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2.2. POLICY ON RESEARCH WITH HUMAN SUBJECTS/PARTICIPANTS

2.2.1 Overview

All projects involving the use of human subjects (non-hospital based), including questionnaire administration, must be reviewed by the University Committee on the Use of Human Subjects (ABUCRHS) in Research regardless of whether or not the proposal is funded. This Committee will assure that appropriate facilities and procedures will be provided which respect the "right to privacy" of the individual and protect him/her against physical or stress injury. This applies to all research project proposals (grants and contracts) regardless of the granting agency or institution to which they are being submitted for funding. Committee review of the proposal should be completed before submission to the granting agency. It is appropriate for the faculty or staff member to consult the Committee during preparation of an early draft of the proposal, at which time concise and current details concerning use of human subjects can be obtained.

Functions of ABUCRHS

It is the University's policy that all staff or student projects, researches and coursework sessions, which involve human participants, must receive the approval of the ABUCRHS prior to commencing the research. The function of the ABUCRHS is:

(1) To review all proposed research and teaching projects involving human participants,
(2) To ensure compliance with ethical standards,
(3) To provide advice and assistance with regard to ethical standards to anyone undertaking such research or teaching, and
(4) To provide an avenue for handling complaints or queries made by any interested person.

In undertaking these functions, ABUCRHS is not only concerned with the welfare and interests of research participants, but also with that of researchers and the general interests of the University where appropriate.

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

Researchers should also note that some research which does not involve human participants directly (for example, research involving particular types of human cell lines or other human tissue) may require approval by ABUCRHS.

2.2.2 Guiding Principles

The guiding principles for research in human participants/subjects in the Ahmadu Bello University are designed to ensure good, desirable or acceptable conduct in such researches. The primary purpose of the principle is to protect the welfare and rights of research participants/subjects and to reflect the basic ethical values of respect for persons, beneficence and justice.

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Core Ethical Principles

Four universal principles constitute the basis for ethics in especially human research viz.:

1. The principle of Non-Malfeasance: Research must not cause harm.
2. The principle of Beneficence: Research should make a positive contribution towards the welfare of people or the participants/subjects.
3. The principle of Autonomy: Research must respect the rights and dignity of participants.
4. The principle of Justice: Fair distribution of the benefits and risks of research amongst people.

Rights of Participants

1. Participants must be valued as persons in their own right worthy of protection and respect.
2. Informed and understood consent obtained.
3. Informed on anticipated findings use.
4. Relevance of research to participants must be clarified.

Research Involving Special Groups

Research in these groups requires special consideration i.e.:

1. Children
2. Prisoners
3. Students.
4. Pregnant women
5. Elderly
6. Persons in dependent relationships
7. Mentally impaired persons
8. Vulnerable communities

2.2.3 Informed Consent in Research Engagement

Any research that involves other people requires the free and informed consent of participants, both prior to and throughout the project. Researchers must inform participants, in writing or verbally, as appropriate, of all pertinent information regarding the project, including potential physical and psychological risks, however minimal, to the participant. This information must include procedures for ensuring:

1. Confidentiality and anonymity, the use to which participants' responses or data will be put, and who will have access to this information.
2. Such consent must be obtained from participants in writing, unless cultural or methodological considerations deem otherwise. In such cases, the researcher must document how free and informed consent was obtained.
3. This consent must be unforced. Threats of penalties for refusal to participate or withdrawal part way through a project are unacceptable. Rewards for participation must not provide undue inducement or influence on a participant's decision to participate or withdraw.

ABUCRHS may approve a project, which does not include free and informed consent if all of the following criteria are met:

1. the research involves no, or minimal, risk to participants

2. the lack of free and informed consent is unlikely to adversely affect the rights and well-being of the participants
3. the research could not be reasonably or effectively carried out if free and informed consent were obtained
4. participants will, whenever possible, be given full disclosure of pertinent information after participating, including any debriefing, reassurance, reestablishment of trust, and other follow-up as necessary to protect their welfare and their rights

The concept of an informed Consent should take into cognizance:
1. Areas where community consent may be required.
2. Feedback on research findings
3. Non exploitation
4. Privacy, anonymity and confidentiality
5. Full release of necessary information
6. Minimization of risk and maximization of benefits
7. The obligation to compensate for research related injuries and costs
8. Distributive justice.
9. Inclusion/exclusion criteria.
10. Conflict of interest
11. Safety monitoring.
12. Ownership, storage and transfer of biological materials in collaborative research.

2.2.4 Membership of ABUCRHS

- Chairperson, appointed by the Vice Chancellor
- Chairperson, relevant Departmental Research Committee.
- Representative, Deans of Humanities, Arts and other relevant Faculties.
- A lawyer.

2.2.5 Meetings

1. The Chairperson will call at least a meeting monthly.
2. A quorum will represent 51% of membership. If a quorum is not attained, the Meeting shall be postponed and rescheduled.
3. Decisions at meetings shall as much as possible be reached by consensus.
4. The Chairperson or a majority of members may request for an emergency meeting should the need arise.

2.2.6 Duties of ABUCRHS

1. advise on the principles and guidelines for research involving human subjects.
2. To consider the ethical implications of all proposed research and teaching activities involving the use of human subjects, and to approve only those which conform to the minimal universal standards.
3. To monitor approved activities for continued conformance with the policy.
4. To maintain records of all applications for approval and the decisions of ABUCRHS, and to make appropriate information from these records available in response to requests from a duly constituted authority.
5. To report annually on the activities of the Committee

2.2.6 ABUCRHS Operational Protocol

General Requirements

The protocol must include the following information:

a. Project title (including course number if a teaching program)
b. Project leader(s) (a.k.a. Principal Investigator) name.
c. Names of other Research Staff and other authorized personnel, including personnel qualifications and training.
d. Departmental affiliation, mailing address, phone number(s), and lab location.
e. Proposed start date, proposed end date.
f. Funding agency.
g. An indication of the use of any hazardous material including infectious agents and other biological hazards, toxic or carcinogenic chemical agents, and radioactive materials.
h. Rationale and purpose of the proposed study and the scientific goals of the research.
i. Groups and individuals to be used with scientific justification; the number of participants should be justified statistically.
j. An indication of the categories of discomfort and the classification of research based on primary use.
k. A description detailing the procedures that are to be carried out.
l. Assurance that procedures will avoid or minimize discomfort, distress, and pain to the participants/subjects consistent with sound research design.
m. Any other information considered important or necessary and pertinent.
n. All information must be presented in a form that all members of the ABURCUHSP can readily understand.

2.2.8 ABUCRHS Standard Operating Procedure:

1. All members of staff, students, visiting academics and researchers and any other person using human subjects for research, teaching or demonstrations as an activity in the University must submit an application for ethical approval to the ABUCRHS before the activity may commence.
2. Applications for approval must be submitted in the prescribed format that is obtainable from the ABUCRHS.
3. Applications must be submitted at the latest two weeks before the next scheduled meeting of the ABUCRHS to be circulated to reviewers for comment. If any clarification is needed the applicant will be notified in writing and given the opportunity to reply a week before the meeting in order to avoid unnecessary delays in obtaining approval.
4. Applications are approved by consensus or, if necessary, by a majority vote. The committee may require minor amendments, in which case the Chairman can be authorized to sign the approval as soon as the requirements are met, or major amendments, in which case the application must be resubmitted. In the case of urgent or non-contentious applications the Chairman can be authorized to sign the approval after consultation with one or more members of the committee. Such approvals should be ratified

at the next committee meeting.

5. Researchers have the right to appeal the decision of the Committee. The request to appeal must be submitted through the office of the chair of the Research Subcommittee to the Vice Chancellor. The appeal must contain a clear motivation as to the reasons for the appeal. The documents must include an executive summary and motivation from a subject specialist other than the author of the protocol, stating clearly the reasons for appeal and why this protocol should be reconsidered. The Vice Chancellor may then approach outside consultants to evaluate the protocol and to furnish him/her with a report and a recommendation. The ABUCRHS will then reconsider the entire protocol with new motivations at the meeting following the one on which the appeal was tabled.
6. Approved submissions will be kept on record. Any deviations from the approved procedures with any ethical implications must be submitted for approval.

The ABUCRHS reserves the right to interview the researcher and/or the study director; to inspect the facilities where animals are housed and experimental procedures performed, prior to or during the experiment, to request that records are made available; and to seize any animal and stop an experiment if deemed necessary.

The application process

For new projects based in, supervised/guaranteed by or in liaison with the University, applicants must complete the prescribed application form for consideration at a meeting of the ABUCRHS.

Staff members applying for research grants from funding bodies such as the University Board of Research should make sure that their applications are submitted to the ABUCRHS in time to obtain approval by the required date. A reference number will be issued and the application will be considered at the next scheduled ABUCRHS meeting. If the Principal Investigator has not received an acknowledgement within one week of lodging the application, please contact the Secretary to ensure that the application was received.

Initial Application

1. Application should be submitted to the Secretary of ABUCRHS.
2. The responsible investigator (RI) will receive an acknowledgement from the Secretary to confirm receipt of the application.
3. The application will then be placed on the agenda for the next meeting, this will either be an Executive meeting or a full ABUCRHS meeting depending on the application is received.
4. ABUCRHS meetings are monthly. Dates for meetings and submission of applications can be obtained from the Committee Secretary. Submissions must be received 7 days prior to the meeting.
5. Executive meetings are held approximately a week before Committee meetings. The Executive screens applications to identify ethical concerns and deficiencies before the applications are presented to the Committee. It cannot approve initial or renewal applications but can approve straightforward applications for minor modifications and associate

investigator applications at its discretion. The Committee at its following meeting reviews all decisions of the Executive.

6. If the application has been presented at a full ABUSRHSP meeting, the RI will be informed by the Secretary within 2 working days after the meeting to advice of the outcome.
7. If the application has been presented at an Executive meeting, the RI's attention maybe sought by the Secretary if the Executive has identified any areas of concern that should be addressed prior to the full meeting. Applications will automatically be forwarded to the full ABUCRHS for consideration after presentation at an Executive meeting.

Official notification of the decision will be forwarded to the Principal Investigator as soon as possible following a meeting, or after any required clarifications, amendments, additional information or signatures are received and approved.

2.3.9 Complaint and Appeal Procedure

Complaint Procedures

Complaints can be reported to any member of ABUCRHS. The person reporting the complaint can do so verbally or preferably in writing, and may insist on anonymity. All complaints lodged are to be taken seriously and the Committee should act promptly.

The member of the ABUCRHS to whom the complaint is reported should gather the necessary information to assess the extent of the problem and inform the Chairman who, after consultation with members, will decide on the further course of action. If the problem is of a serious nature, an extra-ordinary meeting of the Committee can be called.

In order to investigate a reported complaint, the Committee can do any or all of the following:

- Conduct an immediate inspection of the reported complaint.
- Inform the responsible person in writing that a complaint has been lodged against him/her, and that the problem should be remedied as soon as possible to comply with ethical requirements.
- Order the research to be suspended until the outcome of the investigation is known.

If the ABUCRHS deems it necessary, the matter could be referred to the Vice Chancellor, in which case the ABUCRHS would be the *pro forma* complainant and will supply the Vice Chancellor/Disciplinary committee with a factual statement regarding the incident.

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ABUCRHS procedure for handling complaints

(i) **Receipt of complaint**
The complaint is brought to the notice of the ABUCRHS Chair. The Secretary records receipt of the complaint.

(ii) **Establishing details of complaint**
The Secretary finds out full details of the complaint and examines the complaint in relation to the approved application.

(iii) **Resolution of complaint at ABUCRHS level**
The complaint is resolved at the ABUCRHS level if possible.
The action to be taken depends on the nature of the complaint.

Appeal Process

1. Informal Appeal
A researcher or instructor who is in disagreement with the decision of the ABUCRHS with respect to an aspect of his/her research project/program may appeal this decision in writing to the UBR. The appeal document will also be sent to the Vice Chancellor. UBR will review the written document and any additional supporting materials provided by the researcher. An informal meeting may be called between the ABUCRHS and the researcher to further discuss the matter. Following consideration of all additional information, UBR will reach a decision as to whether or not the additional information/explanation provided by the researcher will result in a change in the ABUCRHS decision. Every attempt will be made to reach a resolution by informal means.

2. Formal Appeal
In the event that a resolution of the matter has not been reached through the informal appeal, the researcher will refer the matter to the Vice Chancellor for opinion and decision. The Vice Chancellor will review documentation provided by the ABUCRHS and the researcher, and will consult with others as required, including but not limited to, members of the UBR, ABUCRHS, the researcher etc. Subsequently, the Vice Chancellor will issue a decision on the matter in writing with copies to the researcher and ABUCRHS. This decision will be final.