ORI-101 Procedures for Research Blood Draws

Cassandra (Cassie) Myers,
Associate Vice Provost Research Compliance Regulatory Affairs
Drivers for Procedures

01
Researcher and Department Request for Clarity
  • Training Requirements
  • Procedures
  • Criteria for Blood Draw Collection

02
Mitigation of Risk for Human Subjects

03
Mitigation of Institutional Risk
What do these procedures not do?

• Limit departments, offices, or units from developing additional policies, procedures or guidance.

• Negate the need for IRB review and approval of research blood draws.

• Set blood volume limits for blood draws.
  • Due to scientific design and population, blood volume and frequency will be assessed as part of IRB approval

• Affect blood draw policies outside of Drexel University (e.g., St. Chris)

• Define procedures for International Research
  • Contact Cassie Myers, in the ORI for consultation.
What do these procedures do?

• Guidance on Blood Sample Volume and Frequency
  • Limit to the smallest amount required to meet the research objectives.
  • Limit frequency whenever possible and coordinate with clinical collection when possible.
  • Both blood volume and frequency need to be justified in the IRB application considering the following
    • Subjects age, weight, and anatomical location
    • Subject’s overall health and wellness
      • Blood clotting collection
      • Renal failure or currently receiving chemotherapy
      • Vascular grafts, hematoma, history of radical mastectomy
      • Implantable devices for venous access (e.g., ports, central catheters)
What do these procedures do?

• Define the blood draw methods based on experience
  • Finger/Heel Stick or Venipuncture
    • Licensed or Certified Personnel, or
    • Those who have completed a Drexel University permitted training program:
  • Intravenous (IV)
    • As permitted by Office of Research and Innovation by licensed or certified personnel in a clinical setting.
What do these procedures do?

• Identify frequent risks and mitigation plans
  • List of most frequent risks to be included in consent forms as applicable;
    • Bruising, hematomas, infection at the blood collection site, and allergic reaction.

• Investigators are responsible for ensuring adequate emergency procedures.
  • These plans should be documented, available for monitoring, and consider the physical location, training of personnel, and oversight by the PI.
Responsibilities by Role

**Office of Research and Innovation**
- Maintaining Guidance & Resources
- Provide Training to Blood Draw Personnel
- Granting Exception
- Monitoring

**Study or Blood Draw Personnel**
- Training
- HRP 070: Investigator Obligations
- TB, background check, and confirmation of vaccine statuses per CDC requirements.

**Principal Investigator**
- Ensure all personnel meet study or blood draw personnel requirements
- Provide continuous oversight and adherence to HRP 071.
- Ensure dissemination of protocol, consent, and other applicable documents
- Maintain documentation, unless lab is designated*
- Purchase, maintenance and storage of equipment unless lab is designated*

**Environmental Health and Radiation Safety**
- Assess Drexel On-Site Spaces
- Provide bloodborne pathogen training
- Provide hazardous waste management training
## Work Group Members

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<thead>
<tr>
<th>Work Group Co-Leaders</th>
<th>Work Group Members</th>
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<tr>
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Final Guideline Features

- PDF on ORI-Research Compliance and Regulatory Affairs Website
- Hyperlinked Table of Contents
- Versioning
- Revision “Notes”
- Workgroup Members
Guideline Process

- **Establish workgroup members and draft document**
  - December 2022

- **2nd Workgroup Meeting**
  - January 2023

- **Implementation Window**
  - February 2023 - February 2024

- **Future Revisions**
  - Additional Revisions
    - Tools, Checklists
    - International Research

- **1st Workgroup Meeting**
  - October-November 2022

- **Finalize Document and Communicate to Research Community**
  - February 2023
Communication Plan

- Research Community Meetings
- List Serve Communication
- ORI Website
Questions