Title: BIOMETRIC CO-ENROLMENT PREVENTION SYSTEM

SOP Number: EP BCP 958 Effective Date: 17 Sep 2021

Supersedes SOP Dated: 30 Aug 2019

Author: L. Mpete

1. AUTHORISATION

	Name, Title	Signature	Date
Authorized by:	Participant Engagement HOD/Designee		
	QA Manager/ Designee		

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2. REVISION HISTORY

Version	Effective Date	Comments & Revisions	Signature
4.0	1 Nov 2015	Superseded	
5.0	12 March 2018	Superseded	
6.0	30 Aug 2019	Reviewed with updates	
		based on the latest version	
		of the BCEPS manual	
		(Superseded)	
6.0	17 Sep 2021	Reviewed with no changes	
		(Active)	

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4. INTRODUCTION

The purpose of this SOP is to describe the process that should be followed when using the BCEPS data entry system, which ensures that an individual is not co-enrolled in more than one study simultaneously.

5. RESPONSIBILITY AND AUTHORITY

- The Quality Assurance Manager/designee has the authority to determine the format of the SOP.
- The Quality Assurance Unit is responsible for the control of this SOP.
- The Participant Engagement HOD and supervisor are responsible for the implementation of this procedure and for ensuring that all appropriate personnel comply.
- Participant Engagement staffs are responsible for reading and understanding this SOP prior to perform the procedure as outlined and required in specific protocols.

6. ABBREVIATIONS

• BCEP: Biometric Co-enrolment Prevention System

• ID: Identification

• N/A: Not Applicable

SOP: Standard Operations Process

• SRC: Setshaba Research Centre

7. SAFETY

N/A

8. EQUIPMENT

• BCEPS Fingerprint reader

9. MATERIALS AND ACCESSORIES

• BCEPS software installed in the Reception desktop(s)

10. PROCEDURE

10.1 Checking for Co-enrolment and Registering of Participants (Screening Visit)

Ask the participant to provide verbal permission at the beginning of the visit to assess for co-enrolment. Assure the participant that "the database will only be accessed by a few members of the study team using a secure password".

Ask for participants SA ID document (green book, Smart card, SA passport or valid temporary ID) and check date of birth. If the participant's age falls on the required age range, inform the participant that you will check to see if he/she is participating in any other research studies and proceed as follows:

- 1. Login to the Co-enrolment system by entering the site username and password.
- 2. Click on the **BCEPS** application icon.
- 3. Check the site and click on **Select.**
- 4. Enter your user name and password, or scan your fingerprint.
- 5. Click Manage participants.
- 6. Click Select.
- 7. Click **Lookup by ID**.
- 8. Enter participant ID number as per ID document.
- 9. If the participant is not captured previously (read the message in the box), Click Add as new participant.
- 10. Add participant detail as required (Name, Surname, Gender and ID number).
- 11. Follow the steps listed below by clicking on the respective block:
 - Ask the participant's **left hand** and instruct him/her to place the finger on the finger print reader (make sure that the left fingers is taken as it is (do not mix the left with right as it will give wrong results); Scan each finger three times. Successful scanning will display a green cross on the block.
- Continue with the **right hand** following the same process.
- 12. It is important to scan all available fingers to ensure that fingers not scanned are not used to enrol on other studies.
- 13. A minimum of eight fingers must be scanned except in the case of deformity or missing finger, in which case a minimum of two fingers will be used to qualify for screening and accepted to be enrolled on the study.

- 14. If other fingers cannot scan, write notes on the comments box.
- 15. In case whereby not all fingers can scan, inform Project Coordinator who will inform core team.
- 16. Once you complete scanning the participant fingers enter the screened date and comments as required and press **Submit.**
- 17. Double check that participant information is captured correctly as it cannot be changed later.
- 18. Then **Add** participant in the study.
- 10.2 Administering Co-enrolment (Enrolment and Follow-up visits)
 - 1. Log-in to the Co-enrolment system as above.
 - 2. Ask for participant ID document.
 - Click **Attendance** and either enter the participant ID number or scan one of his/hers fingers.
 - 3. Click **Edit** for the participant's status you would like to change. (The participant information will appear on the screen (name and surname, ID number, gender, screened date, etc.).
 - 4. Change the participant's status to enrolled in the study.
 - 5. Click **Submit** then **lo**gout.

11. DATA RECORDING FORMS

N/A

12. REFERENCES

• Biometric Co-Enrolment Prevention System: User Guide: 17 March 2017, Document Version 1.4 by A-H Ebrahim

13. ACKNOWLEDGEMENT OF READING AND COMPREHENSION

 Refer to QF DOC 887 for acknowledgment of reading and comprehension of this document.