

POLICY ON RESEARCH MISCONDUCT AND FRAUD



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POLICY ON RESEARCH MISCONDUCT AND FRAUD

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HEADQUATER

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Vision

To be an institution of excellence in basic, applied and operational research for the promotion of national health and development in Nigeria.

Core Value

- Honesty
- Integrity
- Leadership
- Excellence
- Respect
- Fairness
- Dignity
- Teamwork
- Innovation
- Relevance
- Hard work
- Fair Reward and Recognition
- Accountability and Transparency
- Communication: Internal and External
- Equity

Mission

The mandate of the Institute under the enabling Act of 1977, stipulates that NIMR shall conduct research into health problems in the country essentially in the following areas:

- Communicable diseases of public health importance in the country
- Non-Communicable diseases prevalent in the country
- Basic, applied and operational research for the prevention and control of diseases endemic in the country in cooperation with the federal and state ministries of health
- Develop human and infrastructural capacities for clinical and biomedical research in collaboration with Medical Schools, Universities and other health-related institutions, in and outside Nigeria
- Disseminate the results of health research in the country through training courses, scientific publications, conferences, workshops and other communication channels to the Federal and States Ministries of Health, and relevant stakeholders in the public and private sectors.on of national health and development in Nigeria.



FOREWARD



The mandate of the Institute under the enabling Act of 1977, entrusts it to conduct research into health problems in the country. Thus, the scientific standard and ethical integrity of research activities conducted by the institute assuredly must not be compromised.

Any form of non-compliance with the principles of responsible conduct of research or serious violation of the fundamental principle of truth in the conduct of research and the dissemination of results will defile public trust in the research product and can result in harmful public health consequences. Research integrity is best fostered by developing and propagating clear standards of behaviour in science.

A range of misdeeds by scientists are universally termed "misconduct".

Such deficient act(s) require remediation through administrative mechanisms and modalities (including prevention and investigation/enforcement). An institution needs to define inappropriate research behaviour and outline the administrative system and process of establishing innocence or guilt and alleviating research misconduct.

The Institute recognizing the importance and significance of research translation to products development, public health, and safety, developed this Policy on Research Misconduct and Fraud primarily to outline the procedures for reporting and investigating misconduct in research, as well as the measures to be taken when misconduct is suspected or reported.

NIMR misconduct policy document undoubtedly states the principles on which its research interest is grounded and deliberately bridges the legal and scientific perspectives to research misconduct. This policy specifies prohibited behaviour that may taint the integrity of research emanating from the institute. Adhering highest standards of conduct when pursuing, conducting, and reporting research is germane to upholding the reputation of NIMR and its research faculty.

Finally, this policy applies to all NIMR temporary and permanent staff. It also applies to any other person/institution involved in research supported by NIMR.

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Prof Babatunde Lawal Salako, MBBS (Ib), FWACP, FRCP (Edin), FRCP (Lond), mnim, FNAMed, FAS. **Director-General/CEO**

ACRONYMS

ARF	Allegation Report Form	
GCP	Good Clinical Practice	
ICH	International Conference on Harmonization	
IRB	Institutional Review Board	
NIMR	Nigerian Institute of Medical Research	
NHREC	National Health Research Ethics Committee	
SOP	Standard Operating Procedure	
TOR	Terms of Reference	
WHO	World Health Organisation	

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Section One Introduction

1.1 Background

Health research significantly contributes to best medical practice, and it is therefore expected that health research is conducted by observing the highest standards of research practice at all times. In pursuance of this, it is expected that researchers fully comply with universally acceptable laws, regulations or guidelines governing the conduct of research and good clinical practice.

According to the world health organization, research is a fundamental instrument for the advancement and attainment of health, and as such must be conducted with the highest standards of scientific quality and ethical integrity. The code of conduct for responsible research states that scientists should accurately and honestly present scientific evidence, declare conflicts of interest, and prevent any form of professional misconduct in research.

Similarly, Clinical research plays a critical role in ensuring quality healthcare delivery. As such, several ethical frameworks provide moral guidance for clinical researchers. These include The Belmont Report, The Declaration of Helsinki, The Nuremberg Code and The U.S. Common Rule which guides the protection of patients who participate in clinical trials, ensures that testing is scrupulous and fully compliant with stated clinical protocols, verifies the scientific validity of the results, choose clinical trial participants in a way that is fair and free of prejudice, and enforce the informed consent of volunteers and their knowledge about what the trial involves and potential risks before they offer their consent.

This policy on research misconduct outlines procedures and actions to be taken when reports of wrongdoing in research are brought against staff/individuals working for or collaborating with NIMR. Any wrongdoing in research - intentional, fraudulent or grossly negligent behaviour such as fabrication, falsification, plagiarism, deliberate misrepresentation or other practices by a staff member or collaborator is therefore a seriously deviate from this policy.

It is important to note that this policy did not address other types of transgression that can occur during research concerning the personal behaviour of members of staff. Such types of transgression are dealt with under other specific NIMR policies, such as the Policy on Sexual Harassment and Abuse.

1.2 Principles

This policy has been produced in congruence with the Code of Conduct for Responsible Research, the GCP, the Medicines for Human Use Regulations 2004 and amendments, and local policies and procedures for investigating and responding to allegations of research misconduct & fraud. It outlines the procedure for investigating and responding to allegations of research misconduct made against permanent, contract or adjunct staff undertaking research studies at the Nigerian Institute of Medical Research (NIMR), Yaba, Lagos.

NIMR expects all research being undertaken on NIMR patients or staff and conducted in institute premises, research sites, and with its funds, sponsorship, supervision, or direction to be conducted observing the highest standards of research practice. In pursuance of this, it is expected that employees of NIMR, those working on NIMR premises, research sites, awarded research grants or collaborating with or supervised by NIMR researchers take steps to acquaint themselves with this policy, NIMR IRB guidelines and policies, National Health Research Ethics Committee (NHREC) guidelines and policies, and other local and international research governance framework, guidelines, and applicable regulations.

1.3 Time Limitations on Alleged Research Misconduct

- For NIMR Research There are no time limitations. This policy applies to all research in all fields of biomedical science, and results/outcomes from such proposals or studies, regardless of the date of alleged misconduct.
- For NIMR-funded research This policy does not apply to any alleged research misconduct that occurred more than six years before the allegation was received by NIMR

1.4 Applicability

This policy applies to all NIMR permanent, adjunct, contract and temporary staff. It also applies to any person/institution who, at the time of the alleged research misconduct was:

- Involved in research supported by the Nigerian Institute of Medical Research (NIMR)
- Affiliated by contract or agreement with the Nigerian Institute of Medical Research (NIMR)

• In the case of an allegation being made against an adjunct staff, advice will be sought from the person's employer.

1.5 Scope

The policy relates to reporting, investigating and adjudication for research misconduct and fraud made against NIMR staff members including those individuals holding temporary or adjunct positions or Affiliated by contract or agreement with NIMR.

1.6 Purpose

The purpose of this policy is to:

- i) Enable staff and non-staff to raise legitimate concerns relating to research misconduct/fraud by staff within the period of their employment or stay at NIMR.
- ii) Make it clear to individuals who believe they need to make an allegation against a member of staff that allegations of research misconduct/fraud are taken seriously within NIMR.
- iii) Provide an opportunity for an individual who has inadvertently breached good research / clinical practice to declare the problem openly, allowing the process to occur fairly and transparently.
- iv) Provide a process for concerns to be raised, investigated and, where appropriate, adjudicate fairly and transparently.
- v) Act as a deterrent to potential perpetrators of research misconduct/fraud.
- vi) Strengthen the confidence of all research stakeholders (e.g. participants, funders, investigators, and the researcher.

Section Two: Definitions and Classification of Research Misconduct

This policy adopted a broad and non-exhaustive definition of research misconduct and fraud beyond fabrication, falsification, plagiarism, or deception in proposing, carrying out or reporting results of research data; or deliberate, dangerous, or negligent deviations from accepted methods/practices in carrying out research.

2.1 Definitions of Terms

- a) **Research** is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Health research includes biomedical research, epidemiological studies, health services research, behaviour and social research, as well as economic research that affect health. Perhaps the most familiar form of health research is the clinical trial; however, an increasingly large proportion of health research entails the analysis of data and biological samples that were initially collected for other purposes.
- b) **Fabrication** involves making up research data or results (including recordings) and reporting it for academic publications or gains.
- c) **Falsification** is the manipulation of research materials, equipment, processes, and data or results such that the research is not accurately represented or the outcome is distorted or the research record is false.
- d) **Plagiarism** is the appropriation of another person's ideas, statements, processes, results, or publication words without giving appropriate credit or references.
- e) **Research Misconduct** refers to a wide range of (mis)behaviour by scientists that may infringe on the intellectual property or research work of another person. It is unethical scientific conduct misconduct may involve fabrication, falsification, plagiarism of research data or reporting of research outcome. It is practices which deviate from commonly acceptable scientific conduct. Research misconduct may involve an intent to deceive, disregard the truth, state or present facts or procedure(s) falsely, or intentionally omit a fact so that what is stated or presented as facts is untrue. Research misconduct is committed intentionally, knowingly, or recklessly. Misconduct excludes provable honest error or honest differences in interpretations or judgments of data or information.

- f) Academic Fraud is an intentional deception made for personal gain or to damage another individual, for instance, intentionally falsifying or fabricating research data or misleading reporting of results.
- g) **Misconduct in Clinical Research** is the failure to follow an investigational plan, inadequate and inaccurate record documentation, drug accountability, failure to report adverse drug reactions, and failure to obtain and/or document subject consent.
- h) Research Misconduct in Clinical Trials is the failure to apply the ethical and scientific standards of designing, conducting, recording, and reporting trial studies. Non-compliance with these standards negates the participants/ public assurance that the rights, safety and well-being of trial subjects are protected, and consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.
- i) **Complainant**: A person/researcher/scientist who in good faith makes an allegation of research misconduct.
- j) **Respondent**: A person/researcher/scientist against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.
- k) Whistleblower: An individual / Organization who is not a staff of the institute can act as a responsible whistleblower to disclose lawfully information/evidence to support a reasonable claim of research misconduct involving staff or research conducted by the institute.
- 1) A designee is a person who has been officially chosen to do or be something
- m) Inquiry process enquiring whether You have breached any relevant professional code of conduct
- n) **Investigation** means the formal development of a factual record and the examination of record(s) findings leading to an incident of Research Misconduct.
- o) A preponderance of the Evidence means proof by information/evidence that, compared with that opposing it, leads to the conclusion that the fact at hand is more probably true than not.

Comprehensively, the World Health Organization's (WHO) description of research misconduct or fraud includes but is not limited to the following.

- Inappropriate development of research protocols.
- Failure to disclose or take action on declared conflict of interest.
- Inadequate management of a research project.
- Fabrication of data such as deliberate creation, recording and reporting of nonexistent results.
- Falsification such as the deliberate manipulation of data to change, or omit data.
- Sabotage, which is intentionally damaging, destroying, obstructing or otherwise harming a research project.
- Plagiarism such as the copying of ideas, data or text (or various combinations of the three) without authorization or acknowledgement.
- Piracy is the deliberate exploitation of data from others without authorization.
- Conducting research in a manner which contravenes the terms of approval granted by relevant bodies.
- Conducting research before relevant ethical approvals
- Failure to adhere to accepted ethical principles for the conduct of research
- Failure to follow accepted procedures or exercise due care for avoiding the unreasonable risk of harm to humans, animals or the environment.
- Mismanagement or inadequate preservation of data and/or primary materials.
- Misappropriation of data.
- Improper conduct in peer review.
- Misrepresentation of interests, qualifications, and experience.
- Misrepresentation of involvement or authorship.
- Failure to protect or the inappropriate use or disclosure of confidential or proprietary information, or the misuse of intellectual property.
- Improper dealing with allegations of research misconduct and or fraud.

• Misconduct or fraud in research does not include honest errors or differences in interpretations or judgements of data.

2.2 Classification of Research Misconduct

a) Core Research Misconduct

- Fabrication of data
- Falsification of data
- Plagiarism includes:
 - Selectively excluding data from the analysis
 - Misinterpreting data to obtain desired results (including inappropriate use of statistical methods)
 - Doctoring images in publications
 - Producing false data or results under pressure from a sponsor

b) Data-related Misconduct

- Not preserving primary data
- Bad data management, storage and accessibility
- Withholding data from the scientific community
- c) Publication-related Misconduct
- Claiming undeserved authorship
- Denying authorship to contributors
- Artificially proliferating publications ("salami-slicing")
- Failure to correct the publication record

d) Misconduct in Clinical Trials and Clinical Research

According to the US Office of Research, Integrity research misconduct in clinical trials and clinical research involves:

Falsification

- Substituting one subject's record for that of another subject.
- Falsely reporting to a data coordinating centre that certain clinical trial staff, who were certified to perform the procedures on the subjects, had done so when they had not.
- Altering the dates and results from subjects' eligibility visits.
- Altering the dates on patient screening logs and/or submitting the same log with altered dates on multiple occasions.
- Failing to update the patients' status and represent data from prior contacts as being current.
- Altering the results of particular tests on blood samples to show that the test accurately predicted a disease or relapse.
- Backdating follow-up interviews to fit the time window determined by the study protocol; and
- Falsifying the times that blood samples were drawn from human subjects.

Fabrication

- Creating records of interviews of subjects that were never performed.
- Making up progress notes for patient visits that never took place and inserting them into the medical record to support published and unpublished research reports; and
- Preparing records for calls and follow-up contacts to subjects who had already died.
- Making up progress notes for patient visits that never took place and inserting them into the medical record to support published and unpublished research reports; and
- Preparing records for calls and follow-up contacts to subjects who had already died.

Section Three Moral Principles Covered Under the Research Misconduct Policy

- i. Research misconduct/fraud includes intentional, unauthorized use, disclosure, undisclosed, or removal of, or damage to, research-related property of another, including apparatus, materials, writings, data hardware or software or any other substance or devices used in or produced by the conduct of research.
- ii. Research misconduct/fraud includes failure to follow established scientific protocols/procedures or adhere to established ethical principles; if this failure results in unreasonable harm to human beings, other living organisms or the environment and facilitating of misconduct in research by collusion in, or concealment of, such action by others.
- iii. Research misconduct/fraud does not include honest error or honest differences in the design, execution, interpretation, or judgment in evaluating research methods or results or misconduct unrelated to the research process.
- iv. Research misconduct/fraud does not include poor research, or honest differences in the interpretation of data unless this encompasses the intention to deceive.
- v. It is the responsibility of the DG/management of the institute through the scientific committee, and relevant head of department to sensitize staff responsible conduct of research, types of misconduct which may be encountered during the conduct of research and how to prevent them.
- vi. The identity of the complainant/staff/person(s) making the allegation will, if required, be kept confidential.
- vii. The investigation process may however at some stage have to reveal the source of the information and the individual(s) making the allegation if necessary
- viii. It should be made clear to staff and other individuals that allegations of research misconduct are taken seriously by NIMR and the Sponsor (if different from NIMR).
- ix. Staff should be informed that deliberate false allegations constitute serious misconduct, and will be handled according to the public service rules.

- x. The Institute shall refuse to fund researchers who have engaged in certain misconduct actions, or place certain conditions on their application for or using its funds in connection with research-related misconduct.
- xi. The inquiry/investigation committee shall take judicious steps to ensure an impartial and unbiased investigation.
- xii. The inquiry/investigation committee shall pursue diligently all significant issues relevant to determining and substantiating research misconduct.
- xiii. The administrative actions/ measure or adjudication must be consistent with applicable civil service rules and regulations, and may include, for example:
 - Retraction or correction of all published or pending abstracts and

papers emanating from the research related to misconduct.

- Removal of the responsible staff/person(s) from the particular project.
- Letter of reprimand, probation, suspension, salary reduction.
- Special monitoring of future research work.
- Initiation of actions that may lead to a possible rank reduction or
- termination of employment, or
- Other actions appropriate to the research misconduct sanction.

Section Four Roles and Responsibilities

a. The Director-General (DG)

- i) Shall receive all allegation(s) of research misconduct
- ii) Shall within 15 working days and without notice to any of the parties involved, conduct a preliminary assessment of allegations to determine if an inquiry is warranted. He may seek advice from the administration department or as appropriate decide whether there are grounds for proceeding further with a misconduct allegation
- iii) Shall appoint Chair of the inquiry/investigation committee which may be the Chair of the Institute Scientific Committee or Institutional Review Board
- iv) Shall appoint the relevant person(s) to the inquiry and investigation Committee
- v) Shall set a time for completion of the inquiry/investigation by the committee

b. Senior Management Committee

Where the Director General is connected in any way to the research in question, the Senior Management Committee shall perform the DG's responsibility

c. Chair, Institute Scientific Committee or Institutional Review Board / Research Integrity Officer (If appointed by DG)

- i) Shall Chair the Committee responsible for:
- ii) Assessing allegations of research misconduct to determine if they warrant inquiry on the basis that the allegation is sufficiently credible and specific to gather potential evidence of research misconduct;
- iii) conducting inquiries and investigations into research misconduct allegation(s)

d. The Inquiry/Investigation Committee

- The committee shall be charged with the responsibility to inquire/investigate the alleged report/case of misconduct <u>upon the determination that an investigation is</u> <u>warranted by the DG or his designee.</u>
- The committee will consist of individuals with the appropriate scientific expertise to:
- i) Evaluate the evidence and issues related to the allegation

- ii) Interview the respondent and complainant
- iii) Conduct the investigation

Section Five Reporting Research and Clinical Trial Misconduct/ Fraud

5.1 Responsibility to Report Misconduct

- a) All Institute's staff, including adjunct/staff sub-contracted by NIMR, should report any incident of misconduct, witnessed or detected that is non-compliance with good research, clinical or ethical practice.
- b) An organization or individual who is not a staff of the institute can act as a responsible whistleblower to disclose lawfully information/evidence to support a reasonable claim of research misconduct involving staff or research conducted by the institute

5.2 Misconduct Reporting Guidelines

- All allegations of research misconduct shall be made in writing to the Director General.
- Staff /Complainant shall append their name(s) to any allegation they make for effective investigation of the matter and confirm the allegation, and ensure fairness to any individual(s) mentioned in the allegation.
- Whistleblowers shall adhere to legitimate institutional (NIMR) structures to report allegations of misconduct. A whistleblower cannot make a lawful disclosure that violates institutional ethical rules /confidentiality, otherwise, the institute may thereafter legitimately limit the whistleblower's access to further information about the case.

5.3 Basic Components of Misconduct Allegation Reporting Form/Letter

A written inquiry report prepared must include the following information

- The name, position and contact of the complainant
- The name, position and contact of the respondent/Staff named.
- Description of the allegations of research misconduct including
- Details of study/clinical trial/publications

- Grant applications/ number (If applicable).
- Date & Signature

Section Six: Inquiry/ Investigation of Research Misconduct

6.1 Terms of Reference (TOR) For the Inquiry/Investigation Committee

The DG/Designee shall charge the Inquiry/Investigation Committee with the following TOR:

- i. Describes the allegations and related issues identified during the inquiry/Investigation
- ii. Conduct inquiry/investigation as prescribed in the Research Misconduct Policy
- iii. Evaluate evidence and testimony supported by a preponderance of evidence to prove that research misconduct occurred
- iv. Determine the type and extent of the misconduct if any and who was responsible for any misconduct
- v. Prove a case of research misconduct by a preponderance of the evidence.
- vi. Document a preponderance of the evidence to affirm defences (if any) raised such as <u>honest error or a difference of opinion by the person alleged to have committed</u> <u>misconduct.</u>
- vii. Determine that research misconduct is a significant departure from accepted practices of the relevant research community, and country.
- viii. Review thoroughly all necessary pieces of evidence, data, documents and information to establish if there legitimate case of misconduct
 - ix. Submit a report with recommendations within an assessment period preferably 12 weeks to DG/Management.

6.2 Inquiry Process

- i. The inquiry/investigation procedure shall be aligned with other existing NIMR policies, guidelines, and rules.
- ii. The Staff (temporary or permanent), named in an allegation will be informed of the allegation(s) made against him/her along with the supporting evidence in writing.

- iii. The staff named is offered an opportunity to respond in writing NOT later than 7 calendar days of the receipt of the allegation letter which must be before the commencement of the inquiry/investigation of the alleged misconduct.
- iv. Upon commencement of the inquiry/investigation committee's first meeting, the Committee will:
 - Assess the allegation to determine if the allegation is sufficiently credible and if evidence of research misconduct might be identified.
 - If the allegation falls within the definition of research misconduct (as specified by policy).
 - Interview the complainant, respondent, or any other witnesses.
 - Gather any evidence and data beyond that submitted with the initial allegation necessary to determine adjudication.
 - Treat all allegations/inquiries made will be treated confidentially and sensitively.
 - Ensure those inquiry/investigation procedures are not tainted by partiality arising from personal or institutional conflict of interest or other sources of bias.
 - Ensure allegation of research misconduct/fraud is supported by credible evidence
- v. If/ where the alleged research misconduct involves Clinical trials or Clinical Research, additional inquiry/investigation process will include determining:
 - If misconduct affects public policy.
 - If misconduct affects clinical practice.
 - If misconduct affects public health practice.
 - Determining actual/potential harm to human subjects or the general Public.
- vi Forward its report with recommendations within an assessment period preferably 12 weeks to DG/Management.

6.3 Time for Completion of Inquiry/Investigation

- The inquiry, including preparation of the final inquiry report, should be completed within 60 calendar days of initiation of the inquiry
- The inquiry may be extended if there are circumstances that warrant a longer period.

Section Seven Adjudication, Decision Notification and Appeal of Research Misconduct Inquiry/Investigation

7.1 Adjudication

• DG/Management/AP&DC of the institute makes final determinations on what disciplinary actions should be taken against research misconduct and any other institutional administrative actions in congruence with the public services rules.

7.2 The decision by DG/Management

The DG/Management will:

- i) Determine whether the institution accepts the investigation report and its findings.
- ii) Decide what appropriate administrative actions are to be taken in response to the accepted findings and report of the research misconduct.
- iii) Assist the investigation committee in finalizing the draft investigation report and decisions.
- iv) Transmit the final investigation decision to the:
 - a) Relevant complainant/ persons/staff making the allegation.
 - b) Respondent/ staff against whom the allegation has been made, whilst also
 - c) maintaining confidentiality wherever possible.
 - d) Individual holding an adjunct/honorary position in the Institute and against whom the allegation has been made.
 - v) Employer of individual holding adjunct/honorary position in the NIMR, and against whom the allegation has been made.
 - vi) Granting/sponsor Institutions or bodies who have supported the staff and study involved or mentioned in connection with alleged research misconduct.

***Where the research is externally funded, in whole or in part, by the funding body, a there is a substantiated allegation of research misconduct/fraud DG/Management forward to the funding body the following:

- A copy of the final investigation report with all necessary attachments.
- A statement of whether the NIMR acceptance of the findings of the Investigation report.
- Evidence of misconduct and, who committed the misconduct.
- A description of any pending or completed administrative actions To be taken or have been taken against the respondent/staff named in the research misconduct.
- v) May report misconduct to academic /professional bodies for sanctions (such as journal retractions). In most of these cases, the full investigation report is not released.

7.3 Notification of Misconduct Inquiry/Investigation Report

a) Respondent:

- The DG/designee must give the staff/respondent a copy of the draft investigation report for comment and, concurrently, a copy of or supervised access to the evidence on which the report is based.
- The respondent will be allowed 30 calendar days from the date he/she received the draft report to submit comments to the DG/designee.
- The respondent's comments must be included and considered in the final decision.

b) Complainant:

- Investigation reports are not routinely provided to the complainant.
- The DG/designee of the institution may provide relevant portions of the draft investigation report to the complainant for comment.
- If the complainant is asked to comment, responses must be received within 30 days and must be included and considered in the final report.

c) Respondent (Staff named in misconduct)

• Management Designee/Head of Administration will notify both the respondent and complainant (in writing) of the <u>intent to initiate inquiry/investigation</u> NOT later than two weeks before the commencement of the committee's first meeting.

d) Adjunct Staff

• Where the respondent holds an adjunct position, the DG or Designee will inform the respondent's employ of the <u>intention to pursue an inquiry/investigation</u> of the allegation of research misconduct

e) Funding Agent

• Where the research is externally funded, in whole or in part, the DG or Designee shall <u>issue the intent of inquiry/investigation process</u> to the relevant funding body and give an appropriate cause of action taken on a substantiated allegation of research misconduct/fraud.

7.4 Appeals

- The DG Designee/Head of Administration will notify both the respondent and complainant (in writing) of an adjudicated decision by DG/Management NOT later than 15 calendar days before the final decision is taken.
- The respondent may appeal the decision of DG/Management in writing within 10 calendar days of receipt of the letter on the adjudicated decision of the DG DG/Management.
- The DG/Designee Official may request that the inquiry/ investigation Committee reconvene to review the appeal of the staff/respondent.
- The DG may decide that a separate committee be convened to reopen and investigate the matter.
- Appeals related to funded research activities misconduct must be addressed within 120 calendar days.

Section Eight Documentation and Retention of Research Misconduct Records

- All substantiated allegations should be made in writing by the person making the allegation using the Allegation Report Form (ARF). (See Appendix I).
- The investigating form must be duly signed by the complainant or complaining Institution or Funding Agency.
- NIMR will maintain records of research misconduct proceedings secured for 7 years after the completion of the inquiry/investigation or for as long as may be required by the law.
- If allegations and inquiry/investigation reports/documents are demanded by law, NIMR DG/designee will be responsible for providing applicable information, documentation, research records, evidence, or clarifications related to a particular research misconduct case.

References

- ICH (2016). Harmonized guideline integrated addendum to ICH E6 (R1): a guideline for good clinical practice E6 (R2). Retrieved from https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf.
- NIH (2019). A Guide to the handling of research misconduct allegations. Retrieved from https://oir.nih.gov/system/files/media/file/2021-08/guidehandling_research_misconduct_allegations.pdf
- 3. OECD (2007). Best Practices for Ensuring Scientific Integrity and Preventing Misconduct Retrieved from https://www.oecd.org/science/inno/40188303.pdf.
- 4. The medicines for Human Use (Clinical trials) Regulations 2004. Retrieved from https://www.legislation.gov.uk/uksi/2004/1031/contents/made
- U.S. Department of health and human services. (2019) Integrity and Misconduct in Research. Report of the Commission on Research Integrity. Accessed 27/0802022. https://ori.hhs.gov/sites/default/files/report_commission.pdf
- US National Science Foundation (2002). Research Misconduct: A rule by National Science Foundation. Retrieved from https://www.federalregister.gov/documents/2002/03/18/02-6179/research-misconduct.
- WHO (2017). Code of Conduct for Responsible Research. Retrieved from https://www.who.int/docs/default-source/wpro---documents/regionalcommittee/nomination-regional-director/code-ofconduct/ccrr.pdf?sfvrsn=b2cb450_2&ua=1
- WHO (?). Misconduct in Research. Retrieved from https://cdn.who.int/media/docs/default-source/documents/ethics/code-of-conduct-formisconduct-in-research-pamphlet-en.pdf?sfvrsn=ac5d50fc_2.

Appendix I

Allegation Report Form

Information on Complainant		
Name		
Designation		
Institution/organization/affiliation		
Address		
Phone/Contact/Email		
Date of complain		
Information on staff (person(s) involved in Misconduct)		
Name(s)		
Designation(s)		
Institution/organization/affiliation		
Address		
Phone/ Contact/Email		
Type of case		
28. (Research misconduct, clinical trial etc.)		
Allegation/issue/complain		
Description/ summary of the allegation	Dn	

NIMR Sponsored Study : External Grant Study : Self-Sponsored Study :					
Details of the research study/clinical trials					
Grant details/date					
Details of Published/Unpublished Works					

Additional Documentation (list of attached document(s)				

Receipt/ Signatures and Dates		
Received by:		
Designation/Dept.		
Signature		
Date of receipt		

September 2022

POLICY ON RESEARCH MISCONDUCT AND FRAUD POLICY DRAFTING COMMITTEE

- 1. Professor Olaoluwa P. Akinwale
- 2. Professor Oliver C. Ezechi
- 3. Professor Rosemary A. Audu
- 4. Dr Olayemi A. Nwogbe
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