RESEARCH MISCONDUCT

2.1 RESEARCH MISCONDUCT

Background

Any compromise of the ethical standards required for conducting research should not be tolerated. Even though breaches in such standards are rare, they must be dealt with promptly and fairly by all relevant parties in order to preserve the integrity of the research community. In order to preserve the integrity of the overall process of assessing potential misconduct, the process involves multiple steps. The process begins with an allegation, which shall first be assessed to determine whether it meets the criteria for research misconduct. If those criteria are met, there shall then be an inquiry into the allegation to determine whether there are enough facts to warrant an investigation. If an investigation is warranted, a formal examination and evaluation of all relevant facts shall determine if the allegation of misconduct is valid. If the allegation is valid, the process shall be concluded with an adjudication procedure.

Definition of Research Misconduct

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct, however, does not include honest error or differences of opinion.

Components of Research Misconduct:

- **Fabrication** refers to the deliberate making up of data or results and recording or reporting them.

- **Falsification** refers to the manipulation of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

- **Plagiarism** refers to the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

In cases of allegations involving individuals whose activities are submitted to or supported by a national agency, the definition and procedures for research misconduct specified in the agency's regulations will apply.

Confidentiality

Personnel involved in the inquiry and investigation shall strive to maintain confidentiality of information to the extent consistent with a fair and thorough process and as allowed by their institutional ethics board and regulatory authorities.

It is recommended that all researchers confer with their institutions' guidelines or policies pertaining to the reporting of research misconduct.

2.2 HOW COMMON IS RESEARCH MISCONDUCT?

Is this a real problem?

While the vast majority of researchers here conduct their research by adhering to high ethical standards and requirements of the NHG Domain Specific Review Boards (DSRB) and their institution's and regulatory authorities' policies and guidelines, occasional lapses in integrity still happen.

Recently, a researcher blew the whistle on a local cancer scientist contesting his result on a particular cancer gene. When this research misconduct was brought to light, the institution of the accused carried out a thorough investigation. It was conducted by an experienced and respectable professor and conducted in accordance to the institution's code of conduct, with opinions from expert international scientists while examining data and conducting interviews with the accused.

After the investigation, it was then reported that the findings were inconclusive of research misconduct.

Any allegation of research misconduct for a researcher can be most detrimental. Therefore, the onus is on the researcher to be knowledgeable and mindful of what constitutes to research misconduct.

Did you know?

In the United States, it is often asked whether these high-profile research misconduct cases are anomalies or representative of a real problem. It is difficult to assess whether misconduct cases have increased over the past 50 years, for example, because data on misconduct were not collected until the 1990s. The rate of overall research misconduct in the US has been estimated to be one case per 100,000 researchers in a population of about two million active investigators. The Associate Inspector General for Scientific Integrity, and others writing in the Fall/Winter 2002 Journal of Public Inquiry, reported that between 1990 and 2002, the Office of Inspector General (OIG) at the National Science Foundation (NSF) investigated 800 allegations of misconduct in 600 cases.

The investigations revealed that 60 of those cases, or 10 percent, were misconduct. Penalties levied ranged from debarment to reprimand, with some recovery of funds.

2.3 GUIDELINES FOR THOSE WHO REPORT MISCONDUCT

Protection for whistle-blowers

For their own protection, individuals who report allegations of misconduct will need to adhere to their institution's policies and or guidelines for whistle-blowing. This provides for remedies if it can be shown that a whistle-blower suffered discrimination in retaliation for the allegation brought under the legislation.

Procedures for allegation

How should a whistle-blower proceed with an allegation?

Here are some general guidelines for individuals who report allegations of misconduct:

- *Documentation:* When making an allegation of misconduct, clear documentation of who did what, and when they did it, will provide the best chance for a fair and timely resolution of the allegation.

- *Rules and procedures:* It is recommended that institutions handle misconduct according to their own internal policies and guidelines. As soon as an individual is involved in an allegation, the accused should review institutional procedures on the issue. A whistle-blower needs to know who should be apprised of the allegation, what constitutes evidence for or against an allegation, how the evidence should be obtained, who will review the allegation, what the whistle-blower's role will be, and how much time the process is expected to take.

- *Perspective:* Individuals with little experience in research should seek guidance before making allegations of misconduct. What might appear to be a serious action could be a misunderstanding. It might be appropriate to talk to peers, senior researchers in a team, Head of Department, or the individual in question.

- *Dispute resolution:* Some allegations of research misconduct might be resolved through other means, such as conflict resolution. This involves dealing with a problem as soon as possible; striving for an agreement rather than disagreement; emphasizing the problem, not the people involved; and using a third party, such as head of department, to clarify issues if necessary.

- *Motivation of a whistle-blower:* Whistleblowers should be aware that they may suffer retribution for their actions and that institutions are responsible for a misconduct inquiry and investigation. Institutions also should distinguish between facts and speculation and avoid speculating at the motives of others. Whistle-blowers should ask questions rather than draw conclusions.

Did you know?

In the US, an ombudsman is usually a government official or an individual who investigates and attempts to resolve complaints and problems against other officials or government agencies or between employees and employers or between students and a university.

2.4 THE INQUIRY, INVESTIGATION AND ADJUDICATION PROCESS

Responsibilities lie not only with local research funding agencies

Local research funding agencies commonly rely on *host institutions to bear primary responsibility for the prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of the alleged research misconduct which have occurred in their own institution. They rely on the host institution to make the initial response to allegations of misconduct. Research funding agencies also generally refer to the host institutions any allegations of misconduct made to them. Occasionally, agencies will perform their own inquiries or investigations regarding allegations.

Under certain circumstances, agencies may undertake investigations or act quickly to protect the public interest, such as when public health and safety are at stake.

* Host institution here refers to the institution or administering organization named in the grant letter of award as being responsible for the commitment and management of the research and the supervision of the grant funding.

Definition

- **Inquiry** refers to the assessment of whether the allegation has substance and whether an investigation is warranted.

- **Investigation** refers to the formal development of the factual record and the examination of the record leading to dismissal of a case or to a recommendation for a finding of research misconduct or to other remedies.

- **Adjudication** refers to the, recommendations which are reviewed and corrective actions, such as sanctions, are determined.

In order for an action to be termed misconduct, the action must have been committed intentionally or knowingly or in reckless disregard of known practices. The allegation must be proved by a preponderance of the evidence, which means determining whether the claim or fact is more probably true rather than apocryphal. The standards of "clear and convincing evidence" and "beyond a reasonable doubt" require a much higher burden of proof, derived from a thorough investigation.

2.5 THE REQUIREMENTS FOR REPORT TO OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

How do I go about reporting suspected research misconduct?

Research/ Host Institution is the first contact point

Research/ Host institutions are required to notify the appropriate local research funding agency and the OHRPP if the inquiry into an allegation of misconduct involving publicly funded research leads to sufficient evidence to proceed to an investigation.

When an investigation is complete, the research/ host institution is required to forward a copy of the evidence, the investigative report, recommendations made to the institutional official, and the subject's written response to the recommendations. Institutions must also inform the funding agency and the OHRPP about the decision of the institutional official and if any corrective actions have been or are being taken.

During an inquiry or investigation, if there is any immediate risk to public health or safety, the research activities should be suspended. If there may be violations of criminal or civil law, or if allegations are made public prematurely, the institution must notify the OHRPP & the relevant governmental and/or regulatory authorities immediately.

2.6 SANCTIONS

Sanctions

Sanctions against those found guilty of research misconduct can include:

- Taking appropriate steps to correct the research record
- Issuing letters of reprimand
- Imposition of certification requirements to ensure compliance with the terms of a grant.
- Suspension or termination of a grant; and/or personal suspension or debarment. Institutions are required by the regulations to impose sanctions on those found guilty of research misconduct. This guide does not proscribe specific sanctions.

If there is Involvement of violations

Agencies also may issue additional sanctions beyond those of the institution. If criminal or civil fraud violations have occurred, the agency will refer the findings to the appropriate governmental authority for their necessary review and action.

Annex A

Whistle-Blowing Reporting Guide

1. According to Host Institution's policies and or guidelines for whistle-blowers:-

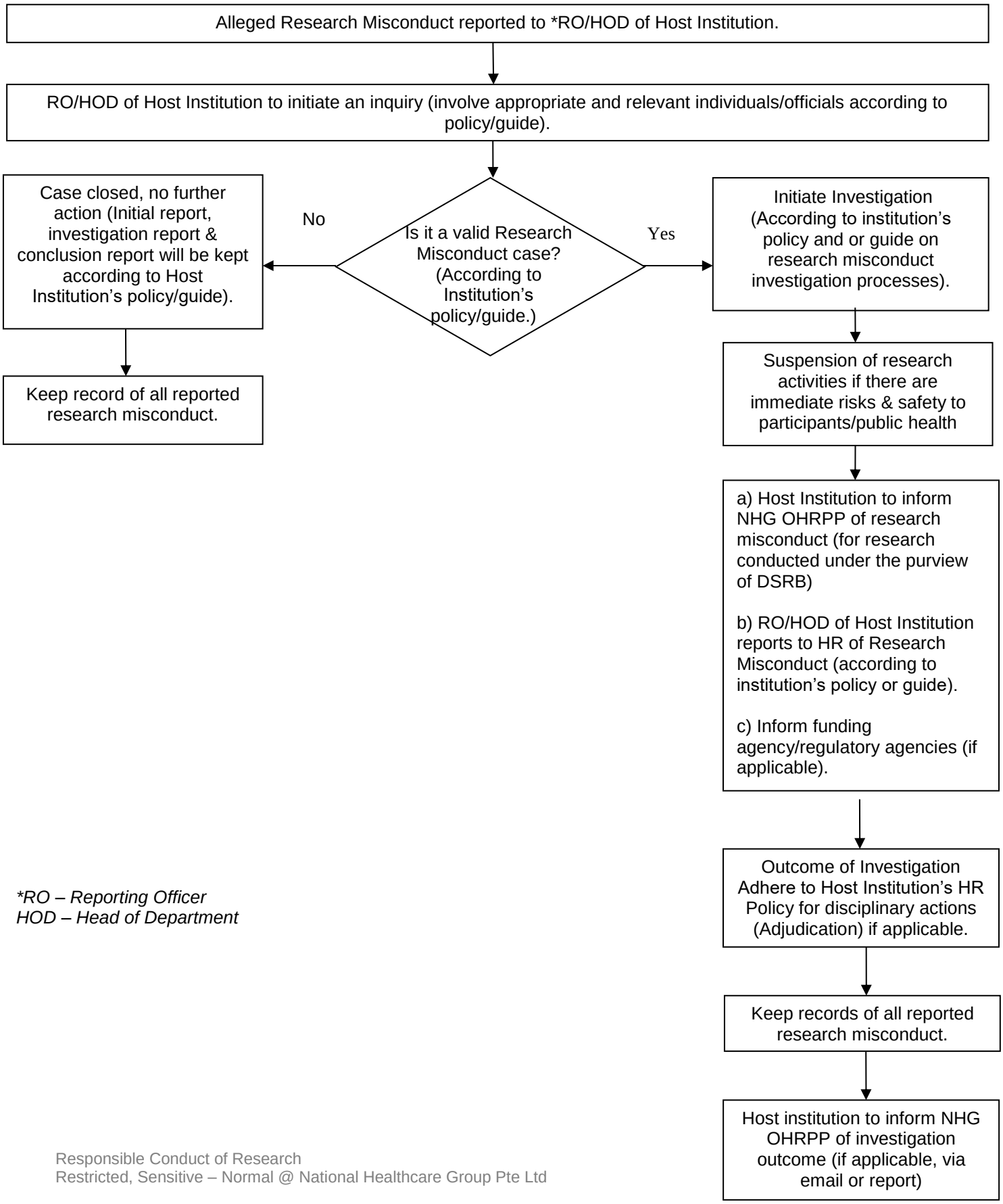
    a. The whistle-blower is encouraged to provide their identity as this may provide for remedies if it can be shown that a whistle-blower suffered discrimination due to retaliation for the allegation brought under the legislation.
    b. The identities of whistle-blowers must be kept confidential so as to protect them from against any retaliatory acts from others.

2. The Reporting Officer(RO)/Head of Department(HOD) of Host Institution and or Institutional Office who receives the allegation from the whistle-blower should take down the following information from the whistle-blower:

    a. Name
    b. Designation, Institution/Organization & Department (if applicable)
    c. Contact details (Telephone/Hand phone number, email address)
    d. Details of the alleged research misconduct
    e. Time and date of the report of the alleged research misconduct
    f. Evidence of the research misconduct
    g. Other information or details which would assist in the investigation

** This Reporting Guide for Whistle-Blowers serves as a guide and should not be viewed as an official policy or statement. OHRPP recommends researchers to ensure that they confer with their institution's policy and guidelines for any components of research misconduct reporting that they are unsure of.*

Annex B Research Misconduct Reporting Flowchart Guide



**RO – Reporting Officer*
HOD – Head of Department

An allegation of research misconduct is reported to the individual's Reporting Officer (RO)/ Head of Department (HOD) of Host Institution.

1. RO/HOD in consultation with appropriate and relevant individuals of Host Institution, determines validity of research misconduct allegations.

2. If the allegation does not contain sufficient specific information and does not fit the criteria of research misconduct, the RO/HOD in consultation with appropriate and relevant individuals of Host Institution then determines that the allegation is invalid and close the case, while maintain all documentations according to Host Institution's Internal Processes/ Standard Operation Procedures (SOP) to manage Research Misconduct.

3. If the allegation contains sufficient specific information and fits the criteria of research misconduct, the RO/HOD in consultation with appropriate and relevant individuals of Host Institution then determines that the allegation is valid, according to Host Institution's Internal Processes/SOP to manage Research Misconduct.

4. The Host Institution should then notify the alleged, NHG OHRPP, Institution's HR, the appropriate funding agency (if applicable), regulatory authorities (if applicable)in writing and initiate an inquiry to determine if the allegation warrants further investigation according to institution's policy and or guide. An investigation is warranted if:-

    a. There is a reasonable basis for determining that the allegation involves grant funding research, fits the criteria and definition of research misconduct; and

    b. Preliminary information and fact gathered from the inquiry by the RO/HOD, indicates that the allegation may be substantial.

5. Investigation process on research misconduct according to Host Institution's policies and or guidelines:

    a. The inquiry should be completed within the stipulated number of days, unless due to unforeseeable circumstances, an extension period may be warranted. The Host Institution should prepare a written report and provide the alleged the opportunity to review and comment on the inquiry report. The Host Institution should notify the alleged whether the inquiry found that an investigation is warranted and may also notify the complainant who made the allegation.

    b. The investigation should commence within the stipulated number of days after determining that an investigation is warranted and the alleged should be notified. The Host Institution should take necessary actions to ensure the procurement and custody of all the research related records, materials and

c. evidence required to conduct the investigation. Whenever additional and pertinent items become known or relevant to the investigation, the alleged should be notified. The investigation should be completed within the stipulated numbers of days.

d. The Host Institution should give the alleged a draft copy of the investigation report with a copy of the evidence (with supervised access) on which the report is based. The alleged response to the draft report should be submitted within the stipulated number of days. The Host Institution may also provide a copy of the draft report to the complainant.

e. Based on the outcome of the investigation, recommendations (which are reviewed) and corrective actions, such as sanction are required to be determined by the Host Institution. The Host Institution should adhere to their HR policies and or guides for disciplinary actions (Adjudication).

6. If at investigation, immediate risk to public health and or safety is apparent; all research activities must be suspended until further notice.

7. The RO/HOD of Host Institution should report the research misconduct to their HR or according to the institution's HR policy and or guide. If required, the Chairman of Medical Board (CME) or Chief Executive Officer (CEO) of the Host Institution may be involved.

8. If the outcome of the investigation warrants disciplinary actions; Host Institution should adhere to their HR policies and or guides for disciplinary inquiry for offences.

9. The Host Institution should inform OHRPP of the outcome of the research misconduct either via email or a formal letter, for valid misconduct cases.

10. If a valid research misconduct is determined, the Host Institution should inform the funding agency. A copy of the evidence, the investigative report, recommendations made by the institutional official, the subject's written response to the recommendations and if any corrective action have been or being taken should also be provided, if required by the funding agency.

** This Research Misconduct Reporting Framework serves as a guide and should not be viewed as an official policy or statement. OHRPP recommends researchers to ensure that they confer with their institution's policy and guidelines for any components of research misconduct reporting that they are unsure of.*

2.9 References & Acknowledgment: Research Misconduct Framework Reporting Guide

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