NIHR IMPERIAL CLINICAL RESEARCH FACILITY
OPERATIONAL POLICY

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Approved by:	ICRF Management Team
Name, signature and date	**UNCONTROLLED COPY FOR PERSONAL USE, THE SIGNED ORIGINAL IS HELD BY THE ICRF QA MANAGER**
Ratified by:	
Name, signature and date	
Date Policy becomes Live:	02 January 2024
Due date for revision:	02 January 2027
Target Audience:	ICRF / CCRF Staff and users
Location of Policy:	Electronic: EQMS, ICRF Website Paper: ICRF Master File, CCRF Mezzanine space ID 5
Related SOPs and Policies:	Protocol Review Board terms of reference SOP ICRF-OR09 ICRF Applications SOP ICRF-OR05 ICRF Staff Induction SOP ICRF-OR03 Training records in the ICRF SOP ICRF-OR16 Staffing Levels SOP ICRF-LE07 Medical Equipment ICRF-LE.COP.01 Laboratory Code of Practice SOP ICRF-OR15 Diet Kitchen

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Document version numbering

Version	Date	Updated by	Reason for change
1	Feb 2015	N/A	New policy
2	Dec 2016	Karen Mosley	Updated details and clarifications including green light procedure,

			amendments, bookings, training and publication statement.
3	Dec 2019	Karen Mosley	Routine review
4	Apr 2021	Jacob Bonner	Updated PRB section
5	Oct 2023	Jacob Bonner	Added CCRF
5.1	Nov 2023	Jacob Bonner	Clarifications to CCRF sections

1. Introduction

The NIHR Imperial CRF (ICRF) is a multi-user facility for clinical research involving both patients and healthy volunteers. The Children's CRF is a multi-user facility for clinical research involving children and adolescents. The role of the ICRF and CCRF is to support clinical research, ensuring that studies comply with, where applicable, International Conference on Harmonisation Good Clinical Practice (ICH GCP), UK Governance Framework for Health and Social Care Research, Medicines for Human Use (Clinical Trials) Regulations 2004 and its amendments, the Human Tissue Act 2004 and all AHSC and Imperial College Healthcare NHS Trust (ICHNT) relevant policies.

2. Purpose

This policy briefly outlines the operational practices of the ICRF and CCRF. Further details can be found in the relevant SOPs.

3. Policy Detail

3.1. Protocol Review Board (PRB) and CCRF Study Review Meeting (SRM)

All requests to undertake clinical research using the ICRF or any of its satellite units or systems (e.g. Healthy Volunteer database) must be approved by the Protocol Review Board (PRB). The PRB meets twice monthly. Dates of meetings, the application SOP ICRF-OR09 and associated forms can be found on the ICRF website.

The project will be assessed according to the:

- Scientific value of the question asked
- Appropriateness of project in terms of ICRF remit as directed by NIHR
- Availability of resources, including access to appropriate numbers of participants
- Existing activity within the CRFs.

PRB outcomes:

Conditional Approval

Approval to commence the Green Light process.

Deferred

The committee is unable to make a decision based on the information submitted.

Rejected

The study is not approved to go ahead in the ICRF.

The PRB has the right to revoke access and use of the ICRF for a PI, or any member(s) of their team, if it is felt that this is an appropriate course of action. This decision would not be taken without exhausting other options and would be fully documented.

Applications to use the CCRF follow a similar process. Refer to the SOP *CCRF-OR01 Applications to Children's CRF* for full details.

3.2. Study setup and conduct

Study Initiation and Green Light Process
Studies may not start until the following have been completed:

- Researchers requiring access to the ICRF/CCRF have completed ICRF/CCRF induction (refer to section 3.3 below). Note that green light may be given before all members of the team have received induction, provided there are sufficient members with ICRF/CCRF access who can conduct the visits as per PRB application form / CCRF application form.
- Copies of all study and training documents have been received and evidence of required SOP reading obtained. Substantive or honorary contracts with the Trust must be in place
- All PRB/CCRF SRM-identified actions have been addressed, and study-specific approvals and requirements are in place (including other Trust / College departments and external organisations)
- Clear contact details for all the research team and representatives of the sponsor e.g. monitoring team, emergency and out of hours contact details have been received
- A Clinical Risk Assessment and Management Plan (CRAMP) has been signed-off by Head of Clinical Studies or delegate for all CTIMP/Device studies (or where PRB / CCRF Study Review Meeting decides one is required).

Each PRB/CCRF approved study will be allocated to a named person who works as a Study Contact. Researchers will liaise with their Study Contact to ensure that the above conditions are met and to keep the ICRF / CCRF informed of study progress.

Once all documents and training records have been received, the General Manager for ICRF or Operations Coordinator / Lead Nurse for CCRF will confirm the Green Light so that the study may start. At this point the study will go live on CRF Manager and the study may begin booking participants.

Annual Renewals
All studies must be reviewed on an annual basis in accordance with SOP ICRF-OR09. The renewal form will be sent to the PI/researcher two months before the due date. The form must be completed in full and returned before the end date of the original approval. Failure to return the renewal form will mean that the study will be suspended from CRF Manager and no further bookings will be taken.

Protocol Amendments
The PRB/CCRF SRM must review all CTIMP substantial amendments. The amendment details will be submitted by the PI, the PI's delegate, or ICRF study contact. Wherever possible this should be prior to or at the same time as ethics/HRA/regulatory submission (as applicable). Protocol amendments will be reviewed by the PRB/CCRF SRM if changes to the protocol are likely to impact significantly on the patient or the CRF. See SOP ICRF-OR09 for further information, including requirements for non-CTIMP studies.

Study Completion
The ICRF / CCRF end of study notification form and the Declaration of the end of trial form (CTIMPs) and/or the HRA declaration of the end of study form (non-CTIMPs) should be submitted to the PRB once the study is completed. For CTIMPs, a copy of the Clinical Study Report must be provided to ICRF / CCRF when available.

Booking procedure for study subjects
Booking request forms must be sent directly to the ICRF reception to arrange room bookings. Requests for bookings will only be accepted if they are presented either electronically (via NHS email only) or by hand on the current version of the booking form, completed in full and received

at least 2 working days prior to the visit. See SOP ICRF-OR09 for further information. A longer notice period may be specified in some circumstances as a condition of approval.

Scheduling of volunteers will be documented in the CRF Manager system.

Research volunteers requiring transport to the Trust will require this to be booked either by the research team or, if agreed at study set up, via the study-specific taxi account. Unless otherwise stated any travel expenses will be charged to the study's expenditure code.

CCRF:

Please ensure that you submit your booking request a minimum of 5 working days before the scheduled participant visit date. Booking requests at short notice of 2 working days can be considered but may be difficult to accept due to the limited size of the CCRF and therefore cannot be guaranteed. You may send the request via email to om.sah@nhs.net, with a copy to amina.mehar@nhs.net. The booking request email should include the following details:

- study name (and Documas no. if known):,
- Participant study ID:,
- visit type/week:,
- duration Start and end time:,
- Requester's name:,
- and study particulars PI.

3.3. Induction and access

Induction
All staff, Users and contractors/third parties must undergo appropriate induction before they receive swipe card access to the ICRF / CCRF (see SOP ICRF-OR05 ICRF Induction and CCRF-OR02 CCRF Induction)

Access
Once staff and users have completed induction and all relevant training documents have been received, they will be granted swipe card access to the ICRF/CCRF. They will also be given a coloured security card holder so that they can be readily identified. Cards must be on display at all times. Researchers who have not yet undergone induction/occasional contractors/third parties will be issued with a visitors pass, must be accompanied at all times, and must sign in and out at reception. Regular contractors/third parties who are known to reception (e.g. domestic staff, Estates, and porters) will only be admitted when in uniform and wearing their ICHNT / ICL pass. New contractors must sign in at reception and be accompanied by a known contractor or a member of ICRF / CCRF staff.

Out of core hours access

Staff and users working out-of-hours at ICRF/CCRF will require the following:

- Lone working documentation if applicable
- Minimum ILS training for ICRF/CCRF Users who wish to see participants in the absence of ICRF/CCRF staff. See *ICRF-OR07 ICRF staffing* for full details.

3.4. Training

All ICRF staff and ICRF users must undertake training which is appropriate to their role (see *ICRF-OR03 Training records*).

All users are expected to comply with all relevant SOPs when using the ICRF/CCRF, as detailed in the training matrix referred to in SOP ICRF-OR03 (separate CCRF and ICRF forms). SOPs are currently held in folders in the ICRF main office and CCRF Mezzanine floor. These are controlled copies and must not be removed. Electronic copies are available via the Qualsys EQMS system.

The PI is responsible for the conduct of the study at their site, and for their study team. It is the responsibility of the PI to ensure that all study team staff have either substantive contracts or honorary contracts with the Trust (or equivalent e.g. Licence to Attend, Letter of Access or Research passport) prior to undertaking unsupervised clinical research activity http://www.imperial.ac.uk/joint-research-compliance-office/project-planning/research-passports/. This includes access to patient identifiers and medical records.

The PI may delegate activities to members of the team, but only if they are appropriately qualified and trained – including protocol-specific training. Delegation must be recorded in a delegation of authority log. Training should be arranged through the team member's manager or the PI. Any specific equipment training should be arranged by the individual.

Training records

Staff

All ICRF/CCRF staff have training files that are held in the ICRF main office (G20) or CCRF Mezzanine Floor Space ID 5. Electronic records will also be maintained on the relevant shared drives. ICRF/CCRF staff are responsible for their own records.

Users

GCP certificates, CVs, life support certificates, and evidence of Honorary Contracts/LTAs (as required) are held on the relevant Shared Drives and in paper files. When users leave ICRF/CCRF, their training records will be scanned and kept indefinitely in electronic format on the relevant shared drive. The paper copies will then be confidentially destroyed.

3.5. Clinical Cover

Medical cover

ICRF / CCRF can provide medical cover during core medical working hours by arrangement. Outside these hours medical cover is the responsibility of the PI or their delegate. Further information is given in *ICRF-OR07 Staffing SOP*. Study-specific arrangements for out of hours cover will be documented in the PRB Application Form or the Clinical Risk Assessment and Management Plan (CRAMP).

Nursing cover

ICRF / CCRF can provide research nurse support for approved studies. This can comprise full nursing cover, partial nursing cover (e.g. cannulation and sampling only) or no planned nursing cover. The extent of nursing input should be requested at PRB / CCRF study review meeting. Any changes post-PRB / CCRF study review meeting must be discussed with the ICRF or CCRF Management team and approved using the relevant change form.

3.6. Safety

All researchers should follow ICHNT and ICL Health and Safety policies for the safety of themselves and others.

Physical Security

All Users must wear a College identification badge when in the ICRF/CCRF, held in a coloured card holder. Researchers may not access or use any part of the facility when ICRF / CCRF staff are not present except in exceptional circumstances, when specific permission has been given in advance

by the ICRF / CCRF Management Team. CCRF is accessed via a Trust swipe-card, which should be kept in a coloured card holder fixed to a lanyard. All facility users should ensure they are familiar with Imperial College's Lone Worker policy and have completed the forms if lone working is required.

Visitors must wear a visitors' pass and sign in and out at reception together with their daily supervisor.

In case of an emergency, contact the relevant security department as shown in the table below:

For immediate emergency involving a hazard to staff or participants, there are emergency buttons at the ICRF nurse's station and reception (ICL security) and CCRF reception (Trust security).

Contact	Contact number	Details
College Security	4444 or 0207 589 1000	Any emergency **at ICRF** other than cardiac arrest or assistance with patients/visitors as below
Trust Security	3333	Assistance with aggressive patients or visitors. Assistance with evacuating patients to Trust premises in emergencies.
Trust switchboard for resuscitation team	2222	Cardiac arrest, also call 445 43457 to ensure doors to the CRF are released

3.7. Equipment

All ICRF / CCRF medical equipment is asset tagged and maintained by ICHNT Clinical Engineering Services. Staff can provide training on equipment use as required. See SOP ICRF-LE07 Medical Equipment.

ICRF Users who need to bring their own medical/electrical equipment into the ICRF / CCRF for use in studies must inform the ICRF Lead Nurse / CCRF Lead Paediatric Research Nurse prior to the start of the study, or the ICRF Lab Manager for laboratory equipment. Equipment must be clearly labelled, showing the department of origin, study number and contact name. Medical devices also need to approved by Trust clinical engineers prior to use.

Unless equipment is formally accepted as a donation to the ICRF, the PI's department continues to be responsible for the equipment's safety i.e. electrical testing, calibration, service and maintenance.

Medical electrical equipment used in close proximity to participants must have passed the relevant tests currently undertaken by ICHNT Clinical Engineering Department, and evidence of this must be provided. PAT testing of non-medical equipment must be done by Trust or College Estates department

3.8. Laboratory (G27)

ICRF has one laboratory providing the equipment required for processing and storage of biological samples. There is also an additional centrifuge in G13A available only for the ICRF Lab team. CCRF has one laboratory which provides the required equipment to process and store biological samples.

Access will only be granted to researchers who have undergone Laboratory induction and have read and understood the Laboratory Code of Practice (*ICRF-LE.COP*) and the relevant lab SOPs.

Laboratory users must store and manage their samples using the ICRF LIMS database to allow identification and traceability. Training will be provided by a member of the ICRF Lab team.

ICRF/CCRF Users are responsible for risk and/or COSHH assessment of equipment and chemicals brought into the ICRF/CCRF labs after approval by the Lab Manager. Note that the lab is only available for pre-analytical processing and storage of samples pending transfer. The labs are not suitable for analytical work or assay validation, which would need to be done at a suitable external laboratory.

3.9. G13A

G13A is a storage and preparation area for Gene Therapy Investigational Medicinal Products at ICRF. It contains a Class 2 Microbiological safety cabinet which is suitable for preparing products for human administration requiring containment level 2. Refer to ICRF-LE15 for further details. Access will be given to staff and researchers that have undergone appropriate training.

3.10. Diet Kitchen

In addition to the staff kitchen, the ICRF and CCRF each has a Diet / Food Preparation Kitchen, solely for the preparation and storage of specific diets for metabolic studies and food for participants. Access to these Kitchens is restricted to ICRF / CCRF staff and Users (see SOP ICRF-OR15 and CCRF-LE01).

3.11. Publications and acknowledgements

Investigators must acknowledge the ICRF in publications, and inform the ICRF of all publications that relate to work facilitated by the ICRF/CCRF, either physically or intellectually. The specific wording approved by NIHR can be found on the ICRF website and must be included in all publications.

3.12. Withdrawal of support

ICRF/CCRF reserves the right to suspend work on any project conducted in the facility should staff become concerned about participant or staff safety or research governance e.g. violation or deviation from study protocols or ICRF policies and SOPs.