INSTRUCTIONAL TEMPLATE ONLY

HREC Office version

INSTITUTE OF PUBLIC HEALTH, OBAFEMI AWOLOWO UNIVERSITY, ILE IFE

INFORMED CONSENT DOCUMENT

Insert an identifier in the footer such as version number and/or date on bottom of this page.

<<Insert Name of Consent Document>>
If there are multiple consent forms, identify each document by the population who will sign it, for example, “Adult Controls”, “Parents”, “Teachers”, etc.

Study Title:

Principal Investigator:

HREC No.:

PI Version Date:

Investigators are expected to write consent forms in simple language.

- Please use the Spelling and Grammar feature of Microsoft Word to check the reading level of the text of the document that you write (instructions for Microsoft Word are at the end of this document after the signature page).
- Check spacing – make sure headings and text flow together, and remove unneeded spaces.

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Participation in this study is optional. You may decide to leave at any time without being penalizes.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

Purpose of research project

Start with an introductory sentence describing the primary aim of the study as stated in the research plan. “This research is being done to….”
Explain what the study is designed to discover or establish. If this is a treatment study, describe how the study intervention is different from standard care. Identify any procedures or objectives that are experimental.

Why you are being asked to participate

Describe the basic eligibility criteria for the study population and why you are asking the participant to join the study. You may include the approximate number of people expected to take part. If the study involves a screening procedure, explain that the screening will determine whether the participant will be eligible for the study intervention or interaction.

Procedures

This section should explain to the subjects what will happen if they join the study. For example, "If you join this study, we will ask you to do the following things:…" Then, describe the procedures chronologically, using lay language and short sentences, or bullets and phrases. Keep paragraphs short. Make sure the procedures listed in the consent form are consistent with those in the research plan.

- *Explain concepts like "randomization" using language like "flipping a coin"*
- *Define and explain any medical or scientific terms in ordinary language, for example, use teaspoons instead of ml. as unit of measurement.*
- *Specify the length of time for participation, frequency of procedures, and the location of the study intervention.*
- *If placebo is used, clearly define what it is.*
- *If applicable, explain whether study test results will be returned to the subject, and whether medical results will be provided to the participant's health care provider.*
- *If your study will include storing of samples for future research, use a separate consent form for that procedure. In it, explain who will store the specimens, for how long, how they might be used, and who may have access to the specimens, and under what conditions. Include any coding or other data security measures that will be taken to protect the identifiers.*

Risks/discomforts

Identify each reasonably foreseeable risk (physical, psychological, social, economic, legal, emotional) that might result from participation in this study. If the study involves sensitive personal issues that, if disclosed, could expose the subjects to risk of legal, economic, emotional, or any other personal risk, acknowledge that risk. If there are medical interventions, describe the potential risks for each type.

- *Include a section on risks related to pregnancy, if applicable.*
- *If you are drawing blood from a participant, include the risks related to blood draw: "Taking blood may cause discomfort, bleeding or bruising where the needle enters the body. In rare cases, it may cause fainting. There is a small risk of infection."*
- *If your study involves exposing research participants to radiation, include the appropriate consent form language provided in the guidance, "Radiation Risk Language in HREC Consent Forms." Include a reference to the risk of radiation for pregnant women, if appropriate.*

Benefits

State the direct personal benefits, or the possibility of direct personal benefits, that are available through participation in the research. If there are no direct personal benefits, state: "There is no direct benefit to you from being in the study".

NOTE: Financial rewards that will be offered in exchange for participation should go under the "Compensation" heading. Results of tests that are available to the subject outside of the study should not be included.

Describe the social, scientific, or community benefits that could accrue from the study.

Payment

For studies that do not offer any financial payment, indicate "There is no payment for participation."
For studies that do offer some kind of payment or token of appreciation, clarify the amount of compensation or what the token will be, when it will be delivered, and whether there will be a change in payment if a study subject leaves the study early.

Protecting data confidentiality

All studies should include the risk of a breach of confidentiality. Sample language: "All research projects carry some risk that information about you may become known to people outside of a study."

Explain how the risk of a breach of confidentiality will be minimized through protection of study data and use of good security practices. If relevant, explain how the identifiers associated with each subject's data will be protected.

For a Certificate of Confidentiality, insert the following language:

[Insert appropriate agency – it could be "The Federal Government" or "The Federal Ministry of Health"] has given us a Certificate of Confidentiality for this study. This Certificate does not mean that the government approves or disapproves of this study. This Certificate adds special protection for research information that identifies you. It allows us, in some circumstances, to refuse to give out study information about you without your consent when it is sought in a legal action. Still, we may disclose identifying information about you if, for example, you need medical help.

We may also give out information about you if the government audits us. The research team will also give information to local or state authorities:

- if they suspect abuse or neglect of a child or dependent adult;
- if certain communicable diseases are present; and
- if the team learns that you plan to harm someone. In this case, the team also may warn the person who is at risk.

Add the Following Sections, if Applicable. ***If none are applicable, skip to section titled, "Who do I call if I have questions or problems?"***

Protecting participant privacy during data collection

If data collection involves asking people about personal matters in a public setting or activities that involve a potential invasion of personal privacy (e.g., a physical examination, a home visit) explain how you will protect the participant from embarrassment or unwanted disclosure of personal information.

Alternatives to procedures or treatments

Include a statement that the participant does not have to join the study, and if applicable, that "your care will not be affected by this decision."

If other treatments are available to the participant, include this language:
"If you decide not to join this study, other options are available. You do not have to join this study to get treatment. Other treatments include <describe treatments.>"

Biological specimens

This provision should be included in all consent forms for studies which collect **biological specimens** *as it establishes ownership of the data/specimens that will be used in the study. If you plan to store the specimens for future research, submit a separate biobank consent form. Include below the appropriate name for the biological material you will collect and use for the study.*

The < **insert specimen name** > and data collected from you during this study are important to science. You will not own the < **insert specimen name** > or data after you give it to the study. You will not receive any financial benefit from any product or idea created by the investigators using the data or materials collected from you.

Cost of participation in the study

If the study provides medical care, clarify whether the cost of that care will be provided by the study or is the responsibility of the subject and the subject's health care insurer.

What happens if you leave the study early?

A participant may leave a study early either because it is his or her choice, or it is the decision of the PI and/or the sponsor. Make the consequences of any of these possible decisions clear.

Sharing your health information with others

Include as a separate section if you intend to share medical information with the participant's medical providers or anyone else. Studies in Nigeria (or elsewhere) which include testing for HIV or other contagious diseases must follow local law and must include in the consent document any reporting requirements

Conflict of Interest

A conflict of interest occurs when a researcher or the University / Institution has a financial or other interest that might affect the researcher's judgment when conducting a research study. In some situations, the results of a study might lead to a financial gain for the investigator(s) and/or your institution. All such conflicts must be disclosed to the HREC.

Payment of treatment costs for injury or illness from study participation

For studies involving a physical or medical intervention, include the following:
Your Institution<and the federal government, if applicable> does not have a program to pay you if you are hurt or have other adverse results from being in the study.

Clinical Trial Registration

- Give registration number for clinical trial for interventional study design research.

Include in all consent forms

Who do I call if I have questions or problems?

Participants must have a way to contact the PI and the study team. Provide a telephone number *that works*, and other contact information, such as an email address, to make it easy for participants to communicate with you. Be sure to update the contact information if it changes after initial approval. Research conducted in an international setting must provide a local contact name and telephone number, address, and email, if appropriate.

- Call the principal investigator, <<insert name>>, at <<telephone number>> if you have questions, complaints, or get sick or injured as a result of being in this study.

Study subjects have the right to contact the HREC if they have questions, concerns, or complaints about the conduct of the study. For international studies, if a local HREC is overseeing the conduct of the study, replace the information below with contact information for the local HREC.

- Call or contact the Obafemi Awolowo University Institute of Public Health HREC Office if you have questions about your rights as a study participant. Contact the

HREC if you feel you have not been treated fairly or if you have other concerns. The HREC contact information is:

Address: Health Research and Ethics Committee
Institute of Public Health
Obafemi Awolowo University
PMB 045, OAU Post Office
Postal Code 220005
Ile Ife
Telephone: +234 808 842 8726
E-mail: iph@oauife.edu.ng
iphoauife@gmail.com

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Keep the questions below on the same page as the signature lines.

What does your signature (or thumbprint/mark) on this consent form mean?

Your signature (**or thumbprint/mark)** on this form means:

- You have been informed about the study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

Add any of the following lines that are required; delete any that do not apply.

_____	_____	_____
Print name of Adult Participant	Signature of Adult Participant	Date
_____	_____	_____
Print name of Legally Authorized Representative (LAR)	Signature of LAR	Date

_____

Relationship of LAR to Participant

Ask the participant to mark a "left thumb impression" in this box if the participant (or participant's parent) is unable to provide a signature above.

Include this Assent Statement in all studies involving children, unless using a separate Assent Form. Delete box and statement below if not applicable.

Assent Statement

_____
Print name of child participant

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

_____	_____	_____
Print name of Parent/Legal Guardian	Signature of Parent/Legal Guardian	Date
_____	_____	_____
Print name of Witness (if needed and approved by HREC)	Signature of Witness	Date

Always include:

_____	_____	_____

Print name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Give one copy to the participant and keep one copy in study records