



Institutional Profile

Purpose

The SMART IRB Institution Profile captures institutional information that is **independent** of a specific protocol. An institution's SMART IRB Point of Contact (POC) should complete this profile to (1) document institutional, local, and state requirements that would apply to **all** protocols, so that a potential Reviewing IRB may refer to this profile (in conjunction with a completed SMART IRB Protocol-specific Document) during the ceding and review of a specific protocol; and, if applicable, to (2) document information about the institution and its IRB(s) so that potential Relying Institutions may refer to this profile when determining whether to cede IRB review to the institution for a protocol.

Instructions

1. An institution's POC should record the appropriate responses (and sub-responses) to each question.
 1. Complete each text box, as applicable.
 2. Select **one** appropriate response from each drop-down list.
 3. For each "yes" response, provide additional details, as applicable.
2. An institution's POC should update the information on this form as needed to ensure accuracy.

Notes

- **Institution Name(s).** Because other institutions may not be familiar with your institution, it is important to include all alternate names, abbreviations, and acronyms by which the institution may be known to avoid confusion and/or potential delays in approvals or correspondence.
- **Components.** When listing all components under your institution's FWA, indicate in the text field if the components are considered separate legal entities. HIPAA. A Reviewing IRB must know whether a Relying Institution is a covered entity under HIPAA for research activities to determine whether HIPAA regulations will apply for the institution. If your organization is a hybrid entity, where only some components and/or research activities are covered by HIPAA, mark this response as "Yes" and provide details regarding the hybrid status in the next question. A Reviewing IRB will need to know the following for any Relying Institution that must apply HIPAA:
 - Whether the institution will **always** require a stand-alone HIPAA authorization.
 - Whether the institution will **always** require a combined HIPAA authorization and informed consent document.
 - Whether the institution will leave the determination of a stand-alone or combined HIPAA authorization to the Reviewing IRB for a specific study.

- **Short form Consents.** You should indicate any institutional policy on the use of short forms for non-English speaking individuals (i.e., short forms are not used at all, short forms are not allowed for certain languages (e. g., Spanish), short forms are only allowable for minimal risk research). Potential Reviewing IRBs will use this information when determining if they have the capacity to serve as a Reviewing IRB for your institution.
- **Minors and Consent.** In addition to knowing the age of majority in a Relying Institution's state, a Reviewing IRB should be informed of specific situations when minors can consent for themselves (e.g., some states allow un-emancipated minors to consent to STD treatment/research).
- **State Laws and Local Requirements.** Provide details for any additional state laws and/or local requirements that would be applicable to all protocols, (e.g., IRB reporting requirements for all studies). If the state laws and/or local requirements would only apply to certain protocols (e.g., mandatory reporting to state health authorities, child abuse reporting, child pregnancy results), do not include this information in your SMART IRB Institutional Profile; instead, provide this information to the Reviewing IRB for an applicable protocol via the SMART IRB Study-specific Document.
- **Flexibility.** Many institutions have implemented flexibility options with regard to review and approval of research at their institutions. Examples of flexibility include declining to apply the regulations to non-federally funded research by "unchecking the box," establishing additional exempt categories, extending IRB approval dates, and/or expanding expedited review categories. If your institution has implemented flexibility options, provide details for the Reviewing IRB.
- **IRB Policies.** If your institution is willing to serve as a Reviewing IRB for another institution, it is important to identify how Relying Institutions may access your IRB policies (e.g., website links, upon request from the Relying Institution).
- **OHRP or FDA Investigations/Inspections.** A potential Reviewing IRB Institution should provide any publiclyavailable information related to investigations or inspections of the IRB that may be relevant to or influence another institution's decision whether to rely upon that IRB. Do not include information related to investigations or inspections of individual investigators at the IRB's institution.
- **Default HIPAA Privacy Board Allocation.** It is anticipated that a Reviewing IRB will also serve as the Privacy Board for all Relying Institutions; therefore, the answer to this question has been defaulted to "yes." If this is not the case for your institution/IRB, change the response to "no."
- **Review of Study Personnel.** Because processes for handling the review of study personnel can vary widely among Reviewing IRBs, it is important that potential Relying Institutions are aware of the process for any IRBs that require all study personnel be reviewed and approved by the Reviewing IRB.

Institutional Profile

All institutions should complete this form and update it as needed to ensure accuracy.

Institution Legal Name
Providence St. Joseph Health

List all other names by which the institution is known.
Providence Health & Services

List all organizations that are considered components under this institution's FWA.

Providence Adolescent Residential Treatment Program Providence Alaska Medical Center Providence Extended Care Providence Horizon House Providence Kodiak Medical Center Providence Medical Group-Alaska Providence Transitional Care Center Providence Valdez Medical Center Providence Seward Medical Center Providence St. John's Health Center Providence Little Company of Mary Home Health Providence Little Company of Mary Sub Acute Care Center - San Pedro Providence St. Elizabeth Care Center - North Hollywood The Roy and Patricia Disney Family Cancer Center Providence House Providence High School Providence Medical Institute dba Providence Little Company of Mary Medical Institute Providence Little Company of Mary Medical Center - Torrance Imaging Providence TrinityCare Hospice - Torrance St. Jude Medical Center St. Joseph Hospital Orange Mission Hospital Queen of the Valley Medical Center Santa Rosa Memorial Hospital Providence Holy Cross Health Center at Porter Ranch Providence Holy Cross Health Center at Santa Clarita Providence Holy Cross Cancer Center Providence Holy Cross Outpatient Diagnostic Center Providence Holy Cross Imaging Services Providence Medical Associates Providence Specialty Medical Group Hematology Oncology Medical Group of the San Fernando Valley Inc. Providence Medical Associates Providence Specialty Medical Group Providence Medical Associates Providence Specialty Medical Group Providence Medical Associates The Doctors of Saint John's Providence Specialty Medical Group Pacific Neuroscience Institute Providence Saint John's Cancer Center Providence Facey Medical Foundation Providence Medical Foundation Providence St. Joseph Medical Center Providence Health & Services - Southern California Providence Holy Cross Medical Center Providence Little Company of Mary Medical Center Providence Little Company of Mary Medical Center Providence Cedars-Sinai Tarzana Medical Center St. Joseph Hospital St. Mary Medical Center St. Jude Hospital Yorba Linda dba St. Joseph Heritage Healthcare Petaluma Valley Hospital St. Joseph Health Northern California St. Joseph Health System Providence Health & Services - Montana SPHSC Radiation Therapy Dept. (Cancer Center) Broadway Imaging Corp. International Heart Institute of Montana Foundation Providence Surgery Center Montana Neuroscience Institute Foundation Montana Cancer Institute Foundation Providence Health and Services - Montana - DBA St. Patrick Hospital Providence Medical Group Montana Providence St. Joseph Medical Center University of Providence St Thomas Child & Family Center Providence Benedictine Nursing Center Providence Child Center Providence Health Plan Credena Health Pharmacy - Specialty Providence Medical Group Southwest Washington The Oregon Clinic Providence Health & Services - Oregon PCC Oncology and Hematology Care Clinic (Eastside) PCC Oncology and Hematology Care Clinic (Newberg) PCC Oncology and Hematology Care Clinic (Southeast) PCC Oncology and Hematology Care Clinic (Westside) PCC Oncology and Hematology Care Clinic (Willamette Falls) Providence Portland Medical Center Providence St. Vincent Medical Center Providence Milwaukie Hospital Providence Newberg Medical Center Providence Seaside Hospital Providence Hood River Memorial Hospital Providence Medical Group-Oregon Providence Medford Medical Center Providence Medical Group-South Oregon Outpatient Surgery Center Providence Willamette Falls Medical Center Clackamas Radiation Oncology Providence Medical Group-Medford Neurology Pacific Coast Research Consortium Covenant Health Providence Medical Group Walla Walla Providence Mother Joseph Care Center-Olympia Providence Mt. St. Vincent Providence Adult Day Health Providence DominiCare Providence Elderplace Providence Emilie Court Assisted Living Providence Regional Medical Center Everett Providence Sound HomeCare and Hospice Providence St. Mary Medical Center Providence VNA Home Health Providence Sacred Heart Medical Center and Children's Hospital Providence Regional Cancer System Providence Regional Cancer Partnership Providence Regional Cancer System-Centralia Providence Regional Cancer System-Aberdeen Providence Regional Cancer System-Yelm Providence Regional Cancer System-Shelton Providence Regional Med Ctr Everett Providence St. Peter Hospital Tri Cities Cancer Center Providence Health & Services - Washington Providence St. Luke Rehabilitation Medical Center Providence Health Care Providence Holy Family Hospital Providence Sacred Heart Medical Center Providence St. Joseph Care Center Providence Mt. Carmel Hospital Providence Medical Group-Providence Health Care Providence Physicians Services Providence Medical Group-Colville Providence Medical Group-Chewelah Providence Visiting Nurses Association-Spokane Providence ElderPlace-Seattle Swedish Medical Center, Ballard Campus Swedish Medical Center, Cherry Hill Campus Swedish

Cancer Institute Swedish Neuroscience Institute Swedish Heart Institute Swedish Home Care Services Swedish Physicians Swedish Physician Division Swedish Multiple Sclerosis Center Swedish Family Medicine Swedish Perinatal Clinic Swedish Addiction Recovery Services Swedish Heart and Vascular Institute Swedish Lake Sammamish Women's Diagnostic Imaging Swedish Medical Center, First Hill Campus Swedish Health Services Swedish Issaquah Swedish Edmonds Puget Sound Cancer Center Swedish Cancer Institute Eastside Oncology/Hematology Kadlec Regional Medical Center dba Kadlec Clinic Hematology and Oncology Kadlec Regional Medical Center Kadlec Medical Associates Kadlec Healthplex Kadlec Clinic Pasco Primary Care Kadlec Clinic Inland Cardiology Kadlec Clinic Rheumatology Kadlec Neuroscience Center First Hill Diagnostic Imaging Institute for Systems Biology Providence Centralia Hospital Providence Home Services King County Providence Hospice and Home Care-Everett Providence Hospice of Seattle Providence Marianwood Providence Medical Group Northwest Washington Providence Rossi House Providence Blanchet House Providence St. Francis House Providence Vincent House Providence Gamelin House Providence St. Elizabeth House Providence Peter Claver House Inland Northwest Health Services Bourget Health Services Providence Joseph House Providence John Gabriel House Providence House

Identify any affiliations this site has, such as university, clinic, or hospital.

a. If any of the sites are within a network or system, identify all sites with separate Federal Assurances (Please note that sites with separate Federal Assurances require separate SMART IRB accounts).

Does your state law or institution require you to apply the Common Rule to all studies?

Does your state law or institutional policy require you to apply any of the subparts (B, C, or D) of the HHS regulations at 45 CFR part 46 that provide additional protections for certain populations in research to all studies, when applicable?

If yes, indicate the subpart(s) your institution applies:

Are there any local considerations (i.e., customs, beliefs, values, or practices of a distinct subject population(s)) that a Relying Institution could expect to be included in the research?

Provide any additional information that may affect the IRB's review of your institution. Some examples may be California Bill of Rights, Virginia law that requires application of the Common Rule to all research, restriction of any vulnerable populations, etc.

Identify the age of majority for your state or territory. For federal agencies or departments, please indicate the applicable age of majority.

18

Is your institution willing to serve as an IRB of record (Reviewing IRB) for other institutions?

No

Contributing Authors

Kimberly Summers, PharmD

Director, Research Protection Programs
University of Texas Health at San Antonio (UT Health San Antonio)

Michele Russell-Einhorn, JD

Vice President, Human Research Protection Services and Institutional
Official Schulman IRB

Jeremy Corsmo, MPH

Senior Director, Research Compliance
Cincinnati Children's Hospital

Michelle Feige, MSW

Executive Vice President
Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Claudia Grossman, PhD

Program Officer, Research Infrastructure
Patient-Centered Outcomes Research Institute (PCORI)

Andreas Klein, MD

Chair, Tufts Health Sciences IRB
Tufts Medical Center

Eric Mah, MPH

Executive Director, Clinical Research Operations
University of California, San Diego Health Sciences (UCSD Health Sciences)

Megan Singleton, JD, MBE, CIP

Director, Human Research Protection Program
Johns Hopkins University School of Medicine

Amy Waltz, JD, CIP

Associate Director, Human Subjects Office
Indiana University

SMART IRB Harmonization Steering Committee Leadership

Barbara E. Bierer, MD

Director of Regulatory Policy, SMART IRB

Co-chair, SMART IRB Harmonization Steering Committee

Valery Gordon, PhD, MPH

Division of Clinical Innovation, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health

Co-chair, SMART IRB Harmonization Steering Committee

Aaron Kirby, MSc

Director, Regulatory Affairs Operations, Harvard Catalyst

Operations Officer, SMART IRB Harmonization Steering Committee