



CSSP-ERB RVW Form 13

CSSP-ERB Final Report Form

CSSP-ERB Code:	
Study Title:	
Principal Investigator:	
Submission Date:	

INITIAL APPROVAL DATE: <dd/mm/yyyy>		
DATE OF LAST CONTINUING REVIEW APPROVAL: <dd/mm/yyyy>		
Version and date of latest approved protocol:		
Version and date of latest approved Informed Consent Form:		
Email:	Telephone:	Mobile:
STUDY SITE: <Name and address>		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	Telephone:	Mobile:
FINAL REPORT:		
1. When did the study start? <dd/mm/yyyy>		
2. When did the study end? <dd/mm/yyyy>		
3. When was the data collection period? <dd/mm/yyyy> to <dd/mm/yyyy>		
4. How many participants were approved to be enrolled by the CSSP-ERB?		
5. How many participants withdrew from the study?		
6. How many participants were there at the end of the study?		
7. What were the deviations from the approved study protocol?		
8. What were the issues/problems encountered?		
9. What were the participants' complaints or grievances documented regarding the conduct of the study?		
10. What were the documented benefits?		
11. What were the indemnifications, and compensations (if applicable)?		
12. What were the study objectives and results?		
13. When was the <i>Continuing Review Application</i> submitted with the corresponding panel action (if applicable)?		
14. Report on outcome of data protection plan (e.g reports of a breach of privacy, and storage of identifiable information):		
DATE OF LAST REVIEW: <dd/mm/yyyy>		
SIGNATURE OF PI:		
FOR STUDENTS, VERIFIED BY:		
<Name and Signature of Research Supervisor>		

RECOMMENDED ACTION:

Note: If **for modification/amendment**, indicate if minor or major modification/amendment by putting a check next to the appropriate choice. Also, highlight the justification for the recommended action from the choices provided.

APPROVE

PROVISIONAL APPROVAL

Specify:

FOR MODIFICATION/AMENDMENT

Minor Modification/Amendment

Justification:

Incomplete Documentation

Incomplete ICF/PIS Elements

Unsatisfactory IC Format

Others:

Major Modification/Amendment

Justification:

Change of Study Objectives

Change in the Recruitment Process

Revision of exclusion/inclusion Criteria

Change of Data Collection Method

Change in the process of mitigation of risk/harm

to participants and the integrity of the research

Others:

ADDITIONAL REMARKS:

PRIMARY REVIEWER

Signature _____

Date: <dd/mm/yyyy>

Name <Title, Name, Surname>

Panel <Name of Panel>
