

	UP OPEN UNIVERSITY Institutional Research Ethics Committee		
	REPORTABLE NEGATIVE EVENT REPORT	REC Form No.	11A (A)
		Version No:	01
		Date of Effectivity:	

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked below (in Section 3. Checklist of Documents).

General Information			
*Title of Study			
Version Number/Date of the EC approved protocol			
*REC Code (To be provided by UPOU IREC)		*Study Site	
*Name of Researcher		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email
*Institution			
*Address of Institution			
Effective period of Ethical Clearance	From:	To:	
Progress Report			
1. Start of study	2. Expected End of Study		
3. Number of enrolled participants	4. Number of required participants		
5. Description of Negative (harms, risks) Events <ul style="list-style-type: none"> a. Involving participants b. Involving members of the Study Team 	6. Actions taken to prevent future RNEs, interventions, and outcomes		



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c. Involving data safety and integrity

7. Recommendations