Inaugural H3Africa Biorepository Principal Investigator Meeting

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October 7-10, 2012 Addis Ababa
Institute of Human Virology Nigeria: Core Mission

**IHVN**

**Research**
- NIH AVERT
- CDC Acute HIV Infection
- API-N-Gates Foundation PMTCT
- Doris Duke CDC Adherence
- NIH-IHV Nigeria AR

**Training**
- CDC PEPFAR PHE
- GCC HIV Malignancy
- NeuroAIDS
- TB - HIV
- NIH Fogarty
- CDC UTAP
- CDC Pre- and In- Servie Training

**Treatment and Care**
- GFATM HSS, Malaria HIV, TB

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

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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

<table>
<thead>
<tr>
<th>Health Programs</th>
<th>Grant Titles</th>
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<tbody>
<tr>
<td>CDC, U2G PS000651</td>
<td>“HIV/AIDS Prevention, Care and Treatment in the Federal Republic of Nigeria”</td>
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<tr>
<td>Global Fund NGA-S10-G16-T</td>
<td>The Global Fund Round 9 TB</td>
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<tr>
<td>Global Fund NGA-809-G14-M-03</td>
<td>The Global Fund Round 8 Malaria</td>
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<tr>
<td>Global Fund NGA-809-G12-S</td>
<td>The Global Fund Round 8 Health Systems Strengthening</td>
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<th>Research Projects</th>
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<tr>
<td>GC-3482-135-01-010</td>
<td>“HIV Epidemic and Surveillance in Selected Targeted Populations in Plateau State Nigeria”</td>
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<tr>
<td>CDC, 200-2003-01716</td>
<td>“Collection of Serum Specimens Suitable for Validation of Assays with HIV-1”</td>
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<tr>
<td>WHO, IVR, African AIDS Vaccine Program</td>
<td>“HIV disease awareness and willingness to participate in HIV vaccine trials differ across sub-populations at risk of HIV in Abuja Nigeria”</td>
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<tr>
<td>Bill and Melinda Gates via the University of New South Wales</td>
<td>“Evaluation of Novel Concepts in Optimization of antiretroviral Efficacy (ENCORE)”</td>
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<tr>
<td>NIH, NCI</td>
<td>“Kaletra Mono-therapy as a Simple Cost Effective Strategy in the Salvage of D4T, 3TC Nevirapine containing Regimens in Resource Limited Settings”</td>
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<tr>
<td>NIH, R01 AI074594-01A2</td>
<td>“Acute HIV infection and Pregnancy”</td>
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<tr>
<td>CDC U2GPS002929</td>
<td>Community in ACTION: Integrating PMTCT Services in Primary Health Care Setting</td>
</tr>
<tr>
<td>CHRI-CHVI (Canadian) 106356</td>
<td>Creating a common platform for HIV vaccine research and HIV care and treatment programs</td>
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IHVN H3 Africa Biorepository (I-HAB) Initiative
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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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
I-HAB Current Activities: DNA Extraction and processing

Sample Preparation → Nucleic Acid Isolation → Enzymatic Reaction → Amplification → Detection

- Homogenisation
- NA Purification
  - Set up PCR Mixes
- Reverse
- Transcription
  - In vitro
  - Transcription
- Real Time (RT-)
  - PCR
  - Melting Curve
- Melting Curve

MagNA Pure LC 2.0

LightCycler480

Gene Detection
Gene Quantification
Genotyping
Gene Scanning

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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
IHV - Nigeria

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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
WHO-AFRO Step-Wise Laboratory Accreditation

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

**Attendees**
An 18-month program with a series of workshops for the same group of lab managers

**Pre-requisites to entry**
1. Lab strategic plan and policy drafted
2. Lab director, with decision-making power, in place
3. QA manager in place
4. Participant committed to same job responsibilities throughout the 18-month program (preferred)

**Baseline Assessment**

**Workshop #1** & site visits (3 months)

**Workshop #2** & site visits (3 months)

**Workshop #3** & site visits (3 months)

**End-of-Training Assessment**

**Quality Control**

**How To Be A Successful QA Manager**

**SOP Writing**

**BioSafety**

**Additional Training/Technical Assistance Based on Gap Analysis** (offered at ACILT or in-country by partners)

**Optional Complementary Training**
- Lab OMS (CLSI, WHO-Lyon)
- Skill-based training (e.g., SMDP)
- Online Virtual Leadership Development Program (e.g., MSH)

**On-going support by partners and CDC in-country staff (on-site mentoring, monitoring of improvement projects)**

**Getting ready for final inspection**

**Accreditation**

**MLSCN**

**WHO-AFRO**

**SLPTA**

**SLMTA**

**NATIONAL INSTITUTES OF HEALTH**

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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.
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
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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Proposed Process for Sample Reception and Shipment

Receipt of Biological Samples

1. Request to IHVN H3-Africa Biorepository for storage using standardized forms
   - Obtain and Review study protocols by committee
2. Reviews:
   - IRB approvals
   - Ensure specimen storage and use in IRB protocol
   - Ensure participants approval for specimen storage and use
   - Further processing required?
   - Additional budget issues resolved
3. Everything in order:
   - Send site protocols for packaging and shipment according to international standard
   - Coordinate shipment with site and World courier shipping services
4. Biorepository receives specimen
5. Specimen inventoried into storage and entered into database
6. Modifications/Clarifications required:
   - Deficiencies and resolution documented
   - Issues resolved through continuous interaction and required modifications
   - Packaging
   - Storage conditions
   - Sample ID
   - Match sample type and ID with documents
7. Discrepancy resolved
8. Storage conditions compromised
9. Record, Report and END

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Proposed Process for Sample Reception and Shipment

Shipment of Biological Samples

- Request to Biorepository for biological samples using standardized forms
- Obtain and Review proposed study protocols by committee
- Everything in order: Send protocols and comments from local committee to H3Africa Steering committee for approval
- Reviews:
  - Scientific content
  - IRB approvals
  - Ensure participants recognition of H3Africa Biorepository
  - Further processing required?
  - Additional budget issues
- Modifications/Clarifications required:
  - Deficiencies and resolution documented
  - Issues resolved through continuous interaction and required modifications
- Yes
  - Biorepository receives approval to ship samples
  - Approval recorded, Samples inventoried into entered into database and shipped to African investigator and collaborators using World Courier shipping Agency
- No
  - No
  - Modifications needed
  - Request denied
  - Record, Report and END

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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.
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.
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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