UHS Sponsorship Application

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| **Section 1 – To be completed for all projects requesting UHS to act as Sponsor** |
| **Study title** |       |
| 1. **Proposed dates**
 | Start Date:       | End date:       | Length of Follow-up:       |
| 1. **Is this project at grant application stage or already funded?**
 | Grant [ ]  | Funded [ ]  | Other – Please specify |
| 1. **Is the project educational?**
 | No [ ]  | Yes [ ]  | Please SpecifyDoctorate [ ]  Masters [ ]  Undergraduate [ ]  |
| **Chief Investigator contact details** (for educational projects insert lead academic supervisor) |
| Title/Name  |       | Principal employer:       |
| Work Address: |       |
| Department |       |
| Telephone |       | **CI holds UHS Substantive or Honorary Contract:** |
| Email |       | Yes [ ]  | Applying [ ]  | No [ ]  |
| 1. **Will the CI also be the PI for the study at UHS:**
 | Yes [ ]  | No [ ] *If No complete Q6.* |
| 1. **If No, please provide details of the PI at UHS if known:**
 |
| 1. **Is this a study of a medical device(s), investigational medicinal product (IMP) or Interventional**
 |
| IMP[[1]](#footnote-1) [ ]   | Medical Device [ ]  | Interventional [ ]  | Other [ ]  Please specify type of study:       |
| **If you have indicated that your study is a Medical Device or CTIMP/ATIMP have you discussed the study with the MHRA?** |
| Yes [ ]  No [ ]  |
| 1. **How many participants will be recruited?**
 |
| Adult Patients       | Child Patients      | Staff       | Healthy Volunteers       | Other       | Please specify:      |
| 1. **Will the study involve UHS resources or premises?**
 |
| No [ ]  | Yes [ ]  | If **Yes** Please Specify:       |
| **Section 2 – Funding details, to be completed for all projects** |
| **Is the research or will the research be in receipt of any external funding?**  |
| Yes [ ]  | If **Yes** has this been applied for or awarded please specify:       | No [ ]   | If **No** please specify how costs will be covered:      |
| 1. **If yes, which type(s) of funding organisation(s) is or will be funding the study?**

**Please tick all that apply:****NB** If a grant is held by a commercial company please tick commercial company below |
| National Institute of Health Research (NIHR) | [ ]  | If NIHR which funding stream? e.g. Research for Patient Benefit |       |
| Medical Research Council | [ ]  | Department of Health | [ ]  |
| Other Research Council | [ ]  | Other Govt Dept | [ ]  |
| Research Charities | [ ]  | European Union | [ ]  |
| Commercial Company | [ ]  | Please give detail: |
| Other, please state:       |
| 1. **Has the study been costed by R&D Finance?**
 |
| Yes [ ]  | No [ ]   | If **No,** who has costed the study? |
| 1. **Will funding cover all costs to deliver the study at UHS?**
 |
| Yes [ ]  | No [ ]   | If **No**, please specify how costs will be covered: |
| 1. **Will funding cover all costs to deliver the study at other sites?**
 |
| Yes [ ]  | No [ ]   | If **No**, please specify how costs will be covered:  | N/A [ ]  Single Site |
| 1. **What type of Scientific Peer review has been performed?**
 |
| **Reviewed by:** | [ ]  Non-commercial funder | [ ]  Commercial funder |
| [ ]  UHS Care Group/Division | [ ]  Multi-centre research group |
| [ ]  Other, please state:       |
| **Is this study:** |
| Single-centre? | Yes [ ]   | No [ ]  |  |
| Multi-centre[[2]](#footnote-2)? | Yes [ ]   | No [ ]  | If yes complete **Section 3** below |
| Pilot? | Yes [ ]  | No [ ]  |  |
| **Will the study be managed by a Clinical Trials Unit or Clinical Research Organisation?**  |
| No [ ]  | Yes [ ]  | If **Yes,**  please specify who:       |
| **Section 3 – To be completed for multi-centre studies** |
| **Will UHS be the lead centre?** |
| Yes [ ]  | No [ ]  |
| If No, which NHS Trust will be the lead centre?       |
| If No, please state why lead Trust are not acting as Sponsor:       |
| 1. **Approximately how many centres do you anticipate becoming involved in the study?**
 |       |
| Where will the sites be located: *Please tick all that apply* |
| Within the UK [ ]  | Outside UK, within EU[[3]](#footnote-3) [ ]  | Please Specify: | Other International [ ]  | Please Specify: |
| Please identify the Sites that will be participating (including UHS):       |

 **\*\*\* PLEASE ALSO COMPLETE FOLLOWING PAGES \*\*\***

**Study Assessment**

|  |  |
| --- | --- |
| **Risk Category Area** | **CI to Complete** |
| **A: Study Legal and Regulatory Needs** Does the Study require MHRA approval?If yes what is the MHRA risk category (see appendix 1 of the guideline for completing the sponsor request form for CTIMP categories)Does the Study require REC approval?Does the Study require HRA approval?Does the Study require CAG approval? | Yes [ ]  No [ ]  Don’t Know [ ]       Yes [ ]  No [ ]  Don’t Know [ ] Yes [ ]  No [ ]  Don’t Know [ ] Yes [ ]  No [ ]  Don’t Know [ ]  |
| **B: Local Alignment** Have you contacted the relevant support departments? PharmacyIf yes who did you speak to?RadiologyIf yes who did you speak to?Pathology If yes who did you speak to?MEMSIf yes who did you speak to?Other (please specify) | Yes [ ]  No [ ]  N/A [ ]       Yes [ ]  No [ ]  N/A [ ]       Yes [ ]  No [ ]  N/A [ ]       Yes [ ]  No [ ]  N/A [ ]             |
| Is the study being carried out on patient wards? | Yes [ ]  No [ ]  N/A [ ]  If Yes which wards:       |
| **C: Investigator Team** Please confirm the number of studies you have been CI onPlease confirm the number of studies you have been PI on  | CTIMP           | Medical Device           | Early Phase            | Interventional/Observational           |
| **D: Research Team**Do you require nursing support?Do you require CTA support?Have you discussed the study with the Lead Nurse?If Yes who did you speak to? Will staff require specific training on the protocol?If Yes please specify | Yes [ ]  No [ ]  Don’t Know [ ]  Yes [ ]  No [ ]  Don’t Know [ ] Yes [ ]  No [ ]  Don’t Know [ ]       Yes [ ]  No [ ]       |
| **E: Science Design** Have any peer review comments been included in the protocol?Has there been a statistican involved in the design of the study?How does this differ from standard of care? | Yes [ ]  No [ ]  N/A [ ]  Yes [ ]  No [ ]  N/A [ ]        |
| **F: Patient Safety Design** Are you receiving informed consent?Are there any special safety monitoring considerations?Are there any additional safety requirements?Have any safety/oversight committees been considered? | Yes [ ]  No [ ]  N/A [ ]  If No, please provide details:      Yes [ ]  No [ ]  N/A [ ]  If Yes, please provide details:      Yes [ ]  No [ ]  N/A [ ]  If Yes, please provide details:      Yes [ ]  No [ ]  N/A [ ]  If Yes, please provide details:       |
| **G: Patient Group Design** What is the planned recruitment period?Is this a rare patient group?What is the incidence of this?Are you recruiting patients that lack capacity to consent? |      Yes [ ]  No [ ]  N/A [ ]       Yes [ ]  No [ ]  N/A [ ]   |
| **H: Management and Monitoring** Do you have a Trial Manager/Coordinator for the study?Is there a need for a CRO/CTU to be involved?What work time equivalent will the CI set aside for this study?Who will be responsible for your safety reporting?Will monitoring be carried out by an external provider or be required by sponsor?Is there a data management plan in place or how will the data be managed? | Yes [ ]  No [ ]  N/A [ ]  If Yes, please provide details:      If No, who will manage the study:      Yes [ ]  No [ ]  N/A [ ]  If Yes, please provide details:                External Provider [ ]  Sponsor [ ]  If external provider, please provide details:      Yes [ ]  No [ ]  N/A [ ]  If Yes, please provide details:       |
| **I: Finance** Are there any excess treatment costs?If Not CRN Portfolio adopted how will the service support costs bo covered? | Yes [ ]  No [ ]  N/A [ ]  If Yes, please provide details:            |
| **J: Third Party Arrangements**Has a supplier been identified for the supply of the IMP or Medical Device?Is any equipment being provided/loaned to the Trust?Is tissue being shipped/moved?Is data being transferred? | Yes [ ]  No [ ]  N/A [ ]  If Yes please provide details:      Yes [ ]  No [ ]  N/A [ ]  If Yes, please provide details:      Yes [ ]  No [ ]  N/A [ ]  If Yes, please provide details:      Yes [ ]  No [ ]  N/A [ ]  If Yes, please provide details:       |

**Please return the completed form, together with a copy of your protocol (version controlled), peer review (unless performed by funder) and evidence of funding to** **sponsor@uhs.nhs.uk**

1. Trials involving IMPs must obtain Clinical Trial Authorisation (CTA) from the MHRA prior to commencing. All costs associated with the CTA must be included as part of the funding application. For more information see the [MHRA](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=723) website. [↑](#footnote-ref-1)
2. Multi-Centre Study: A study conducted according to a single protocol but carried out at more than one site and by more than one investigator. [↑](#footnote-ref-2)
3. Full list of EU countries go to the [UKTradeInfo](http://www.uktradeinfo.com/index.cfm?task=euprofiles) site [↑](#footnote-ref-3)