

# Community participation in epidemiological studies and clinical trials

*Dr. Sanjay Mehendale, MD, MPH*

Deputy Director [Senior Grade]  
National AIDS Research Institute, Pune, India  
Indian Council of Medical Research

- **It is the responsibility of the research team and the investigators to ensure that the human subjects participating in their research studies are protected**

**Well-trained, competent and  
committed researchers**

**Protection of  
human subjects**

**Well-informed  
and empowered  
research  
participants**

**Strict review and  
monitoring  
mechanisms**

**Why are research participants not able to insist on their rights related to safety and welfare?**

- Lack of awareness among research participants
- Absence or lack of information on mechanisms that will look into their complaints

**What can be done?**

- Effort in making research participants aware of their rights, ethical principles in conduct of research and mechanisms to address grievances
- Making such information resources widely known: Development of appropriate education/ study information material
- Involving the community/ stakeholders in research planning and implementation

**Community information, involvement and participation can greatly help in acceptance of research by the people**

# Goals of community involvement

1. Involving community in design and conduct of research
2. Ensure community support to ongoing research: NGO network and GO-NGO partnership
3. Community education and information
4. Identify and recruit participants in research studies

## The genesis and steps in community involvement in clinical research conducted at the National AIDS Research Institute ....

Although the original purpose of establishing Community Advisory Board [CAB] at NARI was to satisfy the foreign funding agencies, it was realized that CAB would significantly contribute to all the projects of NARI

**Community Advisory Board  
CAB**

As the focus of NARI research shifted from clinic-based studies to community based studies, need to involve community was increasingly felt and that led to conceptualization and finalization of Community Involvement Plan [CIP]

**Community Involvement Plan  
CIP**

The commitment to involve community should be at the level of organization as well as community partners.

- **Community inputs in managing issues related to study participation, recruitment and care, support and treatment**

- **Understanding the community concerns and educating the community and potential research participants is crucial**

# Community involvement through additional community education and awareness efforts

---

Awareness programs

Exhibitions

Community oriented research projects

1. Adolescent sexuality study
2. Stigma and discrimination study
3. Women and AIDS study

Rallies, marathon runs

# Summary of lessons learned in community integration with research

1. Participation in protocol team meetings and conference calls helped in getting socio-culturally relevant inputs: male consent
2. Sustained efforts and transparency are necessary to win the confidence of partners
3. Time and resource spent in this effort is likely to give increasing benefits
4. Training or peers is very critical: It takes time, repeated refresher trainings, regular meetings to retain focus
5. Involvement of peers helped in better community response and reduction in stigma
6. We could demonstrate that GO-NGO partnership can be established and this helped in gaining trust of the community: self-referrals
7. We got insights in developing community friendly methods of imparting HIV/ AIDS education and information

Thank you!