Date: **Issued:** August 5, 2013 (*Updated: November 29, 2018*)
To: All iMedRIS Users
Subject: Phlebotomy Related Safety Alert and Advisory for Clinical Investigators and Other Research Personnel

This message is being sent on behalf of the UCSF Subject Injury Group.

Safety Alert: Researchers at UCSF continue to report adverse events related to research phlebotomy (blood draw) procedures. The following practices are intended to help address associated concerns, and to provide research personnel with phlebotomy specific guidance and clarification, applicable to all research settings.

Required:

- All non-licensed personnel performing phlebotomy procedures *must* be currently certified as a phlebotomist through a California Department of Public Health accredited program *before* they can draw blood. For specific information about certification requirements, training programs and FAQs check here.
- Personal Protective Equipment (e.g. lab coat, gloves, etc.) *must* be worn by phlebotomy site research personnel.
- Research personnel *must* complete the online UCSF Bloodborne Pathogens Training annually and be in compliance with the Bloodborne Pathogens UCSF Health Surveillance Program (See Chapter 15; e.g. HBV vaccine, etc). Principal Investigators must maintain training and completion records for all relevant training modules.
- If accidental exposure occurs, reference UCSF Occupational Health Program: Exposures, Injuries, & Emergencies, What to do & Who to contact. Research personnel *must* call the 24-hr UCSF Exposure Hotline at (415) 353-7842 (STIC) and follow their instructions.
- All serious adverse events and other significant incidents *must* be reported to the IRB/HRPP within **5** working days, and all such events involving a possible or definite research injury should also be reported to UCSF's Subject Injury Program.

Recommended:

- Query participants about past or current problems with blood draws such as fainting or pre-syncope symptoms (significant anxiety, light headedness or dizziness, etc.). If problems are reported, implement additional safety precautions during the procedure (e.g., offering to draw the subject in a lying position and more closely observing the participant before and after drawing bloods) and a "phlebotomy alert" should be indicated in the subject's medical record.
- Maintain and follow standard operating procedures for responding to emergency situations that, at a minimum, include an algorithm for activating an emergency response and procedures to provide immediate supportive care to study participants who experience a loss of consciousness event. For an example of this sort of SOP, see the UCSF Clinical Laboratory's *Adverse Patient Reaction* procedures check here.
- Consider the safety of the research phlebotomy setting and how well it accords with clinical care blood draw settings (e.g., easily cleaned room; no cloth chairs, carpet, or rugs in phlebotomy sites; available hand washing facilities or use of hand sanitizer; use of phlebotomy chairs, medical waste and sharps containers; etc.).
- Offer and provide to donors, rapid carbohydrate and fluid replacement (e.g., cookies, fruit juices) *esp. following fasting blood draws*.
- Exercise extra caution when large amounts of whole blood[1] [2] are drawn (e.g., checking for recent hemoglobin, close post-draw monitoring of subjects).

For questions about this advisory, please contact: EH&S for laboratory safety guidance, IRB/HRPP for protocol requirements, and RMIS/Clinical Research Risk Management for phlebotomy certification guidance.

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1. UCSF Clinical Laboratories general policy for phlebotomist
2. IRB/HRPP Expedited Review Blood Sampling guidance