

PROCEDURE FOR THE INVESTIGATION OF MISCONDUCT IN RESEARCH

August 2008



UK Research Integrity Office



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Foreword

This Procedure has been prepared by the UK Panel for Research Integrity in Health and Biomedical Sciences. It provides organisations with a protocol for the investigation of allegations of misconduct in research that is thorough and fair to all parties. It is applicable to all fields of research; while the Procedure was drafted with research in relation to health and biomedical sciences particularly in mind, it can be used to investigate alleged misconduct in any area of research.

The Procedure is designed to meet a need that may arise infrequently in most organisations engaged in research. When it does, it can have wide-ranging and damaging consequences, made worse if not addressed appropriately. When an allegation of misconduct in research is made, timely, thorough and objective actions, as described in this Procedure, should enable employers to carry out a full and fair investigation.

Research is a complex and increasingly specialised activity. It often requires the knowledge and experience of several experts in the field to discern whether misconduct has taken place. The Procedure includes routes through which an organisation may contact the UK Research Integrity Office (UKRIO) for advice and guidance from expert advisers experienced in handling investigations.

We encourage organisations in which staff conduct research to adopt the Procedure as part of their policies and systems for the promotion of good practice and integrity in research. Through the widespread adoption and consistent use of the Procedure, it is anticipated that investigations into allegations of misconduct in research carried out by universities and other organisations will be conducted to the standards of objectivity, rigour and fairness set out here.

The Procedure is a key part of a wider system of governance for research enabling employers to discharge their responsibilities effectively. It is central to the philosophy of the project that the UK Panel works closely with employers, professional networks and other groups to embed good practice in research.

We are grateful to members of the UK Panel for Research Integrity in Health and Biomedical Sciences for the way they applied their time and knowledge to produce this publication and for their continued commitment in support of its use. Thanks also go to the staff of UKRIO involved.



Professor Sir Ian Kennedy
Chair of the UK Panel



Professor Michael Farthing
Vice-Chair



Dr Marc Taylor
Vice-Chair

Procedure for the investigation of misconduct in research

Executive Summary

The Procedure described in this document is designed as a model procedure for universities and other research organisations to follow for the investigation of allegations of misconduct in research. Such allegations might be brought to an Organisation as the employer of the individual against whom the allegations are made, or brought to them in another capacity, such as the host or sponsor of the research. Where a situation is clearly of a very serious nature, the appropriate authority or regulatory body should be notified at the earliest practicable opportunity. Advice and guidance are available from the UK Research Integrity Office (UKRIO) on the most appropriate steps to take in following this Procedure.

It is not intended that the Procedure should be used as part of any disciplinary or regulatory process. Information gathered in the course of an investigation may become relevant to, and disclosed in, any such disciplinary or regulatory process. This document provides a blueprint for how the stages of the investigation should be conducted and how appropriate screening and investigation panels might be organised. The objectives of the Procedure are to:

- ensure that an investigation is thorough and fair;
- demonstrate that, by using an agreed standard process, there should be fewer errors in the conduct of investigations; and
- reassure those who are under investigation that the process of investigation will follow a standard procedure adopted nationally by universities and other research organisations.

By adopting and following the Procedure it should be possible to:

- establish the ethos and mechanisms by which misconduct in research may be addressed appropriately, investigated effectively and handled fairly;
- enable an expert panel to establish whether the allegations have substance and constitute misconduct in research;
- enable an expert panel to establish whether, on the balance of probabilities, the evidence upholds the allegations of misconduct in research (either intentional or reckless in nature); and
- produce a report on the basis of which the Organisation may initiate appropriate action.

The Procedure should only be used in conjunction with the Principles laid out in Annex 1. Investigations of misconduct in research should maintain the highest standards of integrity, accuracy and fairness. All proceedings must be conducted under the presumption of innocence and carried out with sensitivity and confidentiality.

The stages outlined in the Procedure have been developed for the investigation of the acts or omissions defined in Annex 2 as misconduct in research. Alternative processes should be used to investigate other forms of misconduct and misconduct in research that is of sufficient seriousness should be reported to the appropriate authority or regulatory body. Although the Procedure was

designed for particular application to health and biomedical research, it could be used to investigate alleged misconduct in all fields of research.

The steps of the Procedure should be followed as closely as is practicable.

Footnote to the first edition

It is the intention of the UK Panel that the Procedure will be reviewed regularly, initially on an annual basis. The Procedure will be available on the UKRIO website (www.UKRIO.org) and organisations are recommended to check there for updates.

The website also hosts a route to contact UKRIO to gain access to expert advice and guidance and to offer feedback on the use of the Procedure and other good practice in addressing allegations of misconduct in research.

Background for the use of the Procedure

- A1 This Procedure has been developed by the UK Panel for Research Integrity in Health and Biomedical Sciences to assist Organisations to undertake full and fair investigations of allegations of misconduct in research brought to their attention by internal or external sources. Although the Procedure was designed for particular application to health and biomedical research, it could be used to investigate alleged misconduct in all fields of research.
- A2 The Procedure is intended to be used in accordance with the Principles attached at Annex 1. Those responsible for implementing the Procedure should be guided by the Principles at all times to ensure that the Procedure is carried out in a comprehensive, fair, and timely manner, and with integrity, sensitivity and confidentiality.
- A3 The Procedure is a mechanism to investigate allegations of misconduct in research. As such it is designed to provide a means to facilitate full exploration of potentially complex matters in research that can arise in situations where misconduct may have taken place.
- A4 The Procedure has been designed to be additional to the Organisation's existing procedures for handling situations where allegations of misconduct are made. It is designed to be used in its entirety prior to any use of the Organisation's standard disciplinary process. It is intended to allow the full and fair investigation of research-related issues, using an expert panel to investigate the matters raised, and to reach a conclusion on any allegations prior to considering any disciplinary or other non-disciplinary steps that might be required or recommended.
- A5 In addition, the individuals responsible for using this Procedure should do so with a good working knowledge of the statutory obligations of the Organisation and the rights of employees according to employment law and other relevant legislation, such as the Public Interest Disclosure Act. Further, they should have knowledge of any additional rights and obligations that might be particular to the Organisation and/or its employees – for example, those bestowed by the statutes and ordinances of a university.
- A6 Those using this Procedure should also take advantage of advice and guidance available from UKRIO, the Office which supports the Panel, and other relevant bodies, and should seek legal advice where appropriate and necessary.

In situations where the allegations are of a serious nature, formal steps should be implemented immediately (see Parts C 5 and C 6).

- A7 In research, situations arise that might present as misconduct but are the result of either a misunderstanding or a 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 where appropriate, before the formal steps in Part B of this Procedure are initiated. Where appropriate, opportunities to resolve matters through mediation should be considered. Options for internal and/or external arbitration and/or dispute resolution might also be explored. In such situations, Part B of the Procedure should only be taken forward if the informal route is considered to be inappropriate, due to the serious nature of the allegations, or where mediation and/or arbitration has been refused or proved unsuccessful.

Note that allegations can be investigated under this Procedure irrespective of such developments as:

- *the Complainant withdrawing the allegation at any stage;*
- *the Respondent admitting, or having admitted, the alleged misconduct, in full or in part; or*
- *the Respondent or the Complainant resigning, or having already resigned, their post.*

A8 Those entitled to bring complaints about research are not restricted to being a member of staff (present or past) of the Organisation.

Part B

Preparatory steps

- B1** A research Organisation (the Organisation; see definitions in Annex 2) should designate a senior member of staff as the Named Person and another member of staff as a nominated alternate, to act in his/her absence. Additionally, the Organisation should nominate senior individuals in the Personnel Department, Finance Department/Research Grants Office, ideally with some experience of research, who should liaise with the Named Person, to investigate allegations of misconduct in research.
- B2** The Named Person should:
- a be an individual within the Organisation with significant knowledge and experience of research.
 - b have responsibility for:
 - 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.
 - c have a nominated alternate who will receive allegations of misconduct in research and initiate and supervise the Procedure for investigating them in the absence of the Named Person;
- B3** The Named Person and his/her nominated alternate should not be:
- a the Head of Organisation;
 - b the Head of Research; or
 - c the Head of Personnel.
- B4** The Organisation should clearly indicate that it is using the Procedure for the investigation of allegations of misconduct in research and promote it internally and externally in a form that is both readily accessible and user-friendly. It should also clearly state the Principles (Annex 1), which are to be used and make clear that all parties involved have access to advice and guidance from UKRIO and other sources. In support of the Procedure, the Named Person should secure the agreement from experienced members of the permanent academic staff to contribute to the work of the Panels (see Annexes 4 and 5).
- B5** The Procedure is designed specifically for the investigation of allegations of misconduct in research as defined in Annex 2. Allegations of misconduct in research are often raised as departures from accepted procedures in the conduct of research (see definition). The Procedure should only be used for investigating the intentional and/or reckless behaviour set out in the definition of misconduct in research (see definition). Allegations relating to other forms of misconduct should be investigated using the appropriate procedure(s).

For the investigation of allegations in which the respondent is a student at the Organisation rather than an employee, the Organisation should follow the relevant student variant of this Procedure.

- B6 The Procedure defined here is designed to provide a report that might require action using the Organisation's disciplinary process or through other non-disciplinary processes.
- B7 The Procedure is designed to operate in conformity with the Principles outlined in Annex 1. Those using the Procedure should refer to the Principles with respect to all decisions or interpretations. Where they are unable to resolve matters by reference to the Principles, users of the Procedure should seek appropriate guidance from a source such as UKRIO.

Part C

The Procedure

- C1 The Procedure allows allegations of misconduct in research to be investigated once submitted to the Named Person formally in writing (where possible). Situations that are not considered to be serious in nature might be resolved by informal discussion and/or arbitration and/or dispute resolution, without the requirement for a formal investigation, should be reviewed through other means at the appropriate level (Part A 7). The Named Person can seek advice from UKRIO regarding whether such informal mechanisms might be appropriate for a particular allegation.
- C2 The Named Person should establish an accessible means to receive formal allegations from Complainants, from both within and outside the Organisation. This system must be confidential and enable allegations to be made without the name of the Complainant being known except to the Named Person initially. The allegations should be submitted in writing (where possible) and be accompanied by any supporting evidence that is available to the Complainant.
- C3 An initial approach to the Named Person might be anonymous but to take forward allegations the Complainant should make a formal written submission, in confidence if it is so desired, to the Named Person.
- C4 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 (Respondent or Complainant) 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 Head of the Organisation. The Head of the Organisation 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 his/her alternate.

Preliminary steps

- C5 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 he/she should also advise him/her of the Procedure that will be followed.
- C6 The Named Person should review the nature of the allegations and, where they 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 (where this might contravene the law or fall below good practice), then the Named Person should take immediate appropriate 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 to be true by the Organisation.

- a 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, the Organisation may be required to comply with an investigation led by a legal or regulatory body, which will ordinarily take precedence over this 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.
- b Where allegations include behaviour subject to defined sanctions in the Organisation's disciplinary process, then the Named Person should take steps to implement that disciplinary process. As above, the Procedure may continue in parallel with the disciplinary process but may have to be suspended, to be concluded later, or be declared void by the Named Person.
- c The Named Person should review the nature of the allegations by referring to the definition of misconduct in research detailed in Annex 2. 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 this Procedure;
 - which process for dealing with complaints might be appropriate for handling the allegations (if any); and
 - to whom the allegations should be reported.
- d Allegations of misconduct in research that do not require notification to legal or regulatory bodies or immediate referral to the Organisation's disciplinary process should proceed to the next stage in the Procedure.

- C7 Where the allegations are within the definition of misconduct in research, the Named Person should inform the Organisation's:
- Head of Organisation;
 - Head of Personnel;
 - Head of Research; and
 - Head of Finance;

that allegations of misconduct in research have been received on a particular date and that it will be investigated using this Procedure. They should be provided in confidence with the following information:

- the identity of the Respondent;
- the identity of the Complainant;
- details of all sources of internal and external funding;

- details of all internal and external collaborators for the research in question; and
- other details that the Named Person considers appropriate.

It should be stressed that the allegations of misconduct in research that are to be investigated are as yet unproven and that the information is confidential.

The Head of the Organisation should not take charge of the investigation or otherwise become involved in the Procedure at this stage, as he/she may later need to take a role in the management of the investigation. Should it be clear that the Named Person is not handling the investigation effectively the Head of the Organisation should take steps to remedy the situation.

- C8 The Named Person should then, in conjunction with the nominated individuals in Personnel and Finance/ Research Grants Office (see Part B 1), investigate the contractual status of the Respondent and the contractual details specific to the research project(s) related to the allegations.

If the Organisation 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 the Organisation to undertake prescribed steps in the event of allegations of misconduct in research being made. Such an undertaking might be in:

- a contract from a funding organisation;
- a partnership contract/agreement/Memorandum of Understanding; or
- an agreement to sponsor the research.

An external Sponsor, funding organisation and/or collaborators might have a valid interest in, or responsibility for, the way that the investigation is conducted. The Named Person should confirm whether the Organisation has any contractual/legal obligations towards such organisations concerning any aspects of the investigation to ensure that any such obligations are fulfilled at the appropriate time through the correct mechanisms. The Named Person should liaise with the Organisation's Personnel 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.

- C9 Subject to processes that may override the Procedure as defined at Parts C 6 (a) and (b) (legal or regulatory procedures) or C 8 above (the Procedure to be managed by the Respondent's primary employer), the Named Person should inform the Respondent that allegations of misconduct in research have been made which involve him/her. The Respondent should be informed of this in a confidential meeting, with a representative of the Personnel Department in attendance. The purpose of this meeting is to notify the Respondent formally that allegations of misconduct in research have been made against

him/her. The Respondent will be given the opportunity to respond to the allegations and set out his/her case at a later stage.

The Respondent may be accompanied to this meeting by a colleague or trade union representative or whoever else is specified in any additional contractual rights (such as by university statutes and ordinances). If the allegations are made against more than one Respondent, the Named Person should inform each individual separately and not divulge the identity of any other Respondent. A summary of the allegations in writing should be given to the Respondent (and his/her representative by agreement) at the meeting, together with a copy of the Procedure to be used to investigate the allegations. The Named Person should outline the Procedure to be used and the opportunities the Respondent will have to respond. The Named Person should also offer a timetable for the Procedure relating to the Screening stage.

The Named Person should ensure that, in using any part of the Procedure for the investigation of the allegation of misconduct in research, any required actions are carried out to protect the interests of staff and students of the Organisation and colleagues and students of the Respondent and/or the Complainant.

Pre-Screening stage

C10 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 Personnel 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 the Organisation and any of the sites of any partner organisation(s); and/or
 - request a temporary restriction be placed on the Respondent requiring him/her not to have contact with some or all of the staff of the Organisation 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. The reason(s) for taking any such actions should be recorded in writing and communicated to all relevant parties. In taking such action the Named Person should reassure the Respondent that it is not part of any disciplinary action and does not indicate that the allegations are believed to be true by the Organisation; rather it should be stressed that it is essential to ensuring that the allegations of misconduct can be properly investigated. Steps to suspend or bar a member of staff should take into account his/her responsibilities for supervision, teaching and management and make alternative arrangements to meet these responsibilities. Any suspension or barring of the Respondent should be reviewed throughout the Procedure to ensure that it is not unnecessarily protracted.

It should be noted that securing all relevant records, materials and locations associated with the research in question is likely to be essential in order to carry out a full and fair investigation. Also note that the Respondent is to be provided with copies of any records and materials that are secured.

- C11 In considering the allegations and the information available, the Named Person may decide that additional investigations into related but separate issues of misconduct in research need to be instigated.
- C12 The Named Person may wish to consult UKRIO regarding allegations of misconduct in research which have been received. The Named Person can communicate with UKRIO for advice and guidance, using the forms in Annex 3 to inform UKRIO of the matter raised and guidance that might be required. The forms are also used to provide updates as the investigation is taken forward. Information provided to UKRIO will be held in confidence.
- C13 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.
- C14 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.

Screening

- C15 The Named Person should carry out an initial investigation of the allegations to determine whether they are mistaken, frivolous, vexatious and/or malicious. This should be completed within 10 working days.

In circumstances where it is acknowledged that problems exist between individuals, it may still be appropriate to conduct an initial investigation to establish whether the allegation may have sufficient substance to warrant a Formal Investigation of misconduct in research.

- C16 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.

C17 The Named Person should consider recommending to the appropriate authorities that action be taken under the Organisation’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 (see Annex 6).

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) (see Annex 6).

C18 If the allegations cannot be entirely discounted at this point, the Named Person should convene a Screening Panel, as detailed in paragraph C 19 below.

C19 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 at Annex 1 and the process outlined in Annex 4.

C20 The Screening Panel should determine whether the allegations of misconduct in research:

- are mistaken, frivolous, vexatious and/or malicious;
- should be referred directly to the Organisation’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.

C21 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.

C22 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).

C23 When the allegations are considered mistaken, frivolous, vexatious and/or malicious, they will be dismissed. The Named Person should then take such steps, as are appropriate in the light of seriousness of the allegations, to sustain the reputation of the Respondent and the relevant research project(s) (see Annex 6).

In addition, the Named Person should consider recommending to the appropriate authorities that action be taken under the Organisation'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 (see Annex 6).

- C24 When there is clear evidence of an infringement that might contravene the Organisation's disciplinary code, the Named Person should consult the nominated individual in the Personnel Department (see Part B 2) 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.
- C25 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 the Organisation'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 his/her line manager. This programme should include measures to address the needs of staff and students working with the Respondent.
- C26 When the Screening Panel considers that the allegations are sufficiently serious and have sufficient substance to warrant recommending a Formal Investigation, the Named Person should take immediate steps to set up a Formal Investigation.

Formal Investigation

Note that the Formal Investigation is designed to ensure the full and fair exploration of the allegations in the context of research and is not intended to replace or subsume any existing Disciplinary Process. The outcome of the Formal Investigation might be to recommend a transfer to the Organisation's Disciplinary Process

- C27 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.
- C28 The Named Person should inform the following that a Formal Investigation of the allegations is to take place:
- Respondent (and his/her representative by agreement);
 - Complainant (and his/her representative by agreement);
 - Head of Organisation;
 - Head of Personnel;
 - Head of Research; and

- Named Person of any Partner Organisation with which either the Respondent and/or Complainant has an honorary contract, and through him/her the Heads of Organisation, Personnel and Research.

At this stage, the Named Person may wish to consult UKRIO for advice and guidance (see paragraph C 12, above), particularly regarding the nomination of members from outside the Organisation to the Formal Investigation Panel (see C 29 and Composition of the Investigation Panel in Annex 5).

C29 The Named Person should then convene the Formal Investigation Panel. The Investigation Panel should be constituted and work in accordance with the Principles outlined at Annex 1 and the process outlined in Annex 5. The Investigation Panel should examine the evidence collected during the Screening Panel's investigation following the original allegations and investigate further as required.

C30 During the Formal Investigation, the Investigation Panel must interview the Respondent and Complainant (see Annex 5). 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.

C31 The standard of proof used by the Investigation Panel is that of "on the balance of probabilities".

C32 The Investigation Panel may conclude that allegations are not upheld for reasons of being mistaken, frivolous, vexatious and/or malicious.

C33 Should any evidence of Misconduct be brought to light during the course of the Formal Investigation that suggests:

- further, distinct instances of misconduct in research by the Respondent, unconnected to the allegations under investigation; or
- misconduct in research by another person or persons,

then the Investigation Panel should submit these new allegations of misconduct in research to the Named Person in writing, along with all supporting evidence, for consideration under the initial steps of the Procedure.

C34 The Investigation Panel must be appointed within 30 working days of the submission of the Screening Panel's report recommending a Formal Investigation. In carrying out the Formal Investigation the Investigation Panel will not work to a prescribed timetable. The Panel should conduct the investigation as quickly as possible without compromising the Principles of the Procedure.

C35 The Chair of the Investigation Panel should report the progress made by the Investigation Panel, by reference to criteria agreed by the Panel in advance, to the Named Person on a monthly basis. The Named Person should also then provide appropriate information on the progress of the investigation to other interested parties, which may include sending details of progress to UKRIO on the forms included at Annex 3 (see paragraph C 12, above).

- C36 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 (and their representatives by agreement) 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.
- C37 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 the Organisation 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:

- a whether the allegations should be referred to the relevant organisation's disciplinary process;*
- b whether any action will be required to correct the record of research;*
- c whether organisational matters should be addressed by the Organisation through a review of the management of research; and*
- d other matters that should be investigated.*

The Report should be sent to the Named Person.

- C38 If all or any part of the allegations are upheld, the Named Person, the Head of Personnel and at least one other member of senior staff should then decide whether the matter should be referred to the Organisation's disciplinary process or for other formal actions.
- C39 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 Head of Organisation, the Head of Research, the Head of Personnel, the Head(s) of the 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 Personnel 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 at Annex 3.

- C40 Should the allegations proceed to the Organisation'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.

The Disciplinary Panel will receive all information on the case in a meeting with the Chair of the Investigation Panel and the Named Person, to ensure that all relevant material is transferred.

- C41 Where allegations have not been upheld (in full or in part), the Named Person should take such steps as are appropriate, given the seriousness of the allegations, to support the reputation of the Respondent and any relevant research project(s) (see Annex 6).
- C42 As with the Screening Process, where the Investigation Panel concludes the allegations are frivolous, vexatious and/or malicious, the Named Person should consider recommending to the appropriate authorities that action be taken under the Organisation's disciplinary process against anyone who is found to have made frivolous, vexatious and/or malicious allegations of misconduct in research.
- C43 It is not intended that the Procedure should be used as part of any disciplinary or regulatory process. Information gathered in the course of an investigation may become relevant to, and disclosed in, any such disciplinary or regulatory process.
- C44 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 (Annexes 4 and 5). 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 his/her employer's disciplinary process.

Those who have made allegations in good faith should not be penalised and might require support (see Annex 6).

Actions to consider

- C45 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 the Organisation's Disciplinary process. This includes such issues as those that are addressed in Annex 6. The Named Person should consider the use of the recommendations set out in any case where misconduct in research has been investigated.
- C46 The timing of any actions taken should be compatible with the Organisation's Disciplinary Process and Appeals Process.

Annex 1

Principles

- 1 Misconduct in research is a serious matter. Equally, the investigation of allegations of misconduct in research must be conducted in accordance with the highest standards of integrity, accuracy and fairness.
- 2 Those responsible for carrying out investigations of alleged misconduct in research should act with integrity and sensitivity at all times.
- 3 The following principles of Fairness, Confidentiality, Integrity, Prevention of Detriment, and Balance as defined below must inform the carrying out of this Procedure (Parts A, B and C) for the investigation of allegations of misconduct in research

Fairness

- 4 The investigation of any allegations of misconduct in research must be carried out fairly and in accordance with the statutory human rights of all parties involved.
- 5 Those responsible for carrying out this Procedure should do so with knowledge of:
 - the statutory obligations of the Organisation and the rights of employees according to current law;
 - any additional rights and obligations particular to the institution and/or its employees – for example those bestowed by university statutes and ordinances.
- 6 Where anyone is formally accused of misconduct in research, that person must be given full details of the allegations in writing*.

** Note the only exception to this Principle might be in circumstances where the allegations involve matters which are subject to a covert criminal investigation.*

- 7 When someone is formally investigated for alleged misconduct in research, he/she must be given the opportunity to set out his/her case and respond to the allegations against him/her.
- 8 He/she must also be allowed to:
 - ask questions;
 - present information (evidence) in his/her defence;
 - adduce evidence of witnesses;
 - raise points about any information given by any witness (regardless of who has called the witness in question).

- 9 The Respondent, Complainant and any witnesses involved in the Screening Process or the process before the Investigation Panel may:
- be accompanied by a fellow employee or trade union representative when he/she is required or invited to attend meetings relating to this Procedure;
 - seek advice and assistance from anyone of his/her choosing.

In the case of the Respondent(s), this is a statutory right under employment law. Some employees may have additional contractual rights (such as through university statutes and ordinances) to be accompanied by persons other than those listed above, for example a partner, spouse or legal representative.

- 10 To ensure a fair investigation, an individual may not be a member of both the Screening Panel and the Investigation Panel and, if he/she has been involved in either, he/she should not be part of the Organisation's Disciplinary Process.

Confidentiality

- 11 The Procedure should be conducted as confidentially as is reasonably practicable. The confidential nature of the proceedings should be maintained provided this does not compromise either the investigation of the misconduct allegations, any requirements of health and safety or any issue related to the safety of participants in research.
- 12 The confidential nature of the proceedings is essential in order to protect the Complainant, the Respondent and others involved in the Procedure.
- 13 It is important that in the conduct of an investigation using this Procedure that the principles of confidentiality and fairness are applied with appropriate balance for both the Respondent and the Complainant, (see points 40 to 43 inclusive below).
- 14 The identity of the Complainant or the Respondent should not be made known to any third party unless:
- it has been deemed necessary (by those conducting the investigation) in order to carry out the investigation;
 - it is necessary as part of action taken against the Respondent when (at the end of the Procedure and the Organisation's disciplinary/appeals processes) the allegations have been upheld;
 - it is necessary as part of action taken against a person who has been found to have made malicious, vexatious or frivolous allegations;
 - it is the stated policy of the employer/funder/other national body that the identity of individuals proved through appropriate disciplinary and appeals processes to have committed misconduct in research should be made public.

Any steps to reveal the name of the Respondent or Complainant in public, arising from the investigation of allegations of misconduct in research, should be taken only at the conclusion of the Organisation's disciplinary and appeals processes and where there is a requirement and/or provision to do so.

- 15 Any disclosure to a third party of the identity of the Complainant or Respondent, or of any other details of the investigation, should be made on a confidential basis. The third party should understand this, and that he/she must respect the confidentiality of any information received.
- 16 The Organisation and/or its staff may have contractual/legal obligations to inform third parties, such as funding bodies or collaborating organisation(s), of allegations of misconduct in research. In such cases, those responsible for carrying this Procedure out should ensure that any such obligations are fulfilled at the appropriate time through the correct mechanisms, always keeping in mind the legal rights of the employees involved in the allegations.
- 17 While the allegations are under investigation using this Procedure (and/or the Organisation's disciplinary process), the Complainant, the Respondent, witnesses or any other persons involved in this Procedure should not make any statements about the allegations to any third parties, unless formally sanctioned by the Organisation or otherwise required to by law.
- 18 Breaching confidentiality may lead to disciplinary action, unless covered by the Public Interest Disclosure Act and/or the Organisation's own grievance or whistle-blowing procedures.
- 19 In the event of any conflict between the principle of confidentiality and any of the other principles of this Procedure, those conducting the Procedure should consider the principle of Balance (see points 40 to 43 inclusive below).

Integrity

- 20 An investigation into allegations of misconduct in research using the processes of Screening or Formal Investigation of the Procedure must be fair and comprehensive. The investigation should be conducted expediently although without compromise to the fairness and thoroughness of the process.
- 21 Anyone asked to take part in the processes as a Panel member (as detailed at Annexes 4 and 5) must make sure that the investigation is impartial and extensive enough to reach a reasoned judgement on the matter(s) raised.
- 22 Similarly, those who give evidence to the investigation should do so honestly and objectively in accordance with the Principles of the Procedure and should be provided with relevant sections of the Procedure before giving evidence.

- 23 All parties involved must inform the Named Person immediately of any interests that they have which might constitute a conflict of interest as regards any aspect of the allegations, the investigation, the area(s) of research in question, or any of the persons concerned. Where the Named Person has any interest which might constitute a conflict, he/she should declare any such conflicts and refer the investigation to his/her nominated alternate, who should decide if he/she should be excluded from involvement in the investigation, recording the reasons for the decision (see C 4, above).

Note: The declaration of an interest by an individual does not automatically exclude him/her from participating in the investigation. The Named Person should decide if an interest declared by the individual warrants exclusion from involvement in the investigation and record the reasons for the decision.

- 24 In the interests of openness and transparency, inviting members from outside the Organisation to join both the Screening and Formal Investigation Panels of the Procedure is recommended.
- 25 Detailed and confidential records should be maintained on all aspects, and during all stages, of the Procedure. It is the responsibility of the Named Person to see that such records are maintained and made available at all stages for any use of the Organisation's Disciplinary Processes.
- 26 At the conclusion of the proceedings, all records should be retained by the Organisation (Personnel Department), for as long as the Organisation's policy for maintaining such records requires. It is recommended that this should not be shorter than six years.
- 27 To preserve the integrity of this Procedure, great care must be taken to ensure that all relevant information is transferred to those involved in the various stages of the Procedure, such as between the Screening Panel and any Investigation Panel and between the Investigation Panel and any Disciplinary Process.
- 28 Those responsible for carrying out the Procedure should recognise that failure to transfer information could lead to the process being unfair to the Respondent and/or the Complainant. It could also lead to an appeal being made on the grounds of a failure to observe the Procedure or to the collapse of the investigation.
- 29 Suggested good practice on the keeping, transfer and storage of records can be found in Annex 7.

Prevention of Detriment

- 30 In using this Procedure, and in any action taken as a result of using the Procedure, care must be taken to protect:
- individuals against frivolous, vexatious and/or malicious allegations of misconduct in research;

- the position and reputation of those suspected of, or alleged to have engaged in, misconduct, when the allegations or suspicions are not confirmed; and
- the position and reputation of those who make allegations of misconduct in research in good faith, i.e. in the reasonable belief and/or on the basis of supporting evidence that misconduct in research may have occurred.

- 31 The Pre-Screening and Screening stages of the Procedure are intended to determine whether allegations are mistaken, frivolous, vexatious and/or malicious. Only allegations that are judged to be sufficiently serious and of sufficient substance will proceed to a Formal Investigation.
- 32 It is acknowledged that allegations may be made for what appear to be malicious reasons. The Procedure should still be used where the Complainant makes a formal complaint, to establish whether the allegations are of sufficient substance to warrant investigation.
- 33 Anyone accused of misconduct in research is entitled to the presumption of innocence.
- 34 Formal Investigation should establish, on the balance of probabilities, the truth of any allegations.
- 35 Any formal steps taken to discipline or otherwise reprimand the Respondent, or take steps which might undermine his/her good name or reputation (or that of any other party), must be taken through the Organisation's disciplinary process which provides the Respondent with the right of appeal. Only when allegations have been upheld through the Organisation's disciplinary process and, where called upon, the appeals process, may it be appropriate to apply any sanctions to the Respondent.
- 36 The Organisation must take all reasonable steps to ensure that the Respondent (or any other party) does not suffer because of unconfirmed or unproven allegations.
- 37 Involvement of the Respondent in the Procedure should not prevent the Respondent from being considered:
- for promotion;
 - or the completion of probation;
 - or other steps related to his/her professional development.

The Organisation may choose to suspend the implementation of any promotion, completion of probation or any similar step, for the period that allegations are investigated using the Procedure, rather than delay the actual consideration of such matters.

If the allegations are upheld at the end of the Procedure, subject to the Organisation's disciplinary process and/or appeals process, the Organisation's normal rules with respect to steps related to professional development, such as those detailed above, should apply.

- 38 It should be made clear that any actions that might be taken by the Named Person in response to the notification of allegations of misconduct in research are not to be regarded as a disciplinary action and do not in themselves indicate that the allegations are believed to be true by the Organisation. The Named Person and members of any Screening and Formal Investigation Panels should take steps to make it clear to the Respondent,

Complainant and any other involved parties that these actions are necessary to ensure that the allegations of misconduct in research can be properly investigated.

Note: It is recognised that an organisation may have existing internal procedures and/or legal obligations concerning staff who are under Formal Investigation of any type of misconduct and these may take precedence over the above guidelines.

- 39 Appropriate action should be taken against:
- Respondents where the allegations of misconduct in research have been upheld in accordance with this Procedure; and
 - anyone who is found to have made frivolous, vexatious and/or malicious allegations of misconduct in research.

Balance

- 40 Those responsible for carrying out this Procedure must be aware that there may be occasions when a balance has to be struck in the application of the Principles: for example, it may, in certain circumstances prove to be impracticable to undertake a detailed screening of the allegations without releasing the Complainant's identity to the Respondent.
- 41 The Named Person should be responsible for resolving any such conflicts between the Principles, keeping in mind at all times that the primary goal of this Procedure is to determine the truth of the allegations. The Named Person can seek guidance from UKRIO and other bodies, as well as seeking legal advice.
- 42 In addition, the Named Person should be responsible for ensuring the integrity of this Procedure and any actions taken as a consequence of it. The Named Person should decide the course of action to be taken in cases of doubt.
- 43 The Named Person should keep a written record of all decisions taken throughout all the steps of the Procedure. The Named Person should liaise closely with the Chairs of the Screening and Formal Investigation Panels to ensure that a proper record is maintained throughout the Procedure.

Annex 2

Definitions

1 Accepted Procedures (for research)

Accepted procedures include but are not limited to the following.

- 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 the Medicines and Healthcare products Regulatory Authority (MHRA) 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.

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

2 Complainant

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

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

3 **Disciplinary Process**

The Disciplinary Process refers to an Organisation's mechanism for resolving disciplinary issues amongst its staff.

4 **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.

5 **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 the Organisation might make. The Formal Investigation will be preceded by the Screening Stage (see below).

6 **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 clinical academic working in both a university and an NHS organisation, in which case the NHS organisation would issue the honorary contract;
- for an NHS consultant with an arrangement to undertake teaching and/or research in a university, in which case the university would issue the honorary contract;
- for a researcher employed by a university and undertaking a research project in an NHS organisation, in which case the NHS organisation would issue the honorary contract.

There are significant differences in the responsibilities that an Organisation might have for an individual according to the type of honorary contract used. For example, in the case of clinical academics with honorary contracts with an NHS organisation and NHS consultants 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 or the NHS organisation might take the lead in an investigation of allegations of misconduct in research.

In the case of a researcher employed by a university and undertaking research in an NHS organisation, however, the honorary contract issued by the NHS organisation 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 university, 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.

7 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;
- Falsification;
- Misrepresentation of data and/or interests and or involvement;
- Plagiarism; 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; and
 - the environment; and
 - the proper handling of privileged or private information on individuals collected during the research.

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.

8 Named Person

The Named Person is defined in the Procedure as the individual nominated by the Organisation (see below) 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 should have a nominated alternate who should carry out the role in his/her absence or in the case of any potential or actual conflict of interest. The Named Person and the nominated alternate should not be the Organisation's Head, Head of Research or Head of Personnel.

9 Organisation

The Organisation is defined in this Procedure as the establishment that employs the Respondent, the Named Person and, on occasions, other parties involved in the proceedings and is the host and (most likely) the Sponsor for the research to which allegations of misconduct refer.

10 The Procedure

The Procedure refers to this publication, the procedure for the investigation of misconduct in research.

11 Professional Body

A professional body is an organisation with statutory powers to regulate and oversee a particular profession, such as doctors or solicitors. Examples relevant to this Procedure include the General Medical Council, the Nursing and Midwifery Council and the Health Professions Council.

12 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. Examples relevant to this Procedure include the MHRA, the Healthcare Commission, the Health and Safety Executive, the Mental Health Act Commission and the Council for Healthcare Regulatory Excellence.

13 Research and Scholarship

The Research Assessment Exercise (Research Assessment Exercise 2008, p. 34) defines research and scholarship as the following:

'Research'... is to be understood as original investigation undertaken in order to gain knowledge and understanding. It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship*; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.

It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.

14 Respondent

The Respondent is the person against whom allegations of misconduct in research have been made. He/she must be a present or past employee of the Organisation that is investigating the allegations using the Procedure.

Note: Should the policies or practices of an organisation be the subject of allegations of misconduct the Head of the Organisation would serve as the Respondent in the Procedure.

* Scholarship... is defined as the creation, development and maintenance of the intellectual infrastructure of subjects and disciplines, in forms such as dictionaries, scholarly editions, catalogues and contributions to major research databases.

15 **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.

16 **Sponsor**

The Department of Health (DH) Research Governance Framework (Department of Health 2005, p. 22) defines a sponsor as the following:

Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. (A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in this research governance framework that are relevant to the study.)

For full details of the responsibilities of the Sponsor, refer to the latest version of the DH Research Governance Framework, available on the DH website (see reference in Annex 8). The DH definition of sponsor is used here rather than that defined by the MHRA, as it is broader in scope and relevant to research in health and biomedical sciences, rather than specifically to clinical trials.

Annex 3

Forms for communication with UKRIO

Forms for consultation with, and for reporting the progress of an investigation into allegations of misconduct in research to, the UK Research Integrity Office.

Initial Report

To be used by the Named Person to liaise with UKRIO (and others) of the receipt of allegations of misconduct in research.

Information	
1 Title of Organisation	<input type="text"/>
2 Address and contact details for the Named Person and the Organisation	<input type="text"/>
3 Source of allegations	Internal <input type="checkbox"/> external <input type="checkbox"/>
4 Type of allegations (use definitions at Annex 2 of the Procedure)	<input type="text"/>
5 External funding involved	Yes <input type="checkbox"/> No <input type="checkbox"/>
6 If yes to question 5 does it include:	
i) funding from a UK Research Council	Yes <input type="checkbox"/> No <input type="checkbox"/>
ii) funding from a DH or NHS scheme	Yes <input type="checkbox"/> No <input type="checkbox"/>
iii) funding from a Charitable body	Yes <input type="checkbox"/> No <input type="checkbox"/>
iv) funding from a Commercial body	Yes <input type="checkbox"/> No <input type="checkbox"/>
v) funding from a Overseas body	Yes <input type="checkbox"/> No <input type="checkbox"/>
7 Date formal allegations received	Day <input type="text"/> Month <input type="text"/>
8 Does the project have an external Sponsor	Yes <input type="checkbox"/> No <input type="checkbox"/>
9 Does the project have an external partner(s)	Yes <input type="checkbox"/> No <input type="checkbox"/>
10 Does the project involve an international partner(s)	Yes <input type="checkbox"/> No <input type="checkbox"/>
11 Has the Organisation taken any action(s) to contact any regulatory or professional bodies	Yes <input type="checkbox"/> No <input type="checkbox"/>
12 Has the Organisation taken action(s) to use its disciplinary process	Yes <input type="checkbox"/> No <input type="checkbox"/>

Information

- 13 Has the Organisation taken action(s) to bar the Respondent from relevant parts of the workplace
- 14 Date on which the Screening Panel start/started work
- 15 Are external nominations to the Panel required
- 16 Does the Screening Panel include members external to the Organisation
- 17 Other Details (optional)

Yes No
Day Month
Yes No
Yes No

Screening Follow-up

To be used by the Named Person to provide information to UKRIO (and others) of progress made by the Screening Panel when the Panel needs to work for longer than 30 working days.

Information

- 1 UKRIO number
- 2 Date the progress report submitted
- 3 Progress to report (events which have taken place: please do not include the names of any individuals involved).

Day Month

- 4 Planned (estimated) completion date

Day Month

Conclusion of the Screening Panel

To be used by the Named Person to report the conclusions reached by the Screening Panel.

Information

1 UKRIO number

2 Date the report submitted

Day Month

3 The allegations reviewed by the Screening Panel were considered:

i) to be mistaken, frivolous, vexatious and/or malicious;

Yes No

ii) to need to be referred to the Organisation's disciplinary or other internal process;

Yes No

iii) to have some substance but due to a lack of intent or motivation to deceive or due to their relatively minor nature, they should be addressed through education and training, or other non-disciplinary route, rather than through the next stage of the Procedure or other Formal Proceedings;

Yes No

iv) be sufficiently serious and of sufficient substance to justify a Formal Investigation.

Yes No

4 If the Screening Panel found the allegations to be mistaken, frivolous, vexatious and/or malicious, please outline any actions taken to support the Respondent and, if found frivolous, vexatious and/or malicious, whether any actions considered against the Complainant.

5 If the matter does not require formal procedures but rather should be addressed through a different route, please outline steps taken.

6 If to be taken to a Formal Investigation, please specify date planned to start the investigation.

Day Month

7 If to be taken to a Formal Investigation, are external nominations to the Investigation Panel required?

Yes No

8 Any other comments

Formal Investigation Follow-up

To be used by the Named Person to provide information to UKRIO (and others) of progress made by the Investigation Panel.

Information	
1 UKRIO number	
2 Date the progress report submitted	Day <input type="text"/> Month <input type="text"/>
3 Progress (events which have taken place: please do not include names of any individuals involved)	
4 Planned (estimated) completion date	Day <input type="text"/> Month <input type="text"/>

Conclusion of the Investigation Panel

To be used by the Named Person to report the outcome of the Investigation Panel to UKRIO (and others).

Information

1 UKRIO number

2 Date the report issued

Day Month

3 Allegations not upheld

Yes No

Allegations upheld

Yes No

Allegations upheld in part.

Yes No

4 If not upheld, please indicate whether any action should be taken to support the Respondent.

5 If the allegations were upheld in full or in part, whether the allegations will be referred to the Organisation's disciplinary process.

Yes No

6 If yes to question 5, whether a date has been set to start the disciplinary process.

Day Month

7 Whether action to correct the record of evidence is considered necessary.

Yes No

8 Whether there may be organisational issues that the Organisation should address in the management of research.

Yes No

9 Has the outcome of the investigation been communicated to all other interested parties

Yes No

10 Any other comments

Operation of the Screening Panel

- 1 The Screening Stage of the Procedure is intended to determine whether there is *prima facie* evidence of misconduct in research. The Screening Panel should be convened to investigate allegations of misconduct in research, which have passed through initial review by the Named Person and are therefore considered as:
 - not encompassing breaches of the law or areas within the domain of the relevant regulatory authority;
 - not encompassing breaches of the Organisation's regulations such as might require the implementation of the disciplinary process;
 - constituting research activity for which the Organisation is the Sponsor or for which the Organisation has primary responsibility;
 - involving a Respondent where the Organisation is the primary employer or where it has primary responsibility, agreed with other employing organisations; and
 - having substance, in that it is not considered **at this stage**, to be mistaken, frivolous, vexatious and/or malicious.

Terms of Reference for the Screening Panel

- 2 Members appointed to the Screening Panel should:
 - elect a Chair; and
 - make a declaration that they:
 - will adhere to the Principles of the Procedure (see Annex 1);
 - will abide by the Procedure as it affects the work of the Screening Panel;
 - will work within the Terms of Reference for the Screening Panel;
 - have declared any links to the research and/or the individuals involved in the allegations or any interests which might conflict with the Principles of the Procedure; and
 - will maintain the confidentiality of the proceedings throughout the work of the Panel and afterwards, unless formally sanctioned by the Organisation or otherwise required to by law.
- 3 The Screening Panel should:
 - maintain a record of evidence sought and received, and conclusions reached;
 - conduct an assessment of the evidence including interviewing the Respondent and Complainant and other staff whom the Panel consider relevant to the investigation;
 - provide a draft report to the Organisation's Named Person, who will forward it 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.

- produce a final report which considers the allegations of misconduct in research and reaches one of the conclusions below; and
 - aim to complete its work **within 30 working days**.
- 4 In concluding its work, the Panel should make a recommendation that the allegations of misconduct in research:
- should be referred directly to the Organisation's disciplinary process or other internal process;
 - are sufficiently serious and has sufficient substance to justify a Formal Investigation;
 - 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 mistaken, frivolous, vexatious and/or malicious.
- 5 The Report should be sent to the Named Person.
- 6 Once it has completed the report and reached a conclusion, the work of the Screening Panel is complete and it should be disbanded and members should take no part in any further investigation of the matter or make any comment on the continuing investigation, unless formally sanctioned by the Organisation or otherwise required to by law. They should also remember that all information concerning the case was given to them in confidence.

Note: the Organisation may add to the Terms of Reference to address specific aspects of the investigation.

Composition of the Screening Panel

- 7 The Screening Panel should consist of at least three senior members of staff selected by the Named Person from those (within the Organisation), who have previously indicated their willingness to serve on such a Panel.
- 8 In selecting the Panel members, the Named Person should consider:
- the subject matter of the allegations, including whether it would be advantageous for members of the Panel to possess any specialised knowledge or investigative skill;
 - any conflicts of interest that might arise;
 - any links with any of the persons involved (Respondents or Complainants);
 - any personal connections with the subject matter of the allegations; and
 - any connections with the work through, for example, the Organisation's groups established to review proposals for research or ethics committees.
- 9 Members of the Screening Panel should sign a declaration confirming that they will;
- abide by the conditions and provisions of the Procedure as it affects the work of the Screening Panel;

- work within the Terms of Reference for the Screening Panel (detailed above);
 - respect the confidentiality of the proceedings;
 - adhere to the Principles of the Procedure (see Annex 1); and
 - undertake the work of the Panel within the timetable of 30 working days from being convened.
- 10 The Named Person must **not** be a member nor seek to influence the work, of the Screening Panel.
 - 11 It is desirable, but not essential, that one or more members of the Screening Panel be selected from outside the Organisation, rather than members drawn from within the Organisation. Allegations that involve senior staff and/or that are judged to be especially serious, complex or controversial may particularly benefit from the presence of someone external to the Organisation on the Screening Panel. There would be advantage in the review of allegations that involve staff on joint clinical/honorary contracts for there to be on the Screening Panel an appropriate member of staff from the other employing Organisation(s).
 - 12 Both Respondent and Complainant may raise with the Named Person concerns that they may have about those chosen to serve on the Screening Panel but neither has a right of veto over those nominated.
 - 13 The Named Person may choose to consult UKRIO so as to nominate member(s) from their Register of Advisers to sit as member(s) of the Screening Panel.
 - 14 Once convened, the membership of the Screening Panel should not be added to. Members unable to continue should not be replaced. In the event that the Chair stands down or the membership falls below three, the Named Person should take steps to recruit additional members or re-start the Screening process.

The work of the Screening Panel

- 15 The Screening Panel may call expert witnesses to give advice if necessary and as appropriate but such witnesses do not become members of the Screening Panel. The Screening Panel may also seek guidance from UKRIO and its Advisers.
- 16 All contributions to the process of screening should be recorded and maintained for subsequent use.
- 17 The Chair has the responsibility to ensure maintenance of a record of all proceedings.
- 18 To perform its function the Screening Panel should:
 - review the submission and supporting evidence provided by the Complainant;
 - review the evidence and supporting documentation from the Respondent who should be given the opportunity to respond to the allegations, set out his/her case and to present evidence;

- review any background information relevant to the allegations; and
- interview the Respondent, the Complainant and other individuals who might provide relevant information to assist the Panel.

Note that:

- *those interviewed by the Screening Panel may be accompanied by a fellow employee or a trade union representative;*
- *furthermore, some employees may have additional contractual rights to be accompanied by persons other than those listed above, for example, a partner, spouse or legal representative; and*
- *the Organisation may not be in a position to compel those with information to attend, or to provide that information to the Panel.*

The findings of the Screening Panel

- 19 The Screening Panel should consider the evidence and determine whether the allegations:
 - should be referred directly to the Organisation’s disciplinary process or other internal process; or,
 - are sufficiently serious and has sufficient substance to justify a Formal Investigation; 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 mistaken, frivolous, vexatious and/or malicious.
- 20 The Screening Panel’s draft report will be made available to the Respondent and the Complainant for them to comment on the factual accuracy of the report. Only where 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 determine the truth of the comments made and seek the agreement of the majority of Panel members before making amendments of substance to the Panel’s report.
- 21 The Panel should then inform all relevant parties of its conclusion (including representatives of the Respondent and the Complainant by agreement) and the reasons for reaching that conclusion in a final report (see Terms of Reference, above).
- 22 The work of the Screening Panel is then concluded and the Panel is disbanded. Members of the disbanded Screening Panel should not make any comment on the continuing investigation, unless formally sanctioned by the Organisation or otherwise required to by law. They should also remember that all information concerning the case was given to them in confidence.

- 23 Any queries or request for comment should be referred to the Named Person.
- 24 Those who have contributed to the disbanded Screening Panel should have no further involvement in the Procedure, unless formally asked to clarify a point in their written report, at a subsequent part of the investigation.
- 25 Involvement in either the Screening or the Investigation Panel rules out participation in any disciplinary process.

Annex 5

Operation of the Investigation Panel

- 1 The Investigation Panel should be convened to investigate allegations of misconduct in research which have passed through the screening stage and are therefore considered to be:
 - sufficiently serious and of sufficient substance to justify a Formal Investigation.

Terms of Reference of the Investigation Panel

- 2 Members appointed to the Investigation Panel should:
 - elect a Chair;

It is desirable, but not essential, for the Panel to include a member who either holds or has held judicial office or to be a barrister or solicitor of at least ten year's standing.

- declare that they:
 - will adhere to the Principles of the Procedure (see Annex 1);
 - will abide by the Procedure as it affects the work of the Investigation Panel;
 - will work within the Terms of Reference for the Investigation Panel;
 - have declared any links to the research and/or the individuals involved in the allegations or any interests which might conflict with the Principles of the Procedure; and
 - will respect the confidentiality of the proceedings throughout the work of the Panel and afterwards, unless formally sanctioned by the Organisation or otherwise required to by law.
- 3 The Investigation Panel should:
 - receive all relevant information from the Screening Panel as background for the investigation;
 - set a date for the investigation, which should be conducted as quickly as possible without compromising the stated Principles of the Procedure;
 - maintain a record of evidence sought and received, and conclusions reached;
 - conduct an assessment of the evidence;
 - hear the Complainant and such other individuals as the Panel consider relevant to the investigation;
 - hold a Formal Hearing, to hear the Respondent's response to the allegations made;
 - consider the allegations of misconduct in research and reach a conclusion on the allegations with the standard of proof used to reach that decision being "on the balance of probabilities";
 - provide a draft report to the Organisation's Named Person, who should forward it 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 Investigation 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.
- report any further, distinct, instances of misconduct in research by the Respondent which may be disclosed, unconnected to the allegations under investigation and/or misconduct in research by another person or persons, to the Named Person in writing, along with supporting evidence; and
- aim to reach a unanimous decision, failing which a majority decision will be acceptable.

Note that the Investigation Panel may conclude that allegations are upheld in part as well as concluding that they are upheld in full.

- 4 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 the Organisation 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:

- a whether the allegations should be referred to the relevant organisation's disciplinary process;*
- b whether any action will be required to correct the record of research;*
- c whether organisational matters should be addressed by the Organisation through a review of the management of research; and*
- d other matters that should be investigated.*

- 5 The Report should be sent to the Named Person.
- 6 Once it has completed the report and reached a conclusion, the work of the Investigation Panel is complete and it should be disbanded and members take no part in any further investigation of the matter, unless formally asked to clarify a point in their written report at a subsequent investigation.. As the matter may then give rise to disciplinary or other action, members of the disbanded Investigation Panel should not make any comment on the

matter in question, unless formally sanctioned by the Organisation or otherwise required to by law. They should also remember that all information concerning the case was given to them in confidence.

Note: the Organisation may add to the Terms of Reference to address specific aspects of the investigation.

Composition of the Investigation Panel

- 7 The Investigation Panel should consist of at least three, and always an uneven number of, senior members of staff selected by the Named Person from those with relevant skills and experience to serve on such a Panel.
- 8 In selecting members of the Investigation Panel, the Named Person should consider:
 - the subject matter of the allegations, including whether it would be advantageous for members of the Panel to possess any specialised knowledge or investigative skill;
 - any potential conflicts of interest
 - any potential links with any of the persons involved (Respondents or Complainants), or personal connections with the subject matter of the allegations;
 - whether a nominee was involved in the Screening Panel, as this excludes such a person from serving on the Investigation Panel; and
 - any connections with the work through, for example, the Organisation's groups established to review proposals for research or its ethics committee(s).
- 9 It is a requirement that one or more members of the Investigation Panel be selected from outside the Organisation. Such external members replace internal members of the Investigation Panel rather than being in addition to them. Allegations that involve senior staff and/or that are judged to be especially serious, complex or controversial may benefit particularly from a member who is not associated with the Organisation. There would also be advantage in the review of allegations that involve staff on joint clinical/honorary contracts for there to be on the Investigation Panel an appropriate member of staff from the other employing organisation(s).
- 10 The Named Person may choose to consult UKRIO to nominate member(s) from the Register of Advisers to sit as member(s) of the Investigation Panel.
- 11 At least two members of the Panel should have experience in the area of research in which the alleged misconduct has taken place, although they should not be members of the Department concerned. Where allegations concern highly specialised areas of research the Investigation Panel should have at least one member with specialised knowledge of the field.
- 12 The Named Person must **not** be a member nor seek to influence the work of the Investigation Panel

- 13 The Named Person should nominate members of the Investigation Panel for approval by the Head of the Organisation or a nominated deputy. The Head of the Organisation, or his/her deputy, may veto nominations for the Investigation Panel, recording the reason for the veto in writing and communicating it to all parties.
- 14 Both the Respondent and the Complainant may raise with the Named Person any concerns that they may have about those chosen to serve on the Investigation Panel, but do not have a right of veto over those selected.
- 15 The members of the Investigation Panel should sign a declaration confirming that they will:
 - abide by the Procedure as it affects the work of the Investigation Panel;
 - work within the Terms of Reference for the Investigation Panel (detailed above);
 - respect the confidentiality of the proceedings; and
 - adhere to the Principles of the Procedure (Annex 1 of the Procedure).
- 16 Once convened, the membership of the Investigation Panel should not be changed or added to. Members who are not able to continue should not be replaced. In the event that the Chair stands down or the membership falls below three, the Named Person should take steps to recruit additional members or re-start the Formal Investigation process.

The work of the Investigation Panel

- 17 The Investigation Panel may call expert witnesses to give advice, if necessary and as appropriate. Such witnesses do not become members of the Investigation Panel. The Investigation Panel may also seek guidance from UKRIO and its Advisers.
- 18 The Chair is responsible for keeping a full record of the evidence received and of the proceedings.
- 19 To perform its task the Investigation Panel should review:
 - the submission(s) and supporting evidence provided by the Complainant;
 - the response(s) and supporting evidence from the Respondent who should be given the opportunity to respond to the allegations made and to present evidence;
 - background information relevant to the allegations; and
 - any interviews conducted with the Respondent, the Complainant, and other staff who may provide relevant information to assist the Investigation Panel.
- 20 The Panel must hold a Formal Hearing during which:
 - the Respondent must be given the opportunity to set out his/her case and respond to the allegations made against him/her. He/she will also be allowed to ask questions, to present evidence, call witnesses and raise points about any information given by any witness (including the Complainant), regardless of who has called the witness in question; and
 - the Complainant and other staff may be invited to provide evidence when members of the Panel consider that it may have relevance to the investigation.

Note that:

- *those interviewed by the Investigation Panel may be accompanied by a fellow employee or a trade union representative;*
- *furthermore, some employees may have additional contractual rights to be accompanied by persons other than those listed above, for example, a partner, spouse or legal representative; and*
- *the Organisation may not be in a position to compel those with information to attend, or to provide that information to the Panel.*

- 21 Although not working to a prescribed timetable, the Panel should set a date for the completion of the investigation, which should be as soon as is practical without compromising the Principles of the Procedure (Annex 1).
- 22 The Chair of the Investigation Panel should report progress in writing, by reference to the plans agreed by the Panel, to the Named Person during investigations. If it is believed that the investigation should take more than one calendar month, reports should be made on a monthly basis. If it is believed that the investigation will last for one calendar month or less, reports should be made on a bi-weekly basis.
- 23 The Investigation Panel's draft report should be made available to the Respondent and the Complainant (and their representatives by agreement) for comment on its factual accuracy. Only when the report includes error of fact as indicated by either Respondent and/or Complainant should the Investigation Panel modify the report. The Chair should determine the truth of such comments and seek the agreement of the majority of the Panel, before making amendments of substance to the Panel's report.

The findings of the Investigation Panel

- 24 The role of the Investigation Panel is to consider the allegations of misconduct in research and reach a conclusion about those allegations. The standard of proof used by the Investigation Panel is that of "on the balance of probabilities".
- 25 A majority decision is acceptable, though a unanimous decision is desirable.
- 26 It is acceptable for the Investigation Panel to conclude that allegations are upheld in part rather than in full.
- 27 Once the Investigation Panel has reached a conclusion it should produce a final report that:
 - summarises the investigation;
 - states whether the allegations of misconduct have been upheld in full or in part, giving the reasons for its decision and recording any differing views;

- makes informal recommendations to resolve any issues relating to any misconduct it has found and to address any procedural matters which the investigation has brought to light within the Organisation and relevant partner organisations and/or funding bodies; and
- reports other matters that should be investigated.

- 28 The report should be sent to the Named Person. 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 Head of the Organisation, the Head of Research, the Head of Personnel, the Head(s) of the 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 Personnel and the Head of Research of the other employing organisation(s);
 - where appropriate, the Named Person should notify any relevant partner organisations, funding bodies and/or regulatory or professional bodies; and
 - Additionally, the Named Person may wish to inform UKRIO of the conclusion of the Formal Investigation, using the forms at Annex 3.
- 29 The work of the Investigation Panel is then concluded and the Panel should be disbanded. As the matter may then give rise to disciplinary or other action, members of the disbanded Investigation Panel should not make any comment on the matter in question, unless formally sanctioned by the Organisation or otherwise required to by law. They should also remember that all information concerning the case was given to them in confidence.
- 30 Any queries or requests for comment addressed to members of the Investigation Panel should be referred to the Named Person.
- 31 Those who have contributed to the disbanded Investigation Panel should have no further involvement in the Procedure, unless formally asked to clarify a point in their written report at a subsequent investigation.
- 32 Involvement in either the Screening or the Investigation Panel rules out participation in any disciplinary process.

Annex 6

Actions and outcomes

The conclusion of the Procedure for the investigation of allegations of misconduct in research and actions taken either through the Organisation's disciplinary process or through other steps to respond to the conclusions reached by the Investigation Panel should take account of the Principles of the Procedure and the matters listed in (1) to (5) below:

1 Specialised research

It is recognised that the subject area of certain cases may be so specialised as to require equally specialised advice as to how to resolve or correct matters arising from the misconduct in research; the recommendations and experience of the Investigation Panel may prove particularly useful if this is the case.

2 Support provided to the Complainant

Where allegations have been upheld (in full or in part), or found to be mistaken but not frivolous, vexatious and/or malicious, then appropriate support, guidance and acknowledgment should be given to the Complainant, given that his/her role in the process will most likely have been stressful and may well have caused friction with colleagues. The Named Person should take whatever steps he/she considers necessary to support the reputation of the Complainant.

For example, if the case has received any publicity, the Complainant should be offered the possibility of having an official statement released for internal and/or external purposes.

3 Support provided to the Respondent

Where allegations have not been upheld (in full or in part), the Named Person should take such steps as are appropriate, given the seriousness of the allegations, to support the reputation of the Respondent and any relevant research project(s). Appropriate support and guidance should be given to the Respondent, given that his/her role in the process will most likely have been stressful and may well have caused friction with colleagues

As above, where the case has received any publicity, the Respondent should be offered the possibility of having an official statement released for internal and/or external purposes.

4 Handling wrongful allegations

If the Screening Panel and/or Investigation Panel has found that the Complainant's allegations were frivolous, vexatious and/or malicious, the Named Person may consider recommending that action be taken against the Complainant, under the Organisation's disciplinary process.

Those who have made allegations in good faith should not be penalised.

5 Other actions that may be required or be considered appropriate

Following the conclusion of the Procedure, the Investigation Panel may need to recommend additional measures in addition to those that may be taken by way of the Organisation's disciplinary process.

Examples of potential actions that an organisation may consider include:

- retraction/correction of articles in journals;
- withdrawal/repayment of funding;
- notifying patients/patients' doctors of any potential medical issues that may arise;
- notification of misconduct to regulatory bodies (such as the MHRA, the Healthcare Commission, the Home Office [for research involving animals], professional bodies, etc.);
- notifying other employing organisations;
- notifying other organisations involved in the research;
- adding a note of the outcome of the investigation to a researcher's file for any future requests for references; and/or
- review internal management and/or training and/or supervisory procedures for research.

Annex 7

Communications and record-keeping

General

- 1 In accordance with the principle of integrity, appropriate confidential records should be maintained by the Named Person of all stages of any proceedings under this Procedure.
- 2 The Chairs of the Screening and Investigation Panels should assume responsibility for keeping accurate records of the activities, deliberation and reporting of their respective Panels and pass these records to the Named Person for inclusion in the archive of the case upon the completion of their Panel's work.
- 3 At the conclusion of the proceedings, the Head of Personnel should retain all such records for a period that accords with the Organisation's policy. It is recommended that this period should not be less than six years. Access to this archive should be limited to appropriate members of the Personnel Department, the Named Person and his/her nominated alternate.
- 4 The Named Person is responsible for ensuring the accurate, timely and confidential transfer of information between all parties involved in any of the stages of the Procedure.
- 5 Upon the conclusion of the Procedure, at whatever stage, the Named Person is responsible for the accurate, timely and confidential transfer of information to any relevant parties, such as the Organisation's Disciplinary Panel or the Personnel Department.
- 6 If the Organisation's Disciplinary Process is to be invoked as a result of the outcome of this Procedure, the report of the Investigation Panel should form the basis of evidence that the Disciplinary Panel receives. In such a case, all of the information relating to the Procedure should be transferred to the Disciplinary Panel.
- 7 Depending on the outcome of the Procedure, the Named Person should liaise with the Head of Personnel to obtain any further relevant information from any relevant parties, such as an organisation's Disciplinary Panel or Human Resources Department, and add it to the confidential case archive.

Communication with involved parties

- 1 The Screening and Investigation Panels should be supported by a member of the Named Person's staff or a member of staff from the Human Resources Department, through whom all documentation and all other communication should be passed.
- 2 No direct communication, either written or oral, should take place between the members and support staff of the Screening and Investigation Panels and either the Respondent,

Complainant or any other member(s) of staff concerned outside the formal process, for the duration of the Procedure and any subsequent disciplinary process.

- 3 Communication, either written or oral, by any party (to include Respondent, Complainant or any other member(s) of staff) directly with members of the either Panel should not be admitted as part of the documentation relating to the case except when it takes place at the request of the Panel, or at formal meetings called by the Chair of either the Screening or Investigation Panel.

Annex 8

Acknowledgements and Bibliography

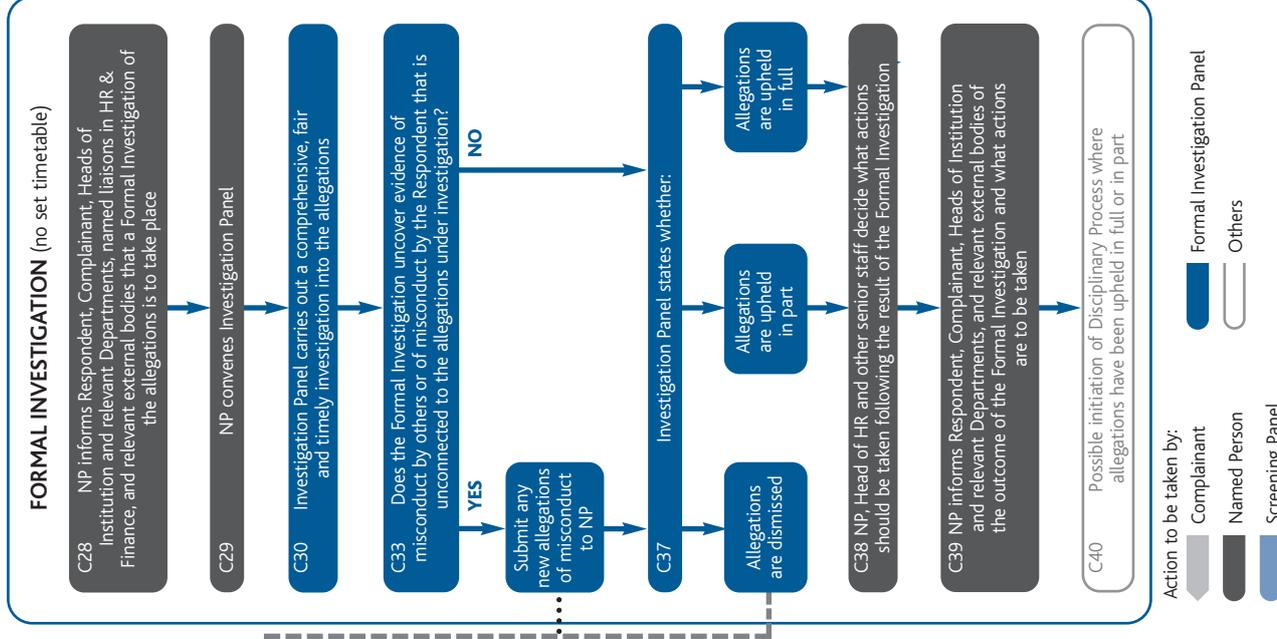
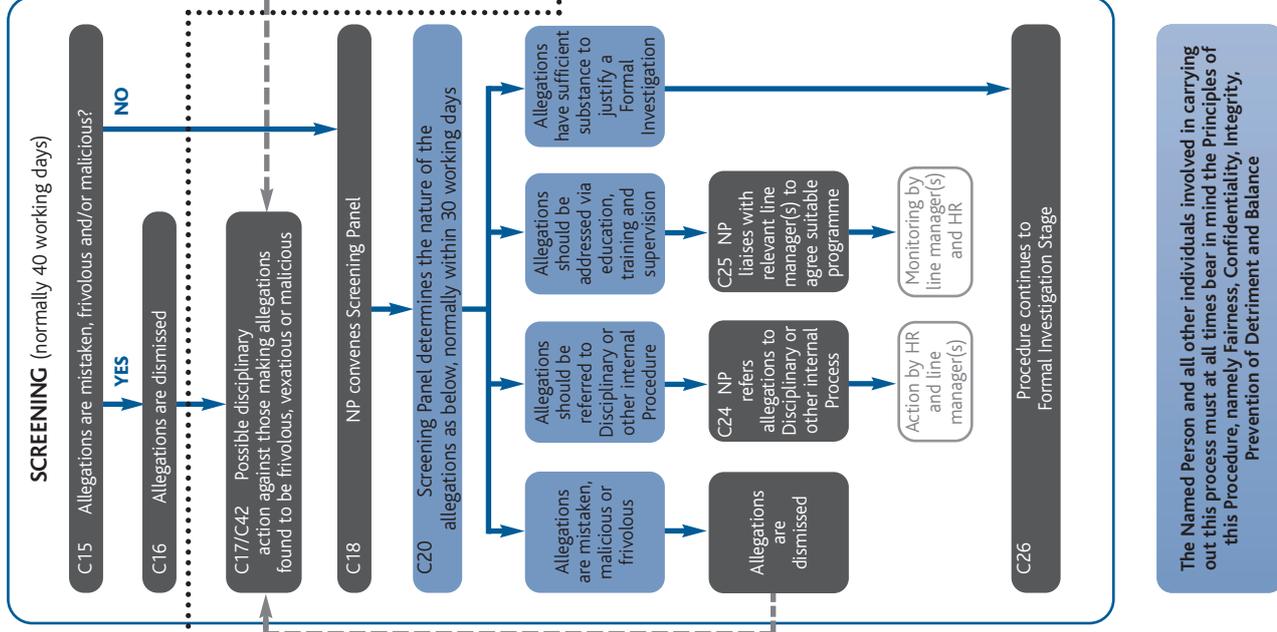
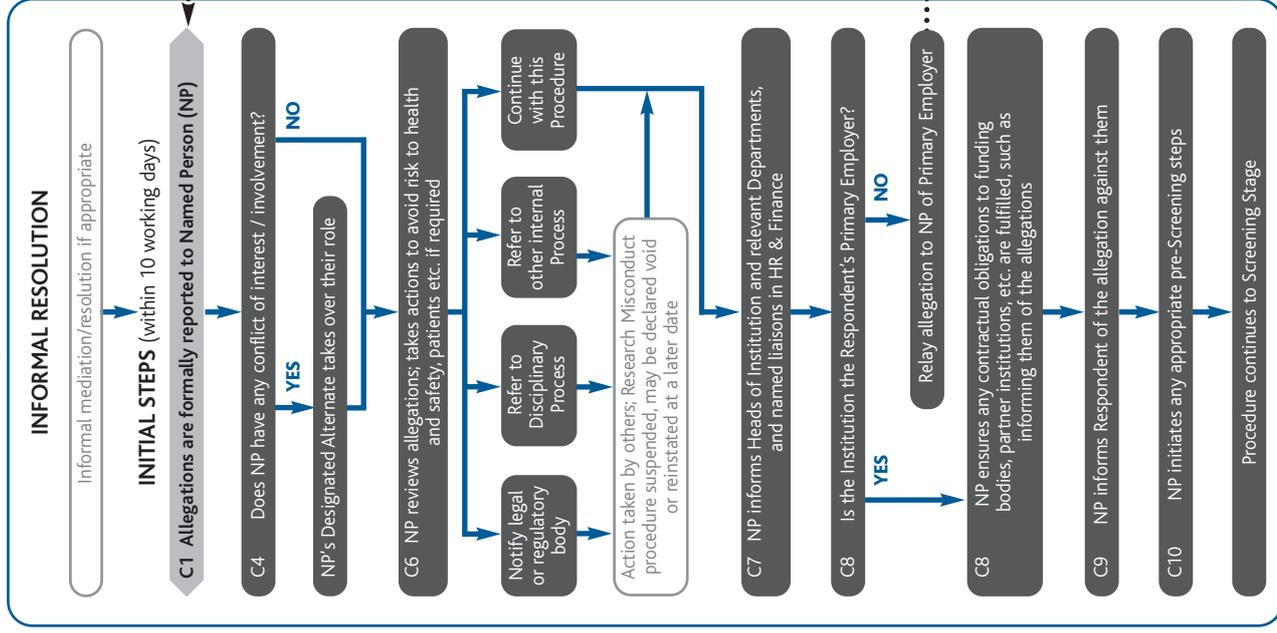
The UK Research Integrity Office wishes to acknowledge the use of the following documents:

- ACAS, 2003. *Code of Practice 1: Disciplinary and Grievance Procedures* [online]. Available from: http://www.acas.org.uk/media/pdf/l/p/CP01_1.pdf [Accessed 18th July 2008]
- Addenbrooke's NHS Trust, 2003. *Good Research Practice: Misconduct and Fraud (Policy and Procedure)* [online]. Available at: www.addenbrookes.org.uk/resources/pdf/research/good_research_pract_270503.pdf [Accessed 18th July 2008]
- Animals (Scientific Procedures) Act 1986* [online]. Available from: <http://www.archive.official-documents.co.uk/document/hoc/321/321-xa.htm> [Accessed 18th July 2008]
- Association of Medical Research Charities, 2002. *Guidelines on Good Research Practice* [online]. Available from: <http://www.amrc.org.uk/HOMEPAGE/?Nav=484,990> [Accessed 18th July 2008]
- Biotechnology and Biological Sciences Research Council, 2006. *Statement on Safeguarding Good Scientific Practice* [online]. Available from: http://www.bbsrc.ac.uk/publications/policy/good_scientific_practice.pdf [Accessed 18th July 2008]
- Bristol Royal Infirmary Inquiry, 2001. *Learning from Bristol* [online]. London: tSO. Available from: http://www.bristol-inquiry.org.uk/final_report/rpt_print.htm [Accessed 18th July 2008]
- Calderdale & Huddersfield NHS Trust, 2005. *Research Misconduct and Fraud* [online]. Available from: www.cht.nhs.uk/fileadmin/departments/research_development/PCT_event/Leaflet_5_aa15501.pdf [Accessed 18th July 2008].
- Cardiff University, 2004. *Procedure for Dealing with Allegations of Misconduct by Employees in Academic Research* [online]. Available from: <http://www.cf.ac.uk/cocom/resources/procedures%20for%20dealing.doc> [Accessed 18th July 2008].
- Committee on Publication Ethics (COPE), 2003. *Guidelines on Good Publication Practice* [online]. Available from: <http://www.publicationethics.org.uk/guidelines> [Accessed 18th July 2008]
- Committee on Standards in Public Life (originally the Nolan Committee), 1995. *First Report on Standards in Public Life* [online]. Available from: <http://www.archive.official-documents.co.uk/document/parlament/nolan/nolan.htm> [Accessed 18th July 2008]
- Council for Science and Technology, 2006. *Rigour, respect and responsibility: a universal ethical code for scientists* [online]. Available from: <http://www.cst.gov.uk/cst/reports/#11> [Accessed 18th July 2008]
- Department of Health, 2005. *Research governance framework for health and social care: second edition* [online]. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962 [Accessed 18th July 2008]
- Eckstein, S. (ed) 2003. *Manual for Research Ethics Committees*. Cambridge: Cambridge University Press.
- Economic & Social Research Council, 2005. *Research Ethics Framework* [online]. Available from: http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf [Accessed 18th July 2008]
- Economic & Social Research Council, 2008. *Research Funding Guide* [online]. Available from: http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/ESRC_Research_Funding_Guide_May_2008_tcm6-9734.pdf [Accessed 18th July 2008]
- Employment Act 2002* [online]. Available from: http://www.opsi.gov.uk/acts/acts2002/ukpga_2002002_2_en_1 [Accessed 18th July 2008]
- Engineering & Physical Sciences Research Council, 2002. *Guide to Good Practice in Science and Engineering Research* [online]. Available from: <http://www.epsrc.ac.uk/CMSWeb/Downloads/Other/GoodPracticeGuideSciEngRes.pdf> [Accessed 18th July 2008]
- European Science Foundation, 2000. *ESF Science Policy Briefing 10: Good Scientific Practice in Research and Scholarship* [online]. Available from: <http://www.esf.org/publications/policy-briefings.html> [Accessed 18th July 2008]
- Federation of American Societies for Experimental Biology, 2006. *Shared Responsibility, Individual Integrity: scientists addressing conflicts of interest in biomedical research* [online]. Available from: http://opa.faseb.org/pdf/FASEB_COI_paper.pdf [Accessed 18th July 2008]
- Goldsmiths, University of London, 2003. *Policy on Safeguarding Good Academic and Scientific Practice and Dealing with Allegations of Misconduct in Research*

- [online]. Available from: <http://www.gold.ac.uk/governance/policies/safeguarding-research-practice.pdf> [Accessed 18th July 2008]
- Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 [online]. Available from: <http://www.archive.official-documents.co.uk/document/hoc/321/321-00.htm> [Accessed 18th July 2008]
- Harvard Medical School, 1991. *Guidelines for Investigators in Clinical Research* [online]. Available from: <http://www.hms.harvard.edu/integrity/clinical.html> [Accessed 18th July 2008]
- Harvard Medical School, 1998. *Guidelines for Investigators in Scientific Research* [online]. Available from: <http://www.hms.harvard.edu/integrity/scientif.html> [Accessed 18th July 2008]
- Harvard Medical School, 2005. *Principles and Procedures for Dealing with Allegations of Faculty Misconduct* [online]. Available from: <http://www.hms.harvard.edu/integrity/miscond.html> [Accessed 18th July 2008]
- Home Office, 2005. *Code of Practice Part 1 - for the housing and care of animals used in scientific procedures* [online]. Available from: <http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/code-of-practice/code-of-practice-housing-care/?view=Standard&pubID=428573> [Accessed 18th July 2008]
- Human Rights Act 1998 [online]. Available from: http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_1 [Accessed 18th July 2008]
- Imperial College London, 2007. *Ordinance D17: The Investigation of Allegations of Scientific Misconduct* [online]. Available from: <http://www3.imperial.ac.uk/secretariat/governance/charterandstatutes/d17> [Accessed 18th July 2008]
- International Committee of Medical Journal Editors, 2007. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication* [online]. Available from: <http://www.icmje.org/> [Accessed 18th July 2008]
- International Society for Environmental Epidemiology, 2000. *Proposed Definitions Relating to Suppression of Research and Repression of Research* [online]. Available from: http://www.isepepi.org/about/ethics.html#Bias_Definitions [Accessed 18th July 2008]
- Joint Consensus Conference on Misconduct in Biomedical Research, 1999. *Consensus Statement* [online]. Available from: http://www.rcpe.ac.uk/education/standards/consensus/misconduct_99.php [Accessed 18th July 2008]
- King's College London, 2007. *Appendix 4: Procedure for investigating & resolving allegations of research misconduct* [online]. Available from: http://www.kcl.ac.uk/college/policyzone/attachments/SectionA_RegulationsAppendix42007-8.pdf [Accessed 18th July 2008]
- Lock, S., Wells, F. and Farthing, M. (eds.), 2001. *Fraud and Misconduct in Biomedical Research Third Edition*. London: BMJ Books.
- Macrina, F., 2005. *Scientific Integrity Third Edition*. Washington DC: American Society for Microbiology Press.
- Medical Research Council, 1993. *Responsibility in the Use of Animals in Medical Research* [online]. Available from: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC001897> [Accessed 18th July 2008]
- Medical Research Council, 1997. *MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct* [online]. Available from: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002454> [Accessed 18th July 2008]
- Medical Research Council, 1998. *Guidelines for Good Clinical Practice in Clinical Trials* [online]. Available from: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416> [Accessed 18th July 2008]
- Medical Research Council, 2004. *Medical research involving children* [online]. Available from: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430> [Accessed 18th July 2008]
- Medical Research Council, 2005. *Research regulation and ethics - MRC position* [online]. Available from: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002462> [Accessed 18th July 2008]
- Medical Research Council, 2005. *Good Research Practice* [online]. Available from: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002415> [Accessed 18th July 2008]
- The Medicines for Human Use (Clinical Trials) Regulations 2004* [online]. Available from: <http://www.opsi.gov.uk/si/si2004/20041031.htm> [Accessed 18th July 2008]
- Missenden Centre for the Development of Higher Education, 2002. *The Missenden Code of Practice for Ethics and Accountability* [online]. Available from: www.missendencentre.co.uk/docs/MissCode.pdf [Accessed 18th July 2008]
- NHS R&D Forum, 2004. *Research Misconduct and Fraud: Good Practice Guidance* [online]. Available from: http://www.rforum.nhs.uk/workgroups/rg/misconduct_0704.doc [Accessed 18th July 2008]
- North West London Hospitals NHS Trust, 2005. *Research Handbook - Scientific Misconduct and Fraud*.
- Office of Research Integrity, 2005. *ORI Sample Policy and Procedures for Responding to Research Misconduct Allegations* [online]. Available from: http://ori.hhs.gov/policies/ori_policies.shtml [Accessed 18th July 2008]

- Public Interest Disclosure Act 1998* [online]. Available from: <http://www.opsi.gov.uk/ACTS/acts1998/19980023.htm> [Accessed 18th July 2008]
- Queen's University Belfast, 2002. *Regulations Governing Investigation into Allegations of Research Misconduct* [online]. Available from: <http://www.qub.ac.uk/rrs/webpages/research-governance.htm> [Accessed 18th July 2008]
- Queen Mary, University of London, 2000. *Procedure for investigating allegations of misconduct in academic research* [online]. Available from: <http://www.qmul.ac.uk/research/qm/docs/p-misconduct.pdf> [Accessed 18th July 2008]
- Research Assessment Exercise, 2008. *RAE 2008 Guidance on Submissions* [online]. Available from: <http://www.rae.ac.uk/pubs/2005/03/> [Accessed 18th July 2008]
- Research Councils UK (1998). *Safeguarding good scientific practice: A joint statement by the Director General of the Research Councils and the Chief Executives of the UK Research Councils* [online]. Available from: <http://www.ukoln.ac.uk/projects/ebank-uk/docs/scientific-practice.doc> [Accessed 18th July 2008]
- Research Councils UK (2006). *Terms and Conditions of Research Council fEC Grants* [online]. Available from: <http://www.rcuk.ac.uk/aboutrcuk/efficiency/tcfec> [Accessed 18th July 2008]
- Sheffield Hallam University, 2004. *Research ethics 2: Safeguarding good specific practice and dealing with allegations of misconduct in research* [online]. Available at: <http://students.shu.ac.uk/rightsrules/resethics2.html> [Accessed 18th July 2008]
- Smith R., 2000. What is misconduct in research? In: C. White, ed., *The COPE Report 2000* [online]. London: BMJ Books. Available from: <http://www.publicationethics.org.uk/reports/2000/> [Accessed 18th July 2008]
- Steneck, N H, 2007. *Office of Research Integrity Introduction to the Responsible Conduct of Research Revised edition* [online]. Washington DC: United States Department of Health and Human Services. Available from: <http://ori.dhhs.gov/documents/rcrintro.pdf> [Accessed 18th July 2008]
- University College London, 2005. *Procedures for Investigating and Resolving Allegations of Academic Misconduct in Research* [online]. Available from: <http://www.ucl.ac.uk/academic-manual/part-e/e21> [Accessed 18th July 2008]
- University of Brighton, 2002. *Code of Good Practice in Research* [online]. Available from: <http://staffcentral.brighton.ac.uk/xpedio/groups/public/documents/staffcentral/doc001431.pdf> [Accessed 18th July 2008]
- University of Cambridge, 2004. *Misconduct in Research* [online]. Available from: <http://www.admin.cam.ac.uk/offices/personnel/policy/misconduct.html> [Accessed 18th July 2008]
- University of Edinburgh, 2002. *Staff Administration Manual – Procedure for Allegations of Research Misconduct* [online]. Available from <http://www.humanresources.ed.ac.uk/policies/sams/Sam33.htm> [Accessed 18th July 2008]
- University of Exeter, 2002. *Policy and Procedures for Responding to Allegations of Misconduct in Research* [online]. Available from: <http://www.ex.ac.uk/research/documents/gnmisconduct.pdf> [18th July 2008]
- University of Glasgow, 2007. *Code of Policy and Procedures for Investigating Allegations of Misconduct in Research* [online]. Available from: http://www.gla.ac.uk/media/media_46516_en.pdf [Accessed 18th July 2008]
- University of Kent, 2000. *Good practice and misconduct in academic research: a policy document* [online]. Available from: <http://www.kent.ac.uk/res/Policy/gpm.pdf> [Accessed 18th July 2008]
- University of Oxford, 2007. *Academic Integrity in Research: Code of Practice and Procedure* [online]. Available from: <http://www.admin.ox.ac.uk/ps/staff/codes/air.shtml> [Accessed 18th July 2008]
- Wellcome Trust, 2005. *Guidelines on Good Research Practice, Including the Statement on the Handling of Allegations of Research Misconduct* [online]. Available from: http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtd002754.pdf [Accessed 18th July 2008]
- World Medical Association 2000. *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* [online]. Available from: <http://www.wma.net/e/policy/b3.htm> [Accessed 18th July 2008]

Flowchart of the Procedure



Procedure for the Investigation of Misconduct in Research

By using this Procedure organisations engaged in research can be confident that:

- every investigation will be thorough and fair
- all investigations will be carried out with confidentiality, fairness and sensitivity
- those who are under investigation will be reassured that the process of investigation will follow a standard procedure adopted nationally by universities and other research organisations.

The Procedure is designed for use in circumstance that may arise infrequently but can have wide-ranging and damaging consequences, made worse if not addressed appropriately. Through widespread adoption and consistent use of the Procedure by universities and other organisations, it is anticipated that investigations into allegations of misconduct in research will be conducted to the standards of objectivity, rigour and fairness set out here.

This publication is also available on the UK Research Integrity Office website www.ukrio.org

About us

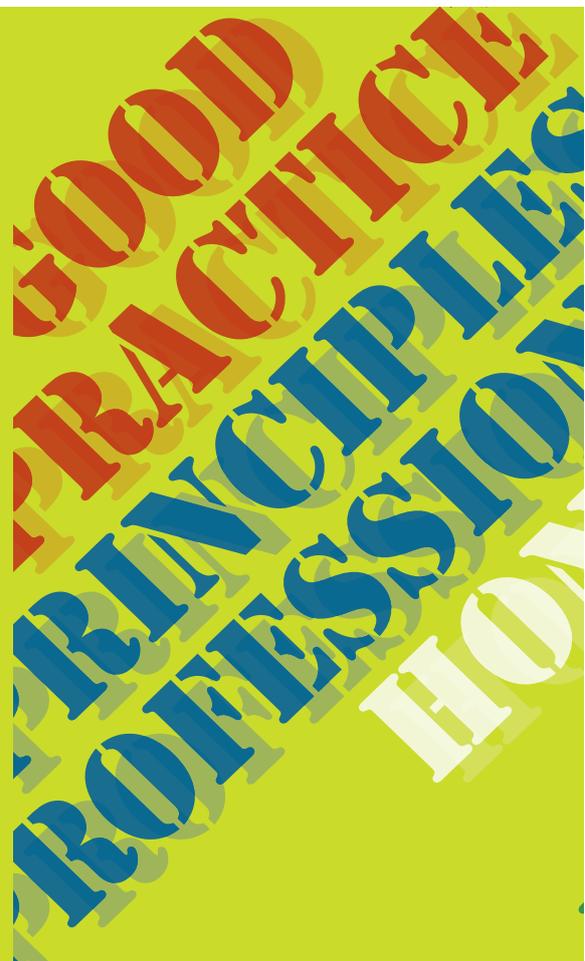
The UK Research Integrity Office (UKRIO) is an independent advisory body, hosted by Universities UK. Launched in 2006, it offers support to both research organisations and individual researchers in order to further the good governance of research and to promote good practice in addressing misconduct in research.

UKRIO welcomes general enquiries on issues relating to integrity in research as well as requests for assistance with specific matters related to the conduct of research.

The advice and guidance provided by UKRIO is available to all, including research organisations and individual researchers. The service can be accessed:

- by calling the UKRIO Research Integrity Helpline on **0844 77 00 6 44**
- by emailing helpline@ukrio.org
- or by contacting the Office, below

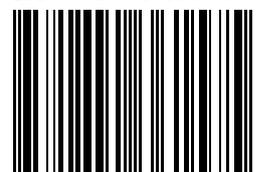
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