UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

5.5.5 Allocation of Participant Identification Numbers

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Introduction / Background

Participants in clinical studies have the right to have their identity protected. Data collected about the participant must be recorded in such a way that it is not possible to link individual study data (held by the IMPACCT Trials Coordination Centre) with the participant. This is done through the use of unique identification numbers to replace the use of participant initials or name.

Objective

This SOP describes the process of assigning identification numbers to participants of studies conducted by the Palliative Care Clinical Studies Collaborative (PaCCSC) or Cancer Symptom Trials (CST), supported by the IMPACCT Trials Coordination Centre (ITCC).

Scope

This SOP applies to all staff involved in clinical studies conducted by ITCC including PaCCSC and CST, irrespective of individual organisational employment, role, or position.

Ownership and Responsibility

Responsibilities of the IMPACCT Trials Coordination Centre (ITCC)

- To develop a unique and unambiguous identification code schema that allows identification of all the data reported for each participant in the study
- To disseminate the code schema to study sites so they can use it to assign Participant Identification (PID) numbers to participants

Responsibilities of the Principal Investigator or delegate as documented in the Staff Signatures and Delegation Log (refer SOP 4.2.4 Delegation of Duties)

- To assign a unique code to each participant as they are referred to the study, in accordance with the schema devised by the coordinating site
- To maintain the Patient Master Index which provides the site specific link between the details of the participant and the unique PID number assigned to them
- To ensure that the unique PID number assigned to each person is correctly used on all data forms and reporting records
- To ensure that the Patient Master Index is kept secure and separate from the study data in order to separate the participant information from the study information

Procedure

Following referral of a potential participant to a study, a pre-screening form is completed containing the 7-digit ID number allocated as described below.

The 7-digit number contains:

- A two (2) digit study code
- A two (2) digit site code
- A three (3) digit participant number

1. Study code

This code identifies each participant within a specific study. The study code is a two-digit number generated from the protocol code and listed in Guidance 8 PID Number Sequencing. Protocol codes for ITCC are usually a 3-digit sequential number associated with the 2 digit year of development (013/15). The study code takes the last 2 numbers, for example 13 for a protocol code of 013/15.

2. Site Code

This code identifies each site within each study. Each site is assigned a unique code number by ITCC. This number forms part of the ID number. This enables recruitment numbers by site to be easily tracked at any point for reporting and monitoring of Key Performance Indicators. The site codes are listed in Guidance 8 PID Number Sequencing.

3. Participant number

This number is a sequential number starting at 001 and is entered along with the participant's details into the site maintained Patient Master Index (Template 12) as a site record of screening.

4. Pre-screening

Upon completion of the pre-screen process a combination of numbers are assigned to the participant.

For example:

The construction of the ID number structure is:

- Study code/Site code/ID number

In practice, the actual ID number is:

- 01/02/001

In this example, this number indicates the following participant details:

- Ketamine study/Braeside/Individual number 001

5. On screening

The number sequence described above continues through the screening process.

Related SOPs

4.2.4 Delegation of Duties

5.5.1 Electronic Data Handling

Related documents

Template 12: Patient Master Index

Guidance 8: PID Number Sequencing

References

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 07/02/2020)

https://www.tga.gov.au/sites/default/files/ich13595an.pdf

Acknowledgments

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

History			
Version	Date	Author	Reason
1.1	6/11/2007	B Fazekas	New procedure
1.2	8/01/2008	B Fazekas	Update after MAB review
1.3	19/02/2008	B Fazekas	Update after David Currow review
1.4	7/06/2010	B Fazekas	Periodic review
2.0	3/02/2011	B Fazekas	Changes ratified by MAB
2.1	18/05/2015	C Hope	Periodic review
2.2	6/05/2016	L Devilee	Update to site and study numbers
2.3	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
2.4	06/12/2018	L Brown	Update to include CST and ©
2.5	07/02/2020	J Lourdesamy	Periodic review
2.6	25/11/2021	B Fazekas	Periodic review

Approval		
Version	Approval Name	Approval Signature
2.6	Meera Agar