**NIHR Cambridge Clinical Research Facility**

**Study Application Form**

 **Applicant Details**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | Click or tap here to enter text | **Department** | Click or tap here to enter text |
| **Post** | Click or tap here to enter text | **Contract Status** | Employer Contract nature |
| **Email** | Click or tap here to enter text | **Contact Number** | Click or tap here to enter text |

**Principal Investigator**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | Click or tap here to enter text | **ORCID ID** | Click or tap here to enter text |
| **Post** | Click or tap here to enter text | **Contract Status** | Employer Contract nature |
| **Email** | Click or tap here to enter text | **Contact Number** | Click or tap here to enter text |

**Research Team** *including trainees*

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Post** | **Contract** | **Medical?** |
| Click or tap here to enter text | Click or tap here to enter text | Choose an item | Choose an item |
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| Click or tap here to enter text | Click or tap here to enter text | Choose an item | Choose an item |
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| **Please indicate which facility you would like to use?** |
| **CCRC** | Choose an item | **HLRI CRF** | Choose an item |

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| **Explain *in detail* why you need access to NIHR CRF\*** |
| Click or tap here to enter text |

**Protocol Details**

|  |  |
| --- | --- |
| **Acronym | Short Title**  | Click or tap here to enter text |
| **Full Protocol Title** | **Version** | Enter | **Date** | Select |
| Click or tap here to enter text |
| **EudraCT No** *if relevant* | Click or tap here to enter text |
| **Protocol Peer Review undertaken by:** *name of organisation* |
| Click or tap here to enter text |

**Research Type**

|  |  |  |  |
| --- | --- | --- | --- |
| **CTIMP/ATMP** | Choose an item | **If ATMP/CTIMP, select phase** | Choose an item |
| **If your study is Phase IIb – Phase IV please provide justification** | Choose an item |
| **Does the HRA or REC approval for this study require the use of The Over Volunteering Prevention System (TOPS)?**  | Choose an item |
| **Other Clinical Trial** Choose an item | **Feasibility / Pilot** Choose an item | **Interventional** *specify* | Click or tap here to enter text |

**Regulatory Information**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **REC/HRA No** | Enter | **Date approved**  | Select | **MHRA approved** | Choose an item | **Date approved**  | Select |
| **R&D No** | Enter | **Date approved**  | Select | **IRAS No** | Enter | **UKCRN No**  | Enter |
| **Is this study supported by NIHR?** | Choose an item |

**Project Funding Source**

|  |  |
| --- | --- |
| **Main Funding Organisation >50%\*** | Click or tap here to enter text |
| **UoC Grant Number or NHS Cost Centre** | Click or tap here to enter text | **£ awarded** | Enter text | **Start date** | Click to enter | **End Date** | Click to enter |
| **Funder Category**  | Choose an item |
| ***If* NIHR funded specify scheme**  | Choose an item |
| **Industry Type** | Choose an item |
| **Sponsor** | Click or tap here to enter text | **Lead Centre**  | Click or tap here to enter text |
| **NCVR Costings (National)** | Choose an item | **Local Costings required** | Choose an item |

**Non Commercial Studies**

|  |  |  |  |
| --- | --- | --- | --- |
| **Does this study receive industry support?** | Choose an item | **If yes, give details** | Click or tap here to enter text. |
| **CCRC ACCESS CHARGES *applicable to all non-commercial studies*** |
| **Set up fee £1500 per study**  | **Please provide UoC Grant Number or NHS Cost Centre for payment**  | Click or tap here to enter text |
| **Note: There is an annual study renewal fee of £500**  |

**Study Recruitment**

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| --- | --- | --- | --- | --- | --- |
| **Global recruitment target** | Enter | **CCRC recruitment target** | Enter | **Visits per participant** | Enter |
| **How will you widen access for recruitment to include those from underserved communities (EDI)?** |
| Click or tap here to enter text |
| **Have patients/public been involved in the design of this study? If Yes please describe** | Choose an item |
| Click or tap here to enter text |
| **If no, would you like to request a PPIE Review?** | Choose an item |

**Study Planning**

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| --- | --- | --- | --- |
| **Proposed Start Date**  | Click or tap to enter a date | **Planned End Date** | Click or tap to enter a date |

**Session Planning**

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| **Sessions preferred** | **AM** | **PM** | **All Day** | **Over night** |
| **Monday** |[ ] [ ] [ ] [ ]
| **Tuesday** |[ ] [ ] [ ] [ ]
| **Wednesday** |[ ] [ ] [ ] [ ]
| **Thursday** |[ ] [ ] [ ] [ ]
| **Friday** |[ ] [ ] [ ] [ ]
| **Saturday** |[ ] [ ] [ ] [ ]
| **Sunday** |[ ] [ ] [ ] [ ]

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| **Please select:** |
| **General facilities** |
| Day Case Bed |[ ]  Inpatient Bed |[ ]  Investigation Room |[ ]
| Outpatient Room |[ ]  Sample Handling |[ ]   |
| **Specialist facilities – CCRC Charges apply\*\*** |
| Audiology Room\*\* |[ ]  Body composition\*\* |[ ]  Clinical Vision Lab |[ ]
| Calorimeter\*\* |[ ]  DEXA\*\* |[ ]  Dietetics |[ ]
| Exercise Testing |[ ]  Exercise Test Room |[ ]  Neurophysiology Lab |[ ]
| Endoscopy suite\* |[ ]  \* Medic performing procedure: Click or tap here to enter text |
| **Specialist facilities - HLRI** |
| 6 minute walking test corridor |[ ]  ECHO room |[ ]  Catheterisation Laboratory |[ ]
| Respiratory physiology (spirometry, DLCO etc) |[ ]   |

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**Study Interventions**

|  |  |  |  |
| --- | --- | --- | --- |
| **Visit types-e.g** | **Complete for all study types***Please do not paste protocol - specify cycle(s), week(s),day(s),*  | **CCRC Team** | **Study Team**  |
| **Screening**  | Click or tap here to enter text |[ ] [ ]
| **Baseline**  | Click or tap here to enter text |[ ] [ ]
| **Dosing**  | Click or tap here to enter text |[ ] [ ]
|  | Click or tap here to enter text |[ ] [ ]
|  | Click or tap here to enter text |[ ] [ ]
|  | Click or tap here to enter text |[ ] [ ]
|  | Click or tap here to enter text |[ ] [ ]
|  | Click or tap here to enter text |[ ] [ ]
| **Sample Handling**  | PBMC [ ]  | ctDNA [ ]  | PK Samples [ ]  | Other*specify* | Click or tap here to enter text |
| **Other interventions / visit types** *please specify in detail* |
| Click or tap here to enter text |
| **Does the study involve the use of Ionising Radiation?***If yes please specify***:** | Choose an item |
| Click or tap here to enter text |

**Medical Cover**

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| --- |
| **On site Medical Cover for participants will be provided by:** |
| **Name** | Click or tap here to enter text | **Email** | Click or tap here to enter text |
| **Job Title** | Click or tap here to enter text |
| **Department** | Click or tap here to enter text | **Ext no** | Enter | **Bleep Number** | Enter |
| **Out of hours and emergency arrangements:** *if different from above*  |
| **Name** | Click or tap here to enter text | **Email** | Click or tap here to enter text |
| **Job Title** | Click or tap here to enter text |
| **Department** | Click or tap here to enter text | **Ext no** | Enter | **Bleep number** | Enter |
| **Does this study require overnight medical cover to be present on the unit?**  *yes / no If yes please specify below* |
| **Name** | Click or tap here to enter text | **Job Title** | Click or tap here to enter text |
| **Department** | Click or tap here to enter text | **Bleep Number** | Click or tap here to enter text |
| **Compliance with CUH and/or RPH VTE Assessment | ReSPECT | GP Discharge Summary** *PI to complete* |
| *Select what is required for participants in this study* |
| **Venous Thromboembolism (VTE) assessment** | Choose an item | *If* ***NO****, please provide justification:*Click or tap here to enter text |
| **Recommended Summary Plan for Emergency Care and Treatment (ReSPECT)** | Choose an item | *If* ***NO****, please provide justification:*Click or tap here to enter text |
| **Sending of discharge summary to participant’s GP** | Choose an item | *If* ***NO****, please provide justification:* Click or tap here to enter text |

**Lead Investigator obligations to CUH NHS Trust and CCRC**

|  |  |
| --- | --- |
| I agree to charges for diagnostic and laboratory investigations being made to the Principal Investigator  | (please tick) |[ ]
| I agree that my research nurses are accountable when working in the CCRC to the Matrons/CRF Manager | (please tick) |[ ]
| I agree to acknowledge the use of the facilities as per NIHR guidance in any publications and or publicity  | (please tick) |[ ]
| I agree that members of my team will comply with local CCRC policies and procedures  | (please tick) |[ ]
| I confirm that all study staff involved in the study have received GCP training  | (please tick) |[ ]
| I confirm that responsibility for indemnity against non-negligent harm is held by my employing organisation | (please tick) |[ ]
| ***Please select:*** |
| (A) Study team staff working on this study with CUH patients/healthy volunteers:I confirm that all study team staff have CUH contracts (Substantive, Honorary, Honorary Research or a Letter of Access) | (please tick) |[ ]
| (B) Study team staff working on this study with Papworth patients/healthy volunteers:I confirm that all study team staff have Papworth contracts (Substantive, Honorary, Honorary Research or a Letter of Access) | (please tick) |[ ]
| (C) For study team staff working on this study with healthy volunteers on non-invasive, non CUH sponsored projects on TRF (CCRC L6): I confirm that study team staff are compliant with UoC Clinical School governance procedures and local TRF Induction as directed by the TRF Clinical Director  | (please tick) |[ ]

###### **Document Checklist** *please submit with your this application*

|  |  |  |
| --- | --- | --- |
| **Documents to be included** | **Y | N | N/A** | **Comments** |
| Final version of Protocol  | Choose an item | Click or tap here to enter text |
| Final version Participant Information Sheet(s) | Choose an item | Click or tap here to enter text |
| Final version of Consent Form(s) | Choose an item | Click or tap here to enter text |
| Copy of IRAS Form | Choose an item | Click or tap here to enter text |
| Copy of NHS REC | HRA or other REC approval letter | Choose an item | Click or tap here to enter text |
| Copy of NHS R&D approval letter | Choose an item | Click or tap here to enter text |
| Phase 1 risk assessment | Choose an item | Click or tap here to enter text |
| Investigators Brochure  | Choose an item | Click or tap here to enter text |
| Lab manual | Choose an item | Click or tap here to enter text |
| Any other relevant documents *Patient diaries | questionnaires | adverts* | Choose an item | Click or tap here to enter text |
| Copy of CUH GMO committee application | Choose an item | Click or tap here to enter text |
| Copy of CUH ATMP committee application | Choose an item | Click or tap here to enter text |
| UKCRF Risk Stratification Matrix and Contingency Plan *(for studies originating from other UK CRFs only)* | Choose an item | Click or tap here to enter text |

|  |  |  |  |
| --- | --- | --- | --- |
| **Applicant’s Signature** | Click or tap here to enter text | **Date** | Click or tap here to enter text |

**Access to CCRC facilities is granted for 1 year and reviewed annually thereafter. Allocation of space is subject to availability.**

**Please send completed application form and documents to:**  cuh.ccrc.applications@nhs.net

**For advice please contact:**

**Email:** cuh.ccrc.applications@nhs.net **Telephone:** 01223 254642