

Milton Park Clinical Research Site (CRS) #30313
Age and Identity Verification Standard Operating Procedure (SOP)

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| SOP #: | MP/008 | |
| Version: | 3.0 | |
| Author(s): | [REDACTED] | |
| Approval: | Approved By [REDACTED] | Date |
| | [REDACTED] CRS Leader | 09 Apr 2021 |

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 Milton Park CRS to verify the age and identity of potential participants before they take part in a clinical research.
- (3) Procedures to prevent co-enrolment of potential participants into other clinical trials when it is not permissible.
- (4) Procedures at Milton Park CRS to verify participant identity at each visit before any clinical trial procedures take place and for each visit for the study's duration.

1.0 SCOPE:

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 Milton Park CRS.

2.0 DEFINITIONS AND ACRONYMS:

ID: Identification
IoR: Investigator of Record
SOP: Standard Operating Procedure

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 prevention system: UZ-CTRC Biometric Co-enrolment Prevention System that uses fingerprint-based biometric technology to identify participants.

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:

The issuance of national identity documents is a statutory requirement in terms of the National Registration Act Chapter 10:17 of Zimbabwe which specifies that every citizen, aliens and refugees (acquired citizen) of 16 years and above should register a national identity card.

National Identification (ID) Card— Every person's national identity card has a unique national identification number that is used for identifications. The national ID card is issued to everyone for life, it does not expire. If lost, an individual applies for a replacement ID card bearing the same unique national ID number. Personal information appearing on the national ID card in addition to the unique national ID number include the holder's photograph, full name, birth date, sex, address, citizenship and more. The law requires every Zimbabwean to have a national ID card, and, in our experience, most people who present to our research clinics have completed the registration process. However, there are still some people without these documents, this being more prevalent in rural areas than urban areas.

Other forms of ID used in Zimbabwe include—

- o Valid passport; bears the individual's unique national ID number and photograph, valid for 10 years and subject to renewal. Expired passports are not used for identification purposes per local regulations.
- o Driver's license; bears the national ID number and photograph
- o Birth record cards for infants; issued upon delivery, affirming the day that the child is born, the sex of the child, the place of birth and the name of the mother. Bears an official stamp from the maternity home at which the child was born. The child's mother is required to produce her ID card as part of this process. Mothers who give birth at home or before arrival at the health centre are required to go to the nearest clinic or hospital as soon as possible so that they can acquire the birth record. The birth record enables one to then get a birth certificate.

- o Birth certificates for children.

The identity documents are used to connect a person to information about the person, often in a database. The connection between the identity document and information database is based on personal information present on the document, such as the bearer's full name, age, birth date, address, an identification number, card number, gender, citizenship and more.

The Children's Protection and Adoption Act defines a child as any person under the age of 16 while the Legal Age of Majority Act defines children as persons under the age of 18. For the purposes of this SOP children are all individuals under the age of 18 years.

3.0 RESPONSIBILITIES:

- o 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.
- o Clinic Clerk: Registering participants into the co-enrolment database, *checking the participant's identity at each clinic visit at the entry point into the clinic.*
- o CRS Coordinator: Responsible for reviewing the obtained ID and ensures that the participant age and identify is verified according to procedure; responsible for certifying copies of participant's IDs as well upkeep of these certified copies in a manner that protects participants identities and confidentiality
- o Counsellors, Research Nurses, and Interviewers: designated to obtain informed consent per the study staff delegation of duties log are responsible for determining age and identity of participants in accordance with this SOP.
- o Counsellors, research nurses, interviewers, medical officers, pharmacists, and pharmacy technicians: Responsible for verifying participant identity before conducting any study procedures.
- o The CRS Coordinator/Clinic Manager: Responsible for ensuring that counsellors, research nurses, interviewers, medical officers, pharmacists, and pharmacy technicians are trained in accordance with this SOP.
- o The CRS Data Manager: is responsible for conducting daily quality control checks to ensure that the participants' correct names and national ID numbers have been captured into the co-enrolment database.
- o Personnel designated by the IoR to conduct study procedures involving interaction with participants are responsible for:
 - o At first contact, determining age and identity of individuals prior to conducting study procedures in accordance with this SOP (for example obtaining informed consent, administering study questionnaires, collecting laboratory specimens, dispensing study product), and
 - o At each subsequent contact, verifying participant identity before conducting any study procedures.

4.0 PROCEDURE:

5.1 Before Enrollment

5.1.1 Determining age and identity of adult participant using identification documentation.

- Outreach workers, when recruiting potential participants in the communities, will advise them to bring their identification documents, as noted in section 2.0 above, to the Clinical Research Site for age and identity verification procedures.
- Registration in the biometric database: The use of a biometric co-enrolment prevention system to capture participant's identification details in real time was approved by the Medical Research Council of Zimbabwe in 2015. At Milton Park CRS, the potential participant reports to the reception area of the CRS first to state the reason for their scheduled/unscheduled clinic visit. The clinic clerk then registers the potential participant before any study procedures are conducted —
 - Views the potential participant's original identification document(s)
 - Verifies age and identity.
 - Obtains consent to capture biometric data from the potential participant.
 - Captures in the database the participant's full name, date of birth, sex, national identity number or passport number, residential address, and contact details (telephone number).
 - Scans three (3) fingerprints from each one of the participant's hands into the database using a biometric scanner. This information is used to check for co-enrolment and identity verification at subsequent visits.
- Prescreening: If the biometric co-enrolment database shows that the participant is not co-enrolled, they are referred to the counsellor for pre-screening procedures. If the participant is deemed eligible for screening, the participant is referred back to the clinic clerk where they will be assigned a unique participant identification number according to the protocol he/she has been screened into.
- The clinic clerk then updates the participant's details entered the biometric co-enrolment database by entering the participant's unique screening identification number, makes a photocopy of the participant's identity document and presents both the original and the copy to the CRS Coordinator/designee.
- The CRS Coordinator/designee inspects both documents and certifies the copy as a true copy of the original.
- The clinic clerk files the certified copy and returns the original to the potential participant.
- The certified copy is used for age and participant identity verification in the clinic thereafter.

- The certified copies are kept securely in the CRS Coordinator's office in a lockable cupboard with restricted access in order to protect participants confidentiality.

At subsequent visits

- Participants are instructed to bring their identification documents to all clinic visits and present them to the clinic clerk when checking in upon arrival. The biometric system is also used to verify identity.
- Before conducting any study procedures, all staff conducting study procedures verify participant identity by verifying with the certified copy of the identity document taken at the screening visit.

5.1.2 Determining age and identity of adults without identification documentation

- Recruitment: The outreach team request for alternative identity documents to verify their age and identity such as antenatal cards for female participants and child health cards with name, date of birth or age for older children.

Suitable documents should:

1. Bear the potential participant's name and date of birth or age; and
2. Be issued by an official institution. This is generally indicated by a letterhead or official stamp.
3. Examples of suitable documents include:
 - Municipality polyclinic cards (eg antenatal card, out-patients card),
 - Ministry of Health and Child Care cards (eg Tuberculosis Treatment Card, Antiretroviral Treatment Card),
 - Documents issued by employers or official associations (eg political parties, church groups).

- *Age and identity verification:*

1. The clinic clerk refers potential participants without valid identification documents to the CRS Coordinator/Clinic Manager for an interview.
2. The CRS Coordinator/Clinic Manager collects information required to determine the name and if a potential participant is of legal age, including: the date of birth as per potential participant's self-report, year enrolled into primary school, completed years of education and year of completion, year of marriage and first child.
3. If the potential participant has a previous medical record, the name and age/date of birth on the record is also checked for consistency.
4. The CRS Coordinator/Clinic Manager reviews all available information for cross validation with the staff delegated to obtain informed consent to decide whether this is sufficient to suggest the correct name and if the potential participant is of legal age.
5. The CRS Coordinator/Clinic Manager writes a chart note to provide details of all information reviewed and the decision process. They state the determination made, for example that the potential participant is determined to be of consenting age based on the information provided.

- *Registration in the biometric database:* The clinic clerk registers the potential participant as outlined previously, using the determination recorded in the chart note.
- *Security questions:* The staff delegated to obtain informed consent ask the participant to choose and answer three security questions. The security questions script which has the answers is maintained in the sensitive data file for reference at subsequent visits. List of security questions—
 1. What primary school did you attend.
 2. In what town/city did you meet your spouse/partner?
 3. In what town or city was your first full time job?
 4. What is the middle name of your oldest child?
 5. What is your grandmother's (on your mother's side) maiden name?
 6. What is your spouse's/partner's mother's name?
 7. In what town or city did your mother and father meet?
 8. What is your childhood nickname?
 9. What is your father's middle name?
 10. What is the name of favourite childhood friend?
 11. What is the middle name of your oldest child?
 12. What is the name of your grade seven teacher?
 13. What is your favourite team?
 14. What is your favourite movie?
 15. What was your favourite sport in high school?
 16. What is the name of the boy that you first kissed?
 17. What was the name of the hospital where you were born?
 18. What school did you attend for sixth grade?
 19. What was the name of your third-grade teacher?

At Subsequent Visits

- Participants' fingerprints are verified in the biometric database by the clinic clerk when checking in upon arrival.
- Before conducting any study procedures, all staff conducting study procedures verify participant identity by asking a security question.
- The clinic clerk asks if such documentation has subsequently been obtained and this follow up will be documented in the participant's study charts (sensitive data).

5.1.3. Determining age and identity of children aged 16-18 years with identification documents

- Children aged 16-18 years Will have their age and identity will be verified as described in section 5.1.1 above if they have identification documents or 5.1.2 if they do not have identification documents.

5.1.4 Determining age and identity of children up to 16 years

- The age of a child will be determined using official documentation such as birth certificate or valid passport where applicable.
- The child's age and identity will be verified as described in section 5.1.1 above.
- In the absence of these documents, age will be determined using the Child Health Card which also has the child's date of birth for children up to the age of five years.
- In the absence of any written documentation of child's date of birth, the CRS Coordinator/Clinic Manager will use the following information to determine the age of the child:
 - Caregiver's verbal report of the date of birth of the child
 - Year child enrolled into pre school.
 - Year child was enrolled into primary school.
 - Current primary/Secondary school grade level
 - Completed years of education.
 - Year of completion of education if applicable.
- This information will be used for cross validation. If they have a previous medical record the age/date of birth on the record is also checked for consistency.
- The CRS Coordinator/Clinic Manager together with the IoR/designee will discuss the information presented by the caregiver to decide whether it is adequate to determine age of the child.
- If the information provided is satisfactory, the CRS Coordinator /Clinic Manager will then document this procedure in chart notes and assess participant's enrolment into the study.
- Registration in the biometric database: The clinic clerk then registers the potential participant (5 years and above) as outlined in section 5.1.1, using the determination recorded in the chart note.
- Procedures followed thereafter will be similar to those described for adults without identification documents.
- The clinic clerk enters the child's details i.e., name, identification number, date of birth as well as scans their fingerprints into the co-enrolment database to confirm their identity as well as check for possible co-enrolment.

5.1.5 Determining age and identity of Newly born children

- Parents/caregivers of these children will be asked to bring their national identity documents to the CRS together with the birth records of the children.
- The identity of the parents/parent/caregivers will be verified as described in section 5.1.1
- Full name, participant identification number, national identification numbers of the caregiver/parent (where applicable) will be entered into the co-enrolment data base by the clinic clerk, while the full name and date of birth of the child is also entered into the database.
- For parents without identification documents, procedures outlined in section 5.1.2 will be followed.
- No fingerprints will be scanned for new born babies
- The age, identity and sex of the children will be verified using the infant birth record.

- Copies of the identification documents will be made, certified, and kept on site as part of the study records.

5.2 Subsequent Visits

- Participants are required to bring their identity documents at all visits to the Milton Park CRS whether scheduled or not which will be used to verify their identities.
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- The biometric system is also used to verify participant's identity. Each time a participant checks into the clinic, their unique participant ID number and fingerprints are checked against the anti-co-enrollment database by the clinic clerk as follows: Scans fingerprints from each one of the participant's hands into the database using a biometric scanner. This information is used to check for co-enrolment and identity verification at subsequent visits.
- For older participants without identity documents, their identification is checked using the biometric system (see above statement) only.
- If participant identity is verified as that of the correct participant , the participant is allowed to proceed to complete the rest of the scheduled visits.
- Before conducting any study procedures, all staff conducting study procedures verify participant identity by verifying with the certified copy of the identity document taken at the screening visit .
- For participants without identity documents the security questions chosen at the screening visit will be used by counsellors, research nurses, interviewers, pharmacists, pharmacy technicians and medical officers to verify participant identity by asking anyone of the three chosen security questions.
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6.0 REFERENCES:

- Zimbabwe National Registration Act Chapter 10:17
- Zimbabwe Age of Majority Act
- Zimbabwe Child protection and adoption act

7.0 REVISION HISTORY

| <i>Revision History:</i> | Version | Effective Date | Description |
|--------------------------|---------|----------------|---|
| | 1.0 | 30-MAY-2020 | <i>First Approval</i> |
| | 1.1 | 29-JUN-2020 | <i>To make SOP site specific</i> |
| | 2.0 | 05-NOV-2020 | To align with name, change to UZ-CTRC |
| | 3.0 | 07-APR-2021 | To comply with new template in the DAIDS SCORE manual |