Sponsorship Request Form

**R&D Governance Office**

**(UHB R&D)**



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| Please submit this form to: | r&d@uhb.nhs.uk |
| Please include the following in the email subject: | Sponsorship Request |

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| **SECTION 1 – Research Team** |
| Project Title: |  |
| Chief Investigator’s name: |  |
| Chief Investigator’s email: |  |
| Chief Investigator’s substantive employer: |  |
| Principal Investigator at UHB: |  |
| Point of Contact (if different to CI): |       |
| Does the Chief Investigator or any other member of the research team have any conflict of interest? | [ ]  Yes [ ]  No If yes, please provide further details:        |

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| **SECTION 2 – Sponsorship Criteria** |

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| Please note that if your project falls into any of the categories below, it is unlikely that UHB will be able to sponsor the study. If you tick yes to any of the criteria, it is therefore recommended that you get in touch with RD&I to discuss the project further before proceeding with the rest of this form. |  |  |
| **Criteria** | **Yes** | **No** |
| This is a Phase 1 CTIMP study involving healthy volunteers | [ ]  |[ ]
| This is a CTIMP/DEVICE study without a Clinical Trials Unit involvement |[ ] [ ]
| This is a randomised trial involving healthy/non-NHS volunteers |[ ] [ ]
| This study includes sites outside UK |[ ] [ ]
| This is researcher led commercially funded |[ ] [ ]
| The Chief Investigator is not substantively employed by UHB  |[ ] [ ]
| The Chief Investigator does not hold an honorary contract with UHB |[ ] [ ]
| This is undertaken study undertaken as part of an academic award including Undergraduate, Masters or PhD degrees **\*** |[ ] [ ]
| This study would involve co-sponsorship with another organisation |[ ] [ ]
| ***\* UHB only sponsors academic projects in exceptional circumstances. For academic projects there is an expectation that the academic organisation would act as sponsor. Please answer the questions in sections 2 and 3*** |

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| **SECTION 2 – Study Details**Select all that applies |
| Study Type: | [ ]  Clinical trial of an investigational medicinal product  [ ] Clinical investigation or other study of a medical device  [ ]  Combined trial of an investigational medicinal product and an investigational medical device  [ ]  Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice  [ ]  Basic science study involving procedures with human participants  [ ]  Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology  [ ]  Study involving qualitative methods only[ ]  Study limited to working with human tissue samples (or other human biological samples) and data\*[ ] Study limited to working with data\*[ ]  Research tissue bank     [ ]  Research database[ ]  Active recruitment of children under the age of 5 (not collation of existing data)[ ]  Active recruitment of pregnant research subjects.[ ]  Study involving AI that will be integrated with existing Trust systems |
| Anticipated start date: |  |
| Anticipated end date: |  |
| How many patients do you plan to recruit? |  |
| Do you plan to recruit from other sites? |  [ ]  Yes  [ ]  No  |
| How many sites will you recruit from in total (including UHB)? |  |
| Have you approached the other sites and have PI’s in place  |  [ ]  Yes  [ ]  No  |
| Where will your sites be based? *(select all that apply)* | [ ] England  [ ]  Scotland[ ]  Wales[ ]  Northern Ireland  Other Please give details  |
| Expected length of patient follow-up: |  |
| Have independent scientific/peer reviews of the project been undertaken? | [ ]  Yes (*If yes, please provide evidence of this when submitting this form)*[ ]  No ***\*\* peer reviewed as part of funding process*** |
| * ***\*For data studies please also complete section 5***

***\*\* if evidence of peer review is not available, RD&I may request peer review is undertaken as part of the sponsorship review process.*** ***\*\* studies with confirmed funding that has been submitted with the support of the R&I Development team do not need to submit evidence of peer review, if that grant/funding award process involved peer review.*** |

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| **SECTION 3 – Academic Projects** |
| Name of HEI with which the requestor is registered to undertake PhD, MD, MSc: |  |
| Has the HEI been approached to Sponsor: | [ ]  Yes [ ]  No  |
| Reasons why HEI declined Sponsorship |  |
| Name of Primary (Academic) Supervisor in HEI with which the requestor is registered: |  |
| Name of the Primary Supervisor’s substantive employer (i.e. NHS Trust employee with Honorary HEI contract or HEI substantive employee with NHS Trust Honorary contract): |  |
| Name of Secondary or other Supervisor – please detail if/who clinical: |  |
| Name of the Secondary Supervisor’s substantive employer (i.e. NHS Trust employee with Honorary HEI contract or HEI substantive employee with NHS Trust Honorary contract): |  |
| Brief description of proposed study: |  |
| Brief description of funding in place to support the proposed study: |  |
| Date of last GCP training |  |
| Date of last IG training: |  |
| Name of HEI contact: |  |

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| **SECTION 4 – IMP/Device studies** Only complete this section if your study is a CTIMP or Device study –  |
| Has the MHRA algorithm been completed? <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949145/Algorithm_Clean__1_.pdf>  | ☐Yes ☐No  |
| Please provide details of the IMP(s)/Device(s): |       |
| Who will provide the IMP(s)/Device(s)? |       |
| If a device study - is the device CE Marked? | ☐Yes ☐No  |
| Have you already discussed this study with pharmacy if an IMP is involved? | [ ] Yes (*If yes, please provide evidence of this when submitting this form)*[ ] No  |
| Name of Clinical Trials Unit involved: |  |

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| **SECTION 5 – Data Studies**  |
| Will you seek consent to use the data from patients? |      ☐Yes ☐No  |
| What are the data fields that you would require |       |
| Could the data be anonymised or does it have to be Pseudonymised | ☐Yes ☐No  |
| With whom do you intend to share the data e.g. will you need to share with individuals outside UHB |   |
| Will the data stay in the UHB TRE for analysis | ☐Yes ☐No  |
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| **SECTION 6 – Funding** **All** projects incur costs and therefore where no funding is available, or there is a shortfall in funding, confirmation of who will underwrite this cost gap may be needed from R&D Directors – we strongly advice you liaise with the RAS Team before submitting this form.Please note that if the sponsorship risk assessment identifies risks that require mitigation, your project may require changes to mitigate these risks. Any costs associated with these changes will need to be met. |
| Do you have confirmed funding obtained via a grant that has been submitted with the support of the RAST  | [ ] Yes (*If yes, please proceed straight to section 6 of this form)*[ ]  No *(if no, please complete the remainder of this section)* |
| Has the study been fully costed? | [ ] Yes (*If yes, please provide a breakdown of costs when submitting this form)*[ ] No *(if no, we may request that you produce a breakdown of costs as part of the*  *sponsorship review process)*   |
| If Yes: |
| **Was RAS Team involved in generating these costs?**[ ] Yes [ ] No *(if no, please indicate who generated the costs): Note: you may need to get the costs ratified by the RAS Team as part of the Sponsorship process*  |
| Has funding been obtained? | [ ] Yes (*If yes, please provide evidence of this when submitting this form)*[ ] No  |
| Have Sponsorship fees been factored into the study costings | [ ] Yes *(if yes, please indicate how much has been costed):*[ ] No  |
| Breakdown of Sponsorship costs |  |
| If no funding has been obtained, how will the costs of the project be met? |       |

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| **SECTION 7 – Study Delivery**  |
| Will any third parties be involved (e.g. a trials units, or other service provider) at any stage of the research (e.g. trial management, databases, supplies, randomisation etc): | [ ] Yes [ ] No If yes, please provide further details:        |
| Will any computer systems be used for managing study data (e.g. databases, spreadsheets, bespoke software): | [ ] Yes [ ] No If yes, please provide further details:        |
| Does the study involve any support departments at UHB (e.g. pathology, radiology, medical photography, statistician etc)? | [ ] Yes [ ] No  |
| If Yes: |
| please summarise:        |
| Please confirm if you have already discussed the study with the relevant departments?[ ] Yes (*If yes, please provide evidence of this when submitting this form)* [ ] No  |
| Have you discussed the study with a member of the proposed delivery team (i.e. research nurse) to discuss feasibility at UHB?**\*** | [ ] Yes (*If yes, please provide evidence of this when submitting this form)*[ ] No [ ] N/A *(Only select this option if no R&I delivery staff will be involved in running the project)* |
| Have you discussed this project with your divisional/directorate Manager?**\*\*** | [ ] Yes (*If yes, please provide evidence of this when submitting this form)*[ ] No  |
| Will you be applying for NIHR Clinical Research Portfolio Adoption  | [ ] Yes [ ] No  |
| ***\**** *If the answer to this is no, please approach the relevant delivery team immediately and provide outcome. Please only select N/A if there will be no involvement from a research nurse or other member of R&I’s delivery infrastructure****\*\**** *This is not mandatory, and at this stage we are assessing existing awareness of the proposed project within your division/directorate* |

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| **SECTION 8 – Document Checklist**Please indicate which supporting documents you are submitting alongside this application (the specific supporting documents you need to submit are determined by your answers to the above questions).  |  |  |
| **Supporting Document** | **YES** | **NO** |
| Draft Protocol |[ ] [ ]
| Draft IRAS Form |[ ] [ ]
| Evidence of Peer Review  |[ ] [ ]
| Full breakdown of costs |[ ] [ ]
| Evidence of Funding |[ ] [ ]
| Evidence of discussion with Pharmacy (CTIMPS only) |[ ] [ ]
| Evidence of discussion with Support Departments |[ ] [ ]
| Evidence of discussion with Research Nurse |[ ] [ ]
| Evidence of support from Divisional/Directorate Manager |[ ] [ ]

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| **NOTE:** You are making an application for UHB to act as Sponsor for a study.For any study that UHB subsequently agrees to sponsor, the following will apply:* The Chief Investigator will have overall responsibility for ensuring that the study is conducted in accordance with all applicable regulations and in accordance with UHB SOPs available on the UHB website at:
* The Chief Investigator must agree to the UHB Sponsorship Policy and to accept their delegated responsibilities under the CI Declaration Form( ), as outlined in the SOP on UHB Sponsorship Procedure ( ).
* The Chief Investigator will be accountable to the Sponsor.
* Sponsorship may be withdrawn where the Chief Investigator fails to comply with the UHB Terms & Conditions of Sponsorship.
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