

FREQUENTLY ASKED QUESTIONS: ORI-101 PROCEDURES FOR RESEARCH BLOOD DRAWS

Q1. Why did Drexel University's Office of Research & Innovation (ORI) conduct workgroup meetings and establish procedures for research blood draws?

A1. Drexel University's ORI has received request from multiple offices, researchers, and departments seeking guidance and clarity about performing blood draws for research purposes. In response ORI developed a workgroup comprised of the Research Community, Compliance Offices, Office of General Counsel, and Environmental Health and Radiation Safety to ensure broad stakeholder input. These procedures are intended to support the University's efforts to protect human subjects and Drexel University Agents while minimizing institutional risk in conducting blood draws for research purposes.

Q2. If I have been conducting blood draws for research purposes, do I need to stop my research until I have fully implemented the requirements in ORI 101-Procedures for Research Blood Draws?

A2. At this time, if you have already been conducting research blood draws, with approval from an IRB, you may proceed at this time as we do not want to increase risk to participants by stopping research procedures, provided this is consistent with your department's guidance.

ORI does expect researchers to align with these guidelines (e.g., sign up for training, EHS evaluation) within 12 months of the 2/10/2023 effective date.

Q3. If I have an upcoming project conducting blood draws for research purposes, am I required to follow the requirements in ORI-101: Procedures for Research Blood Draws?

A3. If you have an upcoming project including research blood draws ORI does expect researchers to be compliant with the requirements prior to enrolling any participants.

Q4. Do I need to submit a modification to the IRB, or do I still need IRB approval for research blood draws?

A4. Provided your approved IRB materials (e.g., protocol, consent forms, application) are still accurate there is no need to submit a modification. If your IRB application is inconsistent with ORI-101: Procedures for Research Blood Draw, please complete an IRB submission in alignment with Q2 and Q3.

Q5. What if I am considered a "non-licensed or certified personnel" and need training, or I am licensed or certified and would like additional training?

Q5. Drexel University's ORI is currently identifying those that require training, and timelines for completion in order to offer training opportunities on a routine basis. If you need to sign-up for training, or have previously received training and are licensed or certified, please complete the following: <u>Phlebotomy Training Request Form</u> and we will contact you with timing, and next steps.

Q6. My school, department or area has additional requirements, procedures, or guidance for conducting blood draws for research purposes, am I required to follow these requirements as well?

A6. ORI-101's procedures do not limit schools, departments, or others from establishing guidance and additional requirements. ORI-101's procedures should be viewed as a baseline for which others may establish additional requirements based on a schools or departments understanding of expertise, physical space, and research portfolio.

Q7. What if I have questions about my specific study, or concerned about my study timing?

A7. If you have questions about ORI-101: Procedures for Research Blood Draws, study specific implementation, training, or other items, please contact Cassandra Myers at cjm523@drexel.edu.