INDIAN JOURNAL OF MEDICAL ETHICS

nbc

national bioethics conference

IJME 4th NATIONAL BIOETHICS CONFERENCE

Ethical and regulatory challenges in health research

Biomedical, public health and social science research

Priority setting and social relevance

Protection of research participants

Benefit sharing

Research integrity

Hosts and Collaborators

Forum for
Medical Ethics Society, Mumbai

Council for Social Development

CONFERENCE PROGRAMME, INTRODUCTION AND ABSTRACTS

University of Hyderabad, Hyderabad

December 6 to 8, 2012

Conference Coordination Committee

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2. **Anant Bhan**, Member, Managing Committee, Forum for Medical Ethics Society, Pune, MH
3. **Geeta Vemuganti**, Dean, The School of Medical Sciences, University of Hyderabad, AP
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INTRODUCTION: 4TH NATIONAL BIOETHICS CONFERENCE

Sunita Sheel Bandewar, Anant Bhan on behalf of the Conference Coordination Committee

National Bioethics Conferences: An overview

The *Indian Journal of Medical Ethics* (www.ijme.in) is a peer reviewed indexed journal (earlier known as *Medical Ethics* and *Issues in Medical Ethics*) which started publication in 1993 (www.ijme.in) as a forum for scientific exchange and debates on bioethics in India. *IJME* has now completed its 20th year as a pioneering platform for discussions in bioethics in India. As a leader in this field in low and middle income countries, it has been fostering a commitment to bioethics while contributing to scholarship in the field. Most importantly, it has been facilitating opportunities for awareness building and sensitisation of institutions and individuals to the ethical dimensions of their work and the role they can play in improving the ethical and regulatory standards of health research, healthcare, and allied activities.

With the evolution of bioethics in India, the need emerged to share ideas and to build a platform for different stakeholders to come together and discuss ethical issues relating to the field of health and other areas that impact health, health systems and health research. There was a necessity to promote original thinking and exploration so as to develop analytical frameworks for ethical issues suitable for the specific contexts of India. It was in recognition of these needs that *IJME* decided to create the platform of the National Bioethics Conferences (NBC).

So far, *IJME* and other collaborating partners have organised three national bioethics conferences, the tradition having been initiated in 2005. The first NBC on the theme '*Ethical challenges in health, global context, Indian realities*', was held at the YMCA International Centre, Mumbai from November 25 to 27, 2005, and was co-organised by 20 institutions. The second NBC, in 2007, was on the theme '*Moral and ethical imperatives of healthcare technologies: scientific, legal and socio-economic perspectives*' and was held at the National Institute for Mental Health and Neurosciences (NIMHANS) Convention Centre, Bangalore from December 6 to 8, 2007. 38 organisations participated in the second NBC. The third NBC, co-organised by 38 organisations from all over India, was on the theme of '*Governance of health care: ethics, equity and justice*'. It was held from November18 to 20, 2010 at the All India Institute of Medical Sciences (AIIMS), New Delhi.

Fourth National Bioethics Conference: significance and goal

The IJME Fourth National Bioethics Conference is being held on the University of Hyderabad campus from December 6 to 8, 2012. The Forum for Medical Ethics Society (FMES), Mumbai, the University of Hyderabad, Hyderabad, and the Council for Social Development (CSD), Hyderabad are joint hosts and collaborators in this conference. The theme of NBC 4 is '*Ethical and regulatory challenges in health research*'

For more than one reason the 4th National Bioethics Conference theme – Ethical standards and regulatory challenges in health research – seems apt and very timely. India remains a key centre for health research in various disciplines ranging from biomedical to social sciences. The growing amount of research has been aided by an increasing number of training courses as well as the establishment of organisations which conduct research. Now is an opportune time to study this phenomenon, with a focus on the ethics and regulatory challenges involved. This conference will bring together key stakeholders to examine the theme, and will also be a gesture of tribute to the IJME on its completing its 20th year of publication.

Goal

To bring together different key constituencies/stakeholders to share their diverse perspectives on the conference theme – Ethical and regulatory challenges in health research- with an aim of building a better research enterprise and an environment that enables the conduct of ethical health research.

Specific objectives

- To bring together key constituencies – individuals and institutions – relating to the health sector, bioethics and health research regulatory bodies to engage with the ethical and regulatory challenges in health care with a view to improving ethical and regulatory standards of health research in India.
- To enable dialogue between key constituencies relating to bioethics health research regulatory apparatuses other relevant from India and abroad on a range of ethical standards and regulatory challenges towards improving health research as a whole.
- To offer a public platform for presenting emerging research in bioethics in India and outside; and encouraging individuals and institutions to publish such scholarship in national and international journals.
- To create a forum via workshops and symposia that will be organised at the Fourth NBC for skill-building and resource sharing in bioethics among different organisations and stakeholders.

CONFERENCE PROGRAMME

Time	Day 1: Thursday, December 6, 2012
8:00 am onwards	**Registration: DST Plenary Hall**
9:30 – 11:00 am	**CONFERENCE INAUGURAL SESSION**
	Introduction to IJME and NBC **Amar Jesani**, Editor, *Indian Journal of Medical Ethics*, Mumbai, India **Introduction to 4th NBC** **Kalpana Kannabiran**, Director, Council for Social Development, Hyderabad **Sunita VS Bandewar**, Member, Managing Committee, Forum for Medical Ethics Society, Mumbai, India **Conference inauguration** **Chairperson:** **GVS Murthy**, Director, IIPH, Hyderabad **Co-chairperson** **Amar Jesani**, Editor, *IJME*, Mumbai **Guest of honour** **Ramkrishna Ramaswamy**, Vice Chancellor, University of Hyderabad, Hyderabad, AP **Inaugural address** **G N Rao**, Founder and Chairperson, L V Prasad Eye Institute, Hyderabad, AP
11:00 – 11:30 am	**Tea break**
11.30 am - 1:00 pm	PARALLEL PAPER PRESENTATIONS: Groups P1 to P3
	Group P1: Socio-political and cultural dimension of research ethics (Venue: Hall A) **Chairpersons** **Bindu Bamba**, Director Women's Studies, Hyderabad Central University, Hyderabad **Soumya Vinayan**, Assistant Professor,Council for Social Development, Hyderabad
	P1a: Supriya Subramani, Sreekumar Nellickappilly: Consent communication and cultural competence: an ethical framework for obtaining informed consent
	P1b: Angus Dawson: Inclusion of the children of minor parents in medical research
	P1c: Anuj Kapilashrami, Rekha Khatri, with Biomedical and Health Experimentation in South Asia (BHESA) team: Collaboration or brokerage? The political economy of local assemblages in global medical research
	Group P2: Empirical bioethics (Venue: Hall B)
	Chairpersons **U Vindhya**, Professor of Psychology, and Chairperson, Academic Programmes, TISS Hyderabad **Usha Raman**, Associate Professor and Head, Department of Communication, Sarojini Naidu School of Arts and Communication, University of Hyderabad, Hyderabad, India
	P2a: Vijayaprasad Gopichandran, Maria Jusler Kalsingh, Geetha Veliah: Public attitudes towards clinical research
	P2b: Asima Jena Methodological and ethical challenges in studying HIV/AIDS
	P2c: Shilpa Krishna, Purendra Prasad N: Ethical issues in recruitment of healthy volunteers: a study in Hyderabad.
	P2d: Nilangi Narendra Sardeshpande, Rashmi Padhye: Interface between research ethics and socio-cultural specificities of a study setting

	Group P3: Public health ethics (Venue: Hall C) **Chairpersons** **Mala Ramanathan**, Achutha Menon Centre for Health Science Studies, SCTIMST, Trivandrum **Pratyusna Patnaik**, CSD, Hyderabad
	P3a: Nausheen Saeed: Growing violence towards healthcare professionals: a public health issue
	P3b: Jayakrishnan T: National Vaccination Policy, India: ethical and equity issues
	P3c: Purnima Madhivanan, Karl Krupp, Reshma Shaheen, Suvarna HC , Sean Philpott , Celia Fischer: Ethical issues in the delivery of prevention of mother-to-child transmission of HIV interventions in Mysore, South India
	P3d: M Santhosh Kumar: Shared risks, shared privacy: research among young men using tobacco in Tamil Nadu
1:00- 2:00 pm	**Lunch**
2:00 to 3:30 pm	**PARALLEL WORKSHOPS: W1 to W4**
	W1: Community involvement in public health intervention research **(Venue: Hall A)** **Facilitators: Angus Dawson**, Professor of Public Health Ethics, University of Birmingham, UK **Neha Madhiwalla**, Coordinator, Centre for Studies in Ethics and Rights, Mumbai.
	W2: Making the voices count: participants' rights and regulation of clinical trials in India **(Venue: Hall B**) **Facilitators: Sarojini N, Anjali Shenoi**, Sama – Resource Group for Women and Health, **Patrick Durisch**, The Berne Declaration
	W3: Playing the ethics monitors: the role of ethics committees in providing continuous oversight of ongoing research studies **(Venue: Hall C)** **Facilitators: S Swarnalakshmi, IRB Manager**, YRG Centre for AIDS Research and education, Chennai. **Anant Bhan**, Researcher, Bioethics and Global Health, Pune **Prabha Desikan**, Institutional Review Board, Bhopal Memorial Hospital, Bhopal **Medha Joshi**, Tata Memorial Hospital, Mumbai.
	W4: Training in public health ethics: views from key stakeholders (Venue: Hall D) **Facilitators: Raman Kutty V, Mala Ramanathan, Sreejini J, Praveen Pai,** Achutha Menon Centre for Health Science Studies, SCTIMST, Trivandrum
3:30 pm to 4:00 pm	**Tea break**
4:00 to 5:30 pm	**PLENARY I: INTERDISCIPLINARY APPROACHES TO RESEARCH ETHICS**
	Chairperson **Sanjay Mehendale**, Director, National Institute of Epidemiology (ICMR), Chennai, India **Co-chairperson** **Purendra Prasad**, Associate Professor, Department of Sociology, University of Hyderabad, Hyderabad, India. **Keynote address 1: Biomedical sciences** **Prathap Tharyan**, Professor and Head, Department of Psychiatry; Christian Medical College, Vellore, India; **Veena Shatrugna**, Former Deputy Director and Head, Clinical Division, National Institute for Nutrition, Hyderabad, India **Keynote address 2: Social sciences** **Kausar S Khan,** Associate Professor, Department of Community Health Sciences, Aga Khan University, Karachi, Pakistan **Keynote address 3: Public health** **Vandana Prasad**, Member, National Commission for Protection of Child Rights, Government of India, New Delhi, India

5:30 – 6:30 pm	**POSTER PRESENTATIONS** 1. **Atul Jaiswal, Shikha Gupta**: Inclusion of disability and people with disabilities in public health research 2. **Rimali Batra:** Scales of protection: physical harm and informational injury. 3. **Saima Bibi**: Ethical issues faced by women experiencing recurrent spontaneous pregnancy loss (3 or more times); a phenomenological study in a peri-urban area of Karachi, Pakistan 4. **Sumitha Chalil**: Enhancing quality of HIV counseling through ethics integration 5. **S Swarnalakshmi, AK Ganesh, Geeta Ramanathan**: Challenges in bioethics training and education in a non-governmental organisation: sharing the YRG CARE experience 6. **Uma Kulkarni, Vina Vaswani**: All that glitters is not gold: website advertisements by eye care centres in India: ethical concerns: 7. **Rekha Raghavan**: Willingness to participate in a clinical trial and the factors that influence the decision in a South Indian population 8. **Sreejini J**: Encouraging reflexivity in students for ethics in public health practice
6:00 to 7:00 pm	**STUDENT COMPETITION (QUIZ)**

Time	**Day 2: Friday, December 7, 2012**
9.00 am onwards	**Registration**
9:30 – 11:00 am	**PARALLEL PAPER PRESENTATIONS: Groups P4 to P6**
	Group P4: Research ethics: advancing debates (Venue: Hall A)
	Chairpersons **D Balasubramanian**, Director (Research), LVPEI, Hyderabad, India **Neha Madhiwala**, Coordinator, FMES, Mumbai
	P4a: Nabeel Mangadan-Konath: 'Vulnerability': a conceptual research beyond its epistemological limitations in research ethics
	P4b: Blair Henry: Investigating the investigators: research misconduct
	P4c: Sridevi Seetharam: Protection of research participants: looking beyond the conventional
	P4d: Sarojini N B: Post trial access: issues and challenges in India
	Group P5: Ethics and traditional medicine (Venue: Hall B)
	Chairpersons **Padmini Swaminathan**, Professor, TISS Hyderabad **Chandi Prasad Nanda**, Professor, Ravenshaw University, Orissa
	P5a: C. Suvetha, Thomas M Walter, M Sri Sakthi logisha, R Sweety Nirmala: Priority setting and social relevance of bioethics in traditional Siddha medicine: lessons from the field
	P5b: Sri Sakthi Logisha, Meena Loshini, Vinodhini Ramamoorthy, Asvini TD, Ravi Chandran: Research integrity of AYUSH systems
	P5c:Venkatesh Vinayak Narayan, Kabir Sheikh, Devaki Nambiar, JK Lakshmi, TN Sathyanarayana, John Porter: Engaging TCAM (Traditional, Complementary & Alternative Medical) providers for essential health service delivery in India: operational and ethical challenges to integration in three states of India
	P5d: Raman Kutty V: Can different systems of treatment co-exist? A perspective from public health ethics

	Group P6: Ethics and regulation (Venue: Hall C) **Chairpersons** **Angus Dawson**, Professor of Public Health Ethics and Head of Medicine, Ethics, Society and History (MESH), University of Birmingham, UK **Chitra Kannabiran**, Scientist, KA Reddy Molecular Genetics Laboratory, LVPEI
	P6a: Manjulika Vaz , Mario Vaz: Ethical and regulatory challenges in biobanking: moving the agenda forward in India
	P6b: Vishwas H Devaiah: Regulating innovative medical treatments: caught between treatment and research
	P6c: Gerard Porter: Sites of contestation: debates and disputes over the governance of international clinical trials
11:00 – 11:30 am	**Tea break**
11:30 am – 1:00 pm	**PLENARY II: CLINICAL TRIALS**
	Chairperson **Vasantha Muthuswamy**, Former Senior Deputy Director General and Scientist G, ICMR, New Delhi, India **Co-chairperson** **Usha Raman**, Associate Professor and Head, Department of Communication, Sarojini Naidu School of Arts and Communication, University of Hyderabad, Hyderabad, India **Keynote address 1: Vulnerability** **Nandini Kumar**, Former Deputy Director General Sr. Grade, Investigator NIH project, National Institute of Epidemiology, Chennai, India **Keynote address 2: Ownership of knowledge** **Roger Jeffery**, Professor of Sociology of South Asia, School of Social and Political Science; and Dean International (India), University of Edinburgh, UK **Keynote address 3: Multi-centric trials** **Arun Bhatt**, Director, Clininvent Research Pvt Ltd, Mumbai, India
1:00 -2:00 pm	**Lunch**
2:00 to 3:30 pm	**PARALLEL WORKSHOPS: W5 to W8**
	W5: Roundtable discussion on three critical policy issues on drug trials in South Asia **(Venue: Hall A)** **Facilitators: Amar Jesani, Deapica Ravindran,** Biomedical and Health Experimentation in South Asia(BHESA) and Centre for Studies in Ethics and Rights (CSER) Mumbai
	W6: Evolving a response to boundary violations in patient care: The Bangalore Declaration and beyond **(Venue: Hall B)** **Facilitators: Sunita Simon Kurpad** ,St John's Medical College, Bangalore, **GD Ravindran**,St John's Medical College, Bangalore, **Anant Bhan**, Researcher, Pune
	W7: Campaign on unethical clinical trial In India: experiences from activists and trial participants **(Venue: Hall C)** **Facilitators: Chinmay Mishra, Amulya Nidhi, Veejay Chaudhary,** Swasthya Adhikar Manch, Indore, MP.
	W8: Managing research ethics: setting up and running an institutional review board **(Venue: Hall D)** **Facilitators: LV Prasad Eye Institute team**
3:30 to 4:00 pm	Tea break

4:00 to 5:30 pm	**PLENARY III: RESEARCH REGULATION LAW AND ETHICS**
	Chairperson **Gitanjali Batmanabane,** Prof of Pharmacology and Officer-in-charge, Department. of Pharmacy Jawaharlal Institute of Postgraduate Medical Education & Research, Pondicherry **Co-chairperson** **Geeta Vemuganti,** Dean, School of Medical Sciences, University of Hyderabad, Hyderabad, India **Keynote address 1:** **Vasantha Muthuswamy**, Former Senior Deputy Director General and Scientist G, ICMR, New Delhi, India **Keynote address 2:** **Chandra M Gulhati**, Editor, *Monthly Index of Medical Specialties (MIMS)*, India **Keynote address 3:** **Chinu Srinivasan**, LoCost Standard Therapeutics, Baroda, Gujarat, India
5:30 to 6:30 pm	**STUDENT COMPETITIONS (Posters and cover design entries)**
6:30 pm onwards	**CULTURAL PROGRAMME**
Time	**Day 3: Saturday, December 8, 2012**
9.00 am onwards	Registration
9:30 – 11:00 am	**PARALLEL PAPER PRESENTATIONS: Groups P7 to P9**
	Group P7: Research ethics and methods **Chairpersons** **Sreekumar Nellickappilly**, Associate Professor, Department of Humanities and Social Sciences, IIT, Chennai **Amar Jesani**, Editor, *Indian Journal of Medical Ethics*, Mumbai
	P7a: Usha Raman, Karthik K: Ethical review in social research
	P7b: Ramdas D Gambhir: Principle of cultural relativism and ethical dilemmas in medical anthropology
	P7c: Kausar Khan: Questioning the neoliberal approach to research ethics
	P7d: Udaya S Mishra, Mala Ramanathan: Ethical dilemmas: statistically valid indicators vs social relevance in public health
	Group P8: Ethics in context **Chairpersons** **Lakshmi Lingam**, Professor and Deputy Director, TISS Hyderabad **Sarojini N B**, SAMA, New Delhi
	P8a: Robyna Khan, Kausar Khan, Anant Bhan: Piecing the fragments together: utilising organisational ethics
	P8b: Vishal Vennu : Unethical human experimentation in India: an overview
	P8c: Tharindi Udalagama, Rekha Khatri, Deapica Ravindran, Jeevan Raj Sharma, Salla Sariola, Ian Harper, Roger Jeffery: Situating evidence in public health interventions: experiences from India, Nepal and Sri Lanka
	Group P9: Clinical trials and ethics (Venue: Hall C) **Chairpersons** **Seshikaran**, Former Director, NIN, Hyderabad, India **Sandhya Srinivasan**, Consulting Editor, *IJME*, Mumbai, India
	P9a: Mala Ramanathan: Can we ascribe altruism as a motivation for participation in clinical trials?
	P9b: Praveen Pai: Building understanding of research ethics among the lay public: case study of an expose in the media

	P9c: Avishek Pal: Clinical Trial Registry, India (CTR-I): trends in quality of registration and its implications on human subject research in India
	P9d: Anand Kumar: Role of money in the conduct of clinical and public health trials in South Asia
11:00 – 11:30 am	**Tea break**
11:30 am to 1:00 pm	**VALEDICTORY SESSION**
	Chairperson **P M Bhargava**, Chairman, Council for Social Development and Founder Director, Cellular and Molecular Biology, Hyderabad **Co-chairpersons** **Anant Bhan**, Member, Managing Committee, Forum for Medical Ethics Society **K D Sen**, Professor, School of Chemistry, University of Hyderabad (to be confirmed) **Conference highlights**: Conference rapporteuring team **Guest of honour:** **T Sundararaman,** Executive Director, National Health System Resource Centre (NSHRC), And Member and Convener, National Rural Health Mission (NRHM), New Delhi **Valedictory address** **Alastair V Campbell**, Chen Su Lan Centennial Chair in Medical Ethics, Director, Centre for Biomedical Ethics, National University of Singapore, Singapore **Vote of thanks** **Soumya Vinayan**, Assistant Professor, Council for Social Development, Hyderabad **Pratyusna Patnaik** , Assistant Professor, Council for Social Development, Hyderabad
1:00 to 2:00 pm	Lunch

ABSTRACTS: DAY ONE

PARALLEL PAPER PRESENTATIONS

GROUP P1: Socio-political and cultural dimensions of research ethics

Consent communication and cultural competence: an ethical framework for obtaining informed consent

Supriya Subramani, Sreekumar Nellickappilly

Obtaining informed consent is both an ethical and a legal requirement for conducting biomedical research involving human beings. The value of obtaining consent recognises the status of the subject as an autonomous individual. Hence, obtaining informed consent is to recognise and acknowledge the human worth of a person. It is to concede that people have certain fundamental rights, which cannot be annulled or forfeited. But the process of obtaining consent involves several challenges. It requires not only a strong commitment from researchers to the subject's rights as a person, but also a deep understanding of the challenges involved in pursuing genuine informed consent from subjects. This process thus involves multiple stages, each raising unique demands that have legal and ethical implications. It primarily involves respecting a subject's autonomy which would be incomplete without a proper understanding of his/her cultural values and beliefs, which is a complex enterprise encompassing several challenges. This scenario may invoke serious ethical dilemmas that complicate consent communications and may lead to the unintentional abuse of human rights.

This paper attempts to identify the relevance of cultural competence in the informed consent process in biomedical research, and examines how they affect the outcome. It is based on a pilot study which intends to identify the perspectives of physicians on cultural competence and their relevance in the informed consent process. The paper aims to carry out the study employing in-depth interviews and interactions with professionals involved in biomedical research. Thus the paper examines how an understanding of culture (cultural competence) enables professionals to communicate with their subjects without compromising on their rights as persons and their autonomy as individuals.

Inclusion of the children of minor parents in medical research

Angus Dawson

It is standard practice around the world when enrolling minors in medical research to gain consent from their parents (in addition to the minor's assent in some cases). However, it is also common for minors to be parents themselves. In the absence of any local laws covering this issue, and where it may be beneficial for the minor's child to be involved in research, what consent requirements are appropriate? This paper explores this question by arguing that in many cases minor parents are no worse at being able to understand (and therefore give informed consent) than adults, and therefore in many cases minor parents' consent for their child ought to be seen as an adequate informed consent. Where there are doubts about the ability of a minor to give consent (e.g. because they cannot comprehend the information, they are too emotionally involved, the design is too complex, etc) then these reasons, where they exist, are also reasons to doubt the adequacy of an adult parent's consent. The fact of being a parent who happens to be a minor, as opposed to being an adult parent, is not ethically relevant.

Collaboration or brokerage? The political economy of local assemblages in global medical research

Anuj Kapilashrami, Rekha Khatri, with Biomedical and Health Experimentation in South Asia (BHESA) team

Clinical and public health research has witnessed an unprecedented growth in trans-national collaborations. In this paper, we take an actor perspective and chart the landscape of such collaborations with a focus on South Asia and explore: how these emerge; what drives research collaborations; and to what extent these redefine local research cultures, institutional practice, and ideas of expertise; and bring about a shift in global economic and political power.

This paper draws on ethnographic fieldwork and interviews conducted between 2010-2011 in India, Nepal and Sri Lanka as part of a multi-country collaborative research on biomedical and health experimentation. We examine how participants in the 'value chain' – sponsors, clinical and contract research organisations, academic collaborators, coordinators and investigators – work through and traverse material, social, technical relations, and institutions to enable trial/ research outcomes. We explore their understanding of collaborations in experimentation and their views on social or intellectual drivers, careers and other motivations; and their positioning (and authority) in these intersecting networks of knowledge, technocratic practices, therapeutic consumption and capital generation. We conclude with a discussion on the ethics of trans-national collaborations, the social and political implications of these practices and how they reconfigure the contours of bioethics in medical experimentation.

GROUP P2: Empirical bioethics

Public attitudes towards clinical research

Vijayaprasad Gopichandran, Maria Jusler Kalsingh, Geetha Veliah

Background: A good understanding of the ethics of clinical research should be grounded in the needs and perceptions of the public. There is evidence, largely from the developed countries, that the public value the importance of clinical research. Little is known about attitudes of the public towards clinical research in developing countries.

Objectives: To describe public perspectives and attitudes towards clinical research in India.

Methods: A semi structured questionnaire was designed based on available literature on attitudes towards clinical research with responses on a Likert scale. The questionnaire survey was conducted both through the internet survey method and the face to face interview method.

Results: A total of 300 internet questionnaires were sent and 88 responses were obtained (response rate 29.3%) and out of a total of 33 individuals approached for personal interviews, 30 responses were obtained (response rate 90.9%). The sample was predominantly urban, educated and younger than 40 years. The mean attitude score was 43.8 (SD 6.8) in a scale of 15 to 75. Factor analysis revealed that a three factor structure explained 47.6% of the overall variance. The three main domains of attitudes were: Clinical research is important, Clinical research is exploitative and Clinical research is harmful and negative. Cluster analysis with the regression factor scores revealed two clusters, those with positive attitudes to clinical research (n=63) and those with negative attitudes (n=55). Those who had positive attitudes were younger than 40 years, had a post graduate degree, were not currently married, had participated or had a family member who participated in clinical research earlier.

Conclusion: Public attitudes to clinical research among a sample of predominantly educated, young and urban population were equivocal with about half of them having positive attitudes. Those having positive attitudes were those with prior experience with clinical research.

Methodological and ethical challenges in studying HIV/AIDS

Asima Jena

The social model of health takes a critical stand towards biomedicine. There is much substance in this model, in terms of pinpointing the social constitution of disease, commodification of health services, medicalisation, the loss of the social identity of patients in laboratory medicine, the violation of the rights of patients in clinical trials and so on. However, the social model of health does not scrutinise at greater length nor critically examine its own practice. By critically reflecting on the author's own ethnographic field work experience in East Godavari district, Andhra Pradesh, this paper first describes the intricacies involved in being a female researcher which turned out to be both risky and beneficial for the research and the researcher whose subject of interest includes sexual relationships and the sex service industry in the broader context of HIV/AIDS. Secondly, it attempts to explain the ways in which the field affects the researcher and research, and vice versa. In this context, the influence of the author's own gendered positioning in exacerbating this tension and further complicating the relationship between the researcher and respondent, as also the ethical dilemmas involved in social science research on HIV/AIDS are discussed. The latter aspect is mostly critical in researching sufferers, especially HIV positive persons, as this process brings more pain to the respondents while unraveling their traumatic illness experiences.

Ethical issues in recruitment of healthy volunteers: a study in Hyderabad

Shilpa Krishna, Purendra Prasad N

The trials registered in the Clinical Trial Registry of India (CTRI) are those conducted on new chemical entities, but not on bioavailability and bioequivalence (BA/BE) studies. BA/BE studies are more prominent and are carried out on healthy volunteers. The Drugs Controller General of India's efforts to make the registration of BA/BE studies mandatory with the CTRI are yet to become a reality. This paper addresses some of the ethical issues involved in the recruitment of volunteers for BA/BE studies through clinical research organisations and their networks. It also explores the reasons for their participation and the manner in which they are managed by the CROs. The data was collected by conducting a case study on a CRO in Hyderabad. The paper dwells on the details of the perceptions of the 50 healthy volunteers participating in the study, their profiles, demands/ problems and their vulnerability. Although informed consent was administered, none of our study participants knew anything about the research study. However, the study participants insisted on knowing the risks involved so that it would help them bargain for a few more incentives for their participation. The study findings also indicated that the very design of the CRO has been structured by surveillance protocols which put the healthy volunteers within strict disciplinary boundaries. The study also analyses the inadequacy of the regulatory bodies.

Interface between research ethics and socio-cultural specificities of a study setting

Nilangi Narendra Sardeshpande, Rashmi Padhye

This paper aims to unravel the interface between research ethics and the socio-cultural context in which a study is conducted, based on the experiences of field researchers during a study conducted by SATHI in ten districts of Maharashtra. The aim of the study was to document gaps in access to healthcare services across social groups based on caste, household asset index, gender and geographical region. The study used the stratified random sampling technique to select over 1650 households from the state.

Given ethnic variations within the state, local dialects differ significantly across geographical regions. Hence, despite explaining the purpose of the study to participants, field researchers were sometimes unsure whether participants had really understood the text of the consent form, leaving them in doubt as to whether the consent was a true 'informed' consent.

In the patriarchal culture, husbands acted as gatekeepers restricting women from taking decisions regarding participation in the study. Within the limited period of interaction, the field researchers were unable to overcome this constraint and ask women about their choice.

Maintaining privacy during interviews is another important ethical requirement of any study. However, in rural settings it is often not possible to interview women alone, as the family members then get suspicious. Similarly, to circumvent language problems, sometimes interpreters were involved. Hence, these practical solutions in a way compromised privacy during interviews.

The conflict between their roles as researchers and as responsible citizens was another ethical issue. For example, when the researchers came across information regarding sex selective abortions, they were prevented by the principle of confidentiality from disclosing that information.

Through this paper, the authors share these ethical dilemmas faced by field researchers in a specific socio-cultural setting.

GROUP P3: Public health ethics

Growing violence towards healthcare professionals: a public health issue

Nausheen Saeed

Background: Violence towards healthcare professionals (HCPs) by patients and their attendants is rising at the global level. It is becoming a pandemic in some countries like Pakistan. HCPs working in ICUs are commonly subjected to violence by the patients' attendants. HCPs who work in emergencies report being threatened by political workers. They also encounter intense pressure from religious fundamentalist groups when there is a terrorist incident.

Purpose: The purpose of this paper is to explain why violence towards HCPs ought to be recognised as an emerging ethical and public health issue as it has negative consequences on the community at large. It argues that all healthcare organisations (HCOs) should have robust policies in place to address this unique ethical challenge.

Discussion: Violence towards HCPs reflects the general attitude of intolerance in a society. It ranges from verbal abuse to physical assault. HCPs also experience a wide range of psychological trauma. Such experiences lead to a negative impact on their professional and personal lives. Hostile patients and families also target other patients, equipment, and property of the hospital. As a result, public hospitals face unnecessary cost and economic instability. The unsafe working conditions have led many qualified professionals to leave the country.

Unfortunately, violence towards HCPs is grossly underreported. It has not been recognised as a crucial ethical and public health issue in Pakistan as yet. The majority of hospitals and public health facilities, in particular, do not have effective systems in place to combat violence. There is also a vacuum of research in this particular area.

To conclude, violence has a deleterious effect on public health. All HCOs ought to develop, implement and maintain effective violence prevention programs. In addition, HCOs need to collaborate with professional medical associations, state, media and community to combat violence towards HCPs.

National Vaccination Policy, India: ethical and equity issues

Jayakrishnan T

Back ground: Vaccines have been among the most successful health interventions, bringing about significant reductions in infectious disease. The ministry of health and family welfare published a National Vaccination Policy in April 2011, which listed certain criteria for the introduction of new vaccines under the Universal Immunisation Programme(UIP) as follows: disease burden in the country, safety, efficacy, programme capacity to introduce new vaccine, cost effectiveness, alternatives other than vaccination, and financial sustainability even if the initial introduction is supported by an external funding agency. The policy paper also supported certain vaccines-- Haemophilus B influenza (Hib), Pneumococcal conjugate, Rota virus, HPV vaccine-- for inclusion in the UIP. This was criticised by some public health scientists as being contrary to the above criteria.

Methods: A literature review was done by searching the web on articles published on the National Vaccine Policy and the above mentioned vaccines.

Results and discussion: The stated rationale in the policy for introducing new vaccines is not based on indigenous surveillance data or on specific local needs, but either on their long time existence in the market or on availability in the private sector. Their efficacy and cost effectiveness have not been considered. The policy of recommending a vaccine only needed for selective immunisation for the universal programme, and vice versa, is also unethical. The draft vaccine policy is silent on the reopening of public sector vaccine manufacturing units which have been closed since 2008. The proposed model for the financing and pricing of the vaccines to be introduced seems to favour the interests of the private vaccine industry and could result in an ill-advised vaccine trap.

To ensure the selection of appropriate vaccines on scientific grounds for the UIP, the universal, well-defined criteria of cost efficacy and appropriateness must be applied, based on the science of public health.

Ethical issues in the delivery of prevention of mother-to-child transmission of HIV interventions in Mysore, South India

Purnima Madhivanan, Karl Krupp, Reshma Shaheen, Suvarna HC, Sean Philpott, Celia Fischer

Background and purpose: The Indian government recently changed HIV testing guidelines from 'opt-out' to routine HIV testing of all pregnant women receiving antenatal care (ANC). NACO guidelines state that clients must be informed of the purpose of the test, give informed consent, and have the right to opt-out of testing if they desire.

Methods: This qualitative study examined experiences of delivered women undergoing HIV testing during ANC, and healthcare workers who conduct HIV counseling testing in hospitals in Mysore. Three focus group discussions (FGD) among recently delivered HIV-ve women, and eight in-depth interviews with HIV+ women were conducted to explore experiences with HIV counseling testing during ANC. Two FGDs with healthcare workers were conducted to assess knowledge, practices and attitudes around HIV testing of pregnant women.

Results: In the FGD, only six women recalled being informed the purpose of HIV testing. The majority of women reported their doctor being the only person who suggested they get tested for HIV if they wished to deliver at the hospital. Only three women recalled signing consent forms for testing; but a majority said they were given forms and told to sign. A majority of women said their husbands/relatives were informed of results either before or at the time they learned about their results. Healthcare workers had sufficient knowledge about HIV testing and maintained confidentiality. Many admitted that other hospital employees occasionally find out about a women's HIV status. Several expressed derogatory stigmatising remarks about 'uneducated rural women' who don't comprehend HIV counseling or reasons for giving consent.

Conclusions: Women are poorly informed about the risks and reasons for routine HIV testing. The level of information given during post-test counseling varies depending on the HIV status. HIV negative women get minimal to no information during post-test counseling. Healthcare workers should be further trained on confidentiality and informed consent in addition to sensitising them about the need for non-stigmatising HIV testing.

Shared risks, shared privacy: research among young men using tobacco in Tamilnadu.

M Santhosh Kumar

Background: The Declaration of Helsinki has assigned protection of privacy as a duty of the physician conducting medical research. It also emphasises that every precaution should be taken to respect the privacy of the research participants.

Description of the ethical issue: Research involving community-based group counseling approaches faces peculiar problems in the maintenance of privacy. In this study, group counseling is used as a strategy for tobacco cessation among young men in rural Tamilnadu.

Results: In the rural context, young men learn to use tobacco products together and share tobacco products, particularly during situations of shortage. When notions of male bonding include the sharing of risks, almost all members of the group share information about each other's consumption patterns and can report accurately about each other. Attempts to separate such individuals from their groups, in the interests of the requirement of privacy, carry with them the problems of sudden isolation from the peer group. Forcing isolation could be detrimental to the research and to the shared sense of camaraderie which has the potential to facilitate cessation efforts. The relative benefits of enforcing privacy for the research process must be weighed against the potential harms of breaking the bonds of such camaraderie.

Discussion: This scenario highlights the need for greater debate on acceptable compromises to privacy guidelines that would facilitate community-based intervention research that depend on group solidarity for results. In public health, one has to weigh the concerns of both the individual and the community. There is no ethical principle which can provide a solution to this perennial tension in public health. Though community is the primary interest of public health, we still need to pay attention to the rights of individuals.

PARALLEL WORKSHOPS: W1 - 4

Community involvement in public health intervention research

Facilitators: *Angus Dawson, Neha Madhiwala*

The workshop will focus on the issue of community involvement in health research, and explore various aspects of the researcher-community relationship, such as accountability, standard of care, sharing of benefits and post-trial access. Researchers approach communities through a series of intermediaries, such as voluntary organisations and local democratic institutions. Each of these also has long-standing complex relationships with the community. Thus, the research participant relationship is multi-layered and multi-dimensional. This workshop will bring together a panel of diverse resource persons, including bioethicists, researchers and non-governmental organisations. The audience will consist of individuals who are involved in research in different capacities as community advisory board members, researchers, service providers, activists and policy makers. The objective of the meeting would be to arrive at a draft document which outlines various ethical issues surrounding community-based research in different contexts and can provide guidance to groups who are planning or collaborating in such research.

Some of the issues that will be discussed at the workshop are as follows:

- The definition of 'participant' in community based research. This can be quite complex and is important for both conceptual and practical reasons.
- The differing perceptions about a project among the various players involved in an intervention research project.
- The need to assess whether the research was designed to provide a feasible solution. Along with issues of design, scientific rigour and multiple stakeholder interests, the context of the community and its interests should also be highlighted.

Making the voices count: participants' rights and regulation of clinical trials in India

Facilitators: *Sarojini N, Anjali Shenoi, Patrick Durisch*

Dynamic shifts in the areas of drug development and global pharmaceutical sales have led to an exponential increase in the recruitment of human participants in middle and low-income countries, thus rendering India an attractive destination with an unprecedented growth in its drug trial markets. The market in India has grown from Rs 423 crore in 2005 to Rs 1,611 crore in 2010, while it is expected to cross Rs 2,721 crore by 2012.

However, several controversies surround this unprecedented economic turnover. The recent past has seen many examples of clinical trials taking place in disregard of ethical principles and participant rights. At the levels of planning, design and implementation, there exists a striking lack of transparency. This jeopardises the reliability and validity of medical research itself, in the absence of adequate regulatory jurisdiction and systematic review of the industry.

This knowledge gap is particularly striking with respect to factors related to and surrounding human participation in these trials. Despite the huge increase in enrolment of Indian participants in clinical trials, very little is known regarding their experiences and motivations, with limited narratives on participants' perspectives of recruitment patterns, protocols followed with regard to informed consent, compensation, adverse event reporting, monitoring systems, follow up, post-trial treatment access, etc.

In this context, the Workshop will draw from an ongoing *Action Research* project focusing on the larger socio-economic processes of participation and their interplay with a range of social indicators to explore the various factors and barriers that determine such participation. The speakers will also highlight international chains of conduct of drug trials, particularly with regard to participant rights and universal compliance with ethical norms and guidelines. In this way, the workshop will attempt to further critically examine and inform current debates surrounding the ethics and regulation of clinical trials in India, from a bottom – up, rights based perspective; where the participants' voices and interests are paramount.

Playing the ethics monitors: the role of ethics committees in providing continuous oversight of ongoing research studies

Facilitators: *S Swarnalakshmi, Anant Bhan, Prabha Desikan, Medha Joshi*

Background and purpose: This workshop is part of a continuing series of workshops organised at NBCs 2 and 3 by the facilitators on setting up of ethics committees and related issues. This workshop will be supported and promoted by 'IEC-Exchange' (IEC-Exchange@googlegroups.com), India's first e-forum for ethics committees.

Research stakeholders depend on ethics committees (ECs) to oversee the ethical aspects of research: this involves not only granting initial approval, but also providing ongoing monitoring of study conduct to ensure protection of the interests of participants, a fair risk-benefit ratio throughout the study, review of any emerging scientific updates which might influence equipoise, and checking for the relevance /futility of continuing the research.

The practical mechanisms for, and challenges faced by, the ECs in monitoring ongoing health research include limited training in bioethics, inadequate administrative support, insufficient time due to heavy workload, space, ambiguity regarding their roles and responsibilities, and limited scope for self evaluation. Lack of infrastructure, manpower, funds and time can be a major hurdle for conducting effective site monitoring.

The purpose of this workshop is to discuss the constraints and challenges for EC monitoring of research studies, and to identify solutions and best practices.

Key learning objectives: (1) to enable EC members to understand what criteria should be adopted for monitoring of ongoing research by ECs; (2) evolving a shared understanding of how to ensure quality ethical review of research and ongoing monitoring in light of the time/resource constraints within which the ethics committees function; (3) identifying best practices in monitoring by ethics committees

Proposed methods: Presentations, case studies and group discussions.

Training in public health ethics: views from key stakeholders

Facilitators: *Raman Kutty V, Mala Ramanathan, Sreejini J, Praveen Pai*

Training in public health cannot be divorced from the ethics of public health practice. This is particularly important because the practice of public health often conflicts with human rights requirements and individual autonomy. However public health is itself much misunderstood and conflated with community medicine or social medicine. Ethics in public health is, therefore, seen either as 'doing good for the community' or the practice of medicine taking into account the socio-economic variations within society. In such circumstances, ethics is seen as a set of rules to be followed to achieve goals.

There is no strong discourse on ethics within educational systems in India in general, and it is extremely limited within medical education in particular. In order to run a module on public health ethics as part of a Master in Public Health (MPH)programme, one has to first situate the practice of public health within this context and then build in recognition of the various ethical dilemmas and possible solutions. We propose to describe the five year experience of running a module on public health ethics in an MPH programme which had incorporated research ethics into the curriculum.

This will be done by describing the rationale for developing a public health ethics module as distinct from a research ethics module within the MPH curriculum. We will follow this up with a description of the module and the challenges faced while teaching the module to MPH participants. The discussion of experiences of the public health ethics module will be completed by two varying learner perspectives. One will focus on ethics in public health and its distinctions from ethics in research; and the other on public health practitioner ethics as distinct from health practitioner ethics.

ABSTRACTS: DAY TWO

PARALLEL PAPER PRESENTATIONS

GROUP P4: Research ethics: advancing debates

'Vulnerability': A conceptual research beyond its epistemological limitations in research ethics

Nabeel Mangadan-Konath

Vulnerability is one of the least understood topics in the context of research ethics. Though introduced as a key aspect of Human Research Participant Protection, it has given rise to several controversies. This study explores the reasons behind these controversies and examines whether and how the concept of vulnerability can be useful in the 21st century.

Vulnerability is often addressed in bioethics deliberations through a very narrow lens. Guidelines, regulations, and research ethics reviews tend to focus on pre-categorised groups called "vulnerable populations" or "vulnerable categories" of research participants, rather than the different types of vulnerabilities of individual participants. Case studies show a paradox within this approach. On the one hand, several research participants with vulnerabilities tend to be missed from our radars since they do not belong to these pre-categorised groups. Secondly, just because participants belong to a particular group, we tend to overprotect them – for example, women, children, the elderly, etc. While the former situation can lead to the argument that every participant is vulnerable, the latter situation denies the benefits of research to some groups. Both these arguments defy the usefulness of the concept of vulnerability. This paradox can be addressed by shifting our focus away from "vulnerable populations" towards potential "vulnerability factors".

To explain this concept, the author has developed a conceptual diagrammatic model of consent, which shows how prospective participants decide to participate or not, based on their relative perceptions of risk and benefit. Different vulnerability factors of an individual can have varying degrees of push-pull effects on the risk-benefit perception threshold of this decision making model.

Attempts to understand the vulnerability factors must start at the stage of research design itself. A key factor in understanding these factors and ways to address them is community engagement. Drawing from this conceptual model, regulators, bioethicists and other researchers must come forward to undertake empirical research on vulnerability factors, through community participation.

Investigating the investigators: research misconduct

Blair Henry

Research integrity is among the foremost concerns for many stakeholders involved in the enterprise of medical research. Incidents of misconduct (actual or even perceived) can have serious implications across the spectrum of human subject research: the potential for a negative impact on the requisite public trust needed to support research; concerns over the implications that charges of professional and ethical misconduct can have; appropriate determination of what type of punishment might appropriately "fit the crime"; burdens (financial and resource-based) created by the added oversight and responsibilities to institutions and sponsors of research with the aim of catching the misconduct early in the process; changes to the role and responsibilities necessitated by this issue on institutional research ethics boards; and, finally the grave concern expressed by journal editors regarding the added responsibility for reviewing manuscripts in the light of misconduct and the reporting of these findings. These examples provide high level perspectives to the inherent complexities of this issue.

The presenter has participated in several independent investigations of research misconduct and will provide an overview of the "extent of the problem" across the complete timeline of research projects: pre clinical trials data and evidence, protocol development, funding and scientific review stages, independent research ethics board reviews, the regulatory approval process, start up, conduct and auditing of clinical studies, and the final data analysis and publication of results.

Any undertaking to investigate a report of potential research misconduct is complex and requires adoption of a unique "ethical lens" , wherein adherence to strict rules of procedural justice need to be built into the process- to help ensure a fair and just process is followed throughout the investigational process. Implications for future research and work in this area will also be touched on in this presentation.

Protection of research participants: looking beyond the conventional

Sridevi Seetharam

Conventionally, only research subjects are regarded as research participants. The other important groups of persons who participate in research are the research staff, particularly field workers, interviewers or data gatherers who come into direct contact with research subjects.

Unlike institution-based research, where the research staff interacts with the subjects in environments familiar to them, research staff in public health research often venture out into difficult-to-access, unfamiliar, intimidating or even hostile environments to collect data. The data-gatherers are exposed to caste, gender and socio-economic hierarchies and experience associated discrimination and harassment. Often they have similar vulnerabilities as research subjects. Under pressure for meeting recruitment targets and their responsibility to respect research subjects and put them at ease, they subject themselves to difficult situations including unpleasant behaviour and personal probing. They are the 'means' for the researchers' 'end'. They can also be exploited by the investigators in various ways.

Through 'evidence' of case studies drawn from the author's research experiences and qualitative interviews with research staff, this paper draws attention to the variety of risks encountered by research staff and the pressing need for their protection. Regulatory frameworks for research should look beyond protecting the research subjects alone, and safeguard research staff also from harm.

Post-trial access: issues and challenges in India

Sarojini NB

Medical research is shaped by a variety of social, political and economic interests. In India, with trials increasingly being conducted on vulnerable populations; profits rather than public health priorities appear to drive this industry. Industry-sponsored trials also present themselves as exercises in generating medical consensus and patient demand, thus launching new pharmaceuticals in the country without public scrutiny of their added value. Drug companies' apparent ease of access to such populations raises serious questions about the unequal social contexts in which research is conducted, and patient welfare once trials are over and experimental drugs are no longer accessible.

In essence, post-trial obligations describes a duty of research sponsors to provide a successfully tested drug to research participants who took part in the relevant clinical trials after the trial has been concluded. In some instances, this duty is extended beyond the research participants. However, aspects surrounding post-trial access (PTA) and obligations have become a contentious topic with both 'principled' and 'practical' objections ranging from a long time lag between research and licensing, and undue inducement, to making trials potentially 'prohibitively expensive'. Legislation and guidelines are inconsistent, ambiguous or silent about many aspects of PTA. With no specific definitions available for PTA, the most disquieting concern is that exploitation can at best be avoided by 'flexible obligations' simply judged on a case-by-case basis and taking risks and profits into account.

This paper will attempt to outline the legal basis of PTA by critically examining its existing ethical foundations through multi-stakeholder stances on what is and should be offered to research participants after a trial is concluded. It will also analyse various national and international regulations and guidelines on the issue. Finally, the presentation will also highlight the rising obstacles and challenges to the implementation of post-trial obligations and map a way out.

GROUP P5: Ethics and traditional medicine

Priority setting and social relevance of bioethics in traditional Siddha medicine: lessons from the field

C. Suvetha, Thomas M.Walter, M.Sri Sakthi Logisha, R. Sweety Nirmala

Background and purpose: The concept of ethics is in no way new to traditional Siddha medicine. Descriptive ethical guidelines are found in the classical Siddha work, *Yamaga Venba* by the great *Siddhar*, Theraiyar. He gives not only ethical guidelines but also eligibility criteria for Siddha practitioners. Description of research method: Based upon the above mentioned Siddha text a questionnaire with 26 questions was framed. The questions are relevant to the themes of biomedical public health and social science research as also priority setting and social relevance. The questions include bio-ethical concepts such as: eligibility criteria for a physician; the role of environmental factors, the appropriate months and days for beginning the treatment; the relevance of *guru-sishya parampara* (the teacher-student relationship) in the present day; conventional pulse reading; the commercialisation of clinical/research practice, etc. Two Siddha medical colleges were selected for the survey, one

being a government college, the other a private college run by a traditional practitioners' Trust.

Results: The survey results shows that 75% of the participants accepted the priority settings found in the text. 15% responded negatively, while the remaining 10% did not give any answer.

Discussion**:** The survey results show that though he text *Theriyar Yamaga Venba* was written by one of the 18 *siddhars* Theriyar some centuries ago, the principles are applicable in day to day clinical practice and research even today.

Research integrity of AYUSH systems

Sri Sakthi Logisha, Meena Loshini, Vinodhini Ramamoorthy, Asvini TD, Ravi Chandran

The word 'AYUSH' is formed from the traditional Indian systems of medicine Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy and includes therapies documented and used in these systems for the prevention and cure of various diseases. India has a large and proven infrastructure for teaching and rendering clinical care under these systems. More attention is being paid to the concept of integrated medicine today and the priority lies in integrating the AYUSH systems before blending them with the mainstream allopathic medicine. The need of the hour is evidence-based support for the efficacy claims of the traditional systems. Safety, quality control and consistency of AYUSH products are also very much required. This paper tries to identify the priority areas of clinical and literary research within the AYUSH systems with relevance to ethical issues.

Engaging TCAM (Traditional, Complementary and Alternative Medical) providers for essential health service delivery in India: operational and ethical challenges to integration in three states of India

Venkatesh Vinayak Narayan, Kabir Sheikh, Devaki Nambiar, JK Lakshmi, TN Sathyanarayana, John Porter

Background and Purpose: This study was undertaken to diagnose how the different health systems actors understood and interpreted integration for the purpose of implementation of current policies for TCAM providers' integration. We also explored the relational ethics of health systems, notably the roles of trust, respect, power and justice in the context of integration.

Research Methods: This study utilises an interpretive policy analysis approach and qualitative research methods. In-depth interviews were conducted with a range of stakeholders, including policy elites, health administrators, TCAM and allopathic practitioners, traditional healers, health workers and community representatives. A total of 61 in-depth interviews were conducted in Kerala, 59 in Meghalaya, and 60 in Delhi.

Results: The meanings and rationale for integration varied across participants, some of whom questioned its necessity. The chief operational gaps to integration were limited formal communication and coordination between actors representing different systems of medicine; diverse levels of collegiality, ranging from hostility to harmony; and dissonance between expectations placed on practitioners against the amenities provided. Ethical challenges were posed by contestations from different strata of actors on validity and reliability of medical evidence from alternative systems and selective implementation of national guidelines. Conflicting loyalties to systems of medicine (including those not officially recognised), patients and health systems, also emerged as key findings from TCAM practitioners in one state.

Discussion: The preliminary findings suggest that national policy articulations are not translated into the state context, possibly because they leave unresolved larger ethical questions of inherent hierarchies and inter-system coherence that could more concretely support integration efforts. There is a profound need to understand the relational ethics underpinnings, and engender receptivity in mainstream health systems to alternative approaches which could result in evolution of a truly integrated health workforce. This may require institutionalising incentives and opportunities for routine interaction across systems of medicine in training, and ideally, in practice.

Can different systems of treatment co-exist? A perspective from public health ethics

Raman Kutty V

Background and purpose: Whether, and how far, the state should support different systems of treatment- such as modern medicine, traditional medicine (Ayurveda, Siddha, Homoeopathy, Unani, nature cure and others) has been debated in different contexts. However, there have not been many attempts to approach this from a perspective of the ethics of public policy.

Results of ethical enquiry: The three main ethical considerations of benefit-harm ratio, justice, and autonomy should prevail in this question also. Proponents of an 'evidence based' approach would insist that the choice of which system should be supported should depend on the evidence of efficacy, or of least harm. However, translating 'efficacy' as it is understood in individual treatment modalities, to public policy choices is problematic, if we consider the additional dimension of distribution of benefits from one choice versus another.

From the perspective of justice, one question that can be raised is whether a situation of uniformly distributed low efficacy is superior to one where there is better efficacy in some respects, and how far this should go. We see that systems where there is a strong primary health care orientation with universal access and referral mechanisms may offer a better platform for co-existence of several systems, when compared to a market dominated health care sector.

Respecting autonomy would demand that several systems or perhaps, all systems that people may demand, should be

available and supported by the state. However, this raises the issue of whether treatment modalities based on unscientific world views, such as magical remedies and exorcism of spirits, should be supported by the state, or even made legal, just because some people demand it.

Conclusion: This brings us back to the question of evidence. However, we need to consider the concept of evidence with a whole new approach if we are to reach any meaningful conclusion.

GROUP P6: Ethics and regulation

Ethical and regulatory challenges in biobanking: moving the agenda forward in India

Manjulika Vaz, Mario Vaz

Background: There is no agreement on the typology and definition of biobanks. Present regulations across countries, including India, focus on genomic and genetic databases and DNA and cell-line biobanking and it is unclear how holdings of biological samples in diagnostic and research laboratories fall under these regulatory frameworks. Advances in sample storage, data processing and management, understanding of the human genome, bioinformatics and high through-put laboratory assays have made biobank- related research attractive, and while there are some ethical guidelines, debates in developing countries related to this field are limited.

Ethical challenges: What makes the issues in biobank research different from other forms of research are the time lag between the collection of samples and their utilisation for research, the potential for use of samples for extended or secondary purposes, the uncertainty of the research intent at the time of sample collection, and the consequent inability to get truly informed consent, ethical obligations of institutional biobanks with regard to storage, governance and use of samples and the need to contextualise "samples" and 'body parts' with socio-cultural attitudes.

Focus of ethical enquiry: This paper is based on extensive review of published data and discussions at a workshop aimed at evaluating ethical frameworks for biobanking in an Indian context. The issues of 'broad consent', commercialisation of samples, and extended sample use will be discussed. The governance of biobanks as an integral part of the ethical responsibilities of institutions will be highlighted. In addition, the potentially 'subordinate' role of the participant in biobanks-related research and its outcomes including potential benefits will be examined. Finally, gaps in knowledge related to the ethical issues of biobanking in India will be addressed as potential paths for future research. Ecological Systems Theory will be used to highlight interactions between constituents in the biobanking process.

Regulating innovative medical treatments: caught between treatment and research

Vishwas H Devaiah

Medical professionals are often in a dilemma when treatment protocols are modified to achieve better results in the best interest of the patients' well-being. They are uncertain as to whether they should pursue a formal clinical trial or whether their treatment falls within the ambit of standard medical treatment. Quite often this could result in either a conservative approach to treatment, or media uproar and medical negligence claims in case of treatments that do not fall within the ambit of standard medical practice.

The objective of this research paper is to explore the legal dimensions related to innovative medical treatments that neither fall within the ambit of standard medical treatment nor come strictly within the purview or definition of a clinical trial.

This paper seeks to conceptualise innovative medical treatments, explore the contours of the term, the need to have this 'third category' and to regulate it. In doing so, this paper explores the legal implications of such a category on medical professionals and patients.

Sites of contestation: debates and disputes over the governance of international clinical trials

Gerard Porter

In recent years, there has been a dramatic rise in the numbers of foreign-sponsored clinical trials conducted in low- or middle-income countries. This paper looks at ongoing disputes in both host and sponsor countries over how best to respond to the challenges raised by this phenomenon. Four case studies - two drawn from the United States and two from India - are examined. Each case study is an example of contestation over the ethical and legal standards that should govern international clinical trials. The case studies reveal substantial differences in the contending stakeholders' ideological frames and in their visions of what is owed to clinical trial participants. Tensions and problems in the functioning of national and transnational regulatory regimes are also apparent. To conclude, the paper draws lessons and themes from the case studies and uses these to consider broader questions about the relationship between bioethics, law and the logic of the market.

PARALLEL WORKSHOPS: W5 to W8

Round table discussion on three critical policy issues in drug trials in South Asia

Facilitators*: Amar Jesani, Deapica Ravindran*

Background and purpose: Outsourcing of clinical trials (CTs) by international commercial pharmaceutical companies has resulted in a phenomenal increase in drugs CTs on vulnerable populations in developing and transitional countries. The drug

CTs are organised through a complex nexus of different types of contract research organisations (CROs), hospital institutions, doctors acting as investigators, committees reviewing scientific and ethical content, government regulators and other increasing numbers of players. It is assumed that actors based in South Asia join the international flow of research to capture the economic benefits of scientific innovation by creating research capacity; gain relevant training, skills and facilities; generate knowledge of neglected health problems on site; update patient care systems; and improve overall research cultures.

The Universities of Edinburgh and Durham, UK, in collaboration with the Centre for Studies in Ethics and Rights (India), the University of Colombo (Sri Lanka) and Social Science Baha (Nepal), conducted systematic primary research from Sept 2009 onwards by interviewing key stakeholders to understand the way such trials are organised, the roles of various key individual and organisational players, the patterns of international collaborations, the ethical and regulatory standards in place, and the kind of knowledge generated and used from such trials.

This roundtable of researchers and experts, with audience participation, will discuss three major policy issues emerging from the findings of the study: (1) What kind of knowledge is generated and who benefits from it? Is there any evidence to show an increase in the local scientific innovation triggered by the drug CTs? (2) How relevant have drug trials been in tackling the health problems of people in developing countries? (3) To what extent are the ethical and legal regulatory mechanisms in India, Sri Lanka and Nepal capable of providing protection and benefits to participants in drug CTs?

Method: A 10-15 minute presentation on the key findings of the study will be followed by discussion on the specific policy questions in the roundtable. Supplementary questions from the audience will be discussed in the roundtable. The workshop will end with a brief summary of the policy issues and pointers for the changes needed.

Evolving a response to boundary violations in patient care: The Bangalore Declaration and beyond

Facilitators: *Sunita Simon Kurpad, GD Ravindran, Anant Bhan*

Background and purpose: The Bangalore Declaration was a consensus document generated by a group of health professionals to address the issue of nonsexual and sexual boundary violations (NSBVs and SBVs) in the doctor-patient relationship in India. It emphasised the need to include the topic of boundaries in the medical undergraduate curriculum and to develop clearer guidelines on the issue in India. Recent Indian literature on the subject and the Bangalore Declaration generated a degree of national debate with many doctors feeling it was long overdue, yet with some feeling boundaries are a Western culture bound syndrome and a non issue in India.

The logical next step would be to have clear '*pathways for redressal*' for cases of BVs. This workshop is intended to initiate a discussion, including a wider group of stakeholders besides doctors, on whether setting up regulatory systems in India is viable, in view of the ethical and legal challenges this issue inevitably raises.

Method: The speakers will provide a background to the issue (with a focus on ethical aspects), present progress to date, and identify mechanisms for ways forward to develop redressal mechanisms. Time will be provided for audience feedback and participation in developing plans for a practical and effective response framework for BVs.

Campaign on unethical clinical trials in India: experiences from activists and trial participants

Facilitators: *Chinmay Mishra, Amulya Nidhi, Veejay Chaudhary, Swasthya Adhikar Manch,*

Case studies of trial participants*: Pradeep Gehlot, Dattatraya Taras*

Goals:

1. To offer an overview of the campaign by Swasthya Adhikar Manch relating to unethical trials in India, motivations behind the campaign and its allied activities.
2. To bring forth and share with the larger bioethics community the experiences of trial participants in unethical and illegal clinical trials and its impact on their lives.
3. To engage with the bioethics committee to seek inputs to better inform our campaign and translate the same into a sustainable initiative to prevent unethical trials and exploitation of prospective trial participants.

Overview: We will be sharing our learning from the aforesaid campaign against unethical clinical trials in which, at various levels, guidelines and rules were violated by the investigators, ethics committee, and institutions, the pharmaceutical company and monitoring body.

Clinical trials are necessary for the development of new drugs. However, our experience working on the issue has indicated that unethical and illegal trials are taking place in various parts of India. Our insights come chiefly from Madhya Pradesh and Maharashtra, the states in which the campaign is active at the moment.

Choice of trial participants: cause for concern: Our experiences shows there are large numbers of examples in which illiterate and vulnerable patients had been selected for clinical trials without their proper consent. Six doctors of M. G. M. Medical College, Indore, conducted drug trials on 3307 patients, including 2500 children, and earned a sum of Rs 5.10 crore between 2006 to 2010.

As a result of these trials, 81 patients suffered serious adverse reactions of which 33 patients died during or after the trial. After the release of a list of all 81 patients, the victims and their family members decided to organise under the Drug Trial Peedit Sangh (Drug Trial Victims Organisation), the main aim of which is to gather information on all clinical trial victims in the country, and raise awareness of unethical practices in the conduct of clinical trials.

We will also present brief case studies of three patients who became victims of these unethical and illegal trials.

We hope to seek inputs from the conference participants to better inform our campaign and also contribute to empowering trial participants.

Managing research ethics: setting up and running an institutional review board

Facilitators: *LV Prasad Eye Institute team*

This workshop will provide participants with guidelines on how to set up and run an ethics committee, and discuss some of the main issues that arise in the process of conducting ethical reviews of research proposals. The panelists will draw upon their own experience of running a long-standing ethics committee at L V Prasad Eye Institute. Individual speakers will cover the following topics:

1. Guidelines for Institutional Review Boards
2. Ethical review and scientific review: what is the difference?
3. Principles of informed consent
4. Prospective and retrospective studies: ethical issues
5. Patient rights versus need for research

The session will include short presentations by the panelists followed by an interactive discussion.

ABSTRACTS: DAY THREE

PARALLEL PAPER PRESENTATIONS

GROUP P 7: Research method and ethics

Ethics review in social research

Usha Raman, Karthik K

Most institutions do not require ethics clearance for social science and humanities research projects, even those where there is direct involvement of human participants. Questions of ethics, if they do arise, are limited to issues such as confidentiality and informed consent, and are raised most often in health-related research. Other areas of social research with human participants rarely undergo systematic ethics review. Apart from the guidelines framed by the Centre for Enquiry into Health and Allied Themes (CEHAT) in 2000, there has been little attempt to discuss or rethink ethics in social research. This discussion paper will re-examine the CEHAT guidelines in the light of the changing context of social research and attempt to suggest modifications and additions that are applicable to a wide range of social questions.

Principle of cultural relativism and ethical dilemmas in medical anthropology

Ramdas D Gambhir

There has been growing incorporation of the social sciences into public health administration and healthcare delivery with the realisation that not every culture has the same perception of and attitude to the phenomena of health and diseases. Disease occurrences are not just biological in nature, but also socio-cultural and therefore need to be understood in the bio-socio-cultural context.

Medical anthropology is concerned with the application of anthropological and social science theory and method for a better understanding of health, illness and healing cross-culturally. The broad framework of the anthropological approach to the understanding of health beliefs and practices consists of emic-etic perspectives, contextualisation, the concept of culture and the principles of ethnocentrism and cultural relativism. The approach as a whole simultaneously provided ethical and analytical orientation specifically in analysing different cultural systems as well as in methodological approach.

While anthropologists and other social scientists share common professional ethics with other sciences, there is a need to address the ethical dilemmas as they arise in the course of applied research in terms of intervention studies and participatory research.

The present paper seeks to clarify and distinguish between concepts such as moral relativism and cultural relativism, and looks critically at the debates arising out of cultural relativism and ethical universalism, and their resolution in practice.

Questioning the neoliberal approach to research ethics

Kausar S Khan

This paper attempts to answer the question: who is to be held responsible for research ethics, the researcher alone or the institution/s and the State as well? The paper draws attention to the absence of 'organizational ethics' in the teaching of research ethics. Without embedding research ethics into the domain of Organizational Ethics, the plight of research ethics appears like that of the individual in a neo-liberal scenario. Under neoliberalism, individuals are expected to shoulder the responsibility for their own well being. When applied to research ethics, the researcher is expected to function as a

morally autonomous agent, with ERCs to ensure that ethics prevails in the individual enterprise – like the patriarch in a household being responsible for the morality of the individual members. Research ethics thus appears to follow the logic of neoliberalism, wherein individuals alone are responsible for their actions, and the structural responsibilities of the research institutions and the State are overlooked. This paper will include a review of the curriculum of research ethics, especially in the South Asian contexts, and argue for the development of a structuralist approach to research ethics. It will also raise the issue that as medical sciences are dominated by the positivist research paradigm, this world view is more likely to support the neo liberal approach. How a structuralist approach is to be applied would be a challenge to all those committed to research for health and development, as opposed to health research seen in isolation. The implications for bioethics under the structuralist approach will also be presented to generate a discussion within the bioethics community.

Ethical dilemmas: statistically valid indicators vs social relevance in public health

Udaya S Mishra, Mala Ramanathan

While developing public health policy, there is no denying the role of building evidence for making a choice. Such evidence inevitably includes developing indicators to measure particular aspects of a condition among a population or a sub group within it. Conventional wisdom dictates that such indicators be scientifically valid. In most such exercises where the condition being examined is measurable using a scale, the representative indicator is taken to be the average or the mean. We contest this conventional wisdom in making the mean the universal choice for all measurements, for conditions that are measurable on a scale, for public health policy decision making.

One of the goals of public health policy is to achieve equity in health and healthcare access. For this reason, policy should be based on evidence that is scientifically valid. Using the average computed from the population satisfies most of the conventional statistical requirements of a consistent, unbiased, efficient and sufficient estimator. However, in terms of representativeness of the group such a measure is representative of the whole group, but will not capture the differences across weaker sub groups. For example, the NFHS3 indicates that 23.7% of Indian children below 5 years of age are severely stunted. This an aggregate of 31.2% children in the lowest two income quintiles, 23.1% in the middle income quintile and only 12.9% of the children in the highest two income quintiles, indicating the higher burden of stunting in the lowest quintiles. Using a ratio of the distribution of a phenomenon by its share in the group and the group's population share will describe heterogeneity better and enable selection of interventions that build equity. This will be demonstrated by using anthropometric measurements for children using the NFHS 3 survey.

GROUP P 8: Ethics in context

Piecing the fragments together: utilising organisational ethics

Robyna I Khan, Kausar S Khan, Anant Bhan

Background and purpose: It is through research that medicine has discovered the cure of disease and improved the quality and length of human life. However, the last few decades have seen a gradual shift in the goals of biomedical research: from patient and public health benefits to profit earning and career progress. These changing goals have changed the models of research conduct as well. In order to save money and time, hence generate better revenues, clinical trials are carried out in developing countries where regulatory processes are poor and a myriad public health and clinical-care problems compound the ethical issues related to research. There is a significant overlap between issues related to public health ethics, clinical ethics and research ethics; and finding solutions for any of these without considering the others, is impractical. It is now time for bioethicists to step back and examine the bigger picture realistically and holistically.

Discussion: The overlapping issues are intermingled and confusing. A common space needs to be discovered and filled, if realistic solutions are to be found. We ask: Can organisational ethics be the essential central hub around which various spokes of ethics hinge and function? The importance and utility of organisational ethics as the central and integral element on which public health, research and clinical ethics can be anchored to function smoothly has not been invoked in the context of the developing countries, to our knowledge. It is time that this is placed on the agenda of bioethics.

Using examples from Pakistan and India, this paper will present a framework to identify and analyse the disconnect between different aspects of bioethics, and propose possible solutions.

Unethical experimentation on human subjects in India: an overview

Vishal Vennu

This paper presents an overview of scientific misconduct and unethical experimentation on human subjects in India. Instances of scientific misconduct such as falsification of informed consent, of experimental data, or of personal qualifications seem to be more commonly reported recently, even in the popular press. Incomplete and biased unethical trials have occurred around the world, in both developed and developing countries. Some of the unethical trials have been recent. It is time to set up ethical review boards (ERBs) in every institute and medical college in India and for adherence to research ethics to become an essential requirement. Generally, clinicians obtain approval for participation, and believe that those who give consent are capable of understanding the risks and benefits of the study. Ethics committees need to have a sound understanding of the changing nature of health risks faced by research participants.

Apex bodies such as the Drugs Controller General of India and the Indian Council of Medical Research should formulate clear and strict guidelines for the conduct of clinical trials. They should also be vigilant in monitoring agencies conducting clinical research. The government must initiate prosecution of organisations and personnel who are responsible for such unethical and illegal practices. Finally, education in bioethics, evidence based medicine, good clinical practice and drug vigilance of all concerned is important.

Situating evidence in public health interventions: experiences from India, Nepal and Sri Lanka

Tharindi Udalagama, Rekha Khatri, Deapica Ravindran, Jeevan Raj Sharma, Salla Sariola, Ian Harper, Roger Jeffery

Over the past decade or so, there has been an increased interest in generating evidence-based public health policies in South Asia. As a part of the research project 'Biomedical and health experimentation in South Asia (BHESA)' we investigated research studies in the public health sector that were concerned with generating 'rigourous' experimental evidence to persuade governments and policy makers to adopt new policies and programmes. Drawing on our fieldwork in three countries—India, Nepal and Sri Lanka—this paper interrogates the processes that intervene between public health science and politics, through a discussion of selected case studies of evidence generation in public health and health policies and programmes in these countries. In addition to unpacking what is meant by 'rigour' in generating evidence in these studies, this paper explores the views of a range of actors, institutions and networks that put emphasis on evidence and underlying factors that influence the uptake of evidence in health policy making in the three countries.

GROUP P9: Clinical trials and ethics

Can we ascribe altruism as a motivation for participation in clinical trials?

Mala Ramanathan

The opening up of the country to clinical trials sponsored by pharmaceutical companies is representative of the prevailing global economic regime. India with its relatively highly trained medical manpower and high proportion of 'treatment naïve' patients is one of the preferred destinations for such clinical trials. The regulatory mechanisms that exist are weak, rendering participants in such research vulnerable to exploitation. The official records indicate that between January 2007 and January 2012, serious adverse events (SAEs) during trials killed 2193 people within the country. In 2011, 438 people died due to SAEs and only 16 of these received compensation to the tune of Rs.34.88 lakhs. The public outcry following these revelations has resulted in drafting regulations regarding compensation that is due to the research participants for death and disability. The methodology assumes an employee-employer framework to research participation. We dispute this perspective and suggest that participation in research should be seen as an altruistic act.

Potential challenges that emerge to this argument are that participation in research trials may have been motivated by money received or the possibility of a cure in case of disease, or in some cases, access to health care that is otherwise unavailable. In these circumstances it might seem appropriate to see participation in research as employment.

We conclude that in spite of these potential challenges to ascribing altruism to research participation, it still applies. Research participation is not an act where the stakeholders are merely the researcher and the participant. While both the negative and positive direct effects of participation accrue to the participant, the positive externalities of that act accrue to society at large. Therefore, what the collective society owes to the research participant is also relevant. This justifies the attribution of altruism to research participation.

Building understanding of research ethics among the lay public: case study of an expose in the media

Praveen G Pai

A grass roots legal education NGO in Kerala undertook an exercise to publicise the Department-Related Parliamentary Standing Committee on Health and Family Welfare 59th Report on the Functioning of the Central Drugs Standard Control Organisation (CDSCO), to create awareness about the relevance of research for scientific development and the need for ethical practices in research among the lay public. Following this, independent journalists explored the ongoing clinical trials in Kerala using the Clinical Trials Registry of the Govt of India and followed up the centres identified. The resulting media exposure through local language channels included evidence by participants, charges and counter charges and politicisation of the whole process of awareness creation. However, the effort at creating awareness soon died out for various reasons.

This paper explores the aftermath of the expose through the examining the various discussions, write-ups and press conferences conducted for a period of one month following the local language broadcast of the report on clinical trials in Kerala.

The qualitative research exercise uses content analysis to determine the possible reasons for the subdued follow up on the controversial clinical trials in Kerala Lack of awareness regarding ethical norms in clinical trials amongst medical professionals; lack of awareness of the need for anonymity and privacy for not only participants but also researchers during any inquiries; and a general lack of awareness about the nature of routine clinical practice hampered lay understanding and media understanding of the issue at hand. There is a need for training in research ethics for clinicians and media ethics for media professionals in order to promote the most essential medical research that is ethical; the first as a means for building research capacity and the second as a means of ensuring transparency and accountability in public systems.

Clinical Trial Registry- India (CTR-I): trends in quality of registration and its implications on human subject research in India

Avishek Pal

Under the aegis of the World Health Organisation International Clinical Trial Registry Network (ICTRP), publicly accessible national clinical trial (CT) registers are providing access to unambiguous information on CTs. The Clinical Trial Registry, India (CTR-I) was launched on July 20, 2007, while the Drugs Controller General, India made CT registration mandatory starting June 15, 2009. This study aimed to assess the quality of registration of vaccine CTs on the CTR-I and to identify trends in the quality of CT registration on CTR-I.

The term "vaccine" on the CTR-I search option on March 25, 2012 yielded 88 CTs (2007-2012); (84 included in analyses). The quality of registration of CTs was assessed on a 10-point-scale (High [8-10]/Medium [5-7]/Low [0-4]), using the CTR-I dataset descriptions and the COCHRANE Collaboration's "Risk of Bias" scale. Chi-square tests of association were used to assess whether funding source (Industry/Non-industry), study design (Structured/Unstructured), phase (1-4), the number of centres (Single/Multi-centre) and timing of registration of a CT (Prospective/Retrospective) influenced the quality of registration. Further, the impact of funding source on the choice of study design and timing of registration of a CT was also assessed.

Overall, 83.33% of studies were graded as having a high quality of registration. Funding source and study design did not appear to influence the quality of registration (p-values:0.177;0.335), whereas multi-centre studies and those registered prospectively had a higher quality of registration (p-values:0.039;0.029). Whether the phase of the study influences the quality of registration warrants further investigation. In addition, funding source did not appear to influence the choice of study design, or whether a study was prospectively/ retrospectively registered (p-values:0.392;0.454).

The data from this study provides insights into the role of CTR-I as the sole CT repository in the region, in terms of providing timely, accurate and complete information on CTs conducted in the Indian sub-continent.

Role of money in the conduct of clinical and public health trials in South Asia

Anand Kumar

Public and private funding for biomedical research has increased vastly over the last decade. A key turning point in putting South Asia on the research map, with particular reference to drug related research and development, was the change in legislation in 2005 with a stronger patent regime that witnessed the emergence of India as a destination for clinical trials in the region. Although money plays a central role, there is little evidence of its sources and uses/ flow, the incentive environment it shapes, and the extent to which it determines the rise in the network of collaboration and interdependencies. Additionally, questions around who and what drive these flows in specific disease areas (clinical need or commercial opportunity/viability), and what is the value generated from this remain unanswered.

Drawing on a subset of data from a multi country ethnographic research and interviews with various stakeholders in Sri Lanka, Nepal and India, this paper examines these issues in greater detail. More specifically, it examines the role of money and the ethical implications of the changing culture and discourse on experimentation in research.

Abstract Review Process

Abstracts were invited for oral paper presentations, poster presentations and workshops/symposia. Submitted abstracts were anonymised and then distributed among a panel of reviewers. Once the review comments were received, a subset of the Conference Organising Committee met in Hyderabad and a final decision was made about the conference programme. The decisions about individual abstracts were then communicated to the authors.

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University Of Hyderabad
Campus Sketch
GOPANPALLI GATE
SCIS
New SIP Office
Integrated Hostels
ACHREM
Nano Lab
New Life Sciences
Tagore International House
DSW Office
Chief Warden Office
MBA HOSTEL
P&T OFFICE
WORK SHOP
GURUBAKSH SINGH HALL
GUEST HOUSE
LIBRARY
RTC STOP
BUS STOP
CAMPUS SCHOOL
TYPE D
STAFF QUARTERS
TYPE C
ASC
DISTANCE EDUCATION
S.N. SCHOOL
VC's LODGE
MANAGEMENT STUDIES
DST SEMINAR COMPLEX
MATHS & CIS
PHYSICS
HUMANITIES
COSIST LAB
CIL
SCIENCE COMPLEX
CHEMISTRY
LIFE SCIENCES
STUDENT CENTRE
WOMEN'S HOSTELS
A I LAB
SPORTS STADIUM
MEN's HOSTELS
H.S. HOSTELS
SHOPPING COMPLEX
FLAT LETS
New SN School
Chemistry
SPORTS FACILITY
PLAY GROUND
FACULTY QUARTERS
HEALTH CENTRE
TYPE B
TYPE A
OFFICERS QUARTERS
ADMISSIONS OFFICE
ADMINISTRATION BUILDING
ILS
CMSD
Small Gate
MAIN GATE
TO MEHADIPATNAM
OLD BOMBAY ROAD
TO LINGAMPALLY / BHEL