

Biobanks and Material Transfer Agreements: Some Developing World Perspectives

Professor A Dhai

Director – Steve Biko Centre for Bioethics
Chairman – SAMA Human Rights, Law and Ethics Committee

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Human tissue

- Holds central place in history of medicine, medical research, values, cultures, traditions
- Evokes strong but diverse emotional and spiritual responses
- Also necessary for remarkable advances on healthcare context as major source of material for knowledge-based genomics revolution.



Biomedical Research

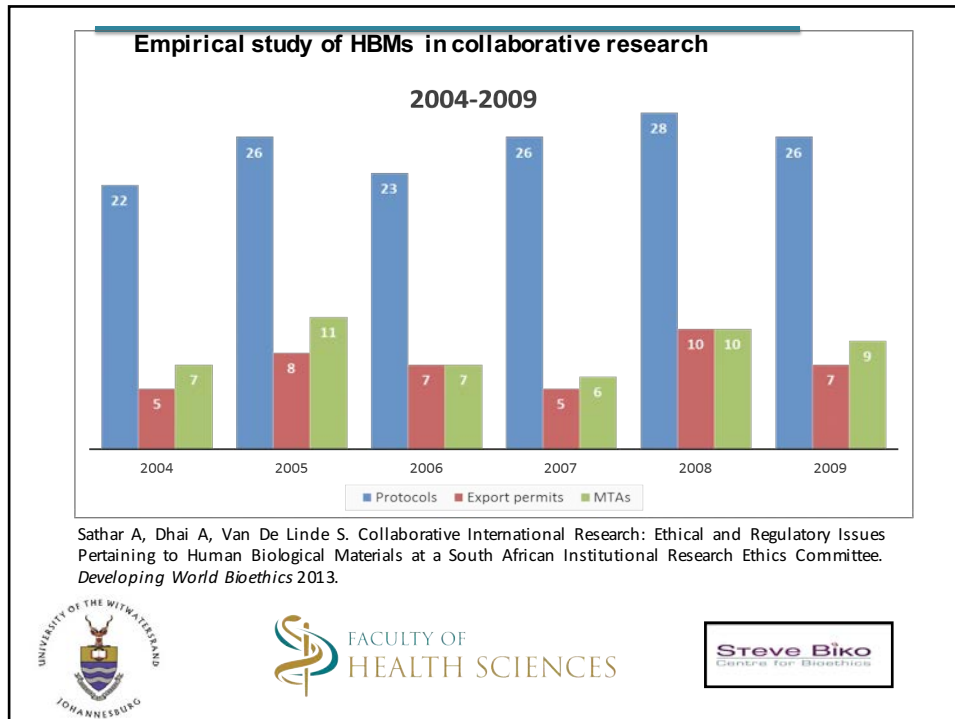
- Like the world economy – is in the era of globalization
- Increasingly being conducted in developing and emerging regions of the world.
- Collaborations increasing - funders from better resourced regions
- Access to HBMs from research communities in developing countries not without controversy.



Controversies

- accusations of fraud and theft
- violation of national guidelines
- cultural insensitivity
- inappropriate or lack of consent
- reluctance of international organisations to address the concerns and recommendations of developing countries
- loss of foreign exchange due to uncontrolled export of HBMs
- inappropriate or lack of benefit-sharing
- paucity of authors from developing countries in scientific publications from collaborations
- African scientists not seen as equal partners
- African institutions and researchers viewed as specimen collection centres and collection technicians





Material Transfer Agreement

- Legal contract
- Governs transfer of materials between organisations
- Sets out:
 - what will be done with material
 - used in humans or not
 - quality, terms and conditions of use
 - any modifications
 - third party transfers
 - benefit sharing, intellectual property rights and any legal, regulatory guidelines or policies.





Risks of not having an MTA

- Materials may not be utilised for the agreed purpose
- Secondary uses may not be regulated
- Third party transfers may take place without the PI's knowledge
- Donor dissatisfaction
- Biopiracy: includes theft, fraud, acquiring of exclusive monopoly control through use of intellectual property and in particular patenting, lack of prior informed consent from research participants.



Wits MTA Template

- Differs from traditional templates
 - Includes Data
 - Incorporates ethico-legal concepts
 - HREC oversight
 - Informed consent & secondary uses
 - Benefit sharing
 - Unique to developing country participants & researchers
- Benefit sharing:
 - process or action of sharing in the benefits that derive from the research project in a fair and equitable manner
 - should be negotiated: sharing of information, royalties, acknowledgement of the provider as the source of the material, publication, transferring of technology or materials, capacity building



Wits MTA – Signatories

- 1.PROVIDER (PRINCIPAL INVESTIGATOR)
- 2.RECIPIENT
- 3.HREC

MTA is subject to the suspensive condition and is of no force or effect unless and until, the HREC has approved the study of which the MTA forms a part of *and* approved the MTA.

MTA template:

http://www.wits.ac.za/academic/researchsupport/19110/ethics_and_research_integrity.html



Recommendation for Declaration

The terms of access for researchers to specimens and data should be set out in a Material Transfer Agreement or other agreement appropriate for that purpose



Public Consultation

Consultation with the public and ensuring that they clearly understand the functioning of and research conducted by the biobank : respect for communities - key

Public confidence and trust in biobanks research as being done for the common good must be cultivated - maximize participant recruitment and retention of samples. Cultural dynamics need to be understood

Become more knowledgeable about:

- Vulnerabilities of groups, values, concerns, life experiences
- Potential group harms & how to minimize harms
- Potential group benefits & how to maximize them



Public Consultation

*Two thirds of respondents surveyed in Europe had not heard of biobanks - Most respondents once aware of the concept were generally supportive.

SA - Large scale survey not been conducted throughout country as yet.

Meaningful conversations on biobanks between the public and researchers are lacking.

* POST NOTE 473. Biobanks. 2014. Available from <http://researchbriefings.files.parliament.uk/documents/POST-PN-473/POSTPPN-473.PDF>



Recommendation for Declaration

Public Engagement and Trust

There must be consultation with the public to enable them to understand their engagement in the process and to foster trust. Ongoing dialogue between the public, researchers and biobank managers is essential.



Intellectual Property – Current Draft

18. Special considerations should be given to the possible exploitation of intellectual property. Protections for ownership of materials, rights and privileges must be considered before collecting and sharing the material.



Recommendation for Declaration

Intellectual Property

18. Special considerations should be given to the possible exploitation of intellectual property. Protections for ownership of materials, rights and privileges must be considered before collecting and sharing the material. *Intellectual property rights should be detailed in a clearly articulated policy which addresses the rights, if any, of the database, biobank, researchers, sponsors, participants / donors.*



Recommendation for Declaration

Biobank / Database Closure

There should be a suitably detailed policy setting out the manner in which the human biological materials and data that it holds will be dealt with in the event of closure of the biobank or database.

The biobank's policy on the destruction and disposal of materials and data should take into consideration the cultural and/or religious beliefs of the participants / donors, and/or their representative groups.



Recommendation for Declaration

Lead-in to Governance :

Governance should be designed such that the rights and well-being of participants / donors prevail over the research interests of the data set or biobank operators and users.



Thank you

