



# Imperial Clinical Research Facility User Guidelines



# Imperial CRF Users Guidelines

The NIHR Imperial CRF (ICRF) is a multi-user facility for clinical research involving both patients and healthy volunteers. The role of all ICRF staff is to support clinical research, ensuring that all studies comply with regulatory policies and are undertaken to a high standard. The staff help undertake studies within the facility whilst ensuring the safety and wellbeing of all research participants. The following guidelines have been developed to enable research to be conducted under optimum conditions with standards for participants and professional colleagues being maintained.

We aim to facilitate your research study in a safe and efficient working environment, ensuring that all studies comply with International Conference on Harmonisation Good Clinical Practice (ICH GCP); UK Policy Framework for Health and Social Care, Medicines for Human Use (Clinical Trials) Regulations 2004 and its amendments, Human Tissue Act 2004 and all RGIT and Imperial College Healthcare NHS Trust (ICHNT) health and safety measures.

The success of a research project in the ICRF relies on collaborative planning and effective communication. This will ensure the delivery of reliable research data to support high quality publications.

We hope this guide clarifies our operational practice, and we look forward to working with you.

## How the ICRF works

The ICRF currently supports studies during the core hours of Monday to Friday between 8am and 8pm (6pm on Fridays). We also offer overnight cover Monday to Thursday night, provided we receive satisfactory notice. Additional hours, including weekends, can be arranged on a case by case basis.

Studies are approved by the Protocol Review Board (PRB) which is held on the second and fourth Thursday of every month. The current versions of the application form and SOP can be downloaded from the ICRF website. The form needs to be sent to us at least a week before the meeting.

During PRB approval, each study is allocated to a named person who acts as the Study Contact. The role of the Study Contact is to ensure that the research team have the required training to undertake a research project in the ICRF, to make sure that the ICRF has copies of all essential documents before the study starts and to liaise with the research team once the study has started to ensure that we are aware of any amendments and are regularly updated with e.g. recruitment figures, SAEs and protocol violations (see Application SOP for further information)

Studies will be granted PRB Green Light and can commence when Imperial Confirmation of Capability and Capacity, HRA, Research Ethics Committee (REC) and any other relevant approvals are in place and when the ICRF study set-up process is complete, including ICRF induction of all research staff. Site initiation visits (SIVs) including the ICRF team and pharmacy where relevant must be conducted for all CTIMPS before the study starts. A mutually agreed start date will be arranged.

## Research Governance

### Protocols and Amendments

All activity must comply with GCP, ICHNT policies, RGIT and the ICRF's SOPs where applicable.

All projects must have written protocols to which the investigator must adhere.

We require written evidence of HRA, REC, ICHNT Confirmation of Capability and Capacity and any other relevant approvals (e.g. MHRA), including approvals for all substantial amendments. Please note that all approvals for substantial amendments must be in place before the amendments are implemented. Your Study Contact should be informed of all proposed amendments as soon as possible.

The REC must be informed if there is a change of PI. Although it is not mandatory to notify the REC of changes in co-investigators or minor protocol amendments, the ICRF must be informed of such changes to ensure effective ongoing facilitation of the studies.

### Consent and Patient Notes

To ensure that your consent forms and patient notes conform to GCP and legislation, please comply with the following points:

- Signed consent must be given before **ANY** research activities are undertaken, i.e. anything that comes outside normal routine care.
- All study participants must be registered on the Trust medical records system, Cerner, including healthy volunteers. Our ICRF Administrators can generate patient numbers and labels if required, provided adequate notice is given. If your study requires blood samples to be sent to ICHNT labs, you will need to know the pathology cost code.
- All patient information sheets (PIS) and consent forms must be printed on ICHNT headed paper
- The signed consent form must be uploaded to Cerner. Two copies should be made: the original should go in the trial master/site file, one copy in the source worksheet folder and one to the patient (unless otherwise specified in the protocol).
- Contact [Imperial.ICTservicedesk@nhs.net](mailto:Imperial.ICTservicedesk@nhs.net) to arrange access to Cerner and the Trust network. You will need to obtain a smart-card and complete relevant training. If required, a generic smart-card can be issued to doctors on a temporary basis while waiting for ICT to provide Cerner access: contact [Jacob.bonner@nhs.net](mailto:Jacob.bonner@nhs.net)
- A research note must be completed on Cerner for every visit and must state when the consent was signed and which procedures were carried out. On subsequent visits participants should also be asked if they are happy to continue with the study, and this should be recorded. In addition, anything relevant to the participant's healthcare, e.g. adverse events, new treatments or concomitant medications, protocol deviations, abnormal clinically significant findings and ECG traces must be recorded on Cerner. The final completed and signed paper prescription should be uploaded to Cerner in the same way as the consent form.
- All participants must wear a wristband while in the CRF if they are in for a visit involving a procedure.

## Adverse Events/ Serious Adverse Events/ Serious Adverse Reactions

If an Adverse Event (AE), Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR, including SUSARs) should occur whilst a participant is taking part in a ICRF-hosted study, the researcher should complete the appropriate documentation and report immediately to the sponsor (within 24hrs) . All SAEs must be followed to completion. Copies of SAEs for CTIMP studies should be forwarded to the ICRF QA & Governance Manager or ICRF Clinical Trials Monitor/Quality Officer

## Standard Operating Procedures (SOPs)

PIs and researchers are expected to comply with all relevant ICRF SOPs when using the ICRF. ICRF SOPs are available electronically via the EQMS system. You are required to read the relevant SOPs as detailed in the Training Matrix and record acknowledgement via EQMS. Copies of SOPs are also held in folders in the ICRF (one in the main office, one at the nurses station and one in the staff/researchers' lounge). Study specific SOPs should be sent to our QA & Governance Manager (QAGM) who will check they are GCP compliant before they are implemented in the ICRF.

## Bookings

All subjects should be booked using the single or multiple admission booking forms. These should be completed in full and returned to the ICRF Administrators, at least 2 working days prior to the proposed visit, either by email (from an @nhs.net ONLY) to [Imperial.CRF@nhs.net](mailto:Imperial.CRF@nhs.net), or hand delivery.

Bookings will be reviewed daily and reserved on a first-come-first-served basis. You will be notified if your booking cannot be accepted, generally due to lack of nursing support or space.

You can only make bookings for a study following final green-light PRB approval.

## Medical Cover

The ICRF can provide medical cover during core medical working hours (Mon-Fri, 9am-4pm) by arrangement and where staff are available. Outside these hours medical cover is the responsibility of the PI or their delegate. The covering clinician must be aware of the details of the study, any procedures to be performed and the nature of any anticipated clinical problems. Additional on-site medical PI or PI-delegate medical cover may be required as identified by the ICRF risk assessment. The PI or named designate must ensure clinical cover on the study day for the required period of time including out-of-hours cover if visits occur late in the day.

The name of the covering clinician and their bleep/pager/extension number must be provided to the allocated nurse. Where the ICRF Clinical Risk Assessment and Management Plan (CRAMP) has determined that there should be a medical presence in the unit, this will need to be in place prior to the commencement of study interventions. If agreed medical cover is not in place, research interventions will be suspended until satisfactory cover is present.

## Contracts, induction and training

Ethics guidelines stipulate that the Principal Investigator (PI) is responsible for the conduct of the study at their site, and for the study team. We provide mandatory induction to the ICRF which all researchers, nurses and students undertake prior to working in the unit. It is the responsibility of the PI to ensure that all study team staff have either substantive contracts, an honorary medical contract or a non-medical Licence to Attend or Letter of Access with the Trust prior to undertaking clinical research activity. Additional requirements include current GCP certification, ANTT training, provision

of a current research CV and reading of essential SOPs which are available on EQMS and the ICRF website. Training must be renewed in a timely manner.

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. GCP training (within the previous two years) is also mandatory for all PIs and researchers. If you are unsure of what training you need, please discuss this with the ICRF QAGM

## Safety in the ICRF

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

### Physical Security

All researchers must wear an identification badge in a ICRF issued badge holder when in the ICRF. Researchers may not access or use any part of the facility when no ICRF staff are present except in exceptional circumstances, when specific permission has been given in advance by the ICRF General Manager, Lead Nurse, or delegate. All facility users should ensure they are familiar with the College's Lone Worker policy and have completed the forms if lone working is required. In general the Lone Worker policy only applies where only one staff member or researcher will be present in the ICRF.

### IT Security

The following guiding principles should always be adhered to:

- Person identifiable data should normally be stored on the Trust network. Storing or copying data to a mobile device should only be undertaken where mobility is essential
- Person identifiable data should never be stored on a non-encrypted mobile device (memory stick, portable hard drive or laptop)
- Person identifiable data should never be stored on a computer not owned and controlled by ICHNT. College computers are not considered appropriate for saving patient identifiable data.
- Person identifiable data health information should never be sent using non-secure email addresses. Only NHS Mail may be used to send this type of data outside the Trust. You must not send patient identifiable information to or from imperial.ac.uk email accounts

### Resuscitation

Two resuscitation trolleys are located in the corridors. Resuscitation equipment is checked daily during standard working days (i.e. not weekends or bank holidays). The ICRF is covered by the ICHNT Resuscitation Team. To contact the team dial 2222 and give your location and the type of emergency; instructions for the exact wording required are detailed on orange cards next to each phone in the clinical area. You will also need to contact College security immediately to ask them to open the doors to allow access for the Resus Team; again instructions are detailed on the cards.

### Equipment

The ICRF has a wide range of specialist equipment which we maintain. Many researchers have specialist equipment that is unique to their field of interest. Investigators must be aware that equipment which is not compliant with safety standards will not be accepted into the ICRF.

Researchers who need to bring their own medical/electrical equipment into the ICRF for use in studies should inform the Lead Nurse prior to the start of the study, or the 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, 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.

Trust equipment will have an asset number attached.

## Equipment Failures

All ICRF clinical equipment failures or maintenance problems should be reported immediately to the Lead Nurse or Nurse in Charge (clinical equipment) or the ICRF Administrators (non-clinical), so that they can resolve the issue. All ICRF lab equipment failures should be reported to the Lab Manager.

## Infection Control

Researchers must adhere to ICHNT Infection Control policies and use the protective equipment provided (e.g. plastic aprons, gloves, goggles) where appropriate. Please see a member of the ICRF staff with any questions or concerns.

Labelling of sample containers may only be undertaken in clinical areas to limit the risk of accidental contamination

## Laboratories

- Access will only be granted to researchers who have undergone Laboratory induction and read and understood the Laboratory Code of Practice and the relevant lab SOPs.
- As a minimum, researchers MUST wear gloves and aprons while working at the bench or using any equipment in the laboratories. Further PPE, such as eye protection and full lab coat, must also be worn if specified by the risk assessment.
- No food or drink is allowed in the lab areas at any time.
- Researchers are responsible for ensuring that they clean up any equipment/spillages after using the facility. These should also be reported to the Lab Manager or Nurse in Charge.
- The lab has limited freezer capacity at -20°C and -80°C. We offer short term storage, but all samples must be stored and managed in accordance with GCLP and as outlined in the specific SOPs. This will require sample specifics to be recorded into a LIMS database to allow their identification and traceability at all times. Samples should be removed by research teams as soon as possible. Freezer temperatures are monitored continuously, and a 24 hour alarm call-out system is in place.
- Researchers are responsible for risk and/or COSHH assessment of equipment and chemicals brought into the ICRF labs. These should be made available to the Lab Manager in advance.

## ICRF Facilities

### Tidiness

The ICRF is a multi-user facility, so please keep the areas you are using clean and tidy, and ensure they are left this way when you have finished with them. Please inform the Clinical Research Practitioner or Nurse in Charge if clinical stocks are running low in either the clinical areas or the stock room.

In the clinical area, any used beds must be cleaned with Clinell wipes and made up with clean bed linen. Used equipment must also be cleaned with Clinell wipes and a signed, green sticker confirming cleaning must be applied to the devices, chairs and tables

### Main Office and Researcher/Staff Lounge Etiquette

PCs are available in the researcher/staff lounge for researchers, but only those that have been marked as such. Please ensure that you comply with the following:

- PCs may not be reserved
- The PCs are for the use of researchers who have volunteers in the unit at the time. Due to limited availability, you may not use the PCs when you do not have participants present.
- PCs are to be used for study related work only.
- Log out as soon as you have finished or if you will be away from the desk for more than 15 min.
- Desks must be left clear after use, including mugs etc
- Avoid lengthy discussion or non-work related conversations in office areas; please respect others who are trying to work
- Confidential calls or lengthy calls to participants must not be made from the main office, staff lounge or staff kitchen (including from mobile phones). Reception will be able to advise if a room is available for use at short notice.
- Do not remove anything from other desks
- Do not unplug PCs for any reason
- No hot or strong smelling food may be eaten in these areas
- Researchers may use spare filing drawers for temporary storage of study documents while they are in the ICRF or if agreed in advance.
- Handbags etc must be kept in any empty filing drawers labelled Day Storage while users are in the ICRF
- Coats must be kept on the coat rack in the Staff Kitchen .

### Filing Room

The filing room is key code protected. The code may only be obtained directly from the QAGM or Quality Officer. The code must not be given out to other users under any circumstances

### Food and Drink

A supply of drinks and snacks are available for study participants. Hot meals and sandwiches can be provided if requested for healthy volunteers, patients and patients' visitors. If required by the study protocol, specially prepared food can be provided and this should be agreed and arranged in

advance via the study contact.

Researchers are welcome to use the staff kitchen provided they leave it as they would expect to find it. Users are responsible for washing up their own crockery/cutlery.

All crockery/cutlery must be returned to the kitchen that it was taken from.

## Diet Kitchen

The diet kitchen is to be used for preparing food for research studies only. All users must have undergone food hygiene training and are expected to leave the kitchen in a clean and tidy condition.

Anyone using the cooker or grill must not leave it unattended while switched on.

## Phones

Trust phones are for business use only and must not be used to make personal calls. Staff call cards can be purchased in Trust reception if you need to make a personal call

## Visitors

Visitor passes are required for the following groups. Visitor passes can be obtained from reception

- Any staff or students who do not have swipe card access
- External contractors
- General visitors to the facility

Participants' friends/family will be issued with a wrist band

## Other Issues

### Withdrawal of support

The 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. Support may also be withdrawn if you do not return your annual renewal request.

## Publications

The ICRF and NIHR must be acknowledged in any publications/abstracts/posters arising out of work undertaken in the facility. This will contribute to the metrics which form part of our reports to NIHR, and ensure subsequent funding to support your studies. **NB: this is a critical metric and so non-compliance may result in withdrawal of support for your future studies**

The following wording (or other standard wording available through the [ICRF website](#)) must be used:

*"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*





## Key contact details

### ICRF General Manager

Karen Mosley: [k.mosley@nhs.net](mailto:k.mosley@nhs.net)

### Lead Nurse

Susanne Fagerbrink:

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### QA and Governance Manager

Jake Bonner: [jacob.bonner@nhs.net](mailto:jacob.bonner@nhs.net)

### Laboratory Manager

Lauren Matthews: [lauren.matthews14@nhs.net](mailto:lauren.matthews14@nhs.net)

### ICRF Reception

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## Address

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