Report of the
Institutional Ethics Committee
CEHAT
(December 2002-December 2004)

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INSTITUTIONAL ETHICS COMMITTEE (IEC), CEHAT
(December 2002 - December 2004)

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PREFACE

CEHAT's experience with ethics in social science research in health is now fairly well consolidated. The Institutional Ethics Committee (IEC) of Anusandhan Trust has now gone through its second phase and the overall experience has been very positive with deeper entrenchment of ethics within CEHAT's work. Apart from the work of the IEC, in the last three years CEHAT has also fostered and advocated ethics review in other institutions through collaborative work as well as through direct training and education.

The present document is the second such report of the work of the IEC and covers the period December 2002 – October 2004. The first report was well received and commended for its candid and transparent nature. The present report continues within the same tradition.

I take this opportunity to thank the IEC members for their devoted and intensive work which has contributed to an enhanced quality of CEHAT's research and action projects as well as improved understanding of ethical concerns amongst staff through the process of interface with the IEC. We hope that this report will help readers to gain insights into practice of ethics in research and we welcome feedback, comments and suggestions.

Ravi Duggal
Coordinator, CEHAT
23rd Nov. 2005

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SIGNIFICANT ISSUES DISCUSSED WITH RESPECT TO THE PROJECTS REVIEWED DURING THE LAST YEAR

The IEC held fifteen meetings from December 22, 2002 to December 19, 2004.[1] During this time it considered projects submitted by CEHAT research teams at various stages of review, for comment or certification. IEC members also met with team members of one study to discuss difficulties they were facing during fieldwork.

Projects were certified using checklists based on the National Committee for Ethics in Social Science Research in Health (NCESSRH) guidelines.[2] They were presented for review at four stages: at the time of submitting proposals; after finalising the methodology and before launching fieldwork; after completing fieldwork, and before publishing the research report. Action projects were not certified but were reviewed based on a perspective note and a checklist.[3]

IEC discussions highlighted a number of difficulties faced by researchers. This section summarises significant issues discussed in proposals reviewed during the year. A list of projects reviewed is given in Appendix A.

1. Unforeseen problems

Some ethical problems could not have been anticipated. For example, researchers in a study on abortion incidence, care and costs in Maharashtra found that in some areas participants spoke neither Hindi nor Marathi, the languages into which the questionnaire had been translated. They were forced to conduct some interviews using local translators and could not be sure that informed consent was taken, or even whether the translations were accurate. Two questions asked were: should these responses be analysed? If so, should they be analysed separately? In fact, the team did the primary analysis separately for the data collected using local translators and the rest of the data. This showed that there was no significant difference in the study's important findings in the two types of data. The team therefore decided to include data from translators in overall analysis of the study.

[1] Projects reviewed by the previous IEC, from December 2002, are also discussed in this report.
[2] The checklists are carried as annexure C in this report.
[3] The perspective note and checklist for action projects are carried as annexures in the previous IEC report.

2. Study including illegal occupants in resettlement

Researchers studying the impact of involuntary resettlement of a Mumbai slum community proposed to look at the impact of the process on people's health, social life and education, comparing conditions before and after resettlement. The problem was that unauthorised occupants made up 10 per cent of the new settlement, and they would be hostile to questions that might identify them as unauthorised. So the interview schedule was modified to exclude questions referring to the pre-relocation period. In later discussions, a new problem came up: including their responses in a study on the effects of an organised resettlement process could distort the results — while analysing their responses separately might put them at risk of government action. The ethical concern here was how to protect them at the time of separating data, if the Slum Rehabilitation Authority asked for their identity. Also, was their inclusion in the study justified? The team first did the analysis separately for illegal occupants. Since their inclusion did not affect overall trends much, these were merged with data from other residents.

3. Defining 'competence'

Researchers require a proper definition of 'competence' to participate in providing data for the research. This was particularly obvious during post-fieldwork discussions of the study on abortion incidence. The team mentioned encountering women who were eligible for the study but who had been labelled mentally ill and 'incompetent' by family members. Should these women be excluded from the study? Researchers reported that they did not go by such judgments alone, but made a personal assessment of the person's competence. This response was seen as unclear and possibly arbitrary. IEC members noted the need to develop a better definition of competence to give informed consent. This definition should be used in all CEHAT projects.

4. Vulnerable populations

A good deal of CEHAT's research is conducted on vulnerable groups. One example is a study on the health of women prisoners in Maharashtra. The IEC asked: How would researchers establish trust with participants and ensure their confidentiality, privacy and protection from victimisation? It suggested changes in the sampling design and questionnaire to ensure that women making adverse comments could not be identified and victimised — gathering basic information from all women and then conducting in-depth interviews with a sub-sample. It was also suggested that the study should not include direct interviews at all if the information could be influenced by the pressures of being in a closed institution. Finally, women should be able to contact the researchers after the project is over.

Another study proposed to assess the impact of crisis counselling at Dilaasa, a response cell for survivors of domestic violence, set up and run by CEHAT in collaboration with a municipal hospital. Interviews would be conducted with women who had attended the centre**.** The IEC noted that research with survivors of domestic violence is extremely sensitive. It can be very distressing for a woman to be asked to speak of her experiences. Confidentiality is particularly important here, and it could be threatened by the research process. For example, audio-taping would help data collection, but women might not be comfortable with this. The IEC asked that specific consent be sought for audio-taping. If it was refused, an alternative method of note-taking should be followed.

The involuntary resettlement study included focus group discussions with children. How would the researchers ensure the children's voluntary consent? It was suggested that taking group consent would decrease the children's vulnerability. It was also suggested that FGDs with children should discuss changes in their lives in general after the resettlement, not merely on the change in educational facilities.

5. Potential conflict between research and service delivery
Some of CEHAT's research projects are also linked to service provision – and there can be conflicts between these two activities.

In the involuntary resettlement study, the collaborating agency, Sahyog, also provided subsidised health care in the area. While clinic records could provide important information to the researchers, using this information for research would be violating the confidentiality between patient and provider. It would be important to keep the agency's roles as provider and as researcher separate. The IEC suggested that researchers should not use clinic records.

In the study of Dilaasa's counselling services researchers needed case papers of the clinic's clients. Could these be used without their consent? Asking a survivor of domestic violence for consent during or before counselling could jeopardise the counselling process. It was decided that consent need not be taken for internal research purposes as long as the data were anonymised. The consent form for research would state that information from the intake form and other case records would be used for the study.

A broader ethical question was who owned the data collected during counselling, in the form of intake sheets. This could not be resolved during this meeting. It was therefore decided that the data from

intake sheets would be used. However, IEC review would be done before publishing the data to ensure that no identity is revealed.

Researchers in the Dilaasa study also initially proposed to conduct telephonic interviews with women who did not return to the centre after the first visit. This was to help document problems with the counselling process. The IEC pointed out that this could put the women in danger.

6. Ensuring implementation of outcomes of collaborations with the government

CEHAT's work has increasingly involved collaborations with government organisations. What are the possible problems in such collaborations?

The collaborative nature of the Dilaasa crisis centre has both advantages and difficulties. The very purpose of this project is to develop crisis counselling within a government institution. However, the obvious restriction is that referrals to Dilaasa depend largely on the training and attitude of municipal hospital staff. Limitations in various departments such as, for example, psychiatry, can affect the functioning of the centre.

These problems are likely to become more acute as the collaboration ends and the centre is handed over to the municipality. During the year, negotiations were on to renew the collaboration as well as expand the initiative to other municipal hospitals. It is not clear if the municipal system will be able to handle the increased demands on it. However, CEHAT is ethically bound to ensure that once handed over, the centre provides services of the same quality. It was recommended that the IEC review the new memorandum of understanding with the municipality.

A similar question was raised when CEHAT proposed a study of the Dilaasa crisis centre – how would it ensure that the study outcomes would be implemented? The researchers stated that CEHAT's eventual goal was to confine itself to capacity building, for which its role in training and research would have to continue. It would assert its monitoring role in the new MoU to be signed.

The Upgraded Pada Swayamsevak (hamlet health volunteer) Scheme is a two-year pilot project to support village-level health services in a selected tribal taluka in Maharashtra. To be implemented in collaboration with a local people's organisation and the goverment, the scheme was a possible model for upgrading health volunteers' services throughout tribal areas in the state. The IEC asked: What mechanism would be used to monitor the government health services? The team responded that monitoring would be done through the hamlet level health committees (HHC). They would be given orientation on their work and a village meeting would be conducted once in six months to review the work of health workers.

In the study of women prisoners' health, one question asked was: How would CEHAT ensure that the study's recommendations are made public and implemented by the prison system? The IEC suggested a joint press conference before handing over the study findings. Another question asked was: Should CEHAT ask NGOs working in prisons to provide logistic and other support and ensure that participants are not victimised after the study? The IEC suggested that other organisations be involved for this purpose.

7. Collaborations with local organisations

There are different types of problems in collaboration with local organisations. In the involuntary resettlement study CEHAT's association with the project was to end after 18 months. The research process could create tensions – and once CEHAT completed its work, the local organisation would be left to face the repercussions.

The Support for Advocacy and Training for Health Initiatives (SATHI) Cell supports innovative initiatives in primary health care, including local advocacy and community-based health initiatives. The project would be carried out with the support of a local organisation. Here, the question asked by the IEC was: How can SATHI ensure that the project becomes sustainable once it withdraws? Further, the community may expect policy changes as a result of the work. What if these changes do not take place?

One concern regarding the Upgraded Pada Swayamsevak Scheme was that the project area included hamlets where the local people's organisation did not have a strong foothold. The CEHAT's employee would have to face hostility here because of the collaboration with the local organisation. It was recommended that care be taken to mitigate this risk.

8. When more than research
Indeed, a number of the projects reviewed had components of advocacy or action research. A perspective note and a checklist for action projects have already been developed and are used for ethical review. However, the IEC felt the need for guidelines on action research, advocacy and lobbying with political parties.

9. Overlap between ethical and methodological review
On some occasions, the IEC felt the need to discuss methodological issues. For example, a community-based study was proposed to establish the proportion of Caesarean section deliveries in a selected group of villages. This was to support action contemplated against the local gynaecologist who was suspected of conducting unnecessary Caesarean sections. The IEC had reservations about the study's relevance and methodology, the risk to participants and how they would be protected. It recommended modification and resubmission. While the team's representative respected the IEC's decision, the team did not completely agree with the issues raised. A detailed response was sent to the IEC about the concerns raised. The study was however ultimately dropped due to the team's observation of a major methodological flaw whereby the rural context of the study, where majority of the deliveries are home based, would not yield comparable results to assess per cent/ proportion of Caesarean section deliveries against WHO standards. That aspect had been completely overlooked in earlier discussions.

10. Local politics
The complex local politics and tensions in some projects put researchers at risk. For example, the Upgraded Pada Swayamsevak scheme was in collaboration with a local organisation but included hamlets where the local organisation did not have a strong foothold. The CEHAT employee could face hostility in these areas. Researchers in the study on involuntary resettlement had to contend with unauthorised occupants wary of questions on their legal status. They also had to deal with a frustrated community: the builder did not meet various commitments, government schemes were not available, another NGO was reportedly making money in the resettlement process, and so on. At one point these tensions led to questioning the
very idea of doing a study.

11. The need for researchers to promote advocacy

As the study on the impact of involuntary resettlement progressed, it was refined in response to changes in the field situation. Tensions were building up and residents expected help from the researchers. Even otherwise, researchers began feeling obliged to do something – whether contacting housing organisations, going to the press, legal action, political lobbying or mobilising the local people. It became clear that the research team would have to promote advocacy at some level.

12. Preparing staff

The need for proper training and support of staff was apparent in a number of projects. In the domestic violence cell, it was essential to train counsellors to respond appropriately to women in distress. The unit also had to be prepared for counsellor burn-out. Researchers interviewing survivors of domestic violence needed to be trained to ensure that they were sensitive, and stopped the interview if the woman got upset. The involuntary resettlement study highlighted the institution's ethical responsibility to prepare staff for the demands made on them. Researchers experienced severe stress when confronted by frustrated residents asking for help for obtaining essential services.

13. Future problems: Growth of CEHAT's work

As CEHAT has grown, it has begun to take on large projects with massive funds which can influence the organisation's direction. This is one reason the proposed programme on establishing the right to health care was brought for IEC review, though it did not need certification. While the Anusandhan Trust is responsible for ensuring that CEHAT's overall functioning is ethical, the IEC noted that the project involves a number of collaborations, and lobbying with political parties. Both can raise ethical concerns requiring further articulation.

ORGANISATIONAL ISSUES

The first report of the IEC described the experiences and problems faced in developing a review mechanism for social science research in health. It also discussed organisational issues such as its

interaction with the peer review committee and other structures at CEHAT; staff orientation to ethical issues and the review process; and logistic problems in the review process. Some of these discussions continued over the previous year also. These are summarised below.

Who appoints the IEC?
In response to the IEC's queries, a joint meeting of Anusandhan Trust and CEHAT's Working Group responded that the Trust, which is the governing body, would appoint the IEC. Members would be selected by CEHAT's Working Group. Prospective members would be given the IEC's document defining its scope and responsibilities. Incoming IEC members would receive appointment letters mentioning the terms of reference. The IEC would report to the Trust and could approach it when necessary.

Should the IEC be a recommending body or a regulatory one?
It was felt that IEC members were not in a position to take on the responsibilities of regulation. Also, the current ethos at CEHAT is such that researchers do not ignore IEC suggestions. For the time being, the IEC should remain a recommending body. It would facilitate discussion on ethics in CEHAT, provide ethical review of projects and contribute to staff education through orientation meetings.

Should action projects come within the scope of the IEC?
Action projects are, at present, not certified though they are reviewed annually. The previous annual report presents guidelines and checklists developed for action projects. Some projects coming up for the IEC review contain a combination of action and research. However, there is some ambiguity about the difference between action projects and action research projects.

Role of the secretariat
Methodological issues are still being dealt with in the IEC. This could be avoided by more co-ordination with the peer review committee and a more rigorous process of scientific review within CEHAT. CEHAT's Peer Review Committee had asked for a joint meeting with the Institutional Ethics Committee. This was planned but did not take place.

Second, IEC members need to be given material for review in a systematic manner and with sufficient time to go through them. If a team is unable to provide documents in time it must wait for the next scheduled meeting. However the IEC recognised that staff are overburdened and must also follow funders' time cycles.

Finally, CEHAT has taken up a number of small initiatives, such as student research, independent of projects. It has been difficult to coordinate the ethical review of such work. It was felt that in such cases, collaborating organisations should be informed in advance of the need for ethical review, so as to prevent delays later. The difficulties faced by the secretariat became apparent when this report was being written. The IEC's self-evaluation concluded that the secretariat did a reasonably competent job. However, it was found that while the minutes were detailed, they did not contain details of some studies, and they did not necessarily clearly reflect the key decisions taken at the meeting.

Reporting and non-compliance regarding the IEC recommendations

In the course of writing this report, it became evident that the IEC is not routinely notified of the action taken on its recommendations. For example, the IEC reviewed a central-government funded proposal to document health facilities in Jalna district. Questions were raised about the value of doing this research, and the implications of CEHAT's involvement in gathering data for a government programme that it did not support, that it would not have control over, and that it even opposed as a member of the JSA. It suggested an in-house discussion on this project. However, it is understood that despite opposition from the peer review committee, this project was undertaken and completed, on the decision of the Coordinator. The implications of acting

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against the decisions of both the peer review committee and the ethics review committee need to be discussed.

Guidance to outside organisations
The Forum for Medical Ethics Society, a voluntary organisation working in medical ethics, requested IEC review for a study it was to conduct of drug promotion practices, since it did not have its own structure for ethical review. The FMES approached members of the CEHAT IEC as independent experts for their comments. This highlighted the need to develop a protocol for providing review to other organisations, with different resources.

Discussion on IEC clearance of short term proposals
Guidelines for clearance of short term projects (duration of six months or less) which may require the IEC clearance on an urgent basis were developed. It was decided that all research projects involving data collection from human subjects will be reviewed by the IEC irrespective of the duration of the project. An urgent meeting of the IEC to review such a project would be called. All other projects may be undertaken with approval of the Coordinator if the timeline is such that it cannot be fitted into the normal schedule of the IEC. The IEC would only review it post facto and not certify if the work has already commenced. In case of action projects, the IEC decided that in case the proposal cannot be reviewed before sending to the funding agency, it would be reviewed later. (Detailed protocol in Annexure B)

Future plans
The IEC plans to hold at least two training programmes in social science research ethics and one staff orientation programme in the coming year. Ethical review services could be extended to two more institutions. These should be involved in social science research with some focus on health. Finally, it is planned to write an article based on the annual report of the IEC and submit it to the *Indian Journal of Medical Ethics.*

IEC SELF-EVALUATION: A SUMMARY

Members conducted an evaluation of the IEC's work using a scale of 1 to 3 with one being 'unsatisfactory' and 3 'very satisfactory'. The evaluation parameters were those developed in the previous year. While the IEC felt it had done a good job in reviewing research it recognised the need to budget time for each project and focus its discussions, and reduce absenteeism. It also saw the need to promote discussion on ethical dilemmas, hold regular training sessions with CEHAT staff and receive formal training in ethics and current debates in research ethics. It was also felt that better coordination with the peer review committee could reduce the IEC's discussion of methodological issues.

Performance parameters relating to objectives – average rating 2.5

   1. **Timely review – rated 3**

Was the IEC able to review projects within a reasonable period of their submission?

Projects received a speedy review. On occasion meetings were rescheduled to meet the needs of project teams. Meetings were held regularly. Starting in December 2002, dates were decided upon and announced well in advance. There were some problems when material reached the IEC secretariat late, or when revised copies of the material were circulated just before the meeting.

2. **Protection of dignity, rights, safety and well being – rated 2.5**

Did the IEC deliberations deal adequately with concern the dignity, rights, safety and well-being of participants, researchers, institutions, funders, and the general public?

The IEC focused largely on participants. It was decided not to scrutinise budgets in detail. It was also decided that protection of participants' rights should take priority over protecting funders' rights. Some attention was paid to protecting the interests of the general public when examining the relevance of the study or its impact on the larger community to which the participants belonged.

3. **Relevant advice on ethical issues – rated 2.5**

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

Generally speaking, it provided relevant advice. In one case, there was a lack of consensus in the IEC and the issue was not resolved. Also, the IEC is still becoming involved in discussions over methodological issues. Finally, the fruitfulness of the review process was partly dependent on the capacity of the team to articulate ethical issues.

4. **Efforts to enhance awareness of ethical practices among CEHAT project staff –**

   rated 1

Has the IEC taken measures to increase CEHAT staff's awareness of the importance of ethics in practice?

No training programme was organised in this year. Teams rarely sought the help of internal members for filling in the checklists or articulating ethical issues. Since the ethical review process has become institutionalised, internal members did not actively seek out researchers to help them; it was expected that teams would follow the rules laid down for ethical review.

5. **IEC meetings – rated 2**

How disciplined have the IEC meetings been in their preparation, conduct and follow-up?

Preparation for the review was inadequate, partly because of the delay in receiving the materials, and was rated 1.5. Absenteeism was a problem; one-third of IEC members were absent at many meetings.

Conduct of meetings was inefficient and rated 2. Without proper time-budgeting too much time was spent on some projects while others got too little time.

Functioning of the secretariat was rated 3. Minutes were prepared on time and circulated. Certificates were made and handed over to the teams promptly. However, clarifications were not sought from the teams about the acceptance or rejection of the suggestions of the IEC.

6. **Efforts made by the IEC for self-training – rated 1**
Has the IEC made attempts to get trained on the job and if so, how? Has there been a progressive improvement in the quality of deliberations at the IEC meetings?
Earlier members of the IEC were invited for inputs, and there was some discussion about current debates in ethics. However, IEC members have not undergone training either individually or collectively.

7. *Effective and optimal use of available resources – rated 2*

Has the IEC made effective use of the expertise, time and facilities at its disposal?Has the IEC used the resources in terms of (a) expertise, (b) time, and (c) infra-structural facilities at its disposal effectively?
The multi-disciplinary team's expertise could not be optimally utilised largely due to absenteeism. It was felt that IEC members should send written comments if they were not going to attend the meeting. While time budgeting was not done properly all projects which requested review in a particular meeting were reviewed.

8. **Quality of the review process – rated 3**
Has the review process been objective, fair, enabling for researchers and forthright?
The quality of the IEC endeavour was perceived to be very satisfactory. Additional improvements in quality could be achieved by paying attention to time budgeting, focused discussion on ethical issues and better preparation. Further, the IEC would gain expertise by reviewing projects of external organisations.

SUMMARY OF
STAFF EVALUATION OF THE IEC

Research teams who had their work reviewed by the IEC in the previous year were asked to comment on their expectations of the IEC, its contribution, the impact of the ethical review process on their work, problems they encountered, and their suggestions for enhancing the IEC's contribution to the ethical conduct of CEHAT projects. Their comments are summarised below.

1. **What were the specific contributions of the IEC?**
   One of the IEC's major contributions seems to have been to make staff conscious of ethical issues in research. Researchers on the sexual assault kit described specific advice they benefited from, such as mentioning the need for separate consents for research and service delivery, the need for the medico-legal process to minimise the trauma it inflicts on survivors and the need to maintain patient confidentiality when speaking to the media. The SATHI cell was prompted to reflect on ethical issues arising from actions which follow research, and wrote a brief note for the PRC on the special needs of action-research projects. The Dilaasa team found the review of methodology and data collection tools useful. For researchers from the involuntary resettlement study, the IEC provided a platform for discussion while dealing with a difficult situation with many ethical problems. The IEC also questioned the feasibility and ethical soundness of some research tools, leading to their modification.

2. **What were your expectations from the ethical review process?**

   Overall, researchers came to the IEC expecting that their proposals would be improved by the review process – they looked for a critical appraisal of the work sent for review and suggestions for changes. Researchers expected an orientation in ethical issues, and also support addressing specific dilemmas. Some reported appreciated what they described as brainstorming on the ethical implications of their project. It was felt that the IEC would pick up issues that might have been overlooked. Researchers also hoped the interaction with the IEC would help them develop the skills to analyse ethical issues in their ongoing research. Finally, researchers also expected guidance when they came across problems during their research.

   The absence of many external IEC members from the discussion was felt; researchers presumably looked forward to their expertise. Some expected more clarity from the IEC about its role in improving the proposal, and more in-depth discussion on the ethics of action research. The need was expressed for the development of guidelines for action research.

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3. **What was the impact of the ethical review process on your project?**

On occasion, questions raised by the researchers during the review process resolved issues they had been grappling with earlier – such as how to maintain confidentiality in a focus group discussion. Others felt the project was not changed except that the IEC's advice was noted. Sometimes, the IEC comments on scientific aspects of the research were productive, whether by prompting a re-examination of scientific details or strengthening the methodology. One team reported that the IEC's comments sharpened its understanding of ethical dimensions of work with the health system. The review process helped teams anticipate ethical issues they might face and also suggested measures to make the process ethically sound. It also led to more frequent debates within the team on ethical problems and how to deal with them.

4. **What were the problems that you experienced during the process of review?**

The project on the sexual assault kit found IEC members were confused about whether it was an action or research project. Researchers from the Caesarean section action-research study found IEC members spent too much time on scientific aspects such as sample size which had no direct relation to ethical aspects of the project. This also left little time to discuss ethical issues, or for the researchers to respond to the IEC's comments on the consent form. It was felt that while scientific and ethical aspects are interrelated, the role and focus of the IEC discussions should not be lost sight of. The Dilaasa team reported that IEC members received the wrong versions of some of the documents to be reviewed, as a result of miscommunication with the Pune office. The involuntary resettlement study stated that it had not had any problems with the review process.

Unanticipated problems cropped up that could not be taken to the IEC for a response. For example, during the abortion study, researchers had to decide on people's competence to be interviewed.

5. **What are your suggestions for enhancing the (IEC's) contribution to the ethical conduct of CEHAT projects?**

Though the IEC's suggestions are not binding, the importance of adhering to the IEC's suggestions was noted. It is also important for researchers to communicate to the IEC any difficulties they have in following its suggestions. Finally, ethical review must become **better known.** Staff members making public presentations must discuss the ethical review process as well as their research experiences, so as to aid wider dissemination of the process.

A number of researchers felt the need for regular interaction between CEHAT staff and the IEC. It was felt that researchers had not really internalised the ethics of research and action. New members in particular need to be educated on ethical practice in social science research. The IEC should hold regular staff orientations on how to address ethical issues that might be anticipated in their projects.

It would also be useful for IEC members to keep themselves updated on the latest debates in the field of ethics and to incorporate these ideas into the review process. Researchers would also benefit from lists of recommended reading.

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ANNEXURE A

Project Certification Summary
December 2002 – October 2004

1. Study on the health status of women prisoners in central prisons of Maharashtra

   Objective: To study the mental and physical health of women prisoners based on interviews.
   Phase of review: Phase 1 review, at the time of submitting the proposal.
   Date of review: December 22, 2002.
   Summary of certification: The study is found relevant and worth pursuing. It is however necessary for the team to study the logistic problems involved, make pilot visits to the prisons, create an environment where there is a possibility of getting credible answers, and organise a meeting of NGOs working in prisons who can give insights and support the study and the implementation of its findings. This study was not undertaken since the government of Maharashtra which was commissioning the study dropped the idea.

2. *Abortion rate, care and cost: a community based study*

   Objectives: To arrive at abortion incidence rate at the state level, and to understand trends on abortion care sought and received, and cost incurred.
   Phase of review: Post fieldwork and before draft report
   Date of review: February 2, 2003
   Summary of certification: There was no certification as this was during phase III of the project post field work. Review at this stage is optional. The dilemmas that arose during field work were discussed and documented.

3. *Towards establishing the right to health as a human right*

   Objective: To establish health as a fundamental right through various activities.
   Phase of review: Pre-proposal phase
   Date of review: April 20, 2003
   Summary of certification: There was no certification since this was not a research project. The IEC noted that since the programme included several small projects, which would require IEC certification, time budgeting should be done for each project within the programme, for IEC clearance.

4. Community based study for the estimation of Caesarean section rates and hysterectomy rates

   Objective: To conduct a community-based study to estimate the rate of Caesarean sections and hysterectomies in 14 villages of Aajara Taluka, in the previous three years.
   Phase of review: Phase II, before launching fieldwork.
   Date of review: April 20, 2003
   Summary of certification: The IEC had reservations about the relevance of the study, its methodology, the risk to participants and the methods to protect them. It recommended that if the team wished to undertake this project it should modify the project proposal keeping in mind the IEC's discussions and its recommendations. Modifications to the introductory note and the informed consent note were also suggested.

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5. **Involuntary resettlement of a slum in Mumbai: A human rights perspective**

    Objective: To look at the impact of involuntary resettlement on people's lives, especially on their health, social life and education, across gender and age variables.
    Phase of review: Phase I
    Date of review: April 20, 2003
    Summary of certification: The IEC considered this study to be relevant and certified it with modifications in the study format and interview schedule and the inclusion of an informed consent form in Hindi.

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

    Objectives: 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 to work with a rights-based approach with a focus on Primary Health Care.
    Phase of review: Annual review.
    Date of review: June 15, 2003
    Summary of certification: There was no certification since this is not a research project.

7. **Upgraded Pada Swayamsevak Scheme**

    Objective: To launch and run, for two years as a pilot project, an improved, upgraded version of the PSS (Hamlet Health Volunteer Scheme) supported by strengthening other village level health services, in a selected tribal taluka in Maharashtra. This could provide a model for upgradation of Hamlet Health Volunteers throughout tribal areas in the state.
    Phase of review: Before sending the proposal
    Date of review: June 15, 2003
    Summary of certification: There was no certification since this is not a research project.

8. Involuntary resettlement of an urban slum community

    Objectives: To look at the impact of involuntary resettlement on people's lives, especially on their health, social life and education, across gender and age variables.
    Phase of review: Phase II, prior to fieldwork, after finalisation of methodology. This was the second review of the project at this stage.
    Date of review: June 15, 2003
    Summary of certification: The IEC examined revisions based on the April 20, 2003 meeting. Because of the changed field situation the IEC recommended the addition of questions to the modified questionnaire probing into the impact of changes after resettlement. It also suggested adding qualitative analysis.

9. ***Impact of counselling at the Dilaasa Crisis Centre for Women***

    Objectives: The study to assess the effectiveness and impact of crisis counselling would:
    l   Assess the impact of the crisis intervention model and test indicators of counselling effectiveness in order to develop measurement tools and best practices;
    l   Record women's experiences of accessing services at the Dilaasa Crisis Centre;
    l   Examine processes by which counselling strengthens women's capacities to cope with violence; and
    l   Gain insight into the effectiveness of hospital-based intervention programmes for women facing violence.
    Phase of review: Phase II, before launching fieldwork, to discuss issues based on the draft methodology.
    Date of review: August 24, 2003

Summary of certification: The study was found relevant since the centre was completing three years and CEHAT was in the process of re-negotiating its collaboration with the BMC. The study was approved with modifications in the protocol and the language of the consent form. These included:

l Restating the objectives of the study as well as the risks and benefits to participants, based on IEC discussions;

l Clearly stating that the information from the intake form and other case records would be used for the study.

l Mentioning the options of audio-taping or note taking in the consent form and seeking written consent accordingly.

10. Dilaasa Crisis Centre for Women

Objectives: To set up a response cell for survivors of domestic
violence in a public health care facility; provide counselling to women facing domestic violence; provide shelter within the hospital for 24 hours, and provide legal aid and services.
Phase of Review: Annual review.
Date of review: September 21, 2003
Summary of certification: There was no certification since this is not a research project.

11. Involuntary resettlement qualitative study proposal (qualitative aspect)

Objectives: To look at the impact of involuntary resettlement on people's lives, especially on their health, social life and education, across gender and age variables.
Phase of review: Phase II, before fieldwork
Date of review: December 7, 2003
Summary of certification: The IEC concluded that the qualitative study would serve as a valuable complement to the earlier quantitative study, with some modifications. Looking at the findings of the quantitative study and the feedback from the research team as well as the current expanded plan of resettlement in Mumbai, the IEC felt that the research team had an ethical responsibility to promote advocacy and actions through its networks. Given this changed trajectory of the study outcome, the consent note needed to incorporate the possibility of community participation in future action. The IEC recommended that the research team seek consensus within the organisation on the emphasis between action and research.

12. Sexual Assault Evidence Kit

Objectives: To finalise the sexual assault evidence kit after consultation and pretesting. To carry out advocacy for collection of proper evidence in case of sexual assault and advocate for the use of the kit to collect evidence.
Phase of review: Before commencing work on the project.
Date of review: 14-15th February, 2004
Summary of certification: This was an action project
so no certification given.

13. Quality of reproductive and child health services

Objectives: To understand women's perceptions about the quality of services and know their path of accessing abortion services. This was an identified gap in the earlier RAI study. It was to be conducted in three states.
Phase of review: Before sending the proposal for funding. (Pre proposal note)
Date of review: 14th and 15th February 2004
Summary of certification: Specific recommendations were given to the team for ethical conduct of the study.

14. **Abortion rate, cost and care: A community based study in Maharashtra**

Objectives: To arrive at abortion incidence rate at the state level, and to understand trends on abortion care sought and received, and cost incurred.
Phase of review: Draft report
Date of review: 14th and 15th February 2004
Summary of certification: Specific recommendations were made which the team incorporated into the report before publishing it.

15. **Integration and replication of Dilaasa project**

Objectives: To integrate and replicate Dilaasa within the public health services.
Phase of review: Before sending the proposal to the funding agency.
Date of review; 25th April, 2004
Summary of certification: No certification at this stage was required.

16. *Quality of reproductive health services*

Objectives: To understand women's perceptions about the quality of services and know their path of accessing abortion services. This was an identified gap in the earlier RAI study. It was to be conducted in three states
Phase of review: Before starting field work
Date of review: 10th May, 2004 and 21st May, 2004
Summary of certification: The team was asked to make extensive modifications in the tools and consent form. The team reworked on the tools and consent form and presented these on 21st May, 2004. The IEC recommended that the team should redesign the tools to ensure that only questions strictly relevant to the scope of the study are included. The consent form should include the time required for the interviews. It was certified during this meeting with the above recommendations.

17. *Resource mapping in Jalna district for rational use of infrastructure*

Objectives: To map the availability and distribution of all facilities in the selected district and to assess the potential for participation of private providers in public health care programmes.

Phase of review: Before starting field work.

Date of review: 4th July, 2004
Summary of certification: Suggestions were made for modifying the consent form. The IEC did not certify it as the study was anyway going to be conducted and the methodology, etc. had come from the government. IEC was not convinced of the benefits of participation in the study to CEHAT as an organisation protecting public heath. It felt that the study was putting CEHAT's credibility at risk, as it would have no control either in shaping the objectives or outcome of the study or control over use of the findings of the study.

18. *Developing Standard Treatment Protocol*

Objectives: To develop guidelines for rational drug use, standard treatment protocols and training guidelines for the same.
Phase of review: Before commencing work.
Date of review: 4th July, 2004
Summary of certification: The IEC suggested that the protocol should also include non-drug aspects of the treatment and the team should conduct training of the staff to use the protocols and give public education about the STPs.

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19. Advocacy on sex selection, age at marriage, gender equity and related issues impinging on reproductive health.

    Objectives: To review the government's IEC material on
    the issues concerned, capacity building of the implementing agencies and to develop a creative brief on the issue of sex selection, age at marriage, gender equity and related issues impinging on reproductive health.
    Phase of review: Before commencing work on the project.
    Date of review: 10th October 2004
    Summary of certification: No certification as it was an action project. There was discussion on possible risks as a close collaboration with the government was involved. It was decided that the team would seek guidance from IEC as and when they face any ethical dilemmas.

20. SATHI Cell for Community Health and Health rights. (Phase II)

    Objectives:

    Phase of review: **Before sending the proposal to the funding agency.**

    Date of review: **10th October, 2004**

    Summary of certification: **No certification as it is an action project.**

21. Support capacity building in monitoring and evaluation in the field of reproductive health and sexuality amongst NGOs in India.

    Objectives: **To develop training modules and conduct training for NGOs working in the field of reproductive health and sexuality, on monitoring and evaluation, to help them improve their quality of work. Opportunity for CEHAT to develop in training.**

    Phase of review: **Before sending to the funding agency.**

    Date of review: **10th October, 2004**

    Summary of certification: **No certification as this project does not fit either in the research or action project category. The possible ethical issues were discussed vis-à-vis CEHAT as an organisation.**

ANNEXURE B

Guidelines for IEC review of
short term projects

The projects of duration less than six months can be termed as short-term projects.

A] Protocol for short-term projects involving data collection from human subjects:
All the projects, which involve data collection from human subjects including those projects where only brief interviews would be conducted, will have to be reviewed by the IEC irrespective of the duration of the project. An urgent meeting can be called for the review of such projects for which only one internal and two external IEC members could be present. Other IEC members can give their comments on email. The coordinator can use his/her discretion to request for such urgent meeting. Only in some special cases, the coordinator can give his/her approval for bypassing the IEC review before sending the proposal of the project to the funding agencies.

B] Protocol for all other projects
All other short-term projects may be undertaken with approval of the coordinator if the timeline/deadline is such that it cannot be fitted into the IEC normal schedule. The researcher/program person proposing this will have to give a commitment that the IEC guidelines in conduct of research/activity will be adhered to. At the next scheduled meeting of IEC, only post facto review of the project would be done. If the work has been already commenced/ completed, then no post facto certification would be done by the IEC. In that case, it should be explicitly mentioned in the report that the IEC has not certified the project. The output/outcome of the research/activity will be reviewed by the IEC provided that the comments given by the IEC would be incorporated in the final report.
For action projects, review would be done as and when possible after the project proposal has been submitted to the funding agencies.
To find out the probable ethical concerns in any activity however small that activity may be, the researcher should ponder over following points and then if satisfactory answers could be found for all these questions only then can the researcher think about taking up that particular activity.
ı What is the necessity of this activity?

- Is there any alternative to this activity?
- What would be the potential public gain due to this activity?
- What is the commitment of CEHAT to follow up on this activity?
- What are the ways to mitigate any risks that arise through this activity?

ANNEXURE C

Checklists

CHECKLISTS: RESEARCH PROJECTS

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 funding agencies 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 as sections (A), (B), (C) and (D).

(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 reviewed brief	Period	IEC review and	by IEC	comments in
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:
   l Project proposal
   l Note on ethical issues involved and strategies envisaged   while addressing them.

(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 brief	Period	IEC review and	by IEC	comments in
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?

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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-à-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:
    l Project proposal
    l Draft methodology
    l Protocols
    l Draft letter of introduction
    l Draft informed consent form
    l Plan of analysis.

(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 IECProject 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 III¹

1. Protecting the rights of research participants:
    a. Lease 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? (E.g. 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?

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

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 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

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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).

(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, funding agency.
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:Duration:
Field-work location:Field-work location:
Collaborators (if any):
Funded by:

Project phases completed and reviewed by IEC

Project phases reviewed in brief	Period	IEC review and	by IEC	comments
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:
    l The draft report.

ETHICAL GUIDELINES AND CHECKLIST: ACTION PROJECTS

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 has 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 effort 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.

(A)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 that 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 (its 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 it's 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-à-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 funding agencies.
  - c. The developments including shortcomings of the activity should be communicated to society at large honestly and faithfully. Similarly, commitments to funding agencies should be respected and communications made to them. Mechanisms should exist to resolve conflicts between commitment to funding agencies 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 over a period of time? The withdrawal strategy, a responsible ensuring of the sustainability of the process and safeguards against backlash or vindictive actions by privileged groups would need to be formulated.
  - f. Crises and unforeseen situations:
    - i. Wherever structures are being disturbed, to ensure that processes to cope with this situation are in place; both in terms of capability building of the community and commitment of the organisation.
    - ii A broad 'contingency plan' should be formulated for crisis situations especially regarding how decision making will be done, how responsibilities will be shared and what would CEHAT's commitment be in this regard.

(B) ANNEXURE III (B)CHECKLIST FOR ACTION PROJECTS
     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 funding agencies are respected? And what mechanism of regular communication with them will be adopted?
   c. By what mechanism will possible conflicts between commitment to funding agencies 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 D

The Institutional Ethics Committee: Member Profile

External Members:

Dr. Jaya Sagade (Chairperson) is the Vice Principal, ILS Law College, Pune. She holds LL.M. and Ph.D. from the University of Pune and S.J.D. (Doctor of Juridical Science)

from the University of Toronto. She has been teaching law for the past twenty-seven years and is associated with many voluntary organizations. She has interest in developing legal aspects of ethics.

Joseph Lobo is Head, Department of Philosophy, Fergusson College, Pune. He was also the founder-director of VACHAN, a development NGO working in Igatpuri taluka, and of the Centre for Development Research and Documentation (CDRD)

Ms Nagmani Rao is a senior lecturer in Social Work in Karve Institute of Social Service, Pune. She holds a masters degree in Social Work and PG Diploma in Women's Studies. She has had a long association with feminist issues and has been a core member of Stri Mukti Sangharash, a rural women's organisation in Sangli district. She has also been a consultant to NGOs, focussing on rural women's issues in Pune district.

Ms Sandhya Srinivasan is a freelance journalist and consultant with master's degrees in sociology and public health. She writes on health and development for *the Inter Press Service*, *Panos Features* and other print publications and websites, and was a Panos Reproductive Health Media Fellow in 1998, writing on the infertility industry in India. She is consultant on health and population for the development website www.infochangeindia.org. Ms Srinivasan is executive editor of the *Indian Journal of Medical Ethics,* member of the editorial board of *Developing World Bioethics and* member of the institutional review board of the National Institute for Research in Reproductive Health. In 2002, she was awarded an Ashoka Fellowship for work in medical ethics.

Dr Saumitra Pathare is a consultant psychiatrist working inPune, India. He has an interest in mental health policy, legislation and human rights issues. Since October 2000 he has been an Adviser to the World Health Organisation (WHO), helping to draft and prepare a mental health legislation manual, primarily for developing countries to update their laws regarding mentally ill. He has also worked on the Policy and Service Development project of the WHO, which is aimed at improving mental health policies and service provision across the world.

Ms Shabana Diler has done her masters in social work. She is actively involved the Kagad Kaachpatra-Kashtakari Panchayat, a union of waste paper pickers since the last five years. Women's issues are her special area of interest and work.

Internal members

Dr Anant Phadke, M.B.B.S, has been one of the leading health advocates in India since the eighties. He is actively involved in organisations like Medico-Friend Circle, LOCOST, Lok Vidynyan Sanghatana. Special areas of interest- rational drug policy,

community health worker training. He is based in Pune and is the Coordinator of SATHI– CEHAT.

Ms Padma Deosthali has done her masters in Social work and is working with CEHAT on issues of women and health, focusing on women's work, violence against women and ethics. She coordinated Dilaasa, joint initiative of CEHAT and the Municipal Corporation of Mumbai. She is also trustee of CHEHAK that runs a community based school called SAHAYOG for adolescent girls and health care programme.

Secretariat

Ms Neha Madhiwalla (Secretary) has a post graduate degree in social work who has worked in CEHAT since 1996 as researcher on studies on women and health, ethics and human rights. She is actively involved in organising workshops for doctors and students of medical sciences on medical ethics. She is currently the managing trustee of CHEHAK Trust which runs a community based programme for primary education and health care called Sahayog.

Nilangi Nanal Masters in Health Sciences and Graduate of Ayurveda stream of Medicine. She has been working in CEHAT since 2002. She has been responsible for training Women Community Health Workers, especially in the field of Women's Health and Herbal Medicine. She has also contributed to research and documentation in the area of Nutrition and Primary Health care.