Annual procedure for carrying out follow-up checks of ethics arrangements and documentation for ESRC-funded research projects

The Economic and Social Research Council (ESRC) includes in its terms and conditions of funding that the University is responsible for monitoring research to ensure good research conduct, and compliance with conditions set out in the ethics review. In order to meet this responsibility, the University Research Ethics Committee (UREC) has set out a procedure for undertaking checks of ethics arrangements and documentation for a proportion of on-going ESRC-funded projects which have received University ethics approval. This procedure will be undertaken on an annual basis.

The procedure is set out below:

1. Research Services will access data from the online Ethics Application System to produce a list of on-going ESRC-funded studies which have received University ethics approval.

2. Two projects will be selected for a follow-up check. The projects will be selected by the Chair of UREC (or Deputy Chair should a conflict of interest arise) using a purposive sampling technique. This technique will be used to ensure that identified studies are at an appropriate stage of progress (e.g., not at a very early stage), have not already been checked in previous years, and will take into consideration the level of risk presented by the research (e.g., risk to participants; risk to the researcher(s)).

3. In consultation with the Chair of UREC, Research Services will facilitate the process of forming small UREC teams to consider each project, comprising:
   - Chair or Deputy Chair (to chair the team)
   - One additional academic member
   - One lay member
The UREC Secretary and Minute Secretary will provide administrative support.

4. For each of the selected studies, Research Services will contact the lead researcher of the two identified projects via email to notify them that their project has been selected for checking. The Head of Department and Principal Ethics Contact for the department will be copied in; if the lead researcher is a student, their supervisor (as identified in the ethics application) will also be copied in. The email will provide a copy of the procedure, and details of the general information that will be required so the researcher has an opportunity to prepare.

5. A date for a meeting of up to 1 hour will be agreed. The meeting will be attended by the chair of the UREC team supported by the UREC Secretary, the lead researcher, and appropriate others as agreed with the researcher (this may include relevant members of their research team and/or the Principal Ethics Contact for the department). For student projects, at least one supervisor is expected to attend.

6. Research Services will download the relevant ethics application(s) and any supporting documents and/or details of subsequent amendments which are available from the online Ethics Application System. This will be sent to the UREC team 3-4 weeks prior to the meeting, with a suggested agenda. Team members will be invited to submit comments on the documentation, and suggestions regarding any points of clarification/further information which should be sought from the researcher at the meeting, for consideration by the chair of the UREC team.
7. At the same time as (6), a copy of the agenda and documentation obtained from the online Ethics Application System will be provided to the researcher and other departmental attendees. The researcher will be invited to provide copies of other relevant documentation which has not been recorded in the System (e.g. records of amendments to the ethics application).

8. Shortly prior to the meeting with the lead researcher, the chair of the UREC team and the UREC Secretary will meet to discuss the ethics documentation, to finalise the format of the meeting, and agree any specific areas for discussion/clarification.

9. The meeting between the lead researcher and the chair of the UREC team will be held on the agreed date; during the meeting, the UREC team chair will seek to enable a supportive and reflective discussion to take place regarding the practical experience of implementing the terms of the ethics approval. In particular, the chair will request information about the following:

- The informed consent process which has been undertaken, and evidence of this e.g. via a physical check of informed consent records (to the extent that data protection provisions allow);
- Any relevant permissions (in addition to the University ethics approval) that were required to undertake the research, and evidence of these permissions;
- How the data collected from participants are being stored and shared;
- Any significant changes that have been made to the project since ethical approval was granted;
- Any specific problems that the researcher encountered, and how these have been addressed;
- Additional information that the UREC team may agree is necessary in light of the conditions of approval placed on the particular project, and the initial review of the application and supporting documents.

10. If additional information requested by the UREC team is not available during the course of the meeting, the lead researcher will be asked to forward this information as soon as possible following the meeting, for consideration by the UREC team.

11. A report of the meeting will be prepared by Research Services, and circulated to the UREC team for comment. The report will highlight areas of good practice, and any areas for improvement/learning points for the researcher and/or wider department. The report may include comments made by the UREC team following the provision of further information that was requested during the meeting.

12. Once the report has been agreed by the UREC team, it will be shared with the other meeting attendees; there will be an opportunity for concerns regarding factual inaccuracies/misrepresentation of information to be raised if needed. Comments received will be considered by the chair of the UREC team, and a final version of the report will be prepared and forwarded to all relevant parties (including UREC team members, lead researcher, supervisor where relevant, Head of Department and Principal Ethics Contact).

13. If the UREC team identifies concerns regarding the project in question, a further meeting may be held between the UREC team and the researcher/relevant colleagues to discuss the concerns and agree how they can be addressed. Serious concerns will be dealt with in accordance with the relevant University policy/procedure.

14. A copy of the final report will be presented to UREC at the next available meeting.