Biobank Ethics Committee for Approval of Biobanks

PEER REVIEWED

The Human Research Ethics Committee (HREC), University of the Witwatersrand (WITS), has regulated that all biobanks being accessed by researches submitting protocols for review are required to undergo a formal approval and registry process through a subcommittee of the HREC known as the Biobank Ethics Committee (BEC). The committee has been assigned with a mandate to review all such research applications for biobank storage, or for the registration of a biobank requesting approval for the storage of human biological material (HBM). The BEC reviews all such applications and makes recommendations back to the HREC. The committee has been tasked with development of principles, policies and guidelines for the biobanks.

This regulated process will ensure that all biobanks approved are in adherence and compliance to the Human Research Ethics Committee (Medical), University of the Witwatersrand principles and policy on biobanks with the adoption and promotion of best practices based standards for biobanks undergoing ethics approval. This will further augment the harmonisation and governance of HBMs and their respective usage, and standardisation across all biobanking facilities. The WITS biobank policy document was officially approved and adopted in August this year and also supported by the National Health Ethics Council (NHREC) and approved for inclusion into the national DoH research ethics guidelines (communication from HREC chair, 20 June 2013).

The preamble established within the policy document mandates that the human rights and wellbeing of participants are respected and prevail over the research and other interests of the owners and users of biobanks, in accordance with the Bill of Rights of the Constitution of South Africa and other pertinent South African law, with the privacy and confidentiality of the participant data and information protected and secured. The principles and standards implemented should be in accordance with accountability, transparency and good governance, and within the legal and ethical framework of South African guidelines for good practice in the conduct of clinical trials in human participants and ICH-GCP, and the WMA Declaration of Helsinki ethical principles for medical research involving human subjects.

The primary objective of the biobank would be to foster research by making human biological materials readily available to researchers for testing, knowledge advancement, scientific development, research breakthrough and long-term storage. The biobanking policies and procedures should be in compliance to good clinical laboratory practice, best bio repository guidelines, best cold chain practices, IATA regulations, and best quality assurance practices.

SANAS biobanking accreditation guidelines are currently not available, and would recommend that all biobanks adopt the following international biorepositories best practices guidelines:

- The National Cancer Institute (NCI) have published best practices and principles by which procedures can be developed and adopted.
- The International Society for Biological and Environmental Repositories (ISBER) has developed best practices for repositories, providing a rich source of information, principles and guidelines collated by professional biobank practitioners for the management of specimen collection and repositories.

A number of regulatory compliances, acts and guidelines must be adhered to at all times within South Africa and are listed below.

- The Bill of Rights of the Constitution of South Africa;
- National Health Act 61 of 20037;
- Proclamation No 11 *Government Gazette* 35081 of 27

February 2012;
- *Government Gazette* 35099 of 2 March 2012 (See Annexure page 8 for some pertinent aspects of the regulations);
- Regulations relating to Blood and Blood Products;
- Regulations relating to Stem Cell Banks;
- Regulations relating to the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes;
- Regulations relating to the Import and Export of Human Tissue, Blood, Blood Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes;
- Regulations relating to the Use of Human Biological Material;
- Regulations relating to Tissue Banks;
- Companies Act 71 of 2008;
- Health Professions Council of South Africa: Guidelines for Good Practice in the Health Care Professions: General Ethical Guidelines for Health

The Human Research Ethics Committee medical (HREC) has published principles and a policy document for biobanks, which needs to be used as a reference and compliance document for biobanks. A senior biobank practitioner should review the above document prior to completion of the BEC2014 application form part 1.

The following BEC application forms part 1 and 2 need to be completed and submitted as part of the biobanking application process.

BEC2014 Application form Part1: The form is part of a technical application document that needs to be completed by a senior biobank practitioner. Once approval is granted, the biobank would have a clearance certificate valid for a period of five years, with renewal application required thereafter.

BEC2014 Application form Part2: Storage/retrieval/transfer of HBM to be completed by principal investigator for each new study protocol submitted for approval.

All application forms and documents are readily available on the WITS Ethics webpage; www.WitsHealth.co.za

In the not too distant future all biobanks will be mandated to be registered with the Department of Health as required by the Regulations of the National Health Act, which is still currently under review. The biobank SANAS and GCLP accreditation is still in the developmental phase and is imminent for biobanks in time to come.

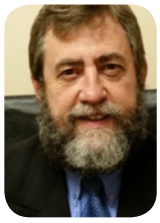
Specimens and data from an approved biobank would only be allowed to be transferred to other approved biobanks, and in the event of temporary closure of the biobank, specimens and data are to be transferred to other biobanks only once approval has been granted from the BEC. All collaborative project/s must have an overarching material transfer agreement in place.

A material transfer agreement (MTA) is a contract governing the transfer of materials between organisations and /or institutions, which set out what will be done with any material supplied, whether used in humans or not, the quality, the terms and conditions of use, any modifications, third-party transfers, benefit sharing, intellectual property rights and other legal, regulatory guidelines and policies. Regulations relating to research on human subjects (GN R 378 in Government Gazette 36508 of 29 May 2013), creates an onus on the researcher to increase the involvement of communities and research participants in the research process.

Complexities that result when considering biobank research, in particular the transfer of HBMs, are immense. Individuals and communities are becoming increasingly aware of their rights. Therefore stipulating the ethico-legal requirements regarding the transfer of HBMs is needed. A balance between the protection of the research participant and the progressive nature of research needs to be recognised in order for effective research to take place. The Biobank Ethics Committee has approved an MTA developed as one of the outcomes of Safia Mohamed's PhD though the Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand, and will be available for usage from the WITS Ethics website, and requires acknowledgement if used.

This new biobanking regulation will ensure that biobanks storing samples are well-founded in biobanking management practices, regulatory guidelines, policies and standards required within industry, able to meet the primary objective of providing the research laboratories with high-end quality biological samples that have not been compromised in any way during storage, in so assisting with research breakthrough needed during the analysis.

Acknowledgement
1. The University of the Witwatersrand Biobank Ethics Committee of HREC (Medical).
2. The Human Research Ethics Committee Medical (HREC) principles and policy on biobanks
3. Safia Mohamed PhD development outcomes of the MTA though the Steve Biko Centre for Bioethics, Facility of Health Sciences, University of the Witwatersrand.
4. Professor Ames Dhai and Safia Mohamed from the Steve Biko Centre for Bioethics; Powerpoint presentation at SACRA conference 2014, Biological Sample Transfer Agreements and Feedback on Biobanking.
5. www.Witshealth.co.za website.



Peter Meewes is currently the Bio Bank Director and National Laboratory Manager for BARC South Africa and has spent more than 20 years working in the laboratory environment of Clinical Trials industry within Southern Africa. Peter is an active member of a number of international working groups and has recently joined the WITS Bio Bank Ethics Committee as a full member. He has Project managed and built a world class Bio bank repository which opened its doors in October 2009 which currently stores in the region of a million samples for various pharmaceutical, NGO groups and academic trials. Peter is also a PBMC specialist in developmental training, cold chain practices, good clinical laboratory practices and international industry standards and best practices for laboratories and Bio Banks.

Safia Mahomed is a PhD student with the Steve Biko Centre for Bioethics in the Faculty of Health Sciences at the University of Witwatersrand (WITS). Her research involves developing an ethico-legal framework for the regulation of Biobanks in South Africa. Safia is a member of the Biobanks Ethics Committee of the Human Research Ethics Committee (Medical) at WITS. safia.mahomed@telkomsa.net/ safia840624@gmail.com