Obafemi Awolowo University Teaching Hospitals Complex – ARGO Biobank Center
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Biobank Governance Plan

1.0 PURPOSE

This governance plan provides helps with planning the resource and defining the authorities, processes, and procedures that are needed to guide key operational decisions and it is part of the biospecimen resource documents.

2.0 SCOPE

This plan specifies the formal and continuing responsibility for custodianship of collected biospecimens and associated data. The plan does address the following issues of the biobank:

- How to ensure the physical integrity of the biospecimens?
- How to ensure the integrity of the human research participant data that accompany the biospecimens?
- The plans and protocols that are in place for the distribution of samples to investigators.
- The roles and responsibilities of the biospecimen resource director(s) and the OAUTHC.
- Contingency plans
- Policies on retention
- Conflict of interest
- Confidentiality and data security
- Public communication
- Informed consent

3.0 ROLES AND RESPONSIBILITIES

This SOP applies to personnel at all ARGO member sites that are responsible for the processing of blood to obtain blood components for storage in the tissue biobank.

Group	Responsibility/Role
1. Management Board *Prof. Durosimi – Chairman* *Prof. Omonisi Esan* *Prof. Kolawole* *Dr. Adedeji*	➢ Ethical and bioethics oversight ➢ Manage identified conflict of interests
2. Director	➢ Provides complete oversight
3. Manager	➢ Implement well-documented Quality Assurance / Quality Control procedures ➢ Ensures • Long-term physical quality of the biospecimens • Integrity and confidentiality of associated data • Privacy of the human research participants • Appropriate use of biospecimens and data • Compliance to all ethical, legal, and operational policy standards • Eliminate any potential conflicts of interest • Appropriate scientific assessment of access requests and proposed research use • Transparency
4. Research assistants	➢ Collect protocol-specific samples and process appropriately for storage in minus 80^0C freezer

4.0 INTEGRITY OF BIOSPECIMENS AND DATA

A. Biological specimens can lose functionality and molecules can degrade at different rates dependent upon type and status of donor and collection circumstances.
   - All biospecimens meant for ARGO biobanking should be processed as rapidly as possible with minimum manipulation.
   - Tissue specimens will be maintained at optimal temperatures, as specified by the collection protocol.
   - All pre-analytical procedures including collection, processing, storage, and shipping will be documented since pre-analytical variables may affect analytical results.
   - Selected methods for specimen collection and preservation will be followed to ensure that any preservatives, dehydration, or other protective treatments used do not have a deleterious effect on future analyses.
   - Continuity of the cold chain will be maintained and documented from the point of collection to deposition in the repository and to eventual use.
   - The number of freeze/thaw cycles of a sample before and after processing will be minimized and documented.

- End-users of the biospecimens will be provided with the recorded pre-analytical variables so that informed, evidence-based assumptions and conclusions about the experimental data can be made.

B. Access to all sensitive data are tracked and controlled through redcap
   - Access to physical and electronic records and documents are restricted and assigned based on roles
   - All physical documents containing sensitive information and personally identifiable information are kept in secure fire and water proof enclosures.
   - A periodic review of data will be performed on electronic data stored remotely or for a prolong period.

5.0 ACCESS TO BIOSPECIMENS AND DATA

A. Access to this repository is only limited to appropriate staff and protects against physical intrusion from unauthorized individuals. Only persons assigned to the repository operations have access to the materials stored within and records of access are maintained. The freezers that store the biospecimens are individually locked.

- Access levels for staff is described and approved by the bioethics/scientific advisory board.
- Access to human research participants' identities and medical, genetic, social, and personal histories is restricted to only the staff members who need to access such records as part of their assigned duties or to those persons permitted access by law.
- Only biobank personnel will be allowed to access links and re-identify information, and their access are appropriately monitored to ensure compliance.

B. Access requests will be based on the scientific merit and the decisions to grant access are guided by the following general principles, as appropriate:

- Timely, equitable, and appropriate access to human specimens without undue administrative burden.
- Scientific merit and institutional research qualifications, proven investigator experience with the proposed method, and a research plan appropriate to answer the study question.
- Community attitudes and ethical/legal considerations as primary factors.
- Fair, transparent, and clearly communicated access procedures.
- Appropriate allocation of biospecimens based on the nature of the scientific investigation (e.g., discovery, prevalence, initial validation, and hypothesis testing) and the need for annotation. The level of identifiability of the biospecimen and related transfer documents are to be appropriate for the proposed research.
- A mechanism for addressing disputes over allocation decisions.
- An investigator agreement covering confidentiality, use, disposition, and security of biospecimens and associated data.
- A written agreement in an MTA or other appropriate document(s)

6.0 RELEASE OF RESEARCH RESULTS

The findings from research performed on the specimen will be reported in medical journal without identifying the identity of the participants.

7.0 LEGACY AND CONTINGENCY PLANS

At any point, if the ARGO biobanking reaches the end of the budget period of a grant; loss of management or termination of funding; accomplishment of the specific research objectives of the study; depletion of biospecimens; achievement of critical data end points; and/or discontinuation of participation by human research participants, an assessment of whether the stored biospecimens still have value for research should be conducted.

If the stored biospecimens still have research value, the ARGO biobanking will consider whether to become financially self-sustaining or will announce the availability of the biospecimens for transfer to suitable research facilities by means appropriate for reaching a wide audience, if permitted by the informed consent document and the relevant bioethics. Transfer of any material will be guided by

- Human subjects' regulations
- Informed consent under which the specimens/data were initially collected
- Material Transfer Agreement
- Institutional policy at OAUTHC

8.0 RETENTION OF BIOSPECIMENS, DATA, AND RECORDS

The ARGO biobank plans to store all biospecimen research materials indefinitely, subject to:

- Sufficient resources and storage space
- Foreseeable research utility—poor-quality biospecimens as determined via QA/QC processes should not be stored indefinitely
- Information on inactive samples may be retained for tracking and documentation purposes
- Biospecimen availability will be reviewed periodically to determine the utility of the retained biospecimens and the need for new biospecimens.
- Biospecimen, data, and record retention policy will be included in the Informed Consent form

9.0 SHARING OF RESOURCES

Through MTAs or other appropriate documents, research data and research resources obtained using biospecimens should be made available to the research community to the greatest extent possible.

- Completely de-identified datasets and resources will be released in a timely fashion, after acceptance for publication of the main findings from the final data set.
- Data and resources developed with biospecimens would be retained only as long as necessary for legitimate and imminent research purposes
- Information that is identifiable or linked to a specific individual would be shared under an agreement with appropriate privacy safeguards and adherence to applicable legal requirements

- The data sharing protocol will be communicated to research participants via the Inform Consent, when practicable.

10.0 CONFLICT OF INTERESTS (COIs)

Any known or likely financial benefit to the OAUTHC or ARGO will be disclosed accordingly. Public disclosure of a significant financial interest of an investigator or an awardee institution will be required. Non-financial conflict of interests will be identified and managed to the extent practicable.

11.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

11.1 Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER) http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositories

11.2 US National Biospecimen Network Blueprint http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

SOP Number	Date Reviewed	Reviewed By	Comments