**SOP for Identification, Admission and Discharge of Research Participants in the NIHR/Wellcome Trust Imperial Clinical Research Facility (ICRF)**

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| Target Audience: | ICRF operational, nursing and medical staff, Researchers using the ICRF |
| Location of SOP: | Electronic: https://sites.google.com/a/nihr.ac.uk/imperial-clinical-research-facility/home<br>Paper: Imperial CRF Master File, Nurses' Station, Staff lounge. |
| Related SOPs and Policies: | ICHNT policies on patient identification and self-administration of medicine policy (see section 8 for links). |

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**Document version numbering**

| Version | Date | Updated by | Reason for change |
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| 1 | March 2014 | N/A | New SOP |
| 2 | July 2017 | S. Fagerbrink | Update of admission procedures. Approval by ICHNT in preparation for Cerner |
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## 1.0 Background

This document describes the processes and responsibilities of all staff in the NIHR/Wellcome Trust Imperial Clinical Research Facility (ICRF) in correctly identifying, admitting and discharging all research participants attending the facility. The ICRF conducts studies where research participants attend for a short visit (less than two hours), a day case visit (more than two hours, but not overnight) or an over-night stay visit (one or more nights). As studies are directed by strict protocols as to who can participate, correct identification is a key element of participant safety. Staff and researchers have a duty of care to ensure correct participant identification and admission procedures are carried out including completion of all required documents.

The implementation of this standard operating procedure (SOP) is required to comply with the NPSA Safer Practice Notice 'Standardising wristbands improves patient safety' (NPSA, 03 July 2007), the NHSLA Risk Management Standards for acute Trusts (April 2008) and ICH-GCP requirements. This document must be read in conjunction with ICHNT policies and procedures including patient identification and self-administration of medicine.

At the ICRF healthy volunteers who participate in research are registered as patients. This facilitates use of Trust premises and services, particularly the analysis of samples in Trust laboratories. Although this creates a healthcare record for each volunteer, medical history will be absent or scant. Recording the GP contact details ensure the researchers can contact the GP as required for the study.

## 2.0 Purpose

This SOP describes the responsibilities and procedures to be followed at the ICRF when research participants attend for a study visit and to ensure participants are correctly identified at each visit.

## 3.0 Scope

This SOP applies to the identification, admission and discharge of all research participants attending the ICRF.

## 4.0 Responsibilities

It is the responsibility of the Lead Nurse, or their delegate, to ensure ICRF nurses are trained in these procedures. For researchers, training is the responsibility of their Principal Investigator.

It is the responsibility of the ICRF Administration Team to carry out the initial identification and registration of all study participants.

It is the responsibility of the ICRF administrative staff and the nurse in charge (NIC) to work together, on a daily basis, to facilitate effective allocation of resources (clinical staff and rooms). It is essential during the process that the admitting nurse/researcher ensures that all the relevant admission documents are completed including an initial assessment of patient status.

It is the responsibility of all clinical staff and researchers in the ICRF to follow this SOP for the admission and discharge of all participants.

## 5.0 Glossary

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| Short visit | A visit less than two hours (e.g. for consent and screening (basic) or a follow-up appointment. This type of visit involves minimal risk engagement e.g. physical examination, blood sampling; it would not usually require invasive procedures or first-time dosing. |
| Day case | A visit of more than two hours, but not an overnight stay, or for invasive |

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| visit | procedure(s) or activities that involve being reviewed by many healthcare workers at different times. This type of visit usually involves more nursing/medical cover than short visits e.g. cannulation, blood sampling, IMP dosing, study specific assessments, etc. |
| Overnight stay visit | A visit for patients or healthy volunteers which extends to staying overnight for the continuation of study assessments e.g. preparation for procedures, monitoring of adverse events, blood sampling, timed overnight study specific assessments etc. |
| Healthy Volunteers (HVs) | Volunteers who have been recruited to research studies as healthy. This may include participants with medical conditions, but their condition does not exclude them from the study (as laid down in the protocol). |
| ICHNT | Imperial College Healthcare NHS Trust |
| ICRF | NIHR / Wellcome Trust Imperial Clinical Research Facility |
| NIC | Nurse in Charge |
| Patients | Research participants who have been recruited to research studies based on their medical condition |
| PRB | Protocol Review Board |
| SOP | Standard Operating Procedure |
| Participants | Research participants including patients and healthy volunteers |

## 6.0 Procedure

### 6.1 Initial Identification - Healthy volunteers

All healthy volunteers are registered as patients of the ICHNT by the ICRF administrators. A set of hospital healthcare records are generated, usually before their first visit to avoid delaying them.

In addition each healthy volunteer must be registered with a GP and be able to provide the details of their NHS number on the date of their registration. For non-UK nationals not normally resident in the UK they must provide the equivalent details (family doctor and relevant reference number).

Where required by the protocol or Protocol Review Board (PRB) the volunteers should be registered on TOPs using their NI number or Passport number to check recent participation in other studies, refer to SOP ICRF OR04 Over volunteering Prevention (TOPs).

The ICRF-OR08 Fm 3 `NIHR/Wellcome Trust Imperial CRF Healthy Volunteer Identity Form` can be used as a document for identification.

### 6.2 Initial Identification - Patients

For each patient the investigator must provide a booking form which includes the following details:

- Name of the patient
- Date of birth
- Address
- NHS number/ hospital number
- GP details, if known

The administrator must check these details with the patient and update the electronic records as required.

### 6.3 Identification at subsequent visits

The identity of each participant must be checked at every visit by the researcher or research

nurse in accordance with the ICHNT Patient Identification Policy. The participant should be asked to state their full name and date of birth. Additional steps must be taken if the participant cannot converse with staff such as asking a relative or a staff member who has cared for them previously for confirmation. Details must be checked against the documentation available e.g. ICRF healthy volunteer identity form or healthcare records.

A wrist band must be applied to all participants who attend for a day case or overnight stay. The wristband must:

- Bear the participant's last name, first name, date of birth and NHS number (or hospital number if NHS number is not possible)
- Be a printed wristband or clearly written by hand in black ballpoint pen using block letters (printed sticky labels from the healthcare records should not be used (ICHNT Trust policy)
- Be a white wristband with black text
- For any known allergies, a red wrist band must be used and the allergy must be documented in the relevant section of the healthcare record.

The research nurse or the researcher is responsible for informing the NIC or the Lead Nurse of participants who cannot or will not wear a wristband due to:

- Their clinical condition or treatment, for example, multiple intravenous access lines
- Skin allergies or other dermatology conditions and treatments
- Refusal to wear a wristband or the participant removes the wristband.

In such cases the participant must be given a clear explanation of the risks of not wearing a wrist band. This discussion and the reason for the participant not wearing the wristband must be documented in the healthcare record.

### 6.4 General Admission Procedure

The ICRF admission procedures described on form ICRF-OR08 Fm1 must be completed and recorded using ICRF-OR08 Fm2. Procedure specific forms and leaflets are available from ICHNT, links are provided in section 7 below.

### 6.5 Discharge

The attending research nurse or the researcher is responsible for the safe discharge of their research participants. Procedures are listed In ICRF-OR08 Fm1.

## 7.0 Procedure specific forms and leaflets

Paper copies stored at the nurses' station:

- Medicine prescription and administration chart
- Early Warning Observation Chart
- Assessment for self-administration
- Self-administration of medicines patient information leaflet

Trust documentation for use in clinical areas as required can be downloaded from the ICHNT Source

- http://source/nursingandmidwifery/core-documentation/index.htm
- http://source/prdcont/groups/intranet/@clinical/@nursing/documents/information/id_051936.pdf

Examples of available documents:

- Adult Basic Admission documentation

- Adult inpatient risk assessments
- Adult inpatient nursing care plans
- Capillary Blood Glucose Chart
- Intake/Output chart
- Nasogastric tube: Insertion and Confirmation of Position chart
- Patient repositioning chart
- Peak Flow Chart
- Stool chart
- Wound, pressure ulcer & continence damage on-going care record

## 8.0 References

- ICHNT Patient identification Policy: http://source/prdcont/groups/intranet/@corporate/@policies/documents/ppgs/id_023319.pdf
- ICHNT policy on self-administration of medicines http://source/cs/groups/intranet/@corporate/@policies/documents/ppgs/id_022723.pdf
- SOP ICRF-OP04 Over volunteering Prevention System (TOPs)

## 9.0 SOP forms

- ICRF-OR08 Fm 1 Procedures for participants' identification, admission and discharge
- ICRF-OR08 Fm 2 ICRF Admission Form
- ICRF-OR08 Fm 3 NIHR/ Wellcome Trust Imperial CRF Healthy Volunteer Identity Form