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.

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- **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 Children's Wisconsin

List all other names by which the institution is known. Children's Hospital of Wisconsin

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

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Children's Research Institute, Inc. Children's Hospital of Wisconsin - Fox Valley SurgiCenter of Greater Milwaukee LLC

Identify any affiliations this site has, such as university, clinic, or hospital.
Our academic affiliate is the Medical College of Wisconsin.

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?
No

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?
No

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?
Children's Wisconsin will not serve as the IRB of record.

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.
Wisconsin Statutes: 54.25 Duties and powers of guardian of the person:
- WSA Chapter 54 [WSA 54.25(2)(d)2.b-d] Describes powers of the guardian with regard to a Ward's participation in research.
- WSA Chapter 155 [155.20(3)] Prohibits a health care agent from agreeing to experimental mental health research or to psychosurgery, electroconvulsive treatment or drastic mental health treatment procedures for an adult subject lacking capacity to consent.

1. Research-Related Radiation Exposure: Wisconsin Administrative Code, Department of Health Services 157. If radiation procedures within the context of a clinical trial are determined to fall outside of the DHS 157 definition of "healing arts," ("healing arts" means a profession concerned with diagnosis and treatment of human maladies, including the practice of medicine, dentistry, osteopathy chiropractic and podiatry.) The state is contacted for approvable prior to trial initiation.

2. Mandatory Reporting: Any medical or mental health professional who has reasonable cause to suspect child abuse is required to report the suspected abuse under Wisconsin statutes. Wisconsin law also requires any health care provider to report the appearance of the communicable disease or a death caused by such a disease to the local health officer.

Reporting to State or Other Appropriate Officials (Mandatory Health Care Providers):
State law requires physicians, nurses, psychiatrists, counselors, and other medical and mental health providers, to report

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reasonable suspicions of child abuse or neglect. Child abuse includes physical injury inflicted on a child other than by accidental means, and sexual intercourse or contact with a child age 15 or under, or age 16 or 17 without the child's consent. Neglect includes failure on the part of a caregiver other than for reasons of poverty to provide for necessary food, clothing, shelter and medical/dental care.

Communicable Diseases: General reporting requirements are described in Wis. Stat. ch.252.
252.05 Reports of cases:
(1) Any health care provider, as defined in s. 146.81 (1) (a) to (p), who knows or has reason to believe that a person treated or visited by him or her has a communicable disease, or having a communicable disease, has died, shall report the appearance of the communicable disease or the death to the local health officer. The health agency of a federally recognized American Indian tribe or band may report this information to the local health officer. The local health officer shall report this information to the department or shall direct the person reporting to report to the department. Any person directed to report shall submit this information to the department.
(2) Each laboratory shall report as prescribed by the department those specimen results that indicate that an individual providing the specimen has a communicable disease, or having a communicable disease, has died, or that the department finds necessary for the surveillance, control, diagnosis, and prevention of communicable diseases.
(3) Anyone having knowledge or reason to believe that any person has a communicable disease shall report the facts to the local health officer or to the department.
(4) Reports under subs. (1) and (2) shall state so far as known the name, sex, age, and residence of the person, the communicable disease and other facts the department or local health officer requires. Report forms, including forms appropriate for reporting under s. 95.22, may be furnished by the department and distributed by the local health officer.
(5) All reports shall be made within 24 hours, unless otherwise specified by the department, by telephone, telegraph, mail or electronic means or by deposit at the office of the local health officer.
(6) Any local health officer, upon receiving a report, shall cause a permanent record of the report to be made and upon demand of the department transmit the original or a copy to the department, together with other information the department requires. The department may store these records as paper or electronic records and shall treat them as patient health care records under ss. 146.81 to 146.835.
(7) When an outbreak or epidemic occurs, the local health officer shall immediately report to the department, and shall at all times keep the department informed of the prevalence of the communicable diseases in the locality in the manner and with the facts the department requires.
(8) The department shall print and distribute, without charge, to all local health departments and, upon request, to health care providers and facilities a chart that provides information about communicable diseases.
(9) Any person licensed, permitted, registered or certified under ch. 441 or 448 shall use ordinary skill in determining the presence of communicable diseases. If there is a dispute regarding disease determination, if the disease may have potential public health significance or if more extensive laboratory tests will aid in the investigation, the local health officer shall order the tests made by the state laboratory of hygiene or by a laboratory certified under 42 USC 263a.
(10) If a violation of this section is reported to a district attorney by a local health officer or by the department, the district attorney shall forthwith prosecute the proper action, and upon request of the department, the attorney general shall assist.

Communicable Diseases: The specific reporting requirements are described in Wis. Admin Code. ch. DHS 145. A list of reportable conditions is provided in Wis. Admin Code. ch. DHS 145 - Appendix A.

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"Any health care provider (Wis. Stats. §§ 146.81(1)(a)-(p)) who knows or has reason to believe that a person treated or visited by him or her has a communicable disease, or having a communicable disease has died, shall report the appearance of the communicable disease or the death to the local health officer. The local health officer shall report this information to the Wisconsin Department of Health Services or shall direct the person reporting to report to the Department. Any person directed to report shall submit this information to the Department (Wis Stat 252.05 (1))."

3. Determining who is a child and who is an adult in Wisconsin. The age of majority is 18-years of age. A “child” is defined as a person less than 18-years of age.

WSA 48.02(1d), 48.02(2):
“Child," when used without further qualification, means a person who is less than 18 years of age, except that for purposes of investigating or prosecuting a person who is alleged to have violated a state or federal criminal law or any civil law or municipal ordinance, “child" does not include a person who has attained 17 years of age."

An emancipated minor, under Wisconsin law, includes a married, widowed or divorced person who is at least 16 years old (except for minors found to be incompetent).

WSA 880.04(1):
"Emancipation of married minors. Except for minors found to be incompetent, upon marriage, a minor shall no longer be a proper subject for guardianship of the person and a guardianship of the person is revoked by the marriage of a minor ward. Upon application, the court may release in whole or in part the estate of a minor ward to the ward upon the ward's marriage. Upon marriage, the guardianship of an incompetent is subject to review under s. 880.34.

WSA 765.02(2):
Marriageable age; who may contract.
(1) Every person who has attained the age of 18 years may marry if otherwise competent.

765.02(2)(2):
If a person is between the age of 16 and 18 years, a marriage license may be issued with the written consent of the person's parents, guardian, custodian under s. 767.225 (1) or 767.41, or parent having the actual care, custody and control of the person. The written consent must be given before the county clerk under oath, or certified in writing and verified by affidavit or affirmation before a notary public or other official authorized to take affidavits. The written consent shall be filed with the county clerk at the time of application for a marriage license. If there is no guardian, parent or custodian or if the custodian is an agency or department, the written consent may be given, after notice to any agency or department appointed as custodian and hearing proper cause shown, by the court having probate jurisdiction.

54.46(6):
"Emancipation of married minors. Except for a minor found to be incompetent, upon marriage, a minor is no longer a proper subject for guardianship of the person and a guardianship of the person is revoked by the marriage of a minor ward. Upon application, the court may release in whole or in part the income and assets of a minor ward to the ward upon the ward's

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marriage."

Children's Wisconsin HRPP SOP Manual Section 15.1:
"According to Wisconsin State Law, minors are persons under the age of eighteen. The general rule is that a person may sign legally-binding agreements and consent for his or her own medical care at the age of eighteen. Therefore, CW defines children as persons who are under eighteen years of age. Wisconsin considers any minor that is married, has joined the armed forces as emancipated. A Wisconsin court may also emancipate a minor in special circumstances. Any emancipated minor may direct their own care as if they were adults. Wisconsin law also permits minors to seek and receive care in certain circumstances without parental consent. None of these circumstances are research in and of itself, however, some of the procedures involved in research may consist of these circumstances. Children's Wisconsin Legal Counsel and the Children's Wisconsin HRPP should be consulted for a case by case determination. NOTE: For research conducted in jurisdictions other than Wisconsin, the research must comply with the laws regarding the legal age of consent in the relevant jurisdictions. Legal Counsel will be consulted with regard to the laws in other jurisdictions or such "local context" information will be sought through other mean (e.g., according to the terms of a reliance agreement)."

•The statute governing parental consent required prior to abortion defines an emancipated minor as "a minor who is or has been married; a minor who has previously given birth; or a minor who has been freed from the care, custody and control of her parents, with little likelihood of returning to the care, custody and control prior to marriage or researching the age of majority." [WSA 48.375(2)(e), 895.037(1)(c)]. NOTE: Children's Wisconsin Research Administration and General Counsel recommend caution in interpreting this statute to mean that a minor who has given birth is emancipated generally and therefore can provide research participation for her child.

Treatments or procedures for which a minor child can give consent (WSA 252.15(2)(a)4.a):
• A minor 14 years or older may consent to HIV testing.[WSA 252.15(2)(a)4.a]
• A minor 12 years or older may consent to preventative or treatment services for the abuse of alcohol or other drugs on an outpatient basis [WSA 51.45(2m)]
• A minor of any age may consent to testing or treatment for sexually transmitted infections [WSA525.11(1), 252.11(1m)]

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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