCY

1. The research or experiment shall be conducted in a fair, honest, impartial and transparent manner after full disclosure is made by those associated with it of each aspect of their interest in it, and any conflict of interest that may exist.
2. 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 considered necessary for the purposes of 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 authorities, if necessary.

VIII. PRINCIPLE OF MAXIMISATION OF PUBLIC INTEREST AND DISTRIBUTIVE JUSTICE

The research and its subsequent applicative use shall be 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 participant themselves.

IX. PRINCIPLE OF INSTITUTIONAL ARRANGEMENTS

1. It shall be a duty of all persons connected with the research or experiment to ensure that all the procedures required to be complied with and all institutional arrangements required to be made in respect of the research or experiment and its subsequent use or application are duly made in a bonafide and transparent manner;
2. All appropriate steps should be taken to ensure that research reports, materials and data connected with the research are duly preserved and archived.

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X. PRINCIPLE OF PUBLIC DOMAIN

The research or experiment and any further research or experiment evaluation in response to, and emanating 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

1. 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 stakeholders 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
2. The responsibility involves due monitoring of the effect of the research or experiment by being constantly subjected to review and remedial action at all stages of the research or experiment and its future use.

XII. PRINCIPLES OF COMPLIANCE

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 Issues:

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 or LAR. 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. It should be ensured that the participant is making an informed-decision and there is a means to record the same. For testing this comprehension, different strategies could be used, namely, discussion during informed consent process, checklist, quiz, or interview based on pre-tested questionnaire.

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

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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. A 'joint literacy' drive is essential between the researcher and the community to acquaint the former with local customs and culture and the latter with understandable information about the science of the project and its significance for reducing the disease burden.

A copy of the participant information sheet should be given to the participant for her/ his record. 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.

Audiovisual methods could be adopted with prior consent and adequate precaution to ensure confidentiality. Approval of Ethics Committee is required for all such procedures. In most community based/ethnographic research it would be necessary to have the assent/ permission 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.

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 assent. Such inducements are not permissible. Undue inducement for enrolment 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.

Researchers involved in Phase I/II clinical trials should be cautious not to create 'therapeutic misconception' or 'preventive misconception' among participants as access to the test drug or vaccine may not be beneficial since its effectiveness is yet to be proven. 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.
2. When person has re-gained consciousness after losing it during study period.
3. When woman participant becomes pregnant during the trial.
4. When child participant becomes major during the trial.
5. When there is a change in procedures and site visits.
6. For re-use of biological material if applicable.
7. Before dissemination/publication if there is possibility of disclosure of identity through data presentation or photographs.

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Special concerns

1. In case of adolescents, to seek parental consent may become problematic due to social reasons and fear of discrimination. In such instances, the inclusion of an adolescent in the CAB/ parent/ caregiver/ representative of local youth organisation may be fruitful for discussion at the protocol designing stage.
2. When woman participant becomes pregnant during trial the drug may still hold potential benefit to the child. So the participant should be fully apprised of this along with the possible risks that could occur to the foetus.
3. Sometimes non-research participant as spouse or partner of participant may be exposed to physical risk as in the case of research on microbicide. Therefore, consent of such people will also have to be taken in which instance community engagement will help.
4. Waiver of consent could be considered if the potential risk is not more than minimal risk and that this will not adversely affect the welfare of the participant. Discussion between stakeholders should be there for waiver of written consent or its waiver totally.
5. A child may not be intellectually mature to understand the implication of HIV status, so parental consent is important. Since this consent can not be obtained for street children and orphans community representatives, caregivers, ethics committees, local or national organizations responsible for welfare of children or appointed advocates could give consent instead. If there is benefit within the context of research for children who can not give assent then ethics committees may waive off consent requirement.

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:

1. Aims and methods of the research
2. Expected duration of the participation
3. Benefits that might reasonably be expected as an outcome of research to the participant or community or to others
4. Investigations
5. 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
6. Any foreseeable risk or discomfort to the participant resulting from participation in the study and whether project involves more than minimal risk
7. Benefits to participant, community or medical science as may be applicable and benefit sharing in the event of commercialization
8. Steps taken for ensuring confidentiality
9. If test for HIV is to be done, counseling for consent for testing must be given as per national guidelines.
10. Right to prevent use of her/ his biological sample at any time during the conduct of the research.
11. Extent to which confidentiality of records could be maintained i.e., the limits to which the investigator would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality.
12. Responsibility of investigators.
13. Compensation to participants for participation in the study.
14. Compensation for research and non-research related injury especially when coming from locally prevalent endemic disease areas.
15. Voluntary participation

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16. 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.
17. Identity of the research teams and contact persons with address and phone numbers.
18. Clearly mention foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research for academic or commercial purpose, for secondary purposes and or possibility of sharing it with others.
19. Storage period of data and biological sample as well with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results.
20. Contact details of PI or local PI/Co-PI in multicentric studies for asking more information related to the research.
21. Contact details of Chairman of the Ethics Committee for appeal against violation of rights
22. If the research proposal is submitted by an NGO then the details about their vision, mandate, achieved goals if any, annual reports, and statement of accounts/ balance sheet should also be submitted.
23. 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. Due to possibility of impending stigma in the HIV/AIDS area, information should be given to participants regarding local sources of violence related services and support following procedures like interviews, FGDs *etc.*

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:

1. only in a court of law under the orders of the presiding judge or
2. there is threat to a person's life or
3. 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 NACO Ethics Committee (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 needs 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.

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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.

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 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 (to name a few, Governmental like National Institutes of Health, USA, non-Governmental like Wellcome Trust Foundation, 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, parent or guardian or LAR should give the consent. If a mature minor refuses to give assent that should be respected despite consent by any of the above, the child should be excluded from the study .

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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 drug or vaccine under study, compensation for injury related to the research, and referral for psychosocial and legal support if necessary, need to be described. If HIV infection occurs during a study it will have to be established that this is directly due to the study product or research related activity for the event to be considered as research related injury.

Ancillary care is the standard of care facilitated and/ or provided to participants during the period of the study or during follow-up for non-research related medical problems which may have no bearing on scientific validity or safety of the study. Poverty would demand more ancillary care needs which should be duly considered and provided for while designing the study. When women are enrolled child care support for her other children may be required. The package of care could be discussed with the stakeholders before finalizing the protocol because of the budgetary implications and should be accurately conveyed during the informed consent process. The package could include treatment for STIs, nutrition supplements and/or nutritional advice, family planning, reproductive health care including care after childbirth, psychosocial support, palliative care, home-based care or referrals to appropriate experts or institutions.

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. For international collaborative or sponsored studies, guidelines, rules, regulations and cultural sensitivities of the participating countries 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 Ethics Committee approval from all trial sites before the initiation of research. The collaboration should be on equal partnership basis and in the event of any dispute the law of the land shall prevail.
9. HIV testing was recognized as different from other blood tests because it presented serious, psychological risks such as being treated as outcast by the 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 be considered which includes pre and post test counseling and HIV and STI risk reduction counseling. The latter could

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include advice on male circumcision and needle exchange if it is culturally and legally appropriate for the local site.

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, migrants, 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, discrimination and criminalization. When recruiting from such a group, a plan to reduce stigma should be in-built in the design of the project with support from community representatives, local human rights group, civil society group or NGOs. For the criminalized group, the police may have to be educated as there is no use of maintaining confidentiality in such cases.
11. Post-trial responsibility - access to the interventions tested in the research program should be made available to the research participants. Modalities of such access in terms of drugs, vaccines or health care should be discussed before initiation of the trial. If the test drug fails to reach the market, then access to and availability of current appropriate antiretroviral treatment should be ensured. The fund for providing the intervention could be through pooled funds provided by the stakeholders. Local health institutions could support by making the intervention a routine care so that the risk of inequity between research and non-research participants is avoided. Creative solutions to long term access could be worked out with local institutions, agencies and health authorities.
12. An independent Data Safety Monitoring Board (DSMB) should be setup if large scale multi-centric clinical trials expected to cause significant risk are to be initiated. Its recommendations should be sent to the ethics committee for appropriate action in the best interests of the 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

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contribution to the article and take responsibility for the published matter can be co-authors. CONSORT Guidelines for reporting should be followed. 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.

While keeping in mind general ethical principles of respect for persons, duty to maximize possible benefits and minimise possible harm, 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 after 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 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.

4.1. Distinction between research and programme evaluation

It is difficult to distinguish 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

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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 in NEC should 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 including culturally appropriate authority 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.

4.2. 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. A community could also include local research partners/ colleagues, influential or opinion leaders or key individuals from the community. At earlier stages of research design the researcher could consult experts, and local community to discuss any ethical concerns, if felt necessary. There are different ways such a dialogue can be facilitated. If an ethics committee reviewing community based proposals does not have a member from community, it may ask a local community representative to be the voice for all participants. On the other hand, community representatives can formally join together to form a group termed as Community Working Group, or Community Advisory Board or Group, which takes monitors 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, especially when research participants are to be drawn from a specific community, 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. This would also be effective when a rumour may be spread which may negate the beneficial purpose of the research. 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 responsible for intervention and conditions under which this would be possible, 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.

4.3. Ethical Issues in Questionnaire Based Research

A questionnaire is a common qualitative or semi-qualitative research method 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

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to implement efficient and ethically appropriate questionnaire based research, it is essential to establish ethical standard that would govern this principle.

4.4. 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 are given. Being honest and keeping participants informed about the expectations of the group and topic, and not pressurizing 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.

5. ETHICAL ISSUES IN INTERNET BASED RESEARCH

The fundamental tenets governing the protection of human participants 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 by 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 on a case-to-case basis.

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 should be provided 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. Provision should be made
 - a. to ensure that the participant has read the informed consent statement;
 - b. all questions have been answered;
 - c. his/her willingness to complete the questionnaire or participate in the research has been documented; and
 - d. access to results whereby a summary or abstract may be posted or sent via email.

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 empowered to authorize consent for themselves. While the child may assent, the parents/ guardians/ LAR 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 participants, data collection, and data analysis may be advantageous in securing larger or more specific samples more efficiently and at a lower cost, but here 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.

6. NACO Ethics Committee

6.1 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.

6.2. Composition of NACO Ethics Committee

The NACO Ethics Committee for Research consists of multidisciplinary experts. 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 from NACO who should organize meetings and co-ordinate 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 experts from epidemiology/ public health/ operational research
3. One clinical expert
4. One basic medical science expert from microbiology, biotechnology *etc.*
5. One pharmacologist or clinical pharmacologist
6. One legal expert or retired judge
7. One behavioral /social science expert
8. One expert in bioethics
9. One representative of PLHA community
10. One representative of non-governmental voluntary agency/ philosopher/ theologian
11. 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

6.3. 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, conflict-of-interest *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.

6.4. 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 categorize 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 with the Chairperson or alternate Chairperson/ designated member of NEC:

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

6.5. 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
7. (with justification), type of study design (observational, experimental, pilot, randomized, longitudinal, cohort, cross-sectional *etc.*), intended intervention.
- 8.

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9. Procedure for seeking and obtaining informed consent with sample of participant/patient information sheet and informed consent forms in English and local languages.
10. An account of storage and maintenance of all data collected during the research.
11. Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.
12. A statement on probable ethical issues and steps taken to tackle the situations.
13. All other relevant documents related to the study protocol.
14. Details of Funding agency/ Sponsors and fund allocation.
15. 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).
16. A statement on conflict-of-interest (COI), if any.

6.6. 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.

6.7. 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.

6.7.1. Periodic review

The ongoing research may be reviewed at regular intervals of six months or earlier 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.

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6.7.2. 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.

6.8. 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.

6.9. 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.

6.10. Administration

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

6.11 Special Considerations:

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 and marginalized participants 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:

- i. Being familiar with the NACP policy on research ethics.
- ii. Submission of request form for ethical clearance in the prescribed format for approval to the Chair of the Committee.

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- iii. Along with the request form, Research/Project Information Sheet and Informed Consent Form (where applicable) should be submitted.
- iv. 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 for technical review, who will, after approval from technical committee, will seek clarifications from the applicant, if necessary, before making a recommendation to the NACO Ethics Committee for Research for review. The Committee shall determine whether or not the proposed project is acceptable on ethical grounds and take any of the following action:

1. 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 approved ethical standards.
2. If the project is ethically acceptable with revision, the Principal Investigator of the project should re-submit an application for approval.
3. 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:

1. Project Identification Number
2. Name/s of Principal Investigator/s
3. Title of the Project
4. Ethical approval/non-approval with date

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ANNEXURE A

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, Organization, 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)

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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"/>

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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 Indirect Identifiers/coded Anonymous/delinked	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
ii. Confidential handling of data by staff	Yes	No
11. Use of biological/ hazardous materials		
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 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
*If written consent is not obtained, give reasons:		
ii. Who will obtain consent ?	PI/Co-PI <input type="checkbox"/> Research staff <input type="checkbox"/>	Nurse/Counsellor <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?	Yes	No
If Yes, Minimal or no risk	<input type="checkbox"/>	
More than minimum risk	<input type="checkbox"/>	
High risk	<input type="checkbox"/>	

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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 <input type="checkbox"/>		
company		
18. Do you have conflict of interest? (financial/nonfinancial)	Yes	No
If Yes, specify :		

Checklist for attached documents:											
Project proposal – 15 Copies Curriculum Vitae of Investigators Brief description of proposal Brief description of institution/NGO Participant information sheet Informed Consent form Investigator’s brochure for recruiting subjects Copy of advertisements/Information brochures Copy of questionnaire HMSC/DCGI/DBT/BARC clearance if obtained	<table border="1" style="border-collapse: collapse; width: 100%;"> <tr><td style="height: 20px;"> </td></tr> <tr><td style="height: 20px;"> </td></tr> <tr><td style="height: 20px;"> </td></tr> <tr><td style="height: 20px;"> </td></tr> <tr><td style="height: 20px;"> </td></tr> <tr><td style="height: 20px;"> </td></tr> <tr><td style="height: 20px;"> </td></tr> <tr><td style="height: 20px;"> </td></tr> <tr><td style="height: 20px;"> </td></tr> <tr><td style="height: 20px;"> </td></tr> </table>										

Signature of Applicant

Countersignature of PI/HOD

(in case of student/fellow)

Place:

Date:

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ANNEXURE B

Informed consent

Purpose of the study

(Greet the man/woman). My name is _____.(Investigating agency/institute) and NACO are conducting a study to This study is being sponsored by the _____ (Sponsor). The investigators will use this information to Your participation in this study will help

Procedure

EXAMPLE:-----You will be asked to participate in two interviews at an interval of 2 months. The first interview will be done today. The second interview will be done after 2 months. You will be asked questions on what you know about HIV, treatment with ART, social support available for PLHAs, quality of services at ICTCs, difficulties people face in getting treatment for illnesses and for HIV infection. After the first interview you will receive a referral coupon to show at the ART treatment centre.

You will be required to provide contact information so that we could contact you to fix a time for the second interview at your convenience. During the second interview you will be asked about your experience in getting treatment, the quality of services at ART centres, how you feel with treatment or reasons for not starting treatment.

We would like to ask for your consent to be interviewed now on the topic, in private by one of our trained interviewers. We would also like your consent for interviewing you again after 2 months.

Benefits and Risks

Compensation

You will receive _____ (reasonable compensation) towards reimbursement of transport costs for interview.

Offer to answer questions and freedom to withdraw from the study:

You can refuse to respond to any question and can stop the interview at any time. There will not be any consequences if you decide to drop out of the study. The interview will take approximatelyminutes. Participation is completely voluntary.

Confidentiality

Everything that you report during the interview will be kept strictly confidential and your name will not be recorded on the questionnaire. The contact information that we collect is kept separate from the questionnaire and will be kept under lock and key. This information will only be used by the researchers. All records of your interviews and data collected from medical records will be kept in a safe place under lock and key.

If you have any questions about the research study you may contact the following persons

Name of investigator:
Telephone:

Name of co-investigator:
Telephone:

For questions/appeal about your rights as a research participant you may contact

Name of chairperson of NACO-Ethics committee:
Telephone:

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Subject's Statement

I have read the consent document regarding my participation in the study / the consent document regarding my participation in the study has been read out to me. I have been given a chance to ask questions and my questions have been answered to my satisfaction.

I understand that all records will be kept private and that I can leave the study at any time. I have also understood that my decision not to be in this study or to leave the study will not affect the services I will receive.

I agree to be in this study as a volunteer.

Name of the subject_____

Signature of the subject:_____

Date:_____

Signature of a witness:_____

Date:_____

Contact information:

Name:

Address:

Telephone:

Any contact telephone, if not of self: (name of person and number)