Ebonyi State University

University Research Ethics Committee (EBSU-UREC)

P.M.B 053, Abakaliki, https://ebsu.edu.ng

EBSU-UREC
Checklist for Principal Investigators

This checklist has been designed by the EBSU-UREC to help investigators to ensure that all elements necessary for the development of a complete and ethically sensitive protocol are covered. Therefore please ensure some time to complete this checklist, and if some of the elements described in this checklist are missing from your protocol, please make changes in the protocol to include them. It is not necessary that all the elements described here are relevant to all research protocols. To prepare a research protocol that satisfies UREC requirements, please see the link https://ebsu.edu.ng/

PI Name:……
Name of Institution: ……
Title of Project:……
Dept./Faculty:……
Phone No:……
E-mail Address.:……
Type of Project:…… **(PGD, M.Sc., Ph.D, others specify)**

A. PROTOCOL (SCIENTIFIC AND TECHNICAL ISSUES) **Please complete sections A,B,C and D**

1.		Yes	No	N/A
2.	Is the rationale for the study clearly stated in the context of present knowledge?			
3.	Has the background Information and relevant review of literature been provided?			
4.	Is the project design scientifically sound?			
5.	Where present, is the control arm adequate?			
6.	Are the inclusion and exclusion criteria complete and appropriate?			
7.	Are the procedures for participant recruitment, admission, follow up and completion appropriate?			
8.	Are the drugs and/or devices to be used fully described?			
9.	Are the clinical procedures to be carried out fully described and appropriate?			
10.	Are the laboratory tests and other diagnostic procedures fully described and appropriate?			
11.	Does the proposal describe how specimens will be coded/anonymised, etc.			
12.	Are adverse events forms prepared and included? (where relevant)			
13.	Have the Stopping Rules/Withdrawal of study participants etc. been described in the protocol?			
14.	Does the study protocol describe how the research participants will be followed up during and after the study?			
15.	Does the protocol include a discussion on the quality assurance mechanisms for data collection, storage and analysis?			
16.	Does the protocol include a discussion of ethical issues			
17.	Does the protocol include a plan for the dissemination of results, not only to the research community (through open access online publication, and other journal publications) but also to policy makers (through meetings, reports etc) and back to the research participants and research communities (through community meetings, flyers, leaflets etc.)?			

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UREC follows the World Medical Association Declaration of Helsinki (1964), amended in 2000, with Notes of Clarifications provided in 2002 and 2004, as well as the International Ethical Guidelines for Biomedical Research Involving Human Subjects published in 2002. During the ethical review of a protocol, the EBSU-UREC evaluates the risks and benefits to the research participants and research communities in the following domains:

Respect for persons
Justice
Autonomy

The following are examples of the sort of risks/harms and benefits that may accrue to the research participants

Risks/Harms	***Benefits***
Physical harm	*Access to treatment/ Free treatment*
Social harm/social risk	*Emotional support*
Emotional harm/risk	*Psycho-social support*
Stigmatization	*Humanitarian*
Loss of privacy	*Feel good effect*
Insensitivity to vulnerabilities, exposing individuals to various types of harms/risks	*Contribution to society*
Sharing of confidential information resulting in tangible or intangible losses	*Others*
Perpetuation of gender and other biases (Social, Cultural & Religious Ethics	
Others	

Please ensure that your protocol minimizes harms and maximizes benefits to the research participants, and discuss under ethical issues how this has been achieved. The checklist on the following pages is prepared in order to inform the UREC how you have dealt with the ethical issues posed by your research protocol. Please tick as appropriate.

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B. PROPOSAL (ETHICAL ISSUES)

Is a vulnerable population being studied? **Yes** **No** **N/A**

If yes, tick the vulnerable population being studied:

☐ Pregnant women ☐ Elderly ☐ Those who can't give consent (unconscious)
☐ Adolescents ☐ Refugees ☐ Persons with mental or behavioural disorder
☐ Children ☐ Prisoners ☐ Others

a. Is the justification for studying this vulnerable population adequate?
b. Have adequate provisions been made to ensure that the vulnerable population is not being exploited?

		Yes	No	N/A
2.	Have the risks vs. the benefits for the research participants been discussed in the research protocol?			
3.	Does the protocol describe how (if at all) the communities from which the participants are to be drawn likely to benefit from the research?			
4.	Does the protocol describe whether the research outcome is likely to benefit communities beyond the research population?			
5.	Is the design free of undue inducements to participate in the research?			
6.	Does the recruitment procedure include adequate protection for the privacy and psycho-social needs of the individuals?			
7.	Have adequate provisions been made to ensure the confidentiality of participants' data?			
8.	Are the research participants free not to participate or to leave the research at any time, without penalty?			
9.	When appropriate, do provisions exist in the protocol for counselling research participants during and after the research?			
10.	Do provisions exist in the proposals to deal with adverse reactions associated with the research (medical/ physical/ emotional/ psychological/social)?			
11.	Do provision exist in the proposal for recruiting participants incapable of reading and signing to the written consent form (e.g. illiterate patients)? (Please explain).			
12.	Do provisions exist in the proposal to recruit participants incapable of giving personal consent, (e.g. because of cultural factors, children or adolescents less than the legal age for consent in the country in which the research is taking place, participants with mental illness, etc.) and to express their decision? (Please, explain where applicable)			
13.	Are **Questionnaires, diary cards etc**. being used in the research?			
	a. Are these provided in English and in the local language?			
	b. Are these written in lay language, and easily understood?			
	c. Are these relevant to answer the research questions?			
	d. Are these worded sensitively?			

Responsible UREC Officer's Comments:……

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C.1 INFORMED CONSENT FORM **Please complete sections A,B,C and D**

		Yes	No	N/A
1.	Is an informed consent form attached If No, please explain:			
2.	Is the information sheet free of technical terms, written in lay-persons' language, easily understandable, complete & adequate?			
3.	Does it explain why the study is being done and why the subject is being asked to participate?			
4.	Does it clearly state the duration of the research?			
5.	Does it provide participants with a full description of the nature, sequence and frequency of the procedures to be carried out?			
6.	Does it explain the nature and likelihood of anticipated discomfort or adverse effects, including psychological and social risks, if any-and what has been done to minimize these risks, and the action to be taken if they occur?			
7.	Does it outline the possible benefits, if any, to the research participants			
8.	Does it outline the possible benefits, if any, to the community or to society?			
9.	Does it outline the procedures that will be followed to protect the confidentiality of participants' data (either that provided by participants or that derived during and from the research itself?			
10.	If confidentiality is not possible due to the research design, has this been conveyed to all relevant persons?			
11.	Does it inform the research participants that their participation is voluntary and they are free to decide not to participate, that refusal to participate (or discontinue participation) will involve no penalty or loss of medical benefits to which they are otherwise entitled to?			
12.	Does it outline the procedure that will be followed to keep participants informed of the progress and outcome of the research?			
13.	Does it provide the name and contact information of a person who can provide more information about the research project at any time?			
14.	Has provision been made for subjects incapable of reading and signing the written consent form (e.g. illiterate patients)? (Please explain)			
15.	Does a provision exist for participants incapable of giving personal consent, (e.g. because of cultural factors, children or adolescents less than the legal age for consent in the country in which the research is taking place, participants with mental illness, etc.) to express their decision? (Please, explain where necessary)			
16.	Does the consent certificate mention a statement such as *"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate as a subject in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".*			

Responsible UREC Officer's Comments:……

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Please complete sections A,B,C and D

C.2 INFORMED CONSENT FORM – When questionnaires are used or human biologic materials are sampled

		Yes	No	N/A
1.	Will **Questionnaires** be used in the study?			
	If yes, does the information sheet and consent form			
	a. Describe the nature and purpose of the questions to be asked?			
	b. State that the participant is free to not answer any question?			
	c. Where applicable, make it clear that some of the questions may prove embarrassing for the participant?			
	d. Where applicable, make it clear that the interviews (in-depth or focus group discussions) are likely to be audio or video taped?			
	e. Where applicable, mention how and for how long are the tapes going to be stored?			
2.	Will **human biologic materials** (tissues, cells, fluids, genetic material or genetic information) be collected as part of the research?			
3.	If yes, does the information sheet and consent form			
	a. Fully describe, in a simple language, the nature, number and volume of the samples to be obtained and the procedures to be used for obtaining them?			
	b. Indicate if the procedures for obtaining these samples are routine or experimental and if routine, as invasive or more invasive than usual?			
	c. Clearly describe the use to which these samples will be put - in the study and in the longer term?			
	d. Include the provision for the subject to decide on the use of left over specimens in future research of a restricted, specified or unspecified nature?			
	e. Cover for how long such specimens can be kept and how they will be finally destroyed?			
	f. Where applicable mention that genetic testing/genomic analysis will be carried out on the human biologic materials -?			

Responsible UREC Officer's Comments:…….....

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Please complete sections A,B,C and D

D. PARTICIPANT RECRUITMENT MATERIAL
(Where Necessary)

		Yes	No	N/A
1.	Will **Participant Recruitment Material** (e.g., advertisements, notices, media articles, transcripts of radio messages) be used to recruit participants?			
	If yes,			
	a. Is the Participant Recruitment Material provided both in English and in the local language?			
	b. Do these materials make claims that may not be true?			
	c. Do they make promises that may be inappropriate in the research setting (e.g. provide undue incentives or emphasize remuneration)?			

Responsible UREC Officer's Comments:…….....

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Please complete sections A,B,C and D

E. CLINICAL TRIAL
Please complete this section if this is a clinical trial

		Yes	No	N/A
1.	Does this trial involve new drugs or vaccines?			
	Is clearance from the national drug regulatory authority attached?			
	Is the Investigator's Brochure (including safety information) attached?			
	Where appropriate, is a plan for adverse event reporting included in the protocol?			
	Is the Adverse Drug Reaction/Adverse Event Reporting form attached?			
	Does the Adverse Event Report Form provide adequate and appropriate information?			

Responsible UREC Officer's Comments:…….....

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F. ETHICAL REVIEW INFORMATION

EBSU-UREC has instituted a pilot study of a proposed new policy of simultaneous reviews. For the initial ethical review by EBSU-UREC, each PI need only submit proof of submission to local IRBs and collaborating institutions' review boards. Below, please provide all fields describing each institutional ethical review committee from which approval has been sought.

After receiving comments from all the ethics review boards, the principal investigator should collate comments from each committee and respond to them under one cover memo. These responses *and all revisions to the protocol and/or the informed consent forms* should then be submitted to the EBSU-UREC **AND all other committees**.

FINAL approval by the EBSU-UREC will not be given until approvals of the revised protocols from **ALL** related ethical review committees are submitted by the applicant to the EBSU-UREC Secretariat.

Part 1. PRINCIPAL LOCAL/NATIONAL ETHICAL APPROVAL COMMITTEE

IRB Name	
Address	
Country	
Committee Contact Name	
Date Protocol Submitted	
Proof of submission to local UREC submitted	*Yes/No*

IRB Name	
Address	
Country	
Committee Contact Name	
Date Protocol Submitted	
Proof of submission to local UREC submitted	*Yes/No*

IRB Name	
Address	
Country	
Committee Contact Name	
Date Protocol Submitted	
Proof of submission to local UREC submitted	*Yes/No*