



## NATIONAL OPEN UNIVERSITY OF NIGERIA

### POLICY ON RESEARCH ETHICS

#### 1.0 INTRODUCTION

A principal and essential function of a University is carrying out research in all areas of human knowledge and experience. The National Open University of Nigeria (NOUN) is committed to high standards of professional ethical conduct in research activities. NOUN recognizes its responsibility to researchers and the wider community to ensure that the highest standards of integrity and professionalism are observed in the conduct of research at the university.

This code of practice provides guiding principles and standard of best practices in research across all subject disciplines and areas of study in the university. It applies to all those undertaking research on the university's premises using its facilities, or, on behalf of the university including staff, students, visiting or affiliate staff, contractors and consultants.

**2.0 DEFINITIONS:** This addresses the application of ethical principles or values to the various issues or fields of research.

- a) **Research:** A systemic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- b) **Researcher(s):** The term 'researcher' includes members of the NOUN's academic, contract research staff, postgraduate research and undergraduate students and anyone of who may be the primary individual responsible for the preparation, conduct, and administration of a research project. In the specific case of student projects, the researcher as the student is duly guided by an academic supervisor.
- c) **Research Ethics:** Research ethics is the application of moral rules and professional codes of conduct to the collection, analysis, reporting, and publication of information about research subjects, in particular, active acceptance of subjects' right to privacy, confidentiality, and informed consent.

- d) **Research Subject:** A research subject is a person or animal who decides or made to participate in a research study.
- e) **Research Integrity:** This is recognized as the attitude and the need for researchers to be guided to conduct research according to appropriate ethical, legal and professional frameworks, obligations and standards. Research Ethics and Research Integrity combine to guide general ethical considerations in Research.

### 3.0 SCOPE OF THE POLICY

- a) The Research Ethics Policy forms a part of NOUN's over-arching research policy.
- b) One of the principal and essential functions of a university is carrying out research. NOUN recognizes its responsibility to researchers and the wider community to ensure that the highest standards of the integrity and professionalism are observed in the conduct of research carried out under its auspices.
- c) The policy relates to research - whether funded or unfunded - involving human participants, or involving data relating to directly identifiable human subjects (whether living or recently deceased), conducted by NOUN researchers.
- d) All research at the NOUN shall comply with the University's research code of practice. Senate, on the advice of the University Research Ethics Committee (UREC), may also require that research in certain areas complies with research – related policies, guidelines and principles published by internationally recognized organizations. These additional requirements can be obtained from the Dean's Office of the relevant Faculty Research Ethics Committee (FREC).

### 4.0 AIMS AND OBJECTIVES

The policy has been adopted in support of the institution's wider commitments to intellectual freedom and research excellence.

The procedures instituted in pursuit of this policy are therefore intended to:

- a) Facilitate, not inhibit, research;
- b) Promote a culture within the University whereby researchers conscientiously reflect on the ethical implications of their research;
- c) Apply a principle of subsidiarity whereby responsibility for research ethics will be embraced by researchers, supervisors, departments or institutes at a level as close as appropriately possible to the actual conduct of the research.

### 5.0 OWNERSHIP OF THE POLICY

The policy is subject to oversight by the University Research Ethics Committee, which is accountable to Senate and which is responsible to Council. It will be reviewed periodically. The policy is freely available to potential research funding agencies in the interests of transparency and to avoid possible pre-contractual misunderstandings.

### 6.0 STATUTORY AND ETHICS OBLIGATIONS

Academic staff and students are required to carry out their research in compliance with NOUN research policy and any ethical and contractual obligations.

All research carried out at NOUN shall adhere to the following principles:

- 1) Research projects that involve human or animal subjects, including those undertaken as part of a teaching programme, must be approved in advance by the NOUN Ethics Research Committee (*see details below*).
- 2) All Academic staff, students and visitors of the University are required to make themselves aware and follow the contents of the University Health and Safety Policy.
- 3) Observe and comply with all legal, regulatory and ethical requirements in Nigeria and in countries where the research is conducted or participants are relevant to the field of study and any funding bodies or collaborative partner organizations.
- 4) Respect the integrity and dignity of persons notwithstanding any perceived greater benefits.
- 5) Follow the “DO not harm” principle; any risk must be clearly communicated to participant involved in the research.
- 6) Recognize the rights of individuals to privacy and personal data protection.
- 7) Honour the requirement of informed consent and continuous dialogue with research participants.
- 8) Design animal research in accordance with the following principles:
  - a) Treat animals with respect and work under humane conditions before, during and after the research.
  - b) Reduce – methods should be used that enables researchers to obtain comparable levels of information from the same number of animals
  - c) Replace – non-animal methods are preferred above animal methods whenever it is possible to achieve the same scientific aim; and
  - d) Refine – all methods used for the research should alleviate or minimize the potential pain, suffering and distress, and enhance the animals’ welfare for the animals used.
- 9) Respect the principle of proportionality: not imposing more than is necessary on research participants or going beyond stated objectives (*mission creep*).
- 10) Treat societal concerns seriously – the first obligation of all those who carry out research is to listen to the public and engage with them in constructive dialogue, transparently, honestly and with integrity.
- 11) Recognize the wholeness of an individual and that any modification (genetic or technological) does not interfere with this principle.
- 12) Respect biodiversity and do not impose irreversible change that threatens the environment or ecological balance.
- 13) Try to prevent being openly available for misuse or malignant dual use by terrorist or military organization.
- 14) Build on the understanding that any benefits are for the good of the society, and any widely shared expressions of concern about threats from research must be considered (with the acceptance that perhaps certain research practices might have to be abandoned ).

## **7.0 GUIDELINES ON THE APPLICATION OF THE OBLIGATIONS**

This section contains practical guidance on how some of the principles outlined in section 5.0 above are to be applied in practice.

### **7.1 OBTAINING CONSENT FROM RESEARCH PARTICIPANT**

**7.1.1** To satisfy the requirement for informed consent and continuous dialogue with research participant, it is very important that all research involving collection and

use of personal data has the consent of each research participant and that research participants are informed about the research and any risk that they may be exposed to.

- 7.1.2** Researchers shall obtain consent from participants in their research prior to processing any personal data. The consent must be specially related to the research being undertaken. Therefore, suitable consent forms may need to be used to obtain consent in writing.
- 7.1.3** Research that does not entail the direct participation of living persons may nonetheless indirectly but significantly affect living persons. Researchers may be assessing information about identifiable individuals, the publication or analysis of which may have ethical (and indeed legal) implications. For example, collection and use of archive, historical, legal, online or visual materials may raise ethical issues (e.g. for families and friends of people deceased), and research on provision of social or human services may impact provision for individuals and groups of service users who did not contribute or consent to, or were not consulted about the research. Researchers should go so far as possible consider such implications.
- 7.1.4** Consent forms, recruitment letters and/or information sheets shall contain the following:
- a) A statement that the study involves research;
  - b) A short explanation of the purpose of the research;
  - c) The expected duration of the research participant's involvements;
  - d) A description of the procedures to be followed;
  - e) A statement on whether it can be reasonably foreseen that research participants may experience any risk or discomfort, which may be psychological or/and physical. If any such risks or discomfort are reasonably foreseen, a description of such risks or discomfort shall be included in the consent form, together with information about where research participants may obtain psychological and emotional support. If no risks are foreseen this should be stated;
  - f) A description of the benefits to the participant or to others which may reasonably be expected from the research. If no benefits are foreseen this should be stated.
  - g) A statement that participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without giving a reason and without penalty or loss of benefits to which the participant is otherwise entitled;
  - h) A statement on what is done with the data gathered about /from participants who discontinue participation;
  - i) A statement describing the extent to which confidentiality of records identifying the subjects will be maintained, who has access to them , and for how long they will be stored;
  - j) A statement informing researcher's participant about their rights under the General Data Protection Regulation (GDPR) to access, rectify, and where applicable, erase the data concerning them;
  - k) Name and contact details of the researcher and supervisor (if applicable). This enables research participant to exercise the right to request written information

about their personal data being processed and to request further information about the research

If the above elements are included in the recruitment letter / information sheet and not in the consent form, they must be incorporated into the consent form by reference, and participants must be given a copy of all relevant documents.

- 7.1.5 For research involving more than minimal risk, the consent form shall also contain an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained, and whom to contact in the event of a research-related injury to the research participant.
- 7.1.6 If applicable, the consent form should also contain full disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the research participant.
- 7.1.7 If the research involves research participants who are unable to give informed consent (e.g. children), the consent form shall be signed by the research participant's legally authorized representative. It is normally considered appropriate that in the case that research participants are children who are able to give assent, apart from the consent of their legally authorized representative, agreement to participate shall also be obtained from the children themselves.
- 7.1.8 Researchers shall ensure that each person signing the written consent form is given a copy of that form. The researchers shall give either the research participant or the research participants legally authorized representative adequate opportunity to read the form before signing it.

## 7.2 ENSURING PRIVACY AND PERSONAL DATA PROTECTION

In order to ensure the right of research participants to privacy and personal data protection, any personal data collected during the course of the research shall be processed fairly and lawfully. The personal data being processed have to be adequate, relevant and not excessive. All reasonable measures shall be taken to ensure that personal data are correct and if necessary, up-to-date. Personal data shall not be retained for period longer than necessary. In relation to this, all measures shall be taken to anonymize data if possible and ensure confidentiality.

## 7.3 RESEARCH INVOLVING VULNERABLE POPULATION

Research proposals in which some or all of the research participants are likely to be vulnerable to coercion or undue influence shall include a statement that the integrity and dignity of research participants shall be respected and that informed consent shall be obtained. In particular, the statement should outline in details the safeguards that will be used to ensure the rights and welfare of these participants.

For the purpose of the clause, vulnerable populations shall include children, prisoners, persons with disabilities, substance abusers, and economically or educationally disadvantaged persons.

## **8.0 RESEARCH ETHICS APPLICATIONS**

### **8.1 Research Involving Human Subjects (Humanities *et al*)**

- a) Where research involves human participants (for example, for interviews, focus groups, surveys, observations, etc.), or involves data relating to directly identifiable human subjects, researchers are required to complete a University Research Ethics Review Checklist (*see Form 1*). The purpose of the Checklist is to give proper consideration to the rights of individuals and to allow researchers to reflect on the potential ethical implications of their research and the risk of harm (including risks to livelihoods, social relationships, emotional well-being, etc.) that might be caused to the participants.
- b) Researcher shall provide the ethics committee (the same as constituted earlier) with detailed procedure or questionnaire for review and approval according to the NOUN ethics policy.
- c) Completed ethics review forms approved by Departmental Certification must be kept on file within the department for three years or until the completion of the research, whichever is the later.
- d) Research involving deception of participants, or that is intentionally conducted without their full and informed consent at the time the study is carried out or when the data are gathered shall require the approval of the committee
- e) Research where informed consent will be obtained orally but not in writing and research which involves or may lead to the publication of confidential information shall as well require the approval of the ethics committee
- f) Research involving any of the following shall be treated under special ethics policy to be considered by the ethics committee. These include: vulnerable groups; sensitive topics;  
groups where permission of a gatekeeper is normally required for initial access to members (where involvement of the gatekeeper might raise issues of whether participants' involvement is truly voluntary); research which would induce undue psychological stress, anxiety or humiliation or cause more than minimal pain.
- g) Research involving more than minimal risk of harm (whether emotional or physical) to the researcher(s).
- h) Research that does not entail the direct participation of living persons may nonetheless indirectly but significantly affect living persons. Researchers may be assessing information about identifiable individuals, the publication or analysis of which may have ethical (and indeed legal) implications. For example, collection and use of archive, historical, legal, online or visual materials may raise ethical issues (e.g. for families and friends of people deceased), and research on provision of social or human services may impact provision for individuals and groups of service users who did not contribute or consent to, or were not consulted about the research. Researchers should so far as possible consider such implications.

### **8.2 Research Involving Animal Subjects (Sciences)**

NOUN recognizes the guidelines as provided by the National Committee for Research Ethics in Science and Technology and that of international bodies in order to ensure standard research practices.

The ethical assessments related to the use of animals in research are wide-ranging. While it became necessary to use laboratory animals in some cases for people, animals or the environment benefits, it is essential to also note that animals have a moral status, and that our treatment of them should be subject to ethical considerations.

### **8.2.1 Responsibility for considering options**

- a) Researchers are responsible for studying whether there are alternatives to experiments on animals.
- b) Ethics committee shall also ensure that alternative options must be prioritized if the same knowledge can be acquired without using laboratory animals and the researcher must comply with the decision of the committee.

### **8.2.2 Use of endangered species**

Researchers are responsible for ensuring that the use of laboratory animals does not endanger biological diversity. The use of endangered and vulnerable species must be reduced to an absolute minimum.

## **8.3 Guidelines**

### **8.3.1 Respect for Animals' dignity**

Researchers must have respect for animals' worth, regardless of their utility value, and for animals' interests as living, sentient creatures. Researchers must be respectful when choosing their topic and methods, and when disseminating their research. Researchers must provide care that is adapted to the needs of each laboratory animal.

The following shall be considered in all cases of experimentation involving animals:

- a) each animal colony must meet international standard
- b) animals shall be provided with adequate shelters that will allow free movement, good ventilation, good temperature and light source
- c) animals' hygiene should be taken with utmost considerations to ensure free contamination of food and water
- d) animals should be provided with adequate food and water at all times
- e) in the event of inflicting the animals with pains during experiment and where necessary, such pains should be minimized by the use of tranquilizers, analgesic and anesthetics.

### **8.3.2 Special Cases of Research Involving Genetically Modified Organisms (GMOs)**

- a) All staff of NOUN shall obtain approval from the ethics committee before venturing into any research which involves the use of GMOs or that which would produce GMOs as the final result or even intermediary.
- b) The committee shall assess the impact of importation, production and testing of such product in NOUN.
- c) The committee shall ensure that the University has met the national and international requirements which allow an institution to venture into such research either as an individual or as a group.

- d) Researchers using GMOs must submit their applications to the ethics committee and obtain approval before commencing the experiment.
- e) In the event of laboratory accident involving GMOs, the researcher must report to the dean of his/her faculty immediately. The ethics committee must constitute an emergency Risk Monitoring Committee who will ensure the containment of all the contaminated facilities as well allow the experiment to continue or otherwise.

### **8.3.3 Special Cases of Research Involving Exposure to Radiation**

It is the duty of the university to ensure protection of her members from exposure to radiation of any kind. Therefore, persons who are in close contact to radioactive substances during their display of duties should ensure that their level of exposure is regulated in such a way that would not have effect on their colleagues or even family members. To achieve this, the following guidelines must be put in place:

- a) The NOUN Ethics Committee shall in conjunction with relevant faculties establish a radiation safety structure
- b) The ethics committee shall review the methodology of the experiment and determine the adequacy of the researcher for handling radioactive substance as well consider if the radiation dosage is within the required level that is being considered safe.
- c) The committee shall instruct the potential researcher to grant access to inspections by the authorized body
- d) The committee shall put a halt to any operation involving radiation especially when the environment is consider not safe for such experiment
- e) Prepare periodic report on radiation experiments and present to UREC

## **RESEARCH ETHICS PROCEDURES**

### **1.0 INTRODUCTION**

Ancillary to the University Policy on Research Ethics is the NOUN's Procedures for the Review of Ethics in Research. This document therefore also applies to all staff, students and any other person or persons in collaborative research with staff of the University.

For easy administration of the Research Ethics Policy, this section establishes the manner and approach requests for ethics and data protection review can be carried out. The committees established in this policy may consider requests for ethics and data protection review by persons other than NOUN staff upon a payment made to the University on the specific advice of the Bursar.

### **2.0 RESEARCH ETHICS COMMITTEE STRUCTURE**

- a) This policy recommends that each Faculty (FREC) should have a sub-committee on Research Ethics answerable to the University Research Ethics Committee (UREC)

- b) Where necessary, each Faculty should have a large board with sub-committees for different programmes created, and subsumed in it.
- c) Sub-committees should be headed by senior academics.

### **3.0 OVERVIEW OF RESEARCH ETHICS REVIEW PROCEDURES**

The procedure commences with the researcher completing a self – assessment exercise on Research Ethics and Data Protection (REDP). Depending on the outcome of this self – assessment, the researcher may either commence the research or submit an application for REDP review to the FREC.

FRECs are authorized to review and approve REDP review applications on behalf of the University, that are not automatically approved through the self-assessment process, except (a) if the proposed research involves special categories of personal data (SCPD) as defined in the Nigeria Data Protection Regulation 2019 ('the Regulation'), and (b) where ethics or data protection issues cannot be resolved with the researcher. In this instance, the FREC shall review the application for any ethics considerations and make a recommendation to UREC.

In all instances, it is the FRECs that communicate with researchers about the outcome of any REDP review. The FREC will, if necessary, assist with the resolution of any matters that require to be addressed and with the preparation of a revised REDP review application.

## **4.0 RESEARCH ETHICS COMMITTEES**

### **4.1 FACULTY RESEARCH ETHICS COMMITTEES**

Faculties shall have a FREC to manage the research ethics review process within that entity and to ensure that the University's research code of practice is adhered to. Institutes, Centres shall normally make arrangements with faculties that carry out research in similar areas for research ethics and data protection reviews to be carried out by the appropriate FREC. Such arrangement need to be agreed by the relevant Faculty Board and approved by Senate.

Each FREC shall have at least three members up to a maximum of five. These shall be appointed by the Senate for a period of three years, on the advice of the faculty board. Members shall have knowledge about the various types of research conducted within the faculty. Where necessary, FRECs may appoint sectoral sub-committees to advise them. FRECs shall normally provide a response to the researcher within 30 work days of receipt of the application.

Applications received shall be assessed by a minimum of three FREC members and the FREC chair person or delegate. A member of a FREC may not participate in a review of research in which the member has a conflicting interest (including being the supervisor of the research), except to provide information.

### **4.2 UNIVERSITY RESEARCH ETHICS COMMITTEE**

The University Research Ethics Committee (UREC) shall have a chairperson and a minimum of ten committee members. UREC is to have two streams: an ethics stream and a data protection stream. The UREC chair person shall chair the committees for both streams.

The chairperson and the members of UREC shall be appointed by Senate for a two-year term, which can be renewed. The chairperson may propose a delegate from amongst the members of the UREC to act on their behalf if necessary.

A member of UREC may not participate in a review of research in which the member has a conflicting interest (including being the supervisor of the research), except to provide information.

#### **4.2.1 UREC-ETHICS COMMITTEE**

The UREC Ethics Committee (UREC-E) shall be composed of the UREC chairperson and a minimum of six members from the UREC Committee who, together, bring expertise in

- i) Arts and Humanities
- ii) Social Sciences
- iii) Natural Sciences
- iv) Applied Science
- v) Medical Science
- vi) Animal Research

At least one of the members of the committee shall have expertise in research ethics.

UREC-E meetings shall be held with an appropriate subset of members who are experts in the area of research of the proposal being reviews. A UREC-E meeting shall have a minimum of two members from the UREC-E committee in addition to the UREC chair person or the chair person's delegate. The chair of the relevant FREC, or their delegate, shall also attend UREC-E meetings when research proposal processed by that FREC are to be discussed.

The role of UREC-E is to:

- a) Carry out annual audits of research ethics self- assessments carried out by researchers and ethics reviews carried out by FRECs to ascertain that self – assessments and reviews are consistent with the policies approved by Senate.
- b) Prepare an annual report to Senate summarizing activities carried out, including the results of the audits.
- c) Arbitrate in those cases where researches do not agree with FREC decision on research ethics issues; and
- d) Prepare recommendations to Senate for improvement of research ethics policies or procedures.

#### **4.2.2 UREC –DATA PROTECTION COMMITTEE**

The UREC-DP Committee (UREC-DP) shall be composed of the URERC chairperson, or delegate, and a minimum of four additional members from the UREC Committee who are knowledgeable in data protection.

UREC-DP meetings are held with an appropriate subset of members who are experts in the area of research of the proposal being reviewed. A UREC-DP meeting shall have a minimum of two members from the UREC-DP committee in addition to the UREC chairperson or the chairperson delegate. The chair of the relevant FREC or their delegate shall attend UREC-DP meetings when research proposals processed by that FREC are being discussed.

The role of UREC-DP is to:

- a) Liaise to obtain any necessary authorization required for research proposals that have been referred to it
- b) Review research proposals referred to it by the FRECs, which deal with special categories of personal data as defined in the Nigeria Data Protection Regulation 2019 ('the Regulation').
- c) Carry out annual audits of research data protection self – assessments carried out by researchers and reviews carried out by FRECs on data protection matters not related special categories of personal data to ascertain that self – assessments and review are consistent with the policies approved by senate, the NDPR ,
- d) Prepare an annual report to Senate summarizing activities carried out, including the result of the audit.
- e) Arbitrate in those cases where researchers do not agree with FREC decisions on data protection matters not related to special categories or personal data ; and
- f) Prepare recommendations to Senate for improvements of research data protection policies or procedures that deal with data protection.

## **5.0 RESEARCH ETHICS REVIEW PROCEDURE (REDP)**

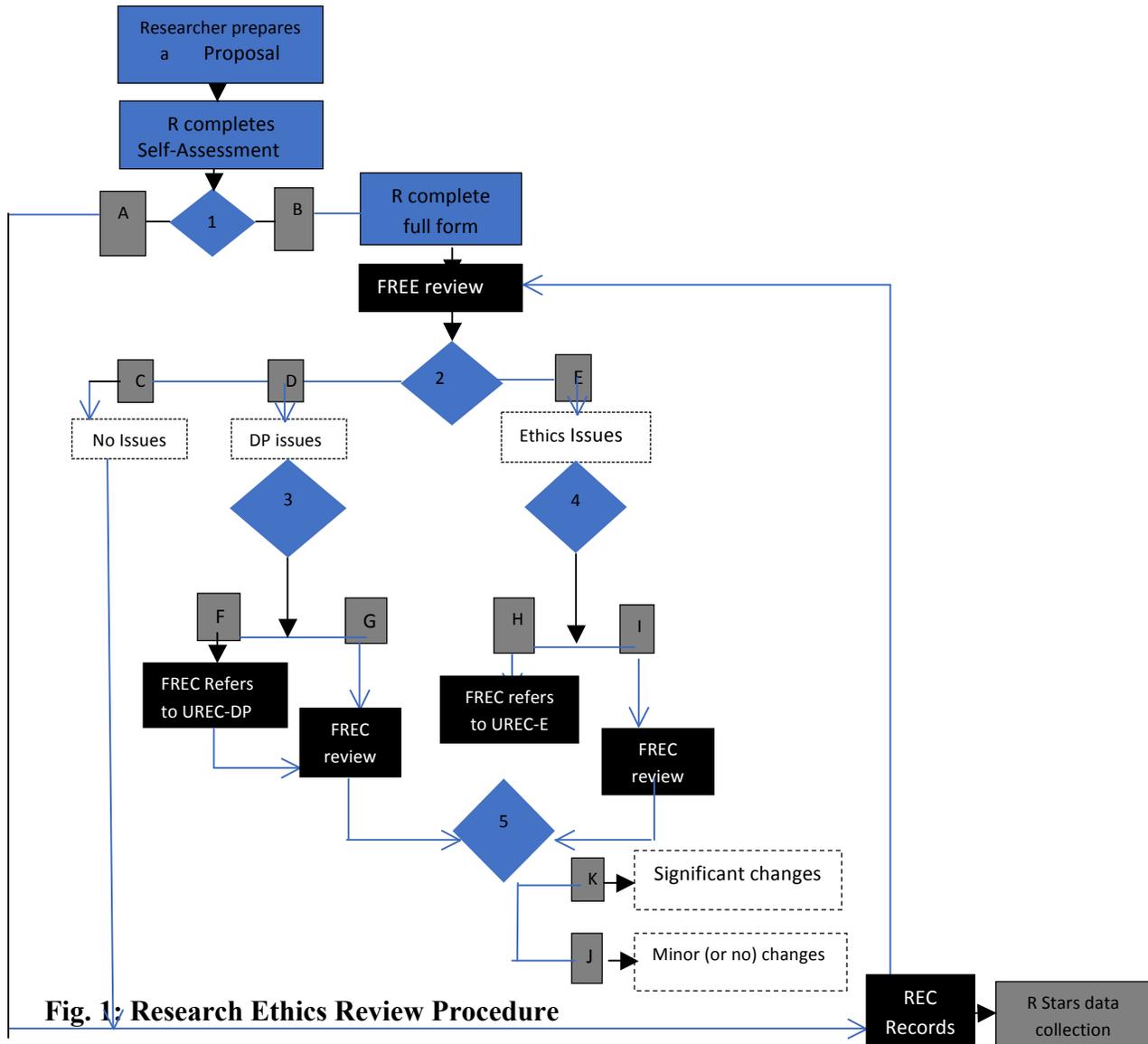
### **5.1 SELF-ASSESSMENT**

Fig.1 presents a diagram of the research ethics review procedure, following the preparation of the research proposal by the researcher. All researchers planning to undertake a research project must complete and submit a REDP form prior to undertaking any data collection. Within the REDP form, applicants first complete a self-assessment. Once the self-assessment has been correctly completed, it will guide researchers to the next step, which can be one of two outcomes (Fig. 1: Decision 1, Outcome **A or B**):

- (A)** The research project has no further ethical and data protection review requirements. In this case, the researchers send the completed form to the appropriate FREC for records and audit purposes and the research may commence. FREC may be required to acknowledge receipt where formal records are required by the researchers. **Or**
- (B)** The research project has some further ethical or data protection review requirements. In this case, the researcher completes the REDP proposal form and submits it to the appropriate FREC. The researcher must await FRECs feedback before commencing any data collection.

In the case of students, the completion of the self-assessment and the full form (where required) shall be guided by the academic supervisor of the research who shall also be required to endorse the form eventually submitted to FREC. Supervisors should be aware that when endorsing the research proposals of their supervisees they are accepting responsibility for ensuring that the

research proposal as presented is in conformity with Senate policies and procedures on research ethics.



**Fig. 1: Research Ethics Review Procedure**

### 5.2 FREC REVIEW

In the case of research proposals referred to FRECs for review (Fig. 1: Decision 2-5) FREC may decide that the issues flagged in the full form raise no serious ethical or data protection issues and duly informs the researcher that they may commence research (Fig. 1:c) .

If the proposal does raise some issues (Fig. 1: D/E), FREC may require some clarification or improvement on ethical issues and / or on data protection issues. The following outcomes are possible:

#### Concerns about ethics

FREC Provides feed back to the researcher and attempts to resolve the issue with the researcher by suggesting changes (Fig. 1: I). If the changes requested by the FREC and carried out by the

researcher address the concerns about ethics, the FREC informs the researcher that they may commence research (Fig. 1: J).

If the issues cannot be resolved by dialogue between the FREC and the researcher, the proposal is forwarded to UREC-E by the FREC (Fig. 1: H). UREC communicates its decision to the FREC which will advise the researcher on how to proceed. A change in the research plan and a revised REDP form may be needed in some case. (Fig. 1: K).

#### Concerns on data protection matters not related to special categories of personal data

The FREC provides feedback to the researcher and attempts to resolve the issue with the researcher by suggesting changes (Fig. 1: G). If the changes requested by the FREC and carried out by the researcher address the concerns about data protection, the FREC informs the researcher that they may commence the research (Fig. 1: J).

If the issue cannot be resolved by dialogue between the FREC and the researcher, the proposal is forwarded to UREC-DP by the FREC (Fig. 1: F). UREC-DP communicates its decision to the FREC which will advise the researcher on how to proceed. A change in the research plan and a revised REDP form may be needed in some cases (Fig. 1: K)

### **5.3 UREC-DP REVIEW**

#### Concerns on data protection matters not related to special categories of personal data

After reviewing the proposal for any ethical issue, the FREC forwards the proposal together with a recommendation to the UREC-DP (Fig. 1: F). UREC-DP reviews the proposal, submits its recommendation to the IDPC, and communicates the IDPC's decisions to the FREC, which will advise the researcher on how to proceed. If no changes to the research proposal are required, approval is granted and the FREC informs the researcher that they may commence the research. If only minor changes to the research proposal are required to address the concerns about data protection, approval is granted on condition that the amendment are carried out by the researcher as requested by the UREC-DP, endorsed by the supervisor (if researcher is a student) and verified by the FREC. The FREC informs the researcher that they may commence the research (Fig. 1: J). If significant changes are required, the researcher must submit a point-by-point response to the issue raised in the UREC-DP report, together with any amended documents as required to the FREC for further review by UREC-DP (Fig. 1:K). These materials must be endorsed by the supervisor in the case of students. Once the FREC has vetted the response and other material and is satisfied that all the issues raised by UREC-DP have been addressed, the FREC submit these materials together with a recommendation to UREC-DP. UREC-DP reviews these materials and communicates the decision to the FREC, which will advise the researcher on how to proceed.

### **5.4 ACCELERATED APPROVAL PROCEDURE**

In most instances, it will be possible to proceed with research upon completion of the self-assessment form. In a scenario where it is necessary for research to go to FREC, the initial response normally takes no more than 30 work days from the time of submission of the application forms to the relevant FREC. If the proposal also needs to be submitted to the UREC-DP, then the initial response shall normally be given within an additional 30 work days.

Certain projects, especially those linked with funded programmes, may involve a specific tight deadline that would make it impossible to go through the research ethics review procedures outlined above.

In such cases, an accelerated approval process should be applied without prejudice to the ethical review. For this purpose, the researcher shall submit a request to the UREC chairperson for an accelerated approval procedure. The UREC chairperson shall consult with UREC subcommittee convened for this purpose in order to assess whether the request is justified. If justified, the UREC chairperson shall request the relevant FREC to review the application with urgency. FRECs shall consider such request and provide a response to the researcher within 10 work days. Except that, should the application require review by UREC-DP, then the FREC will forward the application together with its recommendation to UREC-DP within a minimum of 10 work days. UREC-DP shall provide a response to the researcher within 10 work days.

## Acknowledgements

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