Regulatory Frameworks on Biological Specimens in the Global South

Ogechukwu Erechukwu[1], Ankita Tripathi[1]
and Dr. Francis Barchi
[1]Rutgers School of Arts and Sciences, Aresty Research Center, [2]Rutgers School of Social Work

Purpose

What is the nature and extent of regulatory guidance and standard operating procedures for Research Ethics Committees (RECs) in Southern countries regarding the collection, use, storage, reuse, ownership, and export of Human biological specimens (HBS)?

Background

Human biological specimens (HBS) are samples taken from the human body such as blood, macromolecules, tissues, or urine. HBS are extremely crucial for understanding the pathogenesis of certain diseases and therefore, may lead to the cure of many ailments. They have become increasingly stored for disease-specific, population-based studies as well as unspecified future use. Throughout the past few decades, there has been a vast amount of literature produced on ethics regarding the collection, use, reuse, storage, export, and ownership of biospecimens.

Developing countries with recent economic growth such as Brazil, Indonesia, India, Vietnam and South Africa are gradually translating research findings into pharmaceutical products. This research has raised questions such as: is it ethically correct to store bio specimens for future use? Furthermore, some developed countries have formed national frameworks for systematic development and management of national biobanks. However, not many regulations have been enforced in the developing word regarding the use of biobanks. This form of genetic testing raises many ethical issues such as confidentiality concerns, informed consent problems, and the possible negative impact of newly acquired information on specific communities and family members.[5]

Some discussions have addressed the various faults within the ethical and regulatory guidelines regarding the use of these specimens in developing countries. For example, tabletop discussion was held in Washington, DC, in 2006, prior to the HIV Prevention Trials Network (HPTN) annual meeting. The discussion focused on the collection and storage of human biospecimens for research. The participants acknowledged that biomedical research is a great medical practice, but there are a variety of issues underneath the "social good" that it provides. They insist that there needs to be an understanding of societal norms and cultural beliefs concerning human biological specimens.[4]

Essentially, less is known about how countries in the Global South use and regulate HBS, and research needs to address these issues.

Methods

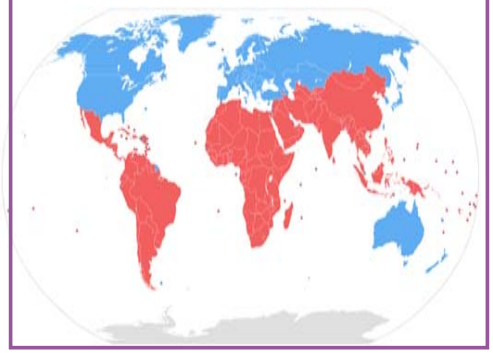
This research project will help to identify the nature and extent of regulatory procedures of human biological specimens (HBS) in the Global South through a two-phased approach of finding research and then, analyzing the findings.

Phase 1: Literature/Internet Review

Check web sites of regional ethics organizations and direct contact via email with Ethics Bodies in countries

A. Scan of journal articles on biomedical research in specific country to identify:
1. Statement on ethics review process for research – listing of in-country reviewing body
2. US researchers who have worked in that country

B. Check web for identified IRB/ERC/approval granting regulatory body
Then, contact individual researchers by email to request information about IRB reviewing procedures and familiarity with regulations (if any) governing collection, use, storage of biospecimens



Findings To Date

•While the research is not at its completion, so far, we have seen some distinct patterns. In selected developing countries in Africa (Kenya, Malawi, Nigeria, Tanzania, Uganda, and Zimbabwe), their respective national research ethics committees or councils are responsible for developing regulations, guidelines, and coordinating all human biological specimens.

•Most countries in both sub-Saharan Africa and Latin America contain some sorts of ethic regulations and an informed consent process.

•Some countries, such as the Democratic Republic of Congo have primitive regulations and lack guidelines on informed consent. In sub-Saharan Africa, there is a lack of ethics guidelines on reuse, storage, disposal and export.

•Guidelines in Kenya do not require informed consent for future research of samples.

•South Africa contains one of the largest set of regulations on all sub-topics relating to human biological specimens. Yet, problems stem from this as well. South African permits for biological specimen export take too long to receive approval and lead to researchers starting projects without approval because the process is too lengthy. [2]

•Some countries in Latin America, such as Brazil, Guatemala, and Mexico, have developed national guidelines for bio repositories and bio banks that address ethical concerns related to HBS research.

•Brazil's CNS 441/11 sets the guidelines for ethical analysis of research projects involving human samples or utilization of samples stored by prior studies; these guidelines are used for the bio banks in Brazil such as A.C. Carmago Biobank.

Discussion

Throughout the past few decades, there has been a vast amount of literature produced on ethical issues surrounding HBS. Research into the regulatory frameworks of HBS in industrialized countries have identified various faults within the ethical and regulatory guidelines regarding the use of these specimens in developing countries. While there has been some work in creating adequate regulations, much still needs to be done. States must consider how thorough their consent process must be, whether or not participants should give consent to future research, or whether transport of biological specimens should be encouraged.

Outcomes

1. A comprehensive database of ethics regulatory systems in the Global South for the collection, reuse, and storage of HBS.
2. A set of models to illustrate different approaches to national regulation of biospecimens.

Refererences:

1; Allen, Jason G. (2010). Group Consent and the Nature of Group Belonging. *Journal of Law, Information and Science 28, 20(2)*, 1-30.
2; Burgess, L J., Pretorius, D. (2013) The South African Clinical Trial Industry: Implications of Problems with the issuing of Human Tissue Export Permits. *SACRA, Vol.6, No.1,* 13-15.
3; Emerson, Cladia et al. (2011). Access and Use of Human Tissues from the Developing World: Ethical Challenges and a Way Forward using a Tissue Trust, *BMC Medical Ethics*, 12:2, 1-5.
4; MacQueen, Cathleen M. and Patty Alleman. (2008). International Perspectives on the Collection, Storage, and Testing of Human Biospecimens in HIV Research. *The Hastings Center,* Vol 30, No. 4, 9-14.
5; Nyika, A. (2009). Ethical And Practical Challenges Surrounding Genetic And Genomic Research In Developing Countries. *Acta Tropica, 112*, S21-S31.