UNIVERSITY OF OREGON

RESEARCH COMPLIANCE SERVICES

Guidance for Human Physiology Investigators on Emergency and Non-Emergency Procedures for Human Subject Research

Scope: The procedures outlined below provide guidance to Human Physiology laboratories on how to respond in the event of an emergency or non-emergency. The goal of this document is to ensure that all Human Physiology laboratories are following identical procedures for emergency and non-emergency responses within their respective labs across campus. This document was developed by the Human Physiology Department faculty in collaboration with the UO Institutional Review Board.

When preparing for a human subject research study, the procedures below need to be reviewed with all lab members to ensure the all personnel are trained to ensure they can appropriate respond in the event of an incident. The procedures described in the IRB protocol materials need to be consistent with those described below.

I. General

Investigators should contact Research Compliance Services (RCS) immediately upon discovery of an unanticipated problem or event involving risks to participants or others. Unanticipated problems and events should be reported no later than 7 days of the investigator becoming aware of the occurrence.

Investigators who conduct research involving more than minimal physical risks to participants will be required to have Basic Life Support (BLS) / Cardiopulmonary Resuscitation (CPR) and First Aid training.

II. Life-Threatening Emergencies

In the event of any life-threatening emergency, investigators should activate the emergency response system by calling 911 and use their Basic Life Support (BLS) / Cardiopulmonary Resuscitation (CPR) and First Aid training appropriately, which includes delivering high quality CPR and the use of an Automated External Defibrillator (AED). Life-threatening emergencies include but are not limited to: Cardiac Arrest, Anaphylaxis, Stroke/Transient ischemic attack, Angina/Acute Coronary Syndrome, Seizure, etc. Human Physiology investigators will not use ACLS drugs or procedures. Any time 911 is called a second individual should also call University of Oregon Police Department (UOPD) at 6-2919.

III. Non-Life-Threatening Incident

In the event of a non-life-threatening incident, Human Physiology Investigators should take the appropriate actions below, based on the given incident. Investigators should report the

incident to the IRB within 24hrs if:

- Syncope: Recline in phlebotomy chair or lie on back and elevate legs until symptoms resolve; provide fruit juice as needed; call 911 if necessary (e.g. syncopal symptoms do not resolve).
- Hyperthermia: Remove from heat; cooling procedures (e.g., cold shower and/or ice-bath immersion if participants is conscious, ice packs applied if participants is weak and/or unconscious, etc.; call 911 if necessary (e.g. hyperthermia symptoms do not resolve).
- Suspected Pneumothorax/Difficulty Breathing: Accompany participant to the emergency department (see UO Medical Transportation Options below); call 911 if necessary (e.g., participant's breathing is excessively labored or appears to be in moderate to severe distress).
- Falls: Assess degree/severity of incident (e.g., if participant can get up and walk after fall, treat as needed); call 911 if necessary (e.g., participants cannot get back up after fall).
- Allergic Reaction to Drugs (e.g. lidocaine, albumin, etc.): Accompany participant to the emergency department; call 911 if necessary (e.g., participants goes into anaphylaxis); epinephrine or anti-histamines will not be administered by HPHY investigators.
- Other Incidents Not Listed Above: Assess degree/severity of incident; provide basic first aid as appropriate and as trained; call 911 as necessary.

IV. Participant Autonomy and Refusal of Treatment

Participation in research is voluntary. In circumstance of an injury or other event occurring during the course of research, participants should be reminded about the voluntariness of participation and the circumstances in which the research team may determine it is appropriate to discontinue participation. In addition, should a participant require medical treatment, if the participant refuses treatment or assistance, the research team should document the nature of the event, the treatment offered, and the refusal of the participant. This information should be included with the report to RCS.

V. Medical Transportation Options

Incident Response			
Nature of Incident	**Non-Emergency**	**Urgent**	**Emergency**
Description	Non-life threatening, possible medical attention necessary	Non-life threatening, medical attention necessary	Non-life threatening or life threatening, immediate care required

Incident Response			
Nature of Incident	**Non-Emergency**	**Urgent**	**Emergency**
Response	• Provide basic first aid • Participant arranged doctor/urgent care • Call 911 if more urgent attention or transport necessary	• Provide basic first aid • Participant arranged doctor/urgent care • Call 911 if more urgent attention or transport necessary	• Call 911 • Provide basic first aid until paramedics arrive.
Transportation Option	• Participant self-transport, OR • Ambulance, if necessary.	• Participant self-transport, OR • Ambulance, if necessary.	• Ambulance

Steps for All Emergency Levels:

1. Care for the injured participant – provide first aid or call for emergency medical support when necessary.
2. If 911 is called, also contact UOPD 541-346-2919 for additional support *(UOPD officers have basic first-aid training)*.
3. Once immediate risk to participant is resolved, the following UO units need to be contacted to make reports as required:
    a. UO Research Compliance Services – 541-346-2510
    b. UO Risk Management – 541-346-8316

Notes:

UO investigators and personnel assume risks if they decide to use personal vehicles to transport a participant. Therefore, UO personnel or investigators should not transport participants.

About this Guidance

Andrew Lovering, IRB Vice Chair and Associate Department head, Human Physiology, created this document. John Halliwill, Hans Dreyer, Anita Christie, Andy Karduna and Chris Minson provided significant input. Consultation with UO Risk Management and the IRB Chairs informed the content of this document. These procedures have been reviewed and approved by Dr. Craig Davidson, IRB Medical Director, and the Committees for Protection of Human Subjects.

Revision History

The most recent iteration should be listed in the row space, with consecutive versions following. Each version must be approved by the current IRB Research Medial Director and the Committees for Protection of Human Subjects.

Version Date	Author(s) Name and Title/Position	Description	RMD Review Date	CPHS #1 Review Date	CPHS#2 Review Date	Final Approval by IRB Executive Team
01/16/2018	Andrew Lovering, Ph.D. IRB Co-Chair	Initial guidance on responding to emergencies/non-emergencies for Human Phys labs. The document was reviewed by CPHS #1 and feedback was incorporated prior to CPHS #2 review. Additional feedback was incorporated and the final version vetted by the IRB executive team.	03/08/2018	02/07/2018	03/21/2018	05/30/2018