

Institute of Human Virology Nigeria H3 Africa Biorepository Initiative (I-HAB):

Inaugural H3Africa Biorepository Principal Investigator Meeting

Alash'le G. Abimiku, PhD

Director, IHVN Lab services and Research

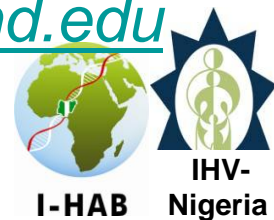
*Associate Professor University of Maryland School of
Medicine*

I-HAB Principal Investigator

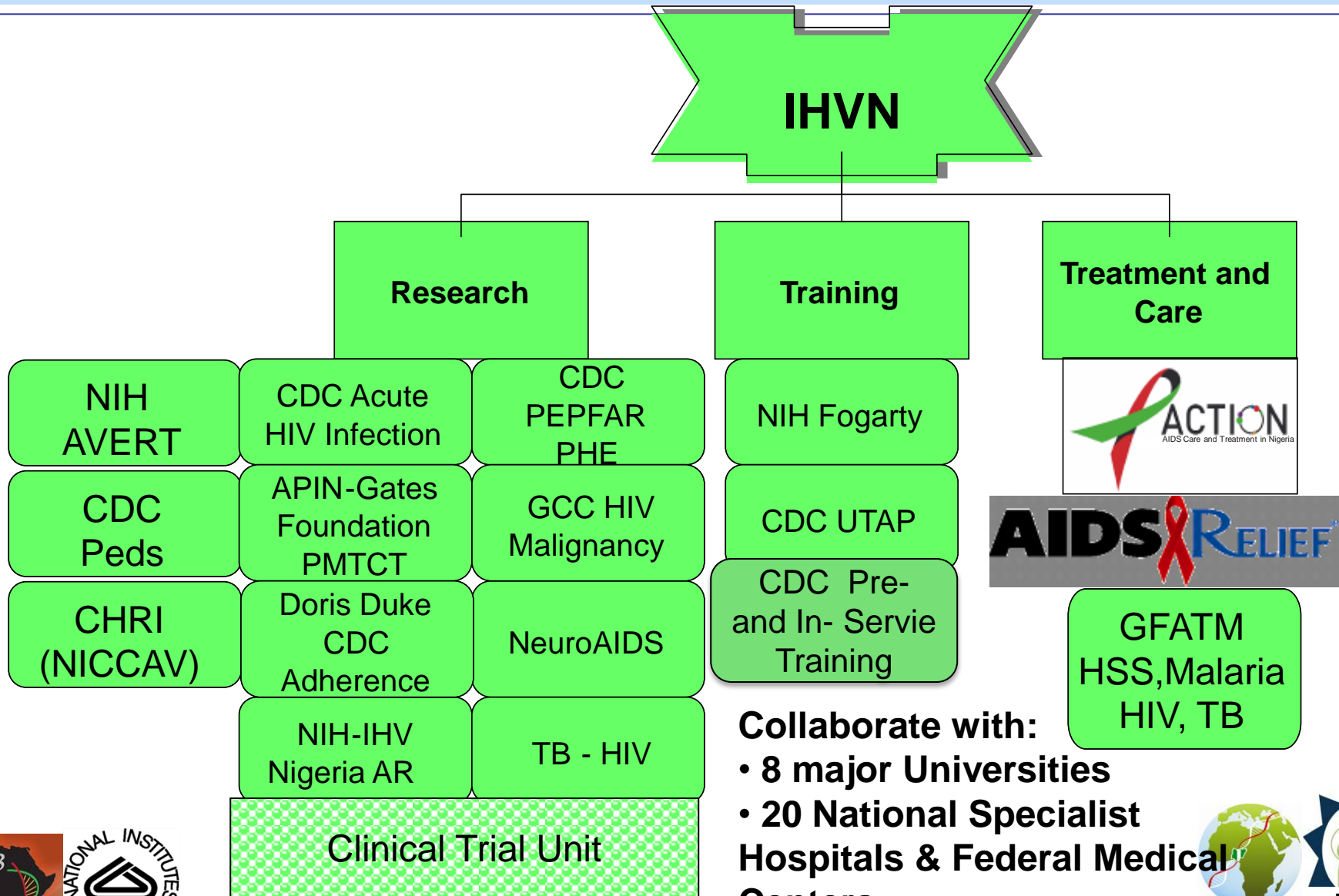
aabimiku@ihvnigeria.org; aabimiku@ihv.umaryland.edu



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Institute of Human Virology Nigeria: Core Mission



Collaborate with:

- 8 major Universities
- 20 National Specialist Hospitals & Federal Medical Centers

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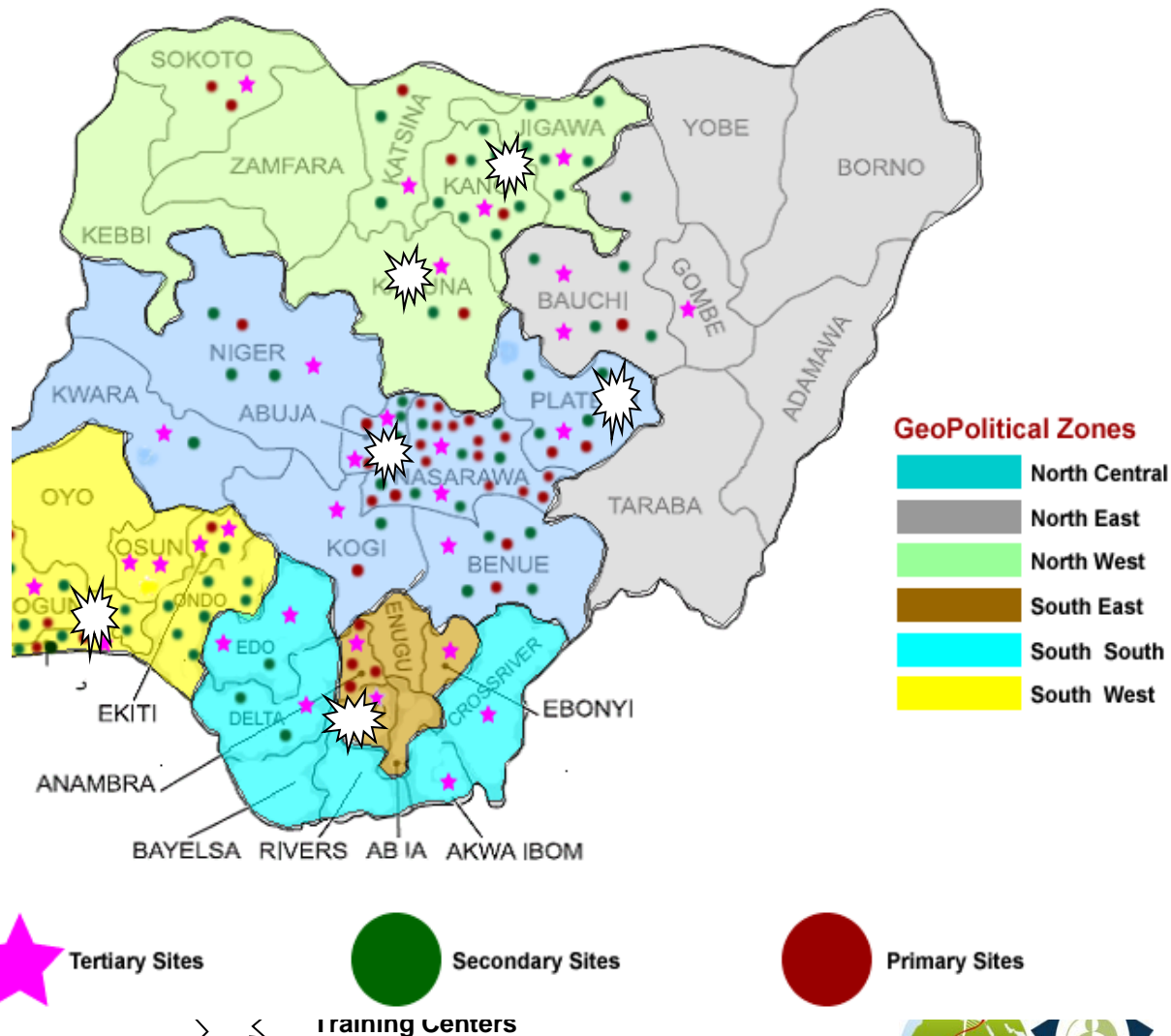
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IHV-N PEPFAR Supported Sites and Training Centers

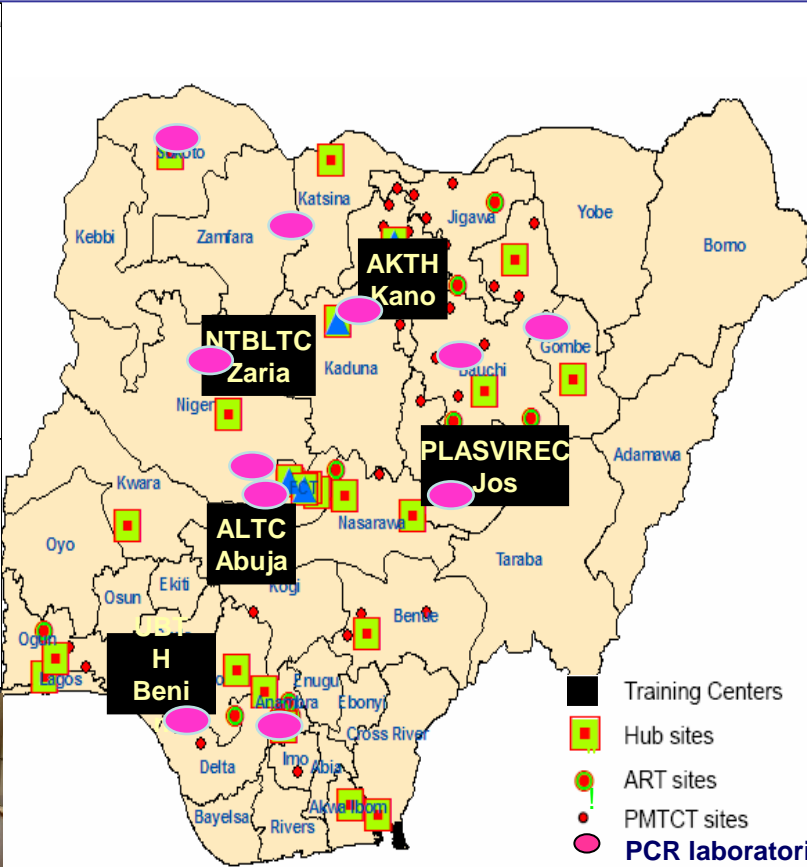
- **931,700** HIV Screened
- **847,912** PMTCT Screen
- **127,895** On ARTs (7,025 children)
- **26,166** HIV Positive TB treated



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Laboratory capacity for Program, Training and Research in Nigeria



- 5 Regional training labs (one dedicated to TB)
- 20 Tertiary level labs
- 15 Secondary labs
- 30 Primary sites
- 185 Health care facilities
- 11 PCR labs (EID, VL, HAIN)
- 1 BSL-3 (TB)
- 3 Developed research facilities & Biorepositories



Grants (UMD and IHVN faculty) supported by IHVN

Table 1. Grant Number	Grant Titles
Health Programs	
CDC, U2G PS000651	"HIV/AIDS Prevention, Care and Treatment in the Federal Republic of Nigeria"
Global Fund NGA-S10-G16-T	The Global Fund Round 9 TB
Global Fund NGA-809-G14-M-03	The Global Fund Round 8 Malaria
Global Fund NGA-809-G12-S	The Global Fund Round 8 Health Systems Strengthening
Research Projects	
GC-3482-135-01-010	"HIV Epidemic and Surveillance in Selected Targeted Populations in Plateau State Nigeria"
CDC, 200-2003-01716	"Collection of Serum Specimens Suitable for Validation of Assays with HIV-1"
WHO, IVR, African AIDS Vaccine Program	"HIV disease awareness and willingness to participate in HIV vaccine trials differ across sub-populations at risk of HIV in Abuja Nigeria"
Bill and Melinda Gates via the University of New South Wales	"Evaluation of Novel Concepts in Optimization of antiretroviral Efficacy (ENCORE)"
NIH, NCI	"Kaletra Mono-therapy as a Simple Cost Effective Strategy in the Salvage of D4T, 3TC Nevirapine containing Regimens in Resource Limited Settings"
NIH, R01 AI074594-01A2	"Acute HIV infection and Pregnancy"
CDC U2GPS002929	Community in ACTION: Integrating PMTCT Services in Primary Health Care Setting
CHRI-CHVI (Canadian) 106356	Creating a common platform for HIV vaccine research and HIV care and treatment program



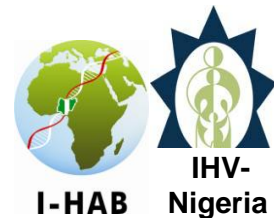
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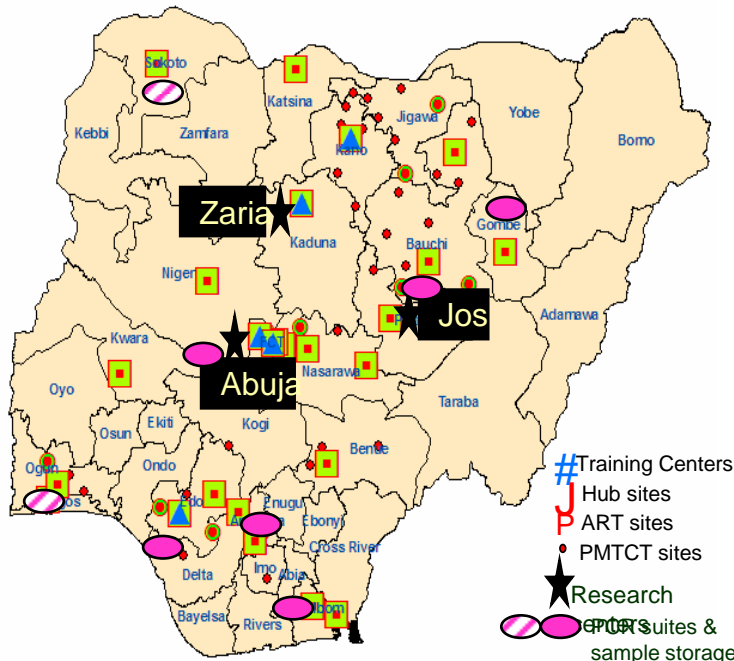
IHAVN H3 Africa Biorepository (I-HAB) Initiative



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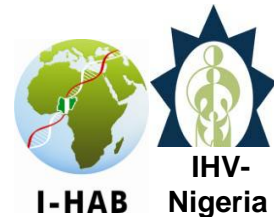
IHVN Biorepository Network



- Created in 2009 to support growing research and clinical activities of IHVN
- 3 biorepositories
 - Central site: Abuja (I-HAB)
 - Satellite sites: Jos and Zaria
- Conduct research and repository activities



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IHVN BIOREPOSITORY

FACILITY

Fully air conditioned, Secure facility maintained at optimal temperature

- Back up power generator
- 24/7 Monitoring System
- -20 to -196°C storage

MANAGEMENT

- Daily manual temperature monitoring and automatic temperature chart recording
- 24/7 monitoring system for ultra-low freezers
- QA/QC check

REPOSITORY SERVICES

ACQUISITION

- Specimen
- Tissues
- Isolates

PROCESS

STORAGE

SHIPMENT

LAB EXPERIMENTS

INVENTORY

DATA BASE

Freezerworks unlimited 4.0 data management system for ease of archival, tracking and retrieval of specimen and associated data

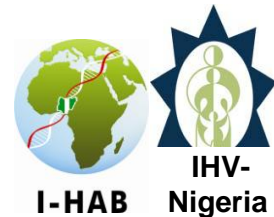
I-HAB Current Activities: Specimen Processing



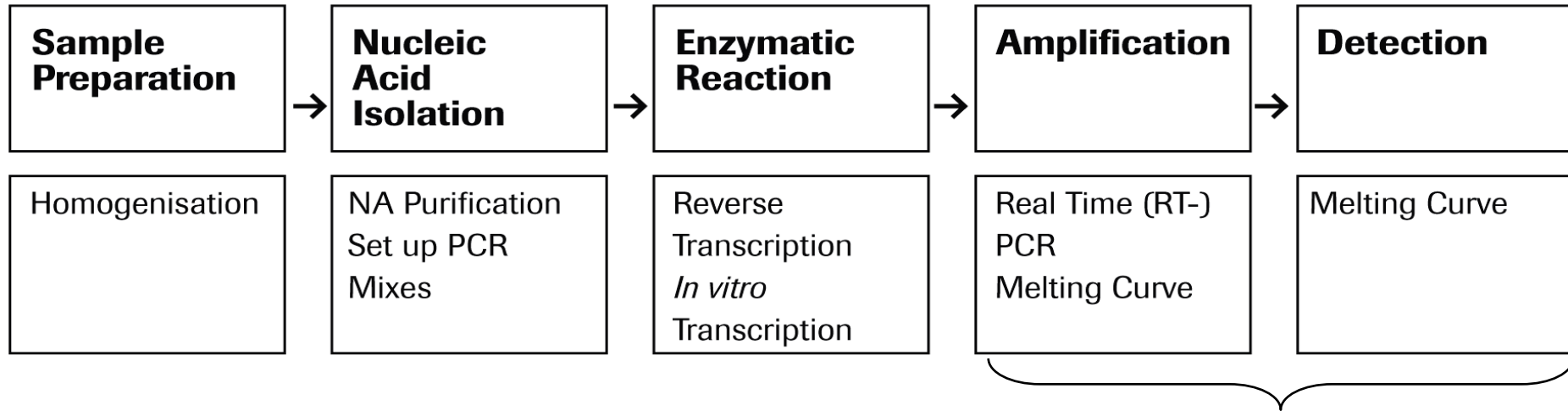
- 70% Biological fluids – Blood, saliva, breast milk processing
 - Characterize PBMCs
 - Plasma
 - Serum
 - Cell pellet
 - DNA
- 30% cancer tissues (breast, colon, head and neck, sarcoma)
 - Cytological slides
 - Extracted DNA



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I-HAB Current Activities: DNA Extraction and processing



MagNA Pure LC 2.0



Gene Detection
Gene Quantification
Genotyping
Gene Scanning .

LightCycler480



I-HAB Current Activities: Archiving, Shipment, and maintenance



- Cryo-preservation and specimen storage at -20, -86 freezers
 - Dedicated back up generators
 - Dedicated back up batteries with converters
- Shipments of biological specimens
 - IATA trained staff
 - World Courier service to other parts of Africa, UK and the USA at RT, ice or dry ice with refills
- Maintenance of biorepository facilities and equipment
 - Service contracts
 - Dedicated trained IHVN biotech engineers



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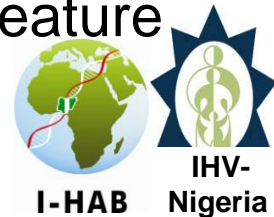
I-HAB Current Activities: Data Entry



- **Freezerworks Unlimited**, a commercially supported FDA compliant freezer inventory and data management system
- Has certification from the National Cancer Institute's Cancer Biomedical Informatics Grid (caBIG™)
- Has automatic electronic audit trail
- Has security interface that engages multiple levels of security and permissions on both freezers and sample data
- Capable of batch data entry, bar code tracking and reporting
- Has an automated data backup feature

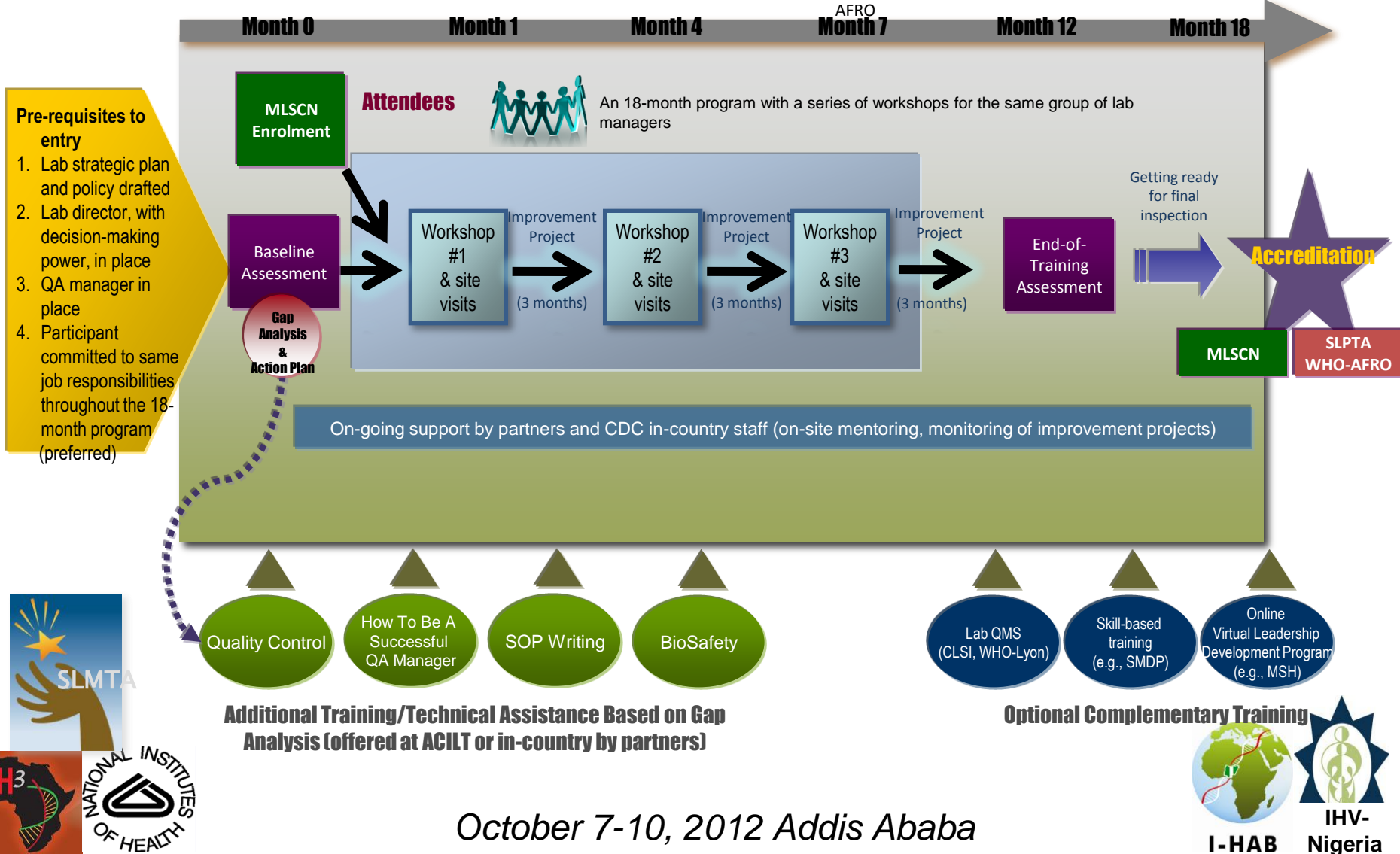


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WHO-AFRO Step-Wise Laboratory Accreditation

◆ Strengthen laboratory management ◆ Achieve immediate laboratory improvement ◆ Accelerate the process toward accreditation by WHO-AFRO

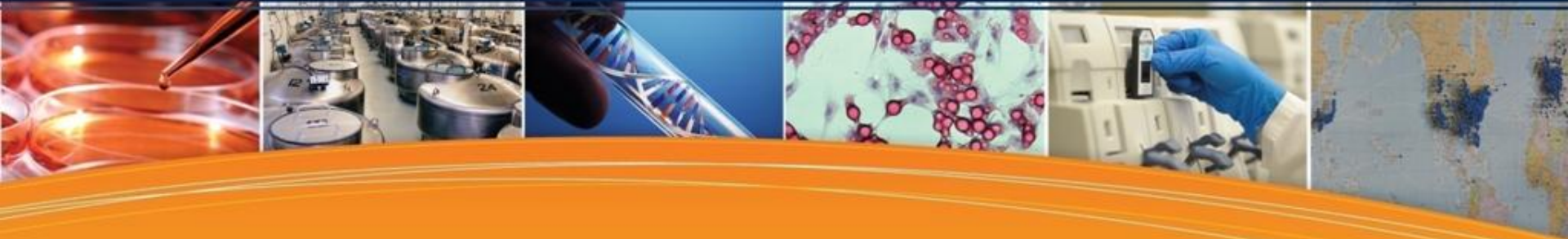




CORIELL INSTITUTE
FOR MEDICAL RESEARCH

H3Africa Biorepository

Partnering with the Institute for Human Virology,
Nigeria



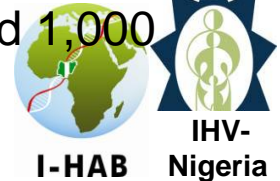
Biorepository Activities at Coriell



- **ISBER, NCI, NHLBI Best Practices; ISO9001-2008 certified**
 - Ship and receive biomaterials from 55-60 countries annually
 - National Institutes of Health (NIH) sponsored Collections under direction of Ph.D. – level scientists:
 - *National Institute of General Medical Sciences (NIGMS)*
 - *National Institute of Aging (NIA)*
 - *National Institute of Neurological Disorders and Stroke (NINDS)*
 - *National Human Genome Research Institute (NHGRI)*
 - 66,000 page, on-line catalog offers ~ 48 M high-quality, clinically-annotated biospecimens – DNA and cell lines – to the scientific community
 - More than 7,000 peer-reviewed papers cite Coriell biospecimens
 - Coriell's repositories supported Human Genome Project; currently supports the International HapMap and 1,000 Genomes Projects



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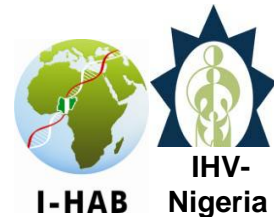
Goal of I-HAB

Phase I : *Advance the capacity of I-HAB to achieve International Society for Biological and Environmental Repositories (ISBER) best practices required for Phase II implementation.*

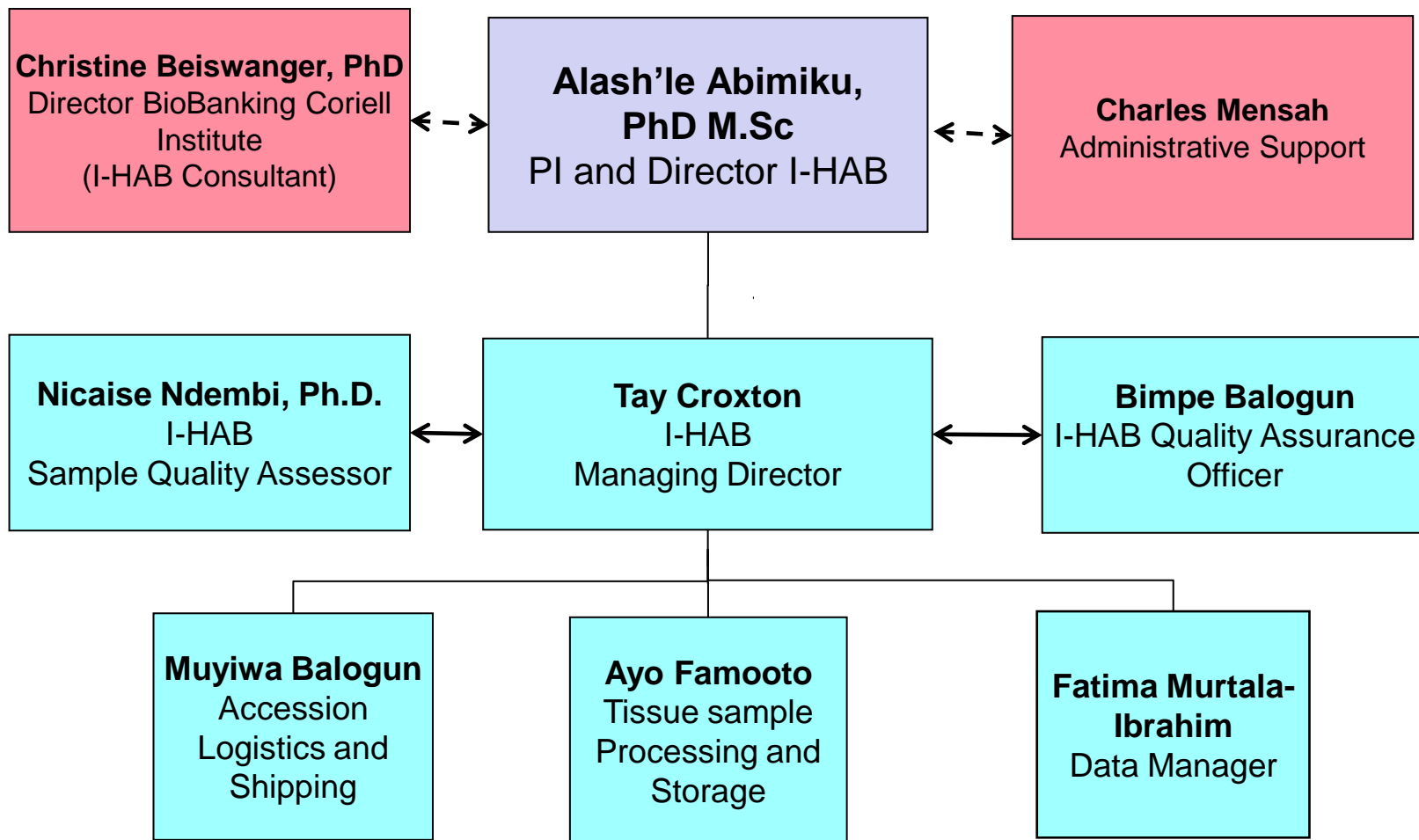
Phase II: *Expand the capacity of I-HAB to support multiple H3Africa investigators to conduct high quality human health and hereditary clinical and translational research in Africa using well processed, preserved and quality controlled and redundantly protected human biological samples accessible to the H3Africa and larger research network*



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Organizational structure for I-HAB Phase I



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Phase 1: Specific Aim 1

Assess current practices and gaps in capacity and map a detailed strategic plan to transition existing IHV-Nigeria biorepository capacity to support full-scale phase II implementation in support of H3Africa investigators.

- Assessment by Coriell to guide training plan
- Evaluate and upgrade infrastructure, management and logistic capacity
- Outline process to upgrade equipment, data software and alarm systems to comply with international standards



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Phase 1: Specific Aim 2

Implement a carefully articulated capacity development process to support phase II implementation.

- Based on needs assessment develop didactic and experiential training program in sample receipt, handling, storage, bioinformatics and distribution in collaboration with Coriell (included regulatory, ethical and administrative trainings)
- Based on needs assessment, detailed roadmap for infrastructure, management and logistics upgrade
- Trained personnel involved in SOP development using ISBER standards governing all aspects of sample flow, security processes, sample receipt and validation, sample rejection, inventory, aliquoting, MTA, distribution, packing , shipping, tracking, QC procedures, safety procedures, data, backups, equipment maintenance and so on.



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Phase 1: Specific Aim 3

Conduct pilot implementation of biorepository monitored through quality control and quality improvement assessment.

- Pilot sample transfer, storage, QC, and distribution with identified H3 Africa investigators
- Based on pilot, identify challenges and implement remedies within I-HAB
- Based on pilot, provide training/support in sample processing and shipment to ensure integrity



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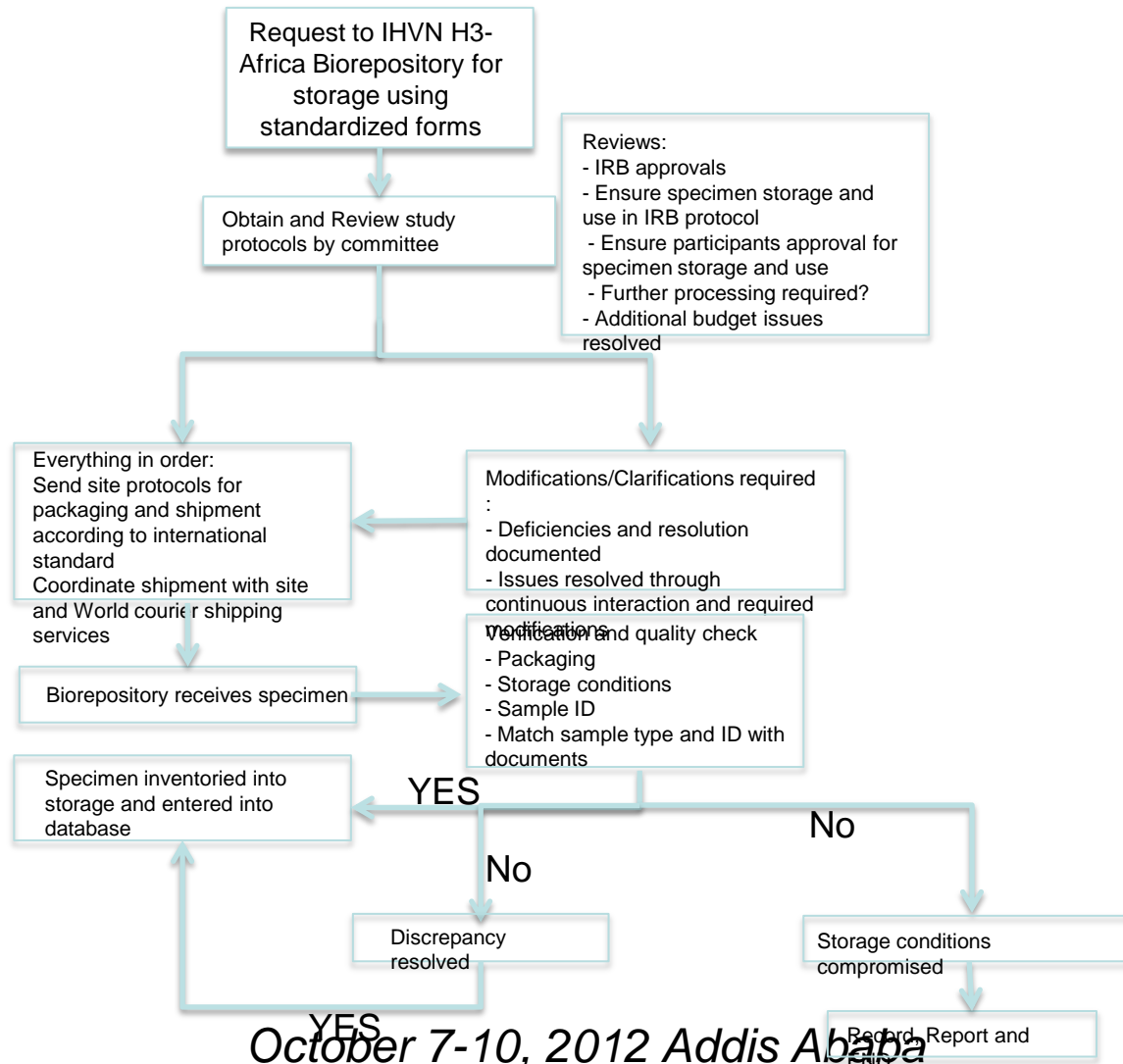
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Proposed Process for Sample Reception and Shipment

Receipt of Biological Samples



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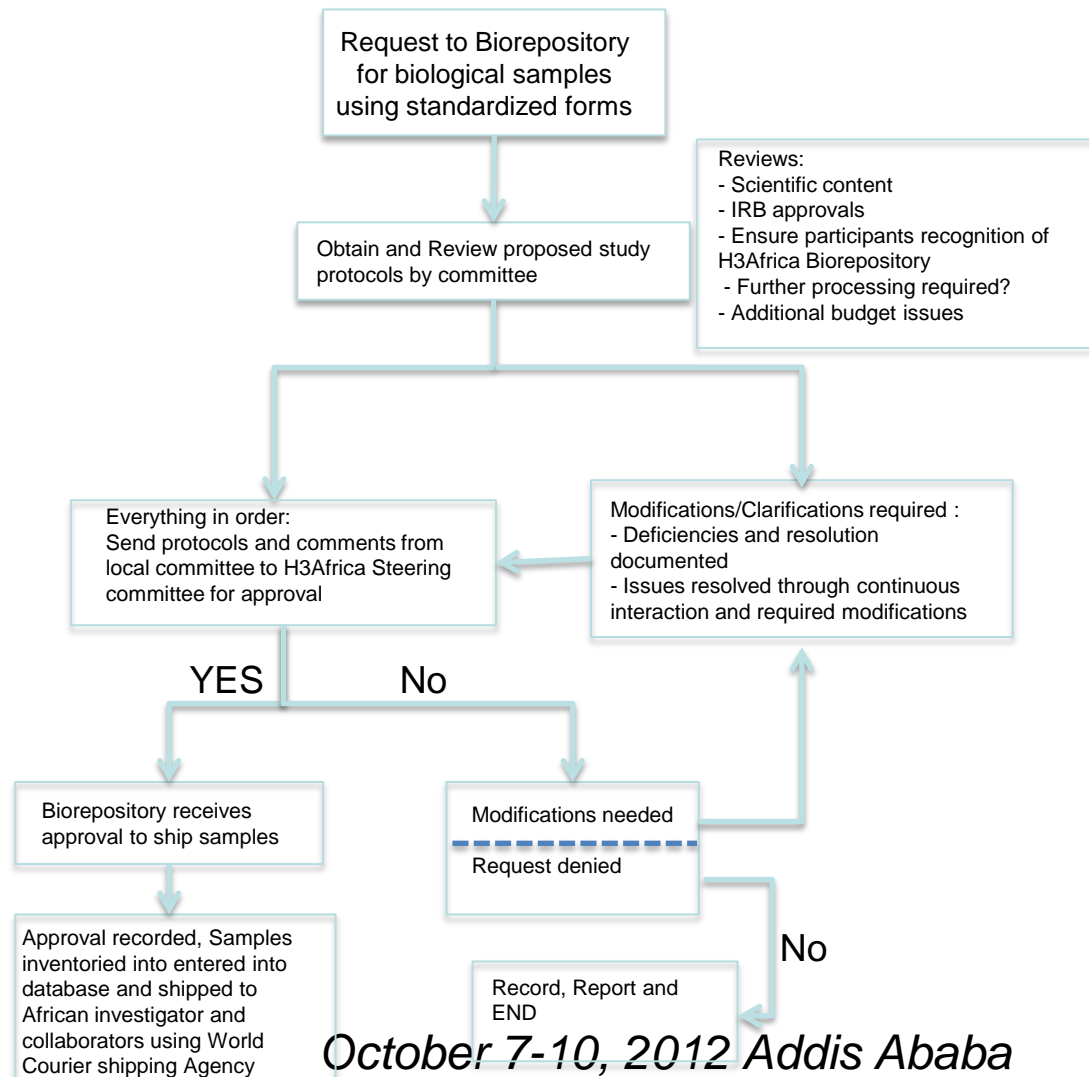
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Proposed Process for Sample Reception and Shipment

Shipment of Biological Samples



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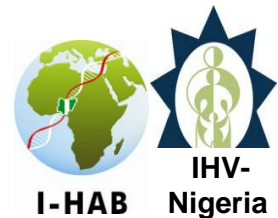
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Phase 2: Specific Aims

1. Implement a central and standardized resource for sample storage of primary human biologic samples and genetic materials in compliance with GLP and ISBER guidelines.
2. Develop, implement, manage and support robust cloud based bioinformatics tool to support biorepository capacity



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Phase 2: Specific Aims Cont'd

3. Establish an administrative governance to effectively promote and facilitate investigators to store, access, and share samples within H3Africa consortium.
4. Provide continuing training and consultation to investigators and study staff on specimen processing, storage, and shipment.
5. Develop a long-term model for sustainable operation of the biorepository.



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Discussion points

1. How can the BioR effectively compliment and synergize with each other to support the H3 Africa goals?
2. What regulations or ethical processes exist in the different H3 Africa countries that may impact the function of the BioR?
3. How can the BioR augment research innovations and collaborations among the H3 Africa network?
4. What are the expectations of the H3Africa investigators from the biorepository in Phase II?



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Acknowledgements

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