Date: **Issued:** August 5, 2013 (*last updated: 10-2014*)
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: Within the last 12 months, researchers at University of California, San Francisco have reported a series of adverse events related to research phlebotomy (blood draw) procedures. The following practices are intended to help address these concerns in all research settings where blood draw procedures are performed.

Required:

- All non-licensed personnel performing phlebotomy procedures *must* be currently certified as a phlebotomist by the California Department of Public Health Phlebotomy 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 enroll in the UCSF Health Surveillance Program (e.g. HBV vaccine, etc.). Principal Investigators must maintain training and completion records for all relevant training modules.
- If accidental exposure occurs, research personnel must call UCSF Exposure Hotline at 353-7842 and follow their instructions.
    - All serious adverse events and other significant incidents must be reported to the HRPP/CHR 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).

---

1. UCSF Clinical Laboratories general policy for phlebotomist

2. CHR/HRPP Expedited Review Blood Sampling guidance