**[insert Clinical Research Site (CRS) name and CRS number]**

 **[**Age and Identity Verification Standard Operating Procedure (SOP)]

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

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

#  PURPOSE:

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

1. *Roles and responsibilities as related to age and identity verification.*
2. *Procedures at [insert CRS name] to verify the age and identify of potential participants before they take part in a clinical research.*
3. *Procedures at [insert CRS name] to verify participant identity at each visit before any clinical trial procedures take place (and for each visit for the study’s duration).*

# 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 verifying age and identity of clinical research participants before enrollment and during all subsequent study visits.*

*This SOP outlines the steps that will be taken in verifying age and identity of clinical research participants before enrollment and during all subsequent study visits 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)).*

*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 verifying participants’ age and identity will follow all applicable laws, regulations, and other requirements.
	2. - Identify the CRS staff members who will be delegated the responsibility for age and identity verification. Specify the roles and responsibilities assigned as they relate to this SOP.

**Note:** Job titles should be used in the SOP instead of specific staff members’ names, to limit SOP revisions due to turnover. Staff members’ names and their respective roles in the Age and Identity verification 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 verifying age and identity follow all applicable laws, regulations, and other requirements, and that designated CRS staff are trained and comply with this SOP*
* *Receptionist: Responsible for obtaining participant ID, as detailed in this SOP*
* *Study Coordinator: Responsible for reviewing the obtained ID and ensures that the participant age and identify is verified according to* procedure]

# PROCEDURE:

[Describe the specific actions to be completed **for participant age and identity verification before any study procedures take place, e.g., during the consent process, and during subsequent visits**. Use simple language, clear and concise.]

**5.1Before Enrollment**

[Describe the following:

* Steps the CRS staff (by role) will follow to verify participants’ age and identity
* When the IDs will be verified — at the consent process, before any study procedures start, at each visit for the study’s duration
* All CRS-acceptable forms of ID and their availability in the local area. (Examples are in the appendix, “*CRS Guidance for Developing an Age and Identity Verification SOP”*. If some participants are expected not to have age or ID documents, please include a description of what measures will be taken to verify the same.
* Where the verification of age and identity will be documented
* Details on storage and maintenance of any copies of ID, including details on how security of PII will be maintained
* The type of personally identifiable information (PII) elements used to verify participant identity
* Alternative procedures to be followed if electronic processes are in use but temporarily unavailable
* Any differences in process for specific populations, providing a rationale.

**Note:** Depending on the number of PII elements needing to be verified, more than one type of acceptable ID may be required.]

**5.2 Subsequent Visits**

* [Describe the steps the CRS staff will follow to confirm participant identity at all subsequent visits. (This may be the same method used for the initial verification or an alternative method like creating a site ID/biometric ID, taking a photograph of the participant for site files.) If alternative forms of ID methods are used, describe the process for creating and implementing the ID, as well as the methods for protecting participant identity.
* Please also ensure that no potentially stigmatizing information is included on the ID, including “Human Immunodeficiency Virus (HIV),” “Acquired Immune Deficiency Syndrome (AIDS),” the title of the protocol, or site, if similar information is included in those phrases.]

**5.3 Alternative Procedures for Age and Identity Verification (as applicable)**

[Describe any of the following that apply to the site process:

* If any exceptions to the primary process are allowed
* Circumstances and what the alternative process includes
* Factors constituting an exception to the primary process (e.g. challenges with certain populations; how widely available certain types of ID are in-country; how often IDs are renewed; acceptance of older, potentially unreliable IDs).
* How the alternative process will be documented
* Any mechanisms (site or community) to help participants obtain ID or inform participants what types of IDs are needed at the site]

# SOP APPENDICES:

**[List any items referenced in the body of this 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* |  |  |  |