CLINICAL AND RESEARCH HUMAN SUBJECT CENTRAL INCIDENT RESPONSE PLAN

Background

This document is intended to set institutional standards for the reporting, coordinating, and independent investigation of a reportable event as defined in this Clinical and Research Human Subject Central Incident Response Plan (the "Response Plan"). The purpose of this document is to ensure that reportable events involving human subjects/patients/constituents are properly disclosed by an applicable department, division or unit, and is reviewed by the Clinical and Research Human Subject Central Incident Response Team (the "Response Team") described below. This Plan is not intended to supersede or replace existing policies, protocols, or mandated reporting requirements, but rather is intended to coordinate efforts when a reportable event occurs.

This Plan also establishes a prevention-first framework, adding near-miss reporting and a proactive Risk & Safety Impact Assessment (RSIA) requirement prior to launching any new or materially changed endeavor.

Reportable Events Definition

A reportable event includes any unfavorable, unintended or harmful occurrence that happens to a person during their participation in University clinical or research activities, including but not limited to, participation in a research study, a clinical trial, or in association with a medical service, product or treatment. An event is considered reportable if it results in one of the following:

- Death
- A life-threatening situation (where the event puts the person at immediate risk of death)
- Inpatient or prolonged hospitalization
- Actual or imminent physical or psychological harm
- Persistently or significant disability or incapacity
- Medical or surgical intervention to prevent one of the above outcomes
- Near-Miss: an unsafe condition, process deviation, or error that could have caused harm but did not, either by chance or timely intervention. Near-misses are reportable under this Plan.

Initial Documentation of a Reportable Event and Notification Protocol

This Plan must be used when anyone observes, learns of, receives a tip or is provided with information which establishes a reasonable basis to infer that a reportable event, serious

safety event, or near-miss may have occurred. All reports must be submitted through the central reporting portal (Clarity system through the self-insured program) for establishing a single point of entry. Reporters are encouraged to submit their contact information for follow up, but also have the option to report anonymously. Retaliation for good faith reporting or participation in an investigation is prohibited. The portal captures facts known at the time and routes the report based on severity. Upon submission, the system/process assigns a severity level (S1 to S3) and triggers automated notifications with tracked response time service level agreements (SLAs). The Office of the General Counsel (OGC) will be notified immediately for a S3, the same business day for a S2, and included in a summary report for a S1 by risk management. The difference between a general reportable event and a serious reportable event is critical for reporting purposes, as serious reportable events require a more urgent response and may trigger required reporting requirements (i.e., to law enforcement, state or federal agencies, the FIU Self Insurance Program and/or compliance committees such as the IRB). Communications should be limited to the Response Team and others on a need-to-know basis only with careful consideration as to what should be communicated verbally or documented in writing.

Notification Matrix & Service Levels (SLA)

Tier	**Definition (examples)**	**Auto-Notify**	**Response SLA**
S3 (Serious AE)	Death; life-threatening; inpatient/prolonged hospitalization; significant disability; major protocol breaches affecting safety.	OGC, Health Affairs, ORED/Research Compliance, HR, Safety/Compliance; page/call tree.	Immediate (≤1 hr) huddle; document actions within 24h.
S2 (AE)	Injury requiring treatment; protocol deviation impacting safety	OGC + core Response Team via email; assigned incident lead.	Same business-day triage; document within 2 business days.
S1 (Near-Miss)	Unsafe condition/error with no harm.	Incident coordinator; unit safety lead.	Acknowledge within 1 business

			day; close within 10 business days.

Central Reporting & Notification

All reportable events must be submitted via the Central Reporting Portal (Clarity system through the self-insured program). Anonymous reporting is available. Retaliation is prohibited. The Portal assigns severity and triggers automated notifications per the matrix above. Legal remains the final authority for external reporting determinations and convening the Response Team, as required.

Areas Generally under the Purview of this Plan

Although each case will have a unique set of circumstances and/or facts that will determine whether the Response Team is the correct forum to manage and investigate, in general, incidents originating from or having a substantial nexus to the following colleges, units or departments should be reported accordingly for initial review:

- All activities from the Center for Children and Families having a clinical, research or component of patient delivery to members of the FIU community or the public.
- All research activities, which include human subject/clinical research care and are under IRB oversight.
- Any reportable event resulting from clinical activity sponsored or organized by any college or unit of the university.

Review by the Response Team

The reported event will be reviewed by the Response Team. Some reportable events (after final determination by legal counsel) may require notification to individuals and/or others based on contractual commitments or applicable laws and regulations. If a regulatory agency must be notified about the reportable event, the Response Team will determine which University unit/official should provide such notification (after Office of General Counsel review). The Response Team also will determine whether interim risk controls are required, assign owners, and track closure through a Corrective and Preventive Action (CAPA) log.

Composition and Actions of the FIU Reportable Event Response Team

The Response Team shall consist of a core team of central administration with the ability to oversee the management of the review/actions to be taken in relation to a reportable event, as may be required. The Legal representative will serve as the Chair of the Response Team and

will schedule the meetings of the Response Team and ensure that the procedures of this Response Plan are followed.

The Vice-Chair of the Response Team shall be the Health Affairs representative and the Vice Chair serves as backup to the Chair.

Adverse Event Member	Role of Reportable Event Member
HR Representative	Provides feedback and guidance to the Response Team regarding employment matters including impact, if applicable.
ORED Representative	Provides feedback and guidance to the Response Team regarding research and research compliance requirements relevant to the reportable event, if applicable, including research sponsor/award requirements and the requirements of compliance committees such as the IRB, etc.
Legal Representative	Provides legal guidance and makes all final legal determinations related to all aspects of the reportable event matter.
Health Affairs Representative	Provides medical / clinical expertise, guidance and analysis related to all aspects of the reportable event matter.

As warranted, the core members of the Response Team will confer to determine if other members of the FIU community should be invited to join the Response Team for a particular reportable event matter in an advisory capacity if the facts surrounding the reportable event warrants such participation.

Proactive Risk & Safety Impact Assessment (RSIA)

At the conclusion of all respective reviews or investigations and prior to initiation of any new or materially changed research, clinical, or service endeavor, the responsible unit must complete an RSIA, if applicable. Screening determines whether a full RSIA is required. Full RSIA uses structured methods (e.g., Failure Modes & Effects Analysis (FMEA), bowtie analysis, Hazard Identification & Risk Assessment (HIRA)). Outputs include a risk plan with owners and due dates, a mitigation plan (engineering/administrative controls, PPE, training, monitoring), and a readiness checklist signed by applicable offices (e.g., Legal, ORED/IRB, Radiation/Biosafety, Health Affairs or any other compliance unit).

Launch approval requires completion of role-based training and closure (or formally accepted residual risk) of high-priority items. Material changes trigger RSIA update. Corrective and Preventive Action (CAPA) items are tracked and reviewed quarterly by the Response Team.

Proactive Rounds, Audits, and Leading Indicators

Units conduct monthly/quarterly safety huddles to review near-misses, high risk items, and overdue mitigations. Quarterly mock audits sample new endeavors. Leading indicators include: near-miss rate, % of RSIA mitigations closed on time, training completion pre-launch, and time-to-mitigation for high-risk items.

Findings of the Response Team

The Response Team, upon completion of its review and in collaboration with the Office of the General Counsel, shall coordinate all appropriate reporting to law enforcement, state or federal agencies, the FIU Self Insurance Program, project sponsors, institutional compliance committees such as the IRB, etc. or any other entity or individual required by law. The Response Team also will provide notice to the President, Provost, and/or other members of executive leadership, as warranted, as well as to the Chair of the Florida International University Board of Trustees Audit and Compliance Committee.

Beyond required notifications, the Response Team issues and tracks a Corrective and Preventive Action (CAPA) plan for systemic risks identified through incidents, near-misses, or RSIAs, with named owners, deadlines, and verification of effectiveness. CAPA status is reviewed at least quarterly and summarized on a Safety Dashboard.

Governance, Training, and Document Control

Non-retaliation for reporters is reaffirmed. Annual micro-learning covers what/when/how to report, how to recognize near-misses, and how RSIA protects participants and staff. This Response Plan is version-controlled; associated SOPs include Reporting SOP, RSIA SOP, CAPA SOP, and Communications SOP with approved templates for internal/external messages.

HISTORY

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