**Screen Failure Tracking Log – Trial-Level**

Audience: Clinical trial staff manager

**KEY CONSIDERATIONS**

**Principal Investigator**:

1. Is the screen failure tied directly to a **protocol-specified exclusion criteria**?
2. Is the screen failure determined based on an **objective measure of eligibility** (lab value, etc.)?
3. Is the screen failure determined based on a **subjective assessment or judgement** (i.e., investigator discretion)?

**Protocol #:**

### Study Title:

Provided by clinical site staff conducting screening

### Sponsor:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Participant\*** | DateScreened | **Reason for Exclusion/Screen Failure** | **Screen Failure Assessment\*\*** | **Initials of Assessor**  |
| Protocol-specified exclusion criteria AND/OR objective measure | Study staff or investigator discretion / judgement |
| **1** |  |  |  | [ ]  | [ ]  |  |
| **2** |  |  |  | [ ]  | [ ]  |  |
| **3** |  |  |  | [ ]  | [ ]  |  |
| **4** |  |  |  | [ ]  | [ ]  |  |
| **5** |  |  |  | [ ]  | [ ]  |  |
| **6** |  |  |  | [ ]  | [ ]  |  |
| **7** |  |  |  | [ ]  | [ ]  |  |
| **8** |  |  |  | [ ]  | [ ]  |  |
| **9** |  |  |  | [ ]  | [ ]  |  |
| **1****0** |  |  |  | [ ]  | [ ]  |  |

\*Use a pre-screening number, initials, or first name to identify individuals at pre-screening, to be HIPAA compliant.

\*\*Assessment made by clinical trial staff manager and/or investigator. Tracking these assessment data can enable an understanding of whether a particular site has justified screen failures over time. Stratifying these assessment data by participant demographics (collected on the Eligibility & Enrollment Log) can enable understanding of the demographics of screen failure, and whether objective assessments are utilized for participants of particular demographic groups.