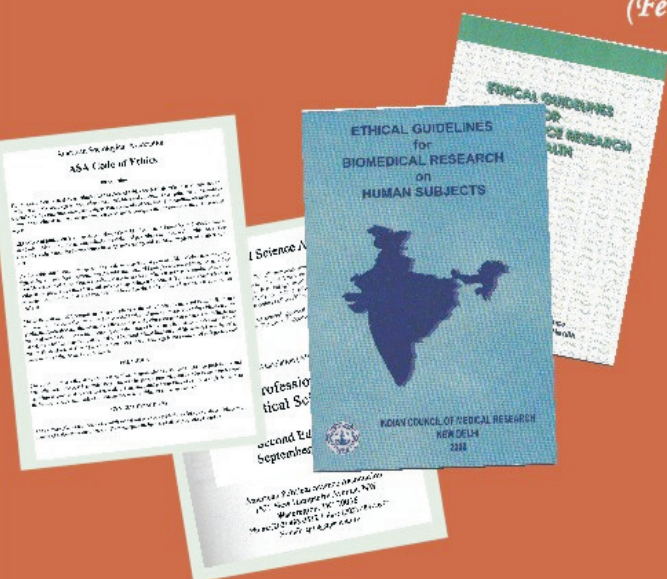


# MOVING TOWARDS INSTITUTIONALISATION OF ETHICAL REVIEW

REPORT OF THE  
INSTITUTIONAL ETHICS COMMITTEE, CEHAT

*(February 2001 - June 2002)*



  
**Cehat**

## **About Cehat**

Cehat, in Hindi is "Health", CEHAT, the research centre of Anusandhan Trust. It is engaged in research, action, service and advocacy in health and allied themes. Socially relevant and rigorous academic health research and health action at CEHAT is for the well being of the disadvantaged masses, for strengthening people's health movements and for realising right to health care. Its institutional structure acts as an interface between progressive people's movements and academia.

## **Our Strategies**

- ◆ To undertake socially relevant research and advocacy projects on various socio political aspects of health.
- ◆ To establish direct services and a programmes to demonstrate how health services can be made accessible, equitably and ethically.
- ◆ To disseminate information through databases and relevant publications, supported by a well-stocked and specialized library and a documentation centre.

## **Our Social Responsibility**

As a principle, we do not regard society as an object of experimentation and data collection merely for intellectual gratification. All efforts in CEHAT endeavor to create space for the participation of people without compromising on academic rigour. The ethical guidelines of CEHAT are structured around informed confidentiality and relaying information back to relevant segments of society. Projects are scrutinized by an Institutional Ethics Committee. A Social Accountability Group, comprising individuals other than the CEHAT team and Anusandhan Trust members, periodically evaluates our functioning as an institution.

## **Our Functioning**

We are a multi disciplinary team with training and experience in Medicine, Life Sciences, Economics, Social Sciences, Social Work, Journalism and Law. We have a democratic and participatory mode of decision making.

## **Our Initiatives (1994-2001)**

CEHAT's projects are based on its ideological commitment and priorities, and are focused on four broad themes,

- ◆ Health Services and Finance
- ◆ Health Legislation, Ethics and Patients' Rights
- ◆ Women's Health
- ◆ Investigation and Treatment of Psycho-Social Trauma

An increasing part of this work is being done collaboratively and in partnership with other organizations and institutions.

# **MOVING TOWARDS INSTITUTIONALISATION OF ETHICAL REVIEW**

## **REPORT OF THE INSTITUTIONAL ETHICS COMMITTEE, CEHAT**

**(February 2001- June 2002)**

**By**

**Institutional Ethics Committee**

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## ACKNOWLEDGEMENTS

The functioning of an Institutional Ethics Committee is contingent upon the ethos the institution has, the work culture it maintains, and the commitment it has to ethical principles of research and other related activities.

We thank all the staff members of CEHAT who facilitated our functioning by actively participating in the processes that we evolved for ethical review.

We thank Mr Dattatrya Taras, Mr. Kiran Mandekar, Ms Shiny Matthew and other staff from the administration unit for providing us the administrative support to keep our work going smoothly.

We thank Sunita Bandewar, Tejal Barai and Neha Madhiwalla, the members of the IEC secretariat for doing arduously a range of ground work from time to time. They provided a bridge between the staff of CEHAT and us making it possible for us to function optimally.

We thank Mr Ravi Duggal, Coordinator, CEHAT for his support.

External Members, IEC, CEHAT

## PREFACE

Addressing ethical concerns and dilemmas in research as well as action programmes have been essential processes within CEHAT. In fact, one of the four founding principles of Anusandhan Trust is that we will conduct research and other activities ethically. In the initial years CEHAT constituted ethics committees for individual projects to honour this principle. But a search for developing an enabling institutional mechanism for doing ethically sound research has always been there. In keeping with our commitment towards building a democratic institutional ethos and encouraging ethical practices in social science and health research and action, CEHAT constituted its first Institutional Ethics Committee(IEC) in January, 2001.

The IEC has been an outcome of a two year long collective process co-ordinated by CEHAT to evolve ethical guidelines for social science research in health. The National Committee for Ethics in Social Science Research in Health (NCESSRH) supported through a secretariat provided by CEHAT evolved these guidelines through research and deliberations over two years and finalised after a National Consultation with eminent researchers and scholars from social sciences and health disciplines.

While at one level CEHAT set an example by setting up its IEC, it also played a lead role by advocating setting up IECs or project ethics committees in partner organisations through the Abortion Assessment Project - India, which is a multi-centric and collaborative initiative on research on various aspects and dimensions of abortion. The latter provided us with the impetus required to set standards for research and to establish a formal mechanism for the same.

### **The objectives of the IEC are**

- ◆ To make all our research and action projects not only scientifically rigorous but also ethical,
- ◆ To provide our staff with more opportunities to actively engage with ethical issues in their work,
- ◆ To provide our staff learning opportunities in ethics by interacting with resource persons from various disciplines,
- ◆ To standardise practices across projects, and
- ◆ To evolve a code of ethics for CEHAT based on hands-on experience of ethical reviews of ongoing projects.



## **Constitution of IEC**

Since December 2000, within CEHAT, there was considerable discussion on the composition of the IEC. There being a lack of trained ethicists in India, we had to think of alternative ways of constituting an IEC. The NCESSRH guidelines and deliberations were also useful in our selection.

The IEC would represent the interests of all the different players involved in research. While the primary objective would be safeguarding rights of participants, the IEC would also play a role in fostering an ethical environment within the organisation. Ethical practice needs to become integral to the organisation's functioning. Thus, the criteria for the composition of the IEC were: it would be multi-disciplinary, autonomous, and representative of society and of different perspectives on research and ethics. The present committee therefore has members with backgrounds in philosophy, public health, medical ethics, psychology, social sciences, human rights and law. There is also one member who can represent the view of the participants as a common (wo)man. Thus, constituting the IEC was a dynamic process of identifying relevant disciplines and people with experience in research or in the practice of ethics.

A total strength of eight members was decided upon keeping in mind the multi-discipline nature of the exercise. Of these, two would be internal members, in order to function as a bridge between the external members and CEHAT. Thus, the IEC of CEHAT at present consists of 8 members. Presently the IEC has 5 external members and three members from amongst CEHAT staff, two of whom manage the IEC Secretariat.

The present report is a collective effort of the members of the IEC and we hope that sharing these experiences will contribute to developing a code of ethical practices in social science research in health and advance ethically sound research. We will appreciate feedback, comments and suggestions which will help us improve in our endeavours in ethical accountability.

Ravi Duggal  
Coordinator, CEHAT  
7<sup>th</sup> Sept. 2002

# MOVING TOWARDS INSTITUTIONALISATION OF ETHICAL REVIEW

We present the report of the IEC for the period Feb '01 to June '02. This report has three objectives namely:

- a. To place before people IEC's work output in relation to projects for ethical review.
- b. To document the ethical and organisational issues emerging in CEHAT through both research as well as action projects.
- c. To share our experiences and problems faced in the process of developing such a mechanism, particularly because of the absence of any paradigms to fall back on.

To begin with, we had many questions about our own competence as members of an ethics committee. As we are not trained ethicists, we have always tried to be self critical about our own work, as well as our own role and responsibilities. We also needed to clarify conceptual and decision making aspects of our work as we went along. Reflecting this tentative approach, our report carries a self-evaluation of our work. An evaluation of our work carried out by the CEHAT staff is also presented.

We look upon this report as a responsibility to be transparent to the public about our functioning

The report reflects the collective effort of IEC.

Joseph Lobo  
Chairperson, IEC, CEHAT

# MOVING TOWARDS INSTITUTIONALISATION OF ETHICAL REVIEW

## 1. WORK DONE

### 1.1 Work done by the IEC

Two broad categories of work done by the IEC in the last year were:

- a. evolving and streamlining procedural aspects of IEC, and
- b. conducting ethical reviews of projects.

#### 1.1.1 Procedural aspects of IEC

To make the IEC's work relevant and enabling of CEHAT's activities, the IEC had the task of developing frameworks and procedures for its own work, and for conducting project reviews. We are presenting two tangible outcomes of this work (a) defining job responsibilities for the IEC, and (b) preparing checklists for ethical review of research and action projects.

- a. **Defining job responsibilities of IEC:** Preparation of the document defining roles and job responsibilities began in the first meeting of the IEC and evolved through four meetings spread over a year. This received feedback from the staff before finalisation. (Annexure I). Thus, there was an interactive process involved between the IEC and the staff of CEHAT.

The scope of the document is as follows:

- i. Overall objectives of IEC,
  - ii. Functions of IEC,
  - iii. Responsibilities of IEC,
  - iv. Rights of IEC,
  - v. Framework for IEC functioning,
  - vi. Structure of IEC,
  - vii. Procedures for ethical review,
  - viii. Format of ethical review, and
  - ix. Documentation and dissemination of review.
- b. **Evolving checklists:** The IEC developed checklists for project teams to respond to while applying for ethical review. The checklists would help project teams identify and clearly articulate ethical issues involved in their work. It would also lead them to respond in a focused manner. To some extent resolving reservations about reviewing action projects, the IEC evolved checklists for both research as well as action projects. In submitting a project for review to the IEC, a studied response to the checklist is required, along with other relevant

documents, such as, the project proposal, study design, tools of data collection, the draft of informed consent letter, and draft plan of analysis. Other relevant documents may be presented at various phases of the project review.

- i. **Research projects:** The guidelines developed by NCESSRH provided a ready framework for developing checklists. The checklists have been prepared for the four phases of research projects, i.e. the phase (a) of submitting proposals, (b) after finalisation of the methodology and before launching field-work, (c) after completing the field work, and (d) prior to publishing the research report. (Annexure II A, B, C,D).
- ii. **Action projects:** Whether action / intervention projects should be brought within the scope of IEC work was itself a subject for discussion. There was no prior framework available for action projects, which could be used. The IEC therefore had reservations about developing a framework and checklists. It was decided that one of the internal IEC members who was engaged in action or action research would evolve a framework. Accordingly, a perspective note was prepared. The former outlined the specific ethical issues involved in action projects and developed a checklist. (Annexure III A,B).

### 1.1.2 Ethical review of projects

The scope of the IEC includes an ethical review of research and action projects of CEHAT. However, certification is restricted only to research projects. In the case of action projects, the role of IEC is limited to deliberating on various ethical issues involved so as to bring greater clarity and heighten understanding of the issues involved.

#### 1.1.2.1 Overview of projects reviewed and decisions made

During the reporting period, 7 projects, components of projects or proposals were reviewed as under:

- a. Abortion rate, care and cost: A community based study (methodology, research tools and field experiences of research investigators),
- b. Aarogyacha Margawar (research component),
- c. Rapid needs assessment of local residents for setting up new health care facility by the Bombay Municipal Corporation (proposal and research tools),
- d. Investigation of starvation deaths and nutritional status of children in Badwani, Madhya Pradesh following long period of drought,

- e. Dilaasa – a response cell for survivors of domestic violence at Bombay Municipal Corporation hospital (protocols for intake and recording of cases and overall functioning),
- f. SATHI (Support for Advocacy and Training for Health Initiatives) Cell,
- g. Fostering People Centred Health Care Reform (proposal submission stage).

The IEC has reviewed four research projects and three action projects. All the research projects reviewed have been either at the proposal stage or prior to data collection. Of the four research projects reviewed, one was certified affirmatively. For others, recommendations were made for improving methodology and re-articulation of aims and objectives and relevance of the research. One project was submitted *post-facto* and thus there was no certification involved.

#### **1.1.2.2 Certification and ethical issues: Project-wise details**

The section presents in brief the projects reviewed and the major ethical issues addressed.

##### **a. *Abortion rate, care & cost: A community based study***

**Objectives:** (i) To arrive at abortion incidence rate at the state level,  
(ii) To understand the trends as regards abortion care sought and received, and cost incurred.

**Phase of Review:** Pre fieldwork and before launching the fieldwork.

**Summary of Certification:** The IEC reviewed the documentation and also interacted with the research team. They concluded that there was clarity of focus and that due consideration had been paid to the ethical issues as per the checklist. The IEC decided that the project could proceed, keeping in mind the points raised during the discussions.

##### ***Ethical Issues involved in this study:***

- i. Concern about ‘misuse’ of micro-level health data,
- ii. Authenticity of information related to abortion,
- iii. Mechanisms for protecting minor women respondents (15-18 age group),
- iv. Seeking informed consent (written or oral),
- v. Individual’s consent v/s community’s consent,
- vi. Ensuring voluntary participation,
- vii. Interviewing only men for household information.

**Month and year of review:** March, '01.

**b. Arogyachya Margawar**

**Objectives:** This project has both research and action components, which are inter-linked. The research component was presented for review.

**Research Objectives:** To study the nature of prevalence and frequency of forms and causes of intra-familial violence and to understand women's help seeking behaviour in a Mumbai slum.

**Phase of Review:** Before launching the survey. Qualitative component consisting of focus group meetings completed. Intervention was in place for more than a year.

**Summary of Certification:** It was decided that the representing research team member would take the IEC discussion and feedback to the team members including the field investigators (especially because they have been part of the qualitative survey and would continue to work during the prospective quantitative survey) and to the project consultants. Feedback was required (a) to decide whether the household quantitative survey was needed at all, (b) if yes, they needed to rework the methodology taking into account specific suggestions given by the IEC. It was suggested to CEHAT that they would have to take an informed decision about doing the quantitative survey, primarily because there was a need for better clarity with respect to the rationale for such a survey. The quantitative survey would have to await IEC's approval.

**Ethical issues involved:**

- i. Methodology problems that have a bearing on the ethics of research,
- ii. Need for a rigorous scientific review prior to ethical review,
- iii. Designing research for advocacy purposes,
- iv. Unsuitability of research tools,
- v. Relevance and usefulness of the study.

**Month and year of review:** March, '01 (review suggesting modification); May, '01 (review and conditional certification).

**c. Rapid Needs assessment of local residents for setting up new health care facility by the BMC**

**Objectives:** To study (i) morbidity in the locality, (ii) the existing pattern of health seeking behaviour and perceptions on the existing health care services, and (iii) community's expectations from General hospital.

**Phase of Review:** Pre-fieldwork phase.

***Ethical issues involved:***

- i. Relevance of the study,
- ii. Designing questionnaire in accordance with the objectives of the study,
- iii. Representation of team during IEC review,
- iv. CEHAT's credibility being exploited by State to further its own purposes,
- v. Confidentiality of data and ownership of data,
- vi. Use of BM C health personnel to collect critical feedback related to health.

***Month and year of review:*** September, '01 (review suggesting modification); October, '01 (review and conditional certification).

**d. Investigation of starvation deaths and nutritional status of children in Badwani, Madhya Pradesh following long period of drought,**

***Objectives:*** (i) To investigate by verbal autopsy whether deaths occurring in a group of villages were related to starvation, (ii) To collect anthropometric measurements of children to record nutritional status, and (iii) To utilise data to ask for immediate relief measures to respond to famine conditions.

***Phase of Review:*** *Post-facto* review of methodology and conduct of study.

***Ethical issues involved:***

- i. Procedure for reviewing unplanned research initiatives emerging in action projects designed to respond to emergency situations,
- ii. Training of field staff to gather sensitive information during situations of crisis,
- iii. Emotional trauma inflicted on relatives during verbal autopsy of deaths.

***Month and year of review:*** October, '01.

**e. Dilaasa**

***Objectives:*** (i) To setup a response cell for survivors of domestic violence in the public health care facility, (ii) To provide counselling to women facing domestic violence, (iii) To provide shelter within the hospital for 24 hours, and (iv) To provide legal aid and services.

***Phase of Review:*** Ethical Review of draft protocol of the intake form and the preparatory phase of the response cell.

***Ethical issues involved:***

- i. risks of starting a centre without effective networks and linkages with shelters and lawyers in place,
- ii. Issues related to recording of information,
- iii. Not having provision for short-term shelter to women approaching Dilaasa,
- iv. Involvement of police,
- v. Excluding women referred from psychiatry department.

***Month and year of review:*** May, '01.

**f. SATHI Cell (Support for Advocacy and Training for Health Initiatives Cell)**

***Objectives:*** (i) To support innovative initiatives including local advocacy, select community based health initiatives, production of appropriate training and awareness material as inputs to these activities, and (ii) To work with a rights based approach with focus on Primary Health Care.

***Phase of Review:*** Pre submission to the funders.

***Ethical issues involved:***

- i. Monitoring the quality of work provided by organisations supported by the Sathi Cell,
- ii. Possibility of backlash against organisations or individuals that were partners and CEHAT's position vis-s-vis this issue.

***Month and year of review:*** May, '01.

**g. Fostering People-Centred Health care Reforms in India**

***Objectives:*** To foster people-centred Health Care Reforms through advocacy and training initiatives with people's organisations.

***Phase of Review:*** Pre submission to the funders for consideration.

***Phase of Review:*** Not applicable (IEC recommended that a detailed ethical checklist be submitted after the approval of funding and before initiating the project).

***Ethical issues involved:***

- i. Issues related to non-allopathic practice,
- ii. Presenting detailed rationale for budgeting.

***Month and year of review:*** February, '02.

## **1.2 Work done by the IEC Secretariat**

Through the IEC's tenure, the roles and responsibilities of the IEC



Secretariat have evolved. The Secretariat has been doing two types of tasks- (a) routine tasks, which were required on a regular basis to enable the functioning of the IEC, (b) specific tasks, which were required in specific situations. The Secretariat functioned as a bridge between the IEC and various other structures of CEHAT. It also played the role of facilitator for some project teams when they applied for ethical review.

### **1.2.1 Routine tasks**

The Secretariat has done the following during the reporting period:

- a. Organised IEC meetings as per requirements,
- b. Provided required administrative support,
- c. Prepared and compiled background material,
- d. Prepared agendas in consultation with the IEC members and focusing CEHAT's requirement,
- e. Interacted with project teams, providing orientation and inputs while applying for ethical review,
- f. Established and maintained regular communication between the IEC and CEHAT Working Group(WG) and Peer Review Committee(PRC),
- g. Prepared and finalized minutes of meetings after addressing feedback of the IEC members in subsequent IEC meetings,
- h. Followed up on IEC decisions.

### **1.2.2 Specific tasks**

Being the first year of the IEC, CEHAT, groundwork and some facilitation was done as follows:

- a. Preparing a document detailing procedural aspects and IEC checklists for project reviews,
- b. Convening a meeting of action project staff with internal IEC members to discuss ethical issues in action projects,
- c. Preparing the status report of the IEC, which formed the basis for self evaluation,
- d. Preparation of the draft annual IEC report for dissemination,
- e. Compiling ethical issues along thematic categories to facilitate the process of codification of ethical guidelines,
- f. Providing support to the IEC in terms of maintaining track of the changes suggested during deliberations, during finalisation of different documents, such as job responsibilities of IEC, check-lists.

### **1.2.3 Facilitation for project teams**

The internal members, and especially the IEC Secretariat also have a role in preempting ethical problems during the planning phase through discussions with the research teams and also serve as a sounding board

for the staff. Some facilitating functions are listed below:

- a. Communication: When necessary independent communication, electronic as well as face to face, was established with the respective teams. (eg. Dilaasa).
- b. In certain cases, especially when revisions were suggested, the problems gathered during the joint meetings of the IEC and project team and as perceived by the Secretariat were communicated to the co-ordinator. This was to facilitate revisions through due processes set by CEHAT to maintain scientific rigour and quality of work. (eg. Arogyachya Margawar -insisting on the need to interact with the consultants' committee members).

Based on experiences the following are some of the mechanisms/systems suggested by the Secretariat to be used by the staff consciously. It may be mentioned that these are in place in CEHAT during different phases of the project (conceptualising the projects, planning and designing the methodology, contemporary analysis, presenting literature review etc.):

- a. The respective teams should discuss various matters with the other staff members on a one-to-one basis as and when required,
- b. There should be formal presentation in the weekly office meetings,
- c. There should be formal consultations with the PRC members and inviting of specific tasks meetings when required,
- d. There should be formal presentations to the WG when required, of the problems faced while working on the project in any phase,
- e. There should be constituting of a consultants' committee as per CEHAT's system and the seeking of timely formal consultation from the committee members,
- f. In addition to the above, the members of the IEC from within CEHAT could be contacted/consulted when required.

#### **1.2.4 Orienting CEHAT's staff for planning ethically sound research**

As described earlier, it was the beginning of the processes involved in ethical review. Thus, in most of the cases there was close interaction of the project teams and/or PIs with member secretaries while working on the response to the checklist/IEC protocols. In the case of action and action research projects, as mentioned earlier, small meetings at the project level were organized to discuss the projects from an ethical point of view. This was followed by a joint meeting to discuss the checklist prepared by one of the IEC members from CEHAT (Dr Abhay Shukla) organized by the IEC Secretariat to discuss the ethical issues in the respective projects and related matters. This was found to be a fruitful and educative exercise.

### **1.2.5 Documentation of processes and deliberations**

This IEC is among the first of its kind in any social science research organisation. There is no specific training available to train ethicists in India. Hence, the role of this IEC has been both to train its own members – self-learning and also to provide a model for others. Against this backdrop, detailed documentation of the deliberations of the IEC has served more than one objective. They are as below:

- a. It enabled the streamlining of the functioning of the IEC,
- b. It provides information about various kinds of ethical issues that arose, the consequent discussions and the manner in which the issues were resolved or not resolved,
- c. It allowed the IEC to reflect on its functioning, problems encountered by it and key decisions taken after discussion. Thus, it provides resource material for self learning for the IEC members,
- d. This documentation will also serve as resource material for other organisations contemplating the setting up of such a committee.

### **1.2.6 Communication with other structures/bodies within CEHAT**

As stated earlier, one of the important tasks of the IEC Secretariat has been to develop and maintain communication links between the IEC and other structures in CEHAT. The tasks performed to achieve this are as below:

- a. The IEC protocols and IEC procedures (the document based on the first IEC meeting containing the IEC constitution, its objectives, responsibilities and rights, the procedures it would follow for ethical review etc. and checklists evolved for the purpose of ethical review) were sent to all the staff members to update and inform them about the IEC,
- b. There has been periodic communication to the WG about the IEC's work,
- c. The ethical review reports, including the intermediate stage certifications were sent to the WG and Trustees in June, 2001. This will be done periodically in the future too, to keep members of these bodies updated on the functioning of the IEC,
- d. A specific issue related to review of methodology and scientific review was raised in the PRC of CEHAT because the IEC felt that considerable time and effort would be saved if proposals/ tools/ reports were vetted for scientific rigor prior to appearing before the IEC.

## 2. EMERGING ORGANISATIONAL ISSUES

CEHAT has devised the following structures to facilitate the organisation's internal and external accountability:

- a. **Working groups (WG):** An elected body which is a decision making body of CEHAT.
- b. **Peer Review Committee (PRC):** A body of senior members from the staff other than administration which as the name suggests is an internal peer review body to look at scientific rigour of CEHAT's work.
- c. **Social Accountability Group (SAG):** This is an appointed body by the Trust to evaluate CEHAT's work for its social relevance as well as the extent to which the institution is adhering to the value of 'social accountability' by feeding its research into people centred policies, planning, action and advocacy.
- d. **Grievance Redressal Panel (GRP):** Eight staff members, chosen by the staff themselves, constitute the GRP. Any staff member can approach the panel members either for her/his own grievances or on behalf of other staff member. The panel then appoints a committee of two members from among the staff, which may or may not consist of members from GRP.

These structures take up ethical concerns/issues appropriate to their respective mandates. The IEC has defined its scope to avoid transgression into these areas.

SAG and IEC are autonomous. However, IEC is the only structure, which is comprised of both external and internal members. Whilst internal members of IEC participate in discussions and are helpful to supplement discussions of ground realities, the certification of projects is the prerogative solely of external members.

Wherever necessary the internal members of the IEC have interacted with these structures to ensure streamlining of their functioning.

### 2.1 Staff orientation

Most of the staff, which presented their work to the IEC for ethical review, have been part of the process through which ethical guidelines were evolved. These staff members also actively participated in the decision to constitute the IEC, its composition, its form and responsibilities. Some staff members have been in CEHAT for a long time and have deliberated upon ethical issues in their earlier work. This experience is not available to new recruits in CEHAT.

Currently, there is no formal mechanism to orient the staff on ethical issues in research, action and related matters. There is a need for CEHAT

to put appropriate procedures in place with IEC support, to serve two types of need of the staff:

- a. To orient recruits on general principles of ethics and procedural aspects of IEC, and
- b. To provide focussed inputs on their research projects

This IEC has planned an orientation of the entire staff of CEHAT in the near future.

## **2.2 Keeping track of the activities in CEHAT**

In general, it has been possible for the Secretariat to track projects so that they can be submitted to the IEC in time. The Secretariat played a proactive role in facilitating project teams to do the needful, in applying for ethical reviews. Also, since the member secretary has been a member of the WG, it was possible to be updated on the ongoing as well as upcoming projects. Despite this, on one occasion a research project taken up by an action project team went without the Secretariat noticing it in time.

The IEC noticed two constraints in continuing with this system. One, internal members of IEC Secretariat may not always be part of the WG. Two, it may not always be possible for the Secretariat to work in this manner. Also, continuing with this system implies that the Secretariat assumes the responsibility of keeping track of projects throughout their tenure. The IEC is founded on the premise that it is not a policing body, but an educative, consultative and facilitating body. If so, it is logical to think that the staff plays a pro-active role and expresses its need to interact with this body. The mechanisms of review as well as follow-up should not be intimidating, threatening and thus de-motivating to the staff. With this understanding, the IEC has suggested the following mechanism for fresh application and for follow-up of projects once they have interacted with the IEC:

- a. The Secretariat interacts with the newly constituted project teams, which are headed by new recruits regarding the procedural aspects of IEC,
- b. The project team plays a proactive role in interacting with the Secretariat and the IEC as regards ethical aspects of the project,
- c. Monthly reports of projects submitted to WG will also communicate in advance the need to meet with the IEC. These copies will be marked to the IEC Secretariat. Given the friendly and informal ethos at CEHAT, it is expected that teams will be interacting with IEC Secretariat directly,
- d. The WG convener will communicate this to the IEC Secretariat immediately,

- e. The IEC Secretariat then schedules an IEC meeting,
- f. The team will take the initiative to interact with the Secretariat to do the needful for applying for an ethical review, and
- g. Other than the mandatory review stages, the project teams are welcome to request IEC meetings at other times as and when required. The Secretariat should be informed about such needs so that IEC meetings could be scheduled.

## **2.3 Overlap of IEC functions with other structures**

### **2.3.1 Overlap with Peer Review Committee/Consultants**

Scientifically unsound research is *per se* unethical. On this premise, the IEC during the course of the year, in several cases, had extensive discussions on methodological issues and also made many suggestions regarding the same. Thus, the question emerged whether

- a. the IEC should comment on methodological issues,
- b. a fairly rigorous peer review takes place before the ethical review,
- c. there should be a channel of communication between the two bodies. (PRC and IEC).

In this regard, the following suggestions were made. They are:

- a. Prior to ethical review, one peer review committee (PRC) member could evaluate the material and submit written comments on the same to the team, which could also be submitted to the IEC.
- b. If any ethical problem is noticed during the process of peer review, it could be pointed out to the team.

### **2.3.2 Grievance Redressal System and the Rights of research staff**

One of the functions of the IEC is to contribute to the dignity, rights, safety and well-being of all the groups and persons related to the concerned project activity. This implies attending to the ethical issues involved in the relationship between different members of the research team. For example, research investigators getting exposed to undue risks during field-work without adequate safeguards. This issue violates the rights of research investigators and thus falls within the purview of the IEC. At the same time, it also constitutes a violation of the organisation's rules as well as its obligation towards its employees. It could also be a result of the lack of sensitivity among those heading the research team and the lack of democracy within the team's functioning. The IEC being an autonomous body, may have an important role to play in such situations.

However, CEHAT has the GRP to address such issues. The IEC, therefore decided that it will not attend to these and other ethical issues for which

there are mechanisms in place to address them unless the cases are specially brought to its notice and an action is requested. For the ethical issues, which lie outside its scope when brought to the notice of the IEC, it will refer to the appropriate bodies and structures within CEHAT, such as, WG, GRP.

The problems that such a strategy may pose will be revealed only through experiences in future.

### **3. PROBLEMS FACED**

Needless to mention that problems and dilemmas were faced on various occasions by the IEC and the Secretariat. The IEC, even today does not have much to fall back on when it stumbles, for the obvious reason, that is, setting up a mechanism by an institution for ethical review of its project activities is almost a first of its type. Also, none of the IEC members are trained ethicists.

Many problems faced by IEC particularly its Secretariat are generic and under normal circumstances would remain unstated. However, if this report hopes to prove of value to subsequent IECs, it is pertinent to state, at least, major/significant hurdles here. The Secretariat faced problems arising out of time pressures, working out logistics, and specific problems related to requests for ethical reviews at short notice. The Secretariat found it difficult to schedule *ad hoc* meetings of the IEC at short notice as it involves co-ordinating with the external members to find suitable dates and time.

### **4. EVALUATION OF IEC<sup>1</sup>**

The IEC evolved a system for self-evaluation and also a mechanism for obtaining feedback from the staff. The discussion focused upon (a) the purpose of evaluation, (b) parameters for evaluation, (c) grading to be used to rate performance, (d) evaluation by the IEC as a group or by individual IEC members.

The purpose of self-evaluation was primarily to assess the extent to which the IEC is fulfilling its responsibilities and meeting the objectives of its setting up. Parameters were evolved based on roles and responsibilities of IEC. A detailed checklist was prepared for self-evaluation. A shorter and appropriate checklist was also prepared for CEHAT staff to respond to. The system of grading was mostly based on the one that is used for evaluating performance of other structures within

<sup>1</sup> Two of the IEC members, Ms. Shradha Karhadkar (maternity leave) and Dr. Jaya Sagade (fellowship in Canada) were not present in the meeting convened for evaluation.

CEHAT and its staff. Thus, the scale we used is 1: below expectation, 2: meeting expectations, 3: somewhat above expectations, 4: outstanding. We decided to use a four point grading scale to evaluate ourselves. The IEC in one of its formal meetings did the self-evaluation collectively.

Feedback from the staff was restricted only to those who interacted with the IEC during the ethical review of their projects. The IEC requested these project teams to undertake a collective exercise within the team to respond to the assessment checklist.

## **4.1 Performance parameters relating to objectives**

### **4.1.1 Timely review**

Has the IEC been able to conduct ethical reviews after the respective project teams applied for the same?

**Rating:** 3

**Rationale:** There were no delays on part of the IEC either in scheduling the meeting as per project's need or in responding to the project teams when requested. In almost all instances results of ethical review of projects were immediately communicated verbally to the team on the same day and certifications/ response notes were issued within the stipulated period of time. Of late, written certifications/ response notes are being issued on the same day or the next day. Projects were not delayed due to lapses at the IEC end.

### **4.1.2 Protection of dignity / rights /safety / well being**

Have the deliberations at IEC meetings dealt adequately to raise issues related to above in respect of (a) volunteer participants,(b) researchers, (c) institution, (d) funders, and (e) general public?

**Rating:** 2

**Rationale:** Deliberations in relation to the first one have been very extensive and elaborate.

As regards researchers' rights, the IEC decided in the beginning itself that it will not deal with it unless requested by CEHAT.

Issues related to the institution and funders do not fall within the scope of the IEC and thus were not addressed. And yet, broader concerns are being expressed and referred to CEHAT for further deliberation.

There were not adequate deliberations specifically on the 'General public'. In future, we need to consciously address



this in a more systematic manner when required.

#### **4.1.3 Relevant advice on ethical issues**

Has the IEC been able to provide relevant advice on ethical issues to the teams approaching the IEC for ethical review?

**Rating:** 3

**Rationale:** This has been one of the prime tasks that the IEC was involved in. Retrospective analysis of joint meetings between the respective project teams and the IEC as regards their content, time spent, modifications suggested, certifications/response notes issues reflect the fact that the IEC has done justice to this responsibility.

#### **4.1.4 Efforts to enhance awareness about ethical practices among the project staff of CEHAT**

Has the IEC taken any measures to increase awareness of the importance of putting ethics into practice with the staff of CEHAT? If it has, what progress has been made in this direction?

**Rating:** 2

**Rationale:** There was no formal orientation programme organized by the IEC.

However, the internal members took the initiative to interact with the project teams, especially while preparing for project reviews.

The IEC recognises the need for planned efforts in the future. It was also premature for the IEC to organise such orientation programmes in the beginning itself.

#### **4.1.5 IEC meetings**

How disciplined have been the IEC meetings in relation to (a) preparatory aspects, (b) conduction of meetings, and (c) follow up aspects?

**Rating:** 2.4

**Rationale:** On these parameters, the IEC would like to distinguish between ratings for the support provided by the Secretariat and ratings for IEC as a collective. The support both at preparation and follow-up level provided by the Secretariat has been rated as 3.

However, the IEC finds that there is scope for improving conduction of the meetings. They need to be more tightly conducted to enable optimal use of time.

#### **4.1.6 Efforts made by the IEC for self-training**

Has the IEC made (a) an attempt to get trained on the job; means and methods used for the same; and (b) whether there was progressive improvement in the “quality” of the deliberations at IEC meetings?

**Rating:** 1.5

**Rationale:** Occasionally, we have referred to resource material from various international websites and used literature in the form of books. During all the brainstorming meetings, we have raised issues for honing skills in perceiving ethical issues, but we have not had structured and planned inputs for training ourselves. The IEC recognises the need to do so and is also conscious about it. The rating we have offered on this is ‘1’.

However, there is substantial improvement in the deliberations over time. We rate ourselves on this aspect as ‘2’.

#### **4.1.7 Work done to facilitate functioning of IECs in future**

Has the IEC made any attempt to ensure that experience of the current IEC can facilitate working for subsequent IECs to come in terms of (a) defining scope of an IEC and its mode of functioning, (b) documentation of discussions, (c) documentation of decisions made and rationale offered, and (d) moving towards codification of ethical guidelines?

**Rating:** 3.3

**Rationale:** Most of our efforts during the first year of tenure have been to put procedures in place. Deliberations of all the IEC meetings have been documented elaborately with nuances. We hope these would be used as resource material by those interested. In addition, Sections 2 in the present report titled ‘Emerging ethical issues’ is a concrete and well thought out step towards contributing to ‘codification of ethical guidelines’.

**Average rating (based on rating for 4.1.1 to 4.1.7): 2.5**

### **4.2 Effective and optimal use of available resources**

Has the IEC used the resources in terms of (a) expertise, (b) time, and (c) infra-structural facilities at its disposal effectively?

**Rating:** 2

**Rationale:** Overall, the resources available to the IEC seem to have been used optimally and effectively. However, the IEC recognises that there is further scope to harness the potential and expertise available.

### 4.3. Impact of IEC on the staff

Has the IEC impacted upon (a) formulation and conduct of projects as regards their ethical aspects, and (b) understanding and articulation of ethical issues among the project staff.

**Rating:** 2

**Rationale:** Impact on formulation and conduct of projects and progressively improving understanding and articulation of ethical issues among the project staff are some of the key functions of the IEC. Expecting impact within a year's time is a high expectation of the IEC. With this caveat, we have done satisfactorily on this front. The IEC recognises the need to formalise processes so that the entire staff is provided opportunities to get oriented to ethical research practices and also to improve an overall understanding of ethics and its principles.

### 4.4. Quality of output of IEC endeavor

Has the process of review at the IEC meeting been (a) objective, (b) fair, (c) enabling for researchers, and (d) forthright?

**Rating:** 3

**Rationale:** The practice to review projects (before IEC) are dealt with without fear or favour on the one hand but there is a conscious effort to help facilitate an enabling environment (from ethics point of view) to the research team.

Deliberate attention is paid to ensure that the certificates issued are unambiguous, forthright and sincere and fair in their content.

### Feedback from the staff

**In consonance with the job responsibilities 'advice' and education' to the staff (II.2, 3 in Annexure 1), IEC sought feedback from the project teams. Following were the questions sent out:**

1. Do you feel formulation and/or understanding of ethical issues has improved after interacting with IEC?
2. Has your articulation of ethical issues been improved?
3. Do you think the ethical review has caused delay in conducting your study?
4. To what extent have IEC's advice and suggestions been useful to improve the quality of your work from an ethical point of view?
5. Do you think the process of ethical review has been educative in general as regards ethical aspects of research and action in health?

Responses of the project teams are tabled below:

Q. No.	Needs assessment survey	SAATHI Cell	Dilaasa
1.	Rating - 4 Definitely improved, making myself conscious about some of the ethical dilemmas, which would otherwise have remained hidden through out the study.	Not much	Rating -2
2.	Rating -3 Actually it was an initiation into research ethics, which will definitely be useful as a researcher while preparing research proposals and while conducting research, in future.	No	Rating-2

Aboration rate, care, cost: A community base study	Arogyachya Margawar
Rating-2 समितीबरोबरच्या चर्चेमुळे बऱ्याच मुद्यांचा खुलासा झाला.	Yes. The team / its members had two interactions with the IEC. The first interaction was a learning experience and helped us to further define and focus on emerging ethical issues, especially in terms of how we could address some of our dilemmas. Moreover, it provided the team with a forum to discuss concerns with a larger group. We would like to share that the project was already underway, when the IEC was appointed. The project comprised of two interrelated components, the research and the action. The IEC and the team only discussed the ethical concerns in relation to the research component. Based on our experience, we feel that the IEC also needs to look at ethical issues concerning action projects in totality.
Rating-3 नक्कीच ! नितीमूल्याधिष्ठित संशोधना बदलची जी मते आता आम्ही मांडतो त्यामध्ये नक्कीच सुधारणा झाली आहे. सर्वेक्षणाच्या दरम्यान आमच्याबरोबर काम करणाऱ्या सगळ्या मुर्लींमध्येही हा फरक जाणवतो.	Yes. It strengthened our understanding and helped us especially during the training of the research team and during fieldwork.

Q. No.	Needs assessment survey	SAATHI Cell	Dilaasa
3.	Rating -1 Yes, but no complaints since the study has gained substantially through this review process.	No. However, we could not send the study design etc. of our malnourishment survey in Badwani area, to IEC for its suggestions, as this survey had to be done in a hurry due to the needs of the field situation. In future some clear guidelines would be required in dealing with such situations.	Not relevant as action research project
4	It was useful to a certain extent. To make it more useful in future, I would suggest the IEC be more cautious on ethical issues that can be practically implemented in the study under review. Also discussions on methodological issues of general nature (not particular to the study under review alone) should be minimal.	A couple of suggestions were made about the SATHI-cell proposal which was tabled in the IEC. These suggestions have been helpful. But larger part of the time during the meeting was spend on clarifying to IEC members about the work of the AS project.	Rating-2
5.	Rating -3 Yes.	Ethical review helps to think about ethical issues more concretely and systematically. This is very useful.	Rating-1

Abortion rate, care, cost: A community base study	Arogyachya Margawar
नाही.	No.
सुरवातीला सर्व IEC सदस्या बरोबर चर्चा झाली त्यानंतर संशोधनासंदर्भातील नितीमूल्यांबद्दलच्या दृष्टीकोनात उपयुक्त बदल झाला आहे असे फारसे जाणवले नाही. परंतु डॉ. जोसेफ लोबो यांचा लिखित अभिप्राय, सूचना व स्पष्टीकरणासाठीचे मुद्दे यामुळे संशोधनातील नितीमूल्यांबद्दल अधिक बारकाव्याने चर्चा होण्यास मदत झाली. त्या मिटींगमुळे सर्वेक्षणाच्या पुढच्या टप्प्यात जे काम आम्ही केले तेव्हा नितीमूल्याधिष्ठित संशोधनाचा नक्कीच जास्त विचार केला गेला. बऱ्याच मुद्यांमधील बारकावे समजले. सर्वेक्षणादरम्यान डॉ. अनिल पिळगावकर व डॉ. अभय शुक्ला यांच्या सोबत ६ डिसेंबर २००१ रोजी जी चर्चा झाली त्याचाही खूपच उपयोग झाला.	Met expectations
Ethical Review या प्रक्रियेमुळे संशोधन प्रकल्पातील नितीमूल्यांची अधिक प्रमाणात माहिती झाली. त्यामुळे बऱ्याच नवीन गोष्टी शिकायला मिळाल्या. या सर्व गोष्टी भविष्यात आम्हाला खूपच उपयोगी ठरतील.	Yes, definitely. Has met expectations

## 5. LOOKING AHEAD

The IEC is evolving systems and procedures and is striving to bring conceptual clarity as regards operationalising principles of ethics and the ethical guidelines with CEHAT's requirements in view. Besides, the efforts are towards evolving a code of ethics. Members of the current IEC intend to achieve the following in the second year of its tenure.

**a. Refining procedural aspects:**

- i. To refine the existing checklist more in line with the ethical guidelines stated in NCESSRH.

**b. Orientation of the staff:** The IEC has been conscious of a need to organise an orientation programme for the staff, in July, 2002.

**c. The codification of the guidelines:** Deliberations that emerge at IEC review meetings could possibly have a potential for providing material for formulating ethics codes to represent guideline brought forth by NCESSRH. This is true for the present IEC as also for IECs to follow. Moving in this direction, this IEC will attempt to make a beginning to operationalise the ethical guidelines laid down into codes of ethics. Hopefully, it was envisaged in the beginning of IEC itself that the IEC at the end of its tenure will have initiated a process in this direction.

Highlights of the deliberation within IEC on 'codification of ethical guidelines' are as follows:

- i. What is 'code of ethics?' This is an applied dimension of Guidelines of ethics. 'Code' will set the minimum standards for ethics but the scope for innovative strategies will remain. A code will be prescriptive and therefore should encompass the whole range of aspects of a particular issue. Also if the 'code' circumvents the spirit of the principles of ethics, the Guidelines may be referred to for more appropriate and meaningful interpretations.
- ii. Is it a static and one point activity? The 'code of ethics' document will keep evolving over a period beyond the tenure of any specific IEC. Developing a 'code of ethics' will be an open process incorporating new issues and innovative strategies to address the ethical issues and dilemmas that will keep emerging.

**d. Bringing our experiences to public domain:** The IEC recognises the significance of dissemination of its experiences by writing in appropriate journals and also of seeking consultations with other similar bodies. Given the role and responsibilities of IEC, it was felt

that the IEC needs to write papers and articles for external journals to share its experiences with the public. It was also thought that that by doing so it would serve the purpose of being accountable to the public and will provide guidance to other organisations interested in setting up similar institutional ethics committee. In this light, efforts will be made to do the following:

- i. Some possible options for wider dissemination of the documentation could include publishing articles in the journals, such as, the Economic and Political Weekly (EPW). EPW has provided adequate and just space for the efforts to evolve the ethical guidelines. Other journals also could be considered.
- ii. The IEC would like to put such writings on the website (possibly interactive) of different organisations. CEHAT's website will carry these writings.
- iii. The IEC will explore the possibilities of setting up communication links with the National level committee, which evolved ethical guidelines and also work out a mechanism for it.

## 6. RESOURCES REQUIRED

This section in our annual report is primarily to share with others the extent of resources – financial, human power, time - required to support an Institutional Ethics Committees. The data presented below indicates that it requires substantial resources and thus indicates the need for advance planning at institutional level.

**a. Financial resources required<sup>2</sup>:** The major heads of expenditure and expenditure incurred are as follows:

Sr. No.	Expense Head	Amount in Rs.
1.	Travel & Conveyance	4,160.00
2.	Hospitality & Meeting exp	1,504.00
3.	Honorarium Charges	5,2100.00
	<b>Total Expenses</b>	<b>57,764.00</b>

All the meetings of the IEC were held in the Pune office of CEHAT.

External members of the IEC were paid honorarium of Rs. 1000 / - per day as well as travel expenses. The total expenditure on the IEC (excluding costs of photocopying and postage) amounted to Rs. 57,764/- for the period of 17 months (Feb 2001- June 2002).

<sup>2</sup> The administration/accounts staff of CEHAT, Pune supplied us the data on financial resources required to support activities of IEC, CEHAT.

Whilst external members of the IEC are paid an honorarium of Rs 1000/- per day as also travel expenses, it is pertinent to note that the staff members (on IEC and other structures) supplement their efforts voluntarily based on CEHAT's inbuilt principle of participatory democracy/management. To them this additional responsibility is part of their work responsibility at CEHAT.

- b. Human resources at the Secretariat:** A day long IEC meeting takes on an average additional three co-ordination days for the Secretariat. This excludes the time required for correspondence, communication and follow-up etc. This also does not include the time spent with researchers/staff from CEHAT on responding to their queries and at times organising meetings with the respective project teams to provide orientation and inputs on the IEC and on conducting ethical research.
- c. Time required/expended:** The IEC had 11 meetings between February 1, 2001 and June 30, 2002. This included 9 full-day meetings and 2 half day meetings. The actual meetings of the Institutional Ethics Committee took about 52 hours. This excludes the time required for preparation for the meetings, perusal of the material and time taken for e-mail discussions.



## ANNEXURE I SCOPE AND JOB RESPONSIBILITIES OF IEC, CEHAT

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It has been a joint venture between the IEC members and CEHAT. We hope that it would evolve further over time.

## ANNEXURE I

### SCOPE AND JOB RESPONSIBILITIES OF THE INSTITUTIONAL ETHICS COMMITTEE OF CEHAT

- I. The overall **objectives** of the of Institutional Ethics Committee are:
  - a. To provide objective and timely ethical review for, primarily, the research activities and secondarily, the action/intervention activities of CEHAT within the framework of the ethical guidelines that have been evolved by the National Committee for Ethics in Soicial Science Research in Health (NCESSRH).
  - b. In the process of operationalising, the experience of the IEC will lead towards transforming the guidelines into a code.
  - c. To progress towards the evolution of an Institutional Ethics Board.
  
- II. To fulfil this role, the IEC will perform the following **functions**:
  - a. *Protection* - the most important function of the IEC is to contribute to the dignity, rights, safety and well being of all the groups and persons related to the concerned project activity. This would include participants in the research and the community at large, the researchers, the research community and the Institution.
  - b. *Advice* - The IEC provides a useful resource for researchers in the sense that, it brings together a group of individuals from different backgrounds, which can comment on a project from a comprehensive ethical perspective.
  - c. *Education*-The IEC has the important *role* of increasing awareness and articulation of ethical issues *among the Cehat project staff*.
  - d. *Analysis and documentation*-The IEC will also therefore document the processes, ethical issues emerging from its deliberations and how they were resolved for its own learning and for educating others.
  
- III. The IEC, in view of the above role and functions has the following **responsibilities**:
  - a. The IEC will review and certify research projects at various stages viz. (a) before submission to Funding Agency, (b) after PRC evaluations and before starting the project, (c) midway through the project and (c) at the end but before publication. All research projects must be presented for ethical clearance at the appropriate stages. Research initiatives emerging in action projects due to the compulsions of the field situation may be reviewed at the earliest feasible time.
  - b. While certifying research at the above stages, the IEC has recommendatory powers and will suggest modifications and advice as and when necessary.
  - c. IEC will review the work of action projects, offer advice, document the process of ethical review, but will not certify such work.
  - d. IEC will submit its report on matters placed before it to CEHAT after the end of

every year. It shall make its report to the general public and CEHAT will be obliged to make sets of these available to pertinent requests from people.

**IV. In order to maintain the autonomy of the IEC, it will have the following rights**

- a. IEC is entitled to an explanation if its recommendations are not fully implemented or if they are partially or fully rejected by the project team or CEHAT.
- b. IEC members will have access to all the relevant material/ documents about the project. (CEHAT would provide a list of such material to the IEC).
- c. IEC has the right to appoint a sub-committee of the members from within IEC to review a particular project, depending upon the nature and scale of the project.
- d. IEC has the right to select and invite experts whenever needed for the work of IEC. For this CEHAT will meet the necessary infrastructure, logistics and payments (if called for).
- e. IEC has right to seek explanations and clarifications that are needed from time to time for the purpose of its work from researchers / the institution.
- f. IEC has the right to decide which debates and deliberations to reveal to the larger public. It would use its own discretion about making information and discourses available for public use.
- g. The IEC has the right to call for a consultation with the larger body of staff within CEHAT. The IEC members should be invited for the public peer workshops organised by CEHAT to report on the work, which has been reviewed by the IEC.

**V. The IEC will work within the following framework:**

- a. Although it has its contracted role with CEHAT. The IEC is autonomous in areas concerned with its professional role.
- b. It is understood that IEC is independent of other committees of the Institution (vice-versa is equally applicable). However, if CEHAT feels that IEC can be helpful in ethics concerns, it may play a consultative role on request. If IEC feels strongly about certain matters concerning ethics in the Institution it shall interact with the WG/CEHAT Coordinator/Anusandhan Trust as appropriate.
- c. Again some matters may require co-ordination between IEC and other committees - for instance IEC and PRC. In these matters, CEHAT shall facilitate this co-ordination.

**VI. The structure of the IEC will be as follows**

- a. **Tenure:** The tenure of the IEC will be of two years.
- b. **Composition**
  - i. The IEC will comprise of external members as well as internal members.
  - ii. The external members will be in a majority.
  - iii. The number of internal members will be adequate to fulfil the role of the secretariat.

- iv. There should be at least one external member who represents the interests of the lay-people.
- v. One external member would be appointed as the chairperson of the IEC.
- vi. In case if one (or more) member of IEC leaves the Committee during its tenure, CEHAT will endeavor to fill this gap in consultation with the then existing IEC.

**c. Schedule**

- i. Looking to the requirements of the urgency of the projects on the one side as well as the constraints of external members on the other, these IEC members can at the maximum commit to 24 days of meetings in two years (@ 1 day a month). It must be borne in mind that an equivalent number of days these members will spend towards preparatory work for meetings.
- ii. Of the 24 meeting days, one day every 6 months will be devoted exclusively to self-review and self-evaluation exercise done by IEC.
- iii. All meetings will be scheduled by mutual agreement within IEC by the Secretariat.

**d. Secretariat**

- i. Constitution and composition: The IEC Secretariat of two members will be constituted by CEHAT from among the internal members. At least one of the members of the Secretariat should be present for IEC meetings.
- ii. Responsibilities of the IEC Secretariat will be:-
  - ◆ To organise IEC meetings as per the requirements of CEHAT. To provide all administrative support.(filing, record keeping, follow-up etc.)
  - ◆ To ensure that all project teams are oriented on ethical aspects and ethical research practices.
  - ◆ To supply to the prospective staff, at the time of recruitment, the relevant IEC document.
  - ◆ To keep CEHAT/WG informed about the IEC activities and debates.
  - ◆ To refer/report it to CEHAT/WG in case of lack of clarity concerning responsibility of IEC.
  - ◆ To prepare minutes and circulate them.

**e. Chairperson**

- i. Chairperson will be from among the external IEC members.
- ii. Appointment: IEC will appoint the chairperson. In the absence of the chairperson for a particular meeting, the members present for that IEC meeting will nominate a chairperson for the same.
- iii. Responsibilities: They are as below
  - ◆ To prepare minutes and circulate them.
  - ◆ To schedule the agenda

- ◆ To oversee conduction of IEC meeting.
  - ◆ To certify the research project and to prepare a response note in case of action projects.
  - ◆ To finalise and sign IEC Annual reports and other official documents.
  - ◆ To play a pro-active role in evolving consensus and enabling the committee to arrive at decisions.
- iv. The IEC will comprise of external members as well as internal members.

**VII The Procedure to be followed by the IEC will be as follows:-**

**a. Review process:**

- i. Review stages: The ethical review of projects would take place in three stages in case of research projects:
- ◆ While sending the proposal to funders.
  - ◆ At the stage of finalizing methodology (Finalizing protocols, consent forms, pilot testing, addressing ethical issues involved etc.)
  - ◆ Prior to report dissemination.
  - ◆ Project teams can seek consultation with IEC at any other appropriate stage, especially during data collection and post data collection.
  - ◆ These are tentatively stated. If required and the need felt, IEC would meet in-between these phases.
- ii. Expected preparation by the team:
- ◆ The researchers would prepare a detailed note along the lines of the checklist and send it to the Secretariat along with other relevant documents 15 days in advance.
  - ◆ The project team should ensure that the project is satisfactory from scientific point of view in consultation with the PRC. The methodology will be adjudged by the assigned PRC member/s before it is tabled to IEC.
  - ◆ The team will mark a copy of the checklist and other relevant documents to the assigned PRC member/s while applying to IEC for ethical review so that PRC member/s is/are provided time and space to respond if pertinent.
- iii. Conduct of a meeting with project team for ethical review:
- ◆ If the PI is not physically present during the consultation, s/he must be available on telephone during the consultation.
  - ◆ Internal members have the freedom to abstain from the discussion, decision making in specific instances after providing an explanation for the same.

- ◆ At the time of taking decisions, there should be a majority of external members. The role of staff members from among the committee has been discussed earlier.
- ◆ The certification shall be done solely by the external members. Staff members comprising the committee shall participate in the discussions of the committee but their opinions shall not determine the certification.

It is understood that IEC members are not required to make field visits. Policing & monitoring field activities is neither expected of IEC nor is it desirable. If external IEC members do need to make field visits, it will be for acquainting themselves with ground realities. IEC will try and foster fiduciary, dignified and forthright relations with members of CEHAT.

- b. **Reporting format:** The IEC would prepare the Ethics Review Report along the lines of the checklist provided to the researchers. This review report by IEC would be prepared within a week's time from the date of consultation between researchers and the assigned IEC members.
  - i. It would specifically lay down its opinion with the following three options:
    - ◆ The project receives the 'go – ahead' without any modifications required.
    - ◆ The project needs modifications to be made before it is approved by the IEC. The modification should address the issues raised by the IEC.
    - ◆ The IEC members have either serious reservations or disagreement with certain components of the project that could not be resolved through discussions during the consultation with the PI/team representative/team.
  - ii. Note of dissent would also be recorded.
- c. **Documentation and dissemination of ethical reviews:**
  - i. Minutes of the IEC meetings, consultations and ethics review reports would be accessible to CEHAT's staff and to all the bodies within CEHAT/ Anusandhan Trust(AT).
  - ii In order to maintain confidentiality, in the report to the people and in any communication to the outside world, care will be taken to ensure that identities of individuals are not revealed.

## ANNEXURE II

### CHECKLISTS: RESEARCH PROJECTS

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This contains checklists to be responded to by researchers at four different phases of the research projects. The four phases are:

- Phase I:** Prior to forwarding a proposal to funders for financial support.
- Phase II:** At the stage of finalisation of methodology and prior to launching the field work.
- Phase III:** After completing the field work.
- Phase IV:** Prior to publishing the research report.

Of these, Phases I, II, and IV are mandatory for researchers to apply to IEC for ethical review whereas, applying for ethical review in Phase III is optional. As part of the preparation for ethical review, researchers have to respond to the checklists at respective phases. Researchers are requested to refer to the document “**Ethical Guidelines for Social Science Research in Health**”, prepared by NCESSRH and published by CEHAT while doing so to facilitate their understanding of the ethical principles of research in the context of specific research work.

The checklists for four phases, along with objectives of ethical review of research projects at respective phases are presented in Annexure II (A), (B), (C) and (D).

## ANNEXURE II (A)

### CHECKLIST I FOR PHASE I: PRIOR TO SENDING A PROPOSAL TO FUNDERS FOR FINANCIAL SUPPORT

#### Objectives

This is for the first time in the life span of the project that researchers would interact with IEC for ethical review. Researchers are expected to address broadly the ethical issues involved in the proposed research.

The specific objectives of an ethical review at this stage are:

1. To facilitate researchers to articulate ethical issues involved in the area of enquiry, especially if it is a new area.
2. To understand the nature of ethical issues involved,
3. To ensure that there are no insurmountable ethical issues involved in the proposed research.

#### About the research project

**Title:**

**Principal Investigator:**

**Team members:**

**Duration:**

**Field-work location:**

**Collaborators (if any):**

**Funded by:**

#### Project phases completed and reviewed by IEC

Project phases reviewed by IEC	Period	IEC review and comments in brief
Proposal pre-submission phase (Mandatory)		
Before launching the field work to discuss issues based on the draft methodology (Mandatory)		
During field-work (Optional)		
Post field work and before draft report (Optional)		
At the time when the draft report is ready (Mandatory)		



## Checklist I

1. A note on the reasons for undertaking the research.
2. A note on the ethical concerns that you anticipate during the course of the entire study.
3. In case of short duration projects (less than 3 months), a statement on the phases for ethical reviews needs to be presented.
4. Researchers are encouraged to respond to the Checklist II at this stage itself.
5. List of the enclosures that should be sent along with a response to this checklist while applying to IEC for ethical review:
  - ◆ Project proposal,
  - ◆ Note on ethical issues involved and strategies envisaged to address them.

## ANNEXURE II (B)

### CHECKLIST II FOR PHASE II: AT THE STAGE OF FINALISATION OF METHODOLOGY AND BEFORE LAUNCHING FIELD WORK

#### Objectives

This is the most critical phase for researchers, as it requires attending to ethical issues in a comprehensive and exhaustive manner. Not attending to ethical issues satisfactorily will have serious implications for research participants and thus the responsibility lies with both the research team and members of IEC to brainstorm the ethical issues involved and design an ethically sound methodology.

The specific objectives of an ethical review at this stage are:

1. To assess whether the study design and methodology laid down attends adequately and sensitively to the ethical issues involved,
2. To assess whether adequate measures are proposed to protect rights of research participants,
3. To assess whether the processes planned to sensitise the research team to ethical issues are adequate and feasible,
4. To assess whether adequate measures are proposed to protect rights of researchers and especially field based staff.

#### About the research project

**Title:**

**Principal Investigator:**

**Team:**

**Duration:**

**Field-work location:**

**Collaborators (if any):**

**Funded by:**

#### Project phases completed and reviewed by IEC

Project phases reviewed by IEC	Period	IEC review and comments in brief
Proposal pre-submission phase (Mandatory)		
Before launching the field work to discuss issues based on the draft methodology (Mandatory)		
During field-work (Optional)		
Post field work and before draft report (Optional)		
At the time when the draft report is ready (Mandatory)		

## Checklist II

1. Do you anticipate any risks to any of the participants (physical, psychological, social and economic)?
2. What steps have been taken to mitigate the risks?
3. How do you balance the potential risks against the prospective benefits?
4. How do you plan to protect the anonymity, confidentiality and the privacy of the participants? Are there any specific concerns in these areas?
5. What is the mode and procedure for seeking informed consent? What is the information that you will be giving to the participants at the time of seeking consent?
6. What are the criteria for the selection of your participants? What is your sampling design?
7. How do you seek to ensure voluntary participation?
8. Do you plan to give any remuneration? If yes, in what form and at what stage? Rationally justify your stand.
9. How many sessions and of what length do you anticipate or plan to have, for data collection with each participant?
10. What are the plans for data sharing and dissemination of the research results vis-a-vis the respondents and society at large?
11. List of the enclosures that should be sent along with a response to this checklist while applying to IEC for ethical review:
  - ◆ Project proposal,
  - ◆ Draft methodology,
  - ◆ Protocols,
  - ◆ Draft letter of introduction,
  - ◆ Draft informed consent form,

## ANNEXURE II (C)

### CHECKLIST III FOR PHASE III: AFTER COMPLETING THE FIELD WORK

#### Objectives

By this time/phase the research team would already have brainstormed on most of the ethical issues and dilemmas specific to the project. The mechanisms/strategies designed to resolve the issues would have been put to use during the field-work. Upon completion of the field-work then is the time for assessment of the strategies conceptualized. It is also the time to document experiences as learning lessons and also an opportunity for the historical documentation of practicing ethical research.

Specific objectives of an ethical review at this stage are :

1. To examine the adequacy of the discourse and debates on various ethical issues and concerns generated during Phase II in the field situation.
2. To assess the appropriateness and applicability of the strategies in the field.
3. To review if things have gone wrong as regards any of the ethical aspects and to examine if there is any need to take corrective measures
4. To keep the IEC informed about the adequacy of strategies to address ethical issues during earlier phases.
5. To document ethical practices and problems faced while doing so for the benefit of others and for one's own learning.

#### About the research project

**Title:**

**Principal Investigator:**

**Team members:**

**Duration:**

**Field-work location:**

**Collaborators (if any):**

**Funded by:**

#### Project phases completed and reviewed by IEC

Project phases reviewed by IEC	Period	IEC review and comments in brief
Proposal pre-submission phase (Mandatory)		
Before launching the field work to discuss issues based on the draft methodology (Mandatory)		
During field-work (Optional)		
Post field work and before draft report (Optional)		
At the time when the draft report is ready (Mandatory)		

### Checklist III<sup>1</sup>

1. Protecting the rights of research participants:
  - a. Please document experiences about seeking informed consent from research participants.  
(written/verbal; minors' assent and consent; post interview consent; differences across the different categories of study population- for example rural/urban; tribal/non-tribal).
  - b. Did you experience any discomfort with the strategies used to comply with the basic ethical principles? Please explain the reasons behind such discomfort with the strategies used.
  - c. Were gatekeepers involved in the process of informed consent? (eg. community leaders in the case of community based work; husbands or other elders in the case of household based studies, especially involving women research participants; medical professionals in the case of hospital based studies). What were the issues involved in this? How did you address them?
  - d. Please document experiences with respect to ensuring voluntary participation? Were there any instances of coercion while seeking participation?
  - e. Please document experiences regarding maintaining privacy, anonymity and confidentiality.
  - f. What was the average time taken for completing interviews with individual research participants?
  - g. Did the communities and research participants express needs as regards health related information and health care? How did you respond to these needs?
  - h. Did you provide any other assistance to communities studied outside the purview of the project activities and commitment?
2. Rights and responsibilities of researchers and the institution:
  - a. Training must have been imparted to the field investigators and new recruits. After completing the field-work do you think it was adequate and appropriate?
  - b. Was adequate support provided to the field investigators in terms of inputs, emergency back up, infrastructural facilities, monetary compensations, emotional support and debriefing?
  - c. Were there any instances of fabrication and manipulation of the data or other research related information which can happen at the field investigators' level or at the level of the core research team? How did you address them?
  - d. Were there instances of conflict because of the gaps in the values of researchers/ field investigators and research participants? How did you address them? Do you think this impacted on the quality of data? Do you think there was any impact

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<sup>1</sup>The response to the checklists for phase I and II and earlier deliberations on ethical issues would function as a guideline while preparing such a note post field-work.

- of this on maintaining the morale of the team? (III.2.7.).
- e. Did you feel a need to consult members of IEC or other experts from the related field to discuss and resolve ethical issues and dilemmas at any time? What were the issues and dilemmas? Did you feel that you could address these issues? In what way did you do so?
  - f. Did any team member other than the seniors in the team feel/sense exploitation in any form at any point of time? (This should not be responded to by the PI. The IEC members may have to discuss this with the team members directly, including the field investigators.).
  - g. What safety measures for field investigators were put in place, if they were required?
  - h. Did field investigators feel the need for additional skills or widening their own information/knowledge to be in a better position to conduct field-work ethically? What mechanisms did you use to meet their needs?
3. Did any ethical issues arise which were not addressed in advance and discussed during ethical review sessions? (In case of the large teams and involving field work stretched over a considerably long period of time, close interactions with the field teams, guided common sharing sessions with the field investigators could be some of the methods to record the ethical issues.).
  4. Given a second chance to conceptualise and conduct the study, what different strategies would your team like to design to address the ethical issues involved? (This is basically to draw 'learning lessons' from experiences in the field.).
  5. Please present the plan of analysis and/or chapter scheme of the main research report. It is advisable to present rigorous comments and rationale for the ways the data are planned to be used.
  6. Do you think that the way an analysis is planned would be utilising all the data obtained? In case there is under utilisation of the data, please state the reasons or comment on it.
  7. Please state the plan for data sharing and dissemination; and any changes made in the strategies proposed at the time of the second phase IEC review.
  8. Please state potential areas/topics for further working upon. For example, documenting or writing based on the experiences obtained during the field-work, or training of field investigators. (These may mostly be outside the commitments made in the formal/official project proposal). Please specify areas/topics, purpose/s, possible modes of documenting (writing, manuals, handbooks, audio-visual material etc.), and type of resources required ( human power and skills, time, finances etc.).

9. Do you plan to work on these? How? In case the existing team does not have adequate resources, the Institution should consider this as part of its responsibility and accordingly resources could be allocated to take this up in consultation with the team.
10. Please state potential areas for further work that could be undertaken either by research, advocacy, action or service-intervention. (This is primarily to identify areas, which could be pursued by the Institution beyond the project tenure and which could also to be shared with peers from outside the Institution. Such areas for further exploration could be given space in CEHAT's Annual Reports and could also be placed on CEHAT's website. ).

## ANNEXURE II (D)

### CHECKLIST IV FOR PHASE IV: POST FIELD WORK AND BEFORE PUBLISHING THE RESEARCH REPORT

#### Objectives

This is the phase after the draft research/project report is completed and before the report is formally presented to external peers for review. By this time in the life span of the project, the team of researchers would have had adequate opportunities to discuss and understand the ethical research practices and issues specific to the subject matter under study.

Specific objectives of preparing for ethical review at this stage are as follows:

1. To review whether the data obtained has been utilized optimally, non-selectively with no biases and in a scientifically sound manner.
2. To review/assess whether the results are presented irrespective of whether they support or contradict the expected outcomes(s).
3. To assess whether the research team have been able to meet the commitments made vis-à-vis concerned stakeholders, such as, research participants, team members, general public, funder.
4. To review/assess whether the dissemination plan is adequate and appropriate to reach out to the concerned stakeholders.

#### About the research project

Title:

Principal Investigator:

Team members:

Duration:

Field-work location:

Collaborators (if any):

Funded by:

#### Project phases completed and reviewed by IEC

Project phases reviewed by IEC	Period	IEC review and comments in brief
Proposal pre-submission phase (Mandatory)		
Before launching the field work to discuss issues based on the draft methodology (Mandatory)		
During field-work (Optional)		
Post field work and before draft report (Optional)		
At the time when the draft report is ready (Mandatory)		



## Checklist IV

1. Do you think the presentation of the data has maintained anonymity and confidentiality of the research participants and other concerned persons? Please explain the way it has been achieved.
2. Do you think the data obtained have been used optimally and non-selectively? Whether any data has been left out deliberately? If yes, explain reasons.
3. Researchers should ensure that the following has been incorporated in the report both at the time of public peer review and at the time of final publication:
  - a. The methodology chapter carries a section, which adequately presents the ethical issues and dilemmas faced at different points and phases during the life span of the project and the ways and methods used to address them.
  - b. The report has carried the IEC certification and the deliberations (or highlights of the deliberations) or excerpts of the deliberations
  - c. The tools of data collection along with the informed consent letter are placed in the report as annexures.
4. Please state the plan for public peer review.
5. Please state the plan for dissemination of the report or other alternative forms of publication based on the research findings.
6. Whether all the findings/results have been reported regardless of whether they conform or not with the expected outcome or stated hypotheses.
7. In case some data and findings are not reported, have you explained it in the report?
8. If subsequent to analysis any issues of ethical concern are noted, have they have been reported to CEHAT?
9. If there were issues, which would have had or may in the future have adverse implications for public health, human rights and law, have they been reported to CEHAT for appropriate action?
10. List of the enclosures that should be sent along with a response to this checklist while applying to IEC for ethical review:
  - ◆ The draft report.

## ANNEXURE III

### ETHICAL GUIDELINES AND CHECKLIST: ACTION PROJECTS

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This contains ethical guidelines for action and action research in health and a checklist to guide an exercise of addressing ethical issues involved.

CEHAT is engaged in both research and action. At the time when the IEC got constituted the 'Ethical Guidelines for Social Science Research in Health' prepared by the National Committee for Ethics in Social Science Research in Health (NCESSRH) provided concrete framework to evolve institutional mechanism for ethical review of research based activities and projects in CEHAT.

There was no such framework available that could be used in case of action and action research projects. Those engaged in health action or action research have been grappling on their own to address the ethical dilemma they face during their work. It was therefore felt that the project teams within CEHAT engaged in action or action research deliberate on the ethical issues and dilemmas they faced to lay down the framework or ethical guidelines for action related activities in a limited sense. As a result of this collective efforts within CEHAT and subsequent consultation with the IEC members the ethical guidelines for action research in health were laid down. This formed the foundation to prepare a checklist for action researchers to use as a tool to guide their exercise to address ethical issues in a more systematic manner.

There is only one comprehensive checklist, unlike four for four stages in case of research projects. This is because it is difficult to demarcate the phases in the action research projects and because they are of a different nature in different projects. Keeping this in mind, action projects are reviewed for their ethical content at least once a year. Action project teams are welcome to approach IEC in other situations, too.

## ANNEXURE III (A)

### ETHICAL GUIDELINES FOR ACTION PROJECTS: A PERSPECTIVE NOTE

#### 1. How are action projects different?

It is clear that the ethical review of action projects needs to be somewhat different from that of research projects. To understand this we need to take a closer look at how action projects differ from research projects in their approach. Some special features are:

- a. There is a deliberate intervention, interfering in an existing situation with the explicit, primary objective of improving it but the possibility of worsening it. When we are systematically 'meddling' with an existing set-up we would like to be very definitely convinced that there is definite benefit and no harm / minimal harm which would justify such an intervention. But is predicting this always possible?
- b. The question of consent: How can we obtain consent from a heterogeneous community, with various groups, strata, conflicting interests...who may never agree or come together?
- c. The partisan nature of certain interventions. Certain of our interventions may lead to benefit for a specific group (women, tribals etc), may even benefit a majority, but there is possibility of loss to some who are presently privileged or dominating. How do we balance this?
- d. Disturbing an existing equilibrium may lead to an intermediate stage of 'chaos'. When an intervention is introduced, there is a period when an element of friction and struggle emerges. Old support structures may collapse while new structures are yet to fully evolve. What are the ethical considerations in creating such a situation?
- e. Confidentiality is problematic when we convert 'private' problems into public issues. By their very nature, addressing issues like domestic violence may involve bringing 'private' issues onto the public domain.
- f. Tremendous flexibility of strategies is required while implementing community-based interventions. It is not always possible to predict beforehand what strategies would be adopted at a later stage. How do we address ethical issues emerging from time to time during an open-ended process?
- g. The question of personal conduct of a social actor: Each person working on behalf of an external agency is also an individual with personal inclinations and weaknesses. When such an individual commits an apparently unethical act, what is the responsibility of the agency? What if personal and community ethical values differ? Is the agency answerable to the community? Can it punish the individual? How is this balanced with the 'image' of the work and the movement?
- h. The question of partnership: There should generally be a sharing of initiative

and responsibility between the external agency (NGO) and the local activists / organisation. This partnership is itself dynamic and generally should lead to more and more responsibility being taken locally. However the nature of this sharing (it's evolution over time, it's status both when a crisis comes up and when issues of credit arise) is central to the dynamics of the process yet often impossible to define in black and white.

- i. The question of responsibility: When we intervene in a situation and unfortunately certain backlash / undesirable consequences ensue (a woman is thrown out of her husband's house, a seriously ill activist is refused treatment by a vindictive doctor) what is the nature of our responsibility to help as a project team and as an NGO?
- j. The question of sustainability of commitment: Most NGOs work on the basis of time bound projects while social action is an endless, ongoing process. The question of withdrawal – when and how – is a tricky one in any intervention process and raises ethical issues of it's own kind.

## **2. What should be the scope and process of the ethical review of action projects?**

When the situation is as complex as outlined above, it is apparent that the ethical review also needs to be broader in its scope and perhaps more indicative than prescriptive. It seems difficult to lay down precise guidelines, which would apply in all details and uniformly to all projects and situations. Often the exact dynamics of a decision taken by the action team in a particular situation may be difficult to comprehend for a person who is 'outside' the entire situation. Yet there is a value in formulating certain broad ethical guidelines and reviewing the projects adherence to these guidelines on a periodic basis. I feel that the following framework could be suitable for ethical review of action projects:(similar to the process for research projects)

- a. The action team may go through the checklist and respond to the major issues
- b. This should be discussed by the team with the assigned IEC members and any contentious issues sent back for further discussion within the team and modifications by them
- c. Wherever technical issues are involved special consultants are asked to give their opinion
- d. The project is reviewed periodically (every six months or one year) and ongoing modifications are made accordingly

## **3. What should be the key issues addressed by the checklist?**

### **a. Benefits and risks:**

- i Perceived benefits of the interventions - major benefits and spin-off effects
- ii Perceived risks of the interventions - those which are inevitable, those which are avoidable, possible catastrophic situations
- iii Key technical issues regarding interventions: relevant experts may be

- consulted for opinions on this
    - iv Identifying any specific groups / individuals which may systematically stand to lose by the intervention
    - v Overall assessment of benefits versus risks
- b. The main partners and the consultative process (parallel to ‘consent’ for research)**
  - i. Identifying the main interventions and the core beneficiary group(s)
  - ii. Mechanisms for dialogue and communication with this group and its representatives at various stages (before initiating the process, to review the process, during withdrawal or change in level of intervention)
  - iii. Defining the specific responsibilities of various partners and how these are expected to evolve over time
  - iv. In case persons with a particular problem are being catered to, the definition of this problem should be clear and those not covered by this definition should be covered by an appropriate protocol.
- c. Local Relationships:**
  - i. Within the CEHAT team
  - ii. Between the CEHAT team and the people
  - iii. Between the CEHAT team and the local organisations
    - ◆ How to ensure that these relationships are based on transparency, fairness, autonomy and overall mutual beneficence? The responsibility of CEHAT vis-a-vis partners should be defined and adhered to.
    - ◆ Recognition of differences in cultural background of external agency staff and community / beneficiaries. Methods of resolving conflicts related to these various relationships.
    - ◆ Confidentiality regarding details of a particular person interacting with the team may have to be maintained. However, it could be made clear to such persons that information revealed to any team member would be shared *within the team*.
- d. Broader relationships:**
  - i Between the CEHAT team and the civil society at large as well as the State.
  - ii Between the CEHAT team and the funders.

The developments including shortcomings of the activity should be communicated to society at large honestly and faithfully. Similarly, commitments to funders should be respected and communications made to them. Mechanisms should exist to resolve conflicts between commitment to funders and to the community.

- e. Processes for empowerment and sustainability**

How would skills, organisation and capability be developed in a phased fashion so as not to create dependence but rather make the external inputs unnecessary

## ANNEXURE III (B)

### CHECKLIST FOR ACTION PROJECTS

1. **Expected benefits and risks of the intervention process**
  - a What are the expected benefits of the interventions?
  - b What are the perceived risks?
  - c What safeguards have been made to maximise the benefits and minimise the risks?
  - d Are there any key technical issues regarding interventions, and if so how are relevant experts going to be consulted on this?
  - e Does the overall assessment of *benefits versus risks* justify the intervention effort?
2. **Partners and consultative process**
  - a Which are the main partners and what is the consultative process (parallel to 'consent' for research) with these partners?
  - b How will you ensure transparency in the process of ongoing communication with these partners?
  - c What is the planned MOU or other explicit definition of specific responsibilities of CEHAT and various partners ?
3. **Local relationships**
  - a Relationships would exist within the CEHAT team, between the CEHAT team and the people and between the CEHAT team and the local organisations. How would it be ensured that these relationships are based on transparency, fairness, autonomy and overall mutual beneficence?
  - b How would decisions be taken within the team and how would differences be resolved?
  - c How would the confidentiality of persons approaching the team be maintained and how would confidential information be shared within the team?
  - d In case training and service delivery are components of the project, how will it be ensured that persons will deliver services only in keeping with the level of training they have received?
4. **Broader relationships**
  - a How will developments including shortcomings of the activity be communicated to society at large?
  - b How will it be ensured that commitments to funders are respected? And what mechanism of regular communication with them will be adopted?
  - c By what mechanism will possible conflicts between commitment to funders and to the community be resolved?

**5. Processes for empowerment and sustainability**

- a How will skills, organisation and capability be developed in a phased fashion so as to not create dependence but rather make the external inputs unnecessary over a period of time?
- b What is the withdrawal strategy, attempting a responsible ensuring of the sustainability of the main processes initiated by the project?

**6. Crises and unforeseen situations**

- a What is the broad 'contingency plan' for crisis situations especially regarding how decision making will be done, how responsibilities will be shared and what is CEHAT's commitment in this regard?
- b What are the 'Safety plans' for persons who may face problems because of involvement in project-initiated processes?
- c What are the mechanisms to ensure the personal safety (while involved in project-related work) of CEHAT staff and other persons directly related to the project activity?

## ANNEXURE IV

### ABOUT THE MEMBERS OF THE INSTITUTIONAL ETHICS COMMITTEE, CEHAT

**Dr Abhay Shukla\***: He is a medical graduate with an M.D. in Community Medicine. He has worked in the area of occupational health with leather workers and has been involved in organising a cooperative movement of construction and contract workers. Since the last seven years, he has been associating with people's organisations, involved in training health workers, developing training material and assisting the development of activities for health rights. He is also involved in activities of Jan Swasthya Abhiyan in Maharashtra and Madhya Pradesh. He is a Jr. Scientist in CEHAT, working as part of the SATHI Cell team.

**Anil Pilgaokar**: He has been the founder trustee of Anusandhan, Trust under which CEHAT functions. He is expected to be alive to ethos conceived, developed and nurtured by the Centre as it has shaped itself through the intervening period.

**Dr. Bhargavi Davar**: With a doctorate in Philosophy and her continuing work in the area of mental health and human rights, this is unique attribute for the IEC. More importantly, ethics was a subject in her doctoral work. Her contribution in the area of on the job learning should be very profitable to IEC members.

**Ms. Chandra Karhadkar**: By training she is an accountant But she has rich experience of varied work in issues related to women's empowerment. She has a day to day experience of the 'feelings' of women subjected to different conditions of life. She should be expected to contribute most meaningfully in living the role of a 'lay person' and a woman.

**Dr. Jaya Sagade**: She is a lecturer in law and also working with NGOs. Legal aspects of ethics is something which is important particularly since the Institution's work is in the field that directly relates to people and involves legal and human rights issues.

**Joseph Lobo (Chairperson)**: He is a lecturer in Philosophy. Ethics is a branch of Philosophy and his thirty years of academic experience should be very useful, not only for that special quality of reviewing but also for on the job training (as ethicists) for members of IEC. Joe has also worked as founder Director of an NGO, VACHAN, working a development programme in villages of Igatpuri taluka. He has also been a founder Director of a research organisation: Centre for Development Research & Documentation. (CDRD)

**Neha Madhiwalla (Jt Secretary)\***: She has done her Masters in Social Work. Has been working in CEHAT since 1996 on various research projects on women and health. She is also engaged in teaching at various institutions. She has been actively involved in organising workshops for doctors and students of medical sciences on medical ethics.



## COVER- 3

**Dr Sunita Bandewar (Secretary)\*:** She has done her doctoral studies in Anthropology. Has long and continuing experience of community based empirical research. Has been working in CEHAT since 1994 on various research and advocacy projects under 'Women and Health Programme', primarily on the issue of abortion.

**Tejal Barai (ex-Jt Secretary)\*:** She has completed her Masters in Political Science. Worked in CEHAT between May 1999 to June 2001 on the project which led to a document titled 'Ethical Guidelines for Social Science Research in Health', the basis for setting the processes and institutional mechanism such as this particular IEC. She with other senior colleagues is currently engaged in editing a book on the theme 'ethics in research'.

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\* Internal IEC members

### United Nations Declarations Principles and Conventions

- Principles of medical ethics relevant to the role of health personnel, particularly physicians, in the protection of prisoners and detainees against torture and other cruel, inhuman or degrading treatment or punishment
- Convention against torture and other cruel, inhuman or degrading treatment or punishment
- Principles on the effective protection and investigation of extra-legal, arbitrary or summary executions
- Declaration on the protection of persons from being declared insane

### Ethical codes and declarations relevant to the health professions

#### Introduction

The following ethical codes and declarations are intended to provide a framework for the health professions in their interactions with patients, the public, and society.

### Convention against and Other Cruel, Inhuman or Degrading Treatment or Punishment (United Nations, 1984)

This Convention against and Other Cruel, Inhuman or Degrading Treatment or Punishment was adopted by the General Assembly of the United Nations on 19 December 1984. It is a landmark instrument in the history of human rights law and is widely regarded as one of the most important and comprehensive human rights instruments ever adopted.

### Amnesty International Declarations and Programs

- Declaration of Stockholm (Conference on the abolition of the death penalty)
- Declaration on the participation of health personnel in the death penalty
- 12 point program for the prevention of torture
- 14 point program for the prevention of extrajudicial executions
- 14 point program for the prevention of disappearances

### The Hippo (sic) Ce

A collection of ethical principles for health professionals.

### International Code of Medical Ethics (World Medical Association, 1948, 1963, 1987)

Adopted at the Declaration of Geneva, the WMA produced a code of ethics which was approved by the 34th Assembly of the World Medical Association in London in 1968. The International Code of Medical Ethics was subsequently amended in 1987 at the 52nd Assembly held in Venice. The text is available in English.

#### Introduction

A physician shall always exercise the highest standards of professional conduct.

A physician shall give priority to the best interests of his or her patient and shall not be influenced by financial considerations.

A physician shall not be involved in any activity that might be considered to be a conflict of interest.

A physician shall not participate in any activity that might be considered to be a violation of the law.

### The Hippocratic Oath

I, a doctor, swear by the gods to do as much good as I can for my fellow human beings, according to my ability and my conscience. I refuse to do anything that would harm my patients. I will keep my hands clean. I will not give or receive bribes. I will not prescribe dangerous drugs. I will not abuse the trust of my patients. I will not divulge any secrets entrusted to me. I will not be guilty of fraud. I will not be guilty of plagiarism. I will not be guilty of theft. I will not be guilty of any other crime.