



Standard Operating Procedures

5.5.5 Allocation of Identification Numbers ©2008

History			
Version	Date	Author	Reason
1.1	6 th November 2007	B Fazekas	New procedure
1.2	8 th January 2008	B Fazekas	Update after MAB review
1.3	19 th February 2008	B Fazekas	Update after review by D Currow

Approval				
Version	Author	Signature	Approval Name	Approval Signature
1.3	B Fazekas	<i>B. Fazekas</i>	D Currow (CI)	<i>D. Currow</i>

Scheduled review

Date November 2009

Responsible person PaCCSC Project Officer

Purpose

People in clinical studies have the right to have their identity protected. Data collected is to be recorded in such a way that it is not possible to link individual study data with a specific person participating in the study. This is usually done through the use of identification numbers.

This SOP details how identification numbers will be allocated to people in the PaCCSC studies.

Other related SOPs

5.23.1 KPI compliance

5.5.1 Electronic Data Handling

Attachments

Other files that apply

Master Patient Index

References

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 250207)

<http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>

Acknowledgments

Trans-Tasman Radiation Oncology Group (TROG), for generous access to the Policy and Procedure Manual – the Red Book.

Definitions

Case Report Form (CRF)

A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject. All events described within the study protocol should be captured the CRF.

Informed Consent

A process by which a person voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to their decision to participate. Informed consent is documented by means of a written, signed and dated consent form, unless otherwise dealt with in an institutional ethics approved trial protocol.

Identification Number (ID number)

A unique identifier assigned by the investigator to each person participating in the study to protect the person's identity and used in lieu of the person's name when the investigator reports adverse events and/or other trial related data.

Pre-screening

The evaluation of a set of characteristics assessed and recorded prior to screening that determine eligibility. For example chart review, and discussion with clinical team. This information assists the study nurse to determine if the person is to be screened.

Screening

Screening involves collection of information that is in addition to clinical care, it is collected for the reason of assessing eligibility for the study. These assessments may be testing for cognition, level of function, taking blood samples, requesting medication history, etc. As such this information is always collected after consent has been obtained.

Person responsible

Coordinating site

Responsible for ensuring that a unique and unambiguous identification code is devised and circulated that allows identification of all the data reported for each person participating in the study.

Site coordinators

Responsible for allocating a unique code in accordance with the schema devised by the coordinating site to each person as they are referred to the study.

Site coordinators are also responsible for maintaining the patient master index, which provides the site specific link between the details of the person participating and the unique number allocated to them.

All data related to individuals is to be de-identified and stored in accordance with GCP and existing PaCCSC SOPs.

Study nurses

Responsible for ensuring that the unique number allocated to each person is used on all data forms and reporting records.

Procedure

On referral to the study.

A pre-screening form is completed containing the ID number allocated as described below.

The 7 digit number will contain;

A 2 digit study code

A 2 digit site code

A 3 digit participant number. This number is a sequential number starting at 001. This number is entered along with the individual's details into the site maintained patient master index as the site record of screening.

Study code

This code will identify each participant within a specific study. The codes are as follows.

Study	Code
Ketamine	01
Risperidone	02
Octreotide	03
Ketorolac	04
Megestrol	05
Ondansetron	06

Site code

Each site will be allocated a code number. This number will form part of the ID number. This will enable recruitment numbers by site to be easily tracked at any point for reporting and monitoring of Key Performance Indicators. The site codes are related to the sites holding the contract with PaCCSC, and are as follows.

Site	Code
Mater Health Services	01
Braeside Hospital	02
Peter MacCallum Cancer Centre	03
Southern Adelaide Palliative Service	04
Hollywood Private Hospital	05
Sydney Cancer Centre	06
Calvary Mater Newcastle	07
Sacred Heart Hospital	08

When a person ends the pre-screen process a combination of numbers will have been allocated.

Example:

The explanation of the ID number structure can be

- Study code/Site code/ID number

In practice, the actual ID number will thus be

- 01/02/001

This number indicates the following participant details

- Ketamine study/Braeside/individual number 001

On screening

If the person proceeds to the screening phase this number sequence continues.

On Randomisation

Should the person become eligible for the study and is randomised to receive a study intervention a further number sequence will be added to the existing ID number.

For those studies where the randomisation is stratified, a code indicating the strata will be provided and added to the ID number, for those studies not stratifying, the letter 'R' will be added to the ID number.

In addition, the randomisation number provided by the clinical trial pharmacist will also be added on to the ID number sequence. This will be a 3 digit number. For example;

- Ketamine has two strata based on type of pain;
 - Nociceptive pain = V
 - Neuropathic pain = P

Example:

The explanation of the ID number structure can be

- Study code/Site code/ID number/strata code/randomisation number.

In practice, the actual ID number will thus be

- (01/02/001/V/001)

This number indicates the following participant details

- (Ketamine study/Braeside/individual 001/nociceptive strata/randomisation number 001).
- Thus the full sequence of numbers will enable the investigators at any point to determine how many people have been referred to any study at any site, how many of them have been randomised and to which strata.

Further examples:

02/06/030/R/003

Risperidone study at Sydney Cancer Centre, 30 people have been referred to the study, and 3 have been randomised (no strata).

05/04/006/R/006

Megestrol acetate study at Southern Adelaide Palliative Services, 6 people referred to the study, all have been randomised, (no strata).