Initial Submission Checklist

*Please include the following with **ALL** new submissions. Additionally, submission of this checklist with the materials would be greatly appreciated.* ***All documents submitted must contain a version date and/or version number.***

Attached	
☐	Signed (PI & Dept. Chair) *Initial Application for Human Research Form*
☐	*Protocol Summary Form*. The following checklists can be used as guides in drafting the Protocol Summary/Detailed Protocol mentioned below: Short Form of Consent Documentation Waiver or Alteration of the Consent Process Waiver of Written Documentation of the Consent Process Advertisements and Payments Research Involving Prisoners Research Involving Pregnant Women Research Involving Non-Viable Neonates Research Involving Neonates of Uncertain Viability Research Involving Children Research Involving Adults Unable to Consent
☐	Sponsor's Protocol/Grant (Note: retract any salary information) or if a grant is not applicable, an Investigator-generated *Detailed Protocol***
☒	*Study Personnel Information Form* Note: All current staff including the PI should be listed within the *Study Personnel Information Form*
☒	English Informed consent form(s)*

If applicable, the following must be submitted for review:

Attached		N/A
☒	Signed (PI) *Secondary Use of Research Samples/Data Application* (no *Initial Application for Human Research Form* or *Protocol Summary* necessary).	☐
☒	Current, unexpired IRB approval(s) from other reviewing institutions	☐
☐	IAA request form if requesting an IRB Authorization Agreement	☒
☐	English Recruitment materials, e.g., letters, postings, advertisements, telephone scripts, etc.* (include version date and/or version number)	☒
☐	Study tools/instruments, e.g., questionnaires, focus group, interview guides, educational materials, etc.* (include version date and/or version number)	☒
☐	Supplemental Review Forms, check all that apply: ☐ *Financial Interest Disclosure Form* ☐ *Drugs, Biologics and Devices Form* ☐ *Radiation Safety Form* ☐ *Translation Attestation Form*	☒
☐	For FDA Regulated research, include all that apply: ☐ Copy of Form FDA 1572 (if PI is Sponsor-Investigator) ☐ Investigator Brochure or Package Insert(s) ☐ Device Manual/product information	☒

*If such materials will be translated, submit a Translation Attestation Form. Submit the locally-approved, translated documents to the HSPH IRB as soon as they become available.

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Secondary Use of Research Samples/Data Application

Instructions: Submit this abbreviated application when the proposed activities include the secondary use of research samples and/or data. This application, however, is not appropriate when the research activities are (1) not limited to secondary use of research samples and/or data; (2) re-consent is planned, and/or (3) the original IRB-approved consent form precludes the proposed activities.

A. PROTOCOL INFORMATION	
Protocol Number (OHRA assigned):	
Protocol Title: **Incidence and risks of liver-related morbidity in an African HIV cohort**	
Principal Investigator / Degree(s):	**Phyllis J. Kanki/ DVM SD**
Department:	**Immunology & Infectious Diseases**
Preferred Mailing Address:	**653 Huntington Ave, FXB 405, Boston, MA 02115**
Email:	**pkanki@hsph.harvard.edu**
Phone:	**617.432.1267**
Additional Contact Person:	**Marykate O'Malley**
Preferred Mailing Address:	**1635 Tremont Street, Boston, MA** ***Please send all correspondence to this address**
Email:	**momalley@hsph.harvard.edu**
Phone:	**617.432.7165**

B. FUNDING SOURCE(S). If no extramural funding, check here and skip to section C: ☒
Attach a copy of each grant application. Remove or black out any salary information.

Sponsor Name	Funding Type	Sponsor Grant # (if applicable)	HSPH Fund # (6 digit), if assigned	Prime Awardee
	Please Choose			☐ HSPH ☐ Other:
	Please Choose			☐ HSPH ☐ Other:

C. SUMMARY OF RESEARCH. Provide a brief description of the study, its objectives, hypotheses, and how the data/specimens will be analyzed.

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Liver-related problems are increasingly being reported among HIV cohorts, particulary during the present era of highly active antiretroviral therapy (HAART). Owing to shared routes of transmission, co-infection of HIV by either HBV or HCV is common. HBV is known to affect 6-9% of HIV infected individuals in some developed countries. Higher rates are found in developing countries, who higherto have had high prevalence of HBV mono-infection. Many studies of liver-related morbidity include subjects from developed countries who have different environmental factors to those of subjects from sub-saharan Africa. Following on from the introduction of HAART, with support from the US government, many more HIV infected people have survived and more and more patients in Africa are anecdotally reporting anecdotal increases in the incidence of liver-associated morbidities such as hepatoxicities to medications, cirrhosis of the liver and liver cancer.

The objectives of this study are to:

1. Determine the incidence of liver-associated morbidities (toxicity to medications, cirrhosis and hepatocellular carcinoma) in HIV patients of African origin.

2. Compare the odds of hepatocellular carcinoma in HIV/HBV co-infected subjects with HBV monoinfected patients.

3. Study the factors responsible for any morbidity (ies) that will be found.

Hypotheses: Incidence of liver-related morbidity is increasing in African HIV patients in the era of HAART; Risk of HCC is higher among HIV/HBV coinfected individuals than in HBV mono-infected patients.

Study design: Retrospective

Methods: This present study shall use the cohort of HIV patients receiving treatment, including HAART, at APIN programme of the Jos University Teaching Hospital. A sub population of HIV/HBV coinfected individuals will be cases, while HBV monoinfected patients from the gastroenterology unit of the same hospital, being recruited in the "case-control" platform of the Prevention of Liver Fibrosis and Cancer in Africa (PROLIFICA) project, will be the controls. Patients registered during January 2005 to December 2010 will be involved.

Inclusion criteria: Age =/> 18yrs; HIV seropositivity, confirmed by Western blot assay; Being HBsAg positive (second hypothesis)

Ethical considerations: Patients in the APIN project have been consented already. However, to ensure confidentiality, the data that will be obtained for this study will be delinked and no attempt will be made to trace individual patients. Ethical clearance for the "case control" study of PROLIFICA has been obtained.

Definition of liver-related morbidity: These will include identified cases of hepatotoxicity of ARVs and anti-TBs, cirrhosis of the liver/advanced fibrosis and liver carcinoma.

Study period: January 2006 to Dec 2010

Personal data: Age, gender, Liver-related morbidity (method and date of diagnosis); HAART regimen (if available), CD4 cell count and HIVRNA copies at baseline; HBsAg and or anti-HCV results plus HBVDNA or HCVRNA (if available)

Planned analyses: Univeriate and multivariate analyses for hypothesis 1 and odds ratio calculation for second hypothesis.

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D. SAMPLES/DATA.

1. Source of Samples/Data. Check all that apply.

☒ Collaborators within HSPH, specify: **Secondary Use of Data from Protocol 16506: Harvard Data Bank: Data and Samples Obtained from APIN Plus/ Harvard PEPFAR-Nigeria Antiretroviral Treatment (ART) Programs for HIV/AIDS**
☒ Collaborators outside of HSPH, specify: **Dr. Nimzing Ladep (Jos University Teaching Hospital, Jos, NIGERIA/ Imperial College London, ENGLAND)**
☒ Other, specify: **Prof Simon D Taylor-Robinson, Dr Oche Agbaji, Dr Patricia Agaba, Dr Shahid Khan, Dr Mireille Toledano, Dr Edith Okeke, Dr Edmund Banwat (Jos University Teaching Hospital)**

2. Samples/Data to be used. Check all that apply.

☐ Personal Data (name, address, social security number)	
☒ Demographic Data (age, gender, race, ethnicity, vital status)	☒ Laboratory Data
☒ Coded Data (diagnoses, procedures, dates)	☐ Images
☐ *Fetal Tissue; original source:	☐ Billing Data
☒ Reports, clinic/office notes	☐ Other, specify:

*The research use of fetal tissue is covered by Federal and State regulations (M.G.L. – Chapter 112, Section 12J). If the original source of the fetal tissue was a supplier of biological materials, the supplier must be in compliance with all applicable Federal and State regulations and laws.

3. Explain why the research could not be carried out without access to this data?
The quality of data that is kept by the JUTH APIN group is continuously being monitored and adjudged to be quite robust. This centre is one of the largest ARV groups in Africa and with support laboratory systems that have attained a high GLP, studies of liver related morbidity is reasonable to be carried out in this cohort. Though, feasible, it would logistically be difficult to obtain similar data without a huge grant. As this study is self- funded by investigator Dr. Nimzing Ladep, it would prove difficult to carry out this work without recourse to this database.

4. Do samples/data retain a code, which could link samples/data to individuals? ☒ Yes ☐ No
If yes, will you, or members of your study team, have access to the coding system? ☐ Yes ☒ No
If yes, explain why you need to identify participants:

5. Will samples/data be sent to individuals or institutions outside HSPH? ☒ Yes ☐ No
If yes, what information will be sent with the samples/data: **delinked data to ensure confidentiality**

E. RISKS TO PARTICIPANTS. Identify the risks to participants (e.g., breach of confidentiality), and address how such risks will be minimized:

Breach of confidentiality is the sole risk. In order to prevent such a breach, patient materials sent to investigators will contain coded patient numbers. Investigators will not have access to the linking codes between ID numbers and indentifiable information.

F. INFORMED CONSENT

1. Were samples/data collected as part of an IRB-approved protocol? ☒ Yes ☐ No
If yes, is the proposed use consistent with the use outlined in the IRB-approved consent form?
☒ Yes ☐ No
If yes, attach a copy of the IRB-approved consent form. If no, complete the Human Research Initial Application or Exemption Request.

2. Do you plan to re-consent participants? ☐ Yes ☒ No
If yes, complete the Human Research Initial Application or Exemption Request.

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G. ATTACHMENTS. The below forms are available under the 'Forms/Instructions' page of OHRA website, www.hsph.harvard.edu/ohra. Refer to the Investigator Manual for additional instructions related to these documents. Check all that apply.

- ☒ Study Personnel Information Form
- ☐ Financial Interest Disclosure Form
- ☐ Other, explain:

H. PRINCIPAL INVESTIGATOR / DEPARTMENT CHAIR CERTIFICATION

As Principal Investigator, I certify the following:

- I will personally conduct or supervise this research.
- I will comply with applicable federal and state regulations, Institutional and School-wide policies, and OHRA policies and procedures, including the Investigator Manual.
- I will conduct the study in accordance with the IRB-approved protocol and will only make changes in a protocol after receiving approval from the IRB, except when necessary to protect the safety, rights, or welfare of research participants.
- I will maintain adequate and accurate records in accordance with HSPH Office of Human Research Administration (OHRA) policy and make these records available for QA/QI inspection.
- I will provide adequate supervision of those to whom the study-related tasks are delegated and I am accountable for regulatory violations resulting from failure to adequately supervise the conduct of this research.
- My participation and the participation of any co-investigators do not, in any way, violate the HSPH policy on conflicts of interest.
- I have completed the applicable HSPH institutional requirements and/or credentialing processes required to conduct this research.
- I will comply with the Harvard Research Data Security Policy, available at http://www.security.harvard.edu/research-data-security-policy

Principal Investigator's Signature _____ Date 1/8/12

As Department Chair, I certify the following:

- The Principal Investigator is qualified by education, training and experience to personally conduct and/or supervise the research described in the protocol.
- The Principal Investigator has completed all applicable institutional credentialing processes to conduct this research.
- The Principal Investigator has sufficient resources to carry out this research as proposed.
- The protocol is scientifically valid and employs research procedures which are consistent with sound research design.

Department Chair's Signature _____ Date 1/18/12

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Study Personnel Information Form

Instructions: Submit this form (or create your own with the fields below) at the time of initial and continuing review or submit it with a Modification Request when adding individuals to the study staff.

A. PROTOCOL INFORMATION	
Version #/Date:	**January 09, 2011**
Protocol Number:	
Protocol Title:	**Incidence and risks of liver-related morbidity in an African HIV cohort**
Principal Investigator / Degree(s):	**Phyllis J. Kanki/DVM SD**

B. STUDY PERSONNEL. Include here the Harvard School of Public Health (HSPH) Principal Investigator and all HSPH affiliates that have either 1) contact with human subjects or 2) access to identifiable data, directly or indirectly via a coding system or key. Include external (non-HSPH) collaborators only in the absence of local IRB review. Each of the individuals named below must complete human subjects training (refer to the Investigator Manual to learn about OHRA's training requirements).

Name, Degree(s), and Affiliation (when not HSPH)	*Role in Study*	**Does this person have a financial interest related to the research*? If Yes, submit Financial Interest Disclosure Form.**	
		Yes	**No**
Phyllis Kanki, DVM, SD	***Principal Investigator***	☐	☒
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

*"**Financial Interest Related to the Research**" means any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family: (a) Ownership interest of any value including, but not limited to stocks and options; (b) Compensation of any amount including, but not limited to honoraria, consultant fees, royalties, or other income; (c) Proprietary interest of any value including, but not limited to, patents, trademarks, copyrights, and licensing agreements, or (d) Board or executive relationship, regardless of compensation. "**Immediate Family**" means spouse, domestic partner, and dependent children.

AIDS PREVENTION INITIATIVE NIGERIA

APIN Plus/Harvard PEPFAR Program Sample/Data Bank
JOS UNIVERSITY TEACHING HOSPITAL

ADULT INFORMED CONSENT FORM

Because you are a member of the APIN Plus/Harvard PEPFAR HIV Care and Treatment Program, you are invited to enter your samples and data that are collected through this program into a research protocol to store them for later use in program evaluations and research studies. The Harvard PEPFAR program provides prevention, treatment, and care for HIV and is not a research program; the APIN Plus/Harvard PEPFAR Program Sample/Data Bank is for program evaluations and (operational) research.

If you agree to participate, your medical information, samples, and their results will be stored in a Sample/Data bank. Information and samples from this Sample/Data Bank may be used in future research projects that are designed to help investigators learn more about and find new treatments for HIV/AIDS or other related diseases. Any future research conducted with your samples/data will be reviewed by an Institutional Review Board (IRB). Participating in this research protocol will take no extra time from you.

Risks

- Although the database staff will always try to protect your privacy, someone may accidentally find out that you have HIV/AIDS or see some of your other private identifiable information through the Sample/Data Bank.

Benefits

- Research that uses your materials/information from the Sample/Data Bank may help future HIV patients.
- You may not be helped directly by participating in this Sample/Data bank. However, if any important information is discovered about your health through any research on your samples/information, we will give that information to your doctors to use for providing medical care to you.

Confidentiality

- Your name will not be on your samples. Samples will be labeled only with your APIN Plus identification number. If your samples are provided to researchers outside this program, they will NOT receive your name or other identifying information.
- Any medical information that is a part of the Sample/Data Bank will be stored on computers that are protected with passwords. Only authorized staff and researchers have the passwords to access these computers. These staff, researchers, those who fund this research, and the ethical review boards that oversee the research may see your private information.
- The researchers in this program will use your samples or information only as described in this form. If they publish the research, they will not identify you unless you allow it in writing. These rules apply even if you take back this permission.

Participation is Voluntary

- You get to decide whether or not you want to participate in the Sample/Data bank.
- If you decide to participate, you may decide to withdraw at any time. If you do so, you may also tell the researchers to remove all of your information and samples from the Sample/Data bank.
- If you do not want to be included in or withdraw from the Sample/Data Bank, it will not affect whether or not you can get medical care at this clinic or through the APIN Plus/Harvard PEPFAR HIV Care and Treatment Program in the future. Refusal to participate or withdrawal from the research will not involve any penalty or loss of benefits to which you are otherwise entitled.

CONTACT INFORMATION

If you ever have questions, concerns, or complaints about this research; or if you are hurt as a result of participation in it, no longer want to take part in it, or wish to remove your information or samples from the Sample/Data Bank, you should contact Dr. Ernest Ekong, APIN Plus office, NIMR, Lagos - tel. 234-802-310-7612.

If you would like to contact someone independent of the research team for questions concerns, or complaints about the research; or have questions about your rights as a research participant, want to obtain information about it, or to offer input contact:

- HSPH Office for Human Research Administration: +1-617-384-5480; 1552 Tremont Street, Boston, Massachusetts 02120, USA; or ohra@hsph.harvard.edu

or

- Dr. Oche Agbaji, Jos University Teaching Hospital, Dept. of Medicine; tel. 234-803-349-1851

If there is anything in this consent form that you do not understand, you should ask the Counseling Health Care Worker at the clinic before signing.

CONSENT STATEMENT

Name of Patient (First, Last): _____ **PEPID:**_____
I have read (or have been read to) and understand the informed consent form for the **APIN Plus/Harvard PEPFAR Sample/Data Bank.** I have been given the chance to ask questions about this research. I understand that I can withdraw my consent at any time for any reason.

Check one of the below if you would like to participate in this research:

☐ I agree to allow my medical information and samples to be included in the **APIN Plus/Harvard PEPFAR Sample/Data Bank** ***for use in HIV/AIDS-related research only.***

☐ I agree to allow my medical information and samples to be included in the **APIN Plus/Harvard PEPFAR Sample/Data Bank** ***for use in any kind of research.***

_____ Date: _____/_____/_____
Signature of Patient

_____ Date: _____/_____/_____
Signature of Legally Authorized Representative (if applicable)

_____
Name of Legally Authorized Representative (if applicable)

I have read aloud and explained the details **of** the **APIN Plus/Harvard PEPFAR Sample/Data Bank** to the above-named participant and have answered questions about this information.

_____ Date: _____/_____/_____
Signature of Counseling Health Care Worker

HSPH OHRA
IRB Protocol No: 1656
Effective: 8/29/11
Expiration: 8/28/12

JOS UNIVERSITY TEACHING HOSPITAL
JOS, NIGERIA

Phone: 073-450226 - 9
E-mail:juth@infoweb.abs.net

Cables & Telegram: JUTH
P.M.B. 2076
Jos.

Ref: JUTH/DCS/ADM/127/XIX/4449

Date: 17th February, 2011

Dr.O. Agbaji
APIN Centre,
JUTH,
Jos.

RE: ETHICAL CLEARANCE/APPROVAL

I am directed to refer to your application dated 2nd February, 2011 on the research proposal titled:

"Harvard PEPFAR APIN Plus/PEPFAR-Nigeria Antiretroviral Programs for HIV/AIDS Database and Repository Bank: Data and Samples Obtained from the APIN Plus/PEPFAR- Nigeria Antiretroviral Programs for HIV/AIDS"

Following recommendation from the Institutional Health Research Ethical Committee, I am to inform you that Management has given approval for you to proceed on your research topic as indicated.

You are however required to obtain a separate approval for use of patients and facilities from the department(s) you intend to use for your research.

The Principal Investigator is required to send a progress report to the Ethical Committee at the expiration of three (3) months after ethical clearance to enable the Committee carry out its oversight function.

Submission of final research work should be made to the Institutional Health Research Ethical Committee through the **Secretary in Room 14, Administration Department**, please.

On behalf of the Management of this Hospital, I wish you a successful research outing.

Hajia R. Danfillo
For: *Chairman, MAC*

INSTITUTIONAL HEALTH RESEARCH
ETHICAL COMMITTEE
DESPATCHED
17 FEB 2011
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