# Application to use the NIHR Imperial CRF

## **Before PRB meeting**

## **Section 1: Submission of ICRF application form**

## Please complete and submit Section 1 of this form, the completed appendix if relevant and the following supporting documentation to the ICRF General Manager Karen Mosley ([k.mosley@nhs.net](mailto:k.mosley@nhs.net)) at least 1 week prior to the PRB meeting:

## **All studies:** Study protocol and PI CV (only for PIs new to the CRF)

## **Phase I studies:** Investigators Brochure (where available)

**Data is required for NIHR annual returns and so all relevant fields must be completed in full.**

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| **Study ID (ICRF completion only)** | |
| **Study Acronym** |  |
| **ICRF Study Number** |  |

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| **Applicant details** | | | | | |
| Principal investigator |  | Job title | |  | |
| PI ORCID ID | If you don’t have an ID, register here: <https://orcid.org/signin> | | | | |
| E-mail address |  | Mobile No. |  | Work number |  |
| Employer details (ICL or ICHNT) |  | If ICL, end date of honorary Trust contract (or LtA) held? | |  | |
| Last GCP training date |  | Can the PI be contacted out of hours and/or in an emergency? | | Yes  No | |
| Do you have Cerner access? | Yes  No |
| ICRF access required? | Yes  No  In place | ICRF induction required? | | Yes  No | |

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| **Study team details**  Include details of all team members who will either use the ICRF or coordinate the study. If more than four, please send details in the cover email. | | | | |
| Name |  |  |  |  |
| Job title |  |  |  |  |
| Role in study |  |  |  |  |
| E-mail address |  |  |  |  |
| Mobile no. |  |  |  |  |
| Work number |  |  |  |  |
| Employer details (ICL or ICHNT) |  |  |  |  |
| If ICL, end date of honorary Trust contract (or LtA) held? |  |  |  |  |
| Last GCP training date |  |  |  |  |
| ICRF access required? | Yes  No | Yes  No | Yes  No | Yes  No |
| Do you have Cerner access? | Yes  No | Yes  No | Yes  No | Yes  No |
| ICRF induction required? | Yes  No | Yes  No | Yes  No | Yes  No |
| Medical cover out of hours?\* | Yes  No | Yes  No | Yes  No | Yes  No |

\***PI/delegate Medical Cover:** The details of two medically qualified staff are required, ideally the PI and an investigator involved in the study, who will be the medical contacts for the study. **NB: At least one person must be contactable after hours**

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| Emergency number to be given to participants (actual phone number must be provided) where required: | **Or not applicable:** |

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| **Study details** | | | | | | | |
| Protocol Title | | | | | | | |
| Study Acronym (to be used as internal study reference) | | | | | | | |
| Outline of overall study design | | | | | | | |
| Study status at PRB application | | | | | | | |
| UKCRC Health Category |  | | | Disease area | | |  |
| Study Intervention name (if applicable) | | | |  | | | |
| If the intervention is classed as an IMP (investigational medicinal product), select IMP status | | | | Unlicensed (anywhere),  UK Unlicensed (not licensed in the UK, but is licensed elsewhere)  Unlicensed Use (UK Licence, but used in new indication)  Licensed Use | | | |
| **Project classification**: select all that apply | | | | | | | |
| IRAS Category | | | | | Project type: CTIMP and ATIMP only | | |
| First in Human (FIH) CTIMP | | | | | | | |
| Experimental Medicine | | Randomised study | | | | Observational | |
| 1y intervention | | 2y intervention | | | | Other intervention/area: please state | |
| Patients or HV? | | | | | | | |
| **HV ONLY**  Do you require access to the ICRF HV Database? Yes  No  Is TOPS required? Yes  No  Is Photo ID Required? Yes  No | | | | | | | |
| CRF involvement category | | |  | | | | |
| Brief summary of required input from the ICRF (staff and/or facilities. Give specific detail, not a list of study visits. If not all of the study will occur in the CRF, specify visits). **MUST BE COMPLETED** | | |  | | | | |

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| **ICRF staff routinely required**  **Indicate below if ICRF staff will be required other than in an emergency. If you answer Yes to any question you must complete Appendix 2. This is a request for ICRF staff only and in some cases we will not be able to support the request. NB: Medical and laboratory staff are available only 9 – 5 and due to limited number of staff their availability for any given visit cannot be guaranteed.** | | | |
| Nursing staff:  Yes  No | Unblinded/unmasked nursing staff:  Yes  No | Medical /Physician Associate (PA):  Yes  No | Clinical Project Manager:  Yes  No |
| Laboratory staff:  Yes  No | Recruitment Manager for HV recruitment (separate to access to HV Database):  Yes  No | | |

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| **NIHR metrics (must be completed)** | |
| NIHR Priority Area (select if applicable) | Purpose of Project |
| RACS code (choose up to 2) *guidance at end of form* | RACS subcategories |
| Geographical scope of the study | Expected impact |
| Is this study sensitive? (ie sensitive commercially or not appropriate for further dissemination) Yes  No | Is the CI based at ICL orICHNT? Yes  No |
| Does the study link to NIHR Translational Research Collaborations eg NIHR Respiratory TRC? | Yes  No  If yes provide details |
| Does the study involve staff from any ICL division other than Medicine/NHLI eg Engineering? | Yes  No  If yes provide details of which divisions/discipline |
| Will the study include any remote monitoring/digital technology? (e.g. e-consent, wearables etc) | Yes  No  If yes provide details |

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| **Regulatory information** | | | |
| Ethics Ref No |  | R&D Ref No (EDGE ID) |  |
| IRAS code |  | NIHR CRN Portfolio No. State n/a if not applying for support |  |
| ICHNT Pathology Code |  | If study has CCC provide approval date |  |

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| Sponsor and Funding details | | | | |
| Sponsor |  | Sponsor reference code | |  |
| Funder |  | Funding category | |  |
| If NIHR | | | If commercial | |
| If commercial, is the company a SME (small, medium enterprise: guidance at end of form)? Yes  No | | | | |
| Have CRF costs been included in the budget? | No  If no, were CRF costs waived?  Not yet, but will be included  Yes  Total costs for CRF | | | |
| Were CRF costs provided at the grant application stage? | Yes  No  If yes, ICRF costing ref ICRF Ref | | | |
| Total funding awarded for whole project if non-commercial | | P code if ICL non-commercial study | | |
| Management of the study (e.g. research team, CRO, ICRF. If CRO give name) | | | | |

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| **CRF visit requirements**  **Full details of all visits to be provided before green light in Appendix 1** | | | | | |
| Total study recruitment target (global) |  | Target recruitment for CRF component | Of which: Patients  Healthy Volunteers | | |
| No. visits/subject at the ICRF (including screening and phone visits) |  | No. overnight stays/subject |  | Does the study require early starts (8-10am)? | Yes  No |
| Expected start date (at ICRF) |  | Expected End Date (at ICRF) |  | | |

**Visit ID for set up of CRF Manager**

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| **Name the visit will be referred to during booking**  *NB: This must be consistently used on booking forms* (e.g. Screening, Cohort 1 Day 1, Visit 1, V2 dosing visit etc.) | **Day/week of visit where specified in protocol (if not detailed in previous column) eg Day 15** | | **Room type preference**  *NB: We cannot guarantee that this room type will always be available.* | **Lab required?** | **Microbiological Safety Cabinet (MSC) Required?** | **Expected duration of visit in hours** | **CRF staff support routinely required** |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |
|  |  |  | | Yes  No | Yes  No |  | Nurse  Medical  Lab staff |

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| **Non-standard sessions required**  Core hours are 8-5 Monday to Friday. Indicate below if you require evening, overnight and/or weekend visits | | | |
| Evening (after 5pm) | Overnight Mon to Thu | Overnight Fri to Sun | Weekend day |
| Details | | | |

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| **Lab requirements** | | | |
| Intensity of lab use per day: | Low <1 hour | Medium>1 <4 | High >4 |
| Other *please specify* | | | |

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| **Hazardous samples or processing methods** | |
| Will laboratory chemicals be used for this study? | Yes  No Details  *If yes, provide a MSDS* |
| Will any samples come from known infectious or high risk patients? | Yes  No  Details  *If yes, complete the ICRF bio1 form* |
| Will PBMC isolation be required in the CRF? | Yes  No |

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| **Equipment required** | | |
|  | Select if equipment required | Select if training required |
| Calorimeter |  | NA |
| Exercise Bike |  | NA |
| IMP Class II Microbiological Safety Cabinet |  |  |
| Laboratory Class II Microbiological Safety Cabinet |  |  |
| Centrifuge |  |  |
| BSI labels |  | BSI account needed: YES  NO  *Provide study template to*  *imperial.icrflabs@nhs.net* |
| -20 freezers (for longer than day storage) |  |  |
| -80 freezers (for longer than day storage) |  |  |
| Study specific equipment supplied by study team |  | Details |

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| **Drug related details**  *Pharmacy must be contacted if your study involves a drug. Contact* [*Victoria.latham@nhs.net*](file:///\\DIRONE\Shared%20Data\Imperial%20CRF\Quality,%20Health%20and%20Safety\ICRF%20QHS%20meetings\SOPs%20ready%20for%20committee%20(temp%20contents)\Ready%20for%20Feb%2018%20meeting\Victoria.latham@nhs.net) *if you have not already submitted a study set-up form and local information pack to the Divisional Feasibility Team* | | | | |
| Does your study involve an IMP and/or other drug? Yes  No | | | | |
| Does your study involve food supplements or other ‘borderline’ products? Yes  No | | | | |
| Has the Pharmacy Clinical Trials team been contacted? Yes  No  Not yet  ***N.B. If there are any drugs involved in your protocol even if not CTIMPs, Pharmacy must be contacted*** | | | | |
| Has the Study Set-up form and local information pack been submitted to Pharmacy via the Divisional Feasibility Team Yes  No  NA | | | | |
| Name of drug | Drug supply (NHS supply or other-give details) | Frequency of administration | By ICRF staff | By study team |
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| Will any drugs require blinding or Aseptic compounding in Pharmacy? Yes  No  Maybe Please specify why if ‘Yes’ or ‘Maybe’ | | | | |
| Where would you prefer to storethe drug(s)? Pharmacy  ICRF  Other  If other give details | | | | |
| Does the drug require reconstitution? Yes  No | | | | |
| If yes, where will this be carried out? Pharmacy  ICRF  TBC | | | | |
| Will you store any food supplements or other products at ICRF? Yes  No  Maybe | | | | |
| If your study is Imperial-sponsored, are any drugs/ physiological products provided free-of-charge?Yes  No  If yes, give details: | | | | |
| If your study is Imperial-sponsored, are any drugs/ physiological products manufactured?Yes  No  If yes, give details: | | | | |

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| **Data collection/monitoring** | | | |
| What type of data collection is required? | Hard Copy CRF  eCRF | Who is responsible for completing the CRF? |  |
| Will there be external monitoring of this study? | Yes  No | If yes, please provide details: |  |

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| **Study specific procedures**  *NB: Wherever possible all procedures should be included in the protocol. Any standalone written procedures must be reviewed by the ICRF QA Manager* | |
| Will written study specific procedures, other than the protocol, be utilised for this study? | Yes  No |
| If yes, please provide details: | |

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| **Patient & Public Involvement and Inclusivity** | |
| Has this study included any PPI | Yes  No  Details if yes |
| If no, would you like input from the ICRF PPI Panel to review your study +/- documents? | Yes  No  Details if yes |
| Have you considered how you will identify which ethnic groups should be included in your trial for its results to be widely applicable, and what challenges there may be to making this possible? Please also consider other protected characteristics.  If no, information is available via the [Include Ethnicity Framework](https://www.trialforge.org/trial-diversity/include/) and the [EDI Toolkit](https://www.rssleicesterresources.org.uk/edi-toolkit) | Yes  No  Details if yes |
| Do you wish the study to be added to the ICRF website to support recruitment (must be included in ethics application)? | Yes  No |

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| **Operational Assessment** | | | | | | | | | | | | | |
| **Risk Area** | **Description (Risk Significance Score\*)** | | | | | | | | | | | | **Score** |
| **Study Design and Management** | | | | | | | | | | | | | |
| 1. Complexity of study design | Double blind/adaptive/multiple arms | **9** | Randomised Controlled Trial | | **6** | | Clinical Trial (Open-Label) | | **3** | Cohort / Cross-Sectional | | **1** |  |
| First in human | 9 | Experimental Medicine/  Phase IIa | | **6** | | Proof of concept | | **3** |  | |  |
| 2. Trial management |  |  | Non-commercial study | | **4** | | Commercial study | | **2** |  | |  |  |
| **Study Procedures** | | | | | | | | | | | | | |
| 3. Interventions (including IMP administration) | New or Non-standard intervention not previously undertaken in the Trust | **9** | Invasive intervention currently undertaken within Trust that are new to the ICRF | | **6** | | Invasive intervention currently undertaken by ICRF Staff | | **4** | Study limited to blood samples and/or questionnaire only | | **1** |  |
| 4. Study Visits | Any visit outside core hours | **9** | Outreach/Lone working/home visit | | | | | | **5** | Visits within core working hours | | **1** |  |
| **Investigational Medicinal Product** | | | | | | | | | | | | | |
| 5. IMP Involvement | ATIMP or GMO | **8** | IMP or Device | | | **6** | No IMP dosing in ICRF | | **2** | No IMP | | **0** |  |
| 6. Phase or type of Clinical Study | Phase I pilot/proof of concept/FIH | **9** | Phase II or other Interventional Experimental Medicine | | | **6** | Non-interventional Exp Med or Phase III, Phase IV | | **4** | Observational or Epidemiological Studies | | **1** |  |
| **Participants** | | | | | | | | | | | | | |
| 7. Participant Group | Adults lacking capacity / Children / Complex or specialist care needs | **8** | Patients | | | **6** | Healthy Volunteers with chronic conditions | | **4** | Healthy Volunteers | | 1 |  |
| **Investigator** | | | | | | | | | | | | | |
| 8. Investigator Experience | PI with no previous clinical research experience | **9** | No previous clinical research studies in NHS | | | **6** | No previous studies in the ICRF | | **4** | Adequate training and experience to support this study | | **1** |  |
| **Laboratory** | | | | | | | | | | | | | |
| 9. New or hazardous samples or lab processing methods | Yes, High risk | 9 | Yes | | | **6** | Maybe | | **4** | No | | **0** |  |
| **Resources** | | | | | | | | | | | | | |
| 10. Intensity Score (to be completed by the ICRF) |  |  | High | | | **6** | Medium | | **4** | Low | | **2** |  |
| **Any other perceived risk** | | | | | | | | | | | | | |
| Add risk | 9 | | **6** | | | | **4** | | | **2** | | |  |
| Add risk | 9 | | **6** | | | | **4** | | | **2** | | |  |
| **Risk Minimisation strategies** | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **Residual Risk** | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **Comments** | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| Protocol version |  | | | Operational risk score checked by | | | |  | | | Total score | |  |
| **Score rating** | High >44 | | | Medium 30-44 | | | | Low 15-30 | | | If score is <15 consider whether ICRF is needed | | |

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| **Documents to be forwarded/in place before study starts.**  **PRB Green Light will not be issued until indicated docs have been received** | | | |
| **Document** | **Required (Yes=x)** | **Further information (e.g. date & version)** | **ICRF checklist** |
| **All studies** | | | |
| Study Protocol |  |  |  |
| Patient Information sheet and consent form |  |  |  |
| IRAS application |  |  |  |
| REC Approval letter |  |  |  |
| HRA approval letter |  |  |  |
| Confirmation of Capacity and Capability (Trust approval-CCC) email |  |  |  |
| Clinical trial agreement/contract/ OID |  |  |  |
| Funding award letter for non-commercial studies |  |  |  |
| GCP certificates for the research team |  |  |  |
| Signed, dated CVs for the research team |  |  |  |
| Training records for the research team (including Induction, SOP reading, equipment training, honorary contracts, ANTT etc) as applicable |  |  |  |
| Visit ID and expected duration for CRF Manager set up |  |  |  |
| **All CTIMP studies and MHRA Regulated Clinical Investigations of Medical Devices** | | | |
| MHRA approval letter / letter of no objection |  |  |  |
| ICRF Clinical Risk Assessment & Management Plan (CRAMP) |  |  |  |
| Investigators Brochure/SmPC |  |  |  |
| Adverse Events Source Worksheet (ICRF template available) |  |  |  |
| **Phase I studies** | | | |
| Dose escalation plan for FIH studies if applicable |  |  |  |
| **Where applicable** | | | |
| Completed Appendix 1 if using CRF staff |  |  |  |
| Laboratory manual |  |  |  |
| ICRF Bio1 Form |  |  |  |
| Chemical /reagent Safety Data Sheets and COSHH Risk Assessments |  |  |  |
| Product datasheets for studies that administer a non-CTIMP intervention (e.g. food supplement or ‘borderline product’; refer to ICRF-CL12) |  |  |  |
| ICRF Clinical Risk Assessment & Management Plan (CRAMP) for non-CTIMP studies where requested at PRB |  |  |  |
| Clinical Biosafety Committee (CBC) approval and risk assessment for GMO and other applicable studies |  |  |  |
| List of all researchers involved in the study with contact details if not all included in this application |  |  |  |
| **NB:**   * **If the trial master file/investigator site file is to be held in the CRF, all study related documents must be submitted** * **ICRF-OR17 Fm1 Study Start Checklist and ICRF-OR25 Fm4 Study Start Shared Drive Checklist must be completed by the CPM if study is managed by ICRF.** | | | |

**After PRB meeting**

**Section 2: PRB Feedback (ICRF completion only)**

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| **Date of PRB Meeting** |  |
| **PRB comments & conditions (where applicable)** | **PRB Comments**    **In addition, all outstanding study documents to be completed and submitted, study-specific requirements put in place, training records received (including GCP, signed CV, honorary contract/LtA/LoA and ANTT), CRF SOPs read, equipment training and CRF induction undertaken where applicable.** |

**Section 3: Acceptance of PI Obligations and PRB Feedback (PI completion only)**

**This section must be completed by the PI to confirm that they accept the PI obligations and the PRB requirements, as described in Section 2. *The study may not start until the signed copy has been received by the ICRF General Manager, and PRB Green Light has been issued.***

###### **Principal Investigator Obligations to Imperial College Healthcare NHS Trust and Imperial CRF**

|  |  |
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| **I agree that as Principal Investigator I will have overall responsibility for the conduct of this research study at this site** |  |
| I confirm that this study will be conducted in accordance with ICH-GCP and in compliance with the protocol |  |
| I confirm that I will read all relevant Imperial CRF SOPs and agree to comply with them and any future updates |  |
| I confirm all study staff involved in the study have letters of access, substantive or honorary contracts with Imperial College Healthcare NHS Trust |  |
| I confirm that responsibility for indemnity against negligent harm is held and that all research related costs will be met where applicable |  |
| **As Principal Investigator (PI), I am responsible for the clinical safety of participants in my research study. I will nominate a suitable delegate if I am unavailable at any time.** |  |
| I agree that I will acknowledge the Imperial CRF in all publications using the following wording:  ***This research was funded by <funders>. Infrastructure support was provided by the NIHR Imperial Biomedical Research Centre and the NIHR Imperial 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 and Social Care***  Other statements are available [*here*](https://www.imperial.ac.uk/nihr-crf/research/acknowledgements/) for studies that have Imperial BRC funding |  |

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| **Name** |  | **Date** |  |
| **Signature** |  | | |

**Permission to use Imperial CRF facilities is granted for one year and reviewed annually thereafter. A study renewal request form will be sent 2 months prior to the annual review date; failure to reply will mean the study is no longer eligible to use the facilities and bookings will be suspended.**

**Appendix 1: only to be completed if CRF staff are involved in the study**

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| **Clinical, Medical and Operational responsibility**  ***NB: This will be reviewed at PRB and changes made where required. Additional forms will be completed if changes are agreed once the study has been approved***  ***Due to a limited number of medical staff, tasks requiring a clinician cannot be guaranteed for any particular visit, and only between 9 – 5.*** | | | | | | | |
| **Version number** | |  | | | **Date** | | |
| **Type** | **Responsibilities** | **NA** | **Study team** | **ICRF** | | **ICRF team where known** | **Comments (If an item is a sponsor/ CRO, pharmacy or 3rd party responsibility, please state here and record as NA on checklist)** |
| Recruitment | Identify potentially eligible participants from clinic lists or healthy volunteer database |  |  |  | |  |  |
| Recruitment | Complete and send letter to GP requesting medical history and/or informing them of participation in clinical trial |  |  |  | |  |  |
| Recruitment | Liaise with potential participants and schedule study appointments |  |  |  | |  |  |
| Recruitment | Provide participant information sheet and document in source data |  |  |  | |  |  |
| Recruitment | Register participants on TOPS (healthy volunteers) |  |  |  | |  |  |
| Recruitment | Maintain Screening and Enrolment and Subject ID logs |  |  |  | |  |  |
| Recruitment | Update EDGE and PowerTrials with enrolment info |  |  |  | |  |  |
| Visits | Obtain informed consent and document in source data |  |  |  | |  |  |
| Visits | ICRF Admission Assessment procedures for overnight stay (eg. VTE, MRSA swabs, checklists) |  |  |  | |  |  |
| Visits | Routine procedures e.g. Vital Signs, ECGs, cannulation |  |  |  | |  |  |
| Visits | Specific clinical procedures (eg. LP, Arterial lines, biopsy) |  |  |  | |  |  |
| Visits | Study specific assessments (neurological scales etc) |  |  |  | |  |  |
| Visits | Book external assessments (e.g. X-Ray, US, Lung Function, ECHO etc) |  |  |  | |  |  |
| Visits | Chase and upload results (i.e CT, ECHO, ECG etc) |  |  |  | |  |  |
| Visits | Manage IMP/drug stored at ICRF (stock checks, ordering, manage temperature excursions etc.) |  |  |  | |  |  |
| Visits | Prepare / Reconstitute IMP |  |  |  | |  |  |
| Visits | Collect IMP from Pharmacy |  |  |  | |  |  |
| Visits | Obtain biological samples (research bloods, urine etc) |  |  |  | |  |  |
| Visits | Complete prescriptions (of IMP or otherwise if applicable) |  |  |  | |  |  |
| Visits | Administer drugs (IMP or otherwise) |  |  |  | |  |  |
| Visits | Complete AE and SAE source worksheets (bar causality and seriousness) |  |  |  | |  |  |
| Visits | Complete causality and seriousness assessments on source worksheets |  |  |  | |  |  |
| Visits | Report SAE/SUSARs to sponsor |  |  |  | |  |  |
| Visits | Reporting SUSARs to MHRA/REC |  |  |  | |  |  |
| Visits | General medical cover (chronic management/ routine follow up/ECG review etc) within hours |  |  |  | |  |  |
| Visits | Study out of hours medical cover (usually study team) |  |  |  | |  |  |
| Visits | Disseminate dose escalation decisions (Phase I CTIMP) |  |  |  | |  |  |
| Visits | Track and order study specific supplies e.g. lab kits, ECG consumables etc |  |  |  | |  |  |
| Visits | Register study-specific equipment with Trust Clinical Engineering |  |  |  | |  |  |
| Visits | Arrange calibration of study specific clinical equipment |  |  |  | |  |  |
| Laboratory | QC of Lab Manual |  |  |  | |  |  |
| Laboratory | Process samples and report deviations |  |  |  | |  |  |
| Laboratory | Book lab shipments |  |  |  | |  |  |
| Laboratory | Despatch and track samples and report deviations |  |  |  | |  |  |
| Laboratory | Request and track pathology samples taken elsewhere (e.g. tumour blocks) |  |  |  | |  |  |
| Laboratory | Arrange calibration of study specific lab equipment |  |  |  | |  |  |
| Data collection | Design and update of Source Worksheet templates |  |  |  | |  |  |
| Data collection | Source Worksheets completion |  |  |  | |  |  |
| Data collection | Source worksheet QC once study is live |  |  |  | |  |  |
| Data collection | (e)CRF design and update |  |  |  | |  |  |
| Data collection | CRF data entry and query resolution |  |  |  | |  |  |
| Data collection | Produce and disseminate eCRF reports |  |  |  | |  |  |
| Data collection | Request eCRF data extraction |  |  |  | |  |  |
| Data management | Code AE etc using MedDra |  |  |  | |  |  |
| Bookings and expenses | Complete and send participant booking forms to ICRF reception |  |  |  | |  |  |
| Bookings and expenses | Book participant accommodation |  |  |  | |  |  |
| Bookings and expenses | Book participant transport |  |  |  | |  |  |
| Bookings and expenses | Set-up relevant systems with sponsor to organise participant travel and accomodation and ensure participants are reimbursed. |  |  |  | |  |  |
| Bookings and expenses | Track study expenditure (ICRF) |  |  |  | |  |  |
| Bookings and expenses | Track study expenditure (external departments i.e PET, lung function etc) |  |  |  | |  |  |
| Study meetings | Record and disseminate key information |  |  |  | |  |  |
| Study meetings | Organise SIV and prepare documentation (delegation log, attendance lists etc) |  |  |  | |  |  |
| Study meetings | Organise any other training required and prepare documentation |  |  |  | |  |  |
| Study meetings | Provide study-specific training |  |  |  | |  |  |
| Study meetings | Organise trial management meetings |  |  |  | |  |  |
| Study meetings | Document, disseminate and file trial management meetings |  |  |  | |  |  |
| Study meetings | Organise Data & Safety Monitoring Committee meetings |  |  |  | |  |  |
| Study meetings | Document, disseminate and file Data & Safety Monitoring Committee meetings |  |  |  | |  |  |
| Regulatory/Governance | Set-up and maintain ISF/TMF |  |  |  | |  |  |
| Regulatory/Governance | Register and update (including recruitment updates) trial on clinicaltrials.gov |  |  |  | |  |  |
| Regulatory/Governance | Draft protocol, PIS and other study documents and update them when necessary |  |  |  | |  |  |
| Regulatory/Governance | Submit new study documents, and amendments (including USM) to relevant authorities for approval (e.g. Ethics, HRA, Trust, PRB & MHRA), and complete supporting application forms. |  |  |  | |  |  |
| Regulatory/Governance | Liaise with external departments at study start and during the study (i.e imaging, pharmacy, lung function, ECHO etc) |  |  |  | |  |  |
| Regulatory/Governance | Ensure all approvals are in place prior to study start and implementation of any amendments and inform all study team members |  |  |  | |  |  |
| Regulatory/Governance | Complete and maintain amendment tracker |  |  |  | |  |  |
| Regulatory/Governance | Coordinate contract negotiations (technical agreements, PK lab, monitors etc) |  |  |  | |  |  |
| Regulatory/Governance | Upload NIHR accruals (if applicable) |  |  |  | |  |  |
| Regulatory/Governance | Maintain Delegation log |  |  |  | |  |  |
| Regulatory/Governance | Ensure SAEs are tracked and followed up to resolution |  |  |  | |  |  |
| Regulatory/Governance | Maintain study team contacts list, including emergency contacts |  |  |  | |  |  |
| Regulatory/Governance | Record and report protocol deviations, violations, potential serious breaches of GCP |  |  |  | |  |  |
| Regulatory/Governance | Submit Developmental Safety Update Reports (DSUR) to MHRA, Annual Progress Reports (APR) to REC and ICRF annual renewal forms to PRB. |  |  |  | |  |  |
| Regulatory/Governance | Submit progress reports to funder |  |  |  | |  |  |
| Regulatory/Governance | Organise and book monitoring visits on CRF manager |  |  |  | |  |  |
| Regulatory/Governance | Host monitoring visits, and prepare relevant documentation for review. |  |  |  | |  |  |
| Regulatory/Governance | Submit end of trial notification(s) |  |  |  | |  |  |
| Regulatory/Governance | Review of final study report and register results on EudraCT. |  |  |  | |  |  |
| Regulatory/Governance | Coordinate close out activities |  |  |  | |  |  |
| Regulatory/Governance | Archive all trial documentation |  |  |  | |  |  |

**Guidance**

**RACS CODES**

|  |  |  |
| --- | --- | --- |
| **RACS codes** | **Main inclusion criteria** | **Advice on research activities** |
| Underpinning research | Research that underpins investigations into the cause, development, detection, treatment and management of diseases, conditions and ill health | This code group is for all types of research into ‘normal’ functions and processes in ‘healthy’ humans or systems. Excludes research where the main aims relate to investigation of the cause, development, prevention, detection, treatment or management of a disease or condition. |
| Aetiology | Identification of determinants that are involved in the cause, risk or development of disease, conditions and ill health | Identification and characterisation of determinants that are involved in the cause, risk and development of diseases or conditions. This includes most epidemiological research including studies aimed at understanding behaviours. Excludes investigation of the mechanism of action of treatments (see 5 Treatment Development or 6 Treatment Evaluation) or studies relating to health services (see 8 Health Services). |
| Prevention of disease and conditions, and promotion of well-being | Research aimed at the primary prevention of disease, conditions or ill health, or promotion of well-being | This code group is for the promotion of health or primary prevention of diseases or conditions in healthy people or people without a pre-existing condition. These are frequently interventions. Interventions aimed at individuals ‘at risk’ but who do not yet have a condition can be coded in this category Includes policy, trial, education and evaluation studies that are aimed at health promotion or disease prevention. Excludes secondary prevention research which will usually be covered in the 6 Treatment Evaluation or 7 Disease Management code groups. |
| Detection, screening and diagnosis | Discovery, development and evaluation of diagnostic, prognostic and predictive markers and technologies | Includes research where the main aim is to develop diagnostic or prognostic tests for clinical use. Excludes development of lab techniques and tools for basic research. Excludes basic research using imaging or detection techniques in the methodology, where the primary aim of the research is not to develop clinical tests. |
| Evaluation of treatments and therapeutic interventions | Testing and evaluation of therapeutic interventions in clinical, community or applied settings | Research coded within this code group should involve patients in the testing and evaluation of therapies or be in a clinical or applied setting. Note not all trial evaluation is in 6 Treatment Evaluation, only if the trial relates to treatment evaluation. Clinical trials in this category will often involve an economic evaluation and quality of life component. Unless one of the primary aims of these trials is assessing quality of life or health economics, just code for the therapy under investigation. |
| Management of diseases and conditions | Research into individual care needs and management of disease, conditions or ill health | This code group is about management of disease from an individual and not an institutional or organisational perspective. There occasionally may be overlap with 8 Health Services and this should be double coded as appropriate. |
| Health and social care services research | Research into the provision and delivery of health and social care services, health policy and studies of research design, measurements and methodologies | Encompasses all research on the provision and delivery of health and social care services. It includes health care delivery and organisation from a health service perspective. |

**SMEs (Small, Medium enterprises)**

The UK government definition of SMEs encompasses micro (less than 10 employees and an annual turnover under £2 million), small (less than 50 employees and an annual turnover under £10 million) and medium-sized (less than 250 employees and an annual turnover under £50 million) businesses