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| **Northern Ireland Clinical Research Facility (NICRF)**  **STUDY APPLICATION FORM** |

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| Please complete this form as fully as possible (boxes will expand to permit full answers). Without these details we will be unable to process your application. Please send your completed application form, along with the supporting documentation to [NICRF@belfasttrust.hscni.net](mailto:NICRF@belfasttrust.hscni.net)  Please contact us on (028) 95040342 if you require assistance & additional information is available on our website [www.qub.ac.uk/nicrf](http://www.qub.ac.uk/nicrf) |

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| **1. PROJECT DETAILS** |

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| **Project Title:** *[As used in Research Governance]*  *Enter the complete study title in this section.* | |
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| **Short Title:**  (acronym) | *[The name you will use for bookings]* |
| **Lay Summary (150-200 words max)**  *Include:*   1. *What is the problem being addressed* 2. *Why is it important* 3. *What is the research question/aim* 4. *Design & methods* 5. *PPI Involvement*   *[Please note the Lay Summary will be displayed on our website]* | |

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| **Research Team :** (I*nclude all relevant team members with full contact details)*  **Please asterisk\* who will be point of contact** | | | | | |
| **Principal/Chief Investigator :** | **E-Mail Address:** | **Employer:** | | **Postal address:** | **Telephone number:** |
| **Research Team:** |  |  | |  |  |
| **For studies only availing of NICRF Services (ECHO, ECG) please insert point of contact for study**   |  |  |  | | --- | --- | --- | | **Name** | **Email Address** | **Telephone No.** | |  |  |  | |  |  |  | |  |  |  | | | | | | |
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| **Participants** | | | | | |
| Number of participants who will attend the NICRF:  *If possible give exact numbers. If exact numbers are not clear then give an estimate.*  *Include a breakdown of numbers for each treatment arm where there is more than one.* | | |  | | |
| Are participants patients or healthy volunteers  *Enter patient or participant as applicable* | | |  | | |
| **Describe any safety aspects of the study relating to the use of the NICRF that NICRF staff need to be aware of e.g. adverse drug reactions, risk to patients from procedures, out-of-hours:**  *[If none this should be stated]*  *[NICRF risk assessments will be discussed with the point of contact during NICRF study set-up]*  *If there is an out-of-hours requirement for study visits this needs to be indicated at the application stage to allow for risk assessment and resource planning / allocation.*  *NICRF core hours are 8am to 5pm Monday to Thursday and 8am to 4pm on Friday.* | | | | | |

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| **Study Details**  *Tick as appropriate* | |
| **Please select the most appropriate study type:** | *Please tick*   |  |  | | --- | --- | | CTIMP |  | | Non CTIMP |  | | ATIMP |  | | Other |  | |
| **Is this study:** | *Please tick*   |  |  | | --- | --- | | Single Site |  | | Multi Site |  |   **Y N**   |  |  |  | | --- | --- | --- | | If so, is Belfast the lead site |  |  | | Is study adopted by a local Network |  |  | |
| **Please select the most appropriate project type:**  *One of the examples MUST be selected. For clinical trials, please select one of the categories rather than choosing ‘other’.* | |  |  | | --- | --- | | Phase I |  | | Phase IIa |  | | Phase IIb |  | | Phase III |  | | Phase IV |  | | Epidemiological studies |  | | Experimental medicine |  | | Observational studies |  | | Screening studies |  | | Translational / Service Evaluation |  | | Cohort |  | | Pilot Feasibility |  | | Other |  | |
| **Please select the two most appropriate principal research areas:** | |

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|  | **First Area** | **Second Area** |  | **First Area** | **Second Area** |
| Alternative Therapies |  |  | Metabolic and Endocrine |  |  |
| Blood / Haematology |  |  | Musculoskeletal / Rheumatology |  |  |
| Cancer / Oncology |  |  | Neurological |  |  |
| Cardiovascular |  |  | Older People |  |  |
| Congenital Disorders |  |  | Opthalmology |  |  |
| Diabetes |  |  | Paediatric |  |  |
|  | **First Area** | **Second Area** |  | **First Area** | **Second Area** |
| Ear |  |  | Renal and Urogenital |  |  |
| Gastrointestinal |  |  | Reproductive Health and Childbirth |  |  |
| Genetic |  |  | Respiratory |  |  |
| Hepatology |  |  | Skin |  |  |
| Infectious Diseases |  |  | Stroke |  |  |
| Inflammatory and Immune System |  |  | Other |  |  |
| Learning Disability |  |  |  |  |
| Mental Health |  |  |  |  |

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| **2. FUNDING DETAILS** | |
| **Main Funding Organisation:** | Please tick the category of the **main** funding organisation for this study: |
| **Industry Led** |  |
| **Investigator Led / Industry supported** |  |
| **Investigator Led (please specify funder):** |  |
| 1. **Health Department/NIHR Programme** |  |
| 1. **Research Councils** |  |
| 1. **EU Funding** |  |
| 1. **UK University** *(HEFCE/SHEFC/HEFCW/DEL)* |  |
| 1. **Other Charity** |  |
| 1. **Own Account** |  |
| 1. **Other** |  |

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| **Please give the name of the main funding organisation, and institution administering funding and the total amount awarded and details of funding for NICRF:**  **Name:***Insert the name of the main funding body and contact details of institution administering funding.*  **Details of funding relevant to NICRF (See NICRF Costing Policy document available on website) ie. Please state which costing Category is applicable i.e.**  **Category 1**  **Category 2**  **Category 3**  **Category 4** | |
| **Sponsor:** | |
| **Which Institution is providing governance / sponsor approval**   * **BHSCT If joint tick appropriate boxes** * **UU** * **QUB** | **Has research governance sponsorship been confirmed?**  *Yes / No / pending* |
| **3. NICRF RESOURCES** | |
| **When do you plan to commence using the NICRF**  *Enter date or anticipated quarter: Q1 (Jan-March), Q2 (April-June), Q3 (July-Sept), Q4 (Oct – Dec)* | |
| **How long do you plan to use it for**  *Estimated final date based on end of recruitment and participant schedule.*  ***Please tick requirements***   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Space / Staff** | **Y** | **N** | **Equipment / Consumables** | **Y** | **N** | | Clinical rooms |  |  | Non- MR Imaging (ECHO) |  |  | | NICRF Laboratory |  |  | Dexa Scanner |  |  | | Sample Storage |  |  | Bronchoscopy |  |  | | Nursing Support |  |  | ECG |  |  | | Hot Desk |  |  | Lung Clearance Index (LCI) |  |  | | Monitor Visit Space |  |  | Other Consumables |  |  | |  |  |  |  |  |  |  |  | | --- | | ***Please indicate details of visits, duration and include a list of required resources for each study visit***  ***(Refer to example of completed application) for further information.***  Day 1 – 8 hours – ECG. ECHO, Spirometry, DEXA  Day 15 – 8 hours – No equipment  Week 4 – 6.5 hours – No equipment  Week 8 – 5 hours – No equipment  Week 16 – 5.5 hours – No equipment  Week 24 – 8 hours (Slit lamp, OCT, ECG, Auto-Refractor, Spirometry – out of hours required)  Week 36 – 5 hours - no equipment  Week 48 – 7 hours - (Slit lamp, OCT, ECG, Auto-Refractor, Spirometry – out of hours required)  Week 60 – 5 hours – no equipment  Week 72 – 5 hours – no equipment  Week 84 – 5 hours – no equipment  Week 96 – 8 hours – ECG, echo, Spirometry, Dexa  Early Termination – 8 hours  Safety Follow-up – 8 hours | | ***Do you plan to store temporary equipment in the NICRF for the duration of the study*** | | *[please provide details, if none state none]* |  |  |  |  | | --- | --- | --- | | *Please note that the application form & full protocol must be provided* ***before the application will be reviewed.*** *(The application must be completed in full and all supporting documentation be provided to facilitate review).* | | | | Before a study can begin, other supporting documentation must also be gathered. Please indicate the status of these items: *Complete as applicable*. | | | | **Supporting Documentation** | **Status** | ***Sent to NICRF*** | | Full Protocol/Grant application |  |  | | Research Governance/Sponsor Approval |  |  | | |