**INFORMED CONSENT TO PARTICIPATE IN RESEARCH**

**Study Title**

You are being asked to be in a research study. You are being asked to do the study because [ ]. Doing this study is your choice. You can decide not to do this study. If you decide to do this study, you can then choose to stop the study at any time, for any reason. If you do not want to be in the study or stop being in this study, it will not affect your care or treatment outside this study.

**KEY INFO**

* ***Study Purpose:*** The purpose of the study is [ ]
* ***Major parts of the Study:*** You will be asked to [ ]
* ***Risks:*** The primary risk of doing the study is [ ]
* ***Potential Benefits:*** The potential benefits are [ ]
* ***How Much Time Will the Study Take:*** We ask you to do the study for [ ]
* ***Consent:*** Consent is being sought for this study. Doing the study is voluntary.
* ***Funding:*** [ ] is funding this study.

# *\* More detailed info below.*

# INTRODUCTION

Please read all of this form carefully. Ask Principal Investigator (PI) [ ] or a member of the study team, to explain any words, or details that you do not know. Ask any questions that you have about this study. Do not sign this consent form unless you know the details. Make sure you have all your questions answered.

If you decide to do this study, you will be asked to sign this form. You will be given a copy of the signed form. You should keep your copy for your records. It has details, including important names and telephone numbers that you may want later.

If you decide to do this study, the PI may still have you stop doing in the study if she/he thinks it is in your best interest. You may choose to stop being in the study at any time. If you choose to no longer be in the study, any details already received from you will still be used for the study.

For the study, your name and data for the study will be kept confidential, except as required by law. The Department of Health and Human Services (HHS), Office of Human Research Protections (OHRP), and the Institutional Review Board (IRB) at Pacific Northwest University (PNWU) may also look at your records, if needed.

If you have questions about the study, call the PNWU IRB at (509) 249-7852 or email research@pnwu.edu. The IRB is a group of people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress.

**WHO IS FUNDING THIS RESEARCH STUDY?**

This study is being funded by a

**SITES OF THE STUDY?**

The study will take place at

**HOW MANY PEOPLE WILL BE IN THIS STUDY?**

We are asking [ ] people to do the study.

**ELIGIBILITY**

People who have [ ] can do the study.

**PURPOSE OF STUDY**

The purpose of this study is to

# PROCEDURES TO BE FOLLOWED

If you agree to be in this study, we will ask you to do the following things:

**WHAT OTHER OPTIONS ARE THERE?**

The alternative to this study is to NOT do the study.

**REMOVAL FROM STUDY**

You may be removed from the study. You may be removed if you choose not to attend the study visits and follow the procedures listed above. You may also be removed if you have any unexpected problems during the study. You can also be removed upon your request.

**RISKS**

Having

**BENEFITS**

People may benefit from

# RESEARCH RELATED INJURY

Emergency medical treatment will be given to you if you are hurt or get sick as a direct result of being in this research study. You or your insurance carrier will be required to pay for any such medical care. Any needed medical care is available at the usual cost. All needed facilities, emergency treatment, and professional services are available to you, just as they are to the general public. The institution will not pay for your treatment if you become ill or injured as part of this study.

**COSTS**There is no cost to do this study.

**COMPENSATION**

Incentives will be made using [ ]. We will give you a [ ] and each time you receive an incentive for doing the study, [ ] after each completed visit.

Due to federal tax law, you need to do a W-9 form. If you get over $600 from PNWU in a single calendar year (either in a single study or multiple studies), you will be issued an IRS 1099 form. This may affect your taxes. Only incentives for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food and other expenses are not included in this IRS disclosure. Research incentives provided to PNWU employees will be reported as income and will be included in your annual W-2.

# PRIVACY AND CONFIDENTIALITY

Doing this study involves some loss of privacy. The study team will make every effort to keep your info private. This is not completely guaranteed. For this study, the study team will get info about [\_\_\_\_\_\_\_\_\_\_\_\_]. This info and anything else we collect will be kept private. Only you and the study team will view it. It will not be shared with anyone else.

You will be assigned a number. This number will be used to identify you during the study. This assigned number will not be based on your name or other info that can identify you. This number will be used only for research purposes. Only people directly related to the study will have access to the info. The data will be stored on a secure computer server or in a locked cabinet if paper is used.

If you agree to do this study, your personal details will not be given to anyone unless we receive your permission in writing. Your details will only be given if the law requires it or to protect your rights or safety. The following groups may have access to study records that identify you:

* OHRP
* HHS
* PNWU IRB
* PNWU, Institutional Official/Chief Research Officer
* People who review the study to make sure you are safe and that the study follows the law.
* Any official at PNWU may be involved to make sure the study quality is maintained
* Any and all law enforcement officials based on a court order may have access.
* Any and all employees of, or consultants to, PNWU as part of their job, may see your info.
* Funding Agency [ ]
* Name of commercial sponsor or manufacturer of the drug, device, or biologic
* Collaborating researchers:

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

Doing this study is up to you. You may stop at any time. You will not be penalized. All of your personal details are private.

If you have any questions or concerns doing this study, you can contact a member of the study team. Below are the details for the study team.

PI: Full name, credentials Phone number email

Co-I: Full name, credentials Phone number email

Research Personnel: Full name, credentials Phone number email

If you have question about your rights as a research study subject, call the PNWU Institutional Review Board (IRB) at (509) 249-7852 or research@pnwu.edu.

HIPAA AUTHORIZATION AGREEMENT – AUTHORIZATION TO USE

OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

FOR A RESEARCH STUDY

State and Federal privacy laws protect your health details. The Privacy Rule is part of the Health Insurance Portability and Accountability Act (HIPAA).

If you agree to do this study, the study team may use, create, or share your health details as part of the study. The study team will do so only if you give permission to use, create or share your health details as part of the study. This form gives you details to help you decide if you will give such permission. Please read this form carefully. After reading this form, you can refuse to sign this form.

If you sign this document, you give permission to the Principal Investigator, [ ] and research staff at PNWU as well as other individuals at [ ] who may need to access your info to do their jobs (such as for treatment, payment (billing) or health care operations) to use or disclose (release) your health info that identifies you for the research study.

The health info that we may use or release for this research study includes info in your medical record related to the diagnosis and management of [ ], including the record of your care, as well as any info collected or created during the course of this study.

The parties listed in the preceding paragraph may disclose the health info described above to the following persons and organizations for their use in connection with the research study.

• People working with the PI of the study

• Outside people or places that need access to this info to do things related to the study

• Other researchers and institutions that are conducting or participating in this study

• The study sponsor [\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_] and any companies that they use to oversee, manage, or conduct the study

• OHRP, FDA, HHS, and other federal and state agencies that have the right to use the info as required by law

• Members and staff of any appropriate IRB

PNWU is required by law to protect your health info. By signing this document, you allow PNWU to use and/or disclose (release) your health info for this research. Those persons who receive your health info may not be required by Federal privacy laws to protect it. If allowed by their laws, they may share your info with others without your approval. You may not be allowed to see or copy the info described on this form as long as the research is in progress, but you have a right to see and copy the info upon completion of the research in accordance with hospital policies.

**This authorization**

You may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization, this site’s clinical, administrative and research staff may still use or disclose health info they already have obtained about you as necessary to maintain the integrity or reliability of the current research.

However, you can change your mind and cancel this Authorization at any time. To revoke this authorization, you must write to:

Chair, PNWU IRB

Office of Scholarly Activity

111 University Parkway, Suite 202,

Yakima, WA 98901

For more info, you may contact the IRB Administrator:

509-249-7852 or research@pnwu.edu

If you revoke this authorization, you may no longer be allowed to participate in the research described in this form.

**WHOM TO CONTACT**

PI: Full name, credentials

Address

Phone number

email

RIGHT TO REFUSE TO SIGN THIS AUTHORIZATION

You have the right not to sign this consent. If you do not sign this form, your non-research

related treatment will not be affected in any way. If you do not sign this form, you will not be

able to participate in this research study.

SIGNATURE OF SUBJECT

I have read (or someone has read to me) the above info. I have been given an opportunity

to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research and authorize the use and disclosure of my protected health info for this study. I will be given a copy of this signed and dated form.

Note: Before you can take part in this study, the consent form must be signed and given to the

researchers. If you have any questions about the info given in this form, please ask the

researchers. If you have questions about anything else relevant to this study, please feel free to ask one of the researchers.

**VOLUNTARY CONSENT**

All of the above has been explained to me. All of my current questions have been answered. I was encouraged to ask questions about this study. I know that future questions will be answered by the study team listed on this form.

By signing this form, I do not waive any of my legal rights. I agree to take part in this study. A signed copy of this consent form will be given to me.

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|  |  |  |
| Date/Time |  | Participant’s Printed Name |
|  |  |  |
| Date/Time |  | Participant’s Signature for Authorization |
|  |  |  |
| Date/Time |  | Principal Investigator or Representative’s Printed Name |
|  |  |  |
| Date/Time |  | Principal Investigator or Representative’s Signature |