

### **Guidance for Departments:**

#### **Investigating a breach of the University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue**

1. The University's Ethics Policy states that, in the event of concerns arising about whether a research proposal or ongoing research activity complies with the Policy, the UREC should be notified as soon as possible. The UREC will then contact the relevant Head of Department to ensure that the research activity is suspended (including the suspension of the marking process if the matter relates to an assessment already submitted), and to initiate an investigation of the situation and report back within a reasonable timeframe (usually 2-3 weeks).
2. In practical terms, this communication is likely to come from the Secretary to the UREC, on behalf of the Chair, when a concern about a potential breach has been raised by, or with, the relevant department. The Department should notify the Secretary of the UREC promptly of any ethics concerns or potential breaches that they become aware of.
3. The investigation should be carried out by a senior member of academic staff with appropriate experience (investigating officer). If this is not carried out by the Head of Department themselves, the Head of Department should appoint an appropriate individual to carry out this role (in many cases this is likely to be the department's Principal Ethics Contact/Ethics Coordinator). However, the investigating officer must be able to undertake the investigation impartially, and have no conflict of interest (i.e., they must not be/have been directly involved with the case of research in question in any capacity, including as supervisor, co-researcher, ethics reviewer etc.). The investigating officer must keep the Head of Department updated regarding progress with the investigation.
4. The purpose of the investigation is usually to establish whether a breach has, in fact, occurred, and if it has, to establish the full circumstances, including the course of events that led to it and the roles played by any individuals involved.
5. The individual(s) alleged to have breached the Ethics Policy should be notified in writing that they must suspend the research activity in question, and of the intention to undertake an investigation, by the Head of Department or the appointed investigating officer. The communication should include full details of the alleged breach and should explain how the investigation will proceed, including details of how the individual(s) can respond to the allegation and submit relevant evidence. They should also be provided with information about relevant support/guidance available to them (e.g. for a student, the support provided by the Student Advice Centre).
6. The individual(s) alleged to have breached the Ethics Policy should be offered the opportunity to be accompanied to any relevant meetings/interviews, if they wish, by a companion (e.g. a friend, fellow worker, or trade union representative). Students should

be advised that they may contact the Student Advice Centre should they wish to seek support in terms of being accompanied to such a meeting.

7. The investigation should ideally involve meetings/interviews with all individuals relevant to the case (if a meeting is not possible then email correspondence should take place instead wherever possible). If the concern relates to a student, the supervisor(s) should be consulted, as well as the student. All individuals relevant to the case should have an opportunity to set out their view of events and provide relevant evidence. Individuals invited to attend meetings/interviews should be given at least three days' notice.
8. Meetings/interviews with the individual(s) alleged to have breached the Ethics Policy should be attended by two representatives from the department concerned (e.g., the investigating officer plus a minute-taker).
9. Meetings/interviews should start by introducing those in attendance and setting out the allegations concerning a potential breach of the Ethics Policy. The investigating officer should check that these are understood by the attendee(s) (who should be given an opportunity to ask questions concerning the allegations and/or the investigation procedure).
10. Minutes/notes of any meetings carried out as part of the investigation process should be taken, and a copy provided to all those present at the meeting.
11. Meetings should be closed by setting out clearly what the next steps will be in the investigation process, and outlining the support available to the individual(s) concerned.
12. The investigation should also take into consideration any written evidence, correspondence or other materials relevant to the case.
13. Once the investigating officer has undertaken all required meetings and reviewed all relevant correspondence/documentation, they should compile a report for consideration by the UREC.
14. The report should normally include the following:
  - An introduction providing the details of the alleged breach, how it was identified and the details of the individual(s) concerned;
  - A summary of the outcomes of any meetings/interviews held with the individuals involved;
  - A summary of the relevant email correspondence/ other written evidence;
  - An assessment of the case and recommendations for how to proceed (see 'guidance concerning recommended outcomes' below).
15. A timeline of events may also be useful in more complex cases. Investigating officers may also wish to provide copies of the minutes of relevant meetings, and/or copies of relevant email correspondence/other written evidence.

16. The report and supporting documentation should be provided in a clear format (e.g. with supporting documents in clearly numbered appendices).
17. Completed reports should be sent to the Secretary of the UREC, Lindsay Unwin (l.v.unwin@sheffield.ac.uk).
18. A sub-group of the UREC will then be constituted to consider the report and situation, and decide the outcome.
19. It is important to understand that the UREC will make a final decision regarding how to proceed, once the sub-group has made its report. This is because the UREC handles such cases regularly and must ensure a consistent approach across the University (it may also make the situation easier to manage for the department concerned).
20. In addition, it should be noted that departments are expected to implement the decision made by the UREC in such cases; should a department disagree with the decision made, then the UREC Secretary should be contacted to discuss the matter further. The UREC requires that departments report back to the Secretary concerning the final outcome of breach cases (i.e. confirming that the UREC's decision has been implemented).

#### Guidance concerning recommended outcomes

The UREC has dealt with many cases of potential breaches of the Ethics Policy; whilst each case is considered individually on its own merits, the UREC aims to ensure a consistent approach across the University.

To help investigating officers with putting forward recommendations for handling such cases, the below outlines the approach that has been taken in previous commonly occurring scenarios. Recommendations may relate to the individual(s) concerned, the research project in question, and/or to broader prevention strategies across the department or wider University.

- In most cases, where the investigation confirms that data have been collected without the necessary ethics approval, or in breach of the ethics approval/application, all copies of/references to the data must be destroyed, and confirmation of this provided by the relevant individual(s) to the investigating officer (who should then pass this on to the UREC). This applies equally to staff and student research.
- In the case of a student who has submitted an assignment containing data which has been collected without the necessary ethics approval, usually the assignment would need to be failed. If the investigation identifies that there are significant mitigating factors (e.g. the student was informed that they did not need ethics approval by the supervisor/department), then the student may be allowed to re-submit the assignment (with no reference to the data collected without ethics approval) to be marked as normal. If there are no significant mitigating factors (e.g. if the student was given the opportunity to be informed of the requirements of the Ethics Policy but

did not attend training/engage properly with departmental processes/read relevant emails), then normally they would be allowed to re-submit but the marks would be capped.

- If the investigation identifies that there was, in fact, no breach of the Ethics Policy (e.g. where the issue related to a failure of the ethics system resulting in the approval not being properly recorded), then the research and/or marking process can normally be allowed to proceed as normal.
- If the investigation identifies failings in departmental processes or teaching/training provision, then the recommendation may include actions for the department, such as improvements in monitoring processes, enhancement of ethics teaching materials, improved methods for communicating ethics requirements to staff/students, etc.
- If the investigation identifies actions required at a University level, then recommendations can be made for the UREC, for example, suggesting additions/changes to the Ethics Policy or associated guidance.

NB. If there is clear evidence that a student or member of staff has committed a serious breach of the Ethics Policy (e.g. if they have deliberately disregarded the requirements of the Ethics Policy and collected data without the necessary ethics approval; placed participants or potential participants at risk of harm through deliberately disregarding the Ethics Policy and/or terms of ethics approval), UREC may recommend that they be considered for disciplinary action in line with the Regulations relating to the Discipline of Students, or be referred to the Procedure for Investigating and Responding to Allegations of Research Misconduct (for staff).