Phlebotomy for Research in the Department of Emergency Medicine

Background

Certain research protocols that occur in the Johns Hopkins Hospital (JHH) Emergency Department (ED) require subjects to provide blood samples. The time points, frequency, and volume of specimen collection vary by study. The ED has a program and plan for specimen collection that includes: ED research staff training in phlebotomy proficiency, a tiered system for blood collection (see below), and a method of uniform documentation of blood specimen collection.

Following is a plan that research staff agree to comply with while collecting blood specimens in the JHH ED.

Training & Documentation

All research staff who may be required to perform phlebotomy in the JHH ED will be trained by the ED nurse educator or designee. The ED nurse educator or designee will sign off on the research staff member's proficiency with three supervised blood draws. All training and supervised blood draws will be documented per the Phlebotomy Sign-Off Protocol and per study-specific requirements.

Presentation to COC

All clinical research studies that take place in the JHH ED clinical space must be presented to Dr. Richard Rothman, the Vice Chair of Research, for approval and then presented and reviewed by the ED's Clinical Operations Committee (COC). When a study requires collection of blood specimens in the clinical area, the research study will provide a schedule of blood draws as part of the review by COC.

Phlebotomy Procedures

Research staff will be placed into 3 tiers according to their experience (see below). Researcher staff will communicate their need to draw research labs with the clinical staff (and if said labs will be obtained via straight stick or IV), collect the research labs as appropriate, and provide the documentation in the patient-subject's electronic medical record (EMR).

When a blood sample is required from an enrolled subject who is a current ED patient, research staff must first ask a member of the clinical staff (e.g., ED nurse or technician) to draw the blood. Research staff will provide necessary supplies. At the discretion of the clinical team (ED nurse and/or technician), the clinical team may request that the research staff collect the specimen. In that case, the research staff will comply with the following guidelines:

- Draw blood in accordance with documented tier
- No blind sticks
- Maximum of two attempts
- Document all phlebotomy attempts in the patient's EMR using a standard template.
- Notify nurse caring for patient if any complaints and/or complications occur

EMR Documentation Template

> [XX Study Name] labs drawn at [site] using [e.g., butterfly] with [needle gauge] by [name – research staff or name of clinical staff member]. [# of attempts/IV insertion]. [Time stamp]

Three-Tiered System: Beginner, Intermediate, Proficient

Number of Blood Draws Performed:

- 0-10 (beginner): may draw labs via straight stick only (after having completed 3 successful draws per the training protocol), must have clinical staff draw from existing IV lines or have an advanced tier researcher draw them from an existing line.
- 11-20 (intermediate): may draw labs independently via straight stick or from an existing IV line under the supervision of an advanced researcher or member of the clinical staff
- >20 (proficient): may draw labs from existing IV line or via straight stick

Regardless of tier, research staff only perform these duties after communicating with the clinical staff. Training will also include restrictions that all researchers must be aware of (e.g., difficult lines, drawing from ports, A lines, when certain meds are being administered through IV lines).

Plan reviewed and approved by:

Richard Rothman, MD, PhD, Vice Chair of Research

Paula Neira, RN, JD, Nurse Educator

Barbara Maliszewski, RN, MS, Assistant Director of Nursing

Maria Toledo, Leadership Development Coordinator

Mustapha Saheed, MD, Associate Clinical Director