Queen Mary University of London

Senate

Paper Title	The investigation and resolution of research misconduct allegations
Outcome requested	Approval of the procedure for this; backing up the high-level policy agreed last year.
Points for Senate members to note and further information	A joint policy for managing allegations of Research Misconduct was agreed in September 2017. At that time there were issues about the practical management of such allegations. The standard operating procedure (SOP), now submitted for sign-off, has been created by the JRMO in consultation with HR and other stakeholders to fill this administrative gap. It sets out procedure covering: (i) Registering a complaint (ii) Undertaking an initial investigation (iii) Running a research misconduct panel (iv) Managing the outcome Roles and responsibilities for various parties are set out within the SOP. For QMUL the Academic Secretariat would be responsible for oversight of the process, with assistance from the JRMO and others as relevant.
Questions for Senate to consider	None specific. The policy was agreed last year.
Regulatory/statutory reference points	
Strategy and risk	
Reporting/ consideration route for the paper	Senate to approve before publication.
Authors	Nick Good, R&D Projects Manager, JRMO
Sponsor	Prof Rupert Pearse, Joint Clinical Director of Research and Development

Attachments to this paper:

Page 2 - SOP 33 (The investigation and resolution of research misconduct allegations)

Page 14 – Associated Document: The investigation and resolution of research misconduct allegations

Page 23 – Related Joint Policy on (agreed in September 2017)

Joint Research Management Office (JRMO) Standard Operating Procedure (SOP) for:			
The investigation and resolution of research misconduct allegations			
SOP Number:	**33**	Version Number:	**1.0 (DRAFT)**
Effective Date:	**[October 2018]**	Review Date:	**[3 years on]**

Authorship & Approval:	
Author:	**Nick Good, R&D Projects Manager**
Reviewer:	**Mays Jawad, Research Governance Operations Manager**

Authorisation:	
Name/Position:	**Director of Research Services and Business Development**

Purpose:

This Standard Operating Procedure (SOP) exists to describe a common procedure for investigating and resolving allegations of research misconduct at both Queen Mary University of London (QMUL) and Barts Health NHS Trust (BHT).

It should be read in accordance with the Joint Policy on Research Misconduct, agreed by both organisations, and the HR policies of each organisation.

Scope:

QMUL and BHT are committed to maintaining the highest standards of integrity and probity in the conduct of research (see the joint Policies on Research Integrity and Research Misconduct).

This Procedure for Investigating Allegations of Research Misconduct is based on the Procedure for the Investigation of Misconduct in Research by the UK Research Integrity Office (UKRIO) and outlines the action to be taken when an allegation of misconduct in research is brought against any present or past member of staff of QMUL and/or BHT in respect of research undertaken while employed by QMUL and/or BHT.

A separate procedure (the Regulations on Assessment Offences) is in place for allegations of research misconduct against students.

The outcome of the Procedure may result in further action using QMUL's or BHT's Disciplinary Procedure or other non-disciplinary processes.

The following principles are to be applied in the implementation of this policy and any associated investigation:

1. The confidential nature of an investigation is essential in order to protect the Complainant, the Respondent and others involved in it. In the conduct of any investigation using this SOP the principles of confidentiality and fairness must be applied with appropriate balance towards both the Respondent and the Complainant. Due care and consideration should be taken when selecting the venue and logistical arrangements of any subsequent Research Misconduct investigation panel meeting to ensure the confidentiality of the Complainant and/ or any witnesses is protected.

2. The identity of the Complainant or the Respondent shall not be made known to any third party unless:
    (i) It is deemed essential by those conducting the investigation in order to properly carry out that investigation;
    (ii) It is deemed necessary to protect evidence, participants in the research, collaborators or the reputations of QMUL or BHT;
    (iii) It is necessary as part of the action taken against the Respondent or to address the consequences of the actions of the Respondent when (at the end of the Procedure and relevant disciplinary/appeals processes) the allegations have been upheld;
    (iv) It is necessary as part of an action taken against a Complainant who has been found to have made a malicious, vexatious or frivolous allegation; and/or
    (v) It is the stated policy of the employer, funder or other involved body that the identity of individuals proved, through appropriate disciplinary and appeals processes to have committed misconduct in research, should be made public.

3. 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 they must respect the confidentiality of any information received. Breaching confidentiality may lead to disciplinary action, unless covered by the Public Interest Disclosure Act and/ or QMUL's or BHT's grievance or whistle-blowing policies and procedures. Where the policies and procedures interact and overlap, the policy with most relevant bearing to the case should be followed.

4. The investigation of any allegations of misconduct in research must be carried out fairly and in accordance with the statutory and human rights of all parties involved. Those responsible for carrying out an investigation in accordance with this SOP shall have regards to:
    (i) The statutory obligations of QMUL and BHT and the rights of employees according to current law. It is the responsibility of the relevant Director of Human Resources to advise on current employment law and relevant legislation; and
    (ii) Any additional rights and obligations particular to the institution and/or its employees – for example those bestowed by university statutes and ordinances.

5. Those responsible for carrying out and taking part in an investigation in accordance with this SOP shall recognise that inaction or delay regarding the transfer of information could lead to the process being unfair to the Respondent and/or the Complainant, contrary to the principle of natural justice.

6. In carrying out an investigation in accordance with this SOP care must be taken to protect:
    (i) Individuals against frivolous, vexatious and/or malicious allegations of misconduct in research;
    (ii) The position and reputation of those suspected of, or alleged to have engaged in,

misconduct, when the allegations or suspicions are not confirmed;

(iii) The position and reputation of those who make allegations of misconduct in research in good faith, i.e. in the reasonable belief and/or on the basis of supporting evidence that misconduct in research may have occurred.

7. The Chair of the Research Misconduct Panel shall assume responsibility with the Academic Secretariat (QMUL) or Medical Director's Office (BHT) for keeping accurate records of the activities, deliberation and reporting of the Research Misconduct Panel. The Academic Registry and Council Secretariat (ARCS, QMUL) or the Medical Director's Office (BHT) will maintain the file for the case and archive this appropriately at the completion of any investigation undertaken in accordance with this SOP.

8. Those responsible for carrying out an investigation in accordance with this SOP shall be aware that there may be occasions when a balance has to be struck in the application of the principles.

9. 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 HR, the JRMO, the UK Research Integrity Office (UKRIO) and other bodies, as well as, where relevant, legal advice.

Abbreviations:

SOP	Standard Operating Procedure
ARCS	Academic Registry & Council Secretariat (QMUL)
BHT	Barts Health NHS Trust
CB	Clinical Board (BHT)
GMC	General Medical Council
HRA	Health Research Authority
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare Products Regulatory Agency
NMC	Nursing and Midwifery Council
QMUL	Queen Mary University of London

Definitions:

Research Misconduct

Research misconduct includes carrying out, attempting or planning any of the following (as well as any other examples that might reasonably fall within the remit of the policy and its documentation):

- The fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research;
- The deliberate, dangerous or negligent deviation from agreed formal protocols or regulations, including accepted professional standards of behaviour and conduct, in carrying out research, and the failure in that context to avoid risk or harm to humans, animals used in research, and the environment where appropriate;
- The facilitation of misconduct in research or collusion in, or concealment of, such

actions by others; and

- The intentional and unauthorised use, disclosure of, removal of or damage to, research related property of another researcher. This may include, but is not limited to, intellectual property, writings, data, apparatus, materials, hardware, software, infringement of data protection or confidentiality requirements.

Misconduct in research can include acts of calculated omission as well as acts of commission. It excludes genuine errors or differences in interpretation or judgement in evaluating research methods or results, or misconduct unrelated to research processes.

Relevant SOPs:

None.

SOP Text:

	Responsibility	Activity/ responsibility
1.	Complainant	The person who brings an allegation of apparent or possible research misconduct to the attention of a person within QMUL or BHT.
2.	Respondent	The person about whom the allegation is made.
2.	Named Person	The person within QMUL or BHT to whom allegations of apparent or possible research misconduct by a member of QMUL or BHT staff are brought. The Named Person is a nominee of the Principal (for QMUL) or the Chief Executive (for BHT). The Named Person will normally be the Vice Principal for Research for QMUL or the Chief Medical Officer for BHT. They shall: • Follow the agreed procedure for the Research Misconduct Panel (see Appendix 1 and the Associated Document: The investigation and resolution of research misconduct allegations) • With the Director of HR, identify and appoint a suitable Named Investigator; • Ensure all relevant parties are informed and are kept informed (as needed and protecting confidentiality as far as is reasonable within this Procedure); • Resolve any conflicts between the principles; • Inform the Respondent of the allegations and the outcome of the Investigation; • Formally recommend the need for a Research Misconduct Panel to be established, based on the findings of the investigation; • With, where relevant, the Named Partner, the HR Director and the QMUL ARCS or Barts Health Medical Directorate (as appropriate) approve and appoint the Research Misconduct Panel members, including its Chair, and maintain the correct composition of membership for the duration of the investigation; • Protect the reputations of the Complainant and the Respondent as appropriate;

		• Provide oversight of any communications with the organisations involved in the process • Receive the Research Misconduct Panel's final report and then inform key people (ie, the Respondent, Complainant, Named Investigator, Senior JRMO Director, Director(s) of the relevant School(s), Institute(s) or Clinical Board(s), the appropriate HR Director and the QMUL ARCS or Barts Health Medical Directorate (as appropriate) of the outcome of the Research Misconduct Panel; • Ensure all actions required as a result of the panel outcome are carried out in a timely manner; • Ensure that appropriate actions are taken depending on the outcome of the investigation and Research Misconduct Panel, both with regard to the Respondent, correcting the research record and ensuring that collaborators, partners, regulators (such as MHRA, HRA, GMC, NMC as applicable) etc. are informed as needed and appropriate actions taken; • Appoint, at their discretion, a Named Partner to assist in the above undertakings.
3.	Named Partner	Where appointed by the Named Person, a Named Partner shall assist in the above activities. This person can be made responsible for liaising with the Named Investigator and ensuring excellent communication and co-ordination within the relevant organisation.
4.	Named Investigator	This person, appointed by the Named Person, shall be responsible for: • Leading the investigation; • Following the Procedure; • Gathering such evidence as is practicable in the period of the investigation and supplying this to the Research Misconduct Panel; • Undertaking a timely assessment (with a recommended guideline of four weeks duration) to determine whether the allegations are credible and whether there is sufficient evidence of research misconduct for a Research Misconduct Panel to be appointed, or other actions are recommended; • Confirming that the Respondent has an employment contract (honorary or substantive); • Ensuring the Named Person, the Director of School, Institute or BHT Clinical Board (CB) and if relevant partner organisations with whom the Respondent has an employment contract (honorary or substantive), are kept informed of progress and issues; • Providing a written report to the Named Person detailing the outcome of the investigation, recommendations and reasoning for the Research Misconduct Panel review; • Informing relevant people and organisations (and keeping them informed). This may include previous employers where the Respondent has previously undertaken research; • Liaison with any partner organisations, keeping them informed, obtaining information and ensuring coordination of activities; • In discussion with the Named Person, Director of Research Services and/or Clinical Director of R&D and Director of HR, advising the Director of School, Institute or CB of appropriate actions that should be taken to protect participants in the research,

		the evidence etc; • Ensuring that all relevant information and evidence are secured; • In discussion with the Named Person and Director of HR, triggering a disciplinary process should it be deemed necessary; • In conjunction with the Academic Secretariat (QMUL) or Medical Director's Office (BHT), keeping a written record of all decisions taken throughout all the steps of the Procedure; • In discussion with the Named Person considering whether it is necessary to inform legal or regulatory authorities; and if so to inform and engage the Director of Research Services and Clinical Director of R&D; and • Ensuring that the rights of the Respondent, the Complainant and the integrity of the investigation are maintained throughout.
5.	Director(s) of the relevant School(s), Institute(s) or Clinical Board(s)	This person or these people (as appropriate) shall have responsibility for: • Taking appropriate actions to protect participants in the research, the evidence etc; • Assisting the Named Person (as necessary) in securing the relevant information and evidence; and • Undertaking follow-up remedial actions regarding the research record, funders and collaborators.
6.	JRMO Lead	The Joint Research Management Office (JRMO) lead shall be a Senior Director within the JRMO, that includes the Clinical Director of Research and Development, who shall have responsibility for: • Providing information about the Respondent's grants, contracts, collaborators etc; • Advising on whether there is a requirement to notify external bodies/persons (e.g. funders, external sponsors, regulators) of the Respondent's temporary dereliction of duties; where possible maintaining principles of confidentiality; • Liaising with others within the JRMO as necessary; • Ensuring the JRMO considers the need to temporarily suspend on-going research work involving the Respondent; • Following-up actions if allegations are upheld and relevant to clinical trials or investigations; liaison with MHRA (if required), follow up audits etc; and • Otherwise supporting the investigation as requested or required.
7.	QMUL Academic Registry & Council Secretariat (ARCS) / Barts Health Medical Directorate	As appropriate, these bodies shall be responsible for: • Documenting the investigation; • Administratively supporting the Research Misconduct Panel and the Named Investigator; • Servicing the Research Misconduct Panel; • Maintaining the file for the case and archiving this appropriately at the completion of the investigation; and • Keeping a written record of all decisions taken at every stage of the investigation, and accurate records of the activities, deliberation and reporting of any subsequent Research Misconduct Panel. Where both QMUL and BHT staff are involved, or where the line of responsibility is otherwise unclear, ARCS and the Medical Directorate

		shall agree on which office will take the lead. Whichever office it is that takes that lead shall then keep the other office informed of progress in a timely manner and shall involve the other organisation in reaching any decisions which may impact upon that organisation, its policies or obligations.
8**.**	Director of HR (QMUL or BHT as appropriate)	This person shall have responsibility for: • Advising the Named Person, Named Investigator and Research Misconduct Panel with respect to HR matters, policies and procedures etc.; • Communications with the Respondent (other than communications by the Named Person or Named Partner); and • Actioning the Research Misconduct Panel's outcomes and initiating the Disciplinary Policy where recommended.
9.	Research Misconduct Panel:	This group, appointed by the Named Person in consultation with others (see above), shall be responsible for: • Following the agreed procedure for the Research Misconduct Panel (see Appendix 1 and the Associated Document: The investigation and resolution of research misconduct allegations); • Examining the evidence collected during the investigation; and • Preparing a final report with a conclusion on whether the allegations are upheld, recommendations with respect to whether the case should go on to a disciplinary procedure, recommendations about necessary actions as a result of the outcome, informing external bodies etc.
10.	Chair of the Research Misconduct Panel:	This person, appointed by the Named Person in consultation with others (see above), shall be responsible for: • With QMUL ARCS or BHTR Medical Directorate, keeping accurate records of the activities, deliberation and reporting of the Research Misconduct Panel; and • Reporting progress of the Research Misconduct Panel to the Named Person on a bi-weekly basis or on a monthly basis if the investigation will take more than one calendar month.

Change control

This section outlines changes from version xx to version xx

Section changed	Summary and description of changes
n/a	

List of appendices

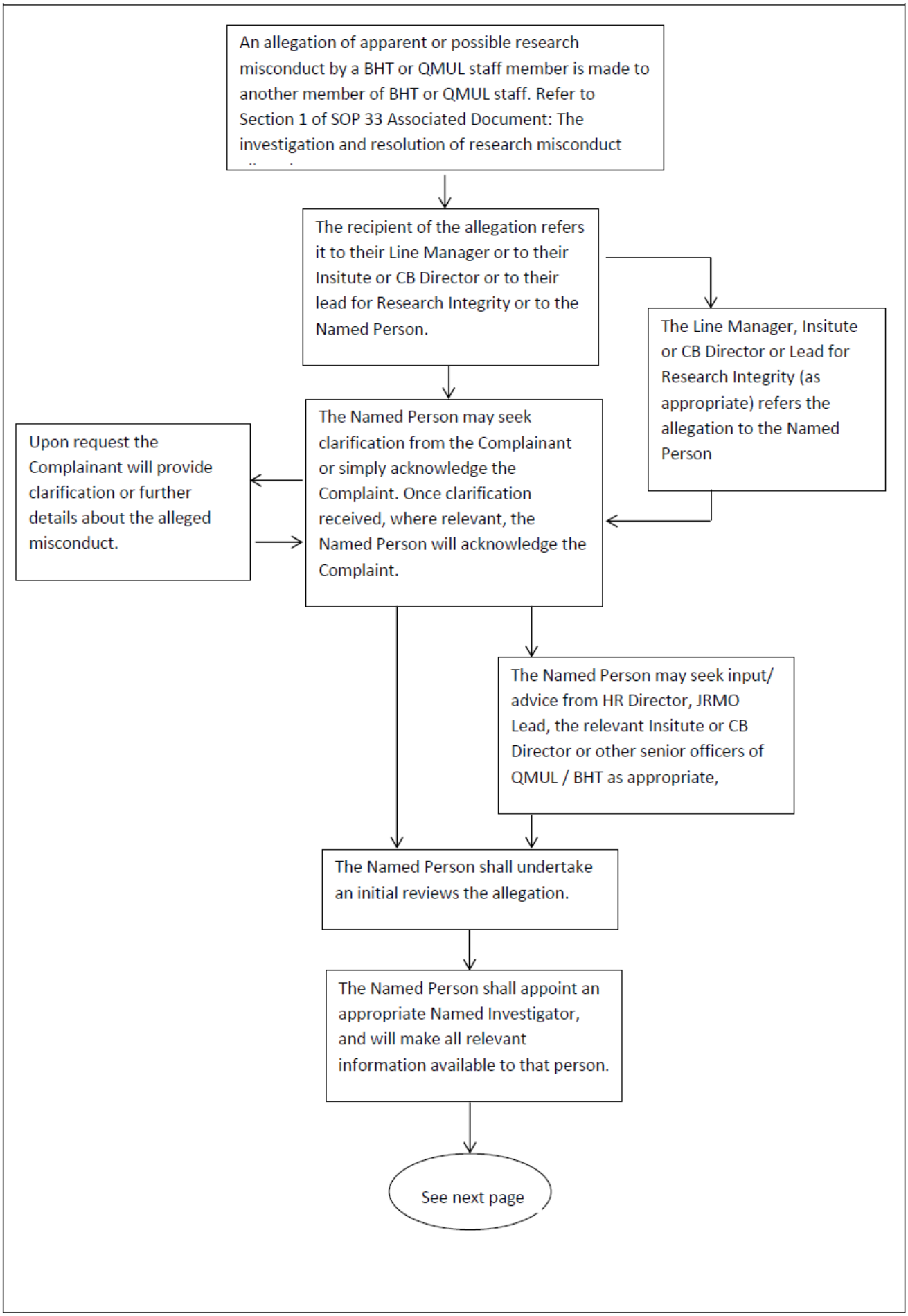
Appendix ref.	Appendix name
1	Research Misconduct procedural flow diagram

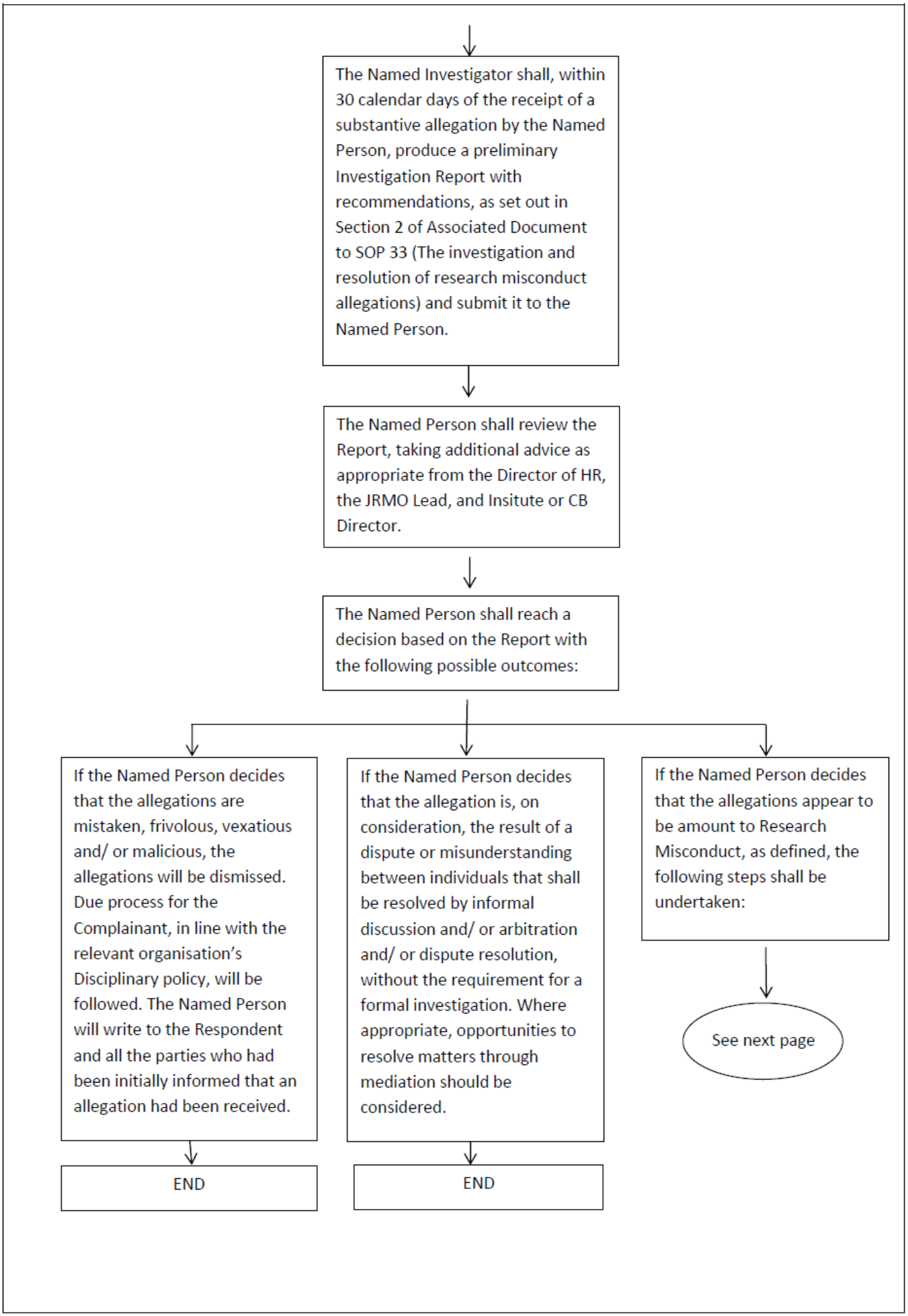
List of associated documents

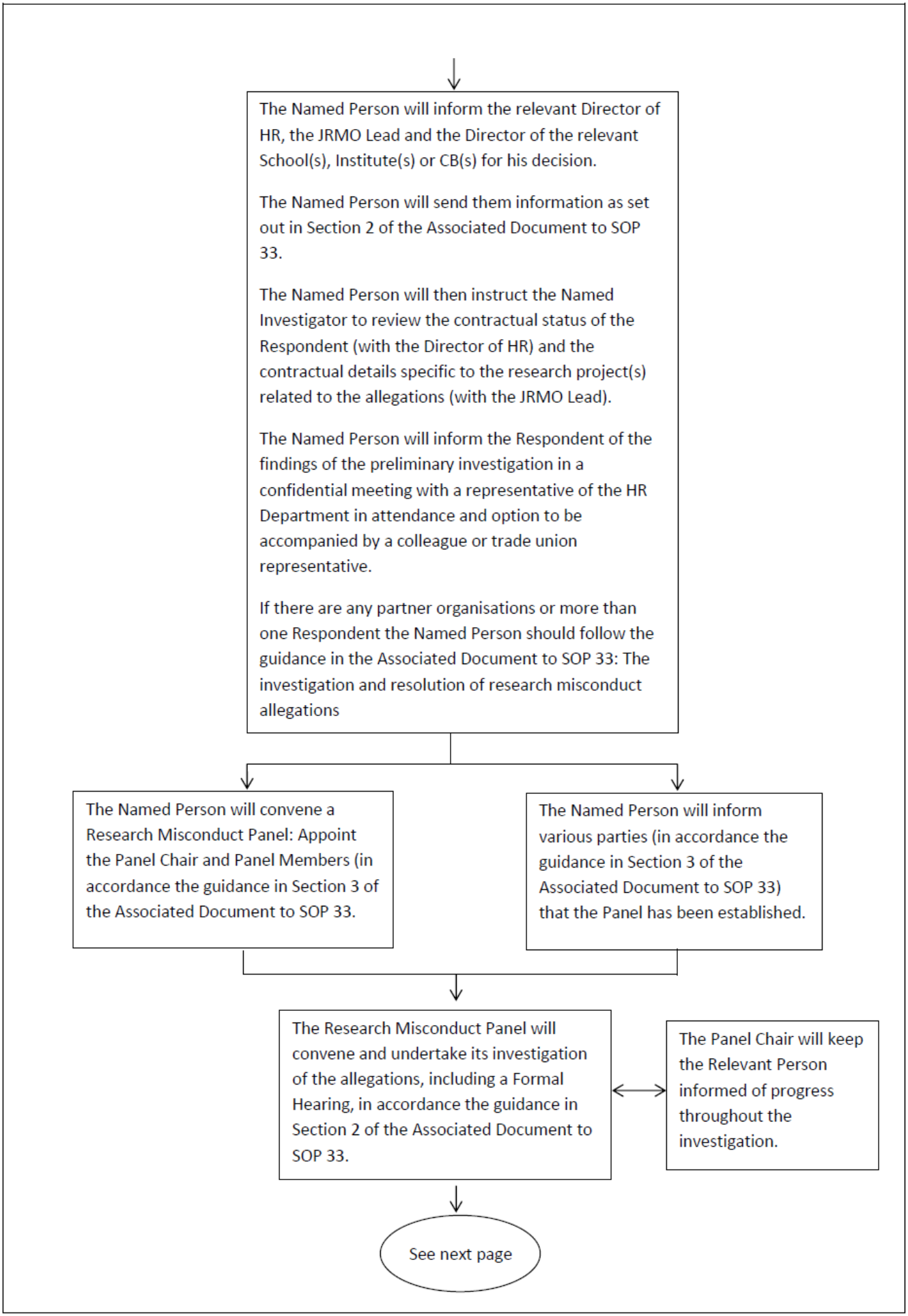
Document ref.	Document name

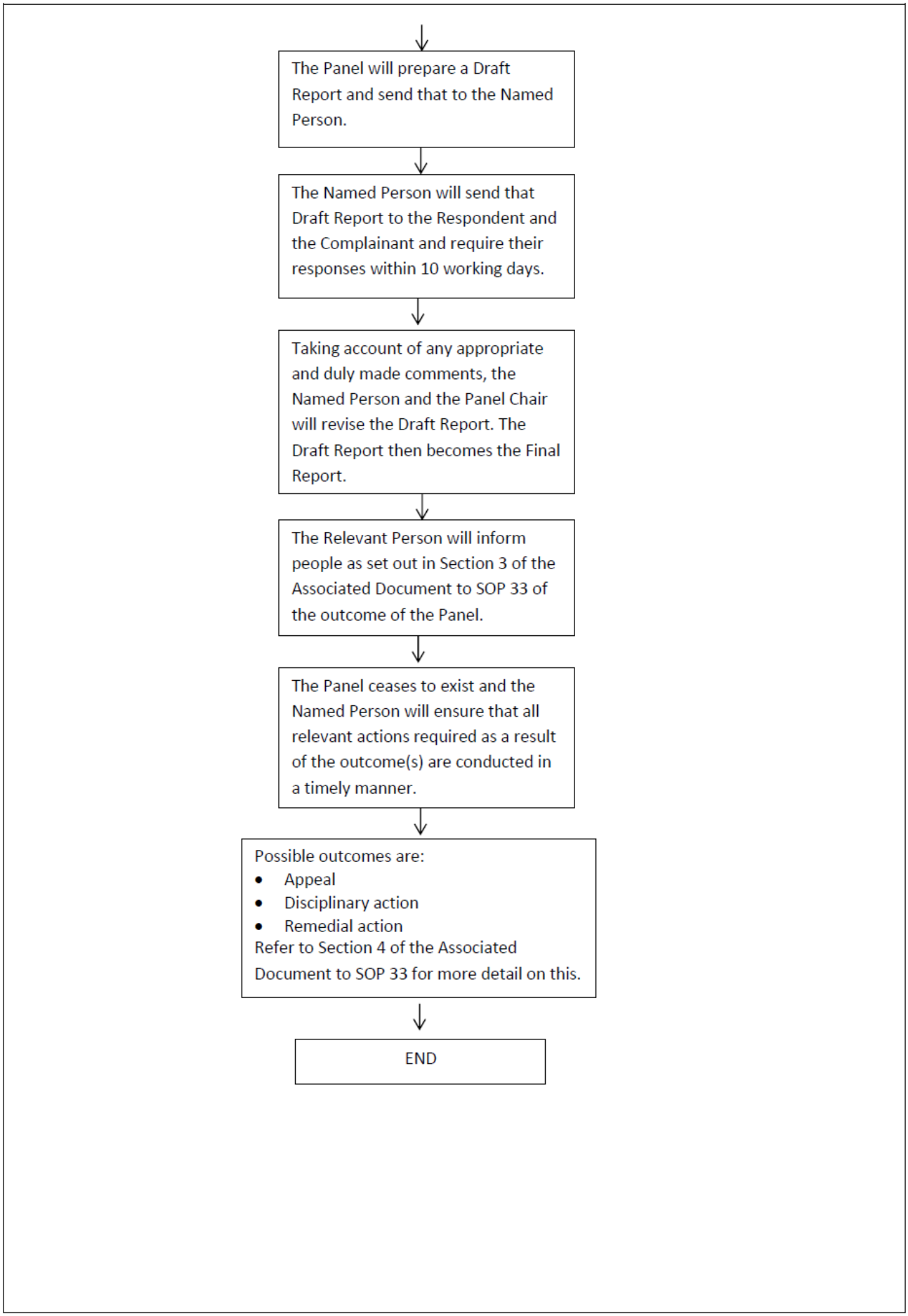
1	The investigation and resolution of research misconduct allegations

Appendix 1: Procedural flow diagram


An allegation of apparent or possible research misconduct by a BHT or QMUL staff member is made to another member of BHT or QMUL staff. Refer to Section 1 of SOP 33 Associated Document: The investigation and resolution of research misconduct
The recipient of the allegation refers it to their Line Manager or to their Insitute or CB Director or to their lead for Research Integrity or to the Named Person.
The Line Manager, Insitute or CB Director or Lead for Research Integrity (as appropriate) refers the allegation to the Named Person
The Named Person may seek clarification from the Complainant or simply acknowledge the Complaint. Once clarification received, where relevant, the Named Person will acknowledge the Complaint.
Upon request the Complainant will provide clarification or further details about the alleged misconduct.
The Named Person may seek input/ advice from HR Director, JRMO Lead, the relevant Insitute or CB Director or other senior officers of QMUL / BHT as appropriate,
The Named Person shall undertake an initial reviews the allegation.
The Named Person shall appoint an appropriate Named Investigator, and will make all relevant information available to that person.
See next page


The Named Investigator shall, within 30 calendar days of the receipt of a substantive allegation by the Named Person, produce a preliminary Investigation Report with recommendations, as set out in Section 2 of Associated Document to SOP 33 (The investigation and resolution of research misconduct allegations) and submit it to the Named Person.
The Named Person shall review the Report, taking additional advice as appropriate from the Director of HR, the JRMO Lead, and Insitute or CB Director.
The Named Person shall reach a decision based on the Report with the following possible outcomes:
If the Named Person decides that the allegations are mistaken, frivolous, vexatious and/ or malicious, the allegations will be dismissed. Due process for the Complainant, in line with the relevant organisation's Disciplinary policy, will be followed. The Named Person will write to the Respondent and all the parties who had been initially informed that an allegation had been received.
END
If the Named Person decides that the allegation is, on consideration, the result of a dispute or misunderstanding between individuals that shall be resolved by informal discussion and/ or arbitration and/ or dispute resolution, without the requirement for a formal investigation. Where appropriate, opportunities to resolve matters through mediation should be considered.
END
If the Named Person decides that the allegations appear to be amount to Research Misconduct, as defined, the following steps shall be undertaken:
See next page


The Named Person will inform the relevant Director of HR, the JRMO Lead and the Director of the relevant School(s), Institute(s) or CB(s) for his decision.
The Named Person will send them information as set out in Section 2 of the Associated Document to SOP 33.
The Named Person will then instruct the Named Investigator to review the contractual status of the Respondent (with the Director of HR) and the contractual details specific to the research project(s) related to the allegations (with the JRMO Lead).
The Named Person will inform the Respondent of the findings of the preliminary investigation in a confidential meeting with a representative of the HR Department in attendance and option to be accompanied by a colleague or trade union representative.
If there are any partner organisations or more than one Respondent the Named Person should follow the guidance in the Associated Document to SOP 33: The investigation and resolution of research misconduct allegations
The Named Person will convene a Research Misconduct Panel: Appoint the Panel Chair and Panel Members (in accordance the guidance in Section 3 of the Associated Document to SOP 33.
The Named Person will inform various parties (in accordance the guidance in Section 3 of the Associated Document to SOP 33) that the Panel has been established.
The Research Misconduct Panel will convene and undertake its investigation of the allegations, including a Formal Hearing, in accordance the guidance in Section 2 of the Associated Document to SOP 33.
The Panel Chair will keep the Relevant Person informed of progress throughout the investigation.
See next page


The Panel will prepare a Draft Report and send that to the Named Person.
The Named Person will send that Draft Report to the Respondent and the Complainant and require their responses within 10 working days.
Taking account of any appropriate and duly made comments, the Named Person and the Panel Chair will revise the Draft Report. The Draft Report then becomes the Final Report.
The Relevant Person will inform people as set out in Section 3 of the Associated Document to SOP 33 of the outcome of the Panel.
The Panel ceases to exist and the Named Person will ensure that all relevant actions required as a result of the outcome(s) are conducted in a timely manner.
Possible outcomes are:
• Appeal
• Disciplinary action
• Remedial action
Refer to Section 4 of the Associated Document to SOP 33 for more detail on this.
END

SOP 33, Associated Document 1

The investigation and resolution of research misconduct allegations

1. Registering a complaint

1.1 Any person becoming aware of an allegation of potential research misconduct should immediately inform an appropriate senior or delegated person, unconnected with the allegation. This might be their line manager, their Institute or Clinical Board (CB) Director, their Research Integrity Officer (if there is one for their Department, School, Institute or CB), the Director of Research Services or the Named Person. Whoever is initially informed should ensure that the Named Person and the Director of the relevant School, Institute or CB is informed of the allegation as soon as is possible.

1.2 Where relevant, for example where an allegation has been made orally or briefly, the Named Person shall then contact the Complainant and seek a more substantive written outline of the allegation along with any relevant supporting evidence.

1.3 On receipt of a substantive written allegation, accompanied by any supporting evidence, the Named Person shall formally acknowledge receipt of the allegations by letter to the Complainant (and his/ her representative by agreement) within which details of the next steps and the SOP will be outlined.

1.4 Any evidence of further, distinct instances of misconduct in research by the Respondent, unconnected to the allegations under investigation, shall be sought by the Named Person from the Director of HR, a Senior JRMO Director, and the Director or Directors of the relevant Institute(s) or CB(s).

1.5 The Complainant, or the person registering the allegation on their behalf, may (or may not) have conducted their own evidence-gathering in order to feel confident of raising a complaint. However, undertaking such an investigation is not recognised as a formal responsibility of the Complainant for the purposes of this Procedure, nor should such an investigation be relied upon by the Named Person, however the Named Person may consider it necessary to take immediate mitigating actions to ensure the integrity of any subsequent investigation.

1.6 The Named Person, on identifying that there appears to be a case to answer, and prior to appointing a Named Investigator, shall inform and seek the guidance of a Senior JRMO Director, which shall be taken to include but not be limited to the Clinical Director of R&D, in order that the impact on patients, participants, on-going studies or other applications in progress, for which Respondent is named CI, are considered.

1.7 The Named Person shall review the nature of the allegations and, where they concern situations that require immediate action to prevent further unreasonable detriment, 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 shall take immediate appropriate action to ensure that any such potential or actual detriment, danger, illegal activity or risk is prevented/ eliminated.

1.8 The Named Person shall ensure that all relevant information and evidence is secured so that it can be accessed by those undertaking any consequential investigation. This may include, but is not limited to:

- Securing all relevant electronic and physical information and records, materials and locations associated with the work; and
- Liaising with Human Resources and the relevant line manager(s) to:
    - Request the temporary suspension of the Respondent from duties on full pay¬ as needed;
    - Request the temporary barring of the Respondent from part, or all, of the premises of QMUL and/ or BHT 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 QMUL and/or BHT and those of any partner organisation(s).

1.9 Such actions shall only be taken where there is a clear risk to individuals or that evidence might be destroyed, and will take into account the Respondent's responsibilities for supervision, teaching and management. A review of any such action may be undertaken throughout the course of an investigation to ensure that it is not unnecessarily protracted and shall not be taken to in any way imply guilt.

1.10 The Named Person shall appoint a Named Investigator to take responsibility for the investigation of a particular allegation. The Named Investigator will be suitably qualified and appropriately senior (e.g. Faculty Research Dean or Clinical Board Research Director), with respect to their field of expertise and research misconduct investigation. The Named Person shall pass details of the allegation and any preliminary fact finding or evidence gathering in the pre-registration phase of the complaint to the Named Investigator.

2. The investigation

2.1 The investigation will normally aim to be completed within 30 calendar days from the receipt of a substantive allegation(s) by the Named Person from the Complainant.

2.2 The Named Investigator may need to contact the Respondent's substantive (primary) employer, where an honorary contract is held and any external Sponsors, funding organisations and/or collaborators. The Named Investigator shall liaise with the Human Resources department to ensure that the rights of the Respondent and Complainant, and the integrity of the investigation are not compromised by any such actions.

2.3 The SOP aligns with the QMUL and BHT Whistleblowing policies. In accordance with those policies, the allegation and identity of the Complainant will be kept confidential so far as is reasonably possible by the Named Person and Named Investigator until any formal investigation is launched, save for the provisions of paragraphs 2 and 3 of the SOP's Scope.

2.4 The Named Investigator, in discussion with the Named Person and JRMO Lead, shall consider whether it is necessary to notify legal or regulatory authorities. As a consequence, QMUL

and/ or BHT may be required to comply with an investigation led by a legal or regulatory body, which will ordinarily take precedence over this Procedure.

2.5 Where allegations appear to include conduct or behaviour subject to defined sanctions in the QMUL and/ or BHT's disciplinary process, then the Named Investigator shall take steps to implement that disciplinary process.

2.6 In cases of multiple investigations, investigations may my undertaken in parallel, but in such case they may need to be suspended, to be concluded later, or may have to be declared void by the Named Person.

2.7 The Named Investigator will undertake a preliminary investigation of the allegations and the facts and will confirm to the Named Person in a written report whether in their opinion the allegations are credible and whether there is evidence of Research Misconduct (as defined in the Joint Research Misconduct Policy and contained in the Definitions Section of SOP Z) or whether the case should be resolved by other means. This stage of the investigation should be concluded as quickly as possible, normally within 30 calendar days from the receipt of a substantive allegation by the Named Person from the Complainant.

2.8 In this preliminary investigation the Named Investigator may, subject to details of the allegation(s):

- Review the submission and supporting evidence provided by the Complainant;
- Review the evidence and supporting documentation from the Respondent;
- Review any background information relevant to the allegations; and/ or
- Interview the Respondent, the Complainant, the Named Investigator and other individuals who might provide relevant information.

2.9 The preliminary Report will include recommendations as below:

- The Named Investigator may conclude that there is insufficient evidence of misconduct and recommend that no action be taken;
- The Named Investigator may conclude that the allegations are malicious, vexatious or frivolous and report this to the Named Person;
- The Named Investigator may conclude that there has been no research misconduct but that there have been some deviations from recommended practice that may be remedied by actions such as additional training or mentoring (capability issue) or other disciplinary policy or procedure;
- The Named Investigator may recommend that immediate mitigating actions need to be taken to protect the safety of subjects, protect the integrity of evidence for any subsequent investigation or inform other organisations;
- Depending on the contractual status of the Respondent, the Named Person may need to inform other organisations with which the Respondent has a substantive or honorary contract; and/ or
- If there is prima facie evidence of misconduct a recommendation should be made to the Named Person as to whether to proceed with a Research Misconduct Panel or whether there is sufficient evidence to refer the matter to a disciplinary panel investigation.

2.10 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 shall be addressed through QMUL's and/ or BHT's competency, education and training mechanisms, or other non-disciplinary processes, rather than through a Research Misconduct Panel. The JRMO Lead may decide it is still

necessary to notify research regulators or other organisations. An investigation undertaken in accordance with this SOP would then be finished.

2.11 If, based on the Named Investigator's report, the Named Person decides that the allegations are mistaken, frivolous, vexatious and/ or malicious, the allegations will then be dismissed and due process for the Complainant, as per the relevant organisation's Disciplinary policy, will be followed. This decision to conclude the investigation at this point must be reported in writing to the Respondent and all the parties who had been initially informed that allegations had been received and an investigation initiated.

2.12 If, based on the Named Investigator's report, the Named Person decides that the allegation is, on consideration, the result of a dispute or misunderstanding between individuals then the investigation shall be resolved by informal discussion and/ or arbitration and/ or dispute resolution, without the requirement for a formal investigation. Where appropriate, opportunities to resolve matters through mediation should be considered. 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.

2.13 If, based on the Named Investigator's report, the Named Person decides that the allegations appear to amount to Research Misconduct (as defined in the Joint Research Misconduct Policy and contained in the Definitions Section of SOP 33) the Named Person shall inform the Director of Human Resources (in the relevant or both organisations), the JRMO Lead and the Director of the relevant School(s), Institute(s) or CB(s). They will then be provided in confidence with the following information:

- The identity of the Respondent;
- The identity of the Complainant;
- A summary of the nature of the allegations;
- Details of all sources of internal and external funding ;
- Details of known internal and external collaborators for the research in question; and
- Other details that the Named Investigator may consider appropriate.

2.14 The Named Person will then instruct the Named Investigator to review the contractual status of the Respondent (with the Director of HR) and the contractual details specific to the research project(s) related to the allegations (with the JRMO Lead).

2.15 The Named Person will inform the Respondent of the findings of the preliminary investigation in a confidential meeting with a representative of the HR Department in attendance and option to be accompanied by a colleague or trade union representative.

2.16 If there is a partner employing organisation that needs to be informed and especially if the allegations pertains to an individual holding employment contracts with both BHT and QMUL, the Named Investigator should ask the Partner Organisation to identify a Named Partner who will be responsible for liaising with the Named Investigator, and ensuring excellent communications and aligned processes in the two organisations.

2.17 If the allegations are made against more than one Respondent, the Named Person shall inform each individual separately and not divulge the identity of any other Respondent. A summary of the allegations in writing shall be given to the Respondent (and his/ her representative by agreement) at the meeting, together with a copy of the Procedure to be used and the timeframe of the investigation.

2.18 All contributions to the process of the investigation will be recorded and maintained for subsequent use by the QMUL Academic Registry & Council Secretariat (ARCS) or Barts Health Medical Directorate (whichever is the lead oversight body).

2.19 The preliminary investigation is now complete and, where appropriate, a second phase, involving a Research Misconduct Panel shall begin (see SOP 33 the second Guidance document for information on that stage).

3. The Research Misconduct Panel

3.1 When there is clear evidence of an infringement that might contravene the QMUL and/or BHT's disciplinary code, the Named Person shall, with the Named Investigator, consult the Director of Human Resources on the full and accurate transfer of all case information to the disciplinary process. A full written record shall be kept of this decision.

3.2 Where those parties agreed that the allegations are sufficiently serious and have sufficient substance the Named Person who will take immediate steps to set up a Research Misconduct Panel ("the Panel").

3.3 The Named Person or their nominee (the 'Named Partner') shall appoint the Panel Chair Panel members. The Panel Chair will be of higher seniority than those previously involved and should be independent of the people and issues involved. The Panel shall normally consist of *at least* three managers and always an odd number of members, including the Chair.

3.4 Where practicable all panel members should be senior to those previously involved in the investigation, with the probable exception of the Named Person. At least one should come from the same Faculty/ Directorate as the employee. In selecting the panel the Named Person shall take into consideration the subject matter of the allegations and any potential conflicts of interest. One or more members of the Panel shall be independent of both QMUL and/ or BHT (as appropriate) and such external members shall replace internal members of the Investigation Panel rather than being in addition to them. In addition, at least two members of the Panel shall have experience in the area of research in which the alleged misconduct has taken place, although they should not be considered colleagues of the Respondent and should be able to exercise sufficient degree of independence. Where allegations concern highly specialised areas of research, the Investigation Panel shall have at least one member with specialised knowledge of the field.

3.5 The Panel must be appointed within 30 working days of the receipt by the Named Person of the report from the Named Investigator. The Panel will not work to a prescribed timetable but will work as quickly as possible without compromising the principles of the SOP and natural justice.

3.6 The Named Person shall inform the following (or their nominees) that a Panel to deal with the specified allegations is to take place:

- Respondent (and his/her representative by agreement);
- Complainant (and his/her representative by agreement);
- Principal and/or Chief Executive;
- Director of Institute, School or CB;

- Director of Human Resources;
- JRMO Lead;
- Academic Secretary;
- Clinical Director of Research and Development (where they are not the JRMO Lead); and
- Named Person of any Named 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 Services.

3.7 Once convened, the membership of the Panel shall not be changed or added to, unless unavoidable and serious events take place. Any change and its reason shall be documented by the Panel Chair. Members who are not able to continue will not be replaced. In the event that the Chair stands down or the membership falls below three, the Named Person will take steps to recruit additional members or re-start the Panel process.

3.8 The Panel shall examine the evidence collected during the investigation following the original allegations and investigate further as required.

3.9 To perform its task the Panel shall:

- Review the submission(s) and supporting evidence provided by the Complainant;
- Review the response(s) and supporting evidence from the Respondent;
- Review background information relevant to the allegations;
- Review any interviews conducted with the Respondent, the Complainant, and other staff who may provide relevant information to assist the Panel;
- Review the Investigation report;
- Seek additional evidence as it sees fit;
- Call expert witnesses to give advice if necessary; and
- Seek guidance from UKRIO and its advisers, where necessary.

3.10 Once initiated the Procedure will progress to the natural end-point irrespective of:

- The Complainant withdrawing the allegations at any stage ;
- The Respondent admitting, or having admitted, the alleged misconduct, in full or in part; and
- The Respondent or the Complainant resigning, or having already resigned their post(s).

3.11 The Panel shall be serviced by ARCS (QMUL) and/or Medical Directorate (BHT), through whom all documentation and all other communication should be passed.

3.12 Only information collected at the request of the Panel, or at formal meetings called by the Chair of the Panel, will be admitted as part of the documentation relating to the case. Any other communication, either written or oral, by any party (to include Respondent, Complainant or any other member(s) of staff) directly with members of the Panel will not be admitted as part of the documentation relating to the case.

3.13 A Formal Hearing will be held during which the Respondent will be invited to attend, with a representative of the Human Resources Department in attendance and option to be accompanied by a colleague or trade union representative, 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 witnesses. The Complainant and other staff may also be invited to provide evidence when members of the Panel consider that it may have relevance to the investigation.

3.14 The Chair shall report the progress of the Panel to the Named Person on a bi-weekly basis. If it is believed that the investigation will take more than one calendar month, progress reports shall be made on a monthly basis.

3.15 The Panel shall provide a Draft Report of its findings to the Named Person. That Report shall:

- Summarise the conduct of the investigation;
- State 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;
- Make recommendations in relation to any matters relating to any other misconduct identified during the investigation; and
- Address any procedural matters that the investigation has brought to light within QMUL and/ or BHT and relevant partner organisations and/ or funding bodies.

3.16 In addition to reaching a conclusion over the nature of the allegations, the Panel should also, in the Report, make recommendations with respect to:

- Whether the allegation(s) should be referred to the relevant organisation's disciplinary process;
- Whether any action will be required to correct the record of research (e.g. informing publishers, correcting or retracting publications etc.);
- Whether action will be required to inform external organisations such as funders, collaborators, business partners, regulators (such as MHRA, HRA, GMC, NMC as applicable), professional bodies etc;
- Whether organisational matters should be addressed by QMUL and/or BHT through a review of the management of research; or
- Other matters that should be investigated e.g. clinical trials the Respondent may have been involved in, in case of any subsequent regulatory inspection.

3.17 The Named Person shall make that Draft Report available to the Respondent and the Complainant for comment solely on the factual accuracy of the report. Such comments are to be requested within 10 working days. Modifications will only be made to the Draft Report where it is found to contain errors of fact or where matters that have a material bearing on the facts are not included or have been misinterpreted.

3.18 On receipt and review of any comments the Named Person and the Panel Chair shall, where relevant, revise the Draft Report and it shall become the Final Report. If there are no comments the Draft Report shall become the Final Report.

3.19 The Relevant Person will inform the following of the outcome of the Panel:

- The Respondent and the Complainant;
- The Named Investigator, Principal (QMUL), Chief Executive (BHT), the Director of the School, Institute or CB; the Director of Human Resources, the JRMO Lead, the Clinical Director of R&D, the Academic Secretary, the Head(s) of the relevant Department(s) and any other relevant members of staff;
- If the Respondent and/ or the Complainant are employed on joint clinical/ honorary contracts or since investigation has commenced, has left the organisation and moved on to alternative employment by a University or in a research role, the Named Partner, the

Director of Human Resources and the Director of Research Services of the partner organisation(s); and

- Where appropriate, the responsible person within any relevant partner organisations, funding bodies and/or regulatory or professional bodies.

4. Managing the Outcome

4.1 The Named Person will ensure that all relevant actions required as a result of the outcome(s) are conducted in a timely manner. This may include:

Right of appeal

4.2 The Respondent has the statutory right of appeal if the matter is referred to QMUL and/or BHT disciplinary processes. The Respondent shall not have the option of appealing against the report of the Panel.

Disciplinary actions

4.3 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 (e.g. Director of CB or Institute) shall then decide whether the matter should be referred to QMUL's or BHT's disciplinary process or other formal actions.

4.4 If the allegations proceed to disciplinary processes, the report of the Panel shall form the basis of the evidence that the Disciplinary Panel receives. All the information collected and brought to light through the Procedure will be transferred to the disciplinary process.

4.5 If the allegations are deemed to be frivolous, vexatious and/ or malicious, the Named Person shall consider recommending to the appropriate authorities that action be taken under QMUL or BHT disciplinary processes against anyone who is found to have made frivolous, vexatious and/or malicious allegations of misconduct in research.

Remedial actions for the Respondent

4.6 When the allegations were found to have some substance, but due to a lack of clear intent to deceive or due to their relatively minor nature, the Panel can decide that the matter should be addressed through QMUL and/or BHT's competency, education and training mechanisms, or other non-disciplinary processes. The Panel would agree remedial actions with the Named Person; who shall ensure that relevant remedial actions are taken through management structures with support from Human Resources.

4.7 As part of the Procedure, the Panel will consider the need for and recommend measures additional to those that may be taken by way of QMUL's or BHT's disciplinary process. The Named Person will ensure that any such recommendations are actioned via the Director of School, Institute or CB, and with the support of the Director of Research Services and/or Clinical Director of R&D where necessary, through QMUL's or BHT's management structure. This may include:

- Retraction/correction of articles in journals;
- Notifying other organisations involved in the research, such as funding bodies, research collaborators, industry collaborators, Queen Mary Innovations etc.;

- Discussion with funders with regard to withdrawal/repayment of funding
- Notifying participants/participants' doctors of any potential medical issues that may arise, ensuring due diligence in line with reporting duties of all clinical professionals' duty of candour and duty of care;
- Notification of misconduct to regulatory bodies (such as the MHRA, the Healthcare Commission, the Home Office (for research involving animals), other professional bodies, etc.);
- Notifying other employing organisations, including future employers of the Respondent;
- Adding a note of the outcome of the investigation to a researcher's file for any future requests for references;
- A review internal management, training, supervisory procedures for research as appropriate; and/ or
- Undertaking further investigations of other projects the Respondent was involved in (especially Clinical Trials of Investigational Medicinal Products) to assure the organisation that the data are robust and there is no evidence of research misconduct with respect to these other projects.

Specialised research

4.8 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 Panel may prove particularly useful if this is the case.

Support for the Complainant

4.9 Where allegations have been upheld (in full or in part), or found to be mistaken but not frivolous, vexatious and/ or malicious, then appropriate support, guidance and acknowledgment shall be given to the Complainant, given that their role in the process will most likely have been stressful and may well have caused friction with colleagues. The Named Person shall take whatever steps they consider necessary to support the reputation of the Complainant. For example, if the case has received any publicity, the Complainant shall be offered the possibility of having an official statement released for internal and/ or external purposes.

Support for the Respondent

4.10 Where allegations have not been upheld (in full or in part), the Named Person shall take such steps as are appropriate, given the seriousness of the allegations, to protect the reputation of the Respondent and any relevant research project(s). Appropriate support and guidance shall be given to the Respondent. Where the case has received any publicity, the Respondent shall be offered the possibility of having an official statement released for internal and/ or external purposes.

September 2018

Joint Policy Statement on Research Misconduct

1. Background

The validity of research and other academic endeavour is based on the implicit assumption of honesty and integrity by the research investigator and on the explicit premise that research data are properly obtained, reliable and verifiable. Queen Mary University of London (QMUL) and Barts Health NHS Trust (BHT), working in partnership, must uphold this principle and endeavour to maintain public trust in the research process. This is summarised in the following Joint Policy Statement on Research Misconduct.

This policy recognises the need for BHT and QMUL to augment their standard policies and guidelines to address issues relating to misconduct in research. The guidelines should be read in conjunction with other relevant related policies of each organisation, including research integrity, whistle-blowing and disciplinary policies.

2. Policy Statement

BHT and QMUL adhere to the Universities UK 2012 Concordat to support research integrity[1] committing us to:

- maintaining the highest standards of rigour and integrity in all aspects of research; ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards;
- supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice and support for the development of researchers;
- using transparent, robust and fair processes to deal with allegations of research misconduct should they arise;
- working together to strengthen the integrity of research and reviewing progress regularly and openly.

BHT and QMUL are responsible for ensuring that the research carried out under their aegis is carried out legally, in the public interest and in accordance with best practice. This policy applies to anyone involved in research at BHT or QMUL, whether as an employee, student, research manager or in some other capacity, and includes researchers holding substantive or honorary employment contracts at either organisation who are responsible for visitors or engaged in external research collaborations.

[1] http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf

All individuals undertaking research at BHT and QMUL are obliged to comply with this policy and to conduct, record and report their research in line with all relevant laws and regulations, and research policies endorsed by BHT and QMUL.

All employees of QMUL or of other Trusts who carry out research involving BHT patients, patient samples, patient records, premises, facilities, staff and services must be bound by BHT policies and hold a current BHT honorary contract or Letter of Access for Research with clear lines of reporting and accountability at BHT. All employees of BHT, or other Trusts and Universities, who carry out research involving QMUL premises, facilities, engagement with staff, research samples, records, information or QMUL's intellectual property, must be bound by QMUL policies, if relevant hold an honorary contract, and have clear lines of reporting and accountability whilst undertaking research in QMUL.

All employees and students of BHT and QMUL, and individuals permitted to work under their oversight, have the responsibility to report any cases of suspected research misconduct and must fulfil their responsibilities where appropriate as outlined in the Research Governance Framework for Health and Social Care[2].

Any designated Chief or Principal Investigator (CI/PI) must accept a key role in detecting and preventing research misconduct and must adopt the role of guarantor on published outputs from the work they have oversight for as CI/PI. Researchers must comply with and aid in any necessary monitoring and auditing of research projects required by BHT or QMUL. Any complaints, incidents or risks relating to research must be reported through the approved BHT/QMUL mechanisms. Any such complaints, incidents or risks should be logged by ARCS for QMUL and using an appropriate Trust reporting system by the JRMO for BHT.

Allegations of misconduct will be handled and investigated in line with the research misconduct procedures of the employing organisation. BHT and QMUL will inform each other's HR Departments (or those of other organisations) immediately upon notification of any allegations of research misconduct that have been reported that involve both organisations and/or employees that have contracts with both organisations. Suitable arrangements between the organisations will then be made to address the allegations with reference to the Joint Procedure.

3.Principles

- BHT and QMUL will investigate all allegations of research misconduct relating to the work of any employee, student, or anyone else involved in research within their organisations.
- No detrimental action of any kind will be taken against any person making an allegation through this policy in good faith, in line with BHT and QMUL Whistleblowing Policies and Public Interest Disclosure Legislation.
- Any allegations made will be investigated thoroughly, and in accordance with the highest standards of integrity, accuracy and fairness.

[2] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf

- Investigations will be carried out in such a way as to appropriately safeguard the confidentiality of the interested parties, as necessary.
- Bearing in mind appropriate levels of confidentiality as needed, the outcome of the investigation will be made known as quickly as possible to all parties with a legitimate interest in the case.

4. Definition of Research Misconduct

For the purposes of this policy, research misconduct includes carrying out, attempting or planning any of the following (as well as any other examples that might reasonably fall within the remit of the policy and its documentation):

- The fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research
- The deliberate, dangerous or negligent deviation from agreed formal protocols or regulations, including accepted professional standards of behaviour and conduct, in carrying out research, and the failure in that context to avoid risk or harm to humans, animals used in research, and the environment where appropriate
- The facilitation of misconduct in research or collusion in, or concealment of, such actions by others
- The intentional and unauthorised use, disclosure of, removal of or damage to research related property of another researcher, including:

  intellectual property, writings, data, apparatus, materials, hardware, software, any other substances or devices used in or produced whilst conducting research, infringement of data protection requirements or the confidentiality of research subjects, misuse or misappropriation of the work of others and, for example, the unethical use of material provided in a privileged way for review or assessment.

Misconduct in research can include acts of calculated omission as well as acts of commission. It excludes genuine errors or differences in interpretation or judgement in evaluating research methods or results, or misconduct unrelated to research processes.