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

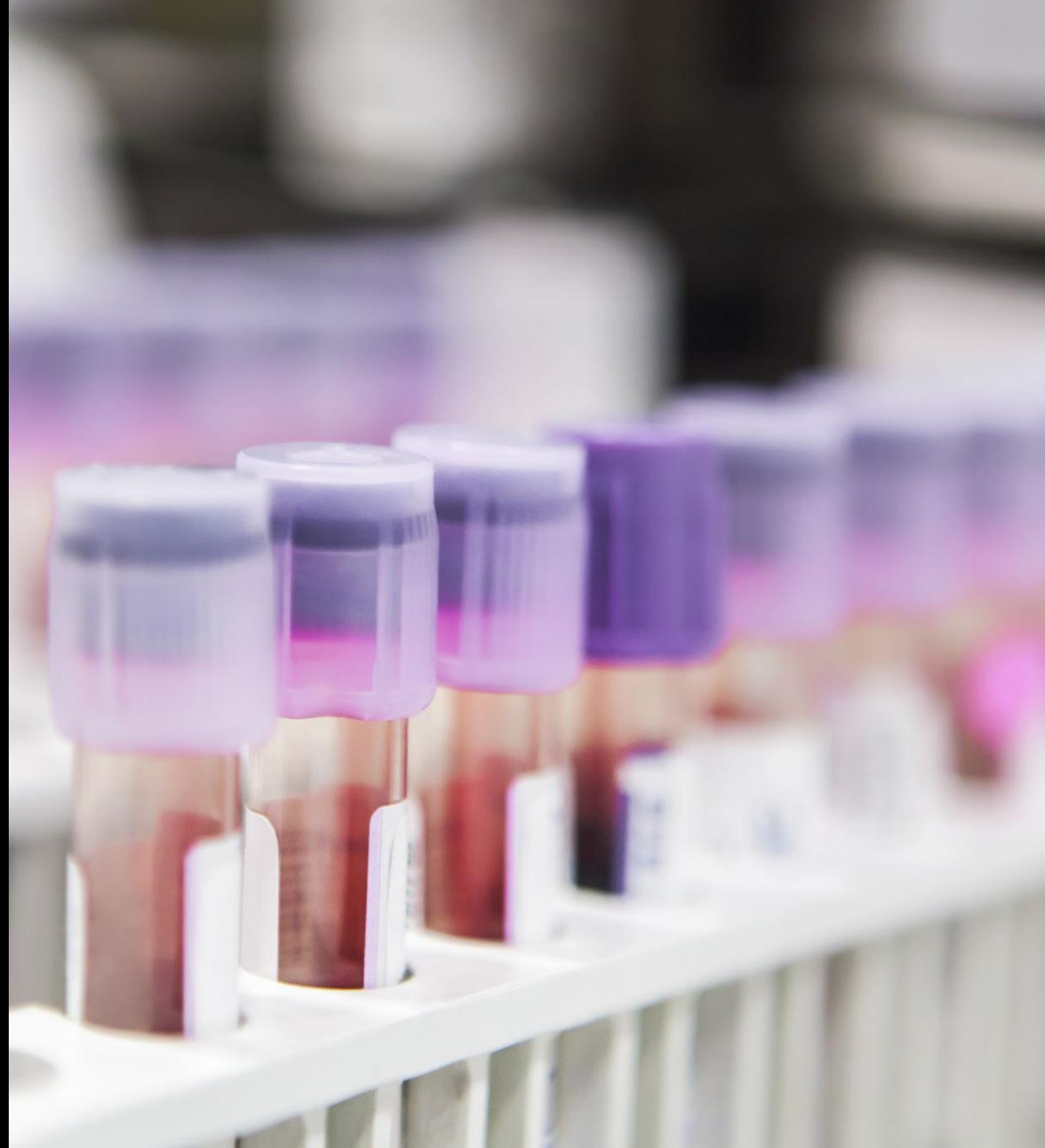
Mitigation of Risk for Human Subjects

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

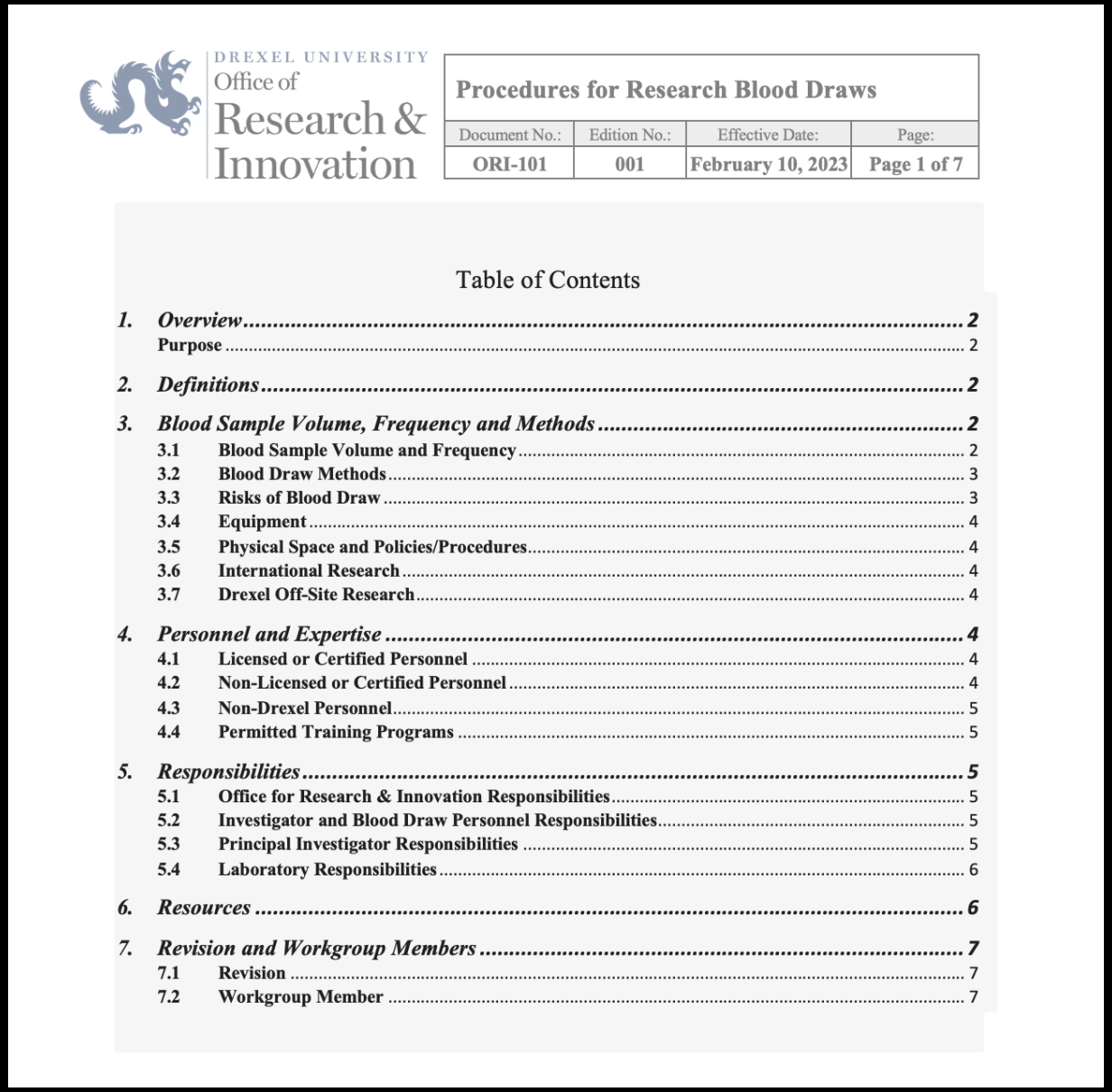
- Assess Drexel On-Site Spaces
- Provide bloodborne pathogen training
- Provide hazardous waste management training

Work Group Members

Work Group Co-Leaders	
Rose Ann DiMaria-Ghalili, PhD, RN, FASPEN, FAAN, FGSA Senior Associate Dean for Research Professor College of Nursing and Health Professions	**Cassandra Myers, BS** Associate Vice Provost Research Compliance and Regulatory Affairs Office of Research and Innovation
Work Group Members	
Jonathan M. Chase, MS Assistant Vice President Environmental Health and Radiation Safety	**Joseph Nihill, MS** Industrial Hygienist Environmental Health and Radiation Safety
Honora Cutler, BSN, RN Clinical Research Operations Manager School of Medicine	**Sara Potter, MSN, BSN, ARM, CPHQ** Director of Risk Management Office of General Counsel
Mary Gallagher Gordon, PhD, MSN, RN, CNE Vice Dean, Strategic Operations, Academic Services and Community Health Clinical Professor of Nursing College of Nursing & Health Professions	**John Roberts, BA, CIP** Executive Director of Human Research Protections Program Office of Research and Innovation
John Gyllenhammer, JD, BA Deputy General Counsel and Chief Counsel for Health Sciences Office of General Counsel	**Gail Schlemback, BS** Assistant Risk Manager Office of General Counsel
Lacee Harris, PhD Executive Director, Research Compliance Office of Research and Innovation	**Deeptha Sukumar, PhD** Associate Professor, Assistant Director, PhD Program in Nutrition Sciences College of Nursing and Health Professionals
Janet Matthews, MSN RN Senior Director, Research Program Development School of Medicine	

Final Guideline Features

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



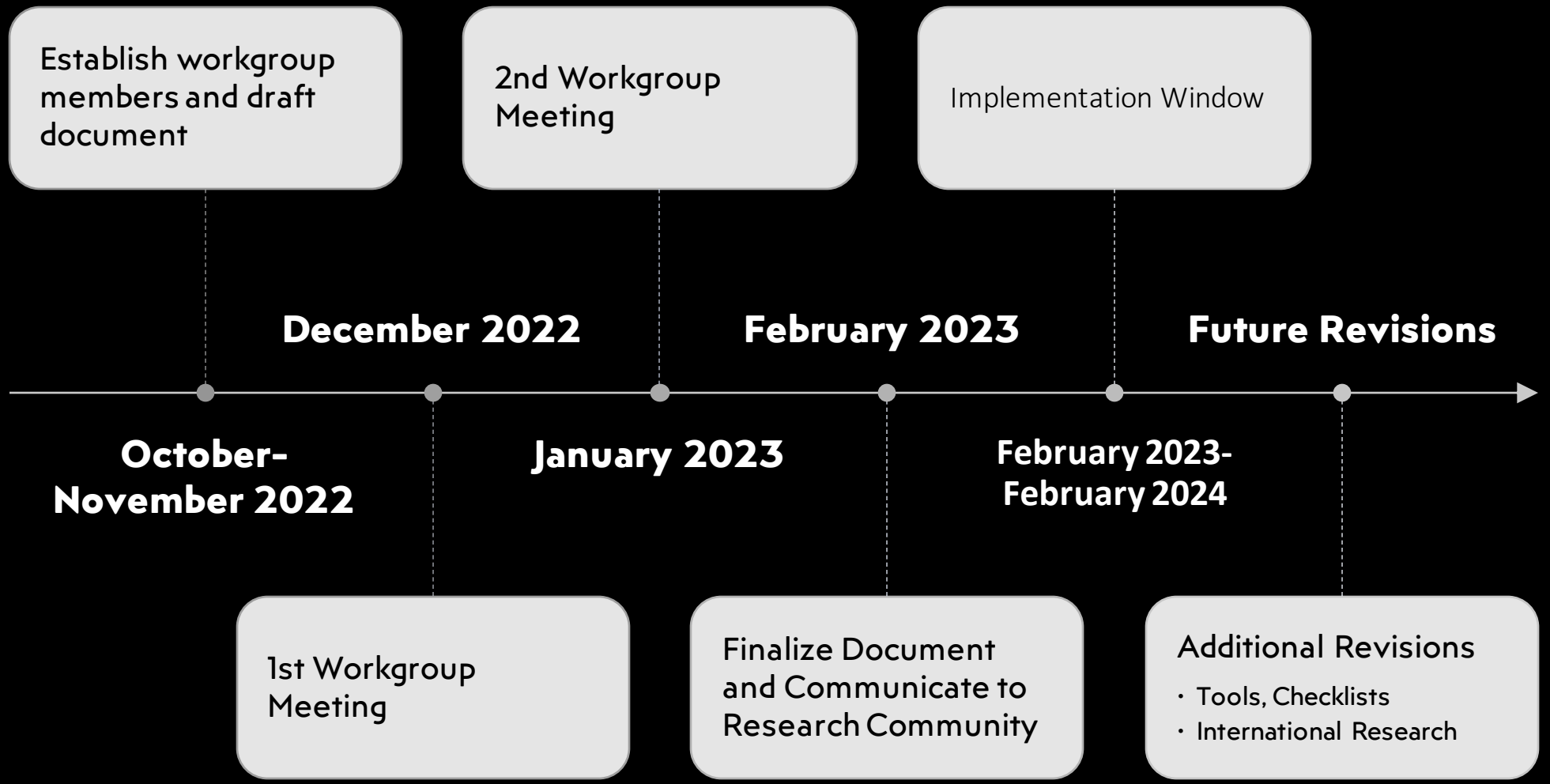
DREXEL UNIVERSITY
Office of
Research & Innovation

Procedures for Research Blood Draws

Document No.:	Edition No.:	Effective Date:	Page:
ORI-101	001	February 10, 2023	Page 1 of 7

Table of Contents

Guideline Process



Communication Plan

RESEARCH COMMUNITY MEETINGS

LIST SERVE COMMUNICATION

ORI WEBSITE

Questions