**Human Research Protection Program**

“Application for Clinical Inquiry Projects (QI/PI/EBP)”

\*Click on gray box to insert text”

1. **Submit completed application and all required documents to:** PSJHIRBDetermination@providence.org
2. **Application must be accompanied by protocol or project summary.**
3. **Documentation of local facility/region approval to conduct project (e-mail ok) must be included with the application.**
4. **Failure to submit protocol/project summary and answer all questions completely will delay ability for project activities to begin.**

**Date:**

**Project Title:**

**Name of Project Lead:**

**E-mail:**

**Providence Sponsor (required for all student/resident projects):**

**E-mail:**

**Core leader granting approval for this project to be conducted:**

 **E-mail:**

**Students submitting a project must also complete the following**

**Name of University:**

**Student University Advisor/Faculty:**

**E-mail:**

**PURPOSE/INTENT:**

Is the project intended to implement or evaluate a process with the aim of improving the process/delivery of care and/or decreasing inefficiencies within a specific health care setting?

*Please note: In order for a project to be considered non-research QI/PI/EBP the project summary must support that the focus of the project is to implement existing knowledge in clinical practice and not generate new knowledge.*

*[ ]* Yes [ ]  No *(Contact HRPP Office for further guidance)*

Describe how the project is intended to directly benefit the facility and to whom the results of the project will be disseminated throughout the facility for the purposes of QI/PI/EBP.

Does your intent include sharing the results of your project with an audience outside of PSJH?

*[ ]* No

*[ ]* Yes, but only to share what we learned at PSJH .

*[ ]* Yes, to share information so that others may use what was learned to improve care at their own facility.

*[ ]* Other, explain:

**RISK:**

Is the risk to patients/individuals 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 (Contact HRPP Office for further guidance)

**PROTECTED HEALTH INFORMATION (PHI):**

Will PHI be collected, used or disclosed for this project (see list of PHI attached)?

[ ] Yes, if yes answer question below [ ]  No

Who will obtain the PHI, their role and from what source?

*Note: Students may not directly access any PHI. Must be a PSJH caregiver, with appropriate institution approvals to do so, and is most often the Providence Sponsor)*

**IF PHI WILL BE USED, SELECT THE APPLICABLE HIPAA BUSINESS NEED(S) (**One answer MUST be selected):

[ ]  Treatment – provision, coordination or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding a patient, or the referral of a patient from one health care provider to another.

[ ]  Payment – For a health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the plan, or obtain or provide reimbursement for healthcare.

[ ]  Health Care Operations – certain administrative, financial, legal and quality improvement activities of a covered entity that are necessary to run its business and to support the core functions of treatment and payment (must directly benefit PSJH organization and patients).

***MISCELLANEOUS INFORMATION***

**DO:**

1. Obtain appropriate permissions to conduct project at your local PSJH facility prior to submitting to the HRPP.
2. If you are a student/resident identify local PSJH 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 HRPP review prior to starting project.
5. Conduct project as submitted to the HRPP. Contact the HRPP Office if revisions are required.
6. Obtain only the data outlined in the summary provided to the HRPP. Projects are subject to audit by compliance.
7. Follow all PSJH and/or local policies.
8. Follow HIPAA law.
9. Present your project finding to appropriate PSJH personnel identified above.

**Don’t:**

1. Make any changes to project without consulting the HRPP Office.
2. Put ANY PHI on personal computers, e-mail or store on thumb-drive.
3. Remove any PHI from PSJH campus.
4. Start your project until a determination has been made by the HRPP.

**What if my project requires IRB review/approval?**

If your proposed project is determined to be research you will be informed by the HRPP Office and submission as research will be required.

**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)