Title: Standard Operating Procedure for Staffing at the Imperial Clinical Research Facility

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Related SOPs and Policies:	ICRF-OR11 Management of Dose Escalation Procedures for Phase I/ First in Human Studies Conducted in the ICRF

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Document version numbering

Version	Date	Updated by	Reason for change
2	31 Aug 2009	Karen Mosley	Periodic review
2.1	13 Oct 2009	Karen Mosley	Addition of cc address for CA and ITU contact
3	22 Jul 2010	Karen Mosley	Exemption for subsequent dosing where subjects have self-administered and change of ITU contacts.
4	24 Aug 2012	Karen Mosley, Vincenzo Libri	Periodic review, change of site and change of CRF name
5	11 May 2015	Ben Lodge	Periodic review, title change, update of processes, merger with nursing and medical cover SOPs
5.1	11 Jan	Susanne Fagerbrink	Periodic review, update of ICRF ILS/BLS requirement

1.0 Background

The NIHR/Wellcome Trust Imperial Clinical Research Facility (ICRF) supports the conduct of a broad range of clinical research studies involving patients and healthy volunteers. This Standard operating procedure (SOP) details the staffing requirements and processes in the ICRF for all studies in both healthy volunteers and patients.

The level of support provided by the ICRF on the management of research studies can vary from full support of project managers, physicians and nurses to very minimal support.

The Principal Investigator (PI) has continuous (24hr) responsibility for participants on their study, including out-of-hours medical cover, and must nominate suitable cover (delegate) if they are unavailable at any time. While the ICRF can provide immediate medical cover during working hours (9am-5pm, Mon-Fri) the PI (or delegate) must still be available, if required, during these times.

2.0 Purpose

This SOP relates to staffing levels within the ICRF of both clinical trials of investigational medicinal products (CTIMPs) and Non CTIMPs.

3.0 Scope

This SOP applies to all research users conducting clinical trials within the ICRF and all staff employed by the ICRF.

4.0 Responsibilities

4.1 The PI is responsible for the clinical safety of participants in their research study. They must nominate suitable cover or a suitable delegate if they are unavailable at any time.

4.2 The PI retains responsibility for all study procedures. They are responsible for ensuring all staffing requirements are agreed with the ICRF Management Team as part of the study approval processes.

4.3 The PI is responsible for agreeing any requests for change in staffing cover with the ICRF Management Team prior to any dosing days.

4.4 The PI is responsible for ensuring all staff working on a study are appropriately trained and have been signed off on the study delegation log prior to undertaking any study activities within the ICRF. The updated delegation log must be available within the ICRF or specific study folder in S:\Imperial\STUDY FOLDER.

4.5 The ICRF Management Team are responsible for ensuring that agreed staffing levels are in place to protect the safety and welfare of subjects, staff and visitors in the ICRF.

4.6 The Lead Nurse is responsible for ensuring that all ICRF nurses receive training in this SOP. The Head of Clinical Studies is responsible for ensuring that all ICRF doctors receive training in this SOP.

4.7 The Lead Nurse is responsible for highlighting any deviation from the ICRF Staffing Level Agreement in the Clinical Risk Assessment and Management Plan (CRAMP) to the ICRF Management Team.

4.8 The nurse in charge (NIC) at the time of any deviation from the staffing level agreed in the CRAMP is responsible for reporting the event to the Lead Nurse and reporting any incidents on DATIX.

4.9 The QA Manager is responsible for organising monitoring, auditing and adherence to these procedures and reporting any findings to the Quality Health and Safety Committee.

5.0 Glossary

BLS	Basic Life Support
CRAMP	Clinical Risk Assessment and Management Plan
CTIMP	Clinical Trial of an Investigational Medicinal Product
DATIX	Imperial College Healthcare NHS Trust online incident reporting form
Delegate	The cover must be an appropriately qualified and experienced doctor trained on the protocol. The ICRF Management Team must be made aware of any changes to the stated cover arrangements in advance.
ICRF	Imperial Clinical Research Facility
ICRF Management Team	Team consisting of the ICRF Head of Clinical Studies, Lead Nurse and General Manager
ICRF Medical cover	Qualified medical cover with appropriate training and experience, including ALS training, and based at the ICRF. A roster is in place to cover 9am to 5pm. Out of hours cover has to be agreed on a study specific basis.
ILS	Immediate Life Support
NIC	Nurse In Charge
Phase 1 Clinical trial	The stage of drug development when the investigational product is first researched in humans and when drug safety is determined.
Physician Cover	A qualified doctor with appropriate training and experience.
PRB	Protocol Review Board
Principal Investigator (PI)	A qualified doctor with appropriate training and experience who has direct responsibility for the study at this site (Imperial College Healthcare NHS Trust: Hammersmith Campus).
'Within the hospital'	Staff referred to as 'within the hospital' must be within contact of the ICRF and must be able to reach the ICRF immediately (within 10 minutes). They also must be contactable by bleep or mobile phone.

6.0 Procedure

6.1 Clinical Risk Assessment and Management Plan and Minimum Staffing Level

6.1.1 There must be a minimum of 2 (two) life support trained staff in the ICRF at all times while trial/study participants are present; 1 (one) Immediate Life Support (ILS) trained and 1 (one) with a minimum of Basic Life Support (BLS) training. They must have received appropriate ICRF induction. Any variation from this must be justified, risk assessed, approved by the Head of Clinical Studies or Director, and documented in the CRAMP or Datix risk assessment section.

6.1.2 The PI must submit an application for the study to be conducted in the ICRF to the ICRF Protocol Review Board (PRB).

6.1.3 The level of ICRF staffing support for all CTIMP studies shall be specified and detailed within the ICRF CRAMP. Staff will be appropriately trained on the CRAMP prior to delegation on any trial, and after any update.

6.1.4 The PRB in consultation with the PI will risk assess the study application and appropriately risk score the study. This will be clearly documented in the CRAMP

and will include any mitigation, pre agreed staffing levels and conditions for usage of the ICRF such a designated rooms or dosing days.

6.1.5 The PRB can, at their discretion and in view of the risk assessment, specify a greater number of ICRF staff to be present than specified in 6.1.1, depending on but not exclusive to, intensity of visit, planned number of subjects dosed and/or category of IMP. This will be documented on the study specific risk assessment and management plan.

6.1.6 Prior to ICRF staff dosing a participant on a CTIMP study in the ICRF, the ICRF Dosing Checklist must be completed and the pre-agreed level of cover (6.1.1 or as detailed on the CRAMP) must be documented and confirmed. Any deviation from this cover must be highlighted to the ICRF Lead Nurse or Head of Clinical Studies (or delegate). Dosing **must not** proceed until any inconsistency has been resolved and documented on the ICRF Dosing Checklist.

6.1.7 Where a pre-agreed level of cover is not maintained or met, final decision to dose lies with the Head of Clinical Studies of the ICRF or delegate.

6.1.8 The ICRF CRAMP will be kept and maintained on the specific study folder in S:\Imperial\STUDY FOLDER. The most up to date hard copy will be kept at the ICRF Nurses' Desk.

6.2 Changes to Staffing Levels during studies

6.2.1 If the research team acquire any further information that may affect the staffing level agreement, they must inform the PRB without delay. This must be before the next planned dosing visit if the study is a CTIMP.

6.2.2 The PRB will review the information and adjust the CRAMP as appropriate. The new CRAMP will be circulated amongst the study team and ICRF staff by the ICRF General Manager or Lead Nurse so that staff may be appropriately re-trained if necessary.

7.0 Related Documents and References:

- Guidelines for Phase 1 Clinical Trials ABPI http://www.abpi.org.uk/our-work/library/guidelines/Documents/phase1-trial-guidelines.pdf
- Annex 5: Guidance for the Conduct of Good Clinical Practice Inspections ENTR/F/2/SF, European Commission http://ec.europa.eu/health/files/eudralex/vol-10/2008_11/vpl10_an5_10-2008_en.pdf

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

- ICRF-OR09 Form 3 Clinical Risk Assessment and Management Plan (CRAMP)
- ICRF-OR11 Form 1 Dosing Checklist
- ICRF-OR05 ICRF Induction SOP