UHNM INTERNAL PEER REVIEW APPLICATION FORM

Instructions

The application form should be completed as concisely as possible and should address the points as applicable. Please state clearly if any section is not applicable to your project. Most of the sections are the same as the Integrated Research Application System (IRAS) form. The boxes can be expanded and text can be ‘cut & pasted’ to/from the IRAS form. For convenience we have indicated the relevant IRAS question numbers that map to this form.

Once you have completed your Peer Review application form, and received appropriate sign off, please forward an electronic copy to academic.research@uhnm.nhs.uk

Your application will be reviewed by the UHNM Research and Development, Quality Assurance Committee, within xx weeks of receipt, after which you will receive feedback.

In order to progress your Health Research Ethics application, through IRAS, you must also request sponsorship from UHNM, through completion of a Sponsorship Request Form and Risk Assessment.

Should you have any queries, please contact:

Applicant Details

Applicant Details

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| Chief Investigator: |  |
| Current Post: |  |
| Address: |  |
| Telephone/Mobile Number: |  |
| Email: |  |

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| Is your study part of an educational programme? | Yes [ ]  | No[ ]  |
| If yes, please provide the following details: |
| Name and level of course: |  |
| Name of Educational Institution: |  |
| Name of Educational Supervisor: |  |

Study Team Details

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| Name:  |  |
| Current Post:  |  |
| Organisation:  |  |
| Email:  |  |
| Role in study |  |
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| Name:  |  |
| Current Post:  |  |
| Organisation:  |  |
| Email:  |  |
| Role in study |  |
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| Name:  |  |
| Current Post:  |  |
| Organisation:  |  |
| Email:  |  |
| Role in study |  |

Study Title

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| --- | --- |
| Full Project Title |  |
| Short Title (Acronym) |  |
| Keywords |  |

Study Design

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| Will your project be eligible for adoption onto the NIHR Portfolio? | Yes [ ]  | No[ ]  |

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| Please indicate the design, type of study and source of funding, if any |
| Design | Feasibility |[ ]  Pilot |[ ]  Full Study |[ ]
| Type | Student |[ ]  Commercial |[ ]  Academic |[ ]
| Funding | None |[ ]  Internal Grant |[ ]  External Grant |[ ]

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| If your project is funded, please indicate the total value: |
| £ |

Study Details

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| 1. What is the principal research question/objective?

Please provide a clear account of the purpose of your investigation, including the primary and secondary objectives (A10 of IRAS Form) |
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| 1. Scientific Background: What is the scientific justification for the research?

What is the background? Why is this an area of importance? Has similar research on this topic been done before? Have all existing sources of evidence, especially systematic reviews been fully considered? What new information will it provide? (A12 of IRAS Form) |
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Methodology

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| 1. Please indicate as many as are appropriate

(A7 of IRAS Form) |
| Case series/case note review |[ ]
| Case-control |[ ]
| Cohort observation |[ ]
| Controlled trial without randomisation |[ ]
| Cross-sectional study |[ ]
| Database analysis |[ ]
| Epidemiology |[ ]
| Feasibility |[ ]
| Pilot |[ ]
| Laboratory study |[ ]
| Systematic Review/Meta-analysis |[ ]
| Qualitative Study |[ ]
| Questionnaire |[ ]
| Interview |[ ]
| Observation |[ ]
| Randomised Controlled Trial |[ ]
| OtherPlease give details: |

Plan of investigation

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| 1. Study Summary

Please provide a summary of methods and overview of the planned research. A flow chart should be attached where appropriate. It should be clear exactly what will happen to the research participant, how many times and in what order (A13 of IRAS Form) |
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| Planned Timescales: |
| IRAS application submission date |  |
| Project start date |  |
| Recruitment start date |  |
| Recruitment end date |  |
| Last patient follow up completion |  |
| Study close date |  |
| Overall Duration |  |

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| 1. Study Population
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| 1. Will the study involve recruitment of human research participants?
 | Yes [ ]  | No [ ]  |
| 1. Inclusion Criteria:

What inclusion criteria will be used to select participants/patient records/tissue or bodily samples? (list cases and controls separately if appropriate). (A17-1 of IRAS Form). |
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| 1. Exclusion Criteria:

If you are excluding participants on the basis of age, sex or ethnicity please explain why (A17-2 of IRAS form). |
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| 1. Study Setting:

Name and description of centres |
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| 1. Participant Identification

How will potential research participants in the study be identified, approached and recruited?Give details for cases and controls separately if appropriate, describe sampling methodology and randomisation procedures. (A27-1, A27.2, A28. A29. A30-1, A31, A32, A33-1, A33-2, A34 of IRAS Form). |
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| 1. Informed Consent
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| Will informed consent be obtained from the research participants? | Yes [ ]  | No [ ]  |
| Please give details of who will obtain consent, how it will be done, and of any particular steps other than an information sheet taken to provide information e.g. video, interactive media. If consent is not to be obtained, please explain why not) (A30-1 of IRAS form)  |

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| 8. Participation in study: (A18, A19, A20, A21, A22, A23, A24, A25, A26 of IRAS Form)1. Please provide details of what research participants will do, e.g. treatment intervention, completion of a questionnaire, participate in an interview.
2. Please provide details of how the research procedures or intervention will be administered (including duration and audit details)
3. Please provide details of any risks to the participant and safeguards to be put in place
4. Please provide details of any follow up procedures and time points, if appropriate.
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| 9. Outcome Measures |
| 1. Primary Outcome Measure (A57 of IRAS Form)
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| 1. Secondary Outcome(s) Measure(s) (A58 of IRAS Form)
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Data Analysis

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| 1. What specialist methodological advice, if any, has been sought in relation to the project?
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| 1. For quantitative studies, what specialist statistical advice, if any, has been sought in relation to this project?
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| 1. Has the sample size been informed by a formal statistical power calculation?
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| Yes | [ ]  If **YES**, indicate how the ample size calculation has been carried out, providing enough information to allow replication. (A60 of IRAS form) |
| No | [ ]  If **NO** please explain how the sample size has been determined, and why a formal sample size calculation has not been required. |
| N/A | [ ]  If **N/A**, please explain why: |

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| 1. Describe the proposed methods of analysis?

Please identify specific procedures in the case of statistical analysis or other analytical methods in the case of qualitative research (A62 of IRAS Form) |
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| 1. Where and how will data be stored, who will have access to the data? How will the security of data be ensured?
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| 1. Where will the analysis of the data take place and by whom will it be undertaken?

Please identify specific procedures in the case of statistical analysis or other analytical methods in the case of qualitative research (A62 of IRAS Form) |
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Authorisations for Submission

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| **Chief Investigator to obtain the appropriate signature****authorisation prior to submission** |
| **YOUR Agreement** | **Signature** |
| **Chief Investigator** |
| I confirm that the information submitted in this proposal is complete and correct and that this project will be conducted in accordance with HRA guidance. | Name: Chief Investigator |
| I understand that before proceeding with this research it is necessary for me to seek:* HRA, including REC, approval if necessary
* UHNM sponsorship approval
 | Name: Chief Investigator |
| **Clinical Director/Supervisor (If applicable)** |
| Having discussed this proposal with the applicant, I confirm:* Is scientifically justified adequately
* The research fits within the scientific aims of the Trust
 | Name: Position:  |
| **Educational Institution (If applicable)** |
| Having discussed this proposal with the applicant, I confirm:* Is scientifically justified adequately
* The research fits within the scientific aims of the Educational Institution
 | Name: Position:  |
| **UHNM Research & Development** |
| I confirm that the project has been reviewed by the Academic Development Team and sources of funding identified, or justification of no funding made. | Name: Academic Development Manager |