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| **Lancashire Clinical Research Facility Study Application Form** |
| * Please ensure **ALL** sections of the application form are completed. * Incomplete forms cannot be accepted for review. * It is the responsibility of the Principal Investigator to ensure all information is accurate and complete.   PLEASE NOTE: The objective of the Lancashire Clinical Research Facility is to support early phase and experimental medicine research of scientific merit. However, all studies will be considered, including phase 3 & 4, and approval will be dependent upon scientific merit and capacity.  To apply to use the NIHR Lancashire CRF please forward the completed application form and relevant documents to LancashireCRF@lthtr.nhs.uk  Please contact [LancashireCRF@lthtr.nhs.uk](mailto:LancashireCRF@lthtr.nhs.uk) if you require assistance. |

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| **Project Title :** |  | | |
| **Short Title:** |  | | |
| **Is REC Required?** | Choose an item. | | |
| **REC reference no:** |  | **IRAS number:** |  |
| **Purpose of study: (select one)** Choose an item. | | | |

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| **Principal Investigator Details** | | | | |
| Name |  | |  | |
| Title: | First Name: | | Surname: | |
| E-mail address: |  | | | |
| Employer |  | | | |
| Postal address: | | Telephone number: | ORCID number: | |
|  | |  |  | |
| **Co-Investigator Details**  Name Email address Employer | | | | |
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| **Primary Contact (Clinical)** *Clinical fellow, Research Nurse, Researcher* | | | | |
| Name: | E-mail address: | | | Telephone number: |
|  |  | | |  |
| **Secondary Contact (Project set up team)**  *Research access team coordinator (LTHTR) or project set up at other sites* | | | | |
| Name: | E-mail address: | | | Telephone number: |
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| **Study Timeline considerations** | |
| Planned date of HRA application submission: | Click here to enter a date. |
| Confirmation of C&C | Click here to enter a date. |

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| **Study Information** | | | |
| Study Sponsor: | |  | |
| Centre leading the study: | |  | |
| Experimental Medicine: | | Choose an item. | |
| Study Type | Study Phase:  If selected ‘other study’ please clarify further: | | Choose an item. |
| If the trial is phase 3 or above please indicate if there are additional experimental elements listed in the protocol. There may be more than 1:  Biomarker  PK sampling  Genetics  DNA  Discovery research  Testing new technology  Other nested experimental element | | ***Please indicate what this EM element is:*** |
| Please choose a research type for your study | | Choose an item. |
| If you have selected ‘Other research’ please clarify further | |  |
| Primary Intervention / Area | Choose an item. | |  |
| If ‘other’ please clarify: | |  |
| Secondary Intervention or area | Choose an item. | |  |
| Randomised trial? | Choose an item. | |  |
| FiH or Phase I trial? | Choose an item. | | **If yes the study needs review by the Early Phase Review Committee. Please liaise with LCRF Manager** |
| Purpose of project | Choose an item. | |  |
| [Impact of project on health and care](#Impact) | Choose an item. | |  |

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| **UKCRC Health Category** Choose an item. |

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| **Funding Organization:** | | | | |
| Name of the Main Funder: | | |  | |
| NIHR Industry Costings Template  Pending  Completed  NA | | | *If a commercial trial please liaise with Industry Lead/CRF Manager* | |
| Full Award Amount (for the lifetime of the study): | | | £ | |
| Funding organisation type: | | | Choose an item. | |
| If industry contract/collaborative, please specify industry type: | | | Choose an item. | |
| If DH/NIHR, please specify type | | | Choose an item. | |
| If you selected “Other infrastructure”, “NIHR Research Schools” or “Other NIHR funding”, please give details | | |  | |
| **Billing contact from funding organisation (if known) Do we need this?** | | | | |
| Name: |  | Email | |  |
| Address |  | Postcode | |  |
| Telephone |  |  | | |

**Project Information**

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| **Recruitment** | | | | |
| SIV Date planned or estimate: | Click here to enter a date. | | | |
| Date of intended First Participant First Visit: | Click here to enter a date. | | | |
| End date of recruitment: | Click here to enter a date. | | | |
| Projected date Last Participant Last Visit: | Click here to enter a date. | | | |
| Global Recruitment Target: |  | | | |
| Site Recruitment Target: |  | | | |
| Is recruitment already open? | Choose an item. | If yes how many are recruited? | |  |
| Is recruitment competitive? | Choose an item. | | | |
| NIHR Portfolio status | Choose an item. | | | |
| Are you aware of any other studies running within this field which might affect recruitment? |  | | | |
| Which protocol visits require CRF support? | Pre-screening  Screening  Recruitment  Delivery  Coordination  Follow up | | | |
| How many participants will be recruited? |  | | | |
| Has the UKCRF Network Intensity Tool been completed? | Choose an item. | | | |
| UKCRFN Intensity | Choose an item. | | | |
| How many CRF visits are required for each participant? |  | | | |
| How frequently will the visits be (approximately)? |  | | | |
| Which protocol activities will take place in other departments and where | Sample processing  Sample storage  Screening/recruitment  Imaging  Examinations  Treatment  Biopsy  Follow-up visits  None | | ……………………  ……………………  ……………………  ……………………  …………………….  …………………….  ……………………..  …………………….  ………………… | |

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| **LCRF Resources (tick Yes or No on every line)** | | |
| **LCRF Service** | **Applying for: Yes / No** | **Comments** |
| Room use | Yes  No |  |
| **LCRF Equipment use** | | |
| ECG machine | Yes  No |  |
| Vital sign machine | Yes  No |  |
| Fridge (temporary storage) | Yes  No |  |
| Freezer -20 (temporary storage) | Yes  No |  |
| Infusion pump | Yes  No |  |
| Centrifuge (chilled) | Yes  No |  |
| Centrifuge (ambient) | Yes  No |  |
| LCRF Pharmacy | Yes  No |  |
| Easy chair (long term) | Yes  No |  |
| Bed | Yes  No |  |
| Height measuring device | Yes  No |  |
| Weighing scales | Yes  No |  |
| BM machine | Yes  No |  |
| Hypoglycaemia kit required? | Yes  No |  |
| Car parking | Yes  No |  |
| Consumables | Yes  No | *Please list (eg cannulation equipment, swabs etc)* |
| Are patients arriving fasted? | Yes  No | NB food is not provided in the LCRF therefore patients will need to bring their own food or arrangements need to be made with the trust restaurant. LCRF hypoglycaemis SOP to be followed |
| Paediatric or Adult Nurse? | Paediatric  Adult |  |
| LCRF Adult Nurse clinical skills support only | Yes  No | *Please list tasks required for*  *(cannulation, venepuncture, observation,):* |
| LCRF Paediatric Nurse clinical skills support only | Yes  No | *Please list tasks required for*  *(cannulation, venepuncture, observation):* |
| LCRF Clinical Trial Support Officer (processing samples) | Yes  No |  |
| LCRF CTSO (data entry) | Yes  No |  |
| Overnight or Weekend use | Yes  No | *Please state specific days & times:* |
| Medic on site | Yes  No | If yes, please list which tasks eg –CO PI performing research tasks as per protocol, purely for observation etc.. |
| Scanning / photocopying/admin | Yes  No |  |
| If you need escalation to ICU processes, please liaise with the Research Access Team and inform CRF team | Yes  No |  |
| Other (please list) | Yes  No |  |
| Will the Sponsor provide any equipment?  Calibration responsibilities: | Yes  No  Choose an item. | If Other, please specify: |

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| **LCRF Rooms for hire** | |
| **Room Facilities Required** | |
| Overnight room (with hoist and ensuite) | Yes  No |
| Individual Assessment Room | Yes  No |
| Two Bedded Bay (shared room) | Yes  No |
| *If yes, can bay be shared with curtain in place?* | Yes  No |
| Venepuncture Room | Yes  No |

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| **Sessions Required – Please be specific** | | | | | |
|  | 08:00 –12:00 | 12:00 –16:00 | 16:00 –18:00 | 18:00 – \_\_\_  (please specify) | 18:00 - 08:00  overnight |
| Monday |  |  |  |  |  |
| Tuesday |  |  |  |  |  |
| Wednesday |  |  |  |  |  |
| Thursday |  |  |  |  |  |
| Friday |  |  |  |  |  |
| Saturday |  |  |  |  |  |
| Sunday |  |  |  |  |  |

**Study Conduct and Recruitment Strategies**

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| Pre-screen notes &/or patient databases to identify potential subjects: | Choose an item. | |
| Attend clinic to identify patients: | Choose an item. | |
| Give PIS: | Choose an item. | |
| Obtain informed consent: | Choose an item. | |
| Equipment – will the study have any specific equipment?  If yes, type: | Choose an item. | |
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**Medical Cover**

**Please refer to LCRF SOPs 02 Management of Medical Emergencies and LCRF 04 Management of an unwell patient, which can be found on CRF Manager.**

**Specialist medical support must be provided by the PI or their team. They must also provide 24-hour emergency contact cover for participants.**

**Please specify how this has been set up.**

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| **Mandatory in order for LCRF staff to use in an emergency: On site Medical Cover for participant visits will be provided by:** | | | | | | | | | |
| Name: |  | | | | Email: | |  | | |
| Job Title: |  | | | | | | | | |
| Department: |  | | | Telephone or ext no: | | |  | Bleep |  |
| Divisionally approved by: | Name: | | | Date: | | | | | |
| **Out of hours and emergency arrangements** (if different from above)**:** | | | | | | | | | |
| **Out of hours arrangements approved by:** | | Name: | | | | Date: | | | |
| **If the PI is not a medic, please list which medical team have authorised contact in the event of an emergency or explain risk management process:** | | | | | | | | | |
| Name / Team: | | |  | | Email: | |  | | |
| Job Title: | | |  | | | | | | |
| Out of hours telephone no: | | |  | | | | | | |
| Department: | | |  | | Ext no: | |  | Bleep |  |

**Risks and Safety**

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| **Safety – to be completed by the PI and research team** | |
| Please outline potential safety or risk issues and minimisation strategies  (Refer to relevant sponsor risk assessments, risks listed in the protocol, local risk assessments or UKCRF risk assessment form. |  |

**For your information**

**There may be charges associated with the application which need to be discussed with the LCRF manager and your local R&I department. Please highlight this application at the earliest opportunity to your local department.**

**If your study is going to be published and you have used the NIHR LCRF, please use this term in your acknowledgment:**

**“This research was supported by the NIHR Lancashire Clinical Research Facility. The views expressed are those of the author (s) and not necessarily those of the NHS, the NIHR or the Department of Health”.**

**Summary & Declaration**

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|  | **Medical Principal Investigator Signature** | **Date** |
| **I confirm that all information contained within this document is accurate and correct** |  |  |
| **I understand that I am responsible for providing medical oversight and cover for all participants attending the Lancashire CRF and will ensure all arrangements are in place.** |  |  |
|  | **Non-medical Principal Investigator Signature** | **Date** |
| **I confirm that all information contained within this document is accurate and correct** |  |  |
| **I have confirmed that there is appropriate medical cover for patients attending the LCRF in case of emergency** |  |  |
|  | **Person Completing Application Signature** | **Date** |
| **I confirm that all information contained within this document is accurate and correct** |  |  |

**Document Checklist** *(Must be submitted with your application)*

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| **Documents to be included** | **Y/N/NA** | **Comments** |
| Copy of risk assessment(s) completed for risky procedures |  |  |
| Final Version of Protocol |  |  |
| Final Version of Participant Information Sheet(s) |  |  |
| Final Version of Consent Form(s) |  |  |
| Copy of IRAS form |  |  |
| Copy of the statement of activities and events schedule |  |  |
| Copy of NHS REC approval letter |  |  |
| Copy of HRA approval letter |  |  |
| Copy of MHRA approval letter (CTIMPS) |  |  |
| Investigators Brochure |  |  |
| Lab Manual (if applicable) |  |  |
| Intensity Tool attachment for the the CRF and R&I aspects of the study to calculate WTE |  |  |
| Any other relevant documents |  |  |

**Thank you for your application**

Please be aware that there may be a possibility that your study will be approved for a set period of time. For example some studies have a lifelong follow up and this may only be approved up until a certain point.

Approval will be based on capacity and capability of the LCRF at the time.

*Please send completed your application form and documents to:* [*LancashireCRF@lthtr.nhs.uk*](mailto:LancashireCRF@lthtr.nhs.uk) *OR Post to: NIHR Lancashire CRF Manager, NIHR Lancashire Clinical Research Facility Manager, Lancashire Clinical Research Facility, Royal Preston Hospital, Sharoe Green Lane, Fulwood, PR2 9HT.*

*For further advice or support please contact Jacqueline Bramley LCRF Manager at* [*jacqueline.bramley@lthtr.nhs.uk*](mailto:Jacqueline.Bramley@lthtr.nhs.uk)or the LCRF Medical Director Dr Hadjiyiannakis at[*dennis.hadjiyiannakis@lthtr.nhs.uk*](mailto:dennis.hadjiyiannakis@lthtr.nhs.uk) *or telephone 01772 522031*

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| **For LCRF staff only** | | | |
| Risk | Choose an item. | | |
| Intensity | Choose an item. | | |
| WTE for study |  | | |
| Amount of external funding for LCRF | £ | | |
| Is study specific equipment being provided? |  | | |
| Confirm equipment, maintenance and calibration requirements |  | | |
| Are there any other department supporting the study? |  | | |
| If yes, please give details, and specify what discussions/arrangements have already been made |  | | |
| Approval Granted: | Yes  No | | |
| Comments |  | | |
| LCRF Medical Director Approval Signature: |  | Date: |  |