

Procedures for the monitoring and audit of research covered by the ESRC *Framework for Research Ethics*

1. Background

1.1 The ESRC *Framework for Research Ethics* (FRE), compliance with which is mandatory for ESRC-funded research, requires that universities “establish and publish working procedures for monitoring research and for undertaking occasional ad hoc audits”.¹

1.2 The procedures below set out a light-touch approach to auditing research projects that fall under the FRE and have received ethical review within the University and to undertake light-touch audits of the decisions of research ethics committees (RECs) that review such projects at the University. They apply to projects that have been reviewed at both departmental/Faculty and at School level.

1.3 Projects that are not covered by the ESRC’s FRE will not be subject to these procedures.

1.4 The procedures respect the independence of the University’s RECs and are not intended to make a judgement on the accuracy or correctness of REC decisions.

1.5 These procedures will only apply to ethical reviews that take place after **04 April 2015**. From that date RECs will be expected to make PIs and supervisors of students undertaking work to which the FRE applies aware of the possibility of audit.

2. Procedures

2.1 Audit of ethically approved research projects

- a) Each year one eligible project will be identified randomly using the annual reports of the University’s RECs. To facilitate this, RECs will be asked to identify, as part of their annual reports to the UREC, all ESRC-funded projects that they have reviewed during that year (or since 04 April 2015 in the first year of the process).
- b) The UREC will request records relating to the project from the relevant REC. The Principal Investigator (PI) of the selected project will be asked to provide, where relevant:
 - i. Copies of consent documents and any necessary permissions
 - ii. Information on data storage and data sharing
 - iii. Details of any changes made to the project since ethical approval and any specific problems encountered
 - iv. Any additional information that the UREC judges to be necessary in light of the conditions of approval placed on the particular project.

¹ ESRC, *Framework for Research Ethics (FRE)* (January 2015), pp. 7, 18. Available from: http://www.esrc.ac.uk/_images/framework-for-research-ethics_tcm8-33470.pdf [Accessed 04/03/2015]

- c) The information provided will be subject to a light-touch review by the UREC, drawing on appropriate expertise if required, which will consider whether the project has complied with the conditions of its ethical approval.
- d) Where concerns are raised by the light-touch review, the case will be referred for full review by the UREC and additional details may be requested from the PI.
- e) Where the UREC considers that a study is being conducted in a way which is not in accordance with the conditions of its approval or in a way that does not protect the rights, dignity and welfare of research participants, it will arrange a meeting of all those concerned with a view to resolving the difficulties identified.
- f) Where necessary the UREC will recommend that the relevant REC suspends or discontinues ethical approval. The UREC will only make such a recommendation where it judges that the serious nature of the concerns identified requires it, for example where the Committee believes that:
 - i. There is an immediate risk to the rights, dignity or welfare of research participants
 - ii. There has been a serious and deliberate breach of good research practice, including failure to report significant issues to the relevant REC, requiring investigation under the University Misconduct in Research policy
 - iii. Discussions with the project team have failed to resolve the difficulties identified.
- g) UREC will report any suspension or discontinuation of approval to the ESRC.
- h) If, at any stage of the process, the UREC is satisfied that the project under review raises no concerns, or that discussions have addressed the issues raised, the PI and relevant REC will be informed that the audit has been completed satisfactorily.
- i) A short report on the audit, including any advice emerging from it, will be provided to the relevant REC.

This procedure sets out the central audit process only; RECs can also audit their own reviewed projects should they so wish.

2.2 Audit of reviews carried out by University research ethics committees

- a) The UREC will undertake a biennial audit of 2-3 reviews carried out by internal RECs of projects that fall under the FRE.
- b) The reviews will be selected randomly, with the following considerations:
 - i. A maximum of 1 project will be selected from any single REC
 - ii. Where possible the audit will consist of a range of award types (PhD, Fellowship, Research Grant, etc.).
- c) The audited REC will be asked to provide all paperwork relating to the selected ethical review.
- d) The audit will be carried out by the UREC, excluding members of the audited REC, and will seek to confirm that:
 - i. the procedures of the REC concerned were followed

- ii. the decision made by the REC was fair and independent.
- e) Where there is evidence that procedures were not followed or that the decision was in any way unfair or conflicted, the UREC will:
 - i. In serious cases, review and, if necessary, overturn the decision made, reporting any suspension or discontinuation of approval to the ESRC
 - ii. Where lesser concerns are raised, provide a short report to the REC concerned setting out how the issues identified can be addressed.