Malaria Consortium

Research Misconduct Policy

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Contents

1 Purpose and context

Malaria Consortium works to improve lives in Africa and Asia through sustainable, evidence-based programmes that combat targeted diseases and promote child and maternal health. Research is central to Malaria Consortium's work and essential to improving health and health care delivery. Malaria Consortium conducts research in a range of locations, transmission settings and health systems to develop and test new approaches and products, and learn from and improve our projects and programmes.

Maintaining high standards of research ethics and code of conduct is critical to generate quality information for decision-making. Misconduct in research encompasses several acts, which may be harmful to study participants and/or lead to the publication of misleading results as detailed under Definitions and terms (Section 3). Misconduct in research is a very serious matter. The investigation

of allegations of such misconduct must be conducted based on principles of balance, confidentiality, integrity, and fairness and must seek to avoid unjustified detriment to any person concerned.

For investigation of allegations of misconduct, Malaria Consortium, being a charity registered in the United Kingdom with its head office in London, will normally follow the *Procedure for the investigation of misconduct in research* (hereafter called *the Procedure*) prepared by the UK Panel for Research Integrity in Health and Biomedical Sciences and published in 2008 by the United Kingdom's Research Integrity Office (UKRIO).[1] However, there may be situations, when it will be appropriate to follow different guidelines and procedures, for example if this is warranted by legislation in the country, where the alleged misconduct has occurred, or by grant agreements. Thus, National Institutes of Health Grants require compliance with the United States Public Health Service Policies on Research Misconduct, 42 CFR Part 93.[2]

The present document has been prepared mainly for persons within or outside Malaria Consortium, who wish or need to know how suspicions of misconduct in research are handled by the Organization.

2 Scope

The Procedure is meant to ensure full and fair investigations of allegations of misconduct in research brought to attention by internal or external sources. For Malaria Consortium it is supplementary to existing general guidance for handling allegations of misconduct, especially the Whistle Blowing Policy.[3]

For ease of reference, the present document reproduces Definitions and terms from *the Procedure* with adaptations to Malaria Consortium, as Section 3.

Section 4, Roles and Responsibilities, identifies the Malaria Consortium staff members, with primary responsibility for implementation of *the Procedure*, to whom any suspicion of misconduct in research should be directed.

Section 5 provides guidance on reporting for persons suspecting misconduct in research related to the work of Malaria Consortium and an overview of *the Procedure*. It explains to whom and how their communication should be submitted and how it will be dealt with. It summarizes the steps to be undertaken by Malaria Consortium, and in some cases, other entities concerned, to deal with allegations of misconduct in research, draw conclusions on their veracity and move to whatever corrective or disciplinary measures may be warranted. The text is a summary of the UKRIO procedure referred to above. Further details – which are mainly needed by those staff members in Malaria Consortium tasked with implementing the procedure - are provided in the full document, which is publicly available on UKRIO's website.

[1] http://ukrio.org/wp-content/uploads/UKRIO-Procedure-for-the-Investigation-of-Misconduct-in-Research.pdf
[2] https://ori.hhs.gov/FR_Doc_05-9643
[3] https://www.malariaconsortium.org/gallery-file/02230530-91/whistle_blowing_policy.pdf

3 Definitions and terms

Accepted Procedures for research

Accepted procedures include but are not limited to the following[4]:

- gaining informed consent where required;
- gaining formal approval from relevant organisations where required;
- any protocols for research contained in any formal approval that has been given for the research;
- any protocols for research as defined in contracts or agreements with funding bodies and sponsors;
- any protocols approved by Regulatory Authorities for a trial of medicinal products;
- any protocols for research set out in the guidelines of the employing institution and other relevant partner organisations;
- any protocols for research set out in the guidelines of appropriate recognised professional, academic, scientific, governmental, national and international bodies;
- any procedures that are aimed at avoiding unreasonable risk or harm to humans, animals or the environment;
- good practice for the proper preservation and management of primary data, artefacts and materials;
- any existing guidance on good practice on research.

Accepted procedures do not include:

- un-consented to/ unapproved variations of the above;
- any procedures that would encourage, or would lead to, breaches in the law.

Although allegations of misconduct in research are often raised as departures from accepted procedures in the conduct of research, investigations should aim to establish intentional and/or reckless behaviour as set out in the definition of misconduct in research (below).

Complainant

The Complainant is a person making allegations of misconduct of research against one or more Respondents (see below)[5].

Disciplinary Process

The Disciplinary Process refers to Malaria Consortium's mechanisms for resolving disciplinary issues amongst its staff.

Employer

The Employer is defined in this Procedure as the person or organisation who has retained the person (e.g. the Respondent (see below)) to carry out work, usually, but not always, through a contract of employment.

[4] Note: As well as complying with accepted procedures, researchers must comply with all legislation that applies to their research.

[5] Note: Where reference is made to defined roles (such as Respondent) or defined bodies (Malaria Consortium) in the Procedure, reference to the singular should be viewed to include the plural as appropriate.

Formal Investigation

The Formal Investigation is that part of the Procedure which is intended to examine the allegations of misconduct in research, hear and review the evidence and determine whether the alleged misconduct occurred, take a view on who was responsible, and which may make recommendations as to any response that Malaria Consortium might make. The Formal Investigation will be preceded by the Screening Stage (see below).

Honorary Contract

Honorary contracts are used in a variety of circumstances. As a result, it is not possible to provide blanket guidance as to which organisation should lead an investigation into allegations of misconduct in research against someone holding such a contract. Examples of arrangements that commonly involve the issue of an honorary contract are:

- for a Malaria Consortium staff member with an arrangement to undertake teaching and/or research in a university, in which case the university would issue the honorary contract;
- for a clinician employed by a hospital and undertaking a research project for Malaria Consortium, in which case Malaria Consortium would issue the honorary contract.
- for a consultant employed by another organisation undertaking a project for Malaria Consortium, in which case Malaria Consortium would issue the honorary contract.

There are significant differences in the responsibilities that Malaria Consortium might have for an individual according to the type of honorary contract used. For example, Malaria Consortium staff with honorary contracts with a university, it is generally held that the honorary contract is a contract of employment in law and, therefore, depending on the circumstances of the case, the university might take the lead in an investigation of allegations of misconduct in research.

In the case of a clinician employed by a hospital and undertaking research for Malaria Consortium, however, the honorary contract issued by Malaria Consortium is not generally considered to be a contract of employment in law (though, in the case of a dispute, whether it is or not would be for a court to decide) and, in these circumstances, only the hospital, as the employer, could take the lead in an investigation of allegations of misconduct in research.

In either case, however, the outcome of any investigation by one party might affect the contractual relationship of the individual investigated with the other party. These are complex issues and it is therefore recommended that legal advice is sought before any investigation commences and that partner organisations liaise closely.

Misconduct in research

In discussing misconduct in research, which could be investigated using *the Procedure*, the following may serve as useful terms by way of guidance. Interpretation of the terms will involve judgements, which should be guided by previous experience and decisions made on matters of misconduct in research:

- Fabrication – the intentional misrepresentation of research results by making up data;
- Falsification – intentional changing or omitting of data such that the research is not accurately represented;
- Misrepresentation of data and/or interests and or involvement;
- Plagiarism – presenting someone else's work as your own without acknowledgement; and

- Failures to follow accepted procedures or to exercise due care in carrying out responsibilities for:
    - avoiding unreasonable risk or harm to:
        - humans;
        - animals used in research;
        - the environment.
    - the proper handling of privileged or private information on individuals collected during the research.
    - Not following procedures agreed by ethics committees or starting a study before ethical approval has been given.

For the avoidance of doubt, misconduct in research includes acts of omission as well as acts of commission. In addition, the standards by which allegations of misconduct in research should be judged should be those prevailing in the country in question and at the date that the behaviour under investigation took place.

The basis for reaching a conclusion that an individual is responsible for misconduct in research relies on a judgement that there was an intention to commit the misconduct and/or recklessness in the conduct of any aspect of a research project. Where allegations concern an intentional and/or reckless departure from accepted procedures in the conduct of research that may not fall directly within the terms detailed above, a judgement should be made as to whether the matter should be investigated using the Procedure.

Named Person

The Named Person is defined in *the Procedure* as the individual nominated by Malaria Consortium (see section 4) to have responsibility for receiving any allegations of misconduct in research; initiating and supervising the Procedure for investigating allegations of misconduct in research; maintaining the record of information during the investigation and subsequently reporting on the investigation to internal contacts and external organisations; and taking decisions at key stages of *the Procedure*.

The Named Person has a nominated alternate who should carry out the role in their absence or in the case of any potential or actual conflict of interest.

The Procedure

The Procedure refers to *Procedure for the investigation of misconduct in research* published in 2008 by the United Kingdom's Research Integrity Office (UKRIO).

Professional Body

A professional body is an organisation with statutory powers to regulate and oversee a particular profession, such as doctors or solicitors.

Regulatory Authority

A regulatory authority is an organisation with statutory powers to regulate and oversee an area of activity, such as health and safety, or medicines to be used on humans.

Research

A systematic investigation designed to develop or contribute to generalisable knowledge, as opposed to knowledge generated for the improvement of a particular project or programme (evaluation).

Respondent

The Respondent is the person against whom allegations of misconduct in research have been made. They must be a present or past employee of Malaria Consortium.[6]

Screening Stage

The Screening Stage is that part of *the Procedure* which is intended to determine whether there is *prima facie* evidence of misconduct in research. The Screening Stage does not determine whether misconduct occurred or who might be responsible.

Sponsor

Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study.

4 Roles and Responsibilities

Named person

James Tibenderana (Technical Director, Head Office, London)

Contact details:

Email: j.tibenderana@malariaconsortium.org

Responsibilities:

i. receiving any allegations of misconduct in research;
ii. initiating and supervising *the Procedure* for investigating allegations of misconduct in research;
iii. maintaining the information record during the investigation and subsequently reporting on the investigation with internal contacts and external organisations;
iv. taking decisions at key stages of *the Procedure*.

Nominated alternate

Charlotte Ward (Senior Research Officer, Head Office London)

Contact details:

Email: c.ward@malariaconsortium.org

[6] Note: Should the policies or practices of Malaria Consortium as an organisation be the subject of allegations of misconduct the Chief Executive Officer of Malaria Consortium would serve as the Respondent in the Procedure.

Responsibilities:

i. receive allegations of misconduct in research and initiate and supervise *the Procedure* for investigating them in the absence of the Named Person or if the allegation involves the Named Person.

5 Implementation

Submission of complaints or allegations

The Procedure is designed for the investigation of allegations of misconduct in research as defined in the Definitions and terms. Allegations of misconduct in research are often raised as departures from *accepted procedures* in the conduct of research (see Section 3).

Allegations of research misconduct must be submitted in writing to the Named Person by email and accompanied by any supporting evidence that is available to the Complainant. Any allegations of research misconduct submitted to the Named Person or Nominated Alternate will be treated confidentially. Should the Complainant prefer, they can make initial enquiries regarding their allegation of research misconduct with the Named Person anonymously. However, to take forward allegations the Complainant should make a formal written submission to the Named Person.

Complaints or allegations should be submitted using one of the two email addresses indicated in Section 4. The Senior Research Officer and Advisor warrant that incoming mails to these addresses are only seen by themselves and that all complaints and allegations of misconduct in research will be handled by them with full confidentiality.

Complaints about research may be brought by anybody concerned, not only Malaria Consortium staff. Therefore, the Research Misconduct Policy is made publicly available on Malaria Consortium's website.

Initial handling of received complaints or allegations

Acknowledgement of receipt

Upon receipt of allegations of misconduct in research, the Named Person should formally acknowledge receipt of the allegations by letter to the Complainant (and his/her representative by agreement), in which they should also advise them of the procedure that will be followed.

Review of allegations by the Named person

The Named Person should review the nature of the allegations by referring to the definition of misconduct in research. If the allegations are judged to fall within the definition, the Procedure should continue to the next stage. Where the allegations are outside the definition, the Named Person should communicate to the Complainant in writing:

- the reasons why the allegations cannot be investigated using *the Procedure*;
- which process for dealing with complaints might be appropriate for handling the allegations (if any); and to whom the allegations should be reported.

Minor issues and misunderstandings

Suspicions of research misconduct are at times the result of misunderstandings or dispute between individuals. It may be possible to mediate or resolve such differences at the individual or local level and this route should be considered and explored, before the formal steps of *the Procedure* are initiated. Thus, *the Procedure* should only be applied, if the allegations are serious, or where mediation and /or arbitration has been refused or proved unsuccessful.

Conflict of interest

Allegations which are in any way linked to the Named Person or which raises the potential for a conflict of interest for the Named Person – including links with any persons involved or where the Named Person is in some way personally concerned with the subject matter of the allegations – should immediately be referred to the Named Person's alternate who should then implement *the Procedure*. The Named Person should declare any such conflicts. The Complainant and Respondent may raise concerns that they might have that the Named Person may have interests which conflict with the fair handling of the allegations with the Chief Executive of Malaria Consortium. The Chief Executive should act on information passed on, or known about, with respect to any conflict of interest and invite the Named Person to refer the investigation to the alternate.

Immediate action

Where the allegations concern situations that require immediate action to prevent further risk or harm to staff, participants or other persons, suffering to animals or negative environmental consequences, the Named Person should take immediate action to ensure that any such potential or actual danger/illegal activity/risk is prevented/eliminated. In taking such actions it should be made clear to all parties that the actions taken are not to be regarded as disciplinary action and do not in themselves indicate that the allegation is considered true by Malaria Consortium.

The nature of the allegations may mean that it is necessary to notify legal or regulatory authorities, such as in situations as detailed above, where an activity is potentially or actually illegal and/or a danger to persons, animals and/or the environment. As a consequence of such notification, Malaria Consortium may be required to comply with an investigation led by a legal or regulatory body, which will ordinarily take precedence over *the Procedure*. *The Procedure* may continue in parallel but may have to be suspended, to be concluded later, or may have to be declared void by the Named Person. Where allegations include behaviour subject to defined sanctions in Malaria Consortium's disciplinary process, then the Named Person should take steps to implement that disciplinary process.

Allegations of misconduct in research that do not require notification to legal or regulatory bodies or other immediate action

Allegations of misconduct in research that do not require notification to legal or regulatory bodies or immediate referral to Malaria Consortium's disciplinary process should proceed to the next stage in the Procedure.

Where the allegations are within the definition of misconduct in research, the Named Person should inform Malaria Consortium's Chief Executive; Human Resources Director; Technical Director; and Chief Finance Officer about the allegations submitted.

If Malaria Consortium is not the Respondent's primary employer, the Respondent having only an honorary or secondary contract with them, the Named Person should contact the Named Person of the Respondent's primary employer and inform him/her of the allegations. The Named Person should investigate whether the research project which the allegations relate to includes contractual obligations that require Malaria Consortium to undertake prescribed steps in the event of allegations of misconduct in research being made.

The Named Person should liaise with Malaria Consortium's Human Resources Department to ensure that the rights of the Respondent and Complainant, and the integrity of the investigation are not compromised by any such actions. At all times, the Named Person should emphasise to all parties that the allegation is to be investigated, is as yet unproven and that the information is confidential.

Subject to processes that may override *the Procedure* as defined above in the legal and regulatory procedures or the Procedure to be managed by the Respondent's primary employee, the Named Person should inform the Respondent that allegations of misconduct in research have been made which involve them in a confidential meeting, with a representative of the Human Resources Department in attendance. The Respondent will be given the opportunity to respond to the allegations and set out their case at a later stage. A summary of the allegations in writing should be given to the Respondent (and their representative by agreement) at the meeting, together with a copy of the Procedure to be used to investigate the allegations.

Pre-Screening stage

The Named Person should ensure that all relevant information and evidence are secured, so that any investigation conducted under this Procedure can have access to them. This may include, but is not limited to:

- securing all relevant records, materials and locations associated with the work;
- liaising with the Human Resources Department and the relevant line manager(s) to:
    - request the temporary suspension of the Respondent from duties on full pay;
    - request the temporary barring of the Respondent from part, or all, of the premises of Malaria Consortium and any of research sites or sites of any partner organisation(s); and/or
    - request a temporary restriction be placed on the Respondent requiring them not to have contact with some or all of the staff of Malaria Consortium and those of any partner organisation(s).

The Named Person should only take such actions in situations where there is a clear risk to individuals or that evidence might be destroyed and only after careful consideration of those risks and consequences.

Once initiated *the Procedure* should progress to the natural end-point irrespective of:

- the Complainant withdrawing the allegations at any stage;
- the Respondent admitting, or having admitted, the alleged misconduct, in full or in part; and/or
- the Respondent or the Complainant resigning, or having already resigned, his/her post.

If the Named Person decides that the allegations are mistaken, frivolous, vexatious and/or malicious, the allegations will then be dismissed. This decision should be reported in writing to the Respondent

and the Complainant (and their representatives by agreement) and all the parties who had been informed initially. The Named Person should consider recommending to the appropriate authorities that action be taken under Malaria Consortium's disciplinary process against anyone who is found to have made frivolous, vexatious and/or malicious allegations of misconduct in research. Those who have made allegations in good faith should not be penalised and might require support. The Named Person should also take steps as required and appropriate to the seriousness of the dismissed allegations, to support the reputation of the Respondent and the research project(s).

The Preliminary and Pre-Screening stages of the Procedure should normally be completed within a maximum of 10 working days from the receipt of the allegations. Any delays should be explained to all parties in writing, and a revised completion date given.

The Named person may wish to consult UKRIO regarding allegations of research misconduct which have been received. The Named person can consult with, and report the progress of an investigation to, the UKRIO using specific forms contained in Annex 3 of the UKRIO Procedure.[7]

Screening stage

If the allegations cannot be entirely discounted at this point, the Named Person should convene a Screening Panel, as detailed below. The Screening Stage is intended to determine whether there is *prima facie* evidence of misconduct in research. The Screening Panel should be constituted and work in accordance with the Principles outlined in Section 2 and defined in Annex. The Screening Panel should determine whether the allegations of misconduct in research:

- are mistaken, frivolous, vexatious and/or malicious;
- should be referred directly to Malaria Consortium's disciplinary process or other internal process; or
- have some substance but due to a lack of intent to deceive or due to their relatively minor nature, should be addressed through education and training or other non-disciplinary approach rather than through the next stage of the Procedure or other Formal Proceedings; or
- are sufficiently serious and have sufficient substance to justify a Formal Investigation.

The Named Person should take great care to ensure that all information on the case is fully and accurately transferred to the Screening Panel. The Screening Panel should normally aim to complete its work within 30 working days of being convened. The Chair of the Screening Panel should make the draft findings available to the Named Person, who will forward them to the Respondent and the Complainant (and their representatives by agreement) for comment on the factual accuracy of the report. Only when the report includes errors of fact, as indicated by the Respondent and/or the Complainant, should the Screening Panel modify the report. The Chair should judge the validity of such comments and seek the agreement of the Panel before making amendments to the Panel's report.

The Chair should then forward the final version of the Screening Panel's report to the Named Person, the Respondent and the Complainant (and their representatives by agreement).

When there is clear evidence of an infringement that might contravene Malaria Consortium's disciplinary code, the Named Person should consult the nominated individual in the Human Resources

[7] *http://ukrio.org/wp-content/uploads/UKRIO-Procedure-for-the-Investigation-of-Misconduct-in-Research.pdf*

Department on the full and accurate transfer of all case information to the disciplinary process. A full written record should be kept of the decision to transfer to the disciplinary process.

When the allegations have some substance, but due to a lack of clear intent to deceive or due to their relatively minor nature, the matter should be addressed through Malaria Consortium's competency, education and training mechanisms, or other non-disciplinary processes, rather than through the Procedure's Formal Investigation stage. The investigation using *the Procedure* would then conclude at this point. The Named Person should take steps to establish a programme of training or supervision in conjunction with the Respondent and their line manager. This programme should include measures to address the needs of staff and students working with the Respondent.

Formal Investigation

Where the Screening Panel recommends that the Procedure should progress to the Formal Investigation stage, the Named Person should take immediate steps to set up the Investigation Panel. The Named Person should inform the following that a Formal Investigation of the allegations is to take place:

- Respondent (and their representative by agreement);
- Complainant (and their representative by agreement);
- Chief Executive;
- Human Resources Director;
- Technical Director;
- and Named Person of any Partner Organisation with which either the Respondent and/or Complainant has an honorary contract, and through them the Heads of Organisation, Human Resources and Research.

The Named Person should then convene the Formal Investigation Panel.

During the Formal Investigation, the Investigation Panel must interview the Respondent and Complainant. The role of the Investigation Panel is to review all the relevant evidence and conclude whether the allegations of misconduct in research are:

- upheld in full;
- upheld in part; or
- not upheld.

The Investigation Panel should provide a draft report of its findings to the Named Person, who should forward it to the Respondent and the Complainant for comment on the factual accuracy of the report. Only when the report contains errors of fact and matters that have bearing on the facts as indicated by the Respondent and/or the Complainant, and accepted by the Investigation Panel, should the Chair modify the report. The Chair should judge the validity of such comments and seek the agreement of the Panel before making amendments to the Panel's report.

The Investigation Panel should then produce a final report that:

- summarises the conduct of the investigation;
- states whether the allegations of misconduct in research have been upheld in whole or in part, giving the reasons for its decision and recording any differing views;
- makes recommendations in relation to any matters relating to any other misconduct identified during the investigation; and

- addresses any procedural matters that the investigation has brought to light within Malaria Consortium and relevant partner organisations and/or funding bodies.

In addition to reaching a conclusion over the nature of the allegations, the Investigation Panel may make recommendations with respect to:

- whether the allegation should be referred to the relevant organisation's disciplinary process;
- whether any action will be required to correct the record of research;
- whether organisational matters should be addressed by Malaria Consortium through a review of the management of research; and
- other matters that should be investigated.

The Report should be sent to the Named Person.

If all or any part of the allegations are upheld, the Named Person, the Human Resources Director and at least one other member of senior staff should then decide whether the matter should be referred to Malaria Consortium's disciplinary process or for other formal actions.

The Named Person should inform the following of the conclusion of the Formal Investigation:

- The Respondent and the Complainant (and their representatives by agreement);
- The Chief Executive, Chief Finance Officer, Technical Director, Human Resources Director, the Head(s) of other relevant Department(s) and any other relevant members of staff;
- If the Respondent and/or the Complainant are employed on joint clinical/honorary contracts, the Named Person, the Head of Human Resources and the Head of Research of the other organisation(s);
- Where appropriate, the responsible person within any relevant partner organisations, funding bodies and/or regulatory or professional bodies;
- Additionally, the Named Person may wish to inform UKRIO of the conclusion of the Formal Investigation using the forms in Annex 3 of the UKRIO Procedure[8].

Should the allegations proceed to Malaria Consortium's disciplinary process, the report of the Investigation Panel should form the basis of the evidence that the Disciplinary Panel receives. All the information collected and brought to light through the Procedure should be transferred to the disciplinary process.

Questions relating to the reports of both the Screening and Investigation Panels can only be raised with the Chair of either Panel over matters of fact. The Respondent should not have the option of appealing against the reports of either stage of the Procedure. The Respondent has the statutory right of appeal should the matter be referred to their employer's disciplinary process.

Actions to consider

Where the Investigation Panel concludes that the allegations are upheld in full or part, there may be a requirement to consider action in addition to any that might be recommended through Malaria Consortium's Disciplinary process. The Named Person should consider the use of the recommendations set out in any case where misconduct in research has been investigated. The timing of any actions taken should be compatible with Malaria Consortium's Disciplinary Process and Appeals Process.

[8] *http://ukrio.org/wp-content/uploads/UKRIO-Procedure-for-the-Investigation-of-Misconduct-in-Research.pdf*

6 The Procedure presented as diagrams

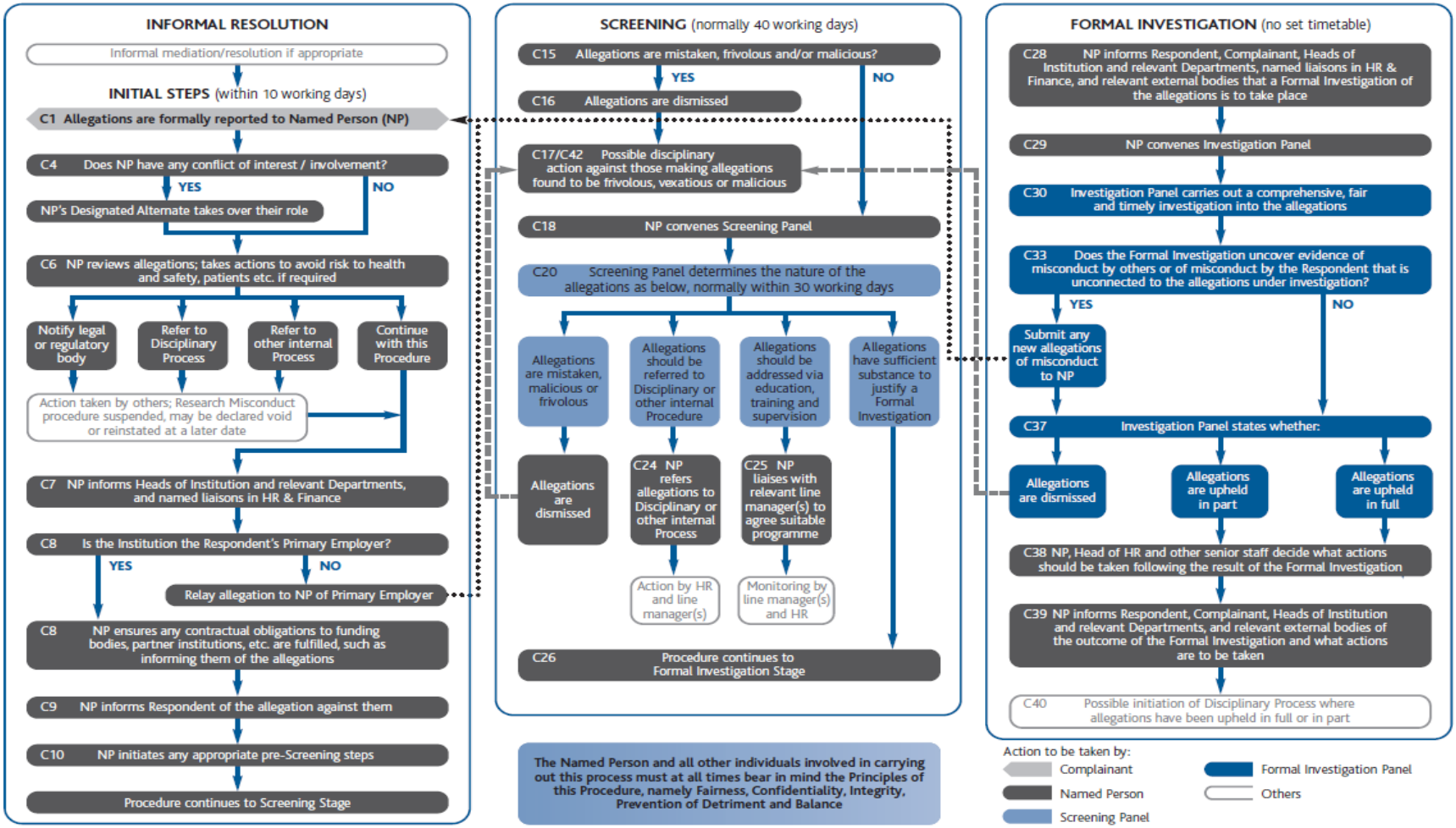

Figure 1 Procedure for the investigation of Misconduct in Research (UK Research Integrity Office). For full description, visit: http://ukrio.org/wp-content/uploads/UKRIO-Procedure-for-the-Investigation-of-Misconduct-in-Research.pdf

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