

RESPONDING TO MEDICAL EMERGENCIES OR UNUSUAL EVENTS

SOP 11.1.02

1. Purpose & Policy

The purpose of this SOP is to provide researchers with recommended responses to a variety of unusual or emergency events which could be encountered during human subjects research at Caltech. These guidelines are intended to be used to help construct an emergency response standard operating procedure (SOP) for a research protocol.

2. General Information

Participants should always be under continuous supervision during any research session. This need not always be visible contact but should always enable immediate communication between the participant and researcher (e.g. the participant might be alone in a room filling out a questionnaire but should be able to contact the researcher nearby and should not be left unattended for a prolonged time). For clinical populations, it may be necessary to maintain visible observation at all times.

Emergency responses should always be initiated through Caltech Security if you are on campus:

By calling Ext 5000 from a Caltech landline,

By calling 626-395-5000 from a cell phone, or

By activating the “call security” feature on the Everbridge App.

Calling 911 directly from campus may delay the emergency response. For an off-campus emergency, calling 911 is appropriate.

Please refer to the [Caltech Emergency Response Guide](#) for additional information regarding how to prepare for and respond to many different types of emergencies. Hardcopies of the Caltech Emergency Response Guide are distributed by the Security office at 626-395-4701 or emergencypreparedness@caltech.edu.

It is recommended that all research personnel recruiting from patient populations should have appropriate briefing and training to recognize and handle specific emergencies associated with that patient group. For example, researchers may wish to read about recognizing and responding to potential emergencies in their participant population, and stay current with American Red Cross CPR/AED, Child CPR, and First Aid Certifications.

Be aware that Caltech offers regular First Aid and Child/Infant/Adult CPR/AED training throughout the year. See <https://emergencypreparedness.caltech.edu/training/CPRFirstAid> for details.

The Good Samaritan law protects personnel from civil liability for engaging in, or omitting from engaging in, any first-aid action. However, the law only applies if the aid was provided in good faith

and without malice or self-serving motivations or to complications from gross negligence or willful misconduct.

It is recommended that nobody should ever study participants alone without a nearby second person (e.g., late at night when nobody else is around in the lab). When working with minors or when a study protocol includes physical contact between a researcher and participant, the IRB recommends that two investigators (one of whom is an adult) be present in the room for the duration of the study. However, for all portions of the study where there is to be physical contact between an investigator and a participant, two attentive investigators must be present. A non-minor participant may be left alone in a room, for example, to fill out a survey or during MRI scanning. When a minor is participating in an MRI scan, they may be alone, however, one investigator must be immediately available outside of the scanning room.

3. Training Requirements

Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with responding to medical emergencies or unusual events for all protocols; however, researchers should carefully read and follow this guidance and implement appropriate training for researchers on a protocol-by-protocol basis.

4. Procedure

A. Panic or Anxiety Attack

Adapted from [\[https://www.webmd.com/first-aid/panic-attacks-treatment\]](https://www.webmd.com/first-aid/panic-attacks-treatment)

Panic attacks often manifest as hyperventilation (rapid breathing), fast heart rate, and/or sweating; patients may feel tingling in their hands due to hyperventilation.

To reduce the possibility of anxiety or a panic attack in participants:

1. Verbally check with the participant about his/her wellbeing.
2. Be especially vigilant if there is an increased risk (e.g., planning rest breaks for a participant with a known anxiety disorder; conducting a protocol intended to induce emotions).

In the event of a panic or anxiety attack:

1. Stop the research session immediately.
2. Ask the person what you can do to help.
3. Make eye contact and try to get the person to pay attention to you. Ask the person what they are feeling, and reassure them that these feelings usually pass quickly.
4. Be calm. Encourage the person to take slow, even breaths WITH YOU. Say that slow deep breaths often help the symptoms the participant is experiencing.
5. Do not minimize the person's symptoms.

6. If it is not possible to calm the person, an emergency response should be initiated via Caltech Security (Ext 5000).
7. Consult with a second researcher, if possible. Ideally, this would be the PI or professor under whom the study is being conducted.
8. The protocol should not be continued with that participant. If the anxiety or panic was more than expected for the protocol and population, the study should not continue until the event is reported to the IRB, reviewed, and approved for continued work with study participants.

B. Despondent or Depressed Participant

In very rare cases, a participant may become despondent or depressed before, during or following a research session. To reduce the probability of such an event:

1. Be cognizant of how your study participant is behaving. If somebody is acting strangely or becomes unengaged and loses interest in the study, consult with a senior researcher immediately (ideally the PI or professor under whom the study is being conducted).
2. Verbally check with the participant about their wellbeing.
3. If you have a bad feeling about a participant based on their behavior, it is appropriate to terminate the study gracefully. Pay the participant for their time, if possible, and provide an innocuous reason for discontinuing the study (e.g., a computer is malfunctioning, sorry).

If you think a participant may be having suicidal thoughts, provide the participant with contact information for the National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255). Use that same number and press “1” to reach the Veterans Crisis Line.¹

If you think a participant may hurt themselves or attempt suicide, call Caltech Security (Ext 5000).

C. Agitated Participant

In very rare cases, a participant may become agitated, confrontational or aggressive before, during or following a study. To reduce the probability of such an event:

¹ <https://www.mayoclinic.org/diseases-conditions/depression/symptoms-causes/syc-20356007>

1. Be cognizant of how your participant is behaving. If somebody is acting strangely or seems unwilling to follow instructions, consult with a senior researcher immediately (ideally the PI or professor under whom the study is being conducted).
2. If you have a bad feeling about a participant based on their behavior, it is appropriate to terminate the study gracefully. Pay the participant for their time, if possible, and provide an innocuous reason for discontinuing the study (e.g., a computer is malfunctioning, sorry).

If a participant becomes agitated, the following² provide a well-established set of approaches to de-escalation:

Ten Domains of De-Escalation

1. Respect personal space.
2. Do not be provocative.
3. Establish verbal contact.
4. Be concise.
5. Identify wants and feelings.
6. Listen closely to what the participant is saying.
7. Agree or agree to disagree.
8. Lay down the law and set clear limits.
9. Offer choices and options.
10. Debrief the participant and research staff.

D. Seizure

Adapted from

[\[https://www.hopkinsmedicine.org/health/conditions-and-diseases/epilepsy/evaluation-of-a-firsttime-seizure\]](https://www.hopkinsmedicine.org/health/conditions-and-diseases/epilepsy/evaluation-of-a-firsttime-seizure)

To reduce the possibility of a seizure in a participant:

1. Verbally check with the participant about their wellbeing if they are at risk for having a seizure (e.g., ask if they are currently on medication, if there are any

² Richmond JS, Berlin JS, Fishkind AB, Holloman GH Jr, Zeller SL, Wilson MP, et al. Verbal De-escalation of the Agitated Patient: Consensus Statement of the American Association for Emergency Psychiatry Project BETA De-escalation Workgroup. West J Emerg Med. 2012;13: 17–25.

specific triggers for the seizure, and ask them to let you know if they feel anything abnormal that might indicate an incipient seizure).

2. Be vigilant of seizures in populations with a known seizure disorder and/or protocols that may increase the risk of a seizure (e.g., TMS, flashing visual stimuli).

Someone having a seizure may experience any or all of the following:

1. Staring
2. Jerking movements of the arms or legs
3. Stiffening of the body
4. Loss of consciousness
5. Breathing problems or stopping breathing
6. Loss of bowel or bladder control
7. Falling suddenly for no apparent reason, especially when associated with loss of consciousness
8. Not responding to noise or words for brief periods
9. Appearing confused or in a haze
10. Nodding their head rhythmically, when associated with loss of awareness or loss of consciousness
11. Periods of rapid eye blinking and staring

During the seizure, lips may become tinted blue and breathing may not be normal. After the seizure, one may be sleepy or confused. The symptoms of a seizure may be like those of other health conditions.

In the event of a seizure:

1. Stop the research session immediately.
2. Remove the participant from the study environment if possible and/or remove objects near the person that can be knocked over or fall on them.
3. Roll the participant onto their side (recovery position) and observe continuously. If necessary, assist them to the floor to lie on their side – to avoid head trauma if they fall.
4. Reassure the person that you will stay with them. Face the person if you can so that they can see your face while you try and comfort them.
5. Look at the clock or your watch so that you can have an estimate of how long the seizure lasts. Try to observe the seizure pattern.

6. Consult with a second researcher, if possible. Ideally, this would be the PI or the professor under whom the study is being conducted. However, do not leave the participant unattended to do this.
7. The research session should not be continued with that participant. If the seizure was more than expected for the protocol and population, the study should not continue until the event is reported to the IRB, reviewed and approved for continued work with study participants.
8. If the seizure persists for more than 1 minute, an emergency response should be initiated via Caltech Security (Ext 5000), or if you are off-campus, call 911.
9. If the seizure persists for more than 1 minute and Caltech Security has been called but has not yet arrived, be prepared to administer CPR, if needed.

E. Heart Attack

Adapted from [<https://www.mayoclinic.org/first-aid/first-aid-heart-attack/basics/art-20056679>] and [https://www.emedicinehealth.com/should_you_do_cpr_or_aed_first/article_em.htm]

To reduce the possibility of a heart attack in a participant:

1. Verbally check with the participant about their wellbeing if they are at risk for having a heart attack (e.g., ask if they are currently on medication, and ask them to let you know if they feel anything abnormal that might indicate a heart attack).
2. Be vigilant of a heart attack in populations with a known risk for heart attack and/or protocols that may increase the risk of a heart attack (e.g., involving vigorous exercise).
3. Know the location of the nearest automated external defibrillator (AED) in your building and how to use it.

Someone having a heart attack may experience any or all of the following:

1. Uncomfortable pressure, fullness, or squeezing pain in the center of the chest;
2. Discomfort or pain spreading beyond the chest to the shoulders, back, neck, jaw, teeth, one or both arms, or occasionally upper abdomen;
3. Shortness of breath;
4. Lightheadedness, dizziness, fainting;
5. Sweating;
6. Nausea

A heart attack generally causes chest pain for more than 15 minutes, but it can also have no symptoms at all. It's important to be aware that symptoms other than chest pain may occur, such as indigestion or persistent neck or jaw pain.

In the event that a participant may be experiencing a heart attack:

1. Stop the research session immediately.
2. Initiate an emergency response via Caltech Security (Ext 5000), or if you are off-campus, call 911.
3. Don't allow the participant to ignore or attempt to tough out the symptoms of a heart attack.
4. If the participant is unconscious and an automated external defibrillator (AED) is immediately available, follow the device instructions for using it.
5. If the participant is unconscious and an AED is not immediately available, begin CPR.
6. If the location of an AED is known and two researchers are present, one should begin CPR while the other gets the AED. Once the AED is located, follow the device instructions for using it.
7. If you haven't received CPR training, doctors recommend performing only chest compressions (about 100 to 120 compressions a minute). Security or the dispatcher can instruct you in the proper procedures until help arrives.
8. Consult with a second researcher, if possible. Ideally, this would be the PI or professor, under whom the study is being conducted. However, do not leave the participant unattended to do this.
9. The protocol should not be continued and the event should be reported to the IRB. The study may not continue until the IRB approves the continued work with study participants.

F. Stroke

Adapted from [<https://www.mayoclinic.org/first-aid/first-aid-stroke/basics/art-20056602>]

To reduce the possibility of a stroke in a participant:

1. Verbally check with the participant about their wellbeing if they are at risk for having a stroke (e.g., ask if they are currently on medication for high blood pressure, and ask them to let you know if they feel anything abnormal that might indicate a stroke).
2. Be vigilant of a stroke in populations with a known risk for stroke and/or protocols that may increase the risk of a stroke (e.g., involving vigorous exercise).

**INITIATE AN EMERGENCY RESPONSE THROUGH CALTECH SECURITY IMMEDIATELY (x5000)
(or if off-campus, call 911) IF ANY OF THE FOLLOWING SIGNS OR SYMPTOMS ARE
OBSERVED:**

In the event of a possible stroke, use F.A.S.T. to help remember warning signs:

1. **FACE:** Does the face droop on one side when the person tries to smile?
2. **ARMS:** Is one arm lower when the person tries to raise both arms?
3. **SPEECH:** Can the person repeat a simple sentence? Is speech slurred or hard to understand?
4. **TIME:** During a stroke, every minute counts.

Other signs and symptoms of a stroke, which come on suddenly, include:

1. Weakness or numbness on one side of the body, including either leg;
2. Dimness, blurring, or loss of vision, particularly in one eye;
3. Severe headaches, a bolt out of the blue, with no apparent cause;
4. Unexplained dizziness, unsteadiness or a sudden fall, especially if accompanied by any of the other signs or symptoms.

Consult with the second researcher, if possible. Ideally, this would be the PI or professor under whom the study is being conducted. However, do not leave the participant unattended to do this.

The protocol should not be continued with that participant and the event should be reported to the IRB. The study may not continue until the IRB approves the continued work with study participants.