Key messages

- All research active organisations are required to implement systems to detect and deal with research misconduct and fraud.

- All employees of the Trust and any other persons working within the Trust have a responsibility to report any incident of research misconduct which is suspected, observed or apparent.

- Any suspected, observed or apparent research misconduct should be reported and dealt with in accordance with this policy. Any suspected, observed or apparent fraud should be reported in accordance with the Trust anti fraud, bribery and corruption policy (link).

- This policy sets out a number of distinct stages in which complaints of an alleged case of research misconduct will be dealt with and the possible outcomes.
1. Scope

1.1 Trust-wide: this policy and procedure applies to all Trust employees undertaking research activity.

1.2 It also applies to individuals appointed on honorary contracts with the Trust if the alleged research misconduct arises by virtue of the research they are undertaking pursuant to their honorary contract and involves NHS staff or patients, their organs, tissue or data.

1.3 The policy also applies to any other persons working within the Trust who are involved in research at the Trust not otherwise covered by 1.1 or 1.2 above.

2. Purpose

2.1 To ensure:

2.1.1 The safety of those involved with research.

2.1.2 That there is fairness and equity in the conduct of the research taking place in the Trust.

2.1.3 That complaints of alleged research misconduct are handled with fairness and equity.

3. Definitions

3.1 The Trust endorses the definition of research misconduct and other unacceptable behaviour identified in RCUK Policy and Guidelines on the Governance of Good Research Conduct (February 2013) and which is attached at Appendix A. Unacceptable conduct includes research misconduct, fabrication, falsification, plagiarism, misrepresentation, mismanagement or inadequate preservation of data and/or primary materials and breach of duty of care.

3.2 Research misconduct does not include honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results or misconduct (including gross misconduct) unrelated to the research process.

4. Abbreviations used

CCTU Cambridge clinical trials unit
CTIMPs clinical trials of investigational medicinal products
GCP good clinical practice
HR human resources
SOP standard operating procedure

5. Introduction

5.1 Research and development is essential for the NHS so that it can achieve its aim of continual quality improvement. Whilst pursuing research, NHS Trusts
must ensure that there are proper systems and processes to protect and safeguard the wellbeing of both participants and researchers.

5.2 Education and training of both supervisors and researchers will play a major part in helping to prevent incidents of research misconduct.

5.3 This policy and procedure forms part of the wider management arrangements for research governance within the Trust. The relevant CCTU and R&D SOPs are listed in the associated documents section below.

5.4 The Trust’s research governance framework sets in place systems and processes which ensure that all research is:

5.4.1 safe
5.4.2 of a high quality and
5.4.3 contributes to improving the treatment and care of patients.

5.5 All research active organisations are required to have implemented a plan for research governance. Additionally, some funders who provide major grants for NHS related research may require a specific policy on research misconduct and fraud.

5.6 Any suspected, observed or apparent research misconduct should be reported and dealt with in accordance with this policy. Any suspected fraud should be reported in accordance with the anti fraud, bribery and corruption policy (link).

6. Principles

6.1 This document is based on the following principles of good practice:

6.1.1 Awareness of the existence of this policy and procedure will form an important first step in good research practice. All staff involved in research at the Trust, whether under a substantive or honorary contract with the Trust or through a letter of access, will be made aware of this policy and procedure and their responsibilities under it.
Research and development (R&D) department

6.1.2 The Trust places considerable emphasis on the prevention of misconduct and fraud.
6.1.3 The Trust will seek to ensure that all concerns raised are dealt with in the timescales set out in this document whilst ensuring the utmost degree of thoroughness.
6.1.4 The Trust will seek to ensure that due consideration is given to safeguarding the confidentiality and professional reputation of members of staff regarding whom concerns are being made.
6.1.5 All research must undergo an independent peer review and must be submitted to an appropriate research ethics committee for approval.
6.1.6 Approval by the Trust R&D office must be sought for all research that involves patients, patient samples (blood, tissue etc.), patient data and/or Trust infrastructure (e.g. research equipment): see the Trust’s NHS permission for research studies policy and procedure (link).
6.1.7 Under the research governance framework, the principal investigator (PI) is responsible for the conduct of his or her research team. If a PI is unsure of due process in relation to any of the above points then s/he should contact the Trust R&D manager for advice.

7. Responsibilities

7.1 All employees of the Trust and any other persons working within the Trust have a responsibility to report any incident of suspected, observed or apparent research misconduct.
7.2 If an individual is unsure whether a suspected incident of misconduct falls within the definition of research misconduct he or she should discuss this with the R&D manager informally.
7.3 Suspicions reported in confidence and in good faith will not lead to disciplinary proceedings against the person making the complaint. However, in the event of a malicious or vexatious allegation, disciplinary action may be considered through the individual’s employer’s procedure (see further paragraph 14.5).
7.4 The R&D director and/or Executive Director for Research will have responsibility for informing the research board of any matters raised under this policy which require their consideration and/or action. In turn, the research board has a responsibility to report to the Trust board where appropriate.
7.5 The R&D manager and/or R&D director and/or Executive Director for Research will have the responsibility for informing the Research Compliance Committee should they consider that any matter raised under this policy is more appropriately dealt with under the Research Compliance Committee and/or if the Research Compliance Committee should be made aware of any matter being progressed under this policy. The R&D manager and/or R&D director and/or Executive Director for Research may also notify any other person of any matters raised under this policy as they consider reasonably necessary.
8. Operational framework

8.1 Individuals who wish to make a complaint in relation to suspected, observed or apparent research misconduct should contact initially the R&D manager. The R&D manager may also involve the following:

8.1.1 the R&D director;
8.1.2 the Executive Director for Research;
8.1.3 the head of the relevant academic department;
8.1.4 the Research Compliance Committee; and/or
8.1.5 any other person as considered reasonably necessary.

8.2 There are a number of distinct stages in which complaints of an alleged case of research misconduct will be dealt with. These stages are set out below and are summarised in the flow diagram at Appendix B. The first person to have responsibility for the alleged case of research misconduct (whether it is the R&D manager, the R&D director or the Executive Director for Research) should consider at the outset whether the case falls under this policy and if not, it should be directed to the researcher’s substantive employer to be dealt with under their policies and procedures.

9. Informal stage

9.1 A complaint or concern in relation to suspected, observed or apparent research misconduct is raised by an individual to the R&D manager.

9.2 If the individual raising the complaint or concern is unsure whether a suspected, observed or apparent incident constitutes misconduct they should discuss this with the R&D manager informally. Please see Appendix A for the definition of research misconduct.

9.3 If the R&D manager has any doubt as to the seriousness of a complaint or concern brought to them, the R&D manager must notify the R&D director. The R&D director may then decide whether the complaint is appropriate to be dealt with at the informal stage or not.

9.4 This complaint or concern may be resolved informally without need for referral to the formal stages if the R&D Manager considers it appropriate and it is able to be resolved informally. If however the complaint or concern cannot be resolved informally then it should be progressed to the formal stage.

9.5 The formal stage is divided into three key areas:

Stage 1: Preliminary action (section 10)
Stage 2: Assessment (section 11)
Stage 3: Formal investigation (section 12)

Each is dealt with below.
Research and development (R&D) department

10. Stage 1: Preliminary action

10.1 Process and purpose

10.1.1 The R&D manager receives communication of a complaint or concern in relation to suspected, observed or apparent research misconduct and decides that the complaint or concern cannot be resolved through the informal stage. The R&D director is to be notified by the R&D manager of the complaint or concern.

10.1.2 The purpose of this stage of the process is to determine whether the complaint or concern needs to be progressed to the next stage, assessment.

10.2 Action

10.2.1 The complainant will be asked by the R&D director to provide a detailed written statement in support of the allegation.

10.2.2 The R&D director must determine within seven working days of receipt of the written statement whether the allegation falls within the definition of misconduct (see Appendix A) and also within the scope of this policy. The R&D director will confirm in writing to the complainant their decision as to whether the allegation falls within the definition of misconduct and the scope of this policy and, if it does, will progress the allegation according to this policy.

10.2.3 The researcher to be informed in writing by the R&D director of the detail of the complaint once the R&D director has received the written statement from the complainant and decided that it falls within the definition of misconduct and the scope of the policy. The researcher will be given 10 working days (or such longer period as may be agreed by the R&D director) to confirm receipt of the detail of the complaint and to respond.

10.2.4 If the R&D director is not satisfied with the researcher’s response or believes that reputations of any parties may remain in jeopardy the R&D director will:

- Take all reasonable steps to secure the necessary evidence, consider the potential risks and take steps to remove or minimise any risk. Risks may relate to the health, safety and security of workers, research participants, or other persons or negative environmental consequences. Immediate action must be taken to ensure that any such potential or actual danger, illegal activity or risk is prevented/eliminated.
- Inform the Executive Director for Research in writing of the allegation and provide the Executive Director for Research with any relevant documents as soon as reasonably practicable in order that this matter can progress to Stage 2: Assessment.
- If the R&D director thinks that it could be appropriate to suspend the researcher on full pay pending the outcome of the assessment or formal investigation, the R&D director will raise this with the Executive Director for Research in order for this decision to be taken by the Executive Director for Research. The Executive Director for Research should refer to the Trust’s HR team before taking any action. In taking action to suspend the researcher, it should be made clear to all parties...
that the actions taken are not to be regarded as an indication of a finding of research misconduct or a disciplinary sanction.

- The R&D director will notify the researcher and the complainant in writing of the outcome of this stage of the process as soon as reasonably practicable.

10.2.5 Where the R&D director decides that an assessment is not warranted, they will record their justification for this initial decision and inform the complainant and the researcher of this outcome in writing. The complainant should be given an opportunity to respond if they believe that they have been misunderstood or key evidence has been overlooked. Reasonable action to safeguard the reputation of the researcher and/or the Trust should be considered (see further paragraphs 14.4).

11. Stage 2: Assessment

11.1 Process and purpose

11.1.1 The purpose of the assessment phase is to gather information and evaluate the facts to determine whether there is sufficient evidence of research misconduct to warrant a formal investigation.

11.1.2 The purpose of the assessment is not to reach a final conclusion as to whether misconduct occurred or who was responsible.

11.2 Action

11.2.1 The Executive Director for Research will notify both the researcher and the complainant of the assessment in writing as soon as reasonably practicable. The researcher must confirm receipt in writing. The Executive Director for Research should also remind both the researcher and the complainant of their obligation to co-operate in the assessment and to observe confidentiality requirements.

11.2.2 The Executive Director for Research will appoint an assessment panel consisting of two individuals who do not have a conflict of interest in the case and have appropriate expertise to evaluate the scientific issues.

11.2.3 The Executive Director for Research will notify the researcher in writing of the proposed assessment panel as soon as reasonably practicable.

11.2.4 The researcher has five working days to object in writing to the membership of the assessment panel. If the researcher raises a valid objection to any member of the panel within this time then the Executive Director for Research may decide to replace the challenged member of the panel with an appropriately qualified substitute.

11.2.5 If the Executive Director for Research does not replace the challenged member of the panel, the reasons will be notified to the researcher in writing by the Executive Director for Research within seven working days of receipt of the objection.

11.2.6 The date of appointment of the assessment panel will be either:

- after the five working days if the researcher has not submitted a written objection; or
Research and development (R&D) department

- after the Executive Director for Research has considered the researcher’s objections and confirmed the membership of the assessment panel to the researcher in writing.
11.2.7 Assessments will normally involve the assessment panel interviewing the complainant, the researcher and key witnesses and examining relevant research records and materials to determine whether there is sufficient evidence of research misconduct to warrant an investigation. The assessment panel will send the researcher copies of relevant research records and materials obtained that are being used in the investigation.

11.2.8 The researcher has the right to be accompanied by a work colleague or a representative of a locally recognised staff organisation of his/her choice at interviews and meetings held under this procedure.

11.2.9 The assessment panel will complete the assessment and submit its report to the Executive Director for Research in writing within 40 working days of the date the assessment panel is appointed. If the Executive Director for Research approves an extension of this time limit, the reason for the extension will be entered in the records of the inquiry and the report. The researcher and complainant will be notified of the extension.

11.2.10 The assessment panel must determine whether there is prima facie evidence of research misconduct and whether the allegations are sufficiently serious and have sufficient substance to justify a formal investigation or whether they can be addressed through education/training or through some other non-disciplinary approach. These conclusions will be set out in the assessment panel’s written report.

11.2.11 The assessment panel will send the researcher a copy of its written report and recommendations at the same time as it is sent to the Executive Director for Research. The researcher has the opportunity to submit any comments on the report to the assessment panel within 20 working days of receipt of the written report.

11.2.12 The assessment panel will review any comments received and will forward its final report and recommendations to the Executive Director for Research and the researcher within five working days of completion of the final report. Any comments received from either the complainant and/or the researcher will be attached as an addendum to the assessment panel’s final report.

11.2.13 After receiving both the written final report and any written comments of the researcher, the medical director shall decide either to accept or reject the assessment panel’s recommendations.

11.2.14 The complainant and the researcher will be informed in writing of the outcome of this assessment process within five working days of the Executive Director for Research making their decision. The Executive Director for Research should also notify the R&D director of the outcome at the earliest opportunity.

11.2.15 Where the Executive Director for Research accepts a recommendation from the assessment panel that the procedure should progress to a formal investigation (Stage 3), the medical director should take steps to set up the formal investigation committee as soon as reasonably practicable.

11.2.16 Where the Executive Director for Research accepts the assessment panel’s recommendations that the allegation be dismissed and/or can be addressed through non-disciplinary measures reasonable action to safeguard the reputation of the researcher and the Trust should be considered.

12. Stage 3: Formal investigation

12.1 Process and purpose
12.1.1 The purpose of the formal investigation is to examine and evaluate all relevant facts to determine whether research misconduct has been committed, and if so, the responsible person, the seriousness of the misconduct and what sanction(s) if any should apply to the researcher.

12.2 Action

12.2.1 The Executive Director for Research will appoint an investigation committee consisting of at least three members, who have not previously been involved, and who do not have a conflict of interest in the case and who have appropriate knowledge/experience to evaluate the scientific issues and who have relevant knowledge of investigating procedures.

12.2.2 The Executive Director for Research will notify the researcher of the proposed investigation committee membership in writing as soon as reasonably practicable.

12.2.3 The researcher has five working days to submit an objection to the Executive Director for Research to a person/s appointment to the investigation committee. If the researcher submits a written objection to any of the persons appointed to the investigation committee, the Executive Director for Research may decide to replace the challenged person with a suitably qualified substitute, and will notify the researcher of that replacement in writing.

12.2.4 If the Executive Director for Research does not replace the challenged person, the reasons will be notified to the researcher in writing within seven working days of receipt of the objections.

12.2.5 The date the investigation committee is formally appointed is either:
   - After the five working days have passed for the researcher to submit a written objection to its membership; or
   - after the Executive Director for Research has considered the researcher’s objections and confirmed the membership of the investigation committee to the researcher in writing.

12.2.6 As soon as reasonably practicable after the investigation committee is appointed, the Executive Director for Research will define the subject matter of the investigation in writing to the investigation committee and will attach a copy of the final report of the assessment panel. A copy of the same will also be sent to the researcher.

12.2.7 The investigation committee will be appointed and the process initiated as soon as possible, and normally within 20 working days of the completion of the assessment process.

12.2.8 The investigation will normally include examination of all documentation including, but not limited to, relevant research data materials, proposals, publications, correspondence, memoranda and notes of telephone calls. The assessment report will also be reviewed and the researcher will be interviewed.

12.2.9 Whenever possible, interviews should be conducted of all individuals involved in the allegation, and any other individuals who may have information regarding key aspects of the allegations. The researcher will also be asked to name any relevant witnesses.
12.2.10 The researcher, and any other individuals who are interviewed, will have the right to be accompanied by an appropriate person of his/her choice at interviews and meetings held under this procedure.

12.2.11 Written notes will be made of the interviews and meetings; these are not meant to be verbatim but will be an accurate reflection of the points discussed and will form the official record and will be included in the investigation report. Each individual will have an opportunity to comment on, and sign, the notes to ensure factual accuracy, but this should not delay the investigation process. Any disagreements will be noted.

12.2.12 An investigation should normally be completed within 65 working days of its appointment.

12.2.13 The investigation committee report must state how the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state whether it considers that research misconduct has been committed, explain the basis for the findings, and an accurate agreed summary of the views of any individual alleged to have engaged in misconduct (including the written notes an interviews conducted).

12.2.14 The investigation committee will also include in its report any general recommendations, as appropriate. These general recommendations may include a recommendation as to whether professional bodies or regulators, research funders/sponsors and other interested parties including collaborators of the researcher in the work should be notified of the outcome of the case.

12.2.15 If the investigation committee considers that there has been research misconduct, it will recommend in its report one or more of the following:
   (a) Implementation of all or some of its general recommendations.
   (b) Referral to the lead employer’s HR department and appropriate disciplinary action. In the case of a referral to the Trust’s HR team, the Trust’s disciplinary procedure policy (link) will apply¹ and be followed. The researcher should be notified that this route may lead to termination of their employment and that they should seek legal advice in relation to this next stage of the process.
   (c) Report to the research board.
   (d) Report to appropriate external regulatory and professional bodies.

12.2.16 Where a distortion or in accuracy in the published research record is found, all necessary steps should be taken to notify all relevant parties and to correct the published record. Such notification should be encouraged to protect the reputation of the Trust. However, save in exceptional circumstances (for example, where a paper was in the process of being published) such notification would not normally happen until all steps of the process had been completed.

12.2.17 The investigation committee will send the Executive Director for Research and researcher a copy of its initial report and the evidence it has considered within five working days of the completion of the report.

¹ The Trust’s disciplinary procedure applies to all non-medical staff. In relation to medical and dental staff, it applies only to issues of personal misconduct which, for the purpose of this research misconduct policy, includes alleged research misconduct.
Research and development (R&D) department

12.2.18 The researcher then has the opportunity to submit any comments on the report. These must be submitted to the investigation committee within 20 working days of receipt of the report.

12.2.19 The investigation committee will review any comments received by the researcher before drafting its final report and recommendations. The researcher's comments will be attached as an addendum to the final investigation report.

12.2.20 The investigation committee will send a copy of the final investigation report and recommendations, including comments from the researcher, to the Executive Director for Research.

12.2.21 The Executive Director for Research will review the investigation committee's final report and will decide whether to dismiss the allegations or follow the investigation committee’s recommendations.

12.2.22 The researcher will be informed in writing of the Executive Director for Research's decision within five working days of the Executive Director for Research making the decision. The Executive Director for Research should also inform the research board of the decision at the earliest opportunity.

12.2.23 If the allegation is dismissed, the complainant should also be informed. Reasonable action to safeguard the reputation of the researcher and of the Trust should be considered.

13. Appeal

13.1 There is no right of appeal in respect of actions 12.2.15(a), 12.2.15(c) and 12.2.15(d).

13.2 Where disciplinary action 12.2.15(b) has been invoked, the researcher would have access to a right of appeal through his or her lead employer’s disciplinary procedure.

13.3 If no disciplinary action has been invoked and the researcher wishes to appeal against the process of the investigation (distinct from the outcome), then an appeal should be submitted under the Trust’s grievance procedure (link).

14. Procedural

14.1 Individuals are to be advised of their right to be accompanied by an appropriate person of their choice at interviews and meetings held during the above processes.

14.2 Where appropriate, the overall aim of the procedure is to try and solve concerns at an informal level. There may be occasions, however, when a formal investigation may be required.

14.3 The R&D manager, the R&D director and/or the Executive Director for Research may, depending on the nature of the complaint or concern, at any stage in the process take any appropriate action pending the outcome of this procedure including restriction of duties, exclusion from work, referral to professional regulator.

14.4 Anonymity and confidentiality of both the complainant and the researcher should be maintained as long as possible. Information will be exchanged for the proper conduct and conclusion of any case (including between
organisations if for example the complaint is forwarded to the substantive employer or a regulatory body) and disclosure of any information will be to those individuals who ‘need to know.’ The Trust will take all reasonable action to safeguard the reputation of the researcher and the Trust. If the researcher is found not to have committed research misconduct:

14.4.1 The R&D director and/or Executive Director for Research will consult with the researcher to ensure that appropriate publicity is given to this outcome where considered necessary.
14.4.2 The R&D director and/or Executive Director for Research will take steps to ensure that all reference to the matter is expunged from the researcher’s personnel file.
14.4.3 All persons who have been interviewed or otherwise informed of the allegations will be notified in writing that the allegations have been found to be without foundation.

14.5 Where the outcome of any of the stages of this policy indicates that an allegation has not been made in good faith, the Trust will:

14.5.1 Pursue disciplinary action against the complainant if they are employed by the Trust.
14.5.2 Pursue action as appropriate against an external complainant.
14.5.3 Take action to safeguard reputations as necessary.

14.6 The Trust may on occasion seek the involvement of an external adviser.

15. Reporting

15.1 The levels of reporting will be governed by four main criteria:

- the outcome of the particular stage of the review process
- the main employer status
- the conditions set by funding body
- the regulations set by professional and regulatory bodies

16. Documentation

16.1 Comprehensive and careful notes should be taken at each stage of the review process.
16.2 All notes should be stored in a safe and secure environment during the process and to be filed in the Executive Director for Research’s office once the matter is concluded.
16.3 All documentation should be handled in accordance with the provisions of the Data Protection Act 1998.
16.4 Any one of the following may grant access rights to these notes:

- R&D director
- Executive Director for Research
- chief executive
17. Monitoring compliance with and the effectiveness of this document

Any reports of research misconduct will be reviewed as per this document and the effectiveness of this document will be monitored by those involved with the review process as and when they occur. The format of the monitoring will be undertaken as a review and any results will be reported to the research board.

18. References

1. Medical Research Council Policy and Procedure for investigating allegations of research misconduct 10 November 2014

19. Associated documents

- Anti fraud, bribery and corruption policy
- disciplinary procedure
- grievance procedure
- NHS permission for research studies policy and procedure

19.1 R&D and CCTU SOPs

- R&D/SOP003 serious breach of protocol or GCP in CTIMPs
- CCTU/SOP018 handling of protocol and regulatory non-compliance in clinical trials
- CCTU/SOP019 urgent safety measures for CTIMPs

These are available from the R&D/CCTU document library at: http://www.cuh.org.uk/cms/research-and-development/document-library

Equality and diversity statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

Disclaimer

It is your responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

Document management

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<td>Tracey Hensman; Kelleher, Stephen</td>
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APPENDIX A – DEFINITION OF MISCONDUCT

The Trust endorses the definitions of research misconduct and other unacceptable research behaviour identified in the RCUK Policy and Guidelines on Governance of Good Research Conduct (February 2013). Unacceptable conduct includes the following:

**Fabrication**
The creation of false data or other aspects of research, including documentation and participant consent.

**Falsification**
The inappropriate manipulation and/or selection of data, imagery and/or consents.

**Plagiarism**
The misappropriation or use of others’ ideas, intellectual property or work (written or otherwise), without acknowledgement or permission.

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

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

Improper dealing with allegations of misconduct

• failing to address possible infringements including attempts to cover up misconduct or reprisals against whistleblowers.

• failing to deal appropriately with malicious allegations, which should be handled formally as breaches of good conduct.