



CSSP-ERB RVW Form 12

Reportable Negative Event (RNE) Report

General Information			
Title of Study			
Protocol Code		Study Site	
Name of Primary Investigator		Contact Information	Tel No.:
			Mobile No.:
Co-investigator/s (if any)			Email:
Institution			
Address of Institution			
Ethical Clearance Effectivity Period			
Start of study		Expected end of study	
RNE Report			
		Reviewer Comments	Reviewer Recommendations
Number of enrolled participants			
Number of required participants			
State the Negative (harms, risks) Events			
a. Involving Participants, Communities			
b. Involving Members of the			

Study Team			
c. Involving Data Safety and Integrity			
d. Involving the study site (e.g., occurrence of calamity or crisis)			
State the actions taken to prevent future RNEs			
State corrective actions taken (Interventions and Outcomes)			

RECOMMENDED ACTION:

Note: Reviewers may choose more than one of the following decision points.

- ☐ Require an amendment to the protocol
- ☐ Submit a plan to mitigate risk/harm
- ☐ Modify sections of the original protocol
- ☐ Suspend the study until the risk from the RNE is mitigated.
- ☐ Terminate the study immediately
- ☐ Uphold original Ethics Clearance
- ☐ Withdraw Ethics Clearance

ADDITIONAL REMARKS:

PRIMARY REVIEWER

Signature _____

Date: <dd/mm/yyyy>

Name <Title, Name, Surname>

Panel <Name of Panel>