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|  | UP OPEN UNIVERSITY Institutional Research Ethics Committee | | |
| | PROTOCOL VIOLATION/ DEVIATION REPORT | REC Form No. | 10 (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. Number of participants who withdrew | | | |
| 6. Deviations from the approved protocol | 7. Explanation for deviation/violation | | |



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8. Impact of deviation/violation on participant's risk/harms and integrity of data

9. Actions taken to prevent future deviation/violation