Title: Induction and Access to Imperial Clinical Research Facilities

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Date SOP becomes Live:	26 October 2023
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Target Audience:	All staff and researchers working at ICRF managed facilities
Location of SOP:	Electronic: EQMS Paper: ICRF Master File, Nurses' Station, Staff Lounge
Related SOPs and Policies:	ICHNT Corporate and Local Induction Policy and Procedure Documents as listed in section 7
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Document version numbering

Version	Date	Updated by	Reason for change
1	Sept 2012	N/A	New SOP
2	June 2013	M Watson	Addition of Lab Manager. Clarification of access hours for users. Updated Induction Form
3	May 2015	A.Sukumaran	Condensed wording, clarification of processes
4	April 2018	J Bonner	Significant change to process
4.1	May 2018	J Bonner	Typographical corrections & referencing updates.
5	Feb 2019	J Bonner	Addition of section 6.3 and new staff checklist created.
6	Mar 2021	J Bonner	Separated more clearly into different types of induction required. Added references and separate induction forms for Hub, Pod and Annexe.

7	Sep 2023	J Bonner	Routine update, removed references to Hub and Pod.

1. Background

It is important that all staff working in the NIHR Clinical Research Facility (ICRF) and other ICRF managed facilities are aware of the need to comply with statutory clinical research legislation and local policies and procedures.

The ICRF requires staff to undertake induction programmes relevant to their role. ICRF staff may be employed by Imperial College Healthcare NHS Trust (ICHNT) or Imperial College London (ICL). Investigators using ICRF or other ICRF managed facilities when conducting a clinical study will require appropriate induction, as will temporary and Bank staff.

The purpose of the induction is to ensure operations and procedures are conducted accurately, safely and effectively in line with the required standards. This SOP does not remove the need for staff to undertake other relevant training or induction separately, such as Trust Corporate Induction for ICHNT employees or College Safety Induction for ICL staff.

2. Purpose

The Purpose of this SOP is to outline the process of induction to ICRF managed facilities and to detail the documentation required.

3. Scope

This SOP applies to all staff employed by the ICRF and anyone using ICRF managed facilities.

4. Process

4.1 Responsibilities

The Senior Management Team (SMT) (or Line Manager as applicable) are responsible for ensuring that:

- All staff working in the ICRF attend induction as outlined in this SOP before they are given access to work in the ICRF or ICRF managed facilities.

- Support staff e.g. cleaners, are provided with induction to local practices where these are not standard or common in their fields.

- The induction procedure is satisfactory to cover staff activity in the centre.

- Those providing induction are fully aware of the procedure and the process.

The ICRF General Manager or their delegate is responsible for ensuring staff receive the ICL Day 1 induction.

The Quality Assurance & Governance Manager (QAGM) or their delegate is responsible for maintaining central staff and user records, and for oversight of this process

All ICRF staff and users are responsible for:

- Ensuring they attend and complete their induction program.

- Ensuring their induction checklist is completed.

- Identifying gaps in their understanding and requesting additional information or

	training.
	• Complying with the instructions provided during the induction.
	• Making sure the unit is safe and secure and only those who are authorised to be in the unit can gain entry. Those who have not been approved for swipe card access must be escorted or supervised appropriately.

4.2 General Principles

Induction will be coordinated by the ICRF Administrator for non-staff, and the QA team for staff, but the following staff will take overall responsibility: • Principal Investigator / Academic Supervisor for users • Head of Clinical Studies for medical staff • Lead nurse for Non-medical clinical staff • ICRF General Manager for non-clinical ICRF staff • QAGM is responsible for overseeing compliance with this process
All users of the ICRF, including ICRF staff must have an induction of the local facilities. ICRF staff will be given a Welcome Pack (ICRF-OR05 Supp1 or ICRF-OR05 Supp2) and ICRF Users sent the User Guidelines (ICRF-OR05 Supp3), which can be retained for reference purposes as a quick guide to ICRF.
Non-ICRF staff will be invited to an Induction only after their study has received conditional approval by the Protocol Review Board and following completion of the required paperwork. Refer to section 4.3 for further details.
New ICRF staff will usually be invited to the first available Induction session after their start date, or where appropriate an ad-hoc induction session may be provided. The staff member's line manager is responsible for ensuring that the required paperwork is completed and filed in their training file. Refer to section 4.4 for further details.
Students, Bank or Agency staff or other temporary staff will have an induction proportionate to the specific work they will be doing. See section 4.5.
Visitors to the ICRF will not have a formal induction process, but they will be supervised while in the unit and where appropriate will be given instructions to follow in case of emergency. Refer to section 4.6 for further details.
The need for repeat induction will be at the discretion of the ICRF SMT, but it will be considered if it has been more than 2 years since the original induction and the user or staff member has not used the ICRF in the last 12 months.
The Induction will involve a tour of the ICRF facilities, instructions to follow in emergencies, introduction to relevant staff groups, overview of relevant policies and SOPs, training requirements and an overview of general information and administrative matters. The following staff (or their delegate) will present as part of each Induction: • ICRF Administrator: Introduction, participant booking process and general information • Lead Nurse: Tour of clinical areas and requirements for using the ICRF • Lab Manager: Tour of labs and requirements for using labs (where applicable)

- Patient and Public Involvement (PPI) Manager: overview of PPI panel and public engagement opportunities

- Healthy Volunteer administrator: overview of Healthy Volunteer database (where applicable)

- Quality Assurance & Governance Manager (QAGM): Evacuation procedures, overview of quality systems, information governance, incident reporting and security

4.3 Process for non-ICRF Staff (e.g. investigators, researchers)

Ensure that your study has received at least conditional approval by ICRF Protocol Review Board. If not, follow the process described in ICRF-OR09 for approval to conduct clinical research at ICRF before continuing your induction application.

Access the application form from the ICRF website or by contacting imperial.icrfinduction@nhs.net. Complete the form and get it signed by your supervisor. The supervisor should be a senior ICL/ICHNT colleague willing to take responsibility for your work at the ICRF. Principal Investigators do not require a supervisor.

Clarify with your supervisor any uncertainties about your role at the ICRF before completing and submitting your application form. Principal Investigators should liaise with the Head of Clinical Studies if necessary.

Email the completed and fully signed application form (ICRF-OR05 Fm1) to imperial.icrfinduction@nhs.net together with the following documents. Collate all the documents and send attached to one email, rather than sending multiple emails:

- Signed CV (dated within last 2 years)
- GCP Certificate (dated within last 2 years)
- Trust or College Substantive Contract (or proof of employment from HR)
- Licence to attend /honorary contract/ letter of access (as applicable)

You will then be registered on the SOP system EQMS. Login to read the relevant documents and acknowledge them electronically.

After providing the application documents and acknowledging the SOPs you will be invited to an on-site induction. Once the induction has been completed you will be given swipe-card access to the facility on your existing card. Your supervisor / line manager is responsible to apply for your cards.

4.4 Induction of ICRF Staff (Line managers' responsibilities)

Inform the QAGM of the new joiner's start date so they can be added on EQMS and check when the next available induction is scheduled. An ad-hoc induction may be arranged when necessary.

Create a training folder (refer to ICRF-OR03) ahead of the staff member's first day and ensure the relevant documents are printed and ready to be completed. QAGM can supply a green folder for this purpose. Follow the Preparation for New Starters checklist (ICRF-OR05 Fm5) to ensure preparation for the new starter is complete.

On the new joiner's first day, complete the staff induction form (ICRF-OR05 Form2 for ICRF staff) which contains a checklist of local training and induction requirements.

	New joiners must also complete a College safety induction on, or soon after their first day. This is conducted by the ICRF GM or their delegate.
	Provide the new staff member with their training folder and ask them to maintain it moving forward. Schedule the induction date in their calendar if it was not completed on their first day.

4.5 Induction of Students, Bank or agency staff or other temporary staff
The ICRF requires all temporary staff to undertake an induction programme relevant and proportionate to their role. The staff member to whom the new starter reports should follow the process described in 4.4, with the following caveats:
Temporary staff will be given an induction proportionate to the tasks they will be conducting at ICRF. Normally such staff are closely supervised and do not conduct complex study tasks or maintain study documentation. Documentation will also be proportionate to the tasks performed.
Bank or agency staff who are booked only to provide clinical cover such as routine nursing or medical duties, and will not be carrying out study specific tasks, are outside the scope of this SOP. They do not require documented induction, a training folder will not be required, nor will CV, GCP or any other research documents. Such staff will not be listed on delegation logs and will not complete CRFs or other study documentation. The lead nurse will assess their clinical competency and arrange appropriate training and access to relevant systems, documented according to the relevant Trust requirement.
Prior approval from the ICRF Lead Nurse or their delegate is required before any Bank or agency staff may be given swipe card access.

4.6 Induction for visitors including service and support staff
There will be no formal induction process for one-off or very occasional visitors to the unit. The access provided will depend on whether the visitor is employed by the Trust / College, the length and purpose of their visit as described below.
College or Trust employed visitors attending for ad hoc work in ICRF will report to the main ICRF reception in order to be given relevant instructions, based on the task for which they are attending. They will be required to sign out a visitors' lanyard together with their supervisor in ICRF at the main ICRF reception. The visitor card must be returned at the end of the day. Inducted researchers or students on longer placements can borrow temporary access badges via the nurse in charge.
Regular support staff (e.g. domestic services) are given relevant training as part of their role in order to work within Trust departments. They are outside the scope of this SOP and there will be no additional ICRF induction for these staff. However they work under the oversight of the lead nurse (or delegate) who will inform them of any additional requirements specific to ICRF facilities.
Students and colleagues of researchers attending the unit for less than one week (e.g. when wishing to 'shadow' colleagues) will not be given induction or issued with swipe card access. The ICRF administrator will advise them of basic emergency and safety procedures. Such staff must be accompanied at all times whilst in the ICRF and may not carry out study tasks.
Visitors from outside the College or Trust, including monitors, couriers and inspectors will not be issued with an access swipe card and must be accompanied when moving around the unit.

	Couriers should collect from and deliver to main reception and therefore will not require access to other areas in the ICRF. External monitors, auditors and inspectors will be expected to remain in the monitoring room for most of the day and must be accompanied by ICRF staff when requiring access to other areas.
	All contractors who carry out work directly impacting on the building infrastructure, must undergo a building induction with the ICL Building Manager before commencing work in the ICRF.
	A Permit to Work must be issued for any contract work in restricted areas (labs).

4.7 Processing non-Staff Applications for Induction and Access to ICRF (ICRF Administrator)	
	Applications to ICRF for non-staff will be processed by the ICRF administrator.
	Upon receipt of an application from a non-staff member, check the spreadsheet *Users waiting for induction LIVE* (*S:\Imperial CRF\Facilities and Environment\Access to ICRF*). If the person is not listed, it may be because their study has not yet been approved by PRB, so that will need to be checked. The spreadsheet also acts as a checklist to help track the required documents.
	Follow the EQMS SOPs 1 and 2 (*S:\Imperial CRF\SOPs, Policies and Procedures\USING EQMS*) to create an account on EQMS and send them the relevant SOPs.
	Update the details on the spreadsheet and save copies of the application documents (CV, GCP etc) on the shared drive under *S:\Imperial CRF\Education and training\Training records\Training records - investigators & pharmacy*. Create a new folder for them if necessary.
	Invite the relevant users to the next induction date upon receipt of their completed CV, GCP certificate and signed induction form
	Check that all induction documents are saved on the shared drive and scan in the completed application form with the signed induction checklist. File paper copies in the ring-binder in the staff lounge.
	Request swipe-card access for the new user by following the ICRF security access guidance.

4.8 Processing Staff Applications for Induction (QA Team)	
	When informed of a new joiner, add them to the spreadsheet *Users waiting for induction LIVE* (*S:\Imperial CRF\Facilities and Environment\Access to ICRF*).
	Add the staff member to EQMS and assign them to the relevant staff group (refer to EQMS SOPs 1 and 3 saved at S:\Imperial CRF\SOPs, Policies and Procedures\USING EQMS). If it is not clear which staff group they belong to, check with their line manager.
	Create an electronic training folder for them at *S:\Imperial CRF\Education and training\Training records\Training records - CRF staff*
	If not already added when badge issued, request swipe-card access for the joiner by following the ICRF security access guidance. This can be done before induction, as they will be supervised by their line manager and other ICRF staff.

4.9 Removal of Swipe Card Access	
	Initially, duration of access will be set according to the expected study completion date documented on the user's application form, although this can be extended. For staff it is indefinite, so will need to be cancelled if the staff member leaves.
	Swipe card access to the ICRF will be cancelled by the ICRF administrator once regular interaction with the ICRF is at an end. Access may also be removed at the discretion of the ICRF Senior Management Team if users breach ICRF policies and procedures.
	To remove access, email id.card@imperial.ac.uk. Coloured ICRF card holders must be returned to the ICRF reception team.

5. Related Documents and References

ICRF Documents

- ICRF-OR05 Form 1 New User Application Form & Checklist
- ICRF-OR05 Form 2 Staff Induction Checklist
- ICRF-OR05 Supp 1 Welcome Pack For Clinical Staff
- ICRF-OR05 Supp 2 Welcome Pack for Non-Clinical Staff
- ICRF-OR05 Supp 3 User Guidelines
- ICRF-OR05 Form 4 Induction form for Annexe and Pod

ICHNT Documents

- Imperial College Healthcare NHS Trust Corporate and Local Induction Policy and Procedure https://intranet.imperial.nhs.uk/Interact/Pages/Content/Document.aspx?id=3039
- Imperial New Starter Orientation and Competency Handbook for Registered nurses http://source/cs/groups/intranet/@clinical/@nursing/documents/doc/id_036652.pdf

ICL Documents

- Day One Safety Induction checklist https://www.imperial.ac.uk/staff/new-staff/guidance-for-managers/safety/

External References

- Induction Framework for Clinical Research Staff. The UKCRF Induction Framework Project Group. UKCRF Network Education & Training Group