**Instructions for use: Pre-Screening Log Template.**

*Please delete this page before using the log. Please also delete the examples provided in the template log. Remember that this document is just a template and can be amended to suit your study.*

**Purpose**: To document pre-screening of potential participants

Good Clinical Practice guidance\* requires that the principal investigator document all pre-study recruitment activities. A Pre-screening Log should be maintained to record limited details of those who were pre-screened, tracking the outcome of the screening (e.g. ineligible, potentially eligible but declined further study involvement, potentially eligible and attended a Screening Visit). This allows study personnel to track reasons and trends for non-inclusion in a study (which may prompt a protocol amendment) and check whether potentially eligible participants are being missed. Completion of a pre-screening log is also useful to ensure that those already excluded or who declined participation are not re-contacted.

Pre-screening refers to any assessment that takes place prior to informed consent being obtained – it is a review of existing information (i.e. does not involve a study-specific procedure to obtain information). Pre-screening can commence once a study has ethical approval and governance (site) authorisation. Sources of existing information could be, for example, a medical record or speaking with a potential participant, telephone/website contact or other sources as appropriate to the study. During pre-screening, the person may be excluded due to one or more of a range of factors such as demographic information (e.g. age, sex), medical history, current and/or previous treatments. Where further information is needed to determine eligibility, the interested person should be invited to a screening visit at which informed consent should first be obtained. At that stage, the participant should be added to the Screening and Enrolment Log

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. **PRE-SCREENING LOG**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Initials** | **Date of birth** | **Date of pre-screening** | **Outcome of pre-screening:** | | |
|  |  |  | **Ineligible at Pre-screening**  *List reason* | **Eligible for Screening/Enrolment Visit**  **– - Declined attendance**  *List reason (if known)* | **Eligible for Screening/Enrolment Visit**  **- Attended –**  *Add to Participant Consent, Screening & Enrolment Log and record assigned ID here* |
| *FBM* | *15/07/1982* | *15/01/2019* |  | *Declined – too busy* |  |
| *MOT* | *1/1/2000* | *15/01/2019* |  |  | *Participant ID 001* |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |