Training in the Imperial Clinical Research Facility

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Target Audience:	All ICRF Staff and Users
Location of SOP:	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:	
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Document version numbering

Version	Date	Updated by	Reason for change
1	Jul 2011	Karen Mosley	New policy
2	Dec 2011	Marion Watson	Rename to MWTCRF, update SOP format, minor clarifications.
3	Sep 2013	Marion Watson	Rename to Imperial CRF, addition of training matrix, addition of electronic tracker record, minor clarifications to procedures
4	Jan 2016	Ben Lodge Marion Watson	Clarification to procedures, definition of training, update to ICRF Users training.

1.0 Background

Clinical Trials Regulations require clinical trials to be conducted according to the principles of ICH-GCP. Staff working on research studies must ensure they are familiar with these requirements and that they maintain their own training records in order to demonstrate that they are 'qualified by education, training and experience to perform his or her respective task(s)' (ICH GCP 2.8).

For the purpose of this standard operating procedure training can be undertaken in a range of formats, including face to face, web-based and as self-directed reading. Training should be appropriate and proportionate to the type of research undertaken.

Employers (ICHNT and ICL) have separate systems for training they wish to record centrally.

2.0 Purpose

To describe procedures pertains to local training and how that training is recorded in the NIHR/Wellcome Trust Imperial Clinical Research Facility (ICRF) in order to ensure standardisation and completeness of documentation held by staff and Users.

3.0 Scope

This SOP applies to all staff and users of the ICRF.

4.0 Responsibilities

4.1 ICRF Management Team

- Agreeing SOP training required for each role in the Imperial CRF. This is recorded via a training matrix (ICRF-OR03 Form 1).
- Identifying any additional training required, on a study by study basis and highlighting this in the Clinical Risk Assessment and Management Plan.

4.2 ICRF Lead Nurse or delegate

- Issuing staff with a record file at induction
- Providing training in the maintenance of the file
- Updating staff and Users onto the ICRF electronic tracker

4.3 QA Manager or delegate

- Forwarding updated SOPs & polices to the ICRF staff and Users.
- Maintaining the ICRF electronic training tracker.
- Archiving copies of training records of staff leaving ICRF employment and Users finishing working at the ICRF.
- Auditing staff training files

4.4 Line Managers

Line managers should ensure that training records of their staff:

- Are reviewed at least annually, usually during staff appraisal or performance review and that they are complete. Review must also identify possible future training needs. This must also include a check on the Statutory and Mandatory Training requirements for the role.
- Comply with the ICRF training matrix.

4.5 All Staff and Users

Are responsible for maintaining their training and recording this in the appropriate record and ensuring that training records are updated on an on-going basis.

5.0 Glossary

CI	Chief Investigator
CRAMP	Clinical Risk Assessment and Management Plan
CTIMP	Clinical Trial Investigational Medicinal Product
ICHNT	Imperial College Healthcare NHS Trust
ICL	Imperial College London
ICNHT JRCO	Imperial College Healthcare NHS Trust Joint Research Compliance Office; the equivalent of Research and Development.
ICRF	Imperial Clinical Research Facility
ICRF staff	Staff directly employed by the Imperial Clinical Research facility, such as Nurses, Doctors or administration personnel.
ICRF Users	A clinical or non-clinical study team member who requires access to the ICRF to conduct a study in the ICRF.
ISF	Investigator Site File
iTMF	Investigator Trial Master File
nIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PRB	Protocol Review Board
R&D	Research and Development
SOP	Standard Operating Procedure

6.0 Procedure

6.1 ICRF Staff

6.1.1 At induction, ICRF staff will receive a Training Record File from the ICRF Lead Nurse or delegate. All SOP reading by the ICRF User must be documented on the Induction check list (ICRF-OR05 Form 1).

6.1.2 This file will contain the standard sections as detailed in Appendix 1 and are to be maintained in the order specified. Where there is more than one record i.e. multiple GCP certificates they will be maintained in the order with the most recent filed first.

6.1.3 During induction the ICRF Lead Nurse or delegate will provide training, on set up and maintenance of training records, including the electronic training tracker.

6.1.4 The Training Record File must be held in the designated area in the ICRF (Room G20) and must be readily available e.g. to managers, monitors, auditors, inspectors or others.

6.1.5 The line manager will ensure ICL safety induction is arranged for day 1 or as soon as possible thereafter. This may be provided by the ICL Campus Safety Manager or local nominee.

6.1.6 Statutory and mandatory training will be undertaken as per ICL or ICHNT systems and policies as applicable to the employees' contract. For ICHNT employees this is located on Induction, core skills and vocational training. For ICL Employees College training records are available via their Secure Access Gateway.

6.1.7 All training undertaken by the individual that supports and demonstrates their ability to undertake their responsibilities in the ICRF must be recorded. This should include but is not limited to the details outlined in Appendix 1.

6.1.8 Where there is prior evidence of training such as Venepuncture or Cannulation the ICHNT Policies and Procedures will apply to verification of such training.

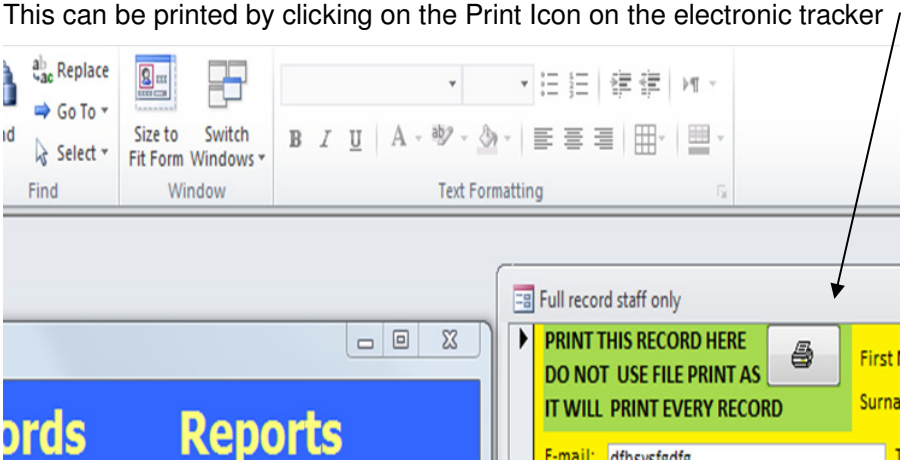
Where the training is below the standard set by the ICHNT Trust, or evidence of training is not supplied, training may need to be re-taken.

6.1.9 Further training that may be identified on a study by study case will be detailed on the Clinical risk assessment management plan (ICRF-OR09 Form 3 Clinical Risk Assessment and Management Plan).

6.1.10 When training is updated previous records and certificates in the Training Record File should be retained in the relevant section. The most recent training certificate or documentation must be filed first. Superseded/out dated filed must be filed after, they must not be discarded.

6.1.11 The ICRF staff member must ensure the electronic training database, stored on the shared drive is updated at regular intervals, at least annually. Once it has been updated or changed a copy of the training record should be printed and stored in the Training Record File.

6.1.12 This can be printed by clicking on the Print Icon on the electronic tracker



6.1.13 When an individual leaves the ICRF they must leave a copy of the contents of their Training Record File for archive. They may take the original certificates etc.

6.1.14 The Line Manager must inform the QA Manager or delegate that the individual has left so that the Training Record File can be archived.

6.1.15 The QA Manager or delegate will archive the individual's Training Record and electronic training tracker.

6.1.16 The archived Training Record File must be retained in archive, in the filing room G34, until no longer required for audit or inspection purposes, as a minimum this will be 15yrs.

6.2 ICRF Users

6.2.1 All ICRF Users must have a record of training received to be approved to conduct a study and have access to the ICRF.

6.2.2 Once a researcher requests access to the ICRF to work on an approved study, the Lead Nurse or delegate will issue them with an induction form.

6.2.3 All SOP reading by the ICRF User must be documented on the Induction check list (ICRF-OR05 Form 1). This training form must be completed and stored in the ICRF Users training file prior to swipe access being authorised. This is the minimum required to run a trial in the ICRF.

6.2.4 The ICRF User must also keep on file the documents outlined in Appendix 2 and in the order specified. Where there is more than one record i.e. multiple GCP certificates they will be maintained in the order with the most recent filed first.

6.2.5 Where there is prior evidence of training such as Venepuncture or Cannulation the ICNHT Trust Policies and Procedures will apply to verification of such training. Where the training is below the standard set by the ICHNT Trust, or evidence of training is not supplied, training may need to be re-taken.

6.2.6 Any study specific training required, or SOP reading above the standard SOPs on the induction worksheet will be detailed in the study specific CRAMP (ICRF-OR09 Form 3 Clinical Risk Assessment and Management Plan).

6.2.7 Any SOP required by the CRAMP must be documented by the ICRF User on the Induction check list (ICRF-OR05 Form 1).

6.2.8 The study specific training will be checked against the ICRF Induction check list prior to authorisation by the ICRF Lead Nurse.

6.2.9 The Training Record must be stored in the ICR Users Training File held in the designated area in the ICRF (Room G20) and must be readily available e.g. to managers, monitors, auditors, inspectors or others.

6.2.10 It is the responsibility of the PI or ICRF Users' Line Manager to ensure statutory and mandatory training is maintained.

6.2.11 The ICRF Users training files will be audited annually by the ICRF Lead Nurse or delegate to ensure training is up to date and in-line with agreed approvals.

6.2.12 Only the documents outlined in this SOP are required for evidence of ICRF training.

6.3 Site File, Study Training & Delegation Log – All ICRF Staff & Users

6.3.1 Site initiation, protocol reading and study specific training such as specific study equipment training will be recorded and stored in the ISF or iTMF as appropriate.

6.3.2 Where there could be any conflict as to whether training for a study constitutes study specific or general ICRF training this will be clarified and documented on the study specific CRAMP (ICRF-OR09 Form 3 Clinical Risk Assessment and Management Plan), including where the training records will be stored.

6.3.3 Where there are sponsor specific templates those will be used. If there are no templates provided to record such training then the following templates can be used; ICRF-OR17 Form 6 Site Staff Delegation log, ICRF-OR03 Form 2 Study Specific Training Log.

6.4 ICRF Electronic Tracker

6.4.1 All training is recorded onto the ICRF Electronic Tracker, to allow for efficient and timely checks of training.

6.4.2 If there is any discrepancy between the tracker and the paper files, the paper files are the primary and final documented evidence of training or lack of training.

6.4.3 Upon update of SOP version numbers, new SOPs or policies the electronic tracker dates will be archived within the database by the QA Manager or delegate.

6.4.4 The ICRF Lead Nurse or delegate will update the tracker for ICRF Users.

7.0 Related Documents and References:

- EU Clinical Trials Regulation 2014 http://ec.europa.eu/health/human-use/clinical-trials/regulation/index_en.htm
- ICH E6 Guideline for Good Clinical Practice (1996) http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html
- Research Governance Framework for Health & Community Care 2nd ed SEHD 2005 (due to be updated in 2016) http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/
- SOP ICRF-OR05 ICRF induction https://sites.google.com/a/nihr.ac.uk/imperial-clinical-research-facility/home

Associated forms and templates

- ICRF-OR03 Fm 1 ICRF Training Matrix
- ICRF-OR03 Fm 2 Training file template

8.0 Appendices

- Appendix 1: ICRF Staff Content of the Training Record File
- Appendix 2. ICRF User Content of the Training Record File

Appendix 1 – ICRF Staff Content of Training Record File

Section	Content
1) Induction	• A copy of the completed ICRF Induction form (ICRF-OR05 Form 1 Induction check list) • A copy of the ICL day 1 safety induction form
2) SOPs & Policies Training	• A printed copy of the staff members training log. The copy must be re-printed at least annually or when there are significant changes. .
3) Curriculum vitae, GCP, Job Description & Professional Registration	• Current CV demonstrating education, training, qualifications and experience to date. Reviewed annually and signed and dated by the individual within the last two years. NB Personal information such as home address and phone number should be omitted or may be blacked out. • Current job description. • Good Clinical Practice (2 yearly) from a recognised GCP course such as NIHR Introduction to GCP (including E-learning option) or NIHR GCP Refresher course or the GCP E-learning course provided by the Imperial JCRO or any GCP course listed on http://www.transceleratebiopharmainc.com/gcp-training-attestation/list-of-training-providers/ • Professional Registration Certificate(s) should be included here (copy verified by manager, updated annually)
4) Competencies & General Training	Competencies (If applicable to role):: • Aseptic Non Touch Technique (if applicable to role) every 3 years or as indicated. • IV administration (if applicable to role) • Venepuncture or Cannulation (if applicable to role). • Administration of Chemotherapy (annually - if applicable to role) • Basic Life Support (3 yearly), Intermediate Life Support (2 yearly) or Advanced Life Support (4 yearly) – as per job description/role. • ICRF Laboratory Competencies (determined per individual) • Point of Care Testing (POCT) - (if applicable to role).
5) Other	• Events relevant to current post and details of any relevant events attended prior to appointment with a bearing on competence. • Evidence of mandatory organisational training e.g. fire safety, manual handling. Signed by the individual. • Seminars & Conferences relevant to role may also be included.

Appendix 2 – ICRF Users Content of Training Record File

1) Induction	• A copy of the completed ICRF Induction form (ICRF-OR05 Form 1 Induction check list)
2) SOPs & Policies Training	• A copy of the ICRF Training Tracker User Form. The copy must be updated by the user upon new training/SOP reading.
3) Curriculum vitae, GCP, Licence To Attend & Professional Registration	• Current CV demonstrating education, training, qualifications and experience to date. Reviewed annually and signed and dated by the individual within the last two years. NB Personal information such as home address and phone number should be omitted or may be blacked out. • Good Clinical Practice (2 yearly) from a recognised GCP course such as NIHR Introduction to GCP (including E-learning option) or NIHR GCP Refresher course or the GCP E-learning course provided by the Imperial JCRO or any GCP course listed on http://www.transceleratebiopharmainc.com/gcp-training-attestation/list-of-training-providers/ • ICHNT Licence to Attend or Honorary Contract, date section as a minimum. This must be in date or evidence of the application or renewal being in progress must be provided.
4) Competencies & General Training	Competencies (If applicable to role): • Aseptic Non Touch Technique (if applicable to role) every 3 years or as indicated. • IV administration (if applicable to role) • Venepuncture or Cannulation (if applicable to role). • Administration of Chemotherapy (annually - if applicable to role) • Basic Life Support (3 yearly), Intermediate Life Support (2 yearly) or Advanced Life Support (4 yearly) – as per job description/role or as determined at PRB review of the researchers studies. • ICRF Laboratory Competencies (determined per individual) • Point of Care Testing (POCT) - (if applicable to role).0.9% Sodium Chloride administration training.
5) Other	• Events relevant to current post and details of any relevant events attended prior to appointment with a bearing on competence e.g. hygiene / food handling training.