Clinical Research Enterprise (CRE)

Standard Operating Procedures

Reporting Errors

SOP #:	1.17		
Version:	1.0		
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			01/24/2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this SOP is to provide the rational and process for reporting errors.

References

UAB Duty to Report and Non-retaliation Policy

- https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=97

The following references are available for view via Compliance 360 on the UAB One Medicine Website.

- https://oneuabmedicine.org/at-the-bedside/clinical-references-resources/compliance-360/
  - Medication Errors, Policy Number: I 384
  - Patient Safety Plan, Policy Number: EFH #50
  - Safety Management Plan UAB Hospital (Inpatient and Outpatient Buildings), Policy Number: I219

Scope

This SOP applies to all member of the CRE staff.

Allowable Exceptions

This SOP is meant to be followed without deviation.

I. Rational

a. Reporting errors is a fundamental process to enable error prevention.

b. Even if an error did not result in a serious or potentially serious event that does not negate the fact that it was and still is an error. Reporting both errors and near

misses is key for improving the safety of the employees and the patients we serve.

c. Reporting sets up a process so that errors and near misses can be communicated to stakeholders and allows for further analysis of processes and procedures that can be improved upon to prevent further errors from occurring.

d. Respect for patient autonomy is paramount, as is the importance of veracity. Fidelity, beneficence, and nonmaleficence are all principles that orient reporting and disclosure policies. Employees can benefit from accepting responsibility for errors, reporting and discussing errors with colleagues, and disclosing errors to patients and apologizing to them.

e. If employees cover up errors and mistakes, they do not necessarily stay hidden and often result in compromising the mission of our institution. Consistent with our mission, UAB has an ethical obligation to admit research mistakes, both clinical and nonclinical.

II. Errors that do not place participants at significant or immediate risk or harm.

a. *Examples include (not limited to):*

i. Data entry error
ii. Extra tube of blood collected
iii. Loss of a sample
iv. Incorrect processing of labs improperly
v. Temperature excursions
vi. Missed procedure or assessment from the schedule of events
vii. Delayed study data entry
viii. Missed or incorrect IRB submission

b. Notification process (within 24 hours of identifying the error)

i. Notify the direct supervisor and team lead
ii. Supervisor or team lead will notify the regulatory team (if applicable)
iii. The supervisor will work with the employee to notify the sponsor and PI (if applicable)
iv. The employee, supervisor, nurse educator, and regulatory team will create a corrective action plan and implement the place

III. Errors that place participants at risk or harm.

a. Examples include (not limited to):

i. Participant received wrong procedure/drug/device/wrong dose
ii. Participant randomized improperly
iii. Participant consented and did not qualify
iv. Failure to report SAEs/AEs
v. Missed a reconsent (for invasive procedure/significant study changes) of a patient,
vi. Visit occurred out of window (for studies involving interventions/therapies, defined study time points, PKs)

vii. PI not notified of abnormal lab values or diagnostic tests
viii. Failing to report findings back to patient.

b. Notification process (immediately upon identifying the error)

i. Notify the supervisor and team lead
ii. Supervisor or team lead will notify the regulatory team (if applicable)
iii. The supervisor will work with the employee to notify the sponsor and PI (if applicable)
iv. The employee, supervisor, nurse educator, and regulatory team will create a corrective action plan and implement the plan