Covenant University

Km 10, Idiroko Road, Canaanland, P.M.B 1023, Ota, Ogun State, Nigeria

Covenant Health Research Ethics Committee (CHREC)

ETHICS REVIEW PROTOCOL FORM (FORM 002)
(ABRIDGED PROPOSAL)

Non-Student Investigator

For Official IRB use only

Reference No.	
Application No.	
Date Received	
Name (or ID) of Receiving Officer	
Signature of Receiving Officer	

***Note:** This Abridged Protocol Form must be accompanied by a complete (full) Project/ResearchProposal*

PROJECT:

Project Title:

Commencement Date

(Plausible)[DD/MM/YY]:

Completion Date (Plausible)

[DD/MM/YY]:

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Covenant University, Km 10, Idiroko Road, Ota, Ogun State Nigeria.
Postcode: 112233. cuhrec@covenantuniversity.edu.ng

S/N	Last name	Initial	First Name	Affiliation	Highest Degree	Phone & Email
FACULTY/PRINCIPAL INVESTIGATOR:						
1						
OTHER INVESTIGATORS:						
2						
3						
4						
5						
6						
7						
8						
9						
10						

HOST SITES:

Indicate the location(s) where the research will be conducted:

Institution (if applicable)

Town/City Country(ies):

Other □ _____(specify site(s)

Note:

It is the responsibility of the investigator(s) to seek appropriate approval/consent of required institution/facility/Municipal authority for the conduct of the research/investigation.

Such approval(s) are not pre-requisite for the application to CHREC, however where such approval(s) exist, it will be expedient to submit such alongside this application.

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BACKGROUND, PURPOSE, AND OBJECTIVES:

Briefly describe the pedagogical goal and scholarly motivation for the project.

Background: (150 words max.)

Purpose of the study: (75 words max.)

Study objectives: (100 words max.)

Expected outcomes: (100 words, max

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METHODS AND DATA:

- If the research takes place in a controlled environment (e.g., clinic, laboratory, formal interview or tests), describe sequentially, and in detail, all procedures in which research participants will be involved.
- If the research involves naturalistic or participant observation, please describe the setting, the types of interactive and observational procedures to be used, and the kinds of information to be collected.
- If the research involves secondary analysis of previously collected data, describe the original source of the data and measures that have been taken to protect data subjects' identities.
- If the project involves using specialized methods with participants, describe the student's relevant past experience, or the nature of any supervision they may receive.

N.B. Attach a copy of all questionnaires, interview guides or other test instruments.

Study area: (provide accurate name, and geographical co-ordinates)

Subjects: (provide exact population size; population stratification)

Study duration: (provide start and stop dates – month and year)

Materials: (List all materials to be employed for the study-This will help the committee judge the strength and correctness of you're the study)

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Sample collection: (provide information of the type of materials (e.g. cell, tissues) to be collected and the region of the subject body to access for these materials. Also provide collection method and preservation before use)

Others: (provide information using appropriate subject headings on other test, and procedures relevant to the study, that will provide the complete picture of the study and facilitate decision on the study

Data collection: (provide information of the method of data collection tool. Where it involves the use of a questionnaire, a copy of the questionnaire should be attached to this application)

Data analysis: (provide the appropriate statistical tool(s) to be employed for the analysis of the study data. Also provide the version and operating system (OS), where software is to be used)

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PARTICIPANTS, INFORMANTS, OR DATA SUBJECTS:

Describe the individuals whose personal information is to be used as part of the assignment (i.e., in terms of inclusion and exclusion criteria, especially where active recruitment is involved). If the assignment involves working with a vulnerable population, describe the PI's relevant past experience.

RECRUITMENT:

Where there is formal recruitment, please describe how and from where the participants will be recruited. Where participant observation is to be used, please explain the form of insertion of the researcher into the research setting (e.g., living in a community, visiting on a bi-weekly basis, etc.) Where relevant, please explain any non-research relationship between the PI and the research participants (e.g., teacher-student, manager-employee, nurse-patient).

N.B. Attach a copy of any posters, advertisements, flyers, letters, or telephone scripts to be used for recruitment.

PARTICIPANTS GROUP VULNERABILITY AND RESEARCH RISK:

Any pre-existing physiological or health conditions, cognitive or emotional factors, and socio-economic or legal status of participants **must not** be impacted, in any way, by this study.

This research must involve *minimal risk*, which means that the probability and magnitude of harm due to participation in the research is no greater than that encountered by participants in their everyday lives.

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RISKS:

Indicate if the participants might experience any of the following risks:

(a) Physical (e.g., bodily contact, administration of any substance)? Yes □ No □

(b) Psychological/emotional (e.g., feeling embarrassed, anxious, upset)? Yes □ No □

(c) Social (e.g., possible loss of status, privacy, reputation)? Yes □ No □

(d) Is there any deception involved (see "Debriefing", below)? Yes □ No □

(e) Are risks to participants greater than in their everyday life? Yes □ No □

If you answered **Yes** to any of the above, please explain the risks, and describe how they will be managed, and how they are proportionate to PI experience and pedagogical goals.

STUDIES INVOLVING BIOHAZARDS AND RADIATION

Describe the potential impact of the infectious agents (bacteria, fungi, parasites, protozoa, viruses) that will be used in this study. This include the potential for transmission, whether by contact or aerosol; risk of by-products, such as spores, toxins, virulence factors; risk of unknown contaminants such as cells or cell lines with latent oncogenic viruses or other associated viruses.

Describe the types and potential impact of radiation involved in this study.

CONTAINMENT FACILITIES

Studies are assigned to different hazard groups with various containment requirements and attendant risk assessment. All work must be carried out in a facility with the correct containment level or higher. Describe the containment facilities that will be used in this research. What biosafety levels are available?

STUDIES INVOLVING GENETICALLY MODIFIED ORGANISMS (GMOs)

Does this study involve the use of genetically modified organisms (GMOs)?
If **YES**, what license have you obtained to undergo this research?

Describe what aspect of this research involves the use of GMOs and the risks involved?

BENEFITS:

Discuss any potential direct benefits to the participants from their involvement in the project. Comment on potential benefits to the PI, the scholarly community, or society that would justify involvement of participants in this study. (See the note on courtesy copies of final reports in the "Debriefing" section, below)

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Expected benefits:

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COMPENSATION:

Will participants receive compensation for participation?		Yes □	No □
	Financial	Yes □	No □
	In-kind	Yes □	No □
	Other	Yes □	No □

(b) If **Yes**, please provide details.

(c) Where there is a withdrawal clause in the research procedure, if participants choose to withdraw, how will you deal with compensation?

_____

CONSENT PROCESS:

Describe the process that the investigators will use to obtain informed consent. Please note, it is the quality of the consent not the format that is important: if there will be no written consent form, please explain (e.g., if culturally inappropriate). If the research involves extraction or collection of personal information from a data subject, please describe how consent from the individuals or authorization from the custodian will be obtained.

N.B. Where applicable, please attach a copy of the Information Letter/Consent Form, the content ofany telephone script, letters of administrative consent or authorization and/or any other material which will be used in the informed consent process.

Brief description of Consent process:

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If the participants are children, or are not competent to consent, describe the proposed alternate source of consent, including any permission/information letter to be provided to the person(s) providing the alternate consent as well as the assent process for participants.

Non-Competent participants:

Where applicable, please describe how the participants will be informed of their right to withdraw from the project. Outline the procedures which will be followed to allow them to exercise this right.

Indicate what will be done with the participant's data and any consequences which withdrawal may have on the participant.

If the participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain.

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PRIVACY AND CONFIDENTIALITY:

Will the data be treated as confidential? Yes □ No □

If **Yes**, please describe the procedures to be used to protect confidentiality during the conduct of research and in preparation of the final report.

Explain how written records, video/audio tapes and questionnaires will be stored (e.g., password protected computer, double locked office and filing cabinet), and provide details of their final disposal or retention schedule. Data security measures should be consistent with Covenant University's policy on Data Security Standards for Personally Identifiable and Other Confidential Data in Research.

If **No**—i.e., confidentiality is not appropriate in the context of this assignment—please explain (e.g., participants are key informants with established reputations in their field).

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DEBRIEFING:

Explain what information (e.g., research summary) will be provided to the participants after participation in the project. If deception will be used in the research study, please explain what information will be provided to the participants after participation in the project—if applicable; attach a copy of the written debriefing form.

N.B. Please note that all copies of the final reports—e.g., for circulation as courtesy copies, or future writing samples—must clearly indicate on the cover page the Ethical Approval No.:

Other Research Ethics Board

Other Research Ethics Board (REB) Approval:

(a) Does the research involve another institution or site? Yes □ No □

(b) Has any other REB approved this project? Yes □ No □

(c) If **Yes**, please provide a copy of the approval letter upon submission of this application.

(d) If **No**, will any other REB be asked for approval? Yes □ No □

If **Yes,** please specify which REB _____

SIGNATURE:

As the **Faculty/Principal Investigator** on this project, my signature testifies that I have the scholarly quality required for the research project and to manage this ethics protocol submission. I will provide the necessary lead and supervision required throughout the project, to ensure that all procedures performed under the research project will be conducted in accordance with University, provincial and national policies and regulations that govern research involving human and other life subjects. This includes ensuring that the level of risk inherent to the project is well understood and managed by all involved in the research and that I provide the necessary oversight functions where required.

_____ _____

Signature of Faculty/Principal Investigator: Date:

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