Title: Induction to the Imperial Clinical Research Facility

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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 SOP becomes Live:	14 May 2018
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Target Audience:	All staff and researchers working in the ICRF
Location of SOP:	Electronic: https://sites.google.com/a/nihr.ac.uk/imperial-clinical-research-facility/home Paper: Imperial CRF Master File, Nurses Station and 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.

1.0 Background

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

The ICRF requires staff to undertake orientation and induction programmes relevant to their role. ICRF staff may be employed by Imperial College Healthcare NHS Trust (ICHNT) or via Imperial College London (ICL). Investigators using the ICRF when conducting a clinical study will require appropriate induction as will temporary and Bank staff plus supervisors of support staff such as cleaners.

The purpose of the induction is to ensure operations and procedures are conducted in the centre accurately, safely and effectively in line with the required standards. This procedure is for induction and orientation to the ICRF. Staff working in other departments or areas are expected to attend the required induction for those areas including Trust Corporate Induction for ICHNT employees, College Safety Induction for ICL staff and other Inductions when relevant.

This SOP has been written according to the guidelines set out in the UKCRF Network Induction Framework for Clinical Research Staff.
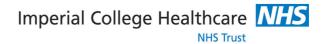
2.0 Purpose

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

3.0 Scope

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

4.0 Responsibilities

4.1   The ICRF General Manager or their delegate is responsible for ensuring that:

4.1.1   All medical, regulatory, administration and support staff working in the ICRF attends induction as outlined in this SOP before they are given access to work in the unit.

4.1.2   Supervisors or managers of support staff e.g. cleaners, are provided with induction to local practices where these are not standard or common in their fields.

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

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

4.2   The ICRF General Manager or their delegate is responsible for ensuring staff receive induction regarding College procedures.

4.3   The Quality Assurance & Governance Manager (QAGM) or their delegate is responsible for providing personal training files and generating staff and user records on the ICRF Training records database located on the ICRF Shared Drive.

4.4   The QAGM or their delegate is responsible for ensuring this SOP is approved, circulated as relevant and updated as required.

4.5 All ICRF staff and users are responsible for:

4.5.1 Ensuring they attend induction events and meetings; ensuring completion of their induction program.

4.5.2 Ensuring their induction checklist is completed.

4.5.3 Identifying gaps in their understanding and requesting additional information or training.

4.5.4 Complying with the instructions provided during the induction.

4.5.5 All staff and users must be aware of the responsibility of 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.
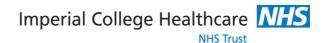
5.0 Glossary

Bank staff/Agency Staff	An individual working temporary shifts or additional shifts either employed by the ICHNT or by a nurse bank provider; generally employed for ad-hoc shifts covering sickness, annual leave or seasonal pressures.
Contractors	An individual working through an external company employed by ICHNT, ICL or Sponsors
GCP	Good Clinical Practice
Honorary staff	An individual employed by one organisation but working part time or full time in another e.g. Imperial College staff working in the ICHNT or vice versa.
ICHNT	Imperial College Healthcare NHS Trust
ICHNT ID Card	Imperial College Healthcare NHS Trust Identification Card
ICL	Imperial College London
ICRF	NIHR Imperial Clinical Research Facility
ICRF users	Study team member who requires access to the ICRF
Induction	A structured and comprehensive process which provides the new member of staff with the initial knowledge they need to be able to work effectively in their roles.
Investigators	Imperial College Healthcare NHS Trust Staff, Imperial College London Staff or other Academic/Industry staff who are involved in trials in the ICRF.
Letter of Access	Required by individuals who are not contractually employed by the Trust, but who will work in Trust premises. Only applicable for staff whose work will **not** impact on patient care.
Licence to Attend	Required by individuals who are not contractually employed by the Trust, but who will work in Trust premises and whose work may impact on care of Trust patients.
Core Skills training	A core training requirement determined by the Imperial College Healthcare NHS Trust (ICHNT) through policy which is compulsory for staff to complete if appropriate to their role. Core skills training does not relate to the requirements of professional registration.
Medical staff	Anyone on the GMC register with full or partial registration
Non-medical –	Any member of staff with no professional clinical qualifications

Non clinical	
Non-Medical – Clinical	Any healthcare professional other than doctors
SOP	Standard Operating Procedure
Swipe Access	An Imperial College London identification card that allows access to Imperial College buildings.

6.0 Procedures

6.1 **General Principles**

6.1.1 Induction will be coordinated by the ICRF Administrator, but the following staff will take overall responsibility:

- Principal Investigator / Academic Supervisor for researchers
- Lead nurse for Non-medical clinical staff
- ICRF General Manager for non-clinical ICRF staff.
- QAGM is responsible for overseeing compliance with this process.

6.1.2 All users of the ICRF, including ICRF staff must have an induction and orientation of the local facilities. They will also be sent a Welcome Pack (ICRF-OR05 Supp1 or ICRF-OR05 Supp2) or Introductory Guidelines (ICRF-OR05 Supp3), which can be retained for reference purposes as a quick guide to the ICRF.

6.1.3 ICRF Users (i.e. those not employed by ICRF) will be invited to an Induction & Orientation only after their study has been approved by the Protocol Review Board and following completion of the required paperwork (as described in section 6.2).

6.1.4 New staff in the ICRF will usually be invited to the first available Induction & Orientation 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 (as described in section 6.2) has been completed, but this can be done after the day of Induction & Orientation.

6.1.5 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 6.4 for further details.

6.1.6 The Induction and Orientation will involve a tour of the ICRF facilities, instructions to follow in emergencies, introduction to relevant staff, overview of relevant policies and SOPs, expectations for professional conduct, training requirements and an overview of general information and administrative matters. The following staff (or their delegate) will present as part of each Induction and Orientation:

- ICRF Administrator: Introduction and general information

- Lead Nurse: Tour of clinical areas and requirements for participants

- Lab Manager: Tour of labs and requirements for using labs (as applicable)

- Quality Assurance & Governance Manager: Evacuation procedures, overview of SOPs, incident reporting and security

6.2 Process for Completing Induction & Orientation

The process for Induction and Orientation of ICRF users (non-staff) will be as follows:

6.2.1 Induction and orientation will be scheduled by the ICRF Administrator to happen at regular time-points and at least once per month.

6.2.2 Anyone wishing to start using the ICRF for a project should send an email to: imperial.icrfrec@nhs.net. This email should state the name of the project, the date it was approved by PRB and the start date from which the user requires access to the ICRF.

6.2.3 Provided the request is accepted and the study has been approved, the CRF administrator will send the applicant an Induction pack including the New User Application Form & Checklist (ICRF-OR05 Form 1) which describes what needs to be completed before booking a visit for Induction and Orientation, and Introductory Guidelines (ICRF-OR05 Supp3).

6.2.4 Before being invited to attend the Induction and Orientation, applicants must provide the following documents, fully completed:

- Signed CV (dated within last 2 years)
- GCP Certificate (dated within last 2 years)
- Trust or College Substantive Contract
- Licence to attend /honorary contract/ letter of access (as applicable)
- Staff requiring access to medical records must complete the Trust *Information Governance* training or the College's *Records Management* and *Freedom of Information & Data Protection* training.
- ICRF New User Application Form and Checklist (ICRF-OR05 Form 1)

6.2.5 Induction will be recorded in the New User Application Form and Checklist (ICRF–OR05 Form1) which will be countersigned on the day of Induction and Orientation.

6.2.6 Once the Induction & Orientation has been completed, and the User Induction Checklist signed, the applicants will be taken to the College security office to obtain a swipe card giving access to the facility.

6.2.7 The QA Manager will register new users on the ICRF training database.

6.3 Induction of Bank or agency staff

6.3.1 The ICRF requires all Bank or agency staff to undertake an orientation and induction programme relevant and proportionate to their role.

6.3.2 Where bank staff are booked to ensure appropriate clinical cover such as nursing or medical duties, such staff may not require a valid GCP certificate. Where they are not expressly carrying out research specific duties but rather administering direct medical or nursing care this will be indicated on the New User Application Form and Checklist (ICRF–OP05 Form1).

6.3.3 Prior approval from the ICRF Lead Nurse or their delegate is required before any Bank or agency staff may be given swipe card access.
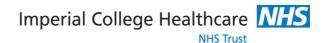
6.3.4 The Lead Nurse will coordinate induction and arrange access to relevant IT systems .

6.3.5 The Lead Nurse or delegate will coordinate and organise an induction and orientation of the local facilities to include as applicable:

- Introduction to colleagues
- Guided tour of Facility, e.g.: Ward/Labs/Offices/ kitchen
- Building facilities, including: Fire escape routes/muster points/Toilets
- Location of emergency equipment.

6.3.6 The appropriate induction will be recorded in the New User Application Form and Checklist (ICRF–OR05 Form1) which will be countersigned on the day of Induction and Orientation.

6.4 **Induction for others including service and support staff**

6.4.1 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.

6.4.2 College or Trust employed visitors will report to the main ICRF reception in order to be given relevant instruction based on the task they are attending for. These staff may be required to sign-in and out of the building at the main ICRF reception and where appropriate will be issued with a temporary swipe access card and a visitors badge to be worn at all times. They will be informed of emergency and safety procedures. The temporary access swipe card must be returned at the end of the day.

6.4.3 Students and colleagues of researchers attending the unit for less than one week (e.g. when wishing to 'shadow' colleagues) will not be given an induction or issued with swipe card access. They will be required to sign in at main reception, will be issued with a paper visitors badge and must be accompanied at all times whilst in the ICRF. Security access will only be granted to those that apply according to the process in 6.2.

6.4.4 Visitors from outside the College or Trust, including monitors, couriers and inspectors will not be issued with an access swipe card and should 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 of the department.

6.4.5 All contractors who will 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.

6.4.6 A Permit To Work must be issued for any contract work in restricted areas (labs).

6.5 **Removal of Swipe Card Access**

6.5.1 Swipe card access to the ICRF will be cancelled once regular interaction with the ICRF is at an end. Access may also be removed at the discretion of the ICRF Management Team if users breach ICRF policies and procedures.

6.5.2 This will be arranged by the ICRF administrator by emailing or phoning security to remove the individual's access. The ICRF QAGM will also ensure a database of all personnel having swipe card access to the facility is maintained.

6.5.3 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.

7.0 Related Documents and References:

ICRF documents available at https://sites.google.com/a/nihr.ac.uk/imperial-clinical-research-facility/home

- ICRF-OR05 Form 1 New User Application Form & Checklist
- ICRF-OR05 Supp 1 Welcome Pack For Clinical Staff
- ICRF-OR05 Supp 2 Welcome Pack for Non-Clinical Staff
- ICRF-OR05 Supp 3 Introductory Guidelines

ICNHT Documents

- Imperial College Healthcare NHS Trust Corporate and Local Induction Policy and Procedure
  http://source/cs/groups/intranet/@corporate/@policies/documents/ppgs/corplocal.pdf
- 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
  http://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/staff-development/public/safety/Day-One-Safety-Induction-Form-22-Aug-17.pdf

Other

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