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|  | Ahmadu Bello University Zaria. Nigeria.**ABU Committee on Use of Human Subjects for Research (ABUCUHSR)**ABUCUHSR F1: Application for Approval to Use  Human Subjects in Research Form  |  |

1. **Official Use Only**

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| **Application/Project Number:** ABUCUHSR/Year/DEPT/ Appl. No? | **Verdict**: Approved Differed Revision Needed Not approved |
| **Date of Submission:** | **Approval/Disapproval Date**: |
| Submission Format: E-mail | **Approval Number:**ABUCUHSR/Year/Serial App. No- |
| **Date Replied:** | **Name & Signature of Chairman:** |

**Duration of approval: From To:**

Any specific issues earlier flagged for re-consideration by the ABUCUHSR? [ ]  Yes [ ]  No

If Yes Give Details: *write your response in Times New Roman 10 point in the box below which will expand as you type*

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It is the University’s policy that all staff or student projects sessions, which involve human participants, should receive the approval of the ABUCUHSR prior to commencing the research.

It should be noted that approval from the ABUCUHSR is required for **research** involving questionnaires, interviews and surveys (including web based surveys) within and outside the University, **before** the research commences.

1. **APPLICATION FOR APPROVAL OF RESEARCH PROJECTS**

**Please type required information. Applications must be signed by supervisor (for student projects) and Head of Department.**

**1. NATURE OF PROPOSED RESEARCH:**

(a) Staff Research/Student Research (mark X in the relevant box)

(b) If Student Research ……..... Degree in View: ………………….……………………………….……

(c) Research Title: …………………………………………………………………….……………………

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**2. INVESTIGATORS:**

**(a) Principal Investigator**

Name …………………………………………………………………………….…….…………………………

Email address ………………………………………………………………………….………………………...

Faculty/Dept./Inst./Centre ……………………………………………………………………….……………..

**(b) Other Researchers** (Supervisor(s) in the case of student research projects)

i) Name …………………………………………………………………………….…….………………………

Email address ………………………………………………………………………….………………………...

Faculty/Dept./Inst./Centre ……………………………………………………………………….……………..

ii) Name …………………………………………………………………………….…….………………………

Email address ………………………………………………………………………….………………………...

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iii) Name …………………………………………………………………………….…….………………………

Email address ………………………………………………………………………….………………………...

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**3. DURATION OF RESEARCH**

(a) Proposed starting date for data collection ………………..………………………..………………..……..

(**Note:** that NO part of the research requiring ethical approval may commence prior to approval being given)

(b) Proposed date of completion of project as a whole ………………………………………………………

**4. PROPOSED SOURCE/S OF FUNDING AND OTHER ETHICAL CONSIDERATIONS**

(a) Sources of funding for the project

Please indicate any ethical issues or conflicts of interest that may arise because of sources of

funding e.g. restrictions on publication of results

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(b) ) Is any other professional code of ethics to be followed **Yes No** (mark X in relevant box)

If yes, give name:

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(c) Is ethical approval required from any other body **YesNo** (mark X in relevant box)

If yes, name and indicate when/if approval will be given

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**5. DETAILS OF PROJECT**

Briefly Outline:

(a) The objectives of the project*write your response in Times New Roman 10 point in the box below which will expand as you type*

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(b) Method of data collection

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(c) The benefits and scientific value of the project

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(d) Characteristics of the participants

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(e) Method of recruitment of Participants(describe all process from the beginning of how you approach the participant, such as

when, by whom. etc.)

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 (f) Payments that are to be made/expenses to be reimbursed to participants (where applicable)

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(g) Other assistance (e.g. meals, transport) that is to be given to participants (where applicable)

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(h) Any special hazards and/or inconvenience (including deception) that participants willencounter (where applicable)

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(i) State whether consent is for (mark X in the relevant box(es):

(i) the collection of data

(ii) attribution of opinions or information

(iii) release of data to others

(iv) use for a conference report or a publication

(v) use for some particular purpose (specify)

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Attach a copy of any questionnaire or interview schedule to the application

(j) How is informed consent to be obtained? (mark X in the relevant box(es):

(i) the research is strictly anonymous, an information sheet is supplied and informed consent is implied by voluntary participation in filling out a questionnaire for example (include a copy of the information sheet)YesNo

(ii) the research is not anonymous but is confidential and informed consent will be obtained through a signed consent form (include a copy of the consent form and information sheet)Yes No

(iii) the research is neither anonymous or confidential and informed consent will be obtained through a signed consent form (include a copy of the consent form and information sheet)Yes No

(iv) informed consent will be obtained by some other method (please specify and provide details)Yes No

With the exception of anonymous research as in (i), if it is proposed that written consent will not be obtained, please explain why*write your response in Times New Roman 10 point in the box below which will expand as you type*

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(k) If the research will not be conducted on a strictly anonymous basis state how issues of confidentiality of participants are to be ensured if this is intended. (e.g. who will listen to tapes, see questionnaires or have access to data). Please ensure that you distinguish clearly between anonymity and confidentiality. Indicate which of these are applicable. (mark X in relevant box)

(i) access to the research data will be restricted to the investigator Yes No

(ii) access to the research data will be restricted to the investigator and their supervisor (student research)Yes No

(iii) all opinions and data will be reported in aggregated form in such a way that individual persons or organisations are not

identifiableYes No

(iv) Other (please specify):*write your response in Times New Roman 10 point in the box below which will expand as you type*

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(l) Procedure for the storage of, access to and disposal of data, both during and at the conclusion of the research (mark X

 in relevant box)

(i) all written material (questionnaires, interview notes, etc) will be kept in a locked file and access is restricted to the

investigatorYes No

(ii) all electronic information will be kept in a password protected file and access will be restricted to the investigator

Yes No

(iii) all questionnaires, interview notes and similar materials will be destroyed

(a) at the conclusion of the research Yes No

(b)……….…….years after the conclusion of the research; or Yes No

(iv) any audio or video recordings will be returned to participants and/or electronically wiped out:Yes No

(v) other procedures (please specify):

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If data and material are not to be destroyed please indicate why and the procedures envisaged for ongoing storage and security

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(m) Feedback procedures. You should indicate whether feedback will be provided to participants and in what form. If feedback will not be given, indicate the reasons why.

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(n) Reporting and publication of results. Please indicate which of the following are appropriate. The proposed form of publications should be indicated on the information sheet and/or consent form.. (mark X in relevant box)

(i) publication in academic or professional journals Yes No

(ii) dissemination at academic or professional conferences Yes No

(iii) deposit of the research paper or thesis in the SPGS and University Library (student research)Yes No

(iv) others (please specify) Yes No

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**C. RESEARCH SYNOPSIS**

1. Background & Rational

2. Objective of the Study

3. Research Plan

3.1 Type of Research (mark X in relevant box)

 Biomedical / Clinical Research (See Hospital based Ethical Policy)

 Social / Behavioral Research; Descriptive study, Observational study, Quasi-Experimental study,

 Experimental study, Pilot study,Participatory action research, other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Epidemiological Research; Retrospective review, Surveillance, Monitoringothers, please specify

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3.2 Sample size \_\_\_\_\_\_\_\_\_

 3.3 Categorisation of Participants (where approprate):

 ❏ vulnerable subjects ❏ children ❏ mentally disable

 ❏ chronic illness

 ❏ others (please specified) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 ❏ healthy volunteers

 ❏ not vulnerable subjects

 3.4 Replacement procedure if subject withdraw from the study

 *write your response in Times New Roman 10 point in the box below which will expand as you type*

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4. Study procedures

5. Study site❏single center \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ multicenter ❏within Nigeria, please specify (State, LG & Town)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ specify other countries and sites)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6. Duration of study\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

7. Data collection process (mark X in the relevant box)

Case Record form

Questionnaire Interview

In-depth interview

other tools)

8. Outcome measurement/Data analysis

 - Primary outcome and secondary outcome (if any) (mark X in the relevant box)

 - Assessment of efficacy

 - Assessment of safety

- Statistical analysis or data Analysis

9. Ethical Consideration

9.1 Reason to be carried out in human, please specify the extent of problem that lead to research question, previous information and its controversy

9.2 Possible benefit for research subject personally and for all society

9.3 Foreseeable risk of research related injury (where applicable)

9.3.1 Explain information from previous study about severity and probability of adverse events

 *write your response in Times New Roman 10 point in the box below which will expand as you type*

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 9.3.2 Management of adverse events

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9.3.3 Responsibility for research related injury

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9.3.4 Contact person in case of adverse events

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9.4 Privacy and confidentiality protection

❏Coded data/specimen

❏ recorded by ❏ photograph ❏Video❏tape recorder❏ when to destroy \_\_\_\_\_\_\_\_\_\_\_\_\_

NB: All investigators and the Head of Department must sign before an application is submitted for approval:

Name…………………………….………Sign……………………………… Date…………………….………...

Name……………………………….……Sign……………………………… Date…………………….………...

Name……………………………….……Sign……………………………… Date…………………….………...

Dean/Director/Head of Department/Unit:

Name……………………………….……Sign……………………………… Date…………………….………...