NIHR/WELLCOME TRUST IMPERIAL CLINICAL RESEARCH FACILITY
OPERATIONAL POLICY

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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	
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Location of Policy:	Electronic: https://sites.google.com/a/nihr.ac.uk/imperial-clinical-research-facility/home Paper: ICRF Master File, Nurses Station, Staff lounge
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.

1. Introduction

The NIHR/Wellcome Trust Imperial CRF (ICRF) is a multi-user facility for clinical research involving both patients and healthy volunteers. The role of the ICRF staff is to support clinical research, ensuring that all studies comply with, where applicable, International Conference on Harmonisation, Good Clinical Practice (ICH GCP), Research Governance Framework for Health and Social Care (DoH) 2005, Medicines for Human Use (Clinical Trials) Regulations 2004 and its amendments (2006, 2008, 2009), the Human Tissue Act 2004 and all AHSC and Imperial College Healthcare NHS Trust (ICHNT) health and safety measures.

2. Purpose

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

3. Glossary

AHSC	Academic Health Science Centre; a partnership between Imperial College London and Imperial College Healthcare NHS Trust,
CRAMP	Clinical Risk Assessment and Management Plan
Contractors/third parties	Includes e.g. agency/bank staff, cleaners, caterers, porters, estates, external building contractors, monitors, visitors etc. They can be classified into occasional or regular to distinguish between e.g. cleaners who have daily access and monitors who may only attend periodically
Core hours	8am-8pm Monday to Thursday, 8am-6pm Friday
CRF Manager	ICRF study and scheduling management system
Green Light	Confirmation that all governance requirements and approval conditions have been met and the study may start in the ICRF
ICHNT	Imperial College Healthcare NHS Trust
ICL	Imperial College London
ICRF	NIHR/Wellcome Trust Imperial Clinical Research Facility
ICRF Management Team	ICRF Head of Clinical Studies, General Manager and Lead Nurse
ICRF staff	Staff employed by the ICRF on either ICHNT or ICL contracts
ICRF Users	Researchers who require access to the ICRF
PI	Principal investigator
Protocol Review Board (PRB)	Committee comprising ICRF Director, Head of Clinical Research, General Manager, Lead Nurse, QA Manager and non-ICRF members covering toxicology, clinical pharmacology, pharmacy, safety and medical statistics. Set up to review all applications to the ICRF.
Researchers	Members of study teams who may or may not require access to the ICRF
SOP	Standard Operating Procedure

4. Policy Detail

4.1. Protocol Review Board (PRB)

All requests to undertake clinical research using the ICRF must be approved by the Protocol Review Board (PRB). The PRB meets twice monthly. Phase I studies will only be reviewed on the second meeting of the month. Dates of meetings, the application SOP ICRF-OR09 and associated forms can be found on the ICRF website http://imperial.crf.nihr.ac.uk.

The project will be assessed according to the:

- Scientific value of the question asked
- Availability of resources, including access to appropriate numbers of subjects
- Existing activity within the ICRF.

PRB outcomes:

Approved to Enter Green Light process
  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.

4.2. 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 have completed ICRF induction (refer to section 4.3 below).
- Copies of all study and training documents have been received and evidence of ICRF SOP reading obtained. Substantive or honorary contracts with the Trust must be in place
- All PRB-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 decide one is required.

Each PRB approved study will be allocated to an ICRF 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 informed of study progress.

Once all documents and training records have been received, the Lead Nurse or General Manager will confirm the Green Light so that the study may start. At this point the study will receive a green tick 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. The request for continuation will be sent to the PRB for review and if successful a renewal letter will be issued. Failure to return the renewal form will mean that the study will be removed from CRF Manager and no further bookings will be taken.

Protocol Amendments
The PRB 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 if changes to the protocol are likely to impact significantly on the patient or the CRF. See SOP ICRF-OR09 for further information

Study Completion
The ICRF end of study notification form and either the Declaration of the end of trial form (CTIMPs) or the NRES declaration of the end of study form (non-CTIMPs) must be submitted to the PRB once the study is completed.

Booking procedure for study subjects
Admission request forms must be sent directly to the ICRF to arrange admission. Requests for admission will only be accepted if they are presented to the ICRF either electronically (via NHS email only), by fax or by hand on the current version of the admission form, completed in full and received at least 48 working hours prior to

the visit. See SOP ICRF-OR09 for further information. PRB may require a longer notice period in some circumstances.

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.

4.3. Induction and access

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

ICRF staff
Full ICRF induction + lab induction if applicable

ICRF Bank or temporary staff
ICRF induction/orientation/lab induction relevant and proportionate to their role as determined by the ICRF Management Team.

ICRF Users
One hour ICRF induction + lab induction, if applicable, for all researchers who require swipe access to the ICRF. Others, e.g. students observing clinical or laboratory practice, must sign in and be supervised at all times

Contractors/third parties
Proportional induction: this will include as a minimum:

- Fire drill
- Facilities e.g. WCs
- Sign in/out procedure
- Tailgating procedure
- Restricted access details.

Access
Once ICRF staff and users have completed induction and all relevant training documents have been received, they will be granted swipe card access to the ICRF. 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. Research participants and their friends/families will be issued with disposable paper wrist bands. 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. Sodexo, Estates, porters) will only be admitted when in uniform and wearing their ICHNT pass. New contractors must sign in at reception and be accompanied by a known contractor or a member of ICRF staff.

4.4. Training
All ICRF staff and ICRF Users must undertake proportional training (see SOPs ICRF-OR05 Induction and ICRF-OR03 Training records). To obtain access to the CRF this will include evidence of the following as a minimum:

Standard access
- ICRF induction
- Signed, dated CV which includes all elements of the NRES template research CV
- Current GCP (within two years, sufficient to cover intended role)
- ICRF SOP reading record (in line with training matrix)
- Asceptic Non Touch Technique training for access to clinical areas
- Additional induction and reading for laboratory access (swipe access to the ICRF does not automatically include the laboratories see section 4.8).

Out of core hours access
- Lone working documentation
- ILS training for ICRF Users who wish to see volunteers in the ICRF in the absence of ICRF staff.

PIs and researchers are expected to comply with all relevant ICRF SOPs when using the CRF, as detailed in the training matrix referred to in SOP ICRF-OR03. SOPs are currently held in folders in the staff/researchers' lounge and the nurses' station. These are controlled copies and must not be removed from the ICRF. Electronic copies are available via https://sites.google.com/a/nihr.ac.uk/imperial-clinical-research-facility/home.

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, 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
ICRF staff
All ICRF staff have training files that are held in the ICRF main office (G20). In addition an Access training log is held on the shared drive. ICRF staff are responsible for their own records.

ICRF Users
GCP certificates, CVs, life support certificates, ANTT certificates, evidence of Honorary Contracts/LTAS and food hygiene certificates (as required) are held on the ICRF Shared Drive or paper files. SOP reading logs are held in the SOP folders in the staff/researcher lounge. ICRF users also have an Access training log that is updated by the QA Manager or delegate.

4.5. Clinical Cover

Medical cover
ICRF 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-OP.16 Staffing levels in the ICRF.

Nursing cover
ICRF can provide research nurse support for PRB-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. Any changes post-PRB must be discussed with the ICRF Management team.

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

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

All research participants and friends/family must wear a wrist band while they are in the ICRF. Other visitors must wear a visitors' pass and sign in and out at reception.

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

Contact	Contact number	Details
College Security	4444 or 0207 589 1000	Any emergency other than cardiac arrest
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

4.7. Equipment

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

ICRF Users who need to bring their own medical/electrical equipment into the ICRF for use in studies must inform the ICRF Lead 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.

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.

4.8. Laboratories

ICRF has one standard and one gene therapy (level 2 containment facility) laboratory providing the equipment required for sampling and storage of biological samples, and the preparation and storage of gene therapy IMPs.

Access will only be granted to researchers who have undergone Laboratory induction and have read and understood the laboratory Code of Practice and the relevant lab SOPs. See ICRF-LE.COP.01 and associated SOPs.

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

ICRF Users are responsible for risk and/or COSHH assessment of equipment and chemicals brought into the ICRF labs.

4.9. Diet Kitchen

In addition to the staff kitchen, the ICRF has a Diet Kitchen solely for the preparation and storage of specific diets for metabolic studies and standard food for participants. Access to the Diet Kitchen is restricted to ICRF staff and Users who have undergone hygiene training (see SOP ICRF-OR15).

4.10.   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, either physically or intellectually. The following statement must be included in all publications:

This article/paper/report presents independent research funded by [name of funder] and supported by the NIHR CRF and BRC [as applicable] at Imperial College Healthcare NHS Trust. The views expressed are those of the author(s) and not necessarily those of the (name of funder), the NHS, the NIHR or the Department of Health.

4.11.   Withdrawal of support

ICRF 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.