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Ethical issues in collection and use of human materials during TB clinical research in Uganda

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Introduction

Human biological materials are useful research materials and are usually stored for possible uses in future research because they preserve valuable biological information, save time and resources and are less burdensome to sample sources

However, use of stored human materials may result in issues like disclosure of genetic information about an individual or community which may have dire consequences like, stigma, psychological harm, discrimination or bio-security implications rendering sample sources vulnerable

Introduction…

Many times HBM are Exported due to:

- In adequate local capacity
- Quality assurance at Central lab— especially in collaborative research
- Citizens studying abroad
- Cheaper to work with samples in more advanced facilities abroad

Introduction…

Aspects like lack of control over the materials or data, where they are stored, who owns and how they are used, for what and by whom and benefits if any have topical in our setting

We evaluated how the TB clinical research protocols conform to the consent requirements in the Uganda national guidelines

Methods

This was a retrospective study of TB clinical research protocols cleared by the UNCST from 2011 to 2015 on how they fulfill the requirement for ethical collection and use of human materials

Data was collected using a template based on the informed consent requirement in the national guidelines, materials transfer agreement as well as review of protocols for information on materials collection and handling

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Results

A total of 55 research protocols were cleared by the UNCST

Most of the protocols 46 (83.6%) collected specimen including sputum, blood and sometimes urine, 13 (28%) had a section on specimen collection and 8 (17%) mentioned ownership of the biological materials

Percent of protocols with available information on materials collection

Items	Clearly Included	Included but not clear	Not available
Material acquisition	28.3	47.8	23.9
Storage & future use	13.0	26.1	60.9
Ownership of materials	0.0	24.4	75.6
Exchange/transfer of materials	0.0	20.0	80.0
Exchange/transfer while abroad	0.0	13.3	86.7
Material acquisition	28.3	47.8	23.9
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Exchange/transfer while abroad	0.0	13.3	86.7

Results…

Review of the consent forms, although many of the studies store materials for future use, only 8 (17.4%) protocols had a separate consent form for storage of materials, 4% of the consent forms explained the risks, 6.5% explained the purpose of the study while 8.7% mentioned the place of storage for the collected materials

Only 8 protocols had their materials transfer agreements accessed

Information in the consent forms for TB clinical studies

Items	Clearly Included	Included but not clear	Not available
Storage & Enrol Separated	9.1	11.4	79.5
Storage purpose	11.4	9.1	79.5
Storage quantity	2.3	2.3	95.5
Storage Place	6.8	4.5	88.6
Confidentiality measures	2.3	6.8	90.9
Sample use governance	0.0	2.3	97.7
Storage risk/benefits	4.5	0.0	95.5
Other inform included	0.0	4.5	95.5
Storage future use"	0.0	4.7	95.3
Ugandan Co-PI	0.0	0.0	100.0
No storage penalty	4.5	0.0	95.5
Storage withdraw	6.8	0.0	93.2
REC to review future	0.0	4.5	95.5

Materials transfer agreements

Items	Clearly Included	Included but not clear	Not available
MTA	8	0	0
Parties involved	7	1	0
Description of materials	4	2	2
Purpose and usage	5	2	1
Users names	4	2	1
Period of use	7	0	1
Description of disposal	4	1	3
Restrictions on usage	2	2	4
Ownership of derivatives	4	2	2
Information on ownership	4	3	1

Discussion

Most of the protocols lacked an elaborate section on specimen collection, use and storage

Additionally the requirement for a separate informed consent form for storage is not adhered to

The informed consent forms lacked the required information

The MTAs lacked the required information

However, all the reviewed protocols had been approved by Research Ethics Committees and cleared by the UNCST. Hence gaps both in the science and regulatory process

Conclusion

Many of the studies cleared by the UNCST do not conform to the requirement by the national guidelines. There is need for continued sensitization of researchers and research regulators on the national guidelines

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References

Uganda National Council for Science and Technology: National Guidelines for Research Involving Humans as Research Participants. Kampala, Uganda 2014.

Tindana et al.: Ethical issues in the export, storage and reuse of human biological samples in biomedical research: perspectives of key stakeholders in Ghana and Kenya. BMC Medical Ethics 2014 15:76.

Verlinden M, Nys H, Ectors N, Huys I. Qualitative study on custodianship of human biological material and data stored in biobanks. BMC Med Ethics. 2016 Mar 1;17(1):15.

National Bioethics Advisory Commission (NBAC). Research involving human biological materials: ethical issues and policy guidance. Rockville, Maryland: U.S. Government 1999;)

REG Upshur, JV Lavery and PO Tindana; Taking tissue seriously means taking communities seriously. BMC Medical Ethics 2007, 8:11

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