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.

JRMO
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