Article

Laws, regulations and guidelines of developed countries, developing countries in Africa, and BRICS regions pertaining to the use of human biological material (HBM) in research

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Human biological material (HBM) is an invaluable resource in biomedical research. Although research ethics committees (RECs) are guided by international guidelines and frameworks, some RECs might not be fully informed about local ethical and regulatory requirements regarding the use, collection, storage, ownership, transfer and benefit-sharing of HBM in collaborative research.

S Afr J BL 2012;5(1);51-54.

Analysis of human biological material (HBM) is quite lucrative.[1] Developing countries' ethical and regulatory frameworks are influenced by debates between Europe and the USA, and their regulations. Hence, traditional cultural values placed on HBM by communities in developing countries might not be considered. The frameworks of selected developed countries[2] (Australia, Canada, the UK and USA), selected developing countries in Africa[2] (Kenya, Malawi, Nigeria Tanzania, Uganda and Zimbabwe) and the BRICS countries[2] (Brazil, Russia, India, China and South Africa) were reviewed and compared for robustness of ethical protection of HBM in research.

Key organisations, laws, regulations and guidelines

All research on humans in Australia and Canada is guided respectively by The National Statement[3] and The Australian Code,[4] and also the Interagency Advisory Panel on Research (PRE) Tri-Council Policy Statement (TCPS2).[5] In the UK, the Human Tissue Act of 2004 (UKHTAct)[6] applies in full in England, Wales and Northern Ireland, but not in full in Scotland. The Act established the Human Tissue Authority (HTA)[7] as the overseeing body corporate which deals with issues about the use of HBM for research. In the USA, the Department of Health and Human Science's (DHHS) Code of Federal Regulations (CFR) (title 45 part 46) [54CFR46][8] (also referred to as the Common Rule) governs human subject research. Oversight of these federal regulations is delegated to the Office of Human Protection Research (OHRP) which monitors compliance.

This paper forms part of a research report for the MSc Med (Bioethics & Health Law) completed by the first author at the Steve Biko Centre for Bioethics.

In the selected developing countries in Africa (Kenya,[9] Malawi,[10,11] Nigeria,[12] Tanzania,[13] Uganda[14] and Zimbabwe),[15] their respective national research ethics committees or councils are responsible for developing regulations, guidelines and co-ordinating all human subject research.

In the RSA, the national ethics regulations are governed by the National Health Act (NHA) [Act No 61 of 2003].[16] Legal aspects of using HBMs are governed by Chapter 8 of the Act. The Department of Health (DoH) has promulgated complementary guidelines.[17,18] The Health Professions Council of South Africa (HPCSA),[19,20] and the Medical Research Council of South Africa (SAMRC),[21,22] have independently published research ethics guidelines. The South African Intellectual Property Rights from Publicly Financed Research and Development Act (IPR Act)[23] regulates intellectual property rights, patents and benefits that may be applicable to HBMs.

In Brazil, the Comissao Nacional de Ethica em Pesquisa (National Commission for Research Ethics) (CONEP) is responsible for assessing ethical issues arising from all research involving human participants. Resolution 196 (the standard guidelines for participant protections) is used. HBM research is regulated in complementary resolutions that include the need for a memorandum of co-operation for foreign research, special protections for indigenous peoples, and information on storage or use of HBM.[24-27]

The Indian Council of Medical Research (ICMR) formulates, co-ordinates and promotes biomedical research in India[28] and collaboration between India and other foreign agencies through the Indo-Foreign Cell (IFC).

Definitions of HBM

In the UK's UKHT Act,[6] 'tissue' refers to 'any, and all, constituent part(s) of the human body formed by cells' and is divided into 'relevant and bodily material'. When a sample contains even a single human cell, it is classified as 'relevant material.' The USA's policy and guideline documents of the OHRP and the National Bioethics Advisory Committee (NBAC) use interchangeably 'biological materials, human biological specimens, human tissue materials and biological specimens' without providing any definitions,[29-31] although the National Cancer Institute of the National Institute of Health (NIH) provides comprehensive definitions for 'biospecimens' and 'specimens'.[32] TCPS25 in Canada and The Australian Code[4] refer to 'biological materials', the latter without providing a definition.

The Ugandan national guideline is the only one in Africa (excluding BRICS) that refers to HBM and includes 'microorganisms' in its definition.[14] 'Human tissue' is defined in the Kenyan[9] and Tanzanian[13] national guidelines. The Malawian guidelines refer to 'genetic resources' in the context of 'agricultural/forestry/fisheries/parks and wildlife resources' and not HBM.[10,11] The Nigerian national guidelines refer to 'samples and biological materials' that include 'herbs and plants' without defining what constitutes 'samples' or 'biological materials.'[12] The Zimbabwean national guidelines provide no definitions[15] except guidelines for the collection of blood samples.[33]

Of the BRICS countries, only India provides a comprehensive definition of HBMs.[28] The RSA national ethics guidelines defines the constituents of 'human tissue',[17] while the National Health Act (NHA) defines 'biological materials'[34] and 'tissues',[35] where 'tissues' is used collectively to indicate cells and tissues, including stem cells. In Brazil, Resolution 196/96 refers to 'scientific material, tissue, organs, other parts of the human body and biological materials' without providing a definition of what constitutes these materials.[24]

Indentifiability of HBM

The various frameworks have no consistency in the level of identifiably used for HBM. Europe[36] and Canada[5] use 5 levels of identifiablity. The Indian[28] and American[37] frameworks distinguish between samples that are stored in repositories and samples that are collected for research. The RSA[17] and Australia[3] define 3 categories, while Kenya[9] and Tanzania[13] guidelines refer to 2 categories. None of the frameworks of the developing countries in Africa provides for nor defines the levels of identifiability for HBM.

Informed consent (IC)

Developed countries favour either broad consent or multilayered consent[3,5,6,7,37,38] for the use of their HBM. Developing countries in Africa9-15 and the BRICS[17,22,27,28] favour specific and multilayered consent. Broad consent allows investigators and other secondary users access to HBM in current and all unspecified future research anytime and anywhere. Multilayered consent provides research participants with several options, while specific consent allows use of HBM only in current research, and research participants must obtain consent for new use of their HBM that is outside the scope of the original consent.

Material transfer agreements (MTAs) and export permits (EPs)

Material transfer agreements (MTAs) are legally binding contracts that govern the transfer of HBM between collaborating researchers and institutions. The frameworks of developed countries, developing countries in Africa and BRICS countries require MTAs and permits for the import and export of HBM. In the RSA, the NHA[16] is silent on the requirement of an MTA or an intellectual property right (IPR) for the transfer and use of HBM in international collaborative research. However, the IPR Act (Act No 51 of 2008) may apply to HBM.[23] Of the national guidelines, only the HPCSA19 makes an MTA mandatory before tissues leave the country.

Discussion

The absence of a globally acceptable uniform definition of HBM causes confusion, ambiguities and difficulties. The extent to which the identity of HBM can be linked with the identity of its source is important in assessing the potential risks and benefits to the provider of the material. The use of many terms to describe different levels of identifiability and their differing interpretations has been problematic in defining confidentiality.[39] As a step towards harmonisation, the International Conference on Harmonisation of Technical Requirements (ICH)[40] adopted 4 levels of identifiability, i.e. identified, coded, anonymised and anonymous. When research is conducted with HBM that is not identifiable and cannot be linked through a system of codes, the OHRP's Common Rule (45CFR 46)[8] considers such research as 'non human.' The Common Rule allows researchers unlimited use of leftover clinical specimens for any type of unspecified future research without IC or REC approval. Some individuals and communities object to certain uses of their HBM to the extent of instigating lawsuits.[41] In the wake of the Tuskegee Syphilis and Guatemala scandals and the Havasupai Indian Tribe Case, President Obama issued an executive order to re-examine the Common Rule and all federal regulations, to consider consistency of regulations across the federal government and to extend federal oversight over all research in the USA.[42]

Defining IC requirements for collecting, storing and using HBM for research remains a controversial international issue.[43] While most developed countries support broad consent, studies suggest that broad consent has not been convincingly embraced by all research communities,[44-49] and they question the appropriateness of applying the IC formats of highly industrialised, individualist countries such as the USA and UK to manage HBM in cross-cultural settings and communitarian societies in developing countries, including those in Africa.[50]

Permits to export and import HMB are a legal requirement in most jurisdictions. In the UK, the HTA recommends that, whenever possible, the import and export of tissues be conducted via the HTA licensing regime under the supervision of a 'designated individual (DI)' named on the license.[7] In the RSA, anecdotal evidence suggests that HBM and data might be reg-

ularly leaving the country, undocumented and unaccounted for at a national level[51] without explicit consent, and the fate of the HBM is unknown.[52] The NHA makes it a criminal offence punishable by a fine or imprisonment to export HBM without an export permit.[53]

It has been recommended that benefits derived from using HBMs are best addressed through MTAs and IPR agreements.[54] Developing countries in Africa and BRICS regions require an MTA when using HBM in collaborative research with developed countries. The latter require MTAs for collaborations intra-nationally and between developed countries and take the position 'that MTAs should not contain legally binding benefit sharing arrangements and restrictions on IP rights and that reference should be made only to guidelines',[55] perhaps because guideline documents are not legally binding.

In landmark cases in the UK and USA,[41] the courts ruled, with reference to their national case laws, state health and safety laws, that research participants who 'donate' their HBM for research, make an irrevocable gift. The courts implied that research participants waived their rights to their HBM in accordance with properly obtained IC. These rulings were based solely on ownership and property rights. The Nuffield Council on Bioethics (NCB) proposed that HBM removed from patients during their treatment should be considered as 'abandoned',[38] effectively denying rights to tissue providers over their removed tissues. Under such circumstances, benefits accrue only to the institutions in possession of HBM. In the Havasupai case, the US Appeal Court ruled that researchers from the University of Arizona return HBM to the Havasupai native Americans.[48] Thus, the court respected the traditional customs of the Havasupai native Americans and recognised their right of custody and ownership of their HBM. Ownership of HBM has not been tested in South African Courts.

The lack of uniformity extends to the duration of storage of HBM obtained for research. Several policy statements recommend that HBM is stored for limited periods and not beyond the end date of a specific research project[56] unless the original IC did not prohibit 'unlimited time' for the storage of HBM. The Royal College of Pathologists (UK) specify storage periods from 24 hours up to 'at least 30 years', depending on donor consent and on the type of HBM.[57] The WHO recommends that genetic material (DNA) should be stored for as long as it can be of benefit to living or future relatives.[58] The RSA national ethics guidelines place the responsibility on institutions to develop policies regulating the conduct of research using HBM.[16] In Brazil, Resolution 347 in the guidelines on biobanks, authorises storage of HBM for 5 years.[27]

Conclusion

Differing definitions of what constitutes HBMs terms to describe identifiability and confidentiality, models of IC, and ambiguous regulatory language, are confusing and make comparisons of laws, regulations and guidelines of the different countries difficult and highly complex. There is also no general consensus as to how long HBM can and should be stored for research. These are serious impediments to ethical conduct of biomedical research involving HBM, and there is an urgent need to harmonise laws and regulations globally. This must reflect and embrace the interests and opinions of communities who altruistically provide HBM, as legitimate stakeholders, to advance medical knowledge and improve healthcare without compromising or hindering collaborative research. There must also be a paradigm shift from viewing HBM not only as a proprietary good, but also as a national resource for the common good.

With the troubled history of vulnerable populations in developing countries being exploited for their HBM, local national guidelines and laws require urgent amendment to include the need for MTAs when HBM is used in collaborative research. This could go a long way to end opportunities for the proliferation of undesirable and unethical practices.

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