

Standard Operating Procedure

<b>Title: RECRUITMENT AND SCREENING RECORDS</b>		
<b>REF: SOP 008</b>	<b>Version: 04</b>	<b>Issue No: 1</b>
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## 1. BACKGROUND

There are several steps involved in patient recruitment. These can be summarised as identifying a potentially suitable patient; obtaining informed consent from the patient screening the patient to ensure that they meet the inclusion and exclusion criteria; and the enrolment in the study.

Study protocols should identify exactly when a patient is considered as enrolled on the study.

ICH GCP requires that records are kept of every patient that undergoes pre-trial screening (ICH GCP 8.3.20) i.e. details of all patients approached for a study should be maintained. For the purposes of this SOP, this shall be referred to as a screening log.

## 2. PURPOSE

To describe the procedure for recruiting patients into a study and maintenance of a screening log.

## 3. OTHER RELATED PROCEDURES

SOP 006     Study files and filing  
SOP 007     Informed consent

## 4. WHEN

Before the first patient is approached for possible participation in a study, a study specific recruitment strategy must be identified. This should include the most appropriate forum for identifying and screening patients, as well as ensuring that the patients are to be approached in a suitable environment.

Recruitment rates should be assessed regularly, and reasons for shortfall identified.

## 5. WHO

The investigator or other specified member of the research team should ensure that a suitable method for documenting patient screening and recruitment is in place.

The research practitioner assigned to the study will be responsible for maintaining the screening log and ensuring that the sponsor is aware of recruitment progress.

All staff involved with the study should be fully familiar with screening and recruitment procedures, including associated paperwork.

## 6. HOW

In discussion with the Principal Investigator, network secretariat and sponsor, local recruitment targets should be set.

Every patient who is identified as potentially suitable for enrolment should be entered into the screening log.

Any paper copies of the screening log should be stored in the Study File.

Written informed consent must be obtained from all patients prior to commencing **any** study specific screening procedures.

The outcome of screening must be recorded on screening log.

If the study involves randomisation to treatment or therapy, the randomisation code should be entered on screening log. This may simply be a study number that is unique to the patient.

The screening log should include, but not be limited to, the following information:

- Patient initials
- Screening outcome:
  - Date consent
  - If consent was refused
  - Did or did not meet inclusion and/or exclusion criteria
- Date entered into study
- Study number or randomisation number
- Study status (ongoing, withdrawn, completed, died)