

H3Africa Kidney Disease Research Network

A U54 H3A Collaborative Clinical Center Award

**The University of Ghana & The Noguchi Memorial Institute
for Medical Research, Accra, Ghana**



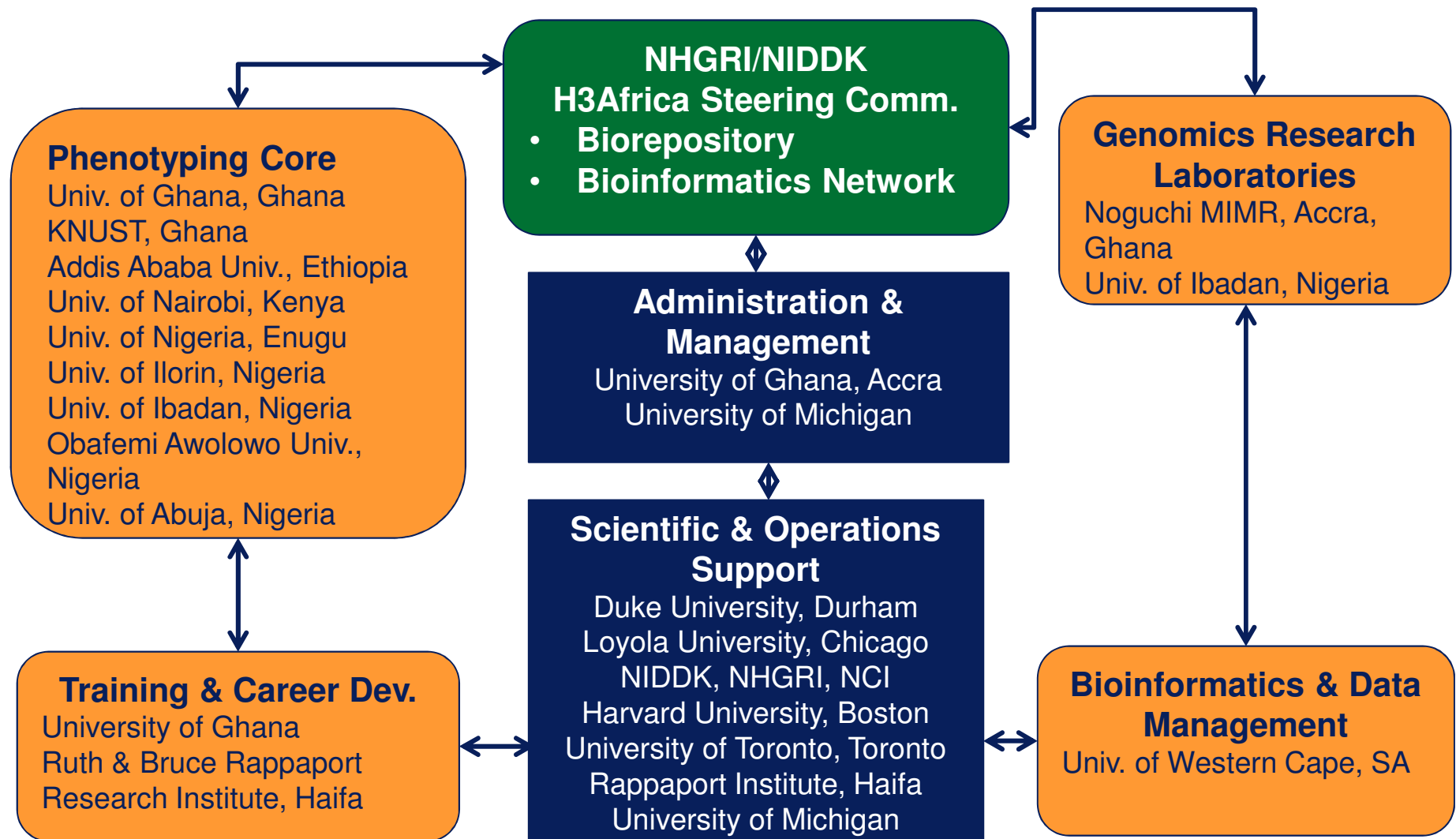
The H3Africa Kidney Disease Study (U54 HG 006939-01)

Dwomoa Adu, MD, FRCP
Principal Investigator (Contact)
University of Ghana, Accra

Akinlolu Ojo, MD, PhD, MBA
Principal Investigator
University of Michigan, Ann Arbor, MI



Organizational Chart: H3A Kidney Disease Research Network



H3Africa Kidney Disease Research Network (U54): Research Objectives

1. Comprehensive phenotyping of the first ever kidney disease cohort of 8,000 cases and controls in four African countries
2. Conduct four genetic and translational research projects of CKD and childhood onset nephrotic syndrome



H3Africa Kidney Disease Research Network (U54): Infrastructure/Capacity Building

1. Two genomic research laboratories in West Africa using sustainable, low capital-intensity laboratory technology platform (Dr. David Burke)
2. Develop mechanism for high throughput whole genomic sequencing in collaboration with overseas institutions (Dr. Rob Lyons, Dr. David Burke and Dr. Michael Boehnke)



H3Africa Kidney Disease Research Network (U54): Training & Career Development Goals

1. Implement training programs genetics and genomics science for laboratory technicians, research scientists and research coordinators in Africa with use of sandwiched approach as appropriate
2. Implement genomics science training and career development program for African scientists in tandem with the Michigan Predoctoral Training Program in Genetics (Dr. John Moran) and the U-M Genome Science Training Program (Dr. Michael Boehnke)
3. Develop system biology training through U.S. platform extension to Africa (Dr. Matthias Kretzler)



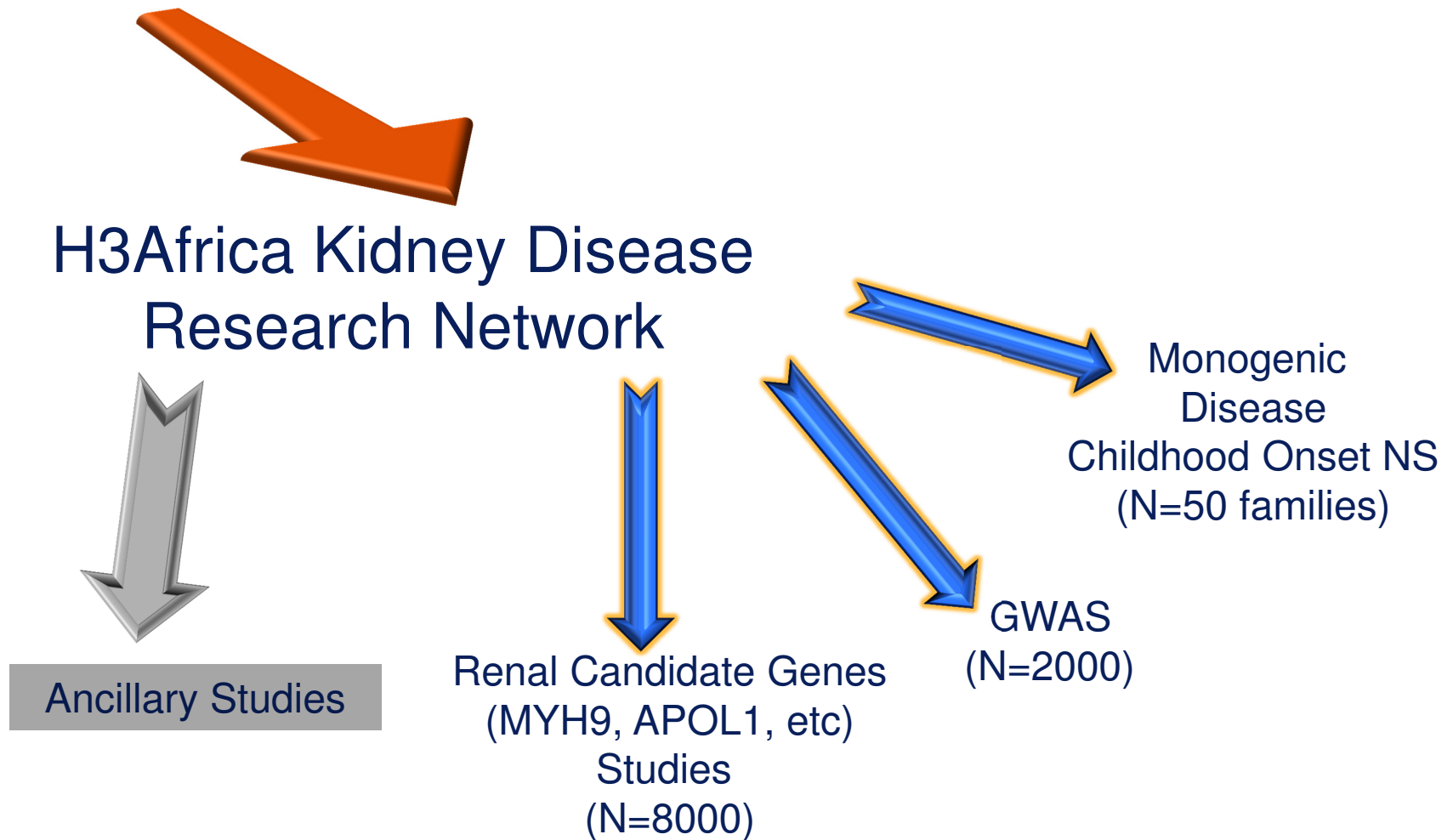
H3A Kidney Study Expanded Recruitment Goals

Recruitment goals for each Clinical Center		
	Number of Participants	
Clinical Center	Kidney Disease	Controls
Addis Ababa University	250	250
Kwame Nkrumah University of Science and Technology	500	500
Obafemi Awolowo University, Ile-Ife	500	500
University of Abuja	250	250
University of Ghana	750	750
University of Ibadan	925	925
University of Ilorin	500	500
University of Nairobi	250	250
University of Nigeria, Enugu	500	500
Total	5,175	5,175



Research Projects in the H3Africa Kidney Disease Research Network

H3Africa Initiative

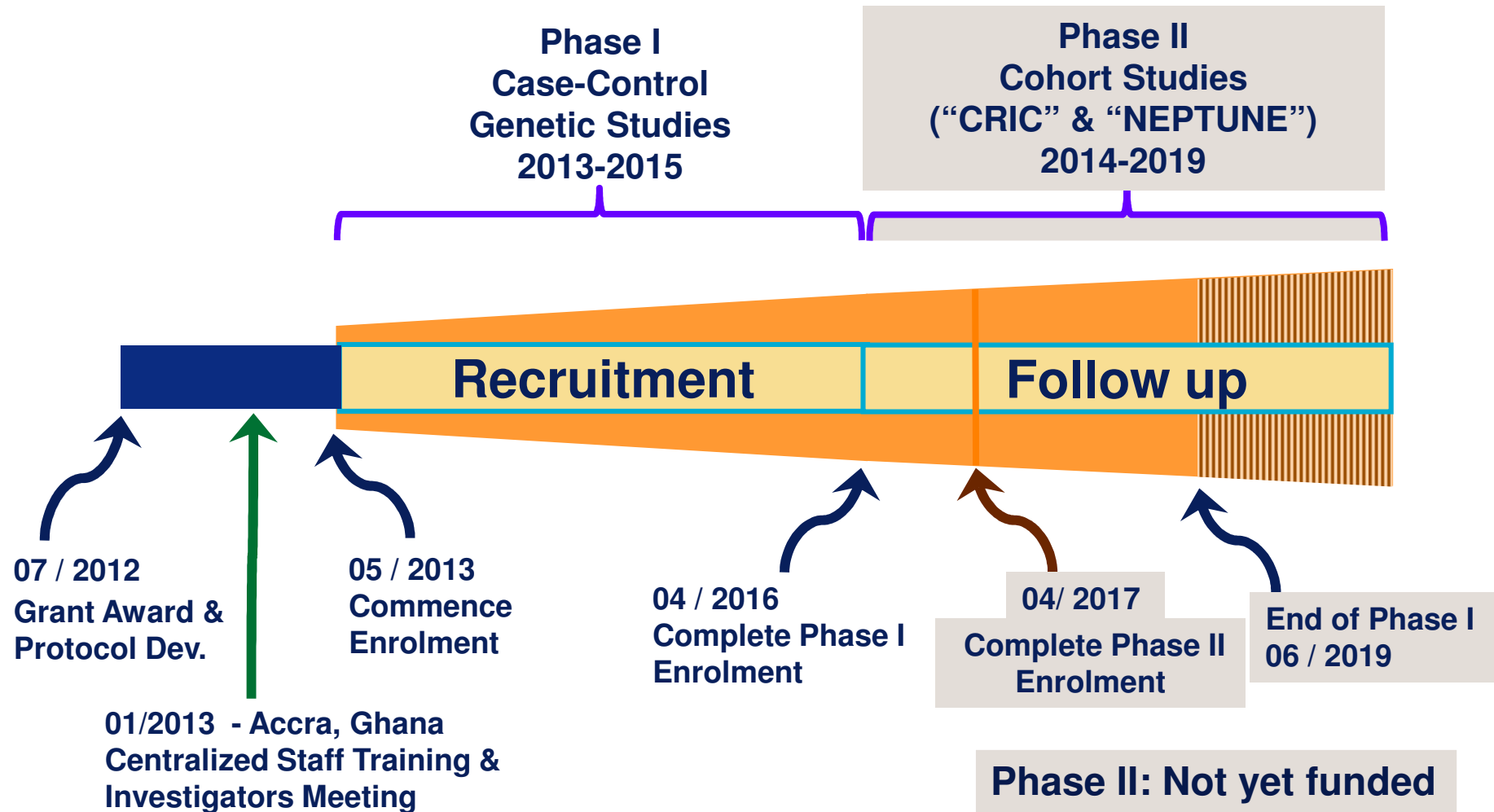


Study Subgroups

Sample Sizes of the Participants and Controls			
Diagnosis-specific eligibility	Age	Cases	Controls
Steroid resistant nephrotic syndrome ¹	<18	200	200
FSGS/MCD & MN	18-70	200	200
HIV nephropathy	18-70	500	500 ²
Sickle cell nephropathy	18-70	500	500 ³
Hypertensive non-diabetics with CKD	18-70	800	800
CKD due to diabetic nephropathy	18-70	800	800 ⁴
CKD – Unknown etiology	18-70	1,000	1,000
Total		4,000	4,000
¹ Includes 50 families with index cases and affected family members ² Patients with HIV and no nephropathy ³ Patients with sickle cell disease and no nephropathy ⁴ Patient with diabetes mellitus and no nephropathy			



H3A Kidney Disease Study: Timeline for Research Studies



Case Report Forms (CRFs)

11 Participant CRFs (640 phenotyping variables)

- 640 phenotype variables on 11 CRFs:
- Medical History
- Blood Pressure Form
- Concomitant Medications
- SF 12
- Environmental History
- Kansas City Questionnaire
- Physical Assessment
- Symptoms List
- Medical Events Questionnaire
- Renal Replacement Therapy – Primary Survey
- Renal Replacement Therapy – Follow-up Survey

11 Administrative CRFs



PHYSICAL ASSESSMENT

Participant ID:

(Example: Site 04 Participant 0001 Enter: 040001)

CRF Date:

(dd-mm-yy)

CRF Version V1.0.20130805

RC ID:

ANTHROPOMETRY:

1. Date of measurement:

(dd-mm-yy)

2. Time of measurement:

(hh:mm)

A. Height and Weight: Height and weight are measured at follow-up clinic visits only. (Baseline height and weight are measured at screening visit and recorded on the Eligibility Assessment (ELIG) case report form.)

3. Standing height: (measured in cm)

(cm)

4. Weight: (measured in kg)

(kg)

BIOSPECIMEN COLLECTION Adult - 57 ML

Participant ID:

(Example: Site 04 Participant 0001 Enter: 040001)

CRF Date:

(dd-mm-yy)

CRF Version V1.0.20130805

RC ID:

1. Type of specimen(s):

- ☐ Blood
☐ Urine
☐ Both
☐ Unable to collect blood or urine

2. Date of birth:

(dd-mm-yy)

2a. Gender:

- ☐ Male ☐ Female

3. Does the participant have a diagnosis of diabetes mellitus?

- ☐ Yes ☐ No

3b. Is the participant on dialysis?

- ☐ Yes ☐ No

Blood Specimens:

4. Collection Date:

(dd-mm-yy)

REDCap: Data & Computing Environment Security

- Web-based clinical research data management system
- Developed at the Vanderbilt University & used by nearly all CTSA
- Interactive tools for:
 - ❑ Participant registration
 - ❑ Data entry and verification
 - ❑ Repository of all study forms
 - ❑ Individual participant calendars
 - ❑ Cumulative site calendars for expected study activities
 - ❑ Calculator of creatinine-based e-GFR
 - ❑ access to the National Drug Data File (NDDF) in the Medication Reference
 - ❑ Link to the Network website
 - ❑ Generate individual participant and investigator-specific reports
 - ❑ Seamless data downloads to common statistical packages (SPSS, SAS, Stata, R)





Logged in as **donnasm** | [Log out](#)

- My Projects
- Project Home
- Project Setup

Project status: **Development**

Data Collection

[Edit instruments](#)

- Scheduling
- Generate schedules for the calendar using your defined events

Data Entry

Applications

- Calendar
- Data Export Tool
- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- User Rights
- Graphical Data View & Stats
- Data Quality
- Report Builder

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature

If you are experiencing problems, please contact your [REDCap administrator](#).

University of Michigan
Michigan Institute for Clinical & Health Research

H3Africa

Data Entry

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: **0**

Choose an existing Participant ID:

-- select record --

Enter a new or existing Participant ID:

Data Search

Choose a field to search
(excludes multiple choice fields)

-- select search field --

Search query

Begin typing to search the project data, then click an item in the list to navigate to that record.

NOTICE:

This project is currently in Development status. **Real data should NOT be entered** until the project has been moved to Production status.



Logged in as **donnasm** | [Log out](#)

- [My Projects](#)
- [Project Home](#)
- [Project Setup](#)

Project status: **Development**

Data Collection [Edit instruments](#)

Scheduling
- Generate schedules for the calendar using your defined events

Data Entry

Participant ID: **1**
Event: **Visit 01: Screening**
Data Collection Instruments:

- DEMO**
- DPCS
- PTCONT
- HPCONT
- BP
- CMED
- KDQOL
- SPEC90
- LABCBC
- SSHIP
- ELIG
- RRTPRIM
- MEDHX

Applications

- [Calendar](#)
- [Data Export Tool](#)
- [Data Import Tool](#)
- [Data Comparison Tool](#)
- [Logging](#)
- [File Repository](#)
- [User Rights](#)
- [Graphical Data View & Stats](#)
- [Data Quality](#)
- [Report Builder](#)

Help & Information

- [Help & FAQ](#)
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DEMO

[Modify this instrument](#)

Download PDF of [- select PDF download option -](#)

Adding new Participant ID: **1**

Event Name: **Visit 01: Screening**

Participant ID:

1

CRF Date:

Today

M-D-Y

RC ID:

Demographics Information

Clinical Centers and Sites

* must provide value

- ☐ University of Ghana Medical School: Accra, Ghana
- ☐ Kwame Nkrumah University of Science and Technology: Kumasi, Ghana
- ☐ University of Ibadan: Ibadan, Nigeria
- ☐ University of Ilorin: Ilorin, Nigeria
- ☐ University of Abuja Teaching Hospital: Abuja, Nigeria
- ☐ Obafemi Awolowo University: Ile-Ife, Nigeria
- ☐ University of Nigeria Teaching Hospital, Enugu: Ituku-Ozalla, Nigeria
- ☐ University of Nairobi: Nairobi, Kenya
- ☐ Addis Ababa University: Addis Ababa, Ethiopia

[reset value](#)

First Name:

Last Name:

Date of Birth:

Today

M-D-Y

Gender:

Street Address:

Town/City, Province/State, Zip code

[Expand](#)

Phone number:

Form Status

Phenotyping and Specimen acquisition resources

- Digital Blood Pressure Monitor – Omron HEM 907XL IntelliSense
- Blood Pressure Monitor Mounting Stand - Omron Floor stand Kit for 907XL
- Digital Floor Scale - SECA 813
- Centrifuge – BD Clay Adams Compact II Centrifuge
- Freezerworks Label Printer - Zebra GX420t
- Freezerworks Hand held barcode label scanner - Symbol 6707
- Portable EKG machine - GE Medical Systems MAC 1200
- Anthropometric Tape Measures - Gulick II Plus G7019
- Bioelectrode Body Composition Analyzer – RJL Systems Quantum II BIA Analyzer System
- Laptop - HP EliteBook 8470p Notebook PC
- Desktop Scanner - HP Scanjet N6350 networked
- Ultrasound Probe – Summit L250 Display Hand Held Doppler (Probe: SD8 8 MHz Vascular)
- Stadiometer - SECA 216



Biospecimen Collection Scheme – H3A Kidney Disease Study (Total phlebotomy = 57cc/adult)

Specimen	Tube	Overnight ship (cold pack) from CC to MDS Lancet Laboratory	Store in Freeze -80 at MDS Lancet Laboratory
A	10ml SST (Yellow Top)		(A1, A2, A3) Light sensitive aliquots (A4, A5, A6) Serum aliquots Stored for future testing
B	5ml SST Yellow top	(B1) Serum aliquot-- Serum creatinine. Serum aliquots stored for Hepatitis B & C, HIV antibody	
C	5ml SST Yellow top		(C1, C2, C3) Serum aliquot Stored for future testing
D	5ml SST Yellow top		(D1) Serum Creatinine
E	3ml Purple (EDTA)	(E1) FBC	
F	6.5ml orange top (DNAgard)	(F1) DNAgard	
G	10ml purple top (EDTA)	(G1, G2, G3, +1 Buffy Coat) DNA Plasma aliquots Stored for future testing	
H	10ml purple top (EDTA)	(H1, H2, H3, +1 Buffy Coat) Plasma aliquots Stored for future testing	
I	4.5ml Blue top (NaCitrate)		(I1, I2, I3) Plasma aliquots Stored for future testing TNF α-Elisa and Fibrinogen Antigen
S	DNA Mouthwash 50ml	**Per Dr. Burke's Saliva Protocol**	S1, S2, S3
U	Random Spot urine 50ml	(U1) Urine aliquot creatinine, albumin	(U2, U3, U4) Urine aliquot Stored for future testing



Freezerworks Data Entry Interface

Search Samples: # 1 of 1 -- Internal Bar Code ID 108918

Samples | DNA | Notes | Transact | Aud Trail | Attachments

Sample ID: 4501 Sample Date: 12/09/2003 Pt. ID#: 13126

Pt. Initials: Pt. Source: EDIC Clinic/Center #: 13

New Pt.: no Transfer Pt.: no Protocol Type: 4A

D Kit Requested: 01/23/2004 D Kit Mailed: 01/23/2004 D Samp. Collect: 03/08/2004

D PIF Received: 03/11/2004 D Sample Rec'd: 03/10/2004 D Check Mailed: 04/16/2004

SubAliquot:

Positions | Status

Total Number of Aliquots: 7 Number of Aliquots with Positions: 7 Total Current Amount is 27

Add Aliquots

Sub-Aliquot

Modify

Delete

Vial	FreezerName	Position1	Position2	Position3	Position4	Position5	Aliquot Type
Tube		Shelf	Stack	Box	Row	Column	
1	PPG Freezer 4	4	K	3	B	5	4th C-PurpV1
2	PPG Freezer 4	2	K	2	C	1	4th P-Orange1
3	PPG Freezer 4	2	K	2	C	2	4th P-Orange2
4	PPG Freezer 4	3	A	1	F	3	4th S-Red1
5	PPG Freezer 4	2	O	2	C	1	4th P-Purp1
6	PPG Freezer 4	2	O	2	C	2	4th P-Purp2
7	PPG Freezer 4	5	A	1	E	5	4th Urine1

Previous Next Save Cancel

H3Africa Kidney Disease Research Network (U54): IRB approval

1. 6 out of 9 centers have IRB approval
2. As of 26/09/2013, 3 out of 9 centers are recruiting
3. By end of October 2013, 7 out of 9 centers recruiting



CURRENT RECRUITMENT

- 138 subjects



TARGET RECRUITMENT

- 228 subjects per month



Pilot Study Recruitment UGMS 05- end 07/2013

- 50 subjects recruited
- Logistics of subject recruitment
- Informed consent document
- Research clinics
- Completeness of CRF
- Logistics of sample transport
- Logistics of result return to subjects



Pilot Study Recruitment UGMS 05- end 07/ 2013

- Completeness of DNA and other biosample storage
- Quality of DNA



DNA isolation of Mouth rinse and Blood Samples from Korle bu



DNA purity and Concentration

- DNA purity and concentration is done using
 1. Nanodrop 2000 UV spectrophotometer (Thermo scientific)
DNA purity Absorbance ratio – A_{260}/A_{280} of 1.7-2.0
 2. Agarose Gel electrophoresis at 1% run in SB buffer at 100V for 40 minutes
 3. Quality Control assays carried out to compare sex of the study participant/donor with recorded information in database



gel 2

335 340 345 350 355 360 365 370
 L 335 340 345 350 355 360 365 370
 375 380 385 390 395

335 340 345 350 355 360 365 370
 L 335 340 345 350 355 360 365 370
 375 380 385 390 395

Comments - on Gel 1

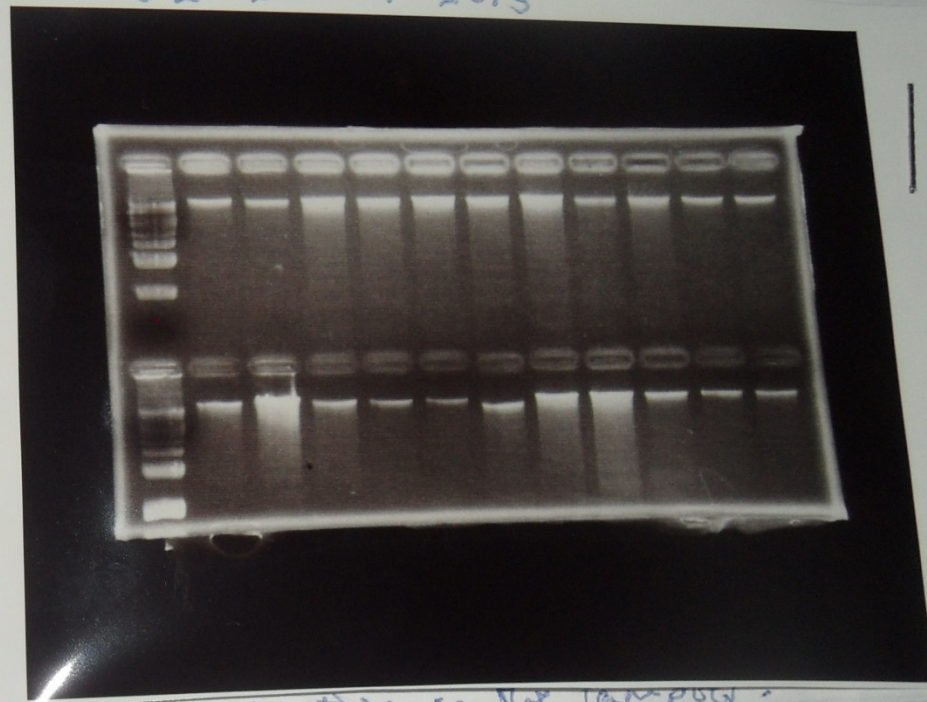
- For the gel 1 the comb size sample + 3 ml of dye LB
- The loading was difficult and
- That accounts for the second gel image as faint bands.
- But all the same, the D

Comments on Gel 2.

- I used a bigger comb size and increased the sample and LB accor

Gel 2 26-09-2013

49.



30/09/2013 09:41 AM

Exp 2
 L 170 160 C1 C2 H1 H2 170 160

24-08-2013.

Amelogenin XY PCR Master

dH₂O

10x Invitrogen Buffer

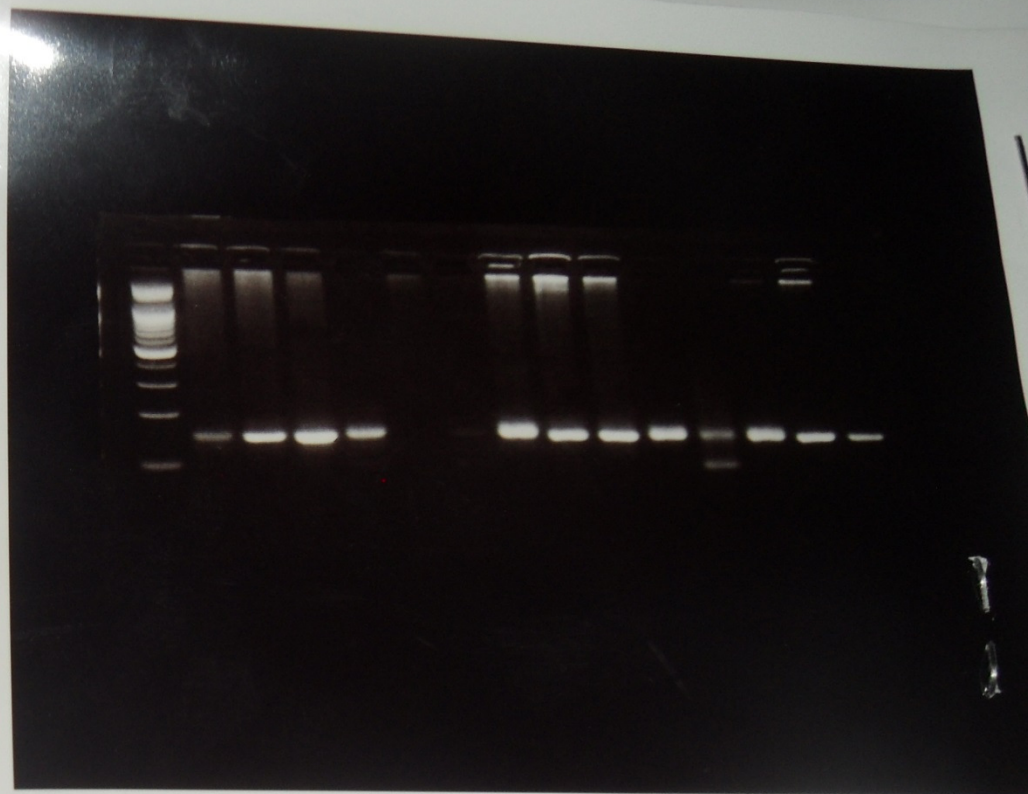
50mM MgCl₂

2.5mM dNTPs

2.5% TX-100

20μM Amelogenin XY Primers

Tag



Gel 2

22-08-2013

0.2x45

9 μl

0.2x45

9 μl

0.12x45

5 μl

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Pilot Study Recruitment

- Conclusions of pilot study disseminated to other centers



Pilot Study Recruitment

- For all the other centers review after 20 patients recruited
- Special focus on transport of specimens to Ghana

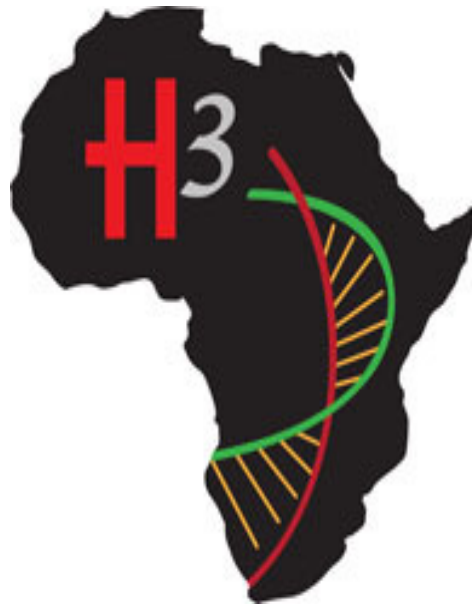




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THANK YOU

