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| **Study Stage:** Start-up, Conduct |

 

**Purpose:** The Screening and Enrollment Log documents and tracks the status of each potential/or enrolled participant in a study.

**Useful to:** Principal Investigators, Study Coordinators, Co-Investigators, and other study team members

**Instructions:**

* This log includes all the information that the research staff agrees will be useful during the screening and enrollment process.
* A sample template is provided below; customize the template below based on your study specific requirements for screening and enrollment.
* Create the log prior to study start and update when each potential participant is screened and/or enrolled into the study.
* Participant initials in this log are for participant identification purpose – they do not indicate that the participant is initialing the form.

**Best Practice Recommendation:**

* Sponsors may require investigators to maintain a Screening and Enrollment Log, in which case the sponsor should specify what information to capture or provide the log prior to the start of the study.
* The log is recommended for all studies including investigator-initiated studies that are non-FDA regulated, studies with large Participant enrollment goals, and/or studies that will be long in duration. The study staff should consider whether a Screening and Enrollment Log will help conduct the study in a more efficient and organized manner.
* The Screening and Enrollment log can be adapted to an Excel spreadsheet.
* If the Participant Screening and Enrollment Log contains HIPAA protected health information, it is necessary to follow the secure data storage practices that were approved by the IRB.
* Make sure not to exceed the number of participants listed in the approved IRB application. A study amendment should be made if your study wants to enroll more than what is approved

**Reference(s):**

 “Enrolled” definition for human subjects studies in eResearch
[enrollmentdefinition\_additionalhelp.pdf (umich.edu)](https://research-compliance.umich.edu/sites/default/files/resource-download/enrollmentdefinition_additionalhelp.pdf)

**Template History:**

**Last updated:** 6/07/2022

**Version:** 2.3

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| **Study Name:**  | **IRB HUM #:** |
| **Principal Investigator:**  |  |

**IRB approved number of subjects to be enrolled:**

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| Screening Number | **Informed Consent Signed: (Date or N/A)*****(Copy to Subject Y/N)*** | **MRN** **(if applicable)** | **Assigned Participant ID #** **(if enrolled)**  | **Date Screened***(MM/DD/YY)* | ParticipantInitials | **Eligibility Criteria Met***(Yes/No)*  | **Reason for Exclusion**(Screen Fail, Refused to Participate, etc.) | **Randomization ID Assigned**  | **Additional Comments**  |
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PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_