

LEAD REVIEWERS GUIDELINES

Application Number & Title: *(As on application)*

Name of Lead Reviewer:

Date of Meeting at which proposal is to be considered:

1. The scientific value and validity of the proposal:

Does the application give sufficient detail to determine whether the study is justified, appropriately designed to answer the research question(s), using robust methods and a sufficient number of subjects/measurements and capable of being completed? Are the aims and objectives achievable?

2. The welfare of the research subject:

Has the applicant considered any issues that may affect the research subject? E.g. time requirements, travel etc. Have any factors been put into place to address these?

3. Hazards, discomfort and distress to the research subject:

Application should identify any issues that may harm/affect research subjects, the level of any harm etc. and methods that will be employed to minimise/remove these.

4. Consent of the research subject:

What consent is being undertaken and how is it being obtained? E.g. written/oral, implied, etc. Is the consent form appropriate and in the recommended format?

5. Patient information sheet:

This should be written in understandable English for a lay person. It should include all explanations of the study and what is required of the research subject as well as contact details for the researcher.

6. Confidentiality:

Has the applicant considered issues of confidentiality, anonymity, data protection etc. and storage of data – both electronic and physical. Have timescales been indicated and are these realistic?

7. Welfare of Investigator:

Has the applicant considered any potential risks/hazards to themselves whilst carrying out the research?

8. R & D approval required? :

Indicate whether you feel the application requires R&D approval

9. Ethics approval required? :

Indicate whether you feel the application requires NRES approval

10. General comments:

Please give any additional comments not covered in previous sections.

11. Outcomes:

- **Pass = The research proposal is satisfactory**
- **Pass subject to amendments = The research proposal requires minor amendments, the applicant is required to revise and resubmit their proposal for approval by the lead reviewer and Chair of the Committee**
- **Amend and resubmit to sub-Committee = The research proposal requires major amendments and will need to be resubmitted to the Research Committee for consideration**
- **Reject = The research proposal is rejected outright**

If you have any issues with the application, please identify these in appropriate sections and comment upon what action you feel is required to improve/enable the application to be passed. These comments will form the basis of the information passed onto the applicant to enable them to amend their research proposal accordingly.