Challenges of Ethical and Regulatory Guidelines in regard to Biobanking in India

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Coverage

- Situational analysis of Biobanking in India
- India’s regulatory framework for biomedical research
- Are India’s public ready for banking of their biological samples and genetic research?
- The ethics of ‘consent’
- The dilemmas of ‘ownership’
- Benefit sharing and return of incidental findings
- Policy gaps – to the way forward

Biobanking in India – a situational analysis

- Biobanking in its infancy.
- Issues of typology
- No formal registration required
- 2006 Indian Council of Medical Research (ICMR) Guidelines had a minimal coverage of biobanking under Human Genetics and Genomics research.
- **2017 ICMR Guidelines has a complete chapter on Biological Material, Biobanking and Data Sets**

Biobanking – its attractiveness has not missed India

- Molecular mechanisms and causes of many diseases
- Discovery of therapeutic targets / biomarkers
- Gene environment interactions
- Infrastructure for sustained research
- Predicting disease patterns over time in populations
- National Pride

16 NOVEMBER 2007 VOL 318 **SCIENCE**

PUBLIC HEALTH

Biobanks in Developing Countries: Needs and Feasibility

Technological advances coupled with use of existing resources can be used to create biological repositories that may lead to better health in developing countries.

S. K. Sgaier,[1*] P. Jha,[1†] P. Mony,[1,2] A. Kurpad,[2] V. Lakshmi,[3] R. Kumar,[4] N. K. Ganguly[5]

Indian Journal of Rheumatology

Volume 6, Issue 3, September 2011, Pages 129-137

Biobanking: Basic concepts and role in rheumatology

Subramanian Shankar, Yanamandra Uday

The role of biobanking in understanding the pathophysiology of various rheumatological illnesses is emphasized.

Ethical Dilemmas not far behind…

Applied & Translational Genomics
Volume 2, 1 December 2013, Pages 17-21

ELSEVIER

Pharmacogenomics, Theranostics and Personalized Medicine - the complexities of clinical trials: challenges in the developing world☆

NimitaLimaye

INDIAN JOURNAL OF MEDICAL ETHICS
JOURNAL OF THE FORUM FOR MEDICAL ETHICS SOCIETY SINCE 1993
ONLINE ISSN: 0975-5691 | PRINT ISSN: 0974-8466

Vol 11, No 2 (2014)

Ethical challenges in biobanking: moving the agenda forward in India

Manjulika Vaz, Mario Vaz, Srinivasan K

INDIAN JOURNAL OF MEDICAL ETHICS
JOURNAL OF THE FORUM FOR MEDICAL ETHICS SOCIETY SINCE 1993
ONLINE ISSN: 0975-5691 | PRINT ISSN: 0974-8466

Vol 12, No 2 (2015)

Listening to the voices of the general public in India on biomedical research – an exploratory study

Manjulika Vaz, Mario Vaz, K Srinivasan

The Journal of Law, Medicine & Ethics

Biobanking and Privacy in India

Sachin Chaturvedi, Krishna Ravi Srinivas, Vasantha Muthuswamy,

First Published March 1, 2016

developing world bioethics

The views of ethics committee members and medical researchers on the return of individual research results and incidental findings, ownership issues and benefit sharing in biobanking research in a South Indian city

Manjulika Vaz , Mario Vaz ,Srinivasan K

First published: 17 May 2017

India’s Regulatory Framework

- **Clinical Trial focussed**

- Drug Controller General of India
  - Central Drugs Standard Control Org
  - Ministry of Health & Family Welfare
- Clinical Trials Registry of India
- Indian GCP Guidelines
- IEC adherence to Sched Y of Drugs & Cosmetics Act1940,2005

- **Science & Technology focussed**

- Dept of Biotechnology
  - Ministry of Science & Technology
  - ‘Make in India’
  - ‘Incredible India’
- Awards and Grants .. “robust bio-economy”
- National Guidelines for Stem Cell Research – 2017
- Bio-safety regulations

India’s Regulatory Framework

- **Indian Council of Medical Research – Section on Biological Materials, Biobanking and Data sets**

- 2017 National Ethical Guidelines for Biomedical and Health Research involving human participants
- Aspects relating to Researchers : Definitions of biological materials, biobanking and datasets, Storage – safety and quality, Sample typology based on identity linkage
- Aspects relating to Donors : Multiple forms and multiple layers of consent, ownership, benefit sharing
- Aspects related to the Institution: Custodianship, National / International Collaborations, Transfer of samples, EC approvals and oversight, Governance of biobank – SOPs, Governance Structure

India’s Regulatory Framework

- **Indian Council of Medical Research – Section on** Biological Materials, Biobanking and **Data sets**

- Data repositories for a specific research purpose or commercialisation requires ethical review
- Data mining, access control and data usage must be approved by the Ethics Committee
- Data privacy, data accuracy, data security and possible legal liability are elements of ethical review when data is outsourced or sold
- Health data sets when exploited for commercial purposes must adhere to open access provisions, sharing rights and benefit sharing.
- Measures to protect privacy and confidentiality of Individuals must be in place

India’s Regulatory Framework

- National Accreditation Board of Hospitals and Healthcare providers

- Patient Health Charter -Ministry of Health & Family Welfare

- Patient’s Health Charter - Right to confidentiality about their medical condition.

- Draft of Patient Charter –August 2018, prepared by the National Human Rights Commission under the Clinical Establishments Act 2010
  - Right to protection of participants involved in biomedical and health research
  - Patient’s Rights to be given adequate protection and operational mechanism to make these rights functional and enforceable by law.

Public Perceptions: a pilot study 2015

Willingness to contribute a biological sample

- Nearly all the participants readily agreed to have their blood and tissue samples stored for future research once their diagnostic tests had been carried out.

- The primary reason was that it was “anyway a waste for me”, the tissue was already outside the body and hence, there would be no harm to the body.

- Also it was alright to use medical records, if it was helping others.

- Consent and confidentiality were not great matters of concern

- As the area was probed, questions such as who was conducting the research, where it would be conducted and what the research was about were asked by some.

Sample : 14 IDIs lasting 1.5 years using an unfolding case vignette, incl college students, school teachers, business professionals, slum dwellers, retired persons

Perceptions towards genetic research

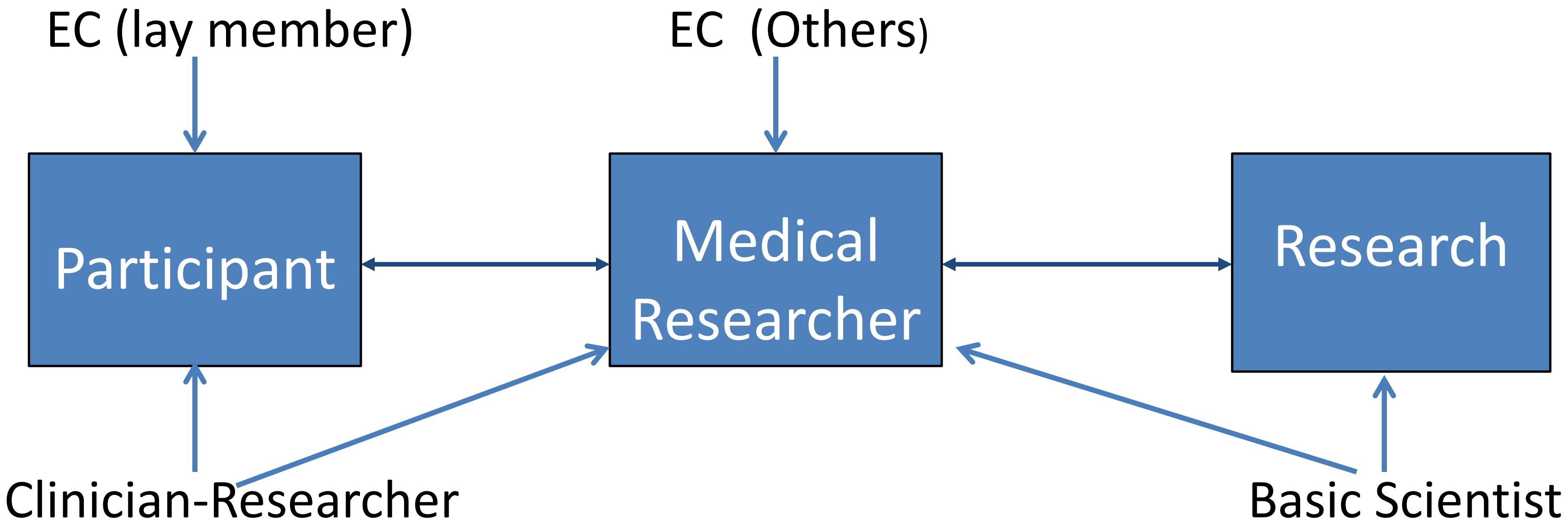
- Only some had a degree of familiarity with genetic research

- Perceived Benefits
  - it may help children in the future,
  - It may be useful; it could be good for us,
  - It could prevent diseases.

- Expressed Concerns
  - Misuse – *"Things could go wrong and there could be misuse of the research"*,
  - Eugenics- " *there's a thin line between research for treatment and trying to create maybe physically better people or trying to play around with nature";*
  - Commercialisation – "*they must not exploit the patient in any way by selling genetic material or what they discover"*

- Felt Needs
  - Disclosure – "*They should inform us if they are doing genetic research"*
    - *"If helpful, good for us to know the results", Anonymization not preferred "if not contactable"*
  - Accountability – "*[Reconsent] will make them accountable ... Otherwise, they feel they can do anything"*

Various sides to ‘**consent**’ *Perceptions of Ethics Committee members and Medical Researchers*



EC (lay member)

EC (Others)

Participant

Medical Researcher

Research

Clinician-Researcher

Basic Scientist

PEOPLE

“person’s right to contribute or to disagree”

SAMPLE

“Consent taken too far … if valuable learning for medicine”

‘Ownership’ of sample *Varying perceptions of Ethics Committee members and Medical Researchers*

Ownership of samples was seen as a ‘grey area’ and was perceived at multiple levels by different respondents:

Patient always the true owner, this emerged as a ‘moral’ construct

Storage facility–bio repository/department lab, as the virtual owner … the “Custodian”

Ownership handed over to the researcher through the consent form

Disclosure of incidental findings *Perceptions of Ethics Committee members and Medical Researchers*

Ethical & Moral Reasoning

THE CASE FOR

- Clinically actionable findings are critical in resource poor environments
- ‘Altruism’ is not one sided
- Principle of reciprocity

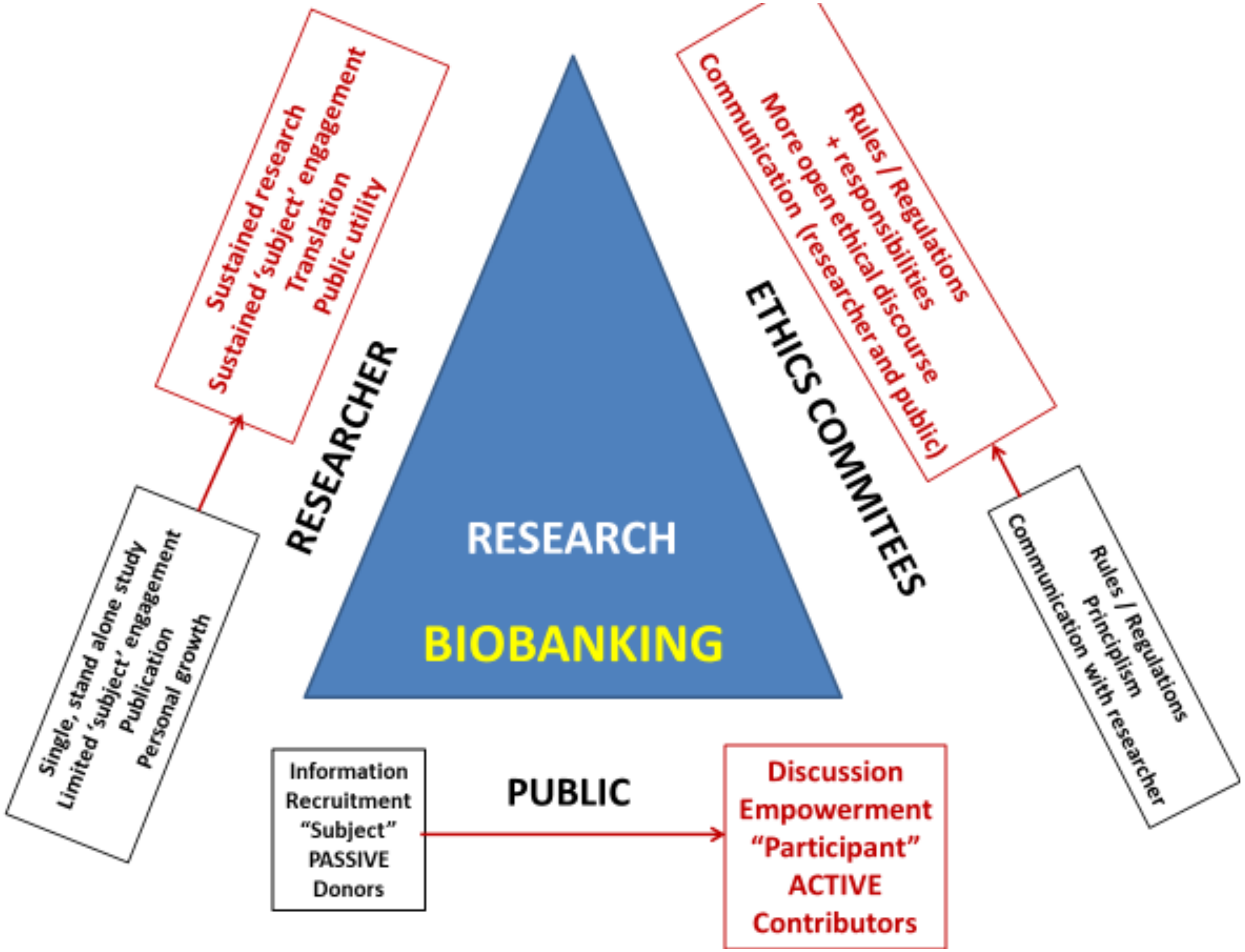
THE CASE AGAINST

- Research driven by generalizable NOT individual findings
- Information harm
- Limitations of resources for researcher

Practical challenges

The ethic of ‘giving back’… fulfilling the principle of distributive justice

Policy Recommendations



RESEARCH

BIOBANKING

RESEARCHER

Single, stand alone study
Limited 'subject' engagement
Publication
Personal growth

Sustained research
Sustained 'subject' engagement
Translation
Public utility

ETHICS COMMITEES

Rules / Regulations
Principlism
Communication with researcher

Rules / Regulations
+ responsibilities
More open ethical discourse
Communication (researcher and public)

PUBLIC

Information
Recruitment
"Subject"
PASSIVE
Donors

Discussion
Empowerment
"Participant"
ACTIVE
Contributors

Policy Recommendations

TRUSTWORTHINESS

Collectivism
[Two way Altruism]

- Societal benefit and the Common good
- Advancement of Science, Balance of rights (individual and societal)
- Avoiding individual financial gain
- Giving back of test results and research findings

Consultation
[not limited to seeking consent]

- Listening to public perceptions -risks and fears
- Transparency of motives and implications
- Move away from paternalistic, regulatory driven approaches
- Move from 'autonomy' of decision making to 'accountability' of researcher to the public

Stake holding
[shared obligations]

- Shared governance of the biobank and shared decision making on the studies being approved
- Engagement in policy development in translational research and benefit sharing
- Long term commitments, health imperatives and health implications

Policy Recommendations

- From Libertarianism to Communitarianism
- Focus on reciprocity and distributive justice - “giving back” incidental and research findings
  - To be mentioned in the Consent form with options of how to connect
- Focus on multiple stakeholders, shared obligations, public engagement, engaged deliberation, and ‘common good’
  - To be included in the governance of the biobank

Policy
Recommendations

- **Capacity Building of Multiple Stakeholders – Researchers, Ethics Committee members, Institutions housing the biobanks/ data repositories, the Public**
  - **Training on regulations pertaining to biobanking and shared data**
  - **Opportunities for deliberation on ethical questions across stakeholder groups**
  - **General awareness on biobanking, governance aspects, benefits of sample and data contribution, safety and confidentiality, public good**

14th WCB, India

14th World Congress of Bioethics
&
7th National Bioethics Conference

INTERNATIONAL ASSOCIATION OF BIOETHICS

INDIAN JOURNAL OF MEDICAL ETHICS

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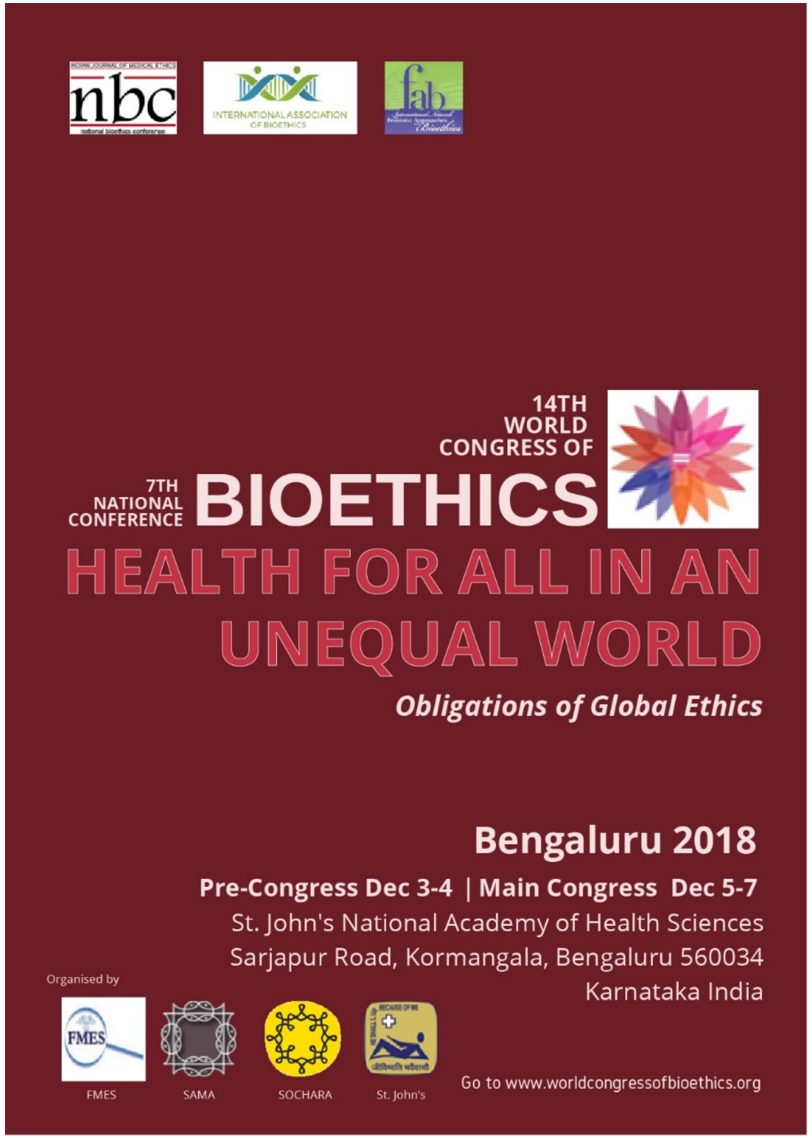
national bioethics conference



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Karnataka India

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THANK YOU !

For the opportunity to share, engage and deliberate!