Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria (PS1.02013)

1. NHREC issues policy guidelines from time to time to address emerging issues in research ethics.
2. The ethical issues of concern with bio-banks in this note relates to appropriate consent for samples being submitted for deposition in the bio-bank, appropriate release of samples, as well as appropriate use of samples released at destination sites.
3. Other issues may be included as bio-banks develop in the future.

Policy statement

A. General comments

A.1 For the purposes of this note, a **biobank** is a type of repository that stores biological samples that may be from human or non-human sources. Such samples may be derived from research, medical or veterinary practice.

A.2 All biological materials stored for more than 2 months after analysis in the context of routine medical practice are considered to be "banked" samples. This excludes organs stored for transplantation.

A.3 Banked samples may be stored indefinitely or for a specified period of time and typically contain identifying information or can be traced back to their origin.

A.2 Biobanks provide researchers with access to samples and a minimal set of relevant data as determined by the biobank and standard practice in the field of biobanking about the source of the materials in the biobank.

B. Category of Review

B.1 Biobanking is not considered a research activities *per se* and is thus not subject to the 'usual' ethics review processes. Extant guidelines for ethics review may not be applicable. In this guideline, NHREC focuses on biobanks that serve only a receiving, handling, storage and distribution of samples function. They do not conduct systematic investigation designed to lead to generalizable knowledge.

B.2 HRECs are expected, under current guidelines, to review the research that is done with samples stored in or received from biobanks. In this case, a HREC has an obligation to ensure that research that incorporates the storage of samples in biobanks or those using samples from biobanks are based on the highest ethical standards that ensures protection for all participants in the human research enterprise.

B.3 Given that only few biobanks are expected to be established in Nigeria at this time, NHREC shall provide sole ethical oversight for the ethical aspects of biobanking establishment and operations in Nigeria.

C. The establishment of bio-banks in Nigeria

C.1 All institutions proposing to establish a biobank in Nigeria shall submit an application using designated forms and additional relevant documents to NHREC in this regard.

C.2 Upon a careful review of the application documents, NHREC shall consider and register the proposed bio-bank as a government recognized bio-bank in Nigeria

C.3 No organization shall operate a biobank in Nigeria without an NHREC assigned registration number and certificate.

D. Continuing oversight

All NHREC registered bio-banks shall be subject to continuing oversight by NHREC or its designee

i. Oversight function shall be conducted by NHREC officials or its designee at intervals to be determined by NHREC and communicated to the Biobank at the time of registration
ii. When an oversight exercise is to be conducted, the Biobank may be given advance notice except where the oversight visit is for cause.
iii. The oversight may include requests for submission of documentation or onsite inspection of documents relating to responsible custodianship, operations of the biobank, and provisions for ethical use of the bio-bank and its resources not limited to the following:
    a. Participants' documented consent forms – copies of which must be available in the bio-bank and can be matched to all the samples in the Bank during NHREC inspection visits.
    b. Documents describing mechanism for ensuring that research volunteers exceptions and limitations are noted and there is sufficient mechanism in place to ensure compliance.
    c. Evidence of how the materials that are taken out of the bio-bank are used only in accordance and in strict compliance with MTA guiding the stored samples
    d. Copies of MTA relating to all samples stored and shipped out of the biobank.
    e. Copies of Researchers', Research teams' or Consortiums' Guidelines, Agreements and SOPs applicable to samples stored in or shipped out of the biobank.
    f. Copies of all versions of previous documents with a summary of changes

g. Documents describing mechanism for removing and destroying the samples of participants who opt out of future participation. If opt-out is not possible, the operators of the bio-bank should explain why so that NHREC can satisfy itself that a good faith effort has been made.
h. Information about the business model that the biobank is using for cost recovery
i. Document or statement within other policies making explicit, the role of the biobank, if any, in "Return of Results" to participants. If the biobank plays no role in return of results, a statement attesting to and the reason this should be provided.
j. Document or statement within other policies describing the role of the biobank, if any, in all matters relating to intellectual property arising from research done on samples kept in the biobank.
k. Evidence of initial and continuing training (when applicable) in (a) Informed consent, (b) Biosafety and (c) the Nigerian National Code of Health Research Ethics for all bio-bank staff responsible for receipt, storage, handling and shipment of biospecimen

iv. The oversight shall include inspection of data storage and data security procedures at the biobank
v. NHREC shall inspect the biobank facilities to ensure safe, secure and standard storage of banked samples including adequacy of infrastructure, administration and management resources supporting biobank operations.
vi. All biobanks will be required to re-register every 2 years at which all re-registration documents must be provided. Other materials listed section D.iii above may also be requested at the time of re-registration.

E. Other ethical consideration

E.1 NHREC supports "broad consent" at this time but not "blanket consent" or "gifting".

E.2 Broad consent for the purposes of this note implies consent in which the type or purpose of research is defined in broad terms and for a work that is not specified by time. A blanket consent on the other hand, is one in which the type or purpose of the research is not defined in any way and does not restrict the use of donated specimen to any type of research.

E.3 Researchers should note the following NHREC definitions with relationship to privacy

i. ***Anonymization:*** The act of permanently and completely removing personal identifiers from data, such as converting personally identifiable information into aggregated data. Anonymized data is data that can no longer be associated with an individual in any manner. Once this data is stripped of personally identifying

elements, those elements can never be re-associated with the data or the underlying individual.

ii. ***De-identification***: Without reference to health information, de-identification involves the removal of personally identifying information in order to protect personal privacy. De-identified data is not necessarily anonymized data because the personally identifying information may be able to be re-associated with the data at a later time. Anonymized data is a particularized subset of de-identified data. NHREC does not consider "de-identified" and "anonymized" as synonymous terms