
Procedure Title: Phlebotomy Qualifications in Human Subjects' Research

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	07-16-2020	Executive Lead:	Chief Research Officer
Effective:	07-24-2020	Revision History:	.00 – 07-16-2020; .01 – 3/22/2023
Approved by:	Institutional Review Board		
Procedure Number:	148.01		
Key Words:	Phlebotomy		
Purpose:	To meet the responsibilities for protecting human subjects as issued by the Office for Human Research Protections (OHRP) requirement for individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved federal wide assurances (FWAs)		

Process:

This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU regarding the necessary qualifications for study team members who perform phlebotomy in the course of research. Individuals who have active phlebotomist licenses in the location where research is occurring may perform phlebotomy in the course of research. In states that do not require licensure, the individual must have national certification. For example, if conducting research-related phlebotomy on PNWU's campus, they need to have Washington State licensure.

General Information:

Washington State is one of only four states in the U.S. that requires licensure for phlebotomy. The other states in PNWU's catchment area (Oregon, Idaho, Montana, and Alaska) do not require licensure for phlebotomy but do recommend national certification. Links to the Washington Administrative Code are provided in the reference section at the end of this document.

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Protecting the rights and welfare of human research participants.
- Impartiality when reviewing human subjects research.
- Remaining unaffected by pressure by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.
- Reviewing and approving data collection protocols regarding patient privacy, confidentiality, and research ethics.
- Reviewing phlebotomy licensure or certification to ensure it is current and appropriate for the location of research.

The Office of Scholarly Activity (OSA) is responsible for:

- Supporting the investigator in the development of research protocols that utilize phlebotomists.
- Overseeing and providing the necessary support to the IRB.
- Providing information on university regulations and Washington State regulations regarding phlebotomy.
- Obtaining phlebotomy licensure or certification to ensure it is current and appropriate for the location of research.
- Posting this SOP for the PNWU community.
- Monitoring compliance of this SOP.

The Primary Investigator is responsible for:

- Being a steward of a research environment that promotes the responsible conduct of research.
- Ensuring compliance with the IRB-approved protocol, federal regulations, state laws, good clinical practice, and applicable FDA guidance.
- Providing adequate guidance, equipment, and procedures for phlebotomy procedures to be performed safely.
- Working with the research team and the Office of Scholarly Activity to design safe phlebotomy protocols for their project.
- Ensuring team members' licensures are current and appropriate for the geographic location of the study.
- Providing copies of study team members' licensures for the IRB application and study binder.
- Seeking support from OSA and the IRB when questions arise.

The phlebotomist is responsible for:

- Maintaining active phlebotomy licensure or certification appropriate for the research location throughout the data collection period.
- Communicating their comfort level of performing phlebotomy and any concerns they may have with the research protocol with the primary investigator or with the Institutional Review Board.

Definitions

Please reference the Glossary for complete definitions of the following terms and additional terms not listed.

- Federal wide Assurance
- Primary Investigator
- Washington Administrative Code (WAC)

Procedures for the Phlebotomist:

1. Maintain active phlebotomy licensure appropriate for the research location throughout the duration of data collection.
 - a. Individuals who received licensure outside of Washington State and are hoping to become credentialed within Washington State must go through the Washington State Department of Health's Credential Verification process and get their credential verified before collecting data.
 - b. More information about renewing your credential or transferring your credential to Washington State can be found at the Department of Health's website:

<https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/MedicalAssistant/LicenseRequirements/Phlebotomist>.

2. Comply with Washington Administrative Code 246-827-0400 when performing phlebotomy procedures within Washington or comply with other appropriate legislation when performing phlebotomy outside of Washington.
3. Communicate their comfort level with performing procedures with their principal investigator (PI) and express any questions or concerns they have about protocol, equipment, or safety to the PI or the Institutional Review Board.

Procedures for Primary Investigators:

1. Verify the individual's credential, upload a copy to the IRB application, and maintain a copy in the study regulatory files/binder.
2. Secure adequate personal protective equipment and specimen collection instruments for phlebotomists to perform procedures safely. PIs may work with their research team to secure these items, but ultimately the responsibility and liability lies with the PI.
3. PIs must work with the research team and Office of Scholarly Activity to ensure protocols for collecting, transporting, analyzing, and disposing of blood are safe for study participants and investigators and are conducive to maintaining the integrity of the data.

Procedures for the Office of Scholarly Activity:

1. Provide information on state regulations for phlebotomy.
2. Help investigators develop safe and appropriate protocols for performing phlebotomy during the course of research.
3. Assist investigators in finding appropriate resources to aid in performing phlebotomy (e.g., grant funding to purchase equipment, information on transporting human specimens, help with finding a lab to run analysis).
4. Including certification for phlebotomy in the IRB approval packet.

Procedures for the Institutional Review Board:

1. Review IRB applications and data collection protocols regarding patient privacy, confidentiality, and research ethics.
2. Review the licensure documentation during the review process to ensure licensure is current and there are no applicable sanctions against the provider.

References:

1. Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D) <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
2. Washington Administrative Code 246-827-0400: Medical assistant – phlebotomist – Certification and training. <https://apps.leg.wa.gov/WAC/default.aspx?cite=246-827-0400>
3. Phlebotomist Certification Requirements for Washington State <https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/MedicalAssistant/LicenseRequirements/Phlebotomist>

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 07-24-2020	L. Lamb	Original SOP
.01 / 3-22-2023	C. Case	Minor punctuation changes and removed the reference to the

		L: drive in the footer as SOPs are now stored in the electronic IRB system.

Appendices: