GUIDANCE FOR RESEARCH ETHICS REVIEWERS
(Staff, Doctoral and MRes Research)

Areas to consider

- Informed consent
- Participant information sheet
- Confidentiality / anonymity
- Protection of participants
- Deception
- Debriefing
- Withdrawal from the research
- Expertise of researchers / quality of study
- Confidentiality
- Conflicts of interest
- Data storage

NB If adult research participants cannot give informed consent because of cognitive impairment due to physical or mental illness then the study must go for approval to an NHS Ethics Committee as required under NHS Governance and the Mental Capacity Act.

Description of the Study

1. Is there a clear rationale for what is being studied? Worthwhile outcomes that justify the time, effort and resources?
2. Do the potential benefits outweigh any potential risk to the participants?

Protecting the Participants

1. Is it clear how access to participants will be obtained? Any gatekeepers identified and if required is there evidence of permission to access the sample?
2. If there are inclusion/exclusion criteria, are they clear and appropriate?
3. Is the information about the study clear?
4. Is there enough information about the study given to participants to make an informed decision about participation?
5. Is consent being obtained appropriately? Is this free from any coercion?
6. If participants are being paid, is this in High Street Vouchers and within the £20 limit unless something else has been agreed?
7. If any participants are vulnerable or potentially vulnerable, has this been addressed satisfactorily?
8. Is the participant's identity and the confidentiality of the material he/she presents to the researcher adequately safeguarded?
9. Are participants able to / been explicitly told that they can withdraw from the research study? How will it be done and has a suitable deadline been specified for withdrawal of data after the event? (1-2 weeks normal). [Exception is anonymised data where withdrawal is not possible.]

10. If the research is likely to uncover other issues unrelated to the research itself (e.g. illegal activity, illness, evidence of abuse etc.) has the researcher specified how this will be handled? [E.g. warnings on the information sheet that anonymity may not hold if illegal activity is disclosed to evidence of practices likely to damage others, etc.]
11. Has the possibility of any physical or psychological harm occurring to participants as a result of the research been acknowledged? Is there an indication of how the researcher will deal with this?

Conflicts of interest

Are there any conflicts of interest in the researcher undertaking this study and/or with these participants? Has it been acknowledged? Is it being addressed properly?

About the methodology and study procedure

1. Can the methodology address the research questions being proposed?
2. If there is some deception in the study, has its use been justified and is there an appropriate debriefing in place?
3. Is the contribution being asked of participants reasonable in terms of time, emotional burden, and the importance of the research question as explained by the researcher?
4. Are the doses of any dietary supplements or pharmaceutical products clearly specified and justified in terms of standard procedures?

Supporting Documents (e.g. adverts, information sheets, consent forms, questionnaires, interview/ focus group questions outlines, debriefing sheet, etc.)

1. Is the language in any advertisements, information sheets or consent forms suitable, not too technical or complex for the research participants being targeted?
2. Should a participant become distressed as a result of participating in the study is it clear how they can contact the researchers to get further information or help? Is there an email address and telephone number of the PI?
3. Can participants find out about the results of the study?
4. If a Risk Assessment for the procedures is required has this been uploaded?

Data management

1. Has a data Management plan been completed?
2. Are the measures taken to anonymise data and keep personal data secured appropriately?
3. Who will access the data?
4. Is storage secure and storage times specified? Is the disposal method appropriate?

Overall

1. Is there enough detail in the application?
2. Is sufficient attention paid to safeguard the dignity, rights and well-being of participants?

Sometimes you may be asked to complete a review as a lay member. Here the core question is, how would you feel if you or a member of your family were asked to participate in the research study being proposed?

This list is not exhaustive but covers the main issues.

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