Working Paper # 38

Establishment of Ethical Review Committee (ERC) / Institutional Review Board (IRB) for NUST Research Sponsored by Research Dte

1. Introduction

The Ethics Review Committee (ERC) or Institutional Review Board (IRB) is a body within a research or academic setup which supports research of only highest ethical standards and ensures that the research adheres to principles that protect the dignity and rights of human participants and other living subjects involved in the research.

The ERC/ IRB mandate involves the following:

- Providing written guidelines and recommending policies on ethical considerations for research involving subjects (human or animals).
- Auditing/Inquiries of research during the research period to ensure compliance with guidelines.
- Withdrawal of research approval if dissatisfied with the conduct of the investigation.

2. Background

2.1. Why a centralized ERC/ IRB is required?

As per the international best practices, to ensure impartiality and neutrality, the international standards recommend the formation of a **standing committee at the institutional level**, instead of a department/ school level.

It is to be noted that an impartial review and certification of such a centralized committee is a mandatory requirement of various national (PSF, HEC etc.) and international funding agencies (American Science Foundation, EU Horizon 2020, etc.) for conducting research involving living subjects.

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2.2 International Best Practices

Internationally acclaimed research institutes and universities have a dedicated ERC/IRB to oversee the ethical concerns of research being carried out, which gives credibility to the research of these institutes. Following are a few examples of renowned institutes with their respective composition/ stature of ERC/IRB:

Serial No.	Name of Institute	IRB Composition
1	Oxford University, UK	Central University Research Ethics Committee (CUREC)
2	John Hopkins Bloomberg School of Public Health (USA)	• 2x on-site Institutional Review Boards (IRB X and IRB FC) • 1x External IRB (the Western IRB)
3	Yale University (USA)	• 5x Institutional Review Boards (IRBs) for biomedical research known as Human Investigation Committee (HIC IA, HIC IB, HIC II, HIC III, HIC IV) • 1x IRB for social, behavioral and educational research known as Human Subjects Committee (HSC)
4	University of Alberta, Canada	A dedicated Research Ethics Office (REO)

2.3 Existing Practice

NUST had established 2x bodies for addressing Plagiarism and Research Ethics as described below.

The first body was titled "NUST Standing Committee on Plagiarism and Research Ethics" notified vide Research Dte letter No. 0986/41/Research/NUST dated 04 Jan 2013. This body largely focused on cases pertaining to plagiarism and academic dishonesty. The body did not address ethical clearance in research research projects.

The second body was a school-based ERC/IRB titled "Approval of IRB Committee – ASAB" notified via ASAB letter No. 0986/02/ASAB/Estb dated 19 Sept 2019. This committee addressed ASAB cases and also partially overlooked NUST-level ethical clearance issues for projects, with the following nominations:

- 4x FMs from ASAB
- 1x FM from S3H
- 1x Legal Member from Main Office

2.4 Rationale for institutional ERC/IRB

There are 6x Research themes encompassing 62+ research areas, in which research is being conducted. Research in these areas involve human and living

subjects, examples of some of the research areas which need frequent ethical clearances, but not limited to, are as follows:

- Health
- Bio Medical
- Biotechnology
- Neuro Sciences & Neuro-informatics
- Social Sciences and Humanities

However, as per international practices, a centralized committee with impartial representatives from all these research areas needs to be formulated in order to address the gaps of the existing NUST ERC/IRB composition and processing constraints. This will also enable NUST to address requirements of funding agencies.

3. Aim of Ethical Review of Research

Following are the cases in which review by an ERC/ IRB is essential:

a. If research involves collecting input and/or information from people (responses, reactions, measurements, opinions, experiences) or input collected by someone else, including in person, online, in writing, over the phone or by any other means
b. When research involves the use of human biological materials and if the sample comes from a human body
c. When research involves using data about people previously collected by someone else (e.g. student records, commercial records)
d. When research involves secondary data (publicly available data, publicly not available, and data based on paid subscriptions)
e. If research involves the collection or use of health information
f. When research involves animals
g. When research has a potential impact on environment
h. When research involves collaboration with someone who is doing any of the above
i. To check whether the research has been plagiarized.

3.1. Exemptions

Some research that involves human subjects may be exempted from the regulations requiring ERC/ IRB approval. Examples include educational research, testing and survey procedures where **no identifying information will be recorded that can link subjects to the data**, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects financial standing, employability, or reputation. Such exemption would be conditional to:

a. The informed consent*(Details in Annex A) is taken from the research subject.
b. The information gathered being relevant/beneficial to the research subject and his/her community.
c. Proposal includes planning for sharing study findings with the research subject/s and the relevant communities planned, as well as mechanisms for informing the research subject.
d. Also exempted are the uses of existing data, documents or specimens, where no identifying information will be recorded that can link subjects to the data.

3.2 Examples of exemptions

a. Literature review; and theoretical analysis. In such cases the only ethical concern would be acknowledgement of sources.
b. Analysis of data, documents, specimens, not linked to individual subjects.
c. Evaluation studies of intervention programs/projects, especially by those who were partners in planning the intervention.

4. Proposed Structure of ERC/ IRB at NUST

4.1. Nomination of ERC/ IRB and Structure

Nominations of members of ERC/IRB will be approved by Rector NUST for a period of 2 years. The ERC/ IRB composition should encompass all relevant research areas identified by the NUST Research Framework. The nominations of ERC/ IRB will not be widely circulated in order to ensure impartiality and neutrality. The composition is provided below:

a.	Pro-Rector (RIC)	Chair
b.	Heads / Deputy Heads of Relevant Thematic Committee	Member
c.	Reps of concerned School / College / Directorate / Office	Member
d.	Legal Expert	Member
e.	External Expert (for dispute cases)	Member
f.	Rep of Research Dte	Secretary

The Committee will meet as per requirement. In case of unavailability of the Chair, a Co-Chair (e.g., a Principal / Senior FM) can be nominated by the Chair. The normal processes will be automatically forwarded to the committee via email through NRP (process flows explained in detail in Annex B) to auto-generate clearance certificate.

The NUST ERC/IRB does not preclude the school/ college/ institute level ethical committees already in place from functioning. However, the guidelines defined in this WP and by the Committee nominated above must be adopted by the school/ college/ institute level sub-committees.

4.2. ToRs of the institutional ERC/ IRB

Following are the ToRs and deliverables expected from an institutional ERC/IRB:

a. The ERC/ IRB has the overall responsibility for the development of ethics review policy and establishment of the University's ethical review process.
b. All the research should be subject to appropriate ethical review and ERC/IRB is responsible for the review of researchers' applications for ethical approval.
c. It is responsible for implementing the University's policy on the ethical conduct of research involving human participants, living beings, and personal data.
d. It is responsible for the protection of the rights and welfare of human subjects in research conducted at NUST by faculty, staff and students, and by investigators from several affiliate institutions.
e. Protection of participants (animals, human beings, environment) by minimizing the harms or risk to which they are exposed.
f. Liaison with National Bioethics Committee (NBC), and similar bodies, in coordination with the university ORIC / Research Dte for ethical clearance.

4.3. Research Cases for Ethical Review by ERC/ IRB:

Following are the three main research cases which are applicable for ethical clearance:

4.3.a. Research proposal/ projects for grants:

The role of ERC/IRB is crucial for screening research projects for upholding high standards of scholarly work at NUST and preventing scientific malpractice towards human and animal subjects. All the project proposals

submitted to national, international, and internal funding, must be ethically cleared before commencement, i.e., during the submission phase. Ethical clearance by an institutional / central IRB has been deemed mandatory by various national and international funding agencies and is being practiced across the globe.

The ethical clearance certificate is usually submitted with the full proposal, therefore, the PI must seek clearance with the initial concept note, and prepare the necessary documents well in advance. Detailed process is covered in the lifecycle management of ethical clearance.

4.3.b. Research Publications

The publications resulting as an output of an ethically cleared research project will be exempted from ethical clearance, whereas a similar procedure for ethical clearance will be followed for all other publications (such as for cases where a publisher requires the ERC/IRB to issue an ethical clearance certificate):

4.3.b.i **Ethics of publication: Plagiarism**

Plagiarism is defined by the HEC policy as "taking and using the thoughts, writings, and inventions of another person as one's own". If proven, plagiarism may have a number of consequences ranging from fines, suspensions, expulsions, and legal proceedings.
The ERC/IRB will deal with cases of publications related plagiarism as defined by HEC policy.

In order to ensure originality of research publications, Turnitin plagiarism checker has been provided to all schools and colleges and the Turnitin report is mandated for the processing of all publications related cases i.e., Article Processing Charges, Financial Awards etc, and for NUST Research Portal.

4.3.c. Research Patents

The patents resulting as an output of an ethically cleared research project will be exempted from ethical clearance, whereas a similar procedure for ethical clearance will be followed for patents as per all the other cases of research.

4.4. Process of ethical clearance by ERC/ IRB in research lifecycle

The complete workflows of the application for an ethical review for different scenarios will be formulated based on case types of research, risks involved, and research area. The case/ scenario will be determined based on the questionnaire filled

and submitted before the commencement of research. A separate step of "Ethical Clearance" will be added in the commencing stage of the life-cycle of each of the three cases of research (publication, project, patent) processed within NUST.

There will be different questionnaires formulated for the ethical review based to determine whether the research requires a review by ERC/ IRB or not. The faculty submitting a research proposal/ publication/ patent will be requested to ask the questions appended in Annex C. The research proposal/ publication/ patent will require an ethical clearance **if any of the questions are true.**

An automated ERC/ IRB module will be incorporated for submissions through NUST Research Portal (workflows explained in Annex B). The publication/ project proposal will undergo review by ERC/ IRB **if any of the questions** are affirmed to be true by the researcher. Once the proposal is automatically assessed as per the answers to the questionnaire, automated emails to the committee members along with the abstract of publication / project proposal copy, will be sent for review. The feedback will be collected again, through the portal, and sent to the researchers for amendments/ updates requested by the committee, or in case of clearance, a clearance certificate will be automatically issued to the researcher and also updated on the NUST Research Portal against the project, for submission to the funding agency.

Recommendations

5. The subject policy has been recommended for approval by the 60th ACM on 17th March 2021 for implementation with immediate effect.

6. Academic council is recommended for decision.

Annex A

Essentials of informed consent are:

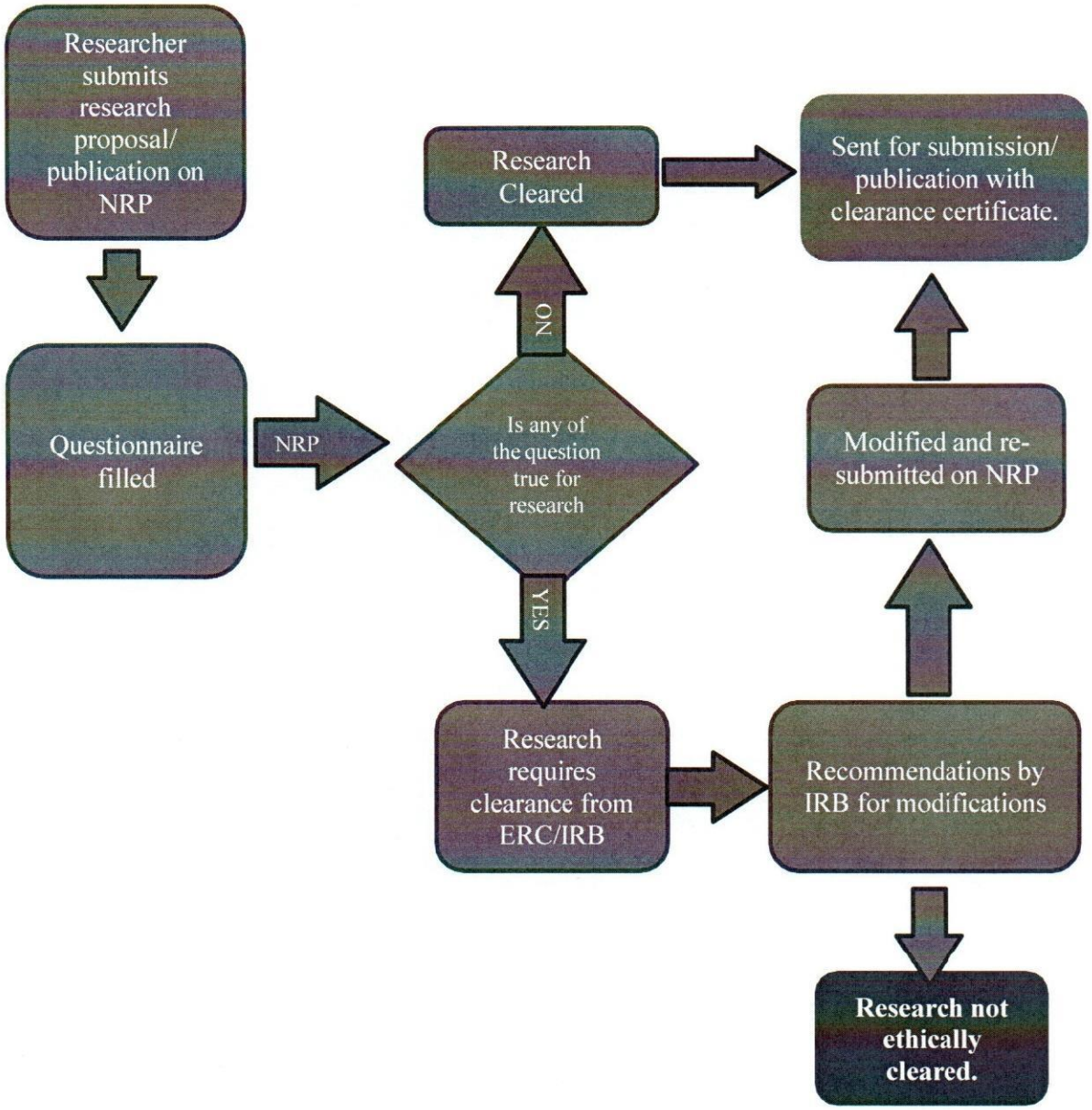
1. Comprehension: Investigator must ensure that the informed consent is clearly comprehended by the subject / guardian
2. Purpose of research must be clearly explained.
3. Procedure: In simple words, describe the procedure that the subjects would be expected to undergo. Identify any procedures that are experimental/ investigational/ non-therapeutic. Indicate type and frequency of monitoring during and after the study.
4. Length of time subject is expected to participate. If subject's participation is expected to continue over a long period of time, please indicate that any new information that develops during the study and may affect the subjects' willingness to continue participation will be communicated to them. This would apply even when the intervention/investigation phase of the study has ended but monitoring continues.
5. Benefits of the research must be shared with/communicated to
    a. Subjects
    b. Other study participants
    c. Society
6. In studies evaluating drugs or other products the subjects should be advised as to the availability of the product after discontinuation of the study. Please indicate whether drug would be available to the patients free of cost. If not, kindly specify expected local cost. Please specify financial burden to be incurred by the research subject while participating in the study.
7. Explain all foreseeable risks or discomforts to the subjects. Note this not only includes physical injury, but also possible psychological, social, or economic harm, discomfort, or inconvenience. If risk is unknown, state so.
8. Treatment for adverse experiences explain what therapeutic measures would be available to the subjects in case of adverse reactions or injury as a result of being a participant in the study. All research related adverse reactions are the financial responsibility of the researcher.
9. Confidentiality: Describe the extent to which confidentiality of records identifying the subject will be maintained.
10. Person to contact for answers to questions, or in event of research related injury or emergency.
11. Statement that participation is voluntary and that refusal to participate will not result in any penalty or any loss of benefits that the person is otherwise entitled to receive.
12. Subjects right to withdraw from the study at any time.
13. How sharing of results with subjects will occur.
14. No abbreviations will be used.
15. Consent document must be clearly written and/or verbally explained so as to be understandable to subjects (local language wherever applicable). The language must be non- technical (comparable to the language in a newspaper or general circulation magazine), and scientific, technical or medical terms must be plainly defined. It is PI's responsibility to ensure quality of consent procedure.

16. The researcher should submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, potential conflicts of interest and incentives for subjects.
17. Specify the cost of management directly related to the study and indicate what portion of the cost would be incurred by the study participants.
18. The researcher should also declare any personal and institutional benefits (monitory or otherwise including travel) accrued through study participation.
19. Please also specify benefits of the study to the funding agency or sponsors if any.
20. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person.
21. Non-medical research should be conducted by suitably qualified persons.
22. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy and confidentiality of the patient's information. Minimize the impact of the study on the subject's physical, mental and social integrity.
23. In the conduct of research, the investigator must at all times respect the personality, rights, wishes, beliefs, consent and freedom of the individual subject.
24. Application: The researcher responsible for the ethical and scientific conduct of the research should submit a typed application for review of the ethics of proposed biomedical research.

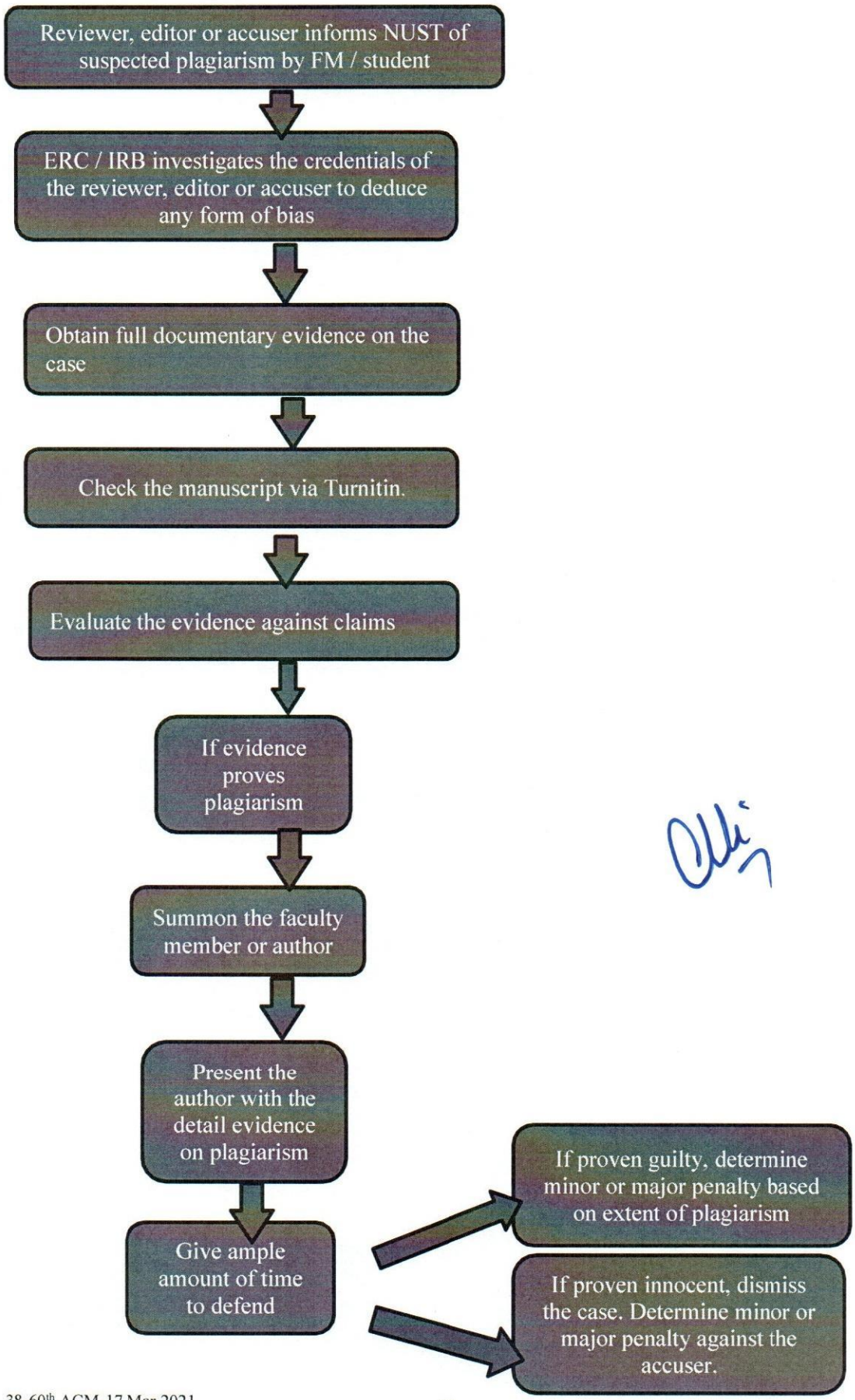
Annex B

The following workflows depict the processing of all the above-mentioned cases of research (publications, projects, and patents) and their ethical clearance:

Workflow of NRP module for screening Research by NUST IRB (Publication, Projects, Patents)



Work-flows for screening publications for plagiarism


Reviewer, editor or accuser informs NUST of suspected plagiarism by FM / student
ERC / IRB investigates the credentials of the reviewer, editor or accuser to deduce any form of bias
Obtain full documentary evidence on the case
Check the manuscript via Turnitin.
Evaluate the evidence against claims
If evidence proves plagiarism
Summon the faculty member or author
Present the author with the detail evidence on plagiarism
Give ample amount of time to defend
If proven guilty, determine minor or major penalty based on extent of plagiarism
If proven innocent, dismiss the case. Determine minor or major penalty against the accuser.

Annex C

QUESTIONNAIRE

Q1. Does the proposal address subject of ethics? If yes, please specify

Q2. Does it involve more than minimal risk (toxic emissions, security of workers, researchers, staff, environment, subjects)? If yes, please identify.

Q3. Does the research involve data of subjects (records, equipment, premises or vulnerable people)? If yes, please confirm that the data will not be linked to individual subjects

Q4. Are there possible conflicts of interest or an appeal?

Q5. Are there any potential hazards to indigenous population, environment, health, animals or fish habitats, endangered species, language, culture?

Q6. Do you think the project could have any legal implications?

Q7. Does the research include literature review? If yes, please indicate the sources