Ethical Guidelines for Bio-Behavioral Research

Involving Human Subjects

ALL INDIA INSTITUTE OF SPEECH & HEARING,

Manasagangotri, Mysore: 570 006.

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Year of Publication	:	July, 2009
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FOREWORD

An ‘ethics committee’ maybe simply viewed as a panel of chosen members bestowed with the responsibility to preserve and protect the rights, privileges, power and liberties of subjects. There are several principles and standards of behavior that every research practitioner needs to adhere. Ethics is not merely providing a model of behavior for prospective and practicing researchers. It is equally important that the moral attitudes are portrayed as explicit rules by any organization. In other words, every institution must spell out its ethical stance in clear writing. In this sense, this document on ‘Ethical Guidelines for Bio-Behavioral Research involving Human Subjects’ is a public pronouncement of a pledge by the AIISH towards the subjects involved in its research. At the same time, it also addresses itself to the legitimate demands of human subjects who are being studied, researched and investigated. The prescribed codes of good practice as given in this booklet seek to infuse trust and confidence in the human subjects involved in research process.

Ethical committees are alternatives, precursors and predecessors, to formal legal reviews. It predates and prevents later litigious complications. Given the contemporary expanding newer technologies and techniques in modern research; nowadays, there is also a widespread disapproval of ethical research committees. They are viewed as interference or as delaying tactics in the hands of autocratic administrators. It is alleged that ethics committees delay the introduction of life-saving drugs and devices. Actually, this is far from truth. The contemporary ethical issues or challenges of modern research given the recent inventions, such as, stem cell research, confidentiality, genetic privacy, consent, intellectual property rights, commercial-in-confidence, and conflict of interest—are all matters of grave technical complexity against their social application for benefit of humankind.

There is need to bridge non-experts on human research ethics committees to the experts and vice versa. There is need to demystify scientific concepts and applied research for the larger and general good of human society. Second, the oversight of the administrative and managerial context of research, which has often fallen to ethical committees by default, has been complicated by regulatory requirements and complex rules of standard practice. It has become so heavily bureaucratic that compliance with it displaces reflection on the human impact and meaning of research. This bleeds ethical consideration of meaning and replaces it with obsessive fussing over bureaucratic detail.

Despite these challenges, we need to free health, medical and bio-behavioral research ethics from legal, scientific and administrative entrapment. There is also a question of public account ability to the tasks, actions and activities of research investigators. In that sense, ethics committees need to be treated and respected in the same manner as one would treat a jury. Above all, the committee and/or its exercise is not to be rated as a ritualistic or routine overseer of research management or administration. That should be done by managers, not by a committee of any sort.

Dr. Vijayalakshmi Basavaraj,
Director, All India Institute of Speech and Hearing,
Mysore: 570 006.

03.03.09

PREFACE

Whether the focus of study is physical, natural, social or behavioral, the endeavor of all sciences is to investigate ‘what is’ in the real world around. Some thinkers differentiate between normative and formal sciences. The study of what ‘ought to be’ is the focus of the former and investigation into ‘what is’ in reality deemed as part of the latter. Thus, the field of speech and hearing becomes an applied aspect of formal behavioral sciences and ethics is part of normative sciences. Further, there is also the field of deontology which is described as the science of duty-all duties that are inherent to the exercise of professional activity!

By its inherent nature, any or all sciences seek to be logical, impartial, objective, experimental, unbiased, rational, neutral, systematic, organized, empirical and skeptical in their approximations towards, on or about truth. Science demands the honest use of scientific method and truthful reports. This responsibility is daunting and gets doubled in case of applied behavior sciences, such as, speech and hearing. The interactions and dealings of the social scientist are live people-not mere rocks, chemicals, plants or even animals!

The role of ethical issues surfaces in the context of applying speech and hearing for rendering benefits to the human society. On one side, the interests and concerns of speech and hearing professional need encouragement; as on other side, the well-being and rights of the participating human subjects need safe-guards too. In their zest for pursuing scientific knowledge, human history is replete with instances of scientists wittingly or otherwise trespassing upon the rights/privileges of participating human subjects. Thereby, benefits have been deprived from those for whom the services were actually intended. Unfairness has been delivered where justice was professed and proclaimed. Coercion was used to seek subject participation while their free-will, autonomy and independent choice-making was abandoned.

Therapeutic interventions on human subjects may sometimes involve children or young people with intellectual/mental disabilities. It could involve vulnerable human subjects, such as, persons dependent on medical care professionals or those involved in unequal relationships, orphans or destitute, peoples from minority or tribal communities, etc. There are special ethical considerations that emerge when such human beings are made part of behavioral interventions. Since these participants cannot protect themselves owing to insufficient intelligence, education, resources or strength, the need and justification for ethical considerations for their inclusion becomes an issue of paramount importance.

It is necessary that certain values guide the choice of research and treatments for these subjects. There is need to develop formal checks and controls for carrying out value based investigations or interventions on human subjects. There is need to screen and scrutinize every research or intervention plan, estimate the implications of their content, procedure or methodology on human rights of the target populations on whom they are being studied. There is a responsibility to recommend rejection, rectification or remediation of any or all those therapies that appear to infringe or violate the rights of individuals being investigated. There must be clear guidelines on discrimination between honest error, negligent error and misconduct on the part of professionals. Eventually, there is need for sentences, sanctions and prescribed punishments for defaulters or trespassers on human dignity and conduct. This booklet on 'Ethical Guidelines for Bio-Behavioral Research Involving Human Subjects' is partly an attempt to address or answer these issues for he field of speech and hearing. It is likely to be useful for students, practitioners as well professionals in the field of behavior sciences in general.

Dr. S. Venkatesan
Professor in Clinical Psychology &
Member Secretary, AIISH Ethics Committee

Mysore: 03.03.09

1.0 INTRODUCTION

The All India Institute of Speech and Hearing (AIISH) is a registered Government of India Society and functions as an autonomous body under administrative control of Ministry of Health & Family Welfare, Government of India. The major objectives of this apex Institute are *manpower development, research, development of appropriate models of service delivery and to serve as information-documentation centre* in the field of speech and hearing in the country.

The term 'research' refers to a class of activity at AIISH which is designed to develop or contribute to 'generic knowledge'. Generic knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. Research activity related to field of speech-hearing is carried out regularly at AIISH as part fulfillment of supervised PG projects, work placement reports and/or doctoral dissertations by research scholars. Further, the faculty at AIISH are actively engaged in individual, collaborative or inter-institutional projects, either funded internally or externally, on various problems areas of their specialization/interests related to the field of speech-hearing.

Research at AIISH is predominantly 'applied' though concurrent interests on 'pure' aspects of normal speech-hearing is also investigated. All types of research including experimental, quasi-experimental, ex-post facto, case study, interview, survey, focus group studies, questionnaire and observation are carried out. Most research at AIISH is behavioral and non-invasive even as they are related to human subjects, their families and/or living communities. Behavioral research entails a colossal communal commitment and collective conscientiousness. This is particularly true in case of speech-hearing research as it involves overlap between several disciplines including speech science, audiology, electronics, psychology, medicine, special education and others.

Several ethical issues surface in the context of 'applied' research and human society. On one side, the interests and concerns of speech-hearing scientists need encouragement; as on other side, the well-being and rights of the participating human subjects need safe-guards. In the zest for pursuing scientific knowledge, history is replete with instances of scientists wittingly or otherwise trespassing upon the rights/privileges of participating human subjects. Thereby, benefits have been deprived from those for whom the research benefits were actually intended. Unfairness has been delivered where justice was professed and proclaimed. Coercion was used to seek subject participation in research while their free-will, autonomy and independent choice-making was abandoned.

Behavioral research on human subjects may sometimes involve children or young people with intellectual/mental disabilities. It could involve vulnerable human subjects, such as, persons dependent on medical care professionals or those involved in unequal relationships, orphans or destitute, peoples from minority or tribal communities, etc. There are special ethical considerations that emerge when such human subjects are made part of behavioral research studies. Since these participants cannot protect themselves owing to insufficient intelligence, education, resources or strength, the need and

justification for ethical considerations for their inclusion as samples in behavioral research becomes an issue of paramount importance.

It is necessary that certain values guide the choice of subjects or the conduct of research. There is need to develop formal checks and controls for carrying out value based research on human subjects. There is need to screen and scrutinize every research proposal, estimate the implications of their content, procedure or methodology on human rights of the target populations on whom they are being studied. There is a responsibility to recommend rejection, rectification or remediation of any or all those research proposals that appear to infringe or violate the rights of individuals being investigated. There must be clear guidelines on discrimination between honest error, negligent error and misconduct on the part of research investigators. Eventually, there is need for sentences, sanctions and prescribed punishments for defaulters or trespassers on human dignity and conduct.

As with behavioral research practice everywhere, the research activities at AIISH is also humbled before the universal triumvirate principles of respect for autonomy, optimal beneficence and distributive justice for the participating human subjects even in the field of speech-hearing. Against this background, the following '**Ethical Guidelines for Bio-Behavioral Research Involving Human Subjects**' is framed and publicly proclaimed for prospective researchers in the field of speech and hearing research at the AIISH. It is also mandated that an **'AIISH ETHICS COMMITTEE'** (AEC) is duly constituted for granting ethical clearance to any or all research activities to be undertaken by the Institute and also to safeguard the interests, rights, privileges, claims, immunities and prerogatives of human subjects included for research in the field of speech-hearing.

2.0 ETHICAL REVIEW & APPROVAL

While the practice and implementation of a policy on ethical review and approval is mandatory, the following sections endeavor to outline their related issues, constitution, purpose, procedure, standard operating procedures and formats for prospective researchers in the field of speech-hearing from the AIISH.

2.1 Issues:

The ethical issues involved in the context of bio-behavioral research largely rest on certain ecumenical principles of understanding human nature and the need to respect them within the context of research in the field of speech-hearing. Some of these principles are enunciated below:

(a) Principle of Recognition and Respect for Human Rights.

(b) Principle of Autonomy for Individual/Collective Choice making of Human Subjects involved in Research.

(c) Principle of Beneficence implying attempts to maximize benefits while minimizing risks of potential harm for human subjects or society. An optimum beneficence for human subjects implies 'non-maleficence' for non-participating subjects as well.

(d) Principle of Distributive Justice meaning equitable selection of human subjects without discrimination on the basis of caste, creed, religion, age, language, status, gender, disability, region or geographical location, etc. This also implies that there is equitable distribution of both the burdens as well as benefits of population research.

(e) Principle of Voluntarism suggests that the choice of either participation or otherwise in an ongoing research activity must be entirely left to the free-will, choice and self-determination of the human subjects included as sample of the study.

(f) Principle of Non-Exploitation signifies that no human subject is used as means for furtherance of the interests of research investigators or at the cost of their abuse, mistreatment or disadvantage during a research process.

(g) Principle of Ethical Neutrality refers to the temperament of 'equipoise' mandated for all prospective investigators in the field of bio-behavioral researches. If a new intervention is being investigated against currently acceptable treatment, the researcher shall be genuinely uncertain in thought, spirit and action. In that sense, s/he should have and feel a true 'null hypothesis' regarding the outcome of the treatments.

(h) Principle of Privacy and Confidentiality protects participating human subjects in bio-behavioral research investigations from unauthorized observations and intrusions into their privacy. There is need for total security of the person from any unforeseen findings that they may or may not want to know.

(i) Principle of Provision for Maximal Safety ensures pre-calculating risk/benefit ratios (if any) owing to the participation of human subjects in the research study. This is not to be viewed or seen as a single event or mere formality. Rather, ensuing safety measures and research practices is continuous ongoing activity along with an attending responsibility on the part of the research investigators.

(j) Principle of Professional Competency is based on an understanding that any given research investigation is being undertaken only after a peer review and thorough study of current literature and previous studies. The investigation must be conducted or supervised by persons/teams with experience, qualification and competence appropriate to the research.

(k) Principle of Accountability and Transparency enunciates research investigators to take the onus on themselves for all the events or happenings to human subjects deemed to have occurred during a research process. The practices and procedures in the research investigation must be visible and easily understood by the participating human subjects.

(l) Principle of Genuine Redress in case of mishaps, calamities, research-injuries, accidents, etc., along with appropriate forums for placing such grievances and heard by concerned and responsible authorities.

(m) Principle of Integration & Mainstreaming is applicable in the context of bio-behavioral researches in the field of speech-hearing. Since a large volume of human subjects in this field are likely to be from vulnerable sections of human society who have suffered exclusion, seclusion and separation, the responsibility of researchers gets doubled towards fostering research protocols and practices that foster social integration, inclusion or mainstreaming of such persons, their families or communities as a whole.

(n) Principle of Promoting Barrier Free Environments is also a unique requirement in the context of bio-behavioral researches in speech-hearing. Given the ubiquitous and prevailing milieu of unfriendly and barrier laden living conditions for persons with disabilities, there is enhanced duty on the part of researchers to minimize such impediments for improving the quality of life of these vulnerable sections of human society.

2.2 Constitution:

The AEC shall consist of the following representatives

(a) Chairperson:
An eminent member of the State/National judiciary

(b) Member Secretary:
One Faculty member not below the rank of any 'Head' among Departments at AIISH.

(c) External Members:
At least three members representing the interests of human subjects commonly involved in the field of speech-hearing research.

(d) Internal Member:
One Faculty member not below the rank of any 'Head' among the Departments at AIISH.

(e) Permanent Invitee Member:
Director, AIISH

(f) Special Invitee Members (Optional):
Any other member specialized in certain areas of speech-hearing and/or related behavioral sciences co-opted for advice in situations or under circumstances requiring such counsel for the AEC.

The chairperson as well as the internal and external members shall serve a term of three years. One third of the members will be replaced by new members after the completion of their term.

The AEC is expected to meet at reasonable intervals as needed. At least five members are required to complete the quorum for any AEC meeting. All decisions shall be by majority vote of those members present or, in case of vote by mail, a majority of members qualified to vote. Attendance at the AEC deliberations is restricted to internal, external and invitee members only.

The project proposals received at least one month in advance before the scheduled date of an AEC meeting will be accepted for presentation in the agenda for that meeting. The principal investigators of the projects or their nominated representatives are expected to make a appropriate presentation before the AEC and defend themselves against any doubts, clarifications, questions, suggestions, recommendations or corrections offered by the members thereof.

The Member Secretary shall advance inform the concerned principal investigator/s who project/s is/are scheduled for review during a given meeting of the AEC. Such advance information as well as the information on final acceptance or rejection of a research proposal should be given well within fifteen days before or after the AEC meeting.

The Member Secretary is expected to coordinate, organize and maintain the minutes of all AEC meetings. All information concerning project proposals received, discussed, debated, modified, accepted or rejected shall be kept confidential. This is equally true of infringements or trespasses made by certain research investigators, penalties discussed, or sanctions recommended by the AEC in individual cases coming up during the meetings. The files of the AEC related to investigation and adjudication of cases shall also be kept confidential in the office of the Member Secretary.

2.3 Purpose:

The objectives of AEC are to:

(a) scrutinize, examine, review and appraise whether the research projects undertaken at the institute necessarily adhere to the guidelines proclaimed in this document.

(b) permit only appraised, approved and accepted research proposals to carry out the implementation of the permitted research activity at Institute.

(c) suggest any changes in the plan, procedure, sample, subjects, methodology, use of instrumentation, research design, inclusion/ exclusion criteria of a study, data collection procedures, etc., in as much they violate the ethical guidelines enunciated here.

(d) take cognizance of any report of misconduct, error out of neglect or honest error of judgment in a research project at the Institute brought to the notice of AEC and give suggestions to set right the mistakes and/or recommend sanctions or penalties on the perpetuators.

(e) suggest to the Institute on measures to educate public and disseminate information on ethical issues or matters related thereof for the participating subjects in bio-behavioral investigations or research related to the field of speech-hearing.

(f) safeguard the interests, rights and welfare of the human subjects participating in research activities at the Institute.

2.4 Standard Operating Procedures (SOP):

The following guidelines are offered as Standard Operating Procedures (SOPs) for the AEC:

(a) Six copies of each research proposals for ethical clearance must be submitted in the prescribed format titled "*Application Form For Seeking Approval From AIISH Ethics Committee*" at least one month in advance a scheduled meeting of the AEC (Annexure 1).

(b) An undertaking must be submitted in the prescribed format (part of Annexure 1) by the principal investigator/s of a project that steps will be undertaken to ensure implementation of all ethical guidelines for inclusion of human subjects in bio-behavioral research in the field of speech-hearing.

(c) A format of the prescribed *'Form for Securing Informed Consent from Human Subjects'* (Annexure 2) included as sample in the proposed investigation must be appended as mandatory use in the project proposals submitted for approval to the AEC.

(d) The Member Secretary ensures that notice for meeting of AEC, copies of research proposals along with its annexure and undertakings by he investigators are sent in advance to all the members of the AEC for their perusal.

(e) Any voice of dissent/difference of opinion between/among members of AEC regarding a particular proposal or research investigation must be clearly recorded in the minutes of the meetings. However, the decision of the Chairman, AEC, shall be final and binding.

(f) If one of the AEC members has his/her own research proposal for consideration, then that member should not be a party to the final decision making on that proposal.

(g) The Member Secretary shall communicate in writing the final decision about acceptance/non-acceptance of a research proposal on behalf of the AEC to principal investigator/s as soon as decisions are available; but, in any case, not later than fifteen days after conclusion of the meeting. A negative decision should always be supported by reasons as approved by Chbairman, AEC, in the prescribed format (Annexure 3).

(h) In case of premature termination of a study or non-accomplishment of sanctioned proposals, the AEC should make a record of such events and secure a summary report on the matter from the principal investigator of the given project.

(i) The investigations into unethical conduct involve two types of investigations: 'show cause' proceedings and 'reviews' of alleged unethical conduct. The AEC may choose to deal with a matter according to either procedure and may convert an investigation from one type to another as appropriate. The AEC may also chose to dismiss an allegation or recommend that it be resolved with a reprimand or censure, with or without supplemental directives, etc.

(j) AEC generally has no authority to impose sanctions on researchers who violate ethical standards in the conduct of research involving human subjects. They may, however, withdraw ethical approval of research projects if judged necessary. They can monitor implementation and progression. A failure to submit a protocol to the committee can be considered a serious violation of ethical standards.

(k) Sanctions, if necessary, can be a recommendation to the Institute and can be in the form of fines, suspension of eligibility to receive research funding, refusal of permission to publish results, etc.

2.5 Formats:

The following formats are given as needed enclosures along with project proposals by principal investigators seeking clearance from AEC:

(a) An Undertaking by Principal Investigator/s (Annexure 1).
(b) Form for Securing Informed Consent from Human Subjects (Annexure 2)
(c) Form of Acceptance/Rejection of 'Ethics Approval' for use by AEC members (Annexure 3).

3.0 MEMBERS OF AIISH ETHICS COMMITTEE

1.	Justice AJ Sadashiv Former Judge High Court of Karnataka 'LAKUMI' No. 672 B, 11th Cross, 7th Block (West), Jayanagar, BANGALORE: 560 082 Phone: 26761453; 9448833821	Chairperson
2.	Dr. Indra Amla, MBBS, Krupanidhi Memorial Foundation, Institute of Mother & Child 426, Contour Road, Gokulam, 3rd Stage, MYSORE: 570 001 Phone: 2410672	Member
3.	Sri R Guru, Rangsons Group, Vanivilas Road, MYSORE: 570 004 Phone: 2521227 Email: guru@nrrs.net	Member
4.	Dr. AR Seetharam, Principal, RIMSE, Yadavgiri, MYSORE: 570 020 Phone: 2547837 ® 2417666 (O)2411140 (O) Email: rimes@eth.net	Member
5.	Sri PS Balakrishnan, Mythri Charitable Trust 775, 'Konarak', 10th Main, 7th Cross, KH Road, Saraswathipuram, MYSORE: 570 009 Phone: 2545997	Member
6.	Dr. E. Roopa Rao Professor, Sharada Vilas Teachers College MYSORE: 570 004 Phone: 2332137 (O) 2561051®	Member

7.	Dr. SR Savithri Professor & Head, Department of Speech Language Sciences, AIISH, MYSORE: 570 006.	Member
8.	Dr. S Venkatesan Professor & Head, Department of Clinical Psychology, AIISH, MYSORE: 570006.	Member Secretary
9.	Director AIISH, MYSORE : 570 006.	Permanent Special Invitee

Annexure 1

APPLICATION FORM FOR SEEKING APPROVAL FROM AIISH ETHICS COMMITTEE

Title of Project: _____

Principal Investigator: _____

Co-Investigators (If any): _____

Proposed Duration of Project: _____

Estimated Budget Requirements: _____

Source of Funding: _____

Statement of the Problem & Objectives:

(a) _____

(b) _____

(c) _____

(d) _____

(e) _____

Method (Include truncated details on subjects, materials to be used and procedure of the proposed study):

_____

_____

_____

_____

CHECKLIST ON ETHICAL PRACTICES TO BE ENSURED BY RESEARCHES

Nos.	***Item***	***YES***	***NO***
1.	*I shall proceed to commence work on my project only after securing a written approval from AEC*		
2.	*I shall ensure to receive/record an informed consent from each of my participating human subject/s*		
3.	*I shall arrange to receive/record an informed consent from authorized guardians in case of children, minors, persons incapable of self decision or other vulnerable groups*		
4.	*I shall maintain complete privacy-confidentiality-anonymity of information collected from each of the participating human subject/s in my investigations.*		
5.	*I shall respect the autonomy and right to self-determination of the human subjects participating in my study*		
6.	*I shall ensure the safety and security of all the participating human subjects in my study by avoiding use of experimental procedures that might cause inadvertent distress during my investigations.*		
7.	*I shall carry out the research wholly on an attitude of beneficence to the individual/groups of human subjects included in my study and those like them in human society at large.*		
8.	*I shall avoid deception, deceit or dishonesty in all my transactions with the human subjects participating in my research study.*		
9.	*I shall recognize and respect the individual/collective dignity of all the human subjects, including their ability to make their own choices (where applicable) about participating or non-participation in my research study.*		
10.	*I understand and shall make it known to my subjects that they have an absolute right to opt out of the project any time they feel like doing so.*		
11.	*I shall ensure that the participation or non-participation of the subjects has no bearing on the treatment or benefits that they are entitled to from the Institute.*		
12.	*I shall ensure maximum beneficence and minimum maleficence for the human subjects during the conduct or completion of this study*		
13.	*I shall ensure equitable distribution of benefits for the included human subjects according to the needs or requirements of scientific sampling techniques and not discriminate on the basis of caste, creed, religion, age, gender, type or severity of disability, etc.*		
14.	*I shall recognize and respect each human subject for their own intrinsic worth or dignity and shall not use them only as means for the furtherance of my research objectives.*		
15.	*I shall ensure that the human subjects included in my study do not suffer any research abuse, accident, injury, mistreatment or disadvantage during the research process*		
16.	*I shall guarantee that no included human subject in my research suffers any indignity just because s/he belongs to a vulnerable section of society*		
17.	*I agree to be held accountable for any unforeseen mishaps, insults, injuries or harms occurring to my human research subjects during their participation in research process*		
18.	*I shall ensure that the participating human subjects in my research study are fully informed about the objectives and nature of anticipated outcomes and sources of financial supports in my investigation*		
19.	*I shall respect the fact even though ethical principles are universal, there can and could be instances wherein such values would vary locally. I shall respect, both, the universal as well as pluralist view points with regard to ethical concerns of human subjects in my study*		
20.	*I shall abide by the rules and regulations of AEC, in letter and spirit, during the entire research process.*		

Date: Principal Investigator

DECLARATION

I, Dr / Mr./ Ms. _____
have read the 'Ethical Guidelines for Bio-behavioral Research Involving Human Subjects' being followed by the All India Institute of Speech & Hearing, Ministry of Health and Family Welfare, Mysore: 6. I promise to abide by all the guidelines enunciated therein during the execution of the project titled _____
_____

Date: Principal Investigator

Annexure 2

SPECIMEN FORMAT FOR SEEKING INFORMED CONSENT FROM HUMAN SUBJECTS INVOLVED IN BIO-BEHAVIORAL RESEARCH PROJECTS AT AIISH

Information to the Participants:

In this section, include information on the title and objectives of the study being undertaken along with the type or number or human subjects being included or excluded as part of this research investigation. Also include under this section, details on 'why' or 'what' of the said research study being undertaken on human subjects. Highlight the risk/benefit elements involved for the human research subjects willing to participate in the said study. Emphasize that the privacy-confidentiality-anonymity of participating human subjects will be ensured from beginning to end of the study. Place on record the view that the investigators respect the autonomy and ability for free-choice of the human subjects and that they are entirely on their own either to participate or reject as per their will or wish without any resulting damage to the later treatment or therapeutic process made available for such persons at the Institute. It is to be clarified that there is no element of coercion, influence or pressure of any kind by the researchers or the investigating institutions to participate as human subjects in the given study. It must be spelled out clearly that the research procedures are different from routine medical or therapeutic care activities at the Institute. There should be information on expected duration of the subject's involvement in the research study, the total time needed and the possible number of visits to be made when included as part of the investigation. If any monies are to be paid towards participation or travel, the subjects should be explained on such terms and conditions in clear and explicit terms. In case, subjects are being given placebos or are likely to be located as member of 'no-treatment' control group-they must be clearly explained on or about such research designs. However, later, they should and could be administered the 'treatment' outside the research design.

Please note that the above format is only a guideline, which may need to be modified according to the situation or need for special research projects. It may also required changes depending on whether the participating human subject is a child, adult, person with disability, guardian or caregiver. Further, if the participant is not proficient in English, it must be ensued that the consent form is given in a language read or understood easily by the subject. The informed consent format could in minimum of three languages including English, Hindi and the local language. The translated version must be necessarily true and representative of the original version.

Informed Consent

I have been informed about the aims, objectives and the procedure of the study. The possible risks-benefits of my participation as human subject in the study are clearly understood by me. I understand that I have a right to refuse participation as subject or withdraw my consent at any time without adversely affecting my/my ward's treatment at AIISH. I am also aware that by subjecting to this investigation, I will have to give more time for assessments by the investigating team and that these assessments may not result in any benefits to me. I have the freedom to write to Chairman, AEC, in case of any violation of these provisions without the danger of my being denied any rights to secure the clinical services at this institute.

I, _____, the undersigned, give my consent to be participant of this investigation/study/program.

Signature of Parent/
Guardian
(Name and Address)

Signature of Witness

(Name of Witness)

Signature of Investigator:
Name and Designation:
Date:

Annexure 3

SPECIMEN FORMAT FOR
ACCEPTANCE/REJECTION OF 'ETHICS APPROVAL' FOR
BIO-BEHAVIORAL RESEARCH PROJECTS INVOLVING
HUMAN SUBJECTS AT AIISH

AIISH ETHICS COMMITTEE

Title of Project: _____

Principal Investigator: _____

Co-Investigators (If any): _____

Proposed Duration of Project: _____

Estimated Budget Requirements: _____

Source of Funding: _____

Reference Number of the Proposal:_____

Date on which AEC Meeting was held: _____

Clear Statement of Decision Reached at AEC Meeting in the event of a proposal being not approved, a statement of reasons for the same must be indicated:

_____

_____

_____

ADVICE & SUGGESTIONS (IF ANY):

_____

_____

DATE: Name & Signature of Member Secretary