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|  <p>Senior Associate Vice Chancellor for Health Sciences</p> <p>Office of Clinical Research</p> | SOP Number | OCR:019 Page 1 of 2 |
| | Date: | 04/02/2025 |
| | Author: | T. Graham |
| | Approved by: | S. Little |
| SOP TITLE: CLINICAL EMERGENCIES MANAGEMENT | | |

1 PURPOSE

- 1.1 The procedure establishes the process that research personnel will follow when clinical emergencies arise in off-campus locations or other locations that are independent of immediate UC San Diego Health system resources to ensure participant and study personnel safety while complying with applicable policies and regulations.
- 1.2 The procedure begins when a clinical study is ready to commence participant visits.
- 1.3 The procedure ends when all clinical study participant visits are complete.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS


- 3.1 Any life-threatening emergency requires immediate activation of local emergency medical services (EMS) with a 911 call, or local equivalent.
- 3.2 Principal investigators (PIs) and research teams must plan for and ensure readiness to manage clinical emergencies in research locations that lack immediate access to UC San Diego Health system resources, while considering staff training and protocol-specific requirements.
- 3.3 All research personnel must respond to clinical events within the scope of their training, licensure, and competency to stabilize research participants experiencing an acute clinical event until clinically-trained personnel or emergency responders arrive.
- 3.4 Regardless of the location of the incident, research participant privacy and data security measures are required, commensurate with UCSDHS policy.
- 3.5 All study personnel will prioritize participant and staff safety during clinical emergencies and adhere to UC San Diego Health Sciences policies and local emergency management requirements.

4 RESPONSIBILITIES

- 4.1 The PI is responsible for ensuring that appropriate emergency protocols, communication tools, and first aid resources are available in any location where research personnel and research participants are present.
- 4.2 The PI or designee will ensure that all team members have been trained on emergency protocols and evacuation procedures.

5 PROCEDURE

- 5.1 In preparation for research participant visits:
 - 5.1.1 The PI or designee will develop site-specific emergency response plans, including clear contact information for local emergency services and nearby hospitals.
 - 5.1.1.1 Conduct and document emergency response plan training with all study personnel. Training may include, but not be limited to, first aid, cardiopulmonary resuscitation (CPR), and site-specific safety measures.

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- 5.1.1.2 Verify that equipment specified in the emergency response plan is available and functional. Equipment may include, but not be limited to, first aid kit, automated external defibrillator, and fire extinguisher.
- 5.2 When an emergency is identified, available personnel will:
 - 5.2.1 Assess the situation and determine safety risks to individuals who are in proximity.
 - 5.2.2 Call 911 or local EMS and provide accurate details about the nature of the incident and the precise location.
 - 5.2.3 Stabilize the individual by administering first aid or CPR if trained and within scope, without exceeding individual competencies.
 - 5.2.4 When EMS arrives, report relevant details of the incident to the EMS team.
 - 5.2.5 Evacuate if necessary to protect others from immediate danger.
 - 5.2.6 Notify the PI and relevant institutional contacts as soon as it is practicable and safe to do so.
- 5.3 Following an incident, the senior team member who was present during the incident will:
 - 5.3.1 Complete an [incident report](#) providing details of the emergency, response actions, and outcomes.
 - 5.3.1.1 The incident report will be submitted to the PI and to UC San Diego Environment, Health & Safety within 24 hours of the event.
- 5.4 The PI or designee will conduct and document a root cause analysis post-incident to identify any contributing factors and implement necessary preventative measures, reporting any relevant safety concerns to [Environment, Health & Safety](#) in a timely manner.
- 5.5 The PI or designee will ensure that staff and participants involved in the incident receive appropriate debriefing and emotional support as needed.
- 5.6 The PI or designee will review the incident and response to ensure that institutional, local, and regulatory requirements were met.
- 5.7 The PI or designee will ensure that follow-up training is provided and documented, as necessary, and changes to procedures are implemented, if required.
- 6 MATERIALS**
 - 6.1 None
- 7 REFERENCES**
 - 7.1 [Environment, Health & Safety - Safety Concern](#)
 - 7.2 [Incident Report for Students & Visitors](#)