**[insert Clinical Research Site (CRS) Name and CRS Number]**

**[**Co-Enrollment Prevention Standard Operating Procedure (SOP)]

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| ***SOP #:*** |  | |
| ***Version:*** | *1.0* | |
| ***Author(s):*** | *,  ,* | |
| ***Approval:*** | **Approved By** | **Date** |
| *[signature]* | , *CRS Leader* |  |
| *[signature]* | , |  |

[Language in brackets are instructions for the site and should be removed from the final version of the site SOP]

[Sites may use the following language (in *italics*) as is or adapt it to their needs. Please ensure you use your CRS Standard Operating Procedure (SOP) shell]

# PURPOSE:

*The purpose of this SOP is to describe the following:*

1. *Roles and responsibilities as related to co-enrollment prevention.*
2. *Procedures at [insert CRS name] for preventing co-enrollment in protocols where it would be exclusionary or pose increased risk of harm to participants based on safety, regulatory, or ethical concerns.*

# SCOPE:

[Explain to whom and what the SOP applies. Edit as appropriate, if the SOP is to be used for all protocols at the site, including non-DAIDS studies].

*This SOP applies to all clinical research site staff involved in preventing co-enrollment of clinical research participants before enrollment into a new study and outlines the process for preventing co-enrollment at [CRS Name].*

# DEFINITIONS:

[Include a list of terms and acronyms that are helpful for the proper understanding of the SOP. Examples are provided below, and sites can add items as appropriate. Consider country, local, or institutional terms and acronyms that may be site specific.]

*Biometric: A method of verifying an individual’s identity based on measurements of the individual’s physical features or repeatable actions where those features and/or actions are both unique to that individual and measurable (FDA 21 CFR 11.3(b)(3)).*

*Co-enrollment: Enrollment of the same individual in more than one study, or in the same study at multiple locations where this is not allowed by the protocol or would pose increased risk of harm to participants based on safety, regulatory, or ethical concerns.*

*Personally Identifiable Information (PII): Any data that could potentially identify a specific individual. Any* ***information*** *that can be used to distinguish one person from another and can be used for de-anonymizing personal data can be considered PII, including but not limited to full or partial names, date of birth, hospital identification, and/or local identification (ID)*

*Locally Acceptable Methods* *of ID:* [Describe all forms of ID acceptable to the CRS (some general examples are included in the guideline within this manual, “CRS Guidance for Developing an Age and Identity Verification SOP”, and their availability in the local area. (Add examples of identification documents as supporting materials for this SOP)]

# RESPONSIBILITIES:

* 1. - [Specify that the CRS Leader is the individual responsible for establishing and implementing a written SOP and that the corresponding processes developed for preventing co-enrollment prevention will follow all applicable laws, regulations, and other requirements].
  2. – [Identify the CRS staff members who will be delegated the responsibility for co-enrollment prevention. Specify the roles and responsibilities assigned as they relate to this SOP].

**[Note:** Use job titles in the SOP instead of specific staff members’ names to limit SOP revisions due to staff turnover. Staff members’ names and their respective roles in the co-enrollment prevention process must be documented in the Delegation of Duties Log.]

*Example*

* *CRS Leader and the Principal Investigator (PI)/Investigator of Record (IoR) for each study: Responsible for ensuring that processes for co-enrollment prevention follow all applicable laws, regulations, and other requirements, and that designated CRS staff are trained on and comply with this SOP*
* *Receptionist: Responsible for obtaining participant ID, as detailed in the Age and Identity Verification SOP*
* *Study Coordinator: Responsible for conducting risk analysis to identify possibilities of co-enrollment at the site. Responsible for reviewing the obtained ID and ensures that the participant age and identity is verified according to procedure, per site Age and Identity Verification SOP. Responsible for following the co-enrollment prevention procedures defined in the SOP.*

# PROCEDURE:

[Describe the specific actions to be completed for co-enrollment prevention before enrolling a participant into a new study, for example verifying age and identity, or checking ID information against a co-enrollment database. Consider if co-enrollment checks throughout the study may be warranted (e.g., large study, multiple participants, multiple staff members). Use simple, clear, and concise language. This section is required even if the site determines that its risk for co-enrollment is low.]

* 1. **Co-enrollment Risk Analysis**

# [Describe the risk analysis that is done to identify potential sources of co-enrollment, and the frequency that the risk assessment is repeated. (See the Guidance Document for Co-enrollment Prevention for example questions to consider at your site and for topics that should be included in risk analysis summaries)

# Describe the location of documentation of the site risk analysis summary, with risk level, for each risk analysis performed.

# Describe the results of the risk analysis and the overall level of risk for the site. Assess each study for risk as well since risk may vary by protocol.]

**5.2 Co-enrollment Prevention Before Enrollment /During Screening**

[Describe the following:

* The type of system used in the site’s co-enrollment prevention process.
* Steps the CRS staff (by role) will follow to verify participants’ age and identity (refer to the site Age and Identity Verification SOP)
* The procedures used to determine whether potential participants within the recruitment area have screened or enrolled at other sites, and the frequency at which these procedures are performed.
* The information used to determine enrollment in another study (biometrics, PII, etc.)
* Where the results of the co-enrollment prevention procedure will be documented for each participant.
* Alternative procedures to be followed if electronic processes are in use but temporarily unavailable]

**5.3 Sharing Information with Other Sites**

[Describe the following:

* + - Procedure for communicating the participant activity to other clinical research sites captured in the site’s co-enrollment prevention system if enrollment is found in one or more trials at other sites, other than the trial currently being screened for at the site. (See FAQs for considerations regarding any inter-site information exchange)]

# SOP APPENDICES and REFERENCES:

[List any items referenced in the body of this SOP

* Age and Identity Verification SOP
* In country/local laws/regulations
* Templates or examples of any acceptable types of IDs
* Any additional documents]

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| *Revision History:* | Version | Effective Date | Description |
| *blank* | *1.0* | *DD-MMM-YYYY* | *First Approval* |
| *blank* |  |  |  |