

Guidance 8

Determining PID Number Sequencing for ITCC Studies

Each PID (Participant Identification) Number is 10 digits and consists of the following:

- A two (2) digit study code (derived from the protocol number or otherwise allocated by ITCC)
- A two (2) digit site code (allocated by ITCC and is maintained across studies)
- A three (3) digit participant number
 - This number is a sequential number starting at 001 and is determined by the study staff at the site.
- Randomisation number
 - This number is determined after reference to the randomisation schedule at the time of randomisation.

Study code

This code identifies each participant within a specific study. Each study protocol is allocated a protocol number, based on the number of the study, and the year of the protocol development. This code is always listed on the front page of the study protocol. The study code itself is a two-digit number generated by ITCC, it is sequential, and is documented within a continuously updated excel file held in the ITCC Project Administration folder on the shared network: Allocation of Site and Study ID summary.

For example, a protocol number may be 035/16, Melatonin study, the study code is 35 and the year of development is 2016. The number '35' thus comprises the first two digits of the PID for all participants of the Melatonin study.

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 also continuously updated within the Allocation of Site and Study ID summary document. The site code does not change over time or between studies, with the exception of the RAPID program.

Participant ID number

When a person is referred to a study, for the purposes of being able to document 'Pre-screen data' a three-digit, sequential number is allocated by the site. The numbers start at 001, and are documented within the Patient Master Index, held and updated at the site.

For example:

The construction of the ID number structure is:

- Study code/Site code/ID number
- The three components of the PID are separated by '/'

The numbers are always

- 2 digits for study code, including '0'
- 2 digits for site code, including '0'
- 3 digits for Patient code, including '0'.

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

Tracking

The listing of studies and sites is tracked by the ITCC in a spreadsheet located on the ITCC network drive. Any new studies or sites are referred to the ITCC for inclusion in this spreadsheet.

Communication

The PID coding is communicated to each site at site initiation and within any site-specific documentation provided to the site. The coding for each study should be documented onto the Master Patient Index at the commencement of each study.