



All communication should be directed to the Director General

What is the National Regulatory Requirement and Position on Accessing, Collection, Storage and Use of Human Biological Specimen for Research in Malawi?

- **Regulatory requirement and position**

The Government of Malawi has been embracing a State practice and a national regulatory position on the accessing, collection, storage and use of human biological specimen for research from the time of the establishment and existence of the then National Research Council of Malawi in 1974 to the present time of the existence of the National Commission for Science and Technology that has the legal mandate to nationally promote, co-ordinate and regulate research, science and technology as empowered by the S&T Act No.16 of 2003. The national regulatory requirement and position of State practice is defined in a number of instruments. **Sections 3.4.7 and 3.4.8** of the National Policy Requirements, Procedures and Guidelines for the Conduct and Review of Human Genetic Research in Malawi (2012) stipulate non permissible areas and forms of research actions related to collection, storage and use of human biological specimens in Malawi. Specifically, section 3.4.7 states that *“all forms of studies and testing aimed at collecting and storing human biological samples for future unspecified genetic research/analyses including any scientific retrospective analyses”* is **non permissible**. Similarly, section 3.4.8 stipulates that *“plans, attempts and requests for obtaining human biological/genetic material for future research”* is also non permissible. Within the regulatory ambit of the national jurisdictional mandate of the NHSRC, it is specifically stipulated in section 10 of the General Guidelines on Health Research in Malawi (2007) that *“researchers should not collect biological specimens that are not required to address the study objectives; tests on biological specimens should only be as described in the approved proposal; and specimens collected for a particular purpose should not be used for other purposes”*

The regulatory requirement on access, collection and use of human biological samples for research has a legislative anchorage as lawfully made under **sections 18 and 48** of the said S&T Act. Stakeholders including researchers are obliged to adhere to this regulatory requirement without let or hindrance.

- **Regulatory interpretation, application and guidance**

The regulatory requirement stated above is self-explanatory. The regulatory requirement permits the access, collection, storage and use of biological samples **but only for a presently defined research study whose protocol clearly describes the study objectives, methodologies and other testing procedures after obtaining an informed consent**. Thus, human biological samples/specimens are only allowed to be accessed, collected and used for tests/analyses necessary and required to answer objective(s) of a particular research study which has presently been approved. It is not permitted in Malawi to consent participants to collection, use and storage of specimens for future use, be it for future research or any other purposes.

Similarly, specimens collected for one clearly defined and approved study are not allowed to be used for another research study nor for any other research purpose other than for tests/analyses required to answer objectives of a particular presently intended study for which initial approval is made. Thus, researchers are only allowed to administer consent to participants to collect specimens for purposes of only answering the study objectives of a presently intended study that has been clearly defined and for which approval is being sought. In the case of accessing and collecting cadaveric tissues/samples for a presently clearly defined research study, the relevant provisions contained in the Anatomy Act (1991) must be adhered to.

Any samples to which participants had been consented for future use remain **null and void** because an action to request potential participants to consent to storage for future use is a regulatory violation, and no committee must have approved such a consent form. Such samples are to be discarded and destroyed.

- **Period of storage**

Depending on the nature of the approved research study, samples can spontaneously be analysed or can be stored for analysis at a later date. Samples that can be stored for testing/analysis at a later date for purposes of answering study objectives of the presently approved study protocol can be kept for the maximum of the initial five year period during which all tests/analyses approved for that particular study should be concluded. In the case of certain studies that may require storage of samples longer than the initial five year period in order to perform the analyses/tests for which a particular study was authorised, approval from the ethics committee that originally approved that study shall be sought for renewal of storage for a further equal period, following a sound justification by the researcher that an ethics committee may consider, **otherwise specimens are required to be discarded and safely destroyed immediately after all the tests/analyses aimed at answering the objectives of a particular study are done.**

- **Material Transfer Agreement (MTA)**

Primarily, testing/analysis of samples in order to answer the objectives of a clearly and presently defined study for which the samples have been collected is required to be done locally within Malawi so as to promote local capacity building and transfer of technology. There are, however, restricted circumstances and reasons where there might be a justifiable need to perform analyses/tests beyond the Malawi borders. Such circumstances would necessitate the transfer/exportation of the samples, subject to the provisions of any national relevant law. In which case, the researcher shall be required to apply for such a transfer under a material transfer agreement that shall be reviewed and approved by the committee undertaking the review. Exportation of specimens is considered a last resort. Thus, it is permissible in exceptional circumstances to export specimens especially where there is no technology available in Malawi to conduct the desired tests and such technology can not be imported into Malawi, or where further tests to adequately answer the study objectives are necessary to confirm the results. Under any allowable circumstances, the researcher shall be required to provide an adequate justification for material transfer under a MTA Form that is available within the approved SOPs of COMREC.
