**Statement of Policy**

Researchers shall report protocol deviations and violations in the conduct of approved researches within a week from the detection of the protocol violation/deviation. Major protocol violations undergo full review.

**Objectives of the SOP**

Review of protocol deviations and violations aims to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility and integrity of data are maintained.

**Scope/Applicability**

This SOP applies to the review of reports of protocol deviations or violations in the conduct of previously approved studies. This begins with the receipt and documentation of the report of protocol violations and deviations in the logbook and ends with the filing of all related documents and update of the database.

**Flowchart**

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| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Receipt and documentation of report of protocol violations and deviations in the logbook. | Staff | 1 day |
| Step 2: Retrieval of pertinent protocol file | Staff | 1-2 days |
| Step 3: Notification of Chair and primary reviewers. | Staff | 1-2 days |
| Step 4: Determination of type of review: expedited (SOP on Expedited Review (SOP# 04)), full review (SOP on Full Review (SOP# 05)) | Chair | 1-2 days |
| Step 5: Inclusion of report in the agenda of the next REC regular meeting (SOP on Preparing the Meeting Agenda (SOP# 18); SOP on Conduct of Meeting (SOP# 19)) | Staff and Chair | 1-2 days |
| Step 6: Communication of decision to the Principal Investigator/researcher (SOP on Communicating REC Decisions (SOP# 21)) | Staff and Chair | 1-2 days |
| Step 7: Filing of all related documents and update of the protocol database (SOP on Managing Active Files (SOP# 23)) | Staff | 1 day |

**Description of Procedures**

Step 1 - Receipt and documentation of report of protocol violations and deviations in the logbook/database: The Staff receives the report on protocol deviation or violation in the appropriate report form (Form # 017) and records this in the logbook for incoming documents.

Step 2 - Retrieval of pertinent protocol file. The Staff retrieves the approved protocol and checks the identity of the primary reviewers for reference and guidance of the Chair in the selection/ designation of reviewers.

Step 3 - Notification of Chair and primary reviewers. The Staff notifies and sends the protocol deviation or violation report and together with the retrieved pertinent documents to the Chair and the primary reviewers.

Step 4 - Determination of type of review: expedited or full review: The Chair and primary reviewers determine the type of review such that major protocol violations undergo full review. Otherwise, the protocol deviation undergoes expedited review. See SOP# 04: Expedited Review and SOP # 05: Full Review.

Step 5 - Inclusion of report in the agenda of the next REC regular meeting. The Chair includes the report on protocol deviation and violation in the Agenda of the next meeting if it is for Full review or the decision report if Expedited review. See SOP on Preparing the Meeting Agenda and SOP on Conduct of Meetings.

Step 6 - Communication of Decision to the Principal Investigator/researcher: The Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. Possible decisions include one or several of the following: (1) submission of additional information, (2) submission of corrective action, (3) invitation to a clarificatory interview, (4) Requirement for an amendment (5) site visit, (6) suspension of recruitment, and (7) withdrawal of ethical clearance.

Step 7 - Filing of all related documents and update of the protocol database. Staff collates and files the retrieved protocol documents, the report on protocol deviation and violation and the decision letter in the appropriate protocol file and updates the protocol database with the relevant information.

**Forms:**

SOP 10 Form 017 Protocol Deviation/Violation Report Form

Form 008 Decision Letter Template

**History of SOP**

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| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 01/28/2015 |  |  |
| 02 | 03/05/2021 | krva | Criteria for early termination when protocol violation / deviation is committed.  Definition of major and minor violation/ deviation. |
| 03 | 09/22/2022 | krva | Revision of SOP |