



NATIONAL COMMISSION FOR SCIENCE AND TECHNOLOGY

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'A nation with scientifically and technologically led sustainable growth and development'

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FROM : DIRECTOR GENERAL, NATIONAL COMMISSION FOR SCIENCE AND TECHNOLOGY, P/BAG B303, CAPITAL CITY, LILONGWE 3

TO : HEAD OF SECRETARIAT OF NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE, C/O BOX 30377, CAPITAL CITY, LILONGWE3

: HEAD OF SECRETARIAT OF COLLEGE OF MEDICINE RESEARCH AND ETHICS COMMITTEE, P/BAG 360, CHICHIRI, BLANTYRE3

: HEAD OF SECRETARIAT OF MALAWI UNIVERSITY OF SCIENCE AND TECHNOLOGY RESEARCH ETHICS COMMITTEE, BOX 5196, LIMBE

CC : SECRETARY FOR HEALTH AND POPULATION, BOX 30377, CAPITAL CITY, LILONGWE3

: PRINCIPAL, COLLEGE OF MEDICINE, P/BAG 360, CHICHIRI, BLANTYRE 3

: VICE CHANCELLOR, MALAWI UNIVERSITY OF SCIENCE AND TECHNOLOGY, BOX 5196, LIMBE

SUBJECT: CIRCULAR ON HUMAN BIOLOGICAL SAMPLES AND PARTICIPANTS RECOMPENSE IN RESEARCH INVOLVING HUMAN SUBJECTS

Having finalised the contextual analysis of international and regional trends in the collection and use of human samples for research and forms of recompense to research participants, and having made an ethical and regulatory equipoise of the same, the National Commission for Science and Technology (NCST) empowered by section 18(1) of the Science and Technology(S&T) Act No 16 of 2003, hereby issues the following advisory guidance;

(a) Collection, Storage and Use of Samples for Research Purposes

- (i) Access, collection, storage and use of samples for the presently defined research study whose protocol clearly describes the objectives, methodologies and any other testing procedures after obtaining consent remains permissible.
- (ii) Access, collection, storage and use of samples for a presently defined research study shall only be done after prior approval by the NCST designated and registered research ethics

committee (REC) and with consent of a targeted participant/or a legally authorised representative/guardian.

- (iii) In the case of accessing and collecting cadaveric tissues/samples, the relevant provisions contained in the Anatomy Act (1991, and as revised) shall be adhered to.
- (iv) **Use of left-over samples (that had been collected for an initial study) is permissible for any new or future study but on approval of a REC that had approved the initial study, notwithstanding the guidance on a(v) and a(vi).**
- (v) **In the event that a REC that had approved the initial study is defunct, approval shall be sought from an institutional REC established in replacement of the defunct REC. In the absence of the replacement of a defunct REC at an institution, approval for use of the left-over samples shall be sought from National Health Sciences Research Committee.**
- (vi) **If the use of left-over samples is for a study in the category of *national interest studies*, the approval of the use of such samples and the intended national interest study shall be made by National Health Sciences Research Committee, a national REC designated by NCST for reviewing and approving studies of national interest.**
- (vii) **The samples are primarily allowed to be stored as long as they are needed for the initial study before being destroyed. However, left-over samples are now permitted to be stored to the extent of time needed for a research endeavour.**
- (viii) Research use of secondary samples such as diagnostic samples is permissible on condition that the authority of a custodial entity of such samples is provided and that approval of a REC for the intended research is granted.
- (ix) A Material Transfer Agreement shall remain an instrument to be used by a researcher in requesting the approval of a REC for the transfer of samples for analysis beyond the Malawi borders.
- (x) Collection of human biological samples for no clearly defined research with the intention of storage for unspecified future use is not allowed.
- (xi) Commercialisation of any human biological samples permitted to be accessed, collected and stored for research use is prohibited.

(b) Participants Recompense

- (i) In order to remain in the preserve of ethical principles for human subject protection, researchers shall not duly induce participants to participate in any proposed research but shall design and implement their studies in a manner that calls for the subject's informed voluntary consent to participation.
- (ii) Payments to participants that are construed to affect the voluntary participation of the subjects shall not be allowed. Lump sum payments for participation in a research study are not permissible. However, participants who incur direct costs for participating in a research study shall have to be reimbursed/refunded by the study. Such payments shall be **acceptable recompense**. **Forms of payments in the category of acceptable recompense shall generally include direct transport refunds and/or cost of travel/communication associated with certain clinical trial routine evaluations.** Such

payment shall be on a research study case by case basis and dependent on the nature and design of a study.

- (iii) The Research Ethics Committees (RECs) shall not request lump sum budgetary incorporation for payments to subject for participation in a study. However, during the review of a protocol, a REC shall make a case by case determination if the study under review attracts any form of acceptable recompense.

All RECs registered by NCST are required to incorporate the elements of this circular accordingly. The elements of this circular are now part of the regulatory auditing of the RECs by NCST. The adherence to this guidance shall necessitate some revision in some particular REC's Guideline, SOP or Application Form to which NCST looks forward to making a regulatory approval.

The Commission should be grateful if the contents of this circular could immediately be brought to the attention of all members of the research ethics committee and entire Secretariat. The contents of this circular should be **adhered to without let or hindrance**.



Anthony C Muyepa

DIRECTOR GENERAL