

Forming Joint Forum of Ethics Committees at Local Level



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Role of Ethics Committee (EC)



Ethics

*Not a natural science but creation of Human Mind
Open to influence of time, place and situation*



Role of Ethics committees

- ❖ *Ensure scientific soundness of the research proposal*
- ❖ *Ensure a competent review of all ethical aspects of research*
- ❖ *Ensure welfare and safety of research participant*
- ❖ *Important regulators of clinical research at local level*

Ethics Committees-The Indian Scenario



- Isolated existence of EC's in India
- Lack of communication with regulatory agencies like DCGI and ICMR
- No communication with other ECs in country
- No central registry of ECs functional in India
- No oversight mechanism in place
- Lack of accountability with a central authority
- Self-sufficient bodies with independent existence

Objective



- Address the need to form joint forum of EC at local level

ECs in India: The need to come together



- Essential to establish a communication network among ECs
- Need to work in collaborative manner to develop a uniform code of conduct
- Work together to develop a network with regulatory agencies
- Need to interact
 - Discuss case studies/issues faced by them during EC operations
 - Share their experiences
 - Update themselves with new information
 - Work towards capacity building
 - Work for betterment of community they represent





Initiative to bring together
EC's functional in Pune

Members of EC's functional
in Pune were contacted

Scientific meeting in “Ethics
for Humans” was organized at
Chest Research Foundation
Pune-Feb 2011

Round table meeting attended
by 30 delegates of various
EC's in Pune

Sponsor representatives were
also invited

Expert talk followed by round
table discussion of various
ethical issues

Our Experimental Initiative : The First Scientific Meeting in Human Ethics





Scientific Meeting in Ethics : Outcomes

Served as an eye-opener on complex ethical issues

Provided clarity on issues related to subject compensation, trial insurance, informed consent

Introduced to working of FERCI ,FERCAP

Proposal of forming a joint forum of EC's in Pune was put forth-encouraged by all participating delegates

Brought together members of ECs in Pune

Served as an initiative for Pune EC forum to meet at regular intervals



Pune ECs Joint forum- Taking it forward



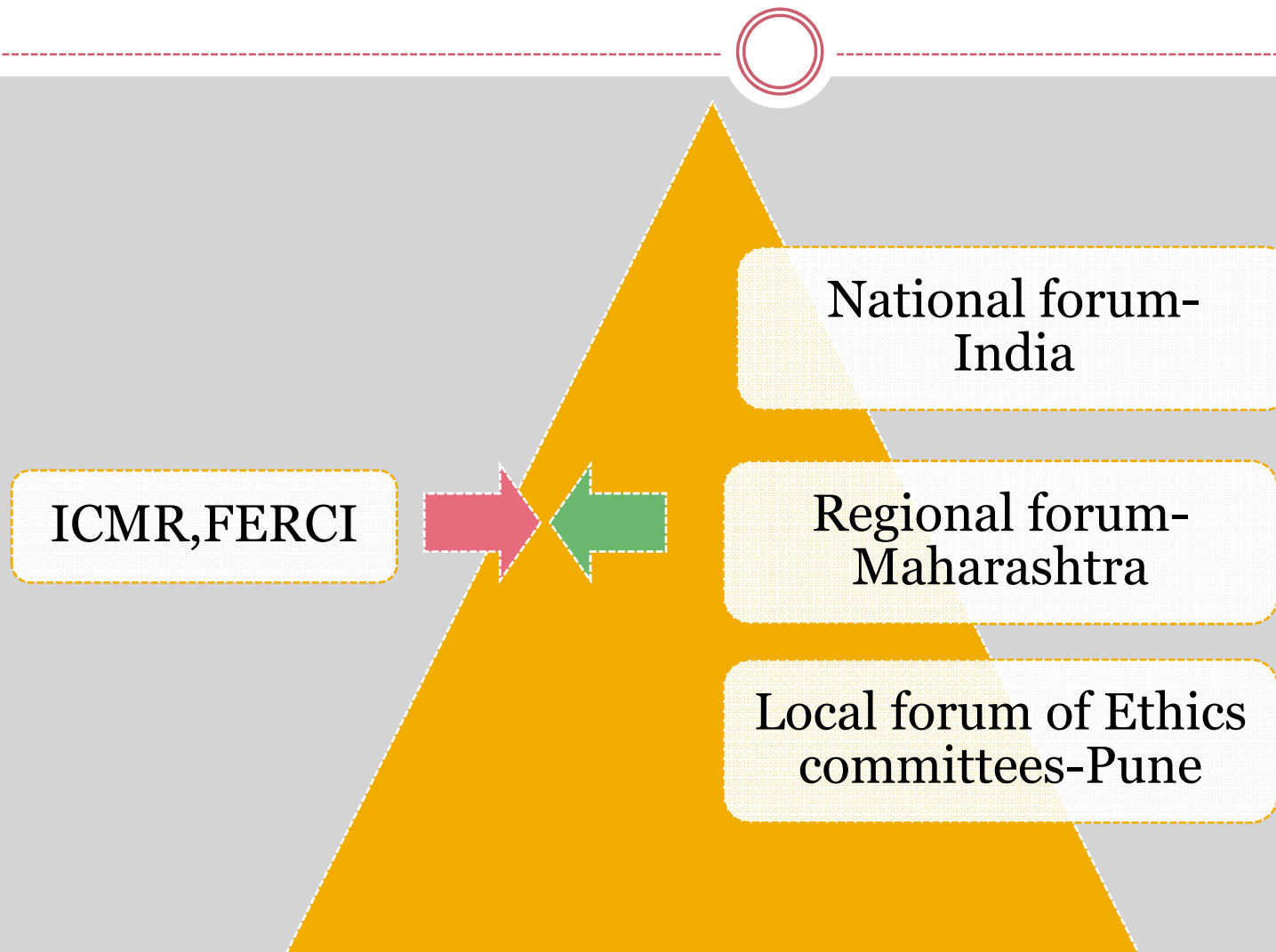
- **Second Meeting** of the joint forum held in October 2011
- Organized by EC associated with Lupin Bio-Research Center Pune
 - Attended by 50 members of EC's
 - Various informative sessions on ethics in clinical research
 - Paper presentation on subject compensation and EC registration

Forming a Joint Forum-The Pune Model



- Form a joint forum of ECs at local level
- Forum to serve as platform to address issues and solve dilemmas faced during EC review process
- Expanding the collaborative network at national level
- Joint forum to network with national committees like FERCI
- Collaborate with ICMR to establish a central EC registry and an effective oversight mechanism

The Pune Model: Proposed Plan



Future Directions



- ECs in India need to come out of isolation and interact
- ECs need to be vocal about the problems faced by them and work together towards solutions
- Need to work together to resolve impending issues such as capacity building, central registration and effective oversight mechanism
- Need to set up a network with regulatory authorities and forums such as FERCI
- Plan to organize strategic training workshops, develop online training modules to train and empower EC members
- ECs in India need to refine their functions to keep pace with increasing research
- To work in a collaborative manner towards enhancing clinical research and achieving better ethical standards in India

*Ethics is not definable,
it is not implementable,
because it is not conscious;
it involves not only our thinking,
but also our feeling.*

... Valdemar W. Setzer

THANK YOU

