# Instructions for use: Participant Consent, Screening & Enrolment Log template

***Please delete this page if instructions before finalising your log – this is a template so customise as needed for your study***

**Purpose**: Good Clinical Practice guidance\* requires that the principal investigator document, in chronological order, all participants screened and enrolled in a study. This document also acts as a master record providing the link between a participant’s personal identifiers and their assigned study code.

\* Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice ICH E6 (R2) - Annotated with TGA comments

For the purposes of this document:

* **Pre-screening** refers to any assessment that takes place prior to informed consent and is a review of existing information (i.e. does not involve a study-specific procedure).
* **Screening** refers to post-consent assessments to determine final eligibility. Those who provide consent but are determined to be ineligible are termed Screen failures.
* **Enrolment** refers to participants who have provided informed consent and have then been determined to be eligible for the study. Note that for clinical trials, enrolled refers to participants who have been assigned to the trial intervention.

**Procedure**:

* Complete this log for every participant who provides informed consent to screening / enrolment.
* This log includes personal information about participants, ensure it is stored securely and only accessed by authorised members of the research team.
* It is suggested that you store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.
* At the end of the study, identify the final page of the log by completing the “Page \_\_\_ of XXX “.

**PARTICIPANT CONSENT SCREENING & ENROLMENT LOG**

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| --- | --- |
| PROTOCOL ID / NAME: | Principal Investigator: |

***Complete this log for every participant consented to the study (in chronological order)***

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| --- | --- | --- | --- | --- | --- | --- |
| **Participant Study ID** | **Participant Name** | **Date of birth** | **Date of consent** | **Date of screening** | **Outcome of screening:** | |
|  |  |  |  |  | **Enrolled**  **Y/N** | **Not enrolled**  *List reason* |
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*\* In a clinical trial, enrolment is defined as assignment to the trial intervention*