Guidance for applicants when completing an application for ethical review (AER)

General guidance

- Allow enough time to complete your application, and for the Committee to review it, prior to your anticipated start date. Applicants are advised that the review process typically takes 4-6 weeks, although this may vary depending upon the nature of your project.

- If you have external deadlines or wish to request an early response, please make this clear at the point of submission. Whilst the Committees and the Ethics Team do their best to meet such deadlines, please be aware that this may not always be possible (particularly during busy periods).

- Use the most up-to-date version of the application form (i.e. the version available at https://intranet.birmingham.ac.uk/finance/documents/public/aer.doc).

- Ensure that all relevant information and documentation is included with your application. Your application may be delayed if: a). Insufficient information is provided and/or documentation (e.g. participant information sheet, consent form, questionnaires, topic guides) is omitted or b). Unnecessary or excessive information and documentation is provided.

- Proof-read your application and accompanying documentation before submission.

- Discipline-specific norms or understandings should be made explicit, as they may not be familiar to Committee members.

- As far as possible, avoid the use of technical or discipline-specific terminology. Your application should be understandable to a lay reader.

Question specific guidance

The guidance below echoes the instructions stated on the application for ethical review form, and also touches upon some of those issues which arise most frequently when reviewing applications.

Q1-5 Basic details of the project (title, PI, funder, PGR/staff, start and end dates)

Please ensure that the required information is complete and is accurate.

Any circumstances that might otherwise be unclear (e.g. that the PI is an honorary member of staff, or that the project is a collaboration between a number of institutions) should be fully explained, if necessary in a separate document.

Q6 Summary of project

Describe the purpose and background rationale for the proposed project, as well as the hypotheses/research questions to be examined and the expected outcomes. It is not necessary to provide extensive academic background material or references.

Q7 Conduct of project

Please provide clear information about the methodology to be used, particularly explaining any unusual or novel methodologies.

For studies which will involve a combination of different methodologies or interventions, it may be helpful to provide a timeline illustrating what each participant will experience.

If the study will include a control group, please also clearly state how participants will be assigned to this group and what they will experience during the study.

Q9 Participants as the subjects of the research

Full information should be provided about the intended participant groups, including any factors which may make them vulnerable.

You should include the number of participants and any important characteristics (such as age, gender, location, affiliation, level of fitness, intellectual ability etc.). Please specify any inclusion/exclusion criteria to be used.

If patient participants will be accessed via the NHS, be aware that your research is likely to require review via the National Research Ethics Service (NRES).

Q10 Recruitment

Please state clearly how participants will be identified, approached and recruited. Explain any relationship between the investigator and the participant (e.g. instructor-student).

Please ensure that all recruitment materials (e.g. posters, draft emails, etc) are included with your application.

Q11 Consent

Voluntary, informed consent from participants should be obtained and recorded, unless satisfactory justification can be provided that this would not be appropriate. Whilst written consent is preferable, in some instances it may be appropriate to record verbal consent rather than to use a written consent form.

If written consent will be obtained, copies of the participant information sheet and consent form should be provided. If consent will be obtained verbally, a sample 'script' of the information which the PI will verbally deliver to participants should be included. In the case of questionnaire studies, it may be appropriate to assume consent from participants' completion of the questionnaire form (although it is still important to ensure that such participants have been fully informed about the study, so an information sheet may still be necessary).

If any participants will be under the age of 16, parental consent should be sought unless satisfactory justification can be provided. In cases where parental consent is required, opt-in consent is considered

preferable – if parental opt-out consent will be used this should be fully justified, and procedures should be in place to i). ensure that parents do receive the opt-out letters and ii). allow parents a sufficient period of time to opt out if they so wish.

Participant information sheets and consent forms should be tailored to their intended audience (e.g. an information sheet for 7 year olds should use age appropriate language and/or pictures).

If any participants will lack the capacity to consent, in line with the Mental Capacity Act 2005 it is likely that your research will require further review by an appropriate body such as the National Research Ethics Service (NRES).

If participants will be deceived in any way as part of the study, justification should be provided and participants should be appropriately debriefed at the end of the study. Copies of any debriefing material should be provided.

Q12 Participant feedback

Please explain what feedback will be provided to participants following their involvement in the project. Feedback should be provided in an appropriate format for the intended audience (e.g. an anonymised summary of the results may be more appropriate than a copy of the PhD thesis).

Q13 Participant withdrawal

Describe how the participants will be informed of their right to withdraw from the project, and explain any consequences for the participant of withdrawing from the study (e.g. the removal of any financial compensation).

The documentation to be given to participants should clearly state whether they will be able to withdraw their data both during and after the study, and what they need to do in order to withdraw (e.g. who to contact). A reasonable time limit should be given for participant withdrawal, as it is not usually possible for participants to withdraw once an analysis of their data has been included in material submitted for publication.

Please indicate what will be done with the participant's data if they withdraw. In the event that a participant withdraws, it is preferable that their data should be removed from the study unless they give explicit consent for it to be retained (rather than retaining the data unless the participant requests that it is omitted).

Q14 Compensation

Provide information about any financial or non-financial compensation which will be offered to participants.

If compensation will be offered, please consider whether it is appropriate in the context of the research, and whether it may be considered excessive (i.e. that it may encourage individuals to take part despite any risks and/or concerns they may have).

Explain how you will deal with compensation in the event that a participant chooses to withdraw. If participants will be compensated per hour/day, in the event that a participant withdraws it is considered best practice to compensate them for the time they have already spent on the project.

Q15 Confidentiality

Explain clearly whether data will be anonymous, or confidential, and the procedures in place to ensure anonymity/confidentiality. Participants' identity/data will be confidential if an assigned ID code or number is used, but it will not be anonymous. Anonymous data cannot be traced back to an individual participant. Anonymity/confidentiality should be clearly explained in the participant information sheet.

If participants will not be afforded anonymity/confidentiality, this should be fully justified and any risks addressed.

Q16 Storage, access and disposal of data

For both hard copy and electronic data, please describe:
- What research data will be stored
- Where the data will be stored and for what period of time
- The measures that will be put in place to ensure security of the data
- Who will have access to the data,
- The method and timing of disposal of the data.

Data management strategies (including the retention of data) should comply with both the University's Code of Practice for Research (http://www.birmingham.ac.uk/Documents/university/legal/research.pdf) and the Data Protection Act 1998 (see https://intranet.birmingham.ac.uk/legal-services/What-we-do/Data-Protection/index.aspx for further information).

Q17 Other approvals required?

Other approvals which may be required include Disclosure and Barring Service (DBS) checks, approvals/agreements to grant access from institutions involved in the research, and governance approvals (e.g. NOMS/MoJ for work with offenders).

Q 19a Risks

Outline any potential risks (both physical and emotional) to individuals, including research staff, research participants, other individuals not involved in the research, and the measures that will be in place to minimise any risks.

Please ensure that the potential risks to all individuals involved in the research are considered – for example, the risks to the researcher (e.g. risks associated with conducting the research overseas, particularly in areas which may be politically unstable or otherwise unsafe) can sometimes be overlooked.

In certain studies, there is a risk that the nature/subject matter of the study may cause distress/anxiety for participants. If this is the case, it should be identified in your application and clear processes should be

in place to deal with any distress caused - both on an immediate basis, and in the longer term (e.g. suggestions of suitable sources of support/information).

Q19b Risks

Outline any potential risks to the environment and/or society and the measures that will be taken to minimise any risks and the procedures to be adopted in the event of mishap.

Examples of such risks include any negative consequences that the outputs of the research may have upon society's view of certain groups/issues, risks associated with the dual use of research findings.

Q20 Are there any other ethical issues raised by the research?

Any other ethical issues raised by the research, not already addressed elsewhere, should be noted here.