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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.**NOTE: This form is designed to be a starting point on a Screening and Enrollment Log. Update it as necessary for your specific study.** * This is not meant to act as a Master Code List that connects individual names or other identifiable information to study ID codes.
* Study teams should use their own discretion on columns to include or not include as all below might not be relevant or applicable. If this information is kept in other places, it might not be necessary to combine into this one tracking log. Study teams should update as necessary for their specific study procedures, definitions, and needs.
* The study team should follow all IRB approved confidentiality procedures. If the study team indicated that this information was stored electronically, this template can be used to develop an electronic spreadsheet within a HIPAA-compliant system.
* An enrollment log is used to document chronological enrollment of subjects by participant ID. An enrollment log can be used for both observational and interventional clinical research studies to provide a comprehensive list of all participants who were screened for eligibility and/or enrolled into the study.
* It is recommended that this type of log is entered in real-time so the information is as accurate as possible.
* Complete every applicable field within the enrollment log. If an entry is unknown or not available at the time of enrollment, add N/A to the field to indicate that the entry is not missing but was intentionally not completed.
* Additional pages should be printed or rows added as required for study needs.
* Page numbers do not automatically update as it is unknown how many pages will be necessary for the entire study. The page information in the footer should be added when study data collection is complete and no additional adverse events will occur.
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| **Participant ID** | **Date Screened** | **Source of Subject Recruitment** | **Eligibility** | **Consent** | **Date Enrolled** (On Study Date) |
| --- | --- | --- | --- | --- | --- |
| **Yes / No** **and Date** | **Reason for Exclusion / Screen Failure** | **Yes / No** **and Date** | **If No, Explain Briefly** |
|  |  |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  |  |
|  |  |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  |  |
|  |  |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  |  |
|  |  |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  |  |
|  |  |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  |  |
|  |  |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  |  |
|  |  |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  | ☐ Yes ☐ NoDate: \_\_\_\_\_\_\_\_ |  |  |