**Purpose:** This template provides a recommended structure for recording participant screening prior to enrollment.

**Responsibility:** To be used byPrincipal Investigators and study team members who are delegated to record screening and enrollment.

**Procedure:**

* This template contains two types of text: instruction/explanatory and example text.
* **Instruction/explanatory text** are indicated by italics and should deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.
* **Example text** is included to further aid in document development and should either be modified to suit the drug, biologic or device (study intervention), design, and conduct of the planned clinical trial or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.

**Participant Pre-Screening and Enrollment Log Template**

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| Study Title | Protocol # | Principal Investigator |
|  |  |  |

| Participant Initials | Date Approached | Name of Person Approaching | Recruited  (Y/N) | Recruited  Date | If Recruited, Participant ID | If Not Recruited, Reason |
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