

Misconduct In Research

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INTRODUCTION

In August 2008 the UK Research Integrity Office (UKRIO) issued a 'Procedure for the Investigation of Misconduct in Research'. This step-by-step Procedure is aimed at all organisations engaged in research using funds from funding bodies such as the Research Councils and other government bodies, as well as from charities, overseas funding bodies and the commercial sector. The objectives of the Procedure are to:

- ensure that an investigation of alleged misconduct in research 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 will follow a standard procedure adopted nationally by universities and other research organisations

The Institute's Board of Trustees agreed in September 2010 (Minute Reference B/9/10/11) that the Institute should adopt a similar procedure to deal with any case that may arise within the Institute. The Institute's Procedure is in line with the UKRIO Concordat to Support Research Integrity (2019) and has been adapted from the UKRIO Procedure (2008) into the Institute's specific context.

Scope

This Procedure provides a guidance to undertake full and fair investigation of allegations of research misconduct brought to the Institute's attention. This Procedure applies to all Institute employees and students, and to all visiting researchers performing research at or on behalf of the Institute, including persons with honorary positions.

A complaint of misconduct in research may be initiated by an individual (an Institute employee, an Institute student or someone outside of the Institute) or an external institution or organisation. Whatever the source, it must always be taken seriously so that justice is seen to be done to both the complainant and the respondent. It is not easy to present a complaint against a colleague, and if complainants cannot be assured that bona fide complaints will be pursued with integrity, confidentiality, and without detriment, then misconduct may remain undiscovered. Conversely, researchers are entitled to expect that their work is regarded as honest until shown to be otherwise, and that they will be protected against mischievous, frivolous or ill-founded complaints.

The Institute may decide to vary the Procedure in any particular cases. Deviations from the Procedure will be documented and communicated accordingly to the parties involved.

What constitutes Misconduct in Research

As defined by Research Councils UK's 'Policy and Code of Conduct on the Governance of Good Research Conduct' - unacceptable conduct includes:

Fabrication

This includes the creation of false data or other aspects of research including documentation and participation consent.

Falsification

This includes the inappropriate manipulation and/or selection of data, imagery and/or consents.

Plagiarism

This includes the general misappropriation or use of others' ideas, intellectual property or work (written or otherwise), without acknowledgement or permission.

Misrepresentation including:

- misrepresentation of data, for example suppression of relevant findings and/or data, or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data
- undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts for publication

- misrepresentation of qualifications and/or experience, including claiming or implying qualifications or experience which are not held
- misrepresentation of involvement, such as inappropriate claims to authorship and/or attribution of work where there has been no significant contribution, or the denial of authorship where an author has made a significant contribution

Mismanagement or inadequate preservation of data and/or primary materials, including failure to:

- keep clear and accurate records of the research procedures followed and the results obtained, including interim results
- hold records securely in paper or electronic form
- make relevant primary data and research evidence accessible to others for reasonable periods after the completion of the research: data should normally be preserved and accessible for ten years, but for projects of clinical or major social, environmental or heritage importance, for 20 years or longer
- manage data according to the research funder's data policy and all relevant legislation
- wherever possible deposit data permanently, with a national collection

Breach of duty of care, which involves deliberately, recklessly or by gross negligence:

- disclosing improperly the identity of individuals or groups involved in research without their consent or other breach of confidentiality
- placing any of those involved in research in danger, whether as subjects, participants or associated individuals, without their prior consent, and without appropriate safeguards even with consent; this includes reputational danger where that can be anticipated
- not taking all reasonable care to ensure that the risks and dangers, the broad objectives and the sponsors of the research are known to participants or their legal representatives, to ensure appropriate informed consent is obtained properly, explicitly and transparently
- not observing legal and reasonable ethical requirements or obligations of care for animal subjects, human organs or tissue used in research, or for the protection of the environment
- improper conduct in peer review of research proposals or results (including manuscripts submitted for publication); this includes failure to disclose conflicts of interest; inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for peer review purposes

PROCEDURE FOR THE INVESTIGATION OF MISCONDUCT IN RESEARCH

(1) This procedure allows allegations of misconduct in research to be investigated once submitted to the Named Person formally in writing. 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. The Named Person can seek advice from UKRIO regarding whether such informal mechanisms might be appropriate for a particular allegation.

(2) Formal allegations, from both within and outside the Institute, should be sent to the Named Person (details in Annex 8). Allegations should be submitted in writing and be accompanied by any supporting evidence that is available to the Complainant.

(3) 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.

(4) Allegations which are in any way linked to the Named Person or which raises the potential for a personal, professional or financial 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 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 personal, professional or financial conflicts. The Complainant and Respondent may raise concerns that they might have that the Named Person may have interests which conflict with the fair handling of the allegations with the Chief Executive. The Chief Executive should act on information passed on, or known about, with respect to any conflict of interest and invite the Named Person to refer the investigation to the Nominated Alternate.

Preliminary Steps

(5) 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.

(6) 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 the allegation is considered to be true by the Institute.

1. 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 Institute 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.
2. Where allegations include behaviour subject to defined sanctions in the Institute'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.
3. The Named Person should review the nature of the allegations by referring to the definition of misconduct. 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

4. Allegations of misconduct in research that do not require notification to legal or regulatory bodies or immediate referral to the Institute's Disciplinary Process should proceed to the next stage in the Procedure.

(7) Where the allegations are within the definition of misconduct in research, the Named Person should inform:

- The Chief Executive
- The Chief Operating Officer
- The Director of Communications
- The Director of Human Resources
- The Scientific Secretary

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
- 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 Chief Executive 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 Chief Executive should take steps to remedy the situation.

(8) The Named Person should then, in conjunction with the Director of Human Resources and the Scientific Secretary, investigate the contractual status of the Respondent and the contractual details specific to the research project(s) related to the allegations.

If the Institute is not the Respondent's primary employer, the Respondent having only an honorary or secondary contract with the Institute, 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 Institute 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
- 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 Institute 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 Director of Human Resources 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.

(9) Subject to processes that may override the Procedure as defined at (6)(a) and (b) (legal or regulatory procedures) or (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 from Human Resources 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 work colleague or Staff Side representative (some employees may have additional contractual rights (such as through university statutes and ordinances) to be accompanied by persons other than those listed above). 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 Institute and colleagues and students of the Respondent and/or the Complainant.

Pre-Screening Stage

(10) 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 Human Resources 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 Institute 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 Institute 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 Institute; 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 those 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.

(11) 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.

(12) The Named Person may wish to consult UKRIO for advice and guidance regarding allegations of misconduct which have been received. Information provided to UKRIO will be held in confidence.

(13) 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
- The Respondent or the Complainant resigning, or having already resigned his/her post

(14) The Preliminary and Pre-Screening stage 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

(15) 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.

(16) 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.

If the allegations refer to an inadvertent mistake or error in a journal article or equivalent, ICR policy is that the authors must submit an Erratum or Corrigendum to the journal.

(17) The Named Person should consider recommending to the appropriate authorities that action be taken under the Institute's Disciplinary Process against anyone who is found to have made frivolous, vexatious and/or malicious allegations of misconduct in research.

Those who have made allegations in good faith should not be penalised and might require support.

The Named Person should also take steps as required and appropriate to the seriousness of the dismissed allegations, to support the reputation of the Respondent and the research project(s).

(18) If the allegations cannot be entirely discounted, the Named Person should convene a Screening Panel.

(19) The Screening Stage is intended to determine whether there is prima facie evidence of misconduct in research.

(20) 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 Institute's Disciplinary Process or other internal processes
- 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
- 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.

(21) **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 then 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.

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

(23) 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).

In addition, the Named Person should consider recommending to the appropriate authorities that action be taken under the Institute'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.

(24) When there is clear evidence of an infringement that might contravene the Institute's disciplinary code, the Named Person should consult the Director of Human Resources 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.

(25) 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 Institute'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.

(26) 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 Institute's Disciplinary Process.

(27) Where the Screening Panel recommends that the Procedure should progress to the Formal Investigation state, the Named Person should take immediate steps to set up the Formal Investigation Panel.

(28) 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)
- The Chief Executive
- The Chief Operating Officer
- The Director of Human Resources
- The Director of Communications
- The Scientific Secretary
- 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, Human Resources and Research

At this stage the Named Person may wish to consult UKRIO for advice and guidance, particularly regarding the nomination of members from outside the Institute to the Formal Investigation Panel.

(29) The Named Person should then convene the Formal Investigation Panel. The Formal Investigation Panel should examine the evidence collected during the Screening Panel's investigation following the original allegations and investigate further as required.

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

- upheld in full
- upheld in part
- not upheld

(31) The standard of proof used by the Formal Investigation Panel is that of "on the balance of probabilities".

(32) The Formal Investigation Panel may conclude that allegations are not upheld for reasons for being mistaken, frivolous, vexatious and/or malicious.

(33) 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(s)

then the Formal 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.

(34) The Formal 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 Formal 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.

(35) The Chair of the Formal 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.

(36) The Formal 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 error of fact and matters that have bearing on the facts as indicated by the Respondent and/or the Complainant, and accepted by the Formal 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.

(37) The Formal Investigation Panel should then produce a final report that:

- summarises the conduct of the Formal 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
- addresses any procedural matters that the Formal Investigation has brought to light within the Institute and relevant partner organisations and/or funding bodies.

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

- (a) whether the allegations should be referred to the relevant organisations' Disciplinary Process*
- (b) whether any action will be required to correct the record of research*
- (c) whether organisational matters should be addressed by the Institute through a review of the management of research*
- (d) other matters that should be investigated.*

The Report should be sent to the Named Person.

(38) If all or any part of the allegations are upheld, the Named Person, the Director of Human Resources and at least one other member of senior staff should then decide whether the matter should be referred to the Institute's Disciplinary Process or for other formal actions.

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

- the Respondent and the Complainant (and their representatives by agreement)
- the Chief Executive, the Director of Research, the Director of Human Resources, the Head of Division(s) of the relevant Division(s) and any other relevant members of staff
- if the Respondent and/or the Complainant are employed on joint clinical/honorary contracts, the Named Person, the Head of Human Resources and the Head of Research of the other organisation(s)
- where appropriate, the responsible person within any relevant partner organisations, funding bodies and/or regulatory or professional bodies
- additionally the Named Person may wish to inform UKRIO of the conclusion of the Formal Investigation

(40) Should the allegations proceed to the Institute's Disciplinary Process, the report of the Formal 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 Formal Investigation Panel and the Named Person, to ensure that all relevant material is transferred.

(41) Where the 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).

(42) As with the Screening Process, where the Formal 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 Institute's Disciplinary Process against anyone who is found to have made frivolous, vexatious and/or malicious allegations of misconduct in research.

(43) 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.

(44) Questions relating to the reports of both the Screening and Formal Investigation Panels can only be raised with the Chair of either Panel over matters of fact. The Respondent should not have the option of appealing against the reports of either stage of the Procedure. The Respondent has the statutory right of appeal should be 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.

Actions to consider

(45) Where the Formal 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 Institute's Disciplinary Process. The Named Person should consider the use of the recommendations set out in any case where misconduct in research has been investigated.

(46) The timing of any actions taken should be compatible with the Institute's Disciplinary Process and Appeals Process.

Review of the Procedure

(47) This procedure will be reviewed every five years or sooner if used. A review of the lessons learnt will be implemented after each case of alleged or confirmed research misconduct to determine whether any update to the Procedure is required.

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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 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 the knowledge of:

- the statutory obligations of the Institute and the rights of employees according to current law
- any additional rights and obligations particular to the Institute 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 allegation 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 be allowed to:

- ask questions
- present information (evidence) in his/her defence
- adduce evidence of witnesses

- raise points about any information given by witnesses (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 Formal Investigation Panel may:

- be accompanied by a work colleague or Staff Side 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.

(10) To ensure a fair investigation, an individual may not be a member of both the Screening Panel and the Formal Investigation Panel and, if he/she has been involved in either, he/she should not be part of the Institute'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 that 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 any 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 Institute'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 Institute'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 Institute 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 Institute's disciplinary process), the Complainant, the Respondent, witnesses or other persons involved in this Procedure should not make any statements about the allegations to any third parties, unless formally sanctioned by the Institute 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 Institute'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 in 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 personal, professional or financial interests that they have which might constitute a conflict of interest as regards any aspects of the allegations, the investigation, the area(s) of research in question, or any of the persons concerned. Where the Named Person has any personal, professional or financial 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.

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 Institute 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 Institute's Disciplinary Processes.

(26) At the conclusion of the proceedings, all records should be retained by the Institute (Human Resources Team), for as long as the Institute's policy for maintaining such records requires. It is recommended that the file be given a six year review date.

(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 Formal Investigation Panel and between the Formal 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, ie 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 appears 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 Institute's disciplinary process which provides the Respondent with the right of appeal. Only when allegations have been upheld through the Institute's disciplinary process and, where called upon, the appeals process, may it be appropriate to apply any sanctions to the Respondent.

(36) The Institute 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 Institute 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 Institute's disciplinary process and/or appeals process, the Institute'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 or 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 Institute. 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
- 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

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).

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 or defined bodies in the Procedure, reference to the singular should be viewed to include the plural as appropriate.

Disciplinary Process

The Disciplinary Process refers to the Institute's mechanism for resolving disciplinary issues amongst its staff and students.

Employer

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

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

Honorary Contract

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

Examples of arrangements that commonly involve the issue of an honorary contract are:

- for a 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 contact 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 the 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.

Misconduct in Research

As defined by Research Councils UK's Policy and Code of Conduct on the Governance of Good Research Conduct - unacceptable conduct includes:

Fabrication

This includes the creation of false data or other aspects of research including documentation and participation consent.

Falsification

This includes the inappropriate manipulation and/or selection of data, imagery and/or consents.

Plagiarism

This includes the general misappropriation or use of others' ideas, intellectual property or work (written or otherwise), without acknowledgement or permission.

Misrepresentation including:

- misrepresentation of data, for example suppression of relevant findings and/or data, or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data
- undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts for publication
- misrepresentation of qualifications and/or experience, including claiming or implying qualifications or experience which are not held
- misrepresentation of involvement, such as inappropriate claims to authorship and/or attribution of work where there has been no significant contribution, or the denial of authorship where an author has made a significant contribution

Mismanagement or inadequate preservation of data and/or primary materials, including failure to:

- keep clear and accurate records of the research procedures followed and the results obtained, including interim results
- hold records securely in paper or electronic form
- make relevant primary data and research evidence accessible to others for reasonable periods after the completion of the research: data should normally be preserved and accessible for ten years, but for projects of clinical or major social, environmental or heritage importance, for 20 years or longer
- manage data according to the research funder's data policy and all relevant legislation
- wherever possible deposit data permanently, with a national collection

Breach of duty of care, which involves deliberately, recklessly or by gross negligence:

- disclosing improperly the identity of individuals or groups involved in research without their consent or other breach of confidentiality
- placing any of those involved in research in danger, whether as subjects, participants or associated individuals, without their prior consent, and without appropriate safeguards even with consent; this includes reputational danger where that can be anticipated
- not taking all reasonable care to ensure that the risks and dangers, the broad objectives and the sponsors of the research are known to participants or their legal representatives, to ensure appropriate informed consent is obtained properly, explicitly and transparently

- not observing legal and reasonable ethical requirements or obligations of care for animal subjects, human organs or tissue used in research, or for the protection of the environment
- improper conduct in peer review of research proposals or results (including manuscripts submitted for publication); this includes failure to disclose conflicts of interest; inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for peer review purposes

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 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 fall directly with the terms detailed above, a judgement should be made as to whether the matter should be investigated using the Procedure.

Named Person

The Named Person is defined in the Procedure as the individual nominated by 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 (Chief Executive), Head of Research (Director of Research) or Head of Personnel (Director of Human Resources).

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.

The Procedure

The Procedure refers to this publication - The Procedure for the Investigation of Misconduct in Research.

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 the Procedure include the General Medical Council, the Nursing and Midwifery Council and the Health Professions Council.

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.

Research and Scholarship

The Research Assessment Exercise 2008 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.
- 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.

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 or student 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 (the Chief Executive) would serve as the Respondent in the Procedure.

Screening Stage

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

Sponsor

The Department of Health Research Governance Framework 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. 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- 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 are available on their website.

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 7700644
- by emailing info@ukrio.org
- or by contacting the Office, below

UK Research Integrity Office

Sussex Innovation Croydon

No 1 Croydon

12-16 Addiscombe Road

Croydon CR0 0XT

Telephone - 020 3828 1325

Fax – 012 7370 4499

Email - info@ukrio.org

Web – www.ukrio.org

ANNEX 4- 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 the 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 the 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 witness/person whom the Panel consider relevant to the investigation
- provide a draft report to the 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 Screening 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 Institute or otherwise required to by law. They should also remember that all information concerning the case was given to them in confidence.

Note: The Institute 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 Screening Panel members, the Named Person should consider:

- the subject matter of the allegations, including whether it could be advantageous for members of the Panel to possess any specialised knowledge or investigative skill
- any personal, professional or financial 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)
- 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
- 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*
- *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 and seek the agreement of the majority of the 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 Formal Investigation Panel rules out participation in any disciplinary process.

ANNEX 5 - OPERATION OF THE FORMAL INVESTIGATION PANEL

(1) The Formal 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 for the Formal Investigation Panel

(2) Members appointed to the Formal 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 Formal Investigation Panel
 - will work within the Terms of Reference for the Formal 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 Formal 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 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 Formal 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 Formal Investigation Panel may conclude that allegations are upheld in part as well as concluding that they are upheld in full.

(4) The Formal 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
- 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 Formal Investigation Panel may make recommendations with respect to:

1. *whether the allegations should be referred to the relevant organisation's disciplinary process*
2. *whether any action will be required to correct the record of research*
3. *whether organisational matters should be addressed by the Organisation through a review of the management of research*

4. *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 Formal 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 Formal Investigation Panel should not make any comment on the matter in question, unless formally sanctioned by the Institute or otherwise required to by law. They should also remember that all information concerning the case was given to them in confidence.

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

Composition of the Formal Investigation Panel

(7) The Formal 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 Formal 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 skills
- 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
- any connections with the work through, for example, the Institute'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 Formal 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 contacts for there to be on the Formal 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 Formal 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 Formal 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 Formal Investigation Panel.

(13) The Named Person should nominate members of the Formal Investigation Panel for approval by the Chief Executive or a nominated deputy (the Director of Research). The Chief Executive, or his/her

deputy, may veto nominations for the Formal 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 Formal Investigation Panel, but do not have a right of veto over those selected.

(15) The members of the Formal Investigation Panel should sign a declaration confirming that they will:

- abide by the Procedure as it affects the work of the Formal Investigation Panel
- work within the Terms of Reference for the Formal Investigation Panel (detailed above)
- respect the confidentiality of the proceedings
- adhere to the Principles of the Procedure (see Annex 1)

(16) Once convened, the membership of the Formal 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.

The work of the Formal Investigation Panel

(17) The Formal Investigation Panel may call expert witnesses to give advice, if necessary and as appropriate. Such witnesses do not become members of the Formal Investigation Panel. The Formal 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 Formal Investigation Panel should review:

- the submission(s) and supporting evidence by the Complainant
- the response(s) and supporting evidence by the Respondent who should be given the opportunity to respond to the allegations made and to present evidence
- background information relevant to the allegations
- any interviews conducted with the Respondent, the Complainant, and other witness/person 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 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 witness/person 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 Formal Investigation Panel may be accompanied by a work colleague or a Staff Side representative*

- *furthermore, some employees may have additional contractual rights (such as through university statutes and ordinances) to be accompanied by persons other than those listed above*
- *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 Formal Investigation, which should be as soon as is practical without compromising the Principles of the Procedure (Annex 1).

(22) The Chair of the Formal 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 Formal Investigation will last for one calendar month or less, reports should be made on a bi-weekly basis.

(23) The Formal 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 Formal Investigation Panel

(24) The role of the Formal 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 Formal Investigation Panel is that of "on the balance of probabilities".

(25) A majority decision is acceptable, although a unanimous decision is desirable.

(26) It is acceptable for the Formal Investigation Panel to conclude that allegations are upheld in part rather than in full.

(27) Once the Formal 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
- 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 Chief Executive, the Director of Research, the Director of Human Resources, the Head of Division(s) of any relevant Division(s) and any other relevant members of staff
- if the Respondent and/or Complainant are employed on joint clinical/honorary contracts, the Named Person, the Director of Research 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
- additionally, the Named Person may wish to inform UKRIO of the conclusion of the Formal Investigation.

(29) The work of the Formal 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 Formal Investigation Panel should not make any comment on the matter in question, unless formally sanctioned by the Institute 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 Formal Investigation Panel should be referred to the Named Person.

(31) Those who have contributed to the disbanded Formal 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 Formal 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 Institute'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 Formal 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 acknowledgement 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 Formal 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 Institute'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 Formal Investigation Panel may need to recommend additional measures in addition to those that may be taken by way of the Institute'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 Formal 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 the Panel's work.

3. At the conclusion of the proceedings, the Director of Human Resources should retain all such records for a period that accords with the Organisation's policy. It is recommended that the file be given a six year review date. Access to this archive should be limited to appropriate members of the Human Resources Team, 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 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 Institute's Disciplinary Panel or the Human Resources Team.
6. If the Institute's Disciplinary Process is to be invoked as a result of the outcome of this Procedure, the report of the Formal 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 Director of Human Resources to obtain any further relevant information for any relevant parties, such as an organisation's Disciplinary Panel or Human Resources Team, and add it to the confidential case archive.

Communication with involved parties

1. The Screening and Formal 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 the support staff of the Screening and Formal 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 the Respondent, Complainant or another member(s) of staff) directly with members of 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 Formal Investigation Panel.

ANNEX 8 - Contact Details

Any allegations under the Institute's Procedure for the Investigation of Misconduct in Research should be made in writing and addressed to the Named Person and the Nominated Alternate c/o of the Institute's solicitors. Currently these are:-

Named Person

Professor Clare Isacke

Academic Dean

The Institute of Cancer Research

c/o Bettina Rigg,

Veale Wasbrough Vizards LLP

24 King William Street

Nominated Alternate

Professor Robert Huddart

Clinical Consultant

The Institute of Cancer Research

c/o Bettina Rigg,

Veale Wasbrough Vizards LLP

24 King William Street

London

London

EC4R 9AT

EC4R 9AT

The Institute of Cancer Research has agreed:

1. That the senior person who would liaise with the Named Person/Nominated Alternate and be responsible for setting the process in motion and administering it would be the Scientific Secretary, who would work with the Director of Human Resources and the Director of Finance.

If the allegation relates to a student the Nominated Alternate would be responsible for setting the process in motion and administering it would be the Research Strategy Co-ordinator, who would work with the Director of Human Resources and the Director of Finance.

2. That the Screening Panel (should this be required) should consist of at least three senior members of staff – the pool of senior members of staff for the Screening Panel includes Heads and Deputy Heads of Division (other than the Chief Executive and the Director of Research). If necessary the Screening Panel could include one or more external expert(s), provided that they have signed a Confidentiality Agreement.
3. That the Formal Investigation Panel (should this be required) should include (desirable, but not essential) a member who either holds or has held judicial office or to be a barrister or solicitor of at least 10 years standing.