INSTITUTE OF PUBLIC HEALTH,
OBAFEMI AWOLOWO UNIVERSITY,
ILE-IFE, NIGERIA.

HEALTH RESEARCH ETHICS COMMITTEE

APPLICATION TO THE HEALTH RESEARCH ETHICS COMMITTEE FOR CLEARANCE OFRESEARCH INVOLVING HUMAN SUBJECTS, OR PATIENT RECORDS

All applications to the Committee will only be considered if:

(a) The application is typed or handwritten in capital letters, using black ink.
(b) The form is completed in full. You should not simply refer to the protocol but complete the form with the information requested. Where a question is not applicable, it is important to make this clear and not to leave it blank.
(c) The application is signed by the applicant, applicant's supervisor (where appropriate) and the Head of Department/Unit.
(d) Fifteen collated sets of application forms and accompanying documents are submitted.
(e) All necessary accompanying documents are attached.
(f) The language used in the application is clear and understandable to lay members.
(g) All abbreviations are explained.

Applicant's Checklist
Please indicate if the following have been enclosed, by ticking the relevant box:

- Application Form (Fifteen copies only) Yes☐ No☐
- Informed consent form " Yes☐ No☐ Not applicable☐
- Subject information sheet " Yes☐ No☐ Not applicable☐
- Advertisement for research subjects Yes☐ No☐ Not applicable☐
- Medical/Dental Practitioners/consultant information sheet/letter Yes☐ No☐ Not applicable ☐
- Letters of invitation to research subjects (Fifteen copies) Yes☐ No☐ Not applicable☐
- Questionnaire or Interview form to be used Yes☐ No☐ Not applicable☐
- Data sheet for all drugs (one copy only) Yes☐ No☐ Not applicable☐
- Statement regarding compensation arrangements(one copy only Yes☐ No☐ Not applicable☐
- Ever submitted ethics application for this research to any other IRB/HREC and the result (one copy only) Yes☐ No☐

All applications and enquiries should be directed to:
Mr. A.L Owokade,
Secretary, Health Research Ethics Committee,
IPH Office,
OAU, Ile-Ife.
08033717111
In order to avoid delays, please quote the Research plan/Protocol number (if available), the title of the study, and the name of the principal investigator when making enquiries.

Closing Date: Applications received **after the 7th of the month** will be carried over to the following month for consideration.

INSTITUTE OF PUBLIC HEALTH, OBAFEMI AWOLOWO UNIVERSITY, ILE IFE, NIGERIA

HEALTH RESEARCH ETHICS COMMITTEE

APPLICATION FOR APPROVAL OF RESEARCH PLAN

Prepare the research plan based on information provided below. Delete this and other instruction boxes as well as the numbered sections that do not pertain to your study.

Brief Background of PI:

Applicant's Name:

Applicant's Status:

Applicant's Address:

Applicant's E-Mail Address:

Name/Status of Co- Researcher (If Applicable):

Study Title:

HREC No.:

PI Version Number/Date:

1. **Aims/objectives/research question/hypotheses:** Describe the primary and secondary aims/objectives of the research, or the project's research questions or hypotheses.

2. **Background and rationale:** Summarize *briefly* what is already known about the issue, where there are gaps in information, and previous relevant research. If applicable, describe pre-clinical and clinical data, current experience with procedures, instruments, drugs or devices. References are not required but may be included if they are directly relevant.

Items 1-2 should total no more than 2 pages in length and may be considerably shorter

3. **Participants**:
   a. Describe the study participants and the population from which they will be drawn. If you plan to include children, specify their ages and gender.

   b. Describe any screening procedures and any inclusion or exclusion criteria.

   c. Provide sample size and a clear justification as to how you arrived at your projected sample size.

*Note: You do not need to provide an exact sample size and you should estimate a somewhat larger number than you think you will actually collect. You may collect data on fewer subjects than stated without further HREC review as long as you still meet the scientific aims of your study, but you may not collect data on **more** subjects without submitting an amendment.*

   d. Describe whether identifying information will be collected.

4. **Study procedures: (ANSWER EITHER a. OR b. UNLESS BOTH APPLY)**
   a. If your study involves analysis of existing data or specimens only:
      1) Describe the source(s) of the data and whether it is publicly available or not.

      2) If the PI or other investigators were involved in the original data collection, provide the HREC number.

3) Describe whether the original dataset included identifying information and whether the form of the dataset to be used in the new study includes identifiers or not.

4) Provide a brief data analysis plan.

Note: Do not describe details of how the data were collected in a manner that would lead a reviewer to think that your study is currently having contact with human subjects.

b. If your study involves contact, direct or indirect, with subjects, provide the following:

1) General study design and methods.

2) Study procedures, including sequence and timing.

3) Number of study contacts or visits required of participants.

4) Expected duration of the study.

5) A brief data analysis plan and description of the nature of the variables to be derived.

Address the items in the remainder of section 4b if they are relevant to your study

6) If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about collection, volume (ml) or number, use, storage, identification, and disposal. Include, if relevant, information about genetic or genomic analyses planned for the biospecimens.

7) Describe how subjects will be screened for eligibility and assigned to study/intervention and comparison/control groups.

8) Explain and justify whether there will be blinding.

9) Explain and justify whether participants will not receive routine care or will have current therapy stopped.

10) Explain and justify the use of a placebo or non-treatment group.

11) Provide a definition of treatment failure or participant removal criteria.

12) Describe what happens to participants receiving therapy when the study ends or if a subject's participation ends prematurely.

13) Describe the process for referring subjects to care outside the study, if needed.

14) For studies that evaluate interventions, have a randomized study design, and/or are a clinical trial, provide power calculations for projected sample size.

15) If you will perform diagnostic tests, provide the following:

a. For non-standard laboratory tests, information about sensitivity and specificity for each test.
b. For all tests, the anticipated "failure rate" (e.g., failure to produce usable data) of each test, and under what circumstances tests will be repeated.
c. Describe any plan for reporting test results to participants. For medical tests, describe how results will be validated.

5. Data Security and Protection of Subject Confidentiality (NOTE: LOSS OR THEFT OF COMPUTER OR HARD COPIES OF DATA COLLECTION SHEETS DURING TRANSPORT IS

GREATEST THREAT TO SUBJECT CONFIDENTIALITY – BE SURE TO TRAIN YOUR STAFF ABOUT THIS PROBLEM.)

a. Will the study data stored in Nigeria be protected by a Certificate of Confidentiality? If yes, explain who will apply for and maintain the Certificate.

b. Identify the data security plan below that best describes how you will minimize the risk of a breach of confidentiality by typing an X in the appropriate box on the left side of each section (A, B, C) of this chart. If your study includes sequential phases that require different procedures, or does not fit these categories, explain in "Other". These categories reflect minimal standards; you may impose more stringent protections.

Note: Identifying information include direct identifying information such as name, address, hospital record number, etc., and other indirect identifying information (e.g., date of birth, tribe) that, when combined with other variables, may make a subject identifiable. It is possible that a unique, randomly-assigned, study identifying information may remain within a dataset, but the dataset could be considered sufficiently 'deidentified' for the purposes of the IPHOAU HREC. This may be the case if the person in possession of the data cannot use the unique identifying information to locate or identify a specific individual without additional codes or identity table linkages.

A. Hard copies of data collection forms:	
	The study collects data that are anonymous; no personal identifying information are recorded or retained from any study participants in either direct or coded form.
	Hard copies of data collection materials <u>have identifying information</u> and are locked in a secure cabinet or room with limited access by specified individuals. COPIES WILL BE KEPT IN INVESTIGATOR'S POSSESSION DURING TRANSPORT. When possible, redacted (de-identified) versions of the data collection sheets will be used for coding and analysis.
	Hard copies of data collection materials include an ID code but <u>do not have personal identifiers.</u> However, a code linking the data to the subject's personal information is stored separately from the data collection sheets, and is either stored in a secure electronic database, and/or locked in a secure cabinet or room with limited access by authorized individuals. CODE WILL BE KEPT IN INVESTIGATOR'S POSSESSION DURING TRANSPORT.
	Data are not collected on paper.
	Other (describe):
B. Electronic Databases: *Note: This refers to the initial database into which study data is entered and stored. If this "Study Database" includes personal identifiers from participants, only de-identified analytic datasets should be used for data analysis except in instances in which identifying information is required.* ***Databases that retain identifying information require a higher degree of electronic security.***	
	The study collects data that are anonymous; no personal identifying information will be recorded or retained from any study participants in either direct or coded form.
	<u>Personal identifying information</u> are included in the database. If breach of confidentiality poses more than minimal risk to participants because data are personally sensitive in nature (for example, involve substance abuse, mental health, genetic propensities, sexual practices or activities), access to identifiers will be restricted. These data are stored on a secure server protected by strong password, and will be only accessible by authorized study personnel. Data will be coded when possible. Identifiable data transferred or stored via portable electronic devices (e.g., laptops, flashdrives) will be encrypted. The devices on which this information is stored are accessible only to individuals who need access to these data.
	Other (describe):
C. Analytic Datasets: *Note: This refers to the use, for analysis, of either discrete subsets or the entirety of the database into which study data is entered and stored. To the extent possible, analytic datasets should be de-identified, except in instances in which identifying information is required.* ***Analytic datasets that retain identifying information require a***	

higher degree of electronic security.	
	The study collects data that is anonymous; no personal identifying information will be recorded or retained from any study participants.
	Electronic database will be managed by a specific data administrator (PI or other designated person) who will track and log issuance of analytic datasets, and return/remove when approved. Access to analytic datasets will be subject to conditions established by the PI. Electronic analytic datasets will be provided to authorized study personnel, or approved investigators outside the study, with the same data protection requirements established for the study database.
	Other (describe):

c. If you are using participants' personal identifying information, describe any plans for disposing of identifying information including if, when and how that will be done.

d. Describe any plans for destroying data including if, when and how that will be done.

Secondary data studies stop here, unless a category below is relevant to this particular proposal

6. Recruitment process:

a. Describe how, and from where, participants will be recruited.

b. Explain how your recruitment materials will be used.

c. If relevant, address any privacy concerns associated with the recruitment process.

7. Consent process and documentation:

a. If you will obtain informed consent from participants, identify the towns, states or countries where the research will take place and the languages into which each consent document will be translated. If the language is unwritten, provide information about how you will ensure accurate and informed translation, including possible use of audio recording.

Town(s), State(s) or Country(ies)	Consent Document (Indicate "All", or specify each document when translations vary)	Languages

b. Describe who will obtain informed consent from participants, and how, when and where consent will be obtained. If you include children, be sure that consent is obtained from the person who has the legal authority to provide informed consent. In Nigeria, that person is usually a biological parent unless a legal proceeding intervenes. Address this issue for international studies. Note: Children in foster care may not be enrolled unless investigators request their inclusion and explain and follow local requirements.

c. If the study will involve vulnerable populations (e.g., children, prisoners, cognitively impaired adults, non-English-speakers, etc.) describe efforts to ensure their understanding of the research and the extra protections that will be in place to ensure their voluntary participation. Include a description of your assent process for children of appropriate age and maturity; and for adults who lack capacity to provide informed consent.

d. If a waiver of consent or a waiver or alteration of signed consent is requested, provide a justification for the waiver/alteration, and describe any alternate procedures for informing participants about the research.

8. Risks:

a. Describe the risks associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks.

b. Describe the anticipated frequency and severity of the harms associated with the risks identified in 8.a., above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an "anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?

c. Describe steps to be taken to minimize those risks.

d. Describe the research burden for participants, including time, inconvenience, out-of pocket costs, etc.

e. Describe how participant's privacy will be protected during data collection if sensitive questions are included in interviews.

9. Benefits:

a. Describe any potential direct benefits to participants from participating in the research (not including payment for participation).

b. Describe potential societal benefits likely to derive from the research.

10. Payment:

a. Describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain.

b. Include the possible total remuneration and any consequences for not completing all phases of the research.

11. Drug Products, Vitamins, Dietary Supplements and Devices:

a. Drug, Vitamin, and Dietary Supplement products:

1) Provide the rationale for the drug, vitamin, or dietary supplement product in the target population. Provide the rationale behind the dose, and specify the route of administration chosen.

2) Provide information here about how you arrived at the dose. This section should include any pre-clinical work, information about other studies upon which you rely

3) International: For products approved by regulatory authorities other than the NAFDAC, provide information about those approvals and whether the product is approved for use in the country of the study site.

4) NAFDAC Regulated Drug Products (including dietary supplements being used to test for a drug effect):

a) If NAFDAC-approved drugs will be administered for non-NAFDAC approved indications, or if doses or routes of administration or participant populations will be different from those approved by the NAFDAC, justify the choices and provide safety information for the method or population.

b) If the study will use a non-NAFDAC approved product with an Investigational New Drug (IND), please provide the IND number.

5) Provide a justification and safety information if the study will administer non-NAFDAC approved drugs without an IND.

6) Explain who will be responsible for drug management and dispensing, and what drug monitoring and/or regulatory oversight will be provided as part of the study.

b. Medical Devices:

1) Provide the rationale for the device chosen.

2) If you are using an investigational device, clarify whether it is a Significant Risk (SR) device, or provide information to support a determination that it is a Non-Significant Risk device (NSR).

12. Safety monitoring:

a. Describe how participant safety will be monitored, by whom, and how often.

b. If a Data Safety Monitoring Board (DSMB), or equivalent. will be established, describe the following:
i. The DSMB membership, affiliation and expertise.
ii. The charge or charter to the DSMB.
iii. Plans for providing DSMB reports to the HREC.

c. Describe plans for interim analysis and stopping rules.

13. Plan for reporting unanticipated problems/adverse events:
Describe plan for reporting to the HREC and (if applicable) to the sponsor. Include plan for government-mandated reporting of abuse or illegal activity.

14. Other IRBs/Ethics Review Boards:
If the research will require review by other HRECs, provide the name and contact information for each HREC/ethics review board.

15. Outside collaborations:
For studies that involve collaboration with non-OAU institutions, describe the collaboration and the roles of each collaborator, including the OAU investigator. Complete the chart for all multi-collaborator studies.

Roles and Responsibilities Matrix for HREC Application
Insert Institutions in Collaborator column(s); add additional columns if necessary.

	HREC	Collaborator 1	Collaborator 2
Primary Grant Recipient			
Subcontractor			

For the following, indicate "P" for "Primary", "S" for "Secondary" as appropriate to role and level of responsibility.) Add additional items if useful.

1	Human subjects research ethics training for data collectors			
2	Day to day management and supervision			

	of data collection			
3	Reporting unanticipated problems to the IPHOAU HREC/Sponsor			
4	Hiring/supervising people obtaining informed consent and/or collecting data			
5	Execution of plan for data security/protection of participant data confidentiality, as described in Sect. 5.			
6	Biospecimen processing, storage, management, access, and/or future use			

16. Oversight plan for student studies:
For student-initiated studies, explain how the PI (Supervisor) will monitor the student's adherence to the HREC-approved research plan, such as communication frequency and form, training, reporting requirements, anticipated time frame for the research, and who will have direct oversight of the student if the study site is not local.

17. Oversight plan for studies conducted at non-OAU sites, including international venues, for which the OAU investigator is the accountable PI:
Explain how the study will be managed, the qualifications of study personnel managing the project, and how personnel involved with the data collection and analysis will be trained in human subjects research protections. If the PI will not personally be on-site during the data collection process, provide details about the supervision of the data collection and the communication plan between the PI and study team to assure adherence to the HREC-approved research plan.

18. Creation of a biospecimen repository:

a. Explain the source of the biospecimens, if not described above, what kinds of specimens will be retained over time. Clarify whether the specimens will be obtained specifically for repository purposes, or will be obtained as part of the core study and then retained in a repository.

b. Describe where the biospecimens will be stored and who will be responsible for them.

c. Describe how long the biospecimens will be stored, and what will happen at the end of that period.

d. Explain whether the biospecimens will be shared with other investigators, inside and outside of OAU, how the decision to share will be made, and by whom. Include the policy on commercial use and secondary distribution. Also explain how downstream use of the specimen will be managed, and what will happen to left-over specimens.

e. Describe whether future research using the biospecimens will include specimen derivation and processing (cell lines, DNA/RNA, etc.), genomic analyses, or any other work which could increase risk to participants. Explain what additional protections will be provided to participants.

f. Explain whether the specimens will be identifiable, and if so, how they will be coded, who will have access to the code, and whether the biospecimens will be shared in linked (identifiable) form.

g. Explain whether the repository will have Certificate of Confidentiality protections.

h. Explain whether a participant will be able to withdraw consent to use a biospecimen, and how the repository will handle a consent withdrawal request.

i. Describe data and/or specimen use agreements that will be required of users. Provide a copy of any usage agreement that you plan to execute with investigators who obtain biospecimens from you.

19. Data Coordinating Center: Note: Complete section 14 for each participating site.

a. How will the study procedures be developed? Who is responsible for considering the feasibility of the study intervention, and the risks the intervention poses to subjects?

b. How will the study documents that require HREC approval at each local site be developed? Will there be some sort of steering or equivalent committee that will provide central review and approval of study documents, or will template consent forms, recruitment materials, data collection forms, etc. be developed by and provided to the local sites by the coordinating center without external review?

c. Will each local clinical site have its own HREC? State whether the coordinating center will collect HREC approvals and renewals from the clinical centers or not; if not, explain why not.

d. How will the coordinating center provide each local site with the most recent version of the protocol and other study documents? What will be the process for requesting that these updates be approved by local clinical center HRECs?

e. What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?

f. What is the process for reporting and evaluating protocol events and deviations from the local sites? Who has overall responsibility for overseeing subject safety: the investigators at the recruitment site, Coordinating Center, the Steering Committee, or a data and safety monitoring board (DSMB)? Is there a DSMB that will evaluate these reports and provide summaries of safety information to all the reviewing HRECs, including the coordinating centre HREC? Please note that if there is a DSMB for the overall study, then the coordinating center PI does not have to report to the coordinating centre HREC each individual adverse event/problem event that is submitted by the local site PIs.

g. Who is responsible for compliance with the study protocol and procedures and how will the compliance of the local sites be monitored and reviewed? How will issues with compliance be remedied, if there are issues?

20. Declaration

The information provided in this Ethical clearance application form is accurate to the best of my knowledge and belief.

Applicant's Name/Signature: **Date:**

HOD's Name/Signature: **Date:**

Supervisor's Name/Signature: **Date:**