ABSTRACT

Although Human Biological Materials (HBMs) are invaluable resources in biomedical research, they have not been without controversy in collaborative research between developed and developing countries. The normative arm of the study compared the key ethical issues in the laws, regulations and guideline documents of developed and developing countries with regard to the use, collection, storage, export and benefit-sharing of HBMs in collaborative research with developed countries. The empirical arm of the study examined how investigators and a Research Ethics Committee (REC) at a South African institution addressed these ethical issues, implemented national and international frameworks with regard to the use of HBMs.

The majority of sponsors (59.6%, 90/151) in the study were from the USA compared to other developed countries (p=0.0001) with the bulk (65.84%) of the funds (R517.19 million) allocated for HIV research. HBMs for storage was obtained largely from adults (80.8%, 122/151) compared to children (12.6%, 19/151) [p <0.0001]. Whilst the principle investigators (PIs) of all 151 protocols informed the REC of their intent to store HBMs, only 87.4% (132/151) of PIs informed research participants (P <0.0001). In 47.7% (72/151) and 71.5 % (57/151) of protocols research participants were informed of the location and duration of storage, respectively, compared to 86% (130/151) and 19.25% (29/151) informing the REC (p < 0.0001), respectively. In 98% (149/151) of protocols informed consent (IC) was obtained from research participants with 76.8% (116/151) of protocols soliciting broad consent compared to specific consent (21.2%, 32/151) [p < 0.0001]. In the remaining 2% (3/151) of protocols IC for storage was not obtained. In 69.5% (105/151) of protocols confidentiality was maintained by a code and in 9.35% (14/151) of protocols HBMs was anonymised [p < 0.0001].

Significantly more protocols informed the REC (90/151, 59.6%) than the research participants (67/151, 44.4%) that HBMs will be exported (p= 0.011). Separate consent forms were not available for 60.9% (92/151) of protocols as per the requirement REC's standard operating procedures (SOP). In 74% (51/69) of protocols the rationale for export was to access specialised laboratories (74%, 51/69) that were not available locally. Export permits were not available for 73.2% (109/151) of protocols. Where export permits were available, there were more exports to the USA (31/42, 73.8%) than to Europe (26.2%, 11/42) [p < 0.0001]. In the majority of protocols research participants were not informed of benefit sharing from any discoveries (129/151, 85.4%) or commercialisation (123/151, 81.5%) of products derived from their HBMs. Material Transfer Agreements (MTAs) were not available for 94.7% (143/151) protocols. Whilst 122/151(80.8%) protocols disclosed the amount of funds available from the sponsors for the research to the REC, not a single PI made such disclosures to the research participants (p < 0.0001).

The varied definitions of what constitutes HBMs, the different terminologies used to describe identifiability, confidentiality, the different models of informed consent and different standards of ownership in the various national and international frameworks are characterised by a maze of definitions, laws, regulations and guidelines that are confusing, conflicting and defy generalisation. International and national laws, regulations and guidelines are fragmented and lack harmonisation. Most developing countries are in favour of severe restrictions on the use of their HBMs in collaborative research with developed countries. The protocols in the empirical study did not adequately address the inter-related ethical issues of export, storage, IC,

commercialisation and benefit sharing derived from HBMs that are currently the subject of intense debate and controversy and central to the access to HBMs in collaborative research with developed countries. Because the empirical study is limited by the use of a convenient sample, the results cannot be generalised to other RECs in South Africa. Nevertheless, the data gives some credibility to the anecdotal evidence that HBMs are leaving the country unaccounted for without export permits and MTAs in place. Given the long delays in harmonizing and publishing new regulations and changes, outdated regulations and regulatory frameworks create opportunities for the proliferation of undesirable and unethical practices. Omissions in the RSA regulatory and ethical frameworks with regard to HBMs and Tissue Biobanking are concerning and require urgent action.