UC San Diego Altman Clinical and Translational Research Institute Center for Clinical Research	SOP Number	CCR:013 Page 1 of 1
	Date:	09/04/2025
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Clinic Protocol Deviation Response		

1 PURPOSE

1.1 This SOP describes the processes to be followed when a protocol deviation occurs in the Altman Clinical and Translational Research Institute's (ACTRI) Center for Clinical Research (CCR). This will ensure that protocol deviations are monitored, and appropriate action is taken.

2 REVISIONS FROM PREVIOUS VERSION

2.1 N/A

3 REQUIREMENTS

3.1 All CCR personnel are required to document, notify management, the PI, study coordinator and submit an iReport for all identified protocol deviations that occur in the ACTRI clinic.

4 RESPONSIBILITIES

4.1 The ACTRI clinic staff are responsible for carrying out these procedures. Clinic leadership is responsible for investigating, tracking and taking appropriate corrective action when necessary.

5 PROCEDURE

5.1 Upon identification of a protocol deviation, the Clinical Research Coordinator (CRC) and the Principal Investigator (PI) will be notified of any protocol deviations from the clinic staff (adjusted time points, specimen collection or processing errors, subject -noncompliance, etc.)

5.2 All protocol deviations and the subsequent notification procedure will be documented in the study participants medical record, protocol flow sheets and the iReport system.

5.3 In the event the PI or designated research personnel appear to be deviating from the protocol, the CCR clinic staff will discuss the situation with the PI.

5.3.1 If the situation is not resolved satisfactorily for the CCR clinic staff, the clinic manager or director will be notified.

5.4 An iReport will be completed within 24 hours of the occurrence by the staff member who identifies the protocol deviation. This could be the CCR clinic staff or the study team Clinical Research Coordinator.

5.5 CCR leadership will track all protocol deviations for quality control.

6 MATERIALS

N/A

7 REFERENCES

7.1 UC Davis Protocol Deviation SOP

7.2 CCR-014 Filing an iReport