Collaborating with Providence Medical Research Center (PMRC)
Standard Operating Procedure (SOP)
WSU Elson S. Floyd College of Medicine Office of Research

WSU FACULTY AND STAFF

For WSU Faculty and Staff wanting to collaborate with Providence Health Care (PHC) in Spokane and the Eastern Washington Region, the below is a brief outline of the necessary steps. These are necessary whether one is planning to submit a collaborative grant or conduct an already funded project at Providence Medical Research Center (PMRC). Our goal is to streamline and clarify processes, and promote the success of collaborations.

Importantly, all research projects conducted through PMRC require that a 'Providence Champion' (i.e., a Providence staff member) be included as an investigator on the project. A Providence Champion can be a clinician or manager (depending on the focus of the project) who has knowledge and expertise on the subject matter of the study and the proposed participants. Preferably, this person has an existing relationship with the investigator. The Providence Champion will be expected to serve in an active role in the study, so they must understand and agree to whatever time commitment is necessary. The expectation is that this person is engaged in the intake process, helps review procedure documents and is an active member of the research team. PMRC can help search and reach out to an appropriate person if the investigator does not have anyone identified. PMRC will discuss the approach and plan accordingly during the intake meeting. PHC prefers investigators to work with PMRC to identify an appropriate Providence Champion.

If you have questions, please contact Dr. Sterling McPherson at sterling.mcpherson@wsu.edu , who can direct you to the correct person or resource at Providence Health and Services.

1. Review the PMRC timelines for review and initiation of new research projects, and review their FAQs that are located on the same page.

2. Complete to the PMRC Clinical Research Services Intake Form.

3. PMRC staff will review the intake form and contact you with questions about your project plan and the funding status of your project. Typically, you will be invited to an intake meeting on the first or third Thursday of every month at 3 PM at the Doctor's Building, 105 W. 8th Ave, Suite 532C, Spokane, WA 99204.

4. If you do not currently have at least a brief protocol that explains your project in detail, consider developing one prior to meeting with staff from PMRC.

5. If the research is to be conducted at PHC or with PHC data, approval from the IRB Spokane will likely be required. Please note that Facility Approval is also a required form. Facility approval for research will require PMRC signatures and will be returned when all credentialing is verified and any questions or concerns have been addressed. Avoid requesting Facility Approval or IRB approval until the protocol is finalized.

6. Review the necessary PMRC Research Credentialing process at PHC. Any investigator who wishes to conduct research at PHC must be appropriately credentialed prior to Institutional Review Board submission of a project.

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*Virtually all of the necessary documentation needed to complete the above steps can be found online. Please note that disorderly documents may be returned for revision before processing. Investigators should also be aware that studies may require review and approval from a clinical service manager and/or director if that clinical service might be impacted by the study. PMRC will facilitate this.

WSU STUDENTS

All students participating in and/or conducting Quality Improvement ("QI"), Process Improvement ("PI"), Evidence Based Practice (EBP), Educational Projects and/or Research must comply with all Federal, State and local laws, Providence Health Care (PHC) and Providence St. Joseph Health System (PSJH) policies. Students are encouraged to participate in and be involved in the various learning opportunities when assigned to a PHC facility/clinic.

Absolutely NO Protected Health Information (PHI) can be accessed, used and/or disclosed unless all criteria within this policy have been complied with. All students must adhere to the following institutional requirements.

1. Identify a Providence champion for the project. A PHC employee that will provide oversight of the project while being conducted within our facilities, including but not limited to, accessing and securing PHI and removing all identifiers prior to providing to student. Must have appropriate permissions to access project data.

2. Prior to starting any project, contact your academic faculty and PHC champion for guidance. If you are a nursing student or allied health sciences student, the Clinical Innovations and Research Council will be able to provide some assistance and guidance. Please contact them via e-mail: clinicalinnovationsandresearchcouncil@providence.org .

3. All PHI and PHC confidential information must remain on the PHC campus, on PHC secure computers, for purposes of improving an internal process or program.

    a. Students cannot directly access any PHI, this must be completed by the Providence Champion.
    b. PHI must not be recorded in personal computers or other electronic devices, including USBs.
    c. PHI cannot leave the Providence campus.
    d. All data required to leave PHC for inclusion in student paper/presentation must be aggregate data only (de-identified by the Providence champion).

4. Submit the completed Application for Student Clinical Inquiry Projects (below) to the IRB via e-mail: institutional.review.board@providence.org . A detailed protocol or project summary must accompany the application. Incomplete or unclear submissions will be returned before IRB review occurs, which will result in a delay to the start of your project. Projects unable to secure an IRB determination after 3 clarification requests from the IRB will not be able to move forward. Contact the IRB prior to submitting responses if there are any questions.

5. The IRB will review submission, determine whether the proposed project is QI/PI/EPB or research, and notify the faculty, student and Providence champion in writing of the determination

    a. If research determination is made the student must comply with all Federal, IRB and Providence Medical Research Center (PMRC) regulations, policies and procedures. Contact information for PMRC will be provided and assistance regarding research regulations, policies and procedures is available.
    b. If the project is QI/PI/EBP, once the written determination has been received, the project may begin.

6. If any part of project changes after IRB determination a modification must be submitted to and reviewed by the IRB to ensure continued compliance with original determination. Contact IRB office for assistance.

7. Failure to comply with PHC/PSJH integrity, compliance, privacy and security education, including Code of Conduct, and if applicable, research regulations and policies will result in appropriate corrective action which may include termination of student assignment within the PHC ministry. Random project audits will occur to ensure compliance.

PROVIDENCE
Sacred Heart
Medical Center &
Children's Hospital

"Application for Student Clinical Inquiry Projects"
Providence Health Care Institutional Review Board

e-mail: institutional.review.board@providence.org

1. **Application must be accompanied by protocol or project summary.**
2. **Failure to submit protocol/project summary and answer all questions completely will delay ability for project activities to begin.**

Project Title:

Name of University:

Student Name:

Contact Information:

Student Advisor/Faculty:

Contact Information:

Providence Sponsor:

Contact Information:

BRIEF DESCRIPTION OF PROJECT:
Include how the project will benefit the hospital or institution and who the project findings will be shared with at the conclusion of the project.

PURPOSE:
Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting?

☐ Yes ☐ No *(Contact IRB for further guidance)*

If yes, provide support that the focus of the project is to implement existing knowledge in clinical practice and not generate new knowledge.

RISK:
*Is the risk to patients/participants no greater than what is involved in the care they are already receiving **OR** can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented within a health care environment?*

☐ Yes ☐ No

DATA COLLECTION PLAN:
Provide a concise description of how data will be collected. Must include how patient data will be identified, who is involved with data collection, and what data will be obtained. Describe where this information is found and how it will be extracted.

PROTECTED HEALTH INFORMATION (PHI):
Will PHI be collected for this project (see list of PHI attached)?

☐ Yes ☐ No

LIST ALL DATA POINTS (INCLUDING PHI) THAT WILL BE EXTRACTED FROM A PATIENT'S MEDICAL RECORD:
*Please note: **ALL PHI MUST** remain within Providence Health Care and cannot be taken off-site. Identified data cannot be stored on personal computers, emailed, or stored on thumb drives. Failure to adequately protect Providence patient data is considered non-compliance with the HIPAA law and Providence policy, which may result in corrective action including but not limited to termination of this project and/or assignment to a Providence facility/clinic. Any data collected **must** be de-identified (ie; not contain ANY of the attached 18 identifiers, see below). If you have questions please contact the IRB office (Institutional.Review.Board@providence.org).*

DISCUSS HOW THE PATIENT'S PRIVACY WILL BE PROTECTED:
Identify where data will be stored; how data will be de-identified; how/when data will be destroyed; and who will have access to the information.

MISCELLANEOUS INFORMATION

DO:
1. Obtain appropriate permissions to conduct project at Providence Health Care facilities.
2. Identify Providence sponsor.
3. Align your project in a way that will provide benefit to the hospital(s) in which the project is being conducted.
4. Allow time for IRB review prior to starting project.
5. Conduct project as submitted to IRB. Contact IRB if revisions are required.
6. Obtain only the data outlined in the summary provided to the IRB.
7. Follow all Providence Health Care policies.
8. Follow HIPAA law.
9. Be prepared to present your project/research finding to appropriate Providence Health Care personnel.

Don't:
1. Make any changes to project without consulting the IRB.

2. Put ANY PHI on personal computers, e-mail or store on thumb-drive.
3. Remove any PHI from Providence campus.
4. Start your project until a determination has been made by the IRB.

What if my project requires IRB review/approval?

If your proposed project is determined to be research you will be informed by the IRB and submission as research will be required including but not limited to:

1. Facility approval from Providence Medical Research Center
2. Completion of CITI Training (human subjects protection)
3. Completion of Conflict of Interest Training
4. Electronic Disclosure of Conflict of Interest
5. Electronic submission of study through IRB

PHI Includes:

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)