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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 (full Protocol), to NICRF@qub.ac.ukIf you require assistance, please contact us on (028) 9504 0342. Additional information is also available on our website [www.qub.ac.uk/nicrf](http://www.qub.ac.uk/nicrf). **Please check our website to ensure that you have the most recent version of the application forms**. |

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| **1. PROJECT DETAILS** |

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| **Project Title:***[As used in Research Governance]* *[Please enter the complete Study title in this section]* |  |
| **Short Title:***[Acronym]**[The name that you will use for bookings]* |   |
| **Lay Summary:(150-200 words max)***To include:*1. *What is the problem being addressed?*
2. *Why is it important?*
3. *What is the research question / aim?*
4. *Design and methods*
5. *PPI Involvement*
6. *Contact details for more information about Study*

**This Lay Summary may be used to promote Studies ongoing in the NICRF. Please tick if you DO NOT agree to have information on your Study available on the NICRF website and social media (Twitter).**[ ] I do not agree to having information  on my Study made available on the  NICRF website or social media (Twitter). |  |
| **Research Team:** *[Please include the PI and all members of the Research Team who will access the NICRF. Include full contact details and* ***please asterisk\* who will be the Point of Contact].*** |

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| **Principal / Chief Investigator** |  |
| **Email Address** |  |
| **Employer** |  |
| **Postal Address** |  |
| **Telephone Number** |  |

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| **Research Team***[Please enter names and job titles]* |  |
| **Name** |  |
| **Position** |  |
| **Email Address** |  |
| **Employer** |  |
| **Postal Address** |  |
| **Telephone Number** |  |
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| * **For studies only availing of NICRF Services (ECHO, ECG), please insert Point of Contact for Study:**
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| **Name** |  |
| **Email Address** |  |
| **Telephone Number** |  |

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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 either patients or healthy volunteers?**

*[Please check relevant box, as appropriate]* | [ ]  Patient [ ]  Healthy Volunteer |
| * **Describe any safety aspects of the Study relating to the use of the NICRF that NICRF need to be aware of, e.g. adverse drug reactions, risk to patients from procedures, out-of-hours visits etc. 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 Monday to Friday, 8am to 5pm. We can additionally support studies on Mondays and Wednesdays until 6pm, subject to staff availability].* |  |
| **Study Details** *[Please check boxes as appropriate]* |  |
| * **Please select the most appropriate Study type:**
 |  *Please check box*

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| --- | --- |
| CTIMP | [ ]  |
| Non-CTIMP | [ ]  |
| ATIMP | [ ]  |
| Other | [ ]  |
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| * **Is this Study:**
 |  *Please check box*

|  |  |
| --- | --- |
| Single-site | [x]  |
| Multi-site | [ ]  |

 **Y N**

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| If so, is Belfast the lead site? | [ ]  | [ ]  |
| Is the Study adopted by a local Network? | [ ]  | [ ]  |
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| * **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’].* |  *Please check box*

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| 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 | [ ]  |
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| * **Please select the two most appropriate research areas:**
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|  | **First Area** | **Second Area** |
| Alternative Therapies | [ ]  | [ ]  |
| Blood / Haematology | [ ]  | [ ]  |
| Cancer / Oncology | [ ]  | [ ]  |
| Cardiovascular | [ ]  | [ ]  |
| Congenital Disorders | [ ]  | [ ]  |
| Diabetes | [ ]  | [ ]  |
| Ear | [ ]  | [ ]  |
| Gastrointestinal | [ ]  | [ ]  |
| Genetic | [ ]  | [ ]  |
| Hepatology | [ ]  | [ ]  |
| Infectious Diseases | [ ]  | [ ]  |
| Inflammatory and Immune System | [ ]  | [ ]  |
| Learning Disability  | [ ]  | [ ]  |
| Mental Health | [ ]  | [ ]  |
| Metabolic and Endocrine | [ ]  | [ ]  |
| Musculoskeletal / Rheumatology | [ ]  | [ ]  |
| Neurological  | [ ]  | [ ]  |
| Nutrition | [ ]  | [ ]  |
| Older People | [ ]  | [ ]  |
| Ophthalmology  | [ ]  | [ ]  |
| Paediatric  | [ ]  | [ ]  |
| Renal and Urogenital | [ ]  | [ ]  |
| Reproductive Health and Childbirth | [ ]  | [ ]  |
| Respiratory  | [ ]  | [ ]  |
| Skin | [ ]  | [ ]  |
|  Stroke | [ ]  | [ ]  |
| Other | [ ]  | [ ]  |

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| **2. FUNDING DETAILS** |

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| **Main Funding Organisation:** | *[Please check the box against the category of the* ***main*** *funding organisation for this study]:* |
| * **Industry-led**
 | [ ]  |
| * **Investigator-led / Industry-supported**
 | [ ]  |
| * **Investigator-led** *[please specify Funder below]*
 | [ ]  |
| * **Health Department/NIHR Programme**
 | [ ]  |
| * **Research Councils**
 | [ ]  |
| * **EU Funding**
 | [ ]  |
| * **UK University** *[HEFCE/ SHEFC/ HEFCW/ DEL]*
 | [ ]  |
| * **Other Charity**
 | [ ]  |
| * **Own Account**
 | [ ]  |
| * **Trust**
 | [ ]  |
| * **Other**
 | [ ]  |

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| **Please provide the following:** |  |
| * **name and contact details of institution administering funding, for NICRF costs**
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| * **the total amount awarded, for NICRF costing**
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| * **Please state which Costing Category is applicable:**

*[Read our Costing Policy online here:]* [Download: NICRF Costing Policy](http://www.qub.ac.uk/research-centres/TheWellcomeTrust-WolfsonNorthernIrelandClinicalResearchFacility/Filestore/Filetoupload%2C829470%2Cen.docx) | **Pilot** [ ] **Capability/Capacity Research** [ ] **Investigator-led** [ ] **Industry-led** [ ]  |
| **Governance Approval / Sponsorship** |  |
| * **Which Institution is providing Governance approval?**
 | **BHSCT** [ ] **UU** [ ] **QUB** [ ]  |
| * **Has approval been confirmed?**
 | **Yes** [ ] **No** [ ] **Pending** [ ]  |
| * **Which Institution is Lead Sponsor?**
 | **If joint, please tick appropriate boxes:****BHSCT** [ ] **UU** [ ] **QUB** [ ]  |
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| **3. NICRF RESOURCES** |
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| * **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)]* | **Date:****Quarter:** |
| * **How long do you plan to use it for?**

*[Estimated final date based on end of recruitment and participant schedule]* |  |
| * **Please tick requirements:**

*[Please refer to NICRF website for resources available]:*[*http://www.qub.ac.uk/research-centres/TheWellcomeTrust-WolfsonNorthernIrelandClinicalResearchFacility/ForResearchers/Facilities/*](http://www.qub.ac.uk/research-centres/TheWellcomeTrust-WolfsonNorthernIrelandClinicalResearchFacility/ForResearchers/Facilities/) |

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| **Space / Staff** | **Y** | **N** |
| Clinical Rooms | [ ]  | [ ]  |
| NICRF Laboratory | [ ]  | [ ]  |
| Sample Storage | [ ]  | [ ]  |
| Nursing Support | [ ]  | [ ]  |
| Hot Desk | [ ]  | [ ]  |
| Monitor Visit Space | [ ]  | [ ]  |
| **Equipment / Consumables**  | **Y** | **N** |
| Non-MR Imaging (ECHO) | [ ]  | [ ]  |
| Dexa Scanner | [ ]  | [ ]  |
| Bronchoscopy | [ ]  | [ ]  |
| ECG | [ ]  | [ ]  |
| Lung Clearance Index (LCI) | [ ]  | [ ]  |
| Other Consumables | [ ]  | [ ]  |

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| * **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, e.g. see overleaf for an example of Study Visits, hours and equipment]**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 no storage is required, please state “none”]* |  |