



**Reviewing public health and social science health  
research, the challenges of collaboration, capacity  
building and defining standards**

**Multi-Institutional Ethics Committee**

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## Status of ethics review of science research

- Not mandatory by law
- Most institutions have no mechanism for ethics review
- Not required by most major peer-reviewed journals
- Unresolved debate about the validity of the ethics review process for social science research – e.g. iterative methodology, unstructured fieldwork processes, complex distinctions between researcher and participants



## **Should Social Science research be considered as 'low risk'?**

- Has potential for misrepresentation and stigmatisation of a particular group
- May selectively exclude reality of marginalised groups
- Exploitation of participants (using their time, hospitality, personal information) without consent or adequate compensation
- May perpetuate unequal relationships of exchange between participants and researchers



## Does social science research have/need to have direct application/benefit?

- More and more research being done directly for programmes
- Benefits may accrue from participation in research itself – conscientisation, reflection, deliberation
- Participant communities' access to the knowledge creation process may empower them to take action



## **Multi-institutional Ethics Committee (M-IEC)**

- Multi-disciplinary committee
- Established in 2000
- Reviews - research activities, as per the Standard Operating Protocol
- Internal and external members
- Collaboratively managed with 3 affiliated institutions and five centres
- Reviews approximately 25-30 new applications per year.
- Process of ongoing review - annual

# Multi-institutional Ethics Committee (IEC)

## *Affiliating Institutions*

- *Anusandhan Trust, Maharashtra*  
(CEHAT). (CSER). (SATHI).
- *(SNEHA).*
- *(SEWA-RURAL).*



# Types of studies reviewed

- Health systems research
- Epidemiological studies
- Operations research – situational analysis, evaluations, cluster randomised control trials
- Action research
- Secondary data based research
- Meta-research (theoretical)



## **Debates and Decision of M-IEC (2000-2010)**

- Ancillary Care
- Post trial access





# Ancillary care

## Major areas

- Counseling/Information provision
- Protecting and promoting access to services and rights
- Follow up on accidental discovery



# Counseling

## Studies on gender-based violence

- *Married women*
- *Adolescent women*
- *Female inmates of prisons*
- *Women with disability*
- *Clients of crisis centre*
- *Female healthcare workers*



## Counseling

- Standard of care: Counseling for distress caused by the interview - Respondents- Psychologically distressed by recollecting past unpleasant, traumatic experiences
- Ancillary care: Participation in research as a therapeutic process. Encouraging women to seek help/assistance



## **Counseling (Cont..1)**

*Women with disability:*

*Responsibility of the researcher to provide both types of counseling*

*Sign a formal collaboration with legal aid, health and women's organisations to provide information, follow-up, support and care for those women who may choose to take action*

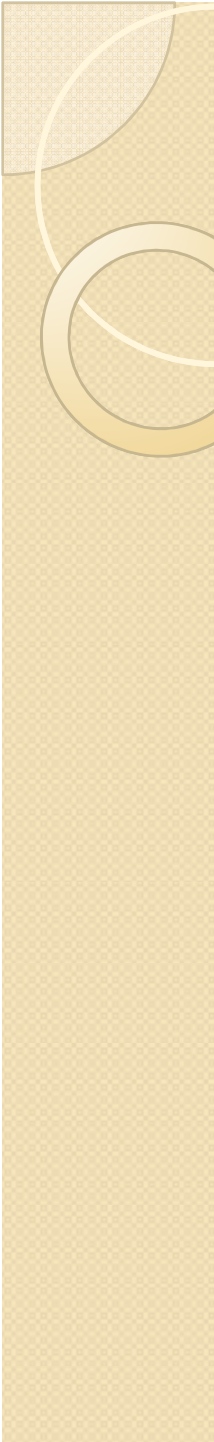


# Counseling

## Adolescent girls

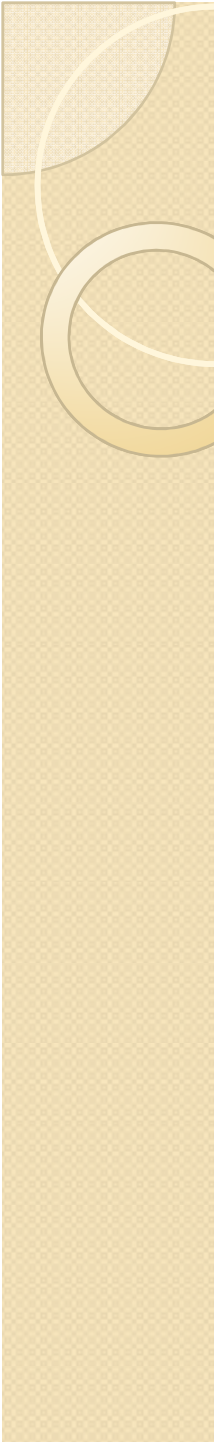
*Responsibility of researchers AND local organisation facilitating research*

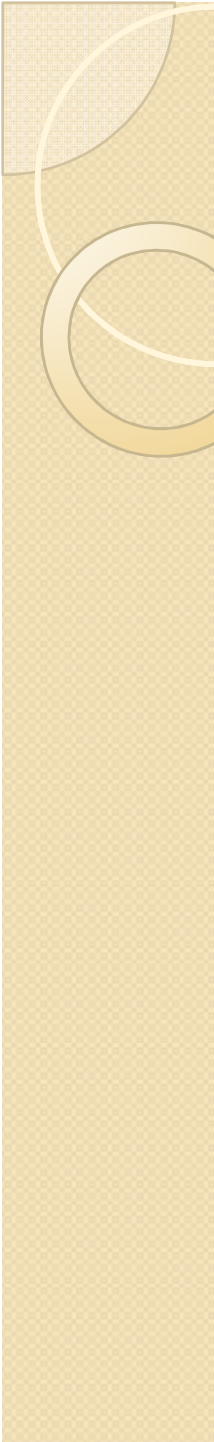
- *Researcher instructed to prepare a complete database of participants and make it accessible to the local organisation facilitating research study*
- *Preparation of a formal MoU outlining the roles and responsibilities of both parties to address requests for help, information and intervention*



## Protecting and promoting access to services and rights

- *Study on Involuntary settlement; Action research study involving partnership with a local service delivering NGO*
- *Debate:*
- *Community faced immediate crisis of water and electricity being cut off*
- *Community deprived of several rights (access to transport, PDS)*
- *Local service delivering organisation only source of medical care*

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- *Decision:*
  - *Change methodology to avoid participant selection from the records of the local service providing NGO so as to prevent a conflict of interest*
  - *Researchers told to stop research during crisis phase and make all possible efforts to advocate with local bureaucracy to restore services*



## Protecting and promoting access to services and rights

- *Measuring Cesarean section deliveries in a village*

### *Debate:*

- *Action research aimed at informing local campaign against medical malpractice (unnecessary C-Section)*
- *Single private obstetrician serving entire sub-district*

### *Decision:*

- *Alter and resubmit proposal to expand the sample size to cover more districts and providers.*
- *End result- Research team dropped the study*





## Follow up on accidental discovery

*Cluster Randomised Control Trial for improvement of urban health through the establishment of information resource centres*

*Debate:*

- *While study was not aimed at providing clinical services, it had a provision of routine surveillance, which would bring cases of serious acute/chronic illness to light*

*Decision:*

- *Responsibility of the research team to establish a protocol for responding to such events in BOTH intervention and control areas.*



# Post trial access

- *Returning findings to the participants*
- *Commitment to utilise findings for advocacy/activism*
- *Ensuring the establishment of institutional mechanisms to provide continued support and care*



# Returning findings to participants

- Standard practice to publish a ‘lay persons’ report of the findings
- Organise local meetings to disseminate the report and seek feedback
- Prepare information/educational material based on the findings to address common concerns and information needs
  - Slide show on abortion rights
  - Fictional narrative stories to highlight findings without risking identification of participants
  - Booklets on rules/procedures for obtaining birth certificate, ration card and school admission



## *Commitment to utilise findings for advocacy/activism/reform*

*Study on acceptability of Vasectomy in an Indian State  
Debate:*

*Study aimed at informing policy on vasectomy  
conducted by international professional research  
organisation not having local roots*

*Decision:*

- Establish an advisory group- Researchers and health ministry decision makers*
- Work with Service Organisations to ensure continuity of action*
- Disseminate to key stakeholders by participating in relevant fora*



*Ensuring the establishment of institutional mechanisms to provide continued support and care*

*Formative research for building a crisis centre for violence affected women*

*Debate: Study conducted by NGO in government hospital with the intention of starting a service*

*Decision:*

- *Research team was asked to provide details about plans for*
  - *training of trainers*
  - *model for crisis centre*
  - *establishment of collaboration with Municipal and local NGO*



## Discussion

- There is a need to evolve standards for ethical obligations such as ancillary care and post-trial access for non-clinical research
- Obligations of social science researchers can be defined either too cursorily (ensure publication of findings) or too stringently (ensure establishment of an institutional mechanism).



# Discussion

- In defining standards, several factors need to be taken into account:
  - Participants' profile and needs
  - Context and change processes
  - Researchers' profile and role
- 'Risk' and 'Benefit' not adequate/appropriate basis for determining the type and quantum of ancillary care and post-trial access. Then what should be the basis for making such judgments?