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1. Overview

Purpose

These procedures support the University's efforts to protect human subjects and Drexel University Agents while minimizing institutional risk in conducting blood draws for research purposes.

These procedures apply to any blood draws for research purposes occurring on the Drexel University's campus or conducted by Drexel University's staff, students, faculty, or otherwise an Agent of Drexel University.

Please note, if the research blood draws are occurring at off-site locations that are not owned or leased by Drexel University (such as hospitals like St. Christopher's Hospital for Children or other non-Drexel healthcare facilities or private physician offices), with their own venipuncture or equivalent policy, then that site's policy supersedes these procedures and should be followed by Drexel researchers. These procedures do not limit departments, offices, or units from developing additional policies, procedures or guidance that further define requirements and supplement these procedures provided they do not conflict with these procedures.

2. Definitions

Finger stick means a type of blood draw where the finger is pricked with a lancet to obtain a small amount of capillary blood.

Intravenous (IV) lines means a thin tube or cannula that is inserted into a vein, typically to administer drug, blood, or fluid products directly into the bloodstream. Some blood tests, such as blood gas analyses or potassium levels, may have degrading sample quality when compared to venipuncture or finger stick.

Phlebotomy/Venipuncture means a type of blood draw in which a needle is used to take blood from a vein. Multiple tubes may be collected; however, it is considered a single blood draw "stick" and the needle is taken out and a bandaged used.

3. Blood Sample Volume, Frequency and Methods

3.1 Blood Sample Volume and Frequency

Blood draws for research purposes should be limited to the smallest amount required to meet the research objectives. The frequency should also be limited whenever possible to mitigate risk to subjects. Both blood sample volume and frequency should be justified in Institutional Review Board (IRB) submissions and supported by sound scientific design, literature, and clinical decision making. Blood draws for research purposes should be coordinated with clinical blood draws, when possible, to mitigate risk to the subject or others. When determining the blood volume and frequency the following should be taken into consideration:

- Subject's age, weight, and anatomical location of blood draw

- Subject's overall health and wellness, including if they have additional conditions or factors that may negatively impact safety of the subject, such as:

    1) Blood clotting conditions (e.g., prothrombin gene mutations)
    2) Renal failure or currently receiving chemotherapy
    3) Vascular grafts, hematoma, history of radical mastectomy
    4) Implantable devices for venous access (e.g., ports, central catheters)

As blood volume draws and frequency are specific to the population and the scientific design of individual projects, approval of blood volumes and frequency will be assessed and approved by the IRB of record. Although this policy does not set maximum blood volume limits or frequencies, departments, specific labs, or other offices at Drexel University may set specific blood volume and frequency limits and the ORI would expect these additional limitations be adhered to.

3.2 Blood Draw Methods

There are multiple blood sampling methods used in a clinical setting for patient care such as arterial blood sampling, including radial artery, drawing blood from a peripherally inserted central catheter (PICC) line or a central venous catheter (CVC). However, given Drexel University's academic setting, only the following methods may be permitted unless Office of Research and Innovation conducts a risk analysis with Drexel University stakeholders and written permission is obtained:

- Finger/heel stick and venipuncture can be performed by a licensed or certified personnel as described in section 4.1 "Licensed or Certified Personnel" as well as by those who have participated in a permitted training program as described in 4.2 "Non-Licensed or Certified Personnel" and 4.3 "Permitted Training Programs".
- Intravenous (IV) lines in general should not be used to conduct research blood draws due to increased risk of infection, infiltration, and phlebitis even if product administration is only limited to saline or heparin lock. Exceptions can be requested to utilize IV lines for serial blood draws, however this exception would need to be given permission by the Office for Research and Innovation (ORI) and could only be conducted by licensed or certified personnel as described in section 4.1 "Licensed or Certified Personnel" and be conducted in a clinical setting.

3.3 Risks of Blood Draw

The most frequent risks of blood draws include bruising, hematomas, infection at the blood collection site, and allergies (e.g., latex, betadyne, bandage/tape). Less common risks include nerve damage or extensive bleeding.

As these blood draws are for research purposes, providing participants with the risks, as part of the informed consent process, ensuring they understand the activity, and answering any questions they may have been required as part of the IRB regulatory criteria.

Investigators are responsible for ensuring they have adequate emergency procedures (e.g., allergic reaction, fainting, or passing out) that are consistent with available resources (e.g., page on-call physician or call 911).

3.4 Equipment

All equipment used to conduct blood draws must be consistent with procurement and Environmental Health and Radiation Safety (EHRS) policies and procedures.

Equipment may include, but is not limited to; carts, gloves, blood collection apparatus with safety measures, blood collection tubes, tourniquet, antiseptic, dressings and gauze pads, waste bin, and transportation equipment (e.g., bags, bins).

3.5 Physical Space and Policies/Procedures

Before conducting any blood draw procedures within this document's scope, EHRS must assess the space to ensure it meets EHRS's requirements. Office of Research and Innovation can be requested by a department or the IRB to conduct an assessment that includes review of study specific policies, procedures, or guidance or a monitoring visit to ensure risk mitigation is adequate at any point in the study's lifecycle.

3.6 International Research

If your research is occurring outside of the United States, please consult with the Office for Research and Innovation as noted in section 5.1 "ORI Responsibilities" and EHRS prior to submitting to the IRB due to licensing requirements, local context, and export control.

3.7 Drexel Off-Site Research

If your research is not occurring at locations owned or leased by Drexel University's premises, please consult with the Office for Research and Innovation as noted in section 5.1 "ORI Responsibilities" prior to submitting to the IRB to conduct a risk assessment.

4. Personnel and Expertise

4.1 Licensed or Certified Personnel

Phlebotomy can be performed by a physician, a nurse, or other applicable licensed clinical professional, or a certified phlebotomist who has an active license or certification and is in good standing with the state of Pennsylvania or the state where the blood draw will be conducted.

4.2 Non-Licensed or Certified Personnel

Drexel University staff, faculty, personnel, or agents who are not licensed or certified must complete an ORI sanctioned/approved training program at Drexel University before conducting blood draws for any research studies.

4.3 Non-Drexel Personnel

If Non-Drexel University organizations or their personnel seek to conduct blood draws for research studies on Drexel University's campus, please consult with the Office for Research and Innovation as noted in section 5.1 "ORI Responsibilities" prior to permitting such blood draws to occur in Drexel facilities.

4.4 Permitted Training Programs

Permitted training programs at Drexel University may be department or institutional based and reviewed by the Associate Vice Provost for Research Compliance and Regulatory Affairs to ensure consistency. The training needs to include a core curriculum, training, individual assessment and sign-off (e.g., observation and documentation of skills checks) that is consistent with best practice, applicable state laws, and any licensing or credentialing requirements.

5. Responsibilities

5.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, training, granting exceptions, and monitoring. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

5.2 Investigator and Blood Draw Personnel Responsibilities

All investigators are responsible as outlined in HRP 070-Investigator Obligations when conducting human subject research. When conducting research blood draws all individuals regardless of expertise and experience will be required to complete the following and remain up to date prior to any blood draw procedures for human subject research:

- Completion of Drexel bloodborne pathogen training and hazardous waste management training through the online Clinical Practice safety training administered by EHRS.
- Background Check in compliance with Drexel University Human Resource Standards.
- Completion of TB testing, and confirmation of vaccine status or titer in alignment with CDC guidelines.

5.3 Principal Investigator Responsibilities

As a reminder the Principal Investigator is ultimately responsible for the conduct of the study, regardless of involvement by a student, laboratory, or study team member, and specifically for research blood draws the following:

1. Ensuring the research personnel and any designated laboratories (section 5.3) are provided the most up-to-date IRB approved version of the protocol, consent form, and other relevant documentation that describes the blood draw.

2. Continuous oversight by ensuring established procedures for emergencies, adverse event reviews, subject complaints, and promptly reporting any reportable information to the Drexel University HRPP/IRB or the IRB of record, as outlined in HRP-071 Prompt Reporting Requirements.

The Principal Investigator can be responsible for the following activities or delegate to a designated laboratory or department provided the delegation is in writing:

1. Maintaining documentation required as part of this procedures (e.g., EHRS Review, training certificates, licensures) and to ensure it remains up to date, unless as identified through a written agreement with a laboratory or department (e.g., departmental HR records for background checks) that these records will be maintained on the investigator's behalf. These records must be made available at the time of inspection, monitoring, or as requested by both internal and external parties.
2. Purchasing, maintenance, and storage of equipment to conduct blood draws is the Principal Investigator or the designated laboratory's responsibility.

5.4 Laboratory Responsibilities

A laboratory may be designated responsibility by the Principal Investigator to maintain documentation required as part of these procedures (e.g., EHRS Review, training certificates, licensures) and to ensure it remains up to date, provided the responsibilities are outlined in a written agreement between the laboratory and the Principal Investigator, at both parties' discretion. Whether the Principal Investigator or the laboratory retains the documentation, these records must be available at time of inspection, monitoring, or as requested by both internal and external parties.

Purchasing, maintenance, and storage of equipment to conduct blood draws may also be designated to the laboratory as outlined in a written agreement. However, the equipment that the lab uses, along with the blood draw volumes, and frequency must align with the IRB approved application and supporting material, and it is the investigator's responsibility to ensure the laboratory is provided the most recently approved IRB documents.

6. Resources

- Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- WHO guidelines on drawing blood: best practices in phlebotomy

7. Revision and Workgroup Members

7.1 Revision

Version/Effective Date 02/10/2023- Original Document-Procedures and Guidance for Drexel University Research Community.

7.2 Workgroup Member

The Office for Research and Innovation appreciates the following individuals who served as Workgroup Members:

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