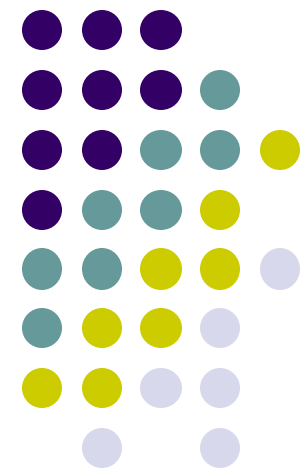
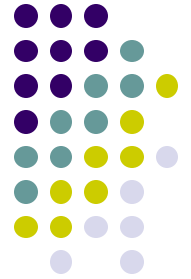


Community Protection and Participation in Health Research

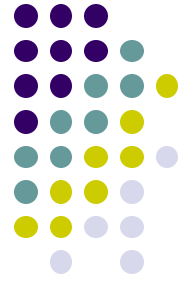
Amar Jesani
Centre for Studies in Ethics & Rights (CSER)
and
Indian Journal of Medical Ethics (IJME)
Mumbai, India



Communities: Uninvited guests, refusing to leave

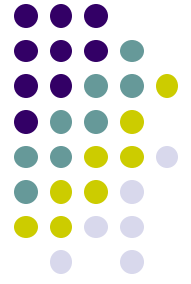


- **Biomedical researchers' unease with communities – general unease with “lay people's” interference**
- **Researcher's lack of motivation to understand “culture”**
- **But often communities and culture have stormed the citadel of research**
- **Difficult to wish them away alleging ‘politicisation’ of mistakes or unintended harm**



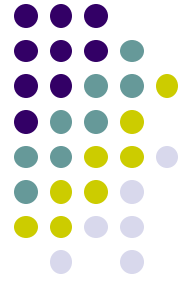
Historical

- **Nazi atrocities and Neuremburg Trial**
 - Not just atrocities, but also anti-semitism, homophobia, condemnation of disabled, etc.
- **Tuskegee**
 - Also racism
- **Camelot (1965)**
 - Not only military sponsorship - also nationalism
- **Sahyog, Almora, India (2000)**
 - Culture and politics



Historical

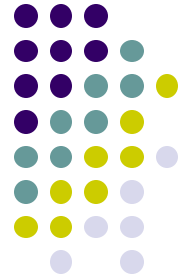
- **Such research also criticised for exploiting vulnerabilities of communities of people**
- **Protests from affected communities against researchers and the state for its failure to protect them**
- **Adverse impact on credibility and refusal to participate**
- **Such scandals led to formulation of guidelines and enactment of laws**



Guidelines

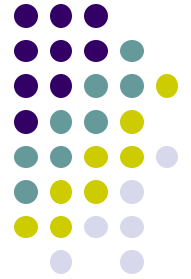
- **Most research bioethics guidelines recommend culture sensitivity and community protection**
- **However, we still do not have enough guidance on their meanings and how to go about doing it – except research on aboriginal people**
- **Difficulties in applying specific guidelines for protection of aboriginal communities to other communities**

Importance of communities in health research - 1

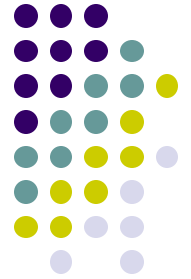


- **Emergency Medical Research involving application of experimental procedures and medications**
 - **Waiver of Informed Consent**
 - **Community consultation to decide process**
 - **Transparency, public disclosure & dissemination**
- **Research on medical conditions having risk of stigmatisation and discrimination of people with such condition**
 - **HIV/AIDS, Tuberculosis, Leprosy etc.**

Importance of communities in health research - 2



- **Research on culturally sensitive issues**
 - Sexuality, reproductive health, etc
- **Research with groups of people already stigmatised and discriminated by the society**
 - Sexual minorities, sex workers, dalits, religious and ethnic minorities, etc
- **Genetic research**
 - Risk of group harm
- **Sensitive way of disseminating results**

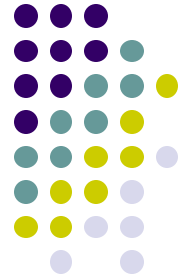


Avoid Denial and instrumentalism

- **Denial**
 - **Communities do not exist (rare), or they exist, but researcher is concerned with only individual participant and his or her protection; not with protection of communities**
- **Instrumentalism**
 - **Communities are only gatekeepers, researcher's job is only to negotiate with them to get access to participants**
 - **Acceptance of the need to protect communities, but refusal to provide them space to participate**

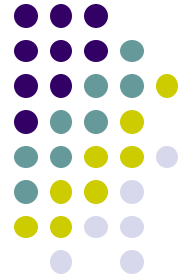
Need for balanced approach – understanding and interacting with community without harming rights of individual participants

Modes of Community Participation Attempted - 1



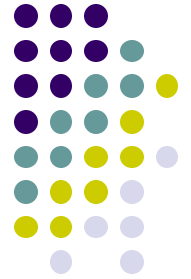
- **Having lay community member(s) on the IEC/IRB (General)**
- **Inviting member of specific community for ethics review of protocol in the IEC/IRB**
- **Consultation in protocol development**
 - **To respect community's culture**
 - **To respect its knowledge and experience**
 - **To ensure usefulness of research to the community**

Modes of Community Participation Attempted - 2



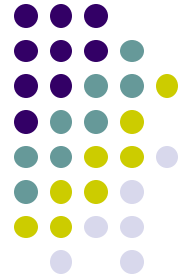
- **Seeking permission**
- **Seeking informed consent**
 - Adequate disclosure – in manner they can understand
 - Providing time for review of protocol
- **Involvement in research conduct**
 - Employing members of community
 - Capacity building and transfer of skill and research expertise
 - Providing resources

Modes of Community Participation Attempted - 3

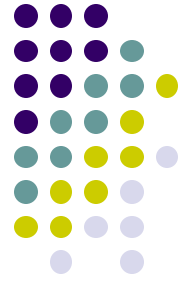


- **Developing community-based participatory research**
 - Participatory research
 - Participatory Action Research
 - Some of the participants also researchers
- **Providing access to data and samples**
 - Agreements on storage and further use of data and samples by researchers and community
- **Dissemination and publication**

Modes of Community Participation Attempted - 4

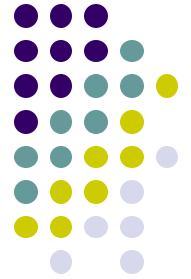


- **Establishment of Community Advisory Boards**
 - Liaison between community and researcher
 - Represent community and culture
 - Assistance in development of study material
 - Advocate rights of the vulnerable
 - Provide potential protection against individual breaches of Informed Consent
 - Help in appropriate dissemination of findings



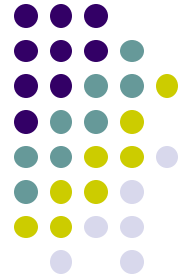
Requirements

- **Clear understanding of**
 - **Meaning of ‘community’ in the specific context of research**
 - **Meaning of ‘participation’ and appropriate ways of operationalising it**
- **Spirit and commitment to partnership with the community for research**
- **Training people from community, and more researchers from it**
- **Mechanism to share power and resources**



Communities

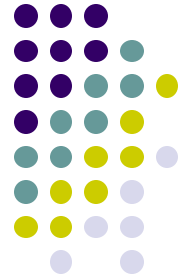
- **Much used and abused term**
- **The Community is Omnibus Term**
- **The Imagined and Real Communities**
- **The communities are not homogenous entities**
- **Power relations and exploitation within communities - Gender, caste**
- **Study focus – single or multiple communities**



Community - Typology

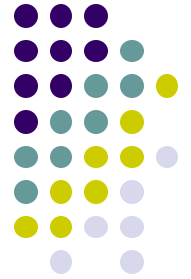
- **Weijer/Emanuel identify 7 types**
 - **1. Aboriginals**
 - **2. Geographical/political**
 - **3. Religious**
 - **4. Disease condition**
 - **5. Ethnic/racial**
 - **6. Occupational**
 - **7. Virtual**

Understanding characteristics of each type of community - 1

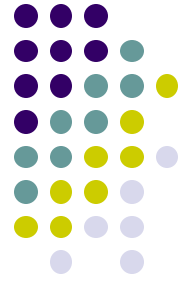


- **Ten characteristics**
 - **1. Common culture/tradition/knowledge /shared history**
 - **2. Comprehensiveness of culture**
 - **3. Health related common culture**
 - **4. Legitimate political authority**
 - **5. Representative group/individuals**

Understanding characteristics of each type of community - 2



- **6. Mechanism for priority setting in health**
- **7. Geographical localisation**
- **8. Common economy/Shared resources**
- **9. Communication network**
- **10. Self-identification as community**

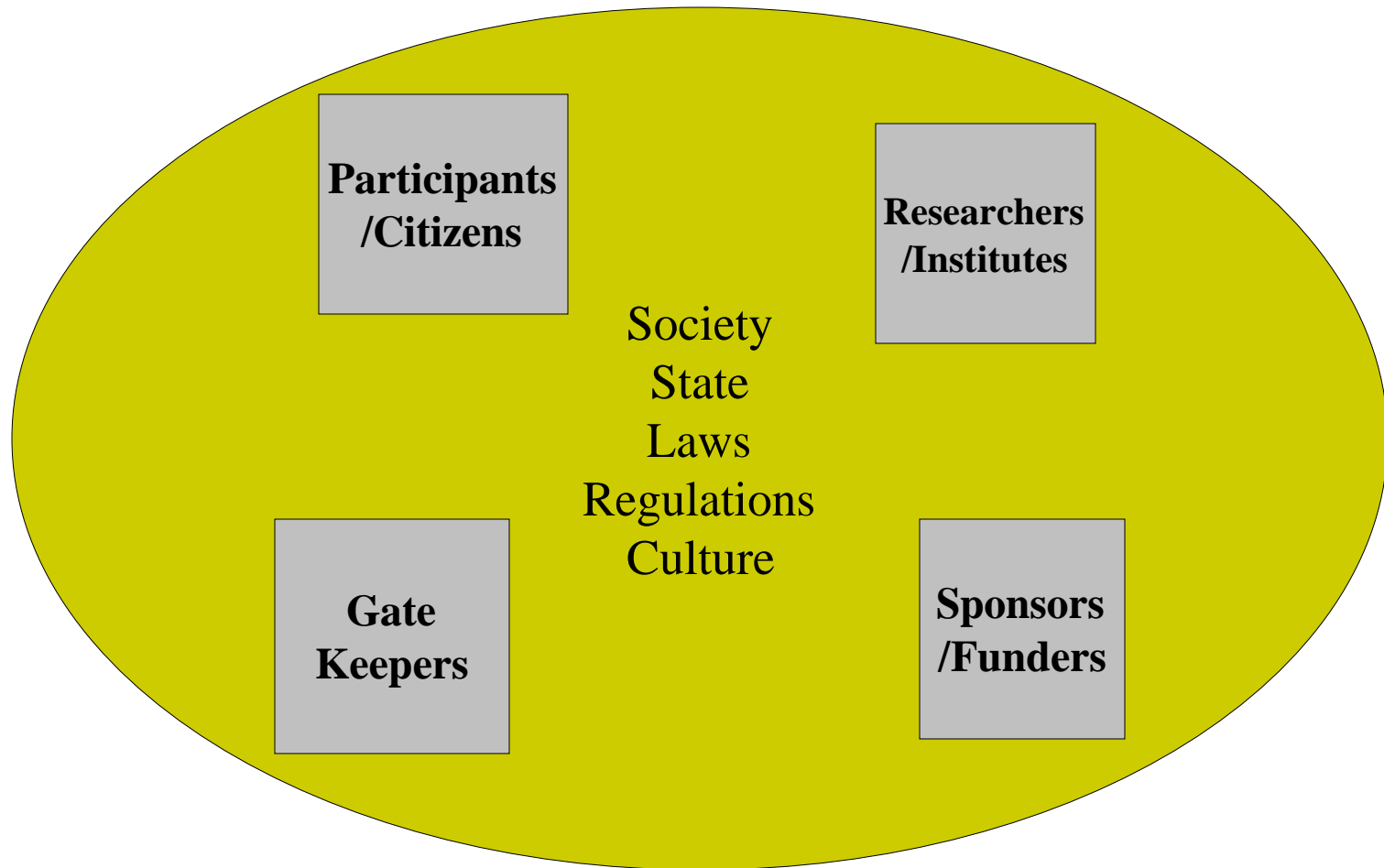
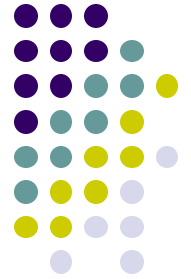


Participation

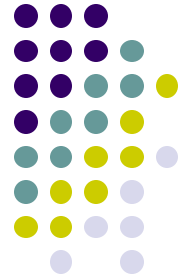
- **Also much used and abused omnibus term**
- **Its typology ranges from ‘consultation’ to total control**
- **Token or cosmetic use more harmful than beneficial in gaining support**
- **A matter of power relation – so sharing power and empowerment key ingredients for success**

Four Parties and Power Relations in research

(JA Barnes, 1979, Diagrammatic representation)



Relating characteristics to guidelines and mode of community participation

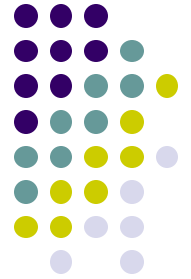


- For participation in protocol development, need individuals with capabilities
- For seeking permission/informed consent of community, need legitimate authority of the community
- Provision of resources need common economy and/or legal organisation
- Etc. etc – In brief, at each level one needs to find appropriate credible and operational mechanism

Researchers need to learn and reorganise too



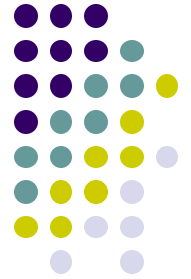
- **No research should be undertaken without doing adequate homework on the community under study.**
- **Learning should include basic aspects of community's social-economic status, political dimensions and cultural practices**
- **Similar training for 'data collectors'**
- **Developing 'cultural competence' of researchers**



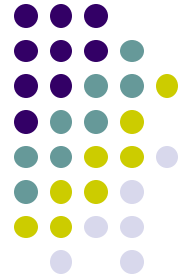
Community as Gatekeeper

- **Entering a community for research be treated on par with entering any institutional setting**
- **Permission/Consent of community does not substitute participant's consent**
- **Community's right to deny permission for research – how valid is the denial by its informal leaders?**
- **Do dissenting individuals have a right to participate even when community leaders have denied permission?**

Taking findings back to participants and community

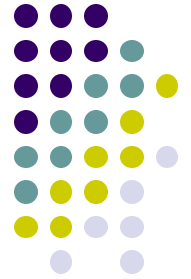


- **Dilemma of adapting to social/cultural “backwardness” of community (self-censorship) and “truth telling”.**
- **Cultural and political sensitivity in writing reports and in publishing of findings.**
- **Circumstances that could harm participants and community, create discord within the community, and harm the researchers.**



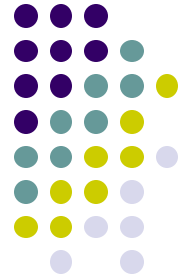
Participatory Action Research - 1

- **Action Research: Combining generation of knowledge with the action for changing social conditions**
- **Cyclical process resembling spiral of steps – each cycle consisting of:**
 - Planning of action
 - Undertaking action – implementing plan
 - Evaluating action and generation of new knowledge
 - Revision of the plan
 - Undertaking action – implementing revised plan



Participatory Action Research - 2

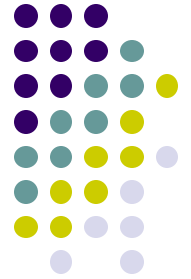
- **Participatory Research**: Participants are a part of research team and also control the process:
 - Those with specialised knowledge come from outside, but committed to participants and in having them as co-researchers
 - Combines research, educational work and action
 - Used for mobilising communities
- **Participatory Action Research**: Combination of the two



Issues in ethics Review - 1

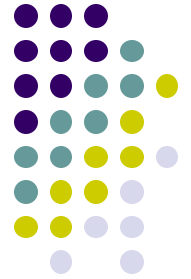
(adapted from Khanlou/Peter, *SS&M*, 60(2005), 2333-40)

- **Has political overtones – but reviewers’ job is not to pass political judgment but to evaluate its social and scientific validity**
 - Does it have potential to affect change, empower the community or section of community?
 - Assess researcher’s commitment and community’s interest in the issue
 - Review appropriateness of mechanism for participation
- **Scientific validity:**
 - PAR uses quantitative and qualitative methods – they need to be assessed for their scientific merits



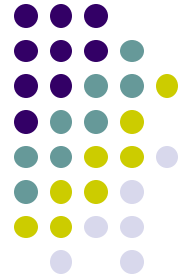
Issues in ethics Review - 2

- **Fair selection of participants:**
 - Generally involves vulnerable people – extra care needed to assess whether they will benefit
 - Fair opportunity to participate
 - Inclusion and exclusion – may have political and cultural ramification
- **Favourable Risk-Benefit ratio:**
 - Education/learning benefits from participation and successful actions



Issues in ethics Review - 3

- Challenges status quo, so possible risk of political, social and cultural consequences
- Ensure that protocol addresses the potential risk
- **Informed consent**
 - A documented process of negotiation between the outside researcher and community of participants
 - Need to include agreement on publication and ownership of data
- **Confidentiality**
 - More individuals know information – so more care



Acknowledgement

- Weijer C, Emanuel EJ, ‘Protecting communities in biomedical research’; *Science*, Vol. 289, 18 August 2000, pgs 1142-4
- Sandra Crouse Quinn, ‘Protecting human subjects: Role of Community Advisory Boards’; *Am J Public Health*, 2004, 94: 918-22
- Khanlou N, Peter E, ‘Participatory action research: Considerations for ethics review’, *Social Science & Medicine*, 60 (2005) 2333-40
- Barnes JA, ‘Who should know what? Social science, privacy and ethics’ (1979), Cambridge: Cambridge University Press