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**
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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	

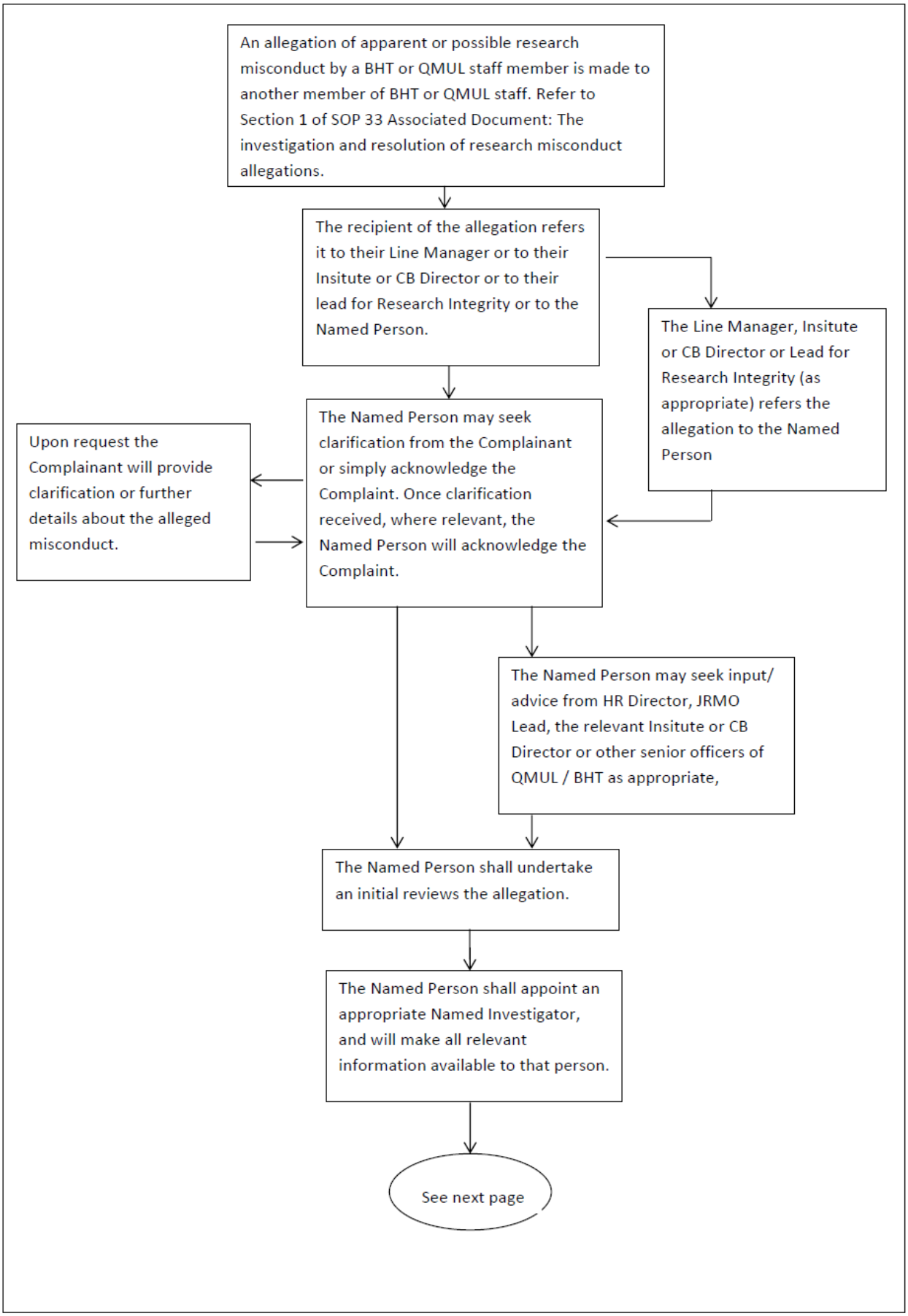
List of appendices

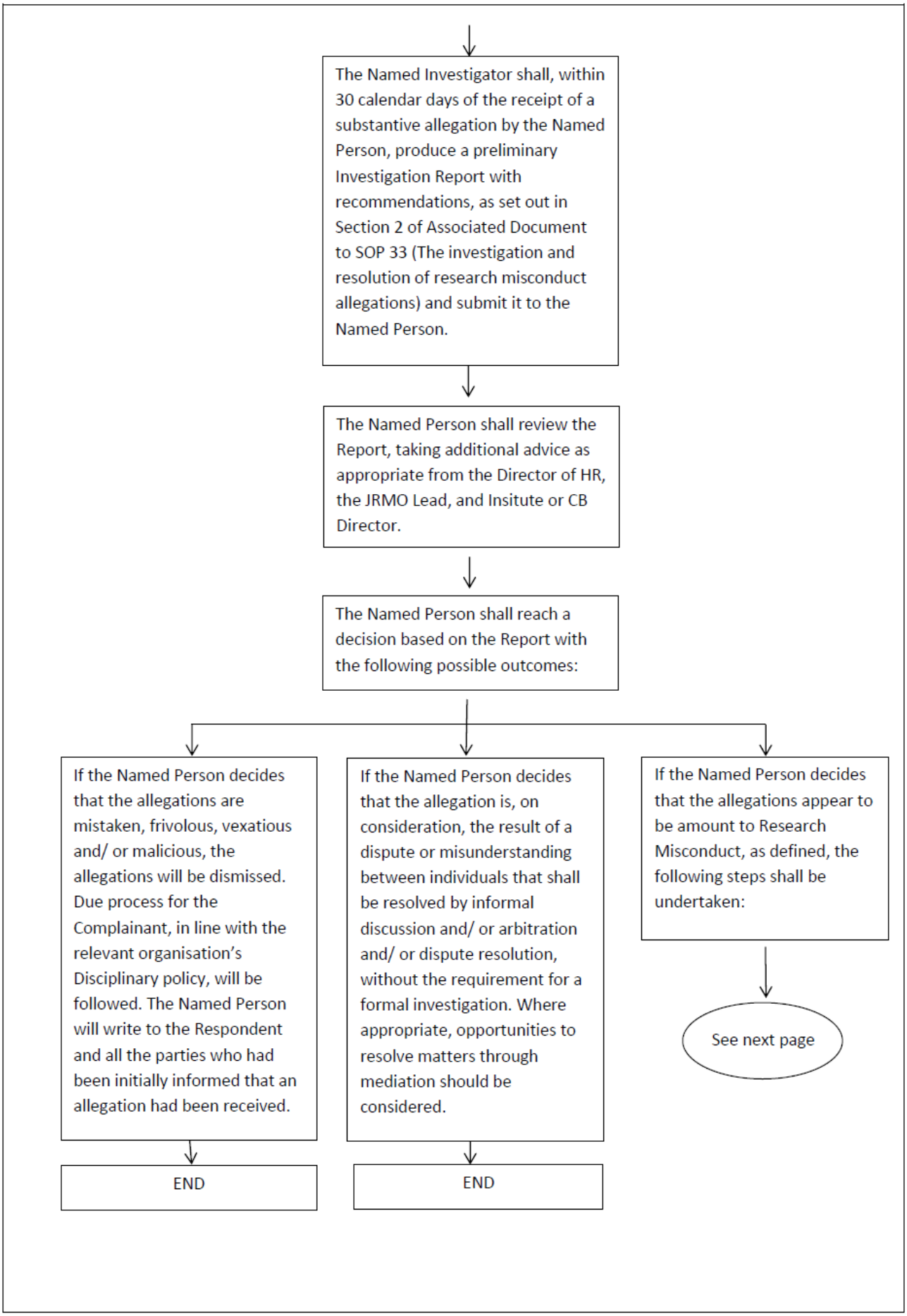
Appendix ref.	Appendix name
1	Research Misconduct procedural flow diagram

List of associated documents

Document ref.	Document name
1	The investigation and resolution of research misconduct allegations

Appendix 1: Procedural flow diagram




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.
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.
If the Named Person decides that the allegations appear to be amount to Research Misconduct, as defined, the following steps shall be undertaken:
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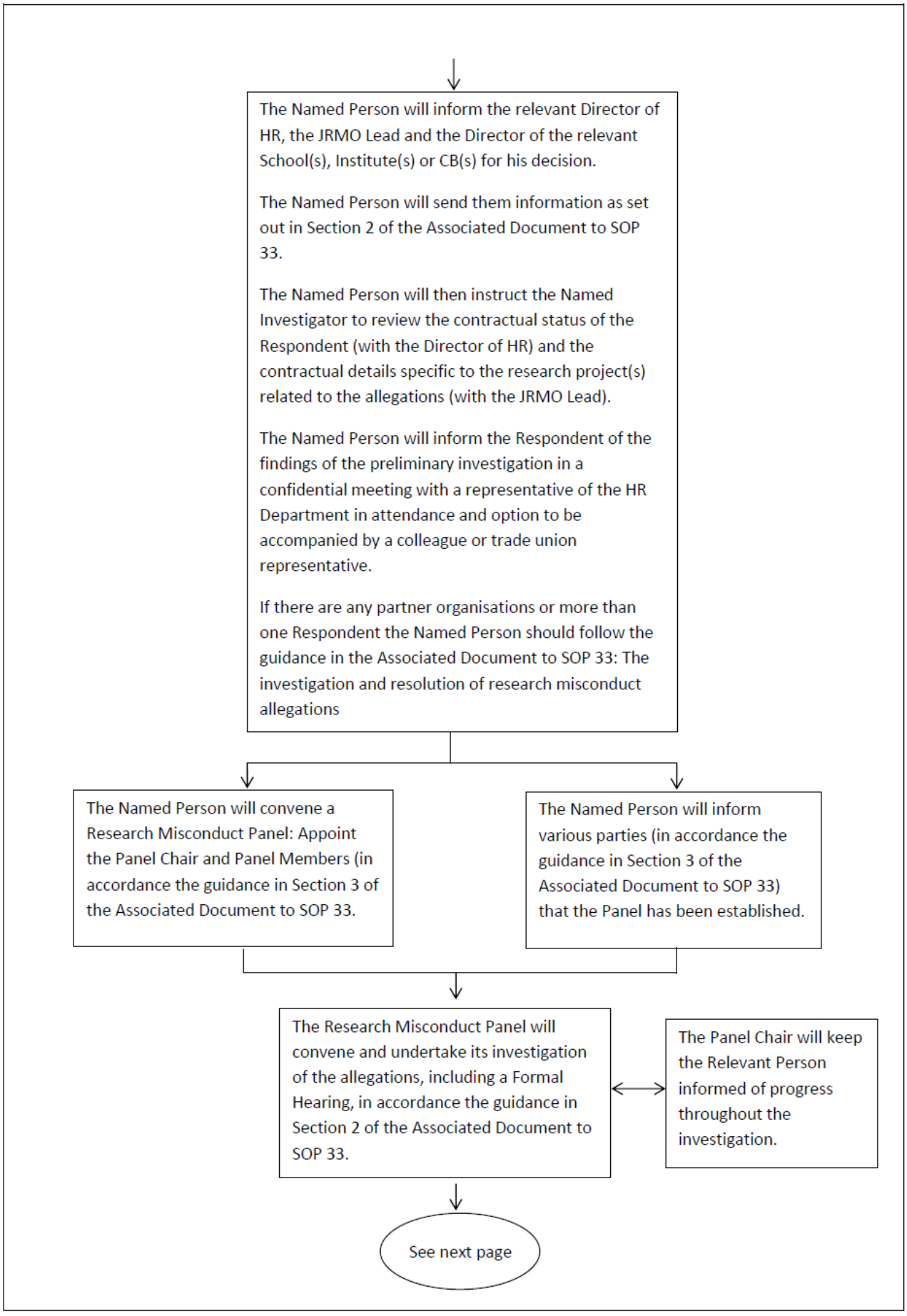
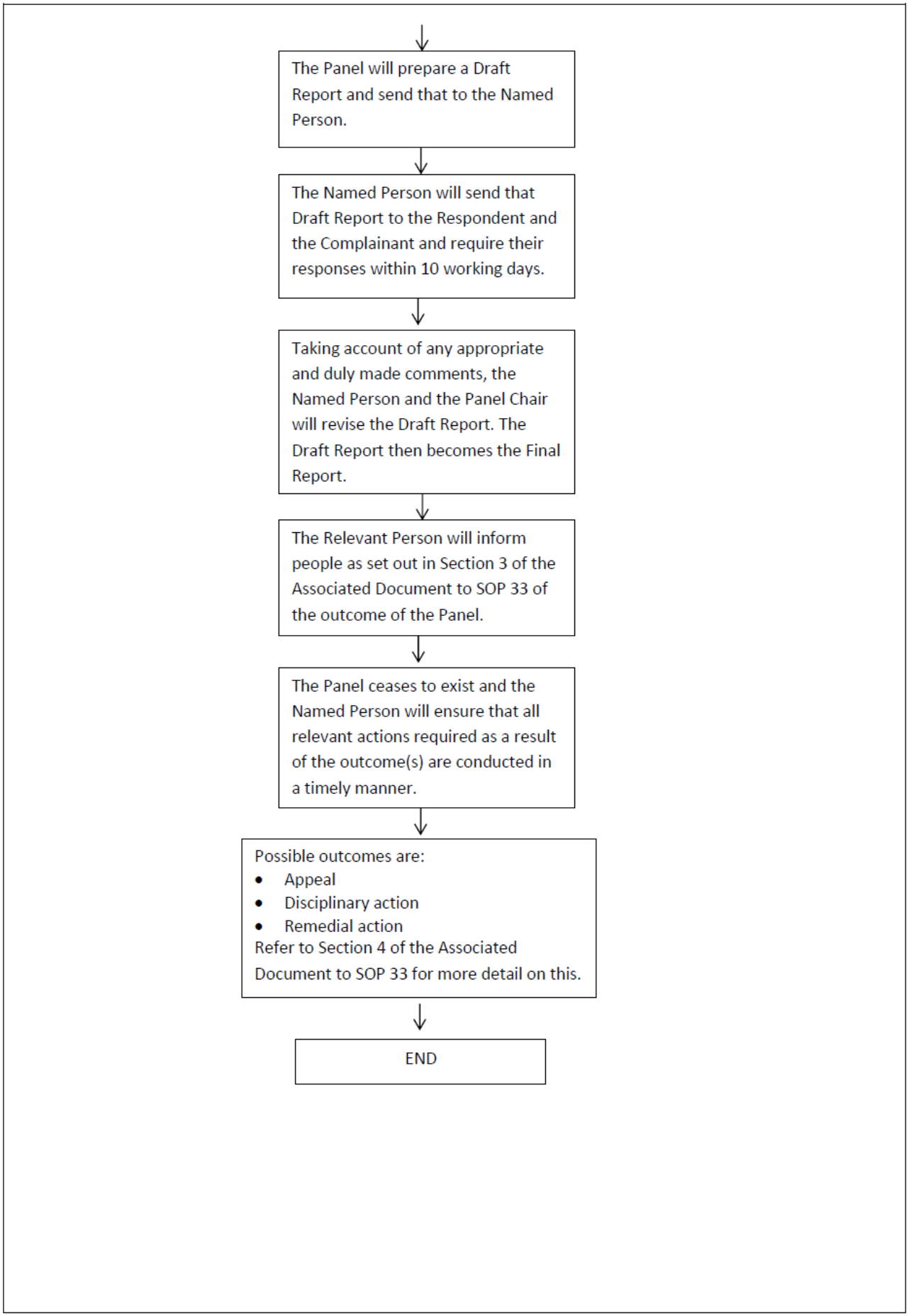

The Named Person will inform the relevant Director of HR, the JRMO Lead and the Director of the relevant School(s), Institute(s) or CB(s) for his decision.
The Named Person will send them information as set out in Section 2 of the Associated Document to SOP 33.
The Named Person will then instruct the 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.
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