



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
Ascension Health

List all other names by which the institution is known.
Ascension Healthcare

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

Ascension Sacred Heart Cancer Center, inclusive of all locations Pensacola FL Ascension Sacred Heart Freestanding Emergency Department Pensacola FL Ascension Sacred Heart Health Hospital - Bay Panama City FL Ascension Sacred Heart Health Systems d/b/a Ascension Gulf Coast Pensacola FL Ascension Sacred Heart Hosp on Emerald Coast Destin FL Ascension Sacred Heart Hosp Pensacola Pensacola FL Ascension Sacred Heart Hospital on the Gulf Port St. Joe FL Ascension Sacred Heart Women's & Children's Hosp Pensacola FL Ascension St. Vincent's Clay County Jacksonville FL Ascension St. Vincent's d/b/a Ascension Florida Jacksonville FL Ascension St. Vincent's Riverside Jacksonville FL Ascension St. Vincent's Southside Jacksonville FL Ascension St. Vincent's St. Johns County Hospital St. Johns FL Studer Family Children's Hospital at Ascension Sacred Heart Pensacola FL Alexian Brothers Health System d/b/a Ascension Illinois Lisle IL Ascension Alexian Brothers - Elk Grove Village Elk Grove Village IL Ascension Alexian Brothers Behavioral Health Hospital - Hoffman Estates Hoffman Estates IL Ascension Alexian Brothers Specialty Group Arlington Heights IL Ascension Alexian Brothers Women & Children's Hospital - Hoffman Estates Hoffman Estates IL Ascension Alexian Rehabilitation Hospital - Elk Grove Village Elk Grove Village IL Ascension Holy Family - Des Plaines Des Plaines IL Ascension Illinois Rainbow Hospice - Chicago Chicago IL Ascension Mercy - Aurora Aurora IL Ascension Resurrection - Chicago Chicago IL Ascension Saint Elizabeth - Chicago Chicago IL Ascension Saint Francis - Evanston Evanston IL Ascension Saint Joseph -Chicago Chicago IL Ascension Saint Joseph -Elgin Elgin IL Ascension Saint Mary - Chicago Chicago IL Ascension Saint Mary - Kankakee Kankakee IL Ascension St. Alexius - Hoffman Estates Hoffman Estates IL Ascension St. Joseph - Joliet Joliet IL Ascension Carmel Ambulatory Surgery Center Carmel IN Ascension St. Vincent Anderson Anderson IN Ascension St. Vincent Cardiac Services Indianapolis IN Ascension St. Vincent Carmel Carmel IN Ascension St. Vincent Clay Brazil IN Ascension St. Vincent d/b/a Ascension Indiana Indianapolis IN Ascension St. Vincent Dunn Bedford IN Ascension St. Vincent Evansville Evansville IN Ascension St. Vincent Fishers Fishers IN Ascension St. Vincent Heart Center Indianapolis IN Ascension St. Vincent Indianapolis Hospital Indianapolis IN Ascension St. Vincent Jennings North Vernon IN Ascension St. Vincent Kokomo Kokomo IN Ascension St. Vincent Mercy Elwood IN Ascension St. Vincent Randolph Winchester IN Ascension St. Vincent Salem Salem IN Ascension St. Vincent Seton Specialty Hosp Indianapolis IN Ascension St. Vincent Sports Performance Center Indianapolis IN Ascension St. Vincent Stress Center Indianapolis IN Ascension St. Vincent Warrick Boonville IN Ascension St. Vincent Williamsport Williamsport IN Ascension St. Vincent Women's Hospital Indianapolis IN Joshua Max Simon Ascension St. Vincent Primary Care Ctr Indianapolis IN Peyton Manning Children's Hosp at Ascension St. Vincent Indianapolis IN St. Vincent Health, Wellness, and Preventive Care Institute Indianapolis IN Ascension Via Christi Hospitals d/b/a Ascension Kansas Wichita KS DePaul Community Health Centers New Orleans LA Ascension St. Agnes Healthcare d/b/a Ascension Maryland Baltimore MD Ascension Borgess Hospital, Kalamazoo, MI Ascension Living, inclusive of all locations St. Louis MO Ascension Medical Group, inclusive of all locations St. Louis MO Ascension Jane Phillips Medical Center Bartlesville OK Ascension St. John Broken Arrow Broken Arrow OK Ascension St. John Health System d/b/a Ascension Oklahoma Tulsa OK Ascension St. John Medical Center Tulsa OK Ascension St. John Owasso Owasso OK Ascension St. John Sapulpa Sapulpa OK Ascension Saint Thomas Dekalb Hospital Smithville TN Ascension Saint Thomas Health d/b/a Ascension Tennessee Nashville TN Ascension Saint Thomas Hickman Hospital Centerville TN Ascension Saint Thomas Highlands Hospital Sparta TN Ascension Saint Thomas Hospital for Specialty Surgery Nashville TN Ascension Saint Thomas Medical Partners Nashville TN Ascension Saint Thomas Midtown Hospital Nashville TN Ascension Saint Thomas River Park Hospital McMinnville TN Ascension Saint Thomas Rutherford Hospital Murfreesboro TN Ascension Saint Thomas Stones River Hospital Woodbury TN Ascension Saint Thomas Three Rivers Hospital Waverly TN Ascension Saint Thomas West Hospital Nashville TN Ascension Academic Medicine Associates Austin TX Ascension Seton d/b/a Ascension Texas Austin TX Ascension Seton Hays Kyle TX Ascension Seton McCarthy Community Health Center Austin TX Ascension Seton Medical Center Austin Austin TX Ascension Seton Northwest Hospital Austin TX Ascension Seton Shoal Creek Austin TX Ascension Seton Smithville Smithville TX Ascension Seton Southwest Austin TX Ascension Seton Williamson Round Rock TX Austin Children's Chest Associates Austin TX Austin CyberKnife Austin TX

Austin Med Education Programs Austin TX Dell Children's Medical Center of Central Texas Austin TX Dell Children's Medical Group d/b/a Specially for Children Austin TX Dell Seton Medical Center at the University of Texas Austin TX Providence Hlth Svcs of Waco d/b/a Ascension Texas Waco TX Seton Brain and Spine Institute Austin TX Seton Family of Hospitals Austin TX Seton Healthcare Network Austin TX Seton Heart Instiute Austin TX Seton Mind Institute Austin TX Seton Spine and Rehabilitation Center Austin TX Seton Spine and Scoliosis Center Austin TX University Medical Center Brackenridge Austin TX Ascension All Saints Hospital Milwaukee WI Ascension Calumet Hospital Chilton WI Ascension Columbia St. Mary's d/b/a Ascension Wisconsin Milwaukee WI Ascension Columbia St. Mary's Hospital Milwaukee Milwaukee WI Ascension Columbia St. Mary's Hospital Ozaukee Mequon WI Ascension Elmbrook Memorial Milwaukee WI Ascension Mercy Hospital, Inc. Oshkosh WI Ascension Sacred Heart Rehabilitation Hospital, Inc. Milwaukee WI Ascension SE Wisconsin Hospital Milwaukee WI Ascension St. Elizabeth Hospital, Inc. Appleton WI Ascension St. Francis Hospital Milwaukee WI Ascension St. Joseph Outpatient Center Milwaukee WI Ascension Wisconsin Laboratories, Inc. Milwaukee WI Ascension Wisconsin Pharmacy, Inc. Milwaukee WI Family Care Center Racine WI Madison Medical Affiliates, Inc. Milwaukee WI Midwest Orthopedic Specialty Hospital, LLC Franklin WI Ministry Health Care d/b/a Ascension Wisconsin Glendale WI Network Health System-Affinity Medical Group Menasha WI Orthopaedic Hospital of Wisconsin, LLC Glendale WI Wheaton Franciscan Healthcare - All Saints, Inc. Racine WI Wheaton Franciscan Medical Group, Inc. Milwaukee WI Wheaton Franciscan, Inc. - Franklin Franklin WI

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.

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

No

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