

“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)

Version: 6-18

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