

Supplement to the Smart IRB Master Reliance Agreement

Institution: Seattle Children's Hospital
Federal wide Assurance (FWA) #: FWA00002443
IRB Registration #: IRB00000277; IRB00009311

Institution: University of Washington
Federal wide Assurance (FWA) #: FWA00006878
IRB Registration #: A (00000241); B (00000242); D (00000727); J (00005647)

Seattle Children's Hospital (SCH) and the University of Washington (UW) have each signed the Smart IRB Master Reliance Agreement, which allows each institution to cede Institutional Board Review (IRB) review to the other institution. This Agreement Supplement establishes the commitment of the two institutions to using the Smart IRB Master Reliance Agreement as the basis of the standing cooperative reliance arrangement for IRB review between the two institutions, for research in which both institutions are engaged. This Agreement Supplement is not intended to modify any terms of the Smart IRB Master Reliance Agreement signed by each institution, except as explicitly noted below.

1. Definitions

- a. **Engagement.** This term refers to a set of criteria used by OHRP to determine whether an institution is involved in human subjects research and must therefore obtain IRB review.
- b. **Relying Institution.** The institution (SCH or UW) that cedes IRB review to the other institution, as described in this Agreement Supplement.
- c. **Reviewing Institution.** The institution (SCH or UW) whose IRB conducts the IRB review on behalf of both institutions.
- d. **Reviewing IRB.** An IRB at SCH or UW, when it conducts IRB review on behalf of both institutions.
- e. **University of Washington (UW).** For the purposes of this Agreement Supplement, the UW Institution is defined as all components listed on the UW Federalwide Assurance except that it does not include the following UW Medicine Affiliated Covered Entities that are non-UW legal entities: (1) King County Public Hospital District No. 1 d/b/a Valley Medical Center and Clinics, and (2) Summit Cardiology.
- f. **Seattle Children's Hospital (SCH).** For the purposes of this Agreement Supplement, the SCH institution is defined as all SCH legal entities, including but not limited to those components listed on the SCH Federalwide Assurance.

2. Scope of the Agreement

This Agreement Supplement applies to all non-exempt human subjects research in which both institutions are engaged except as noted here:

- a. Research in which both institutions are engaged but for which SCH or UW intends to cede review to an IRB at a third institution; i.e., this Agreement Supplement does not allow for "daisy chaining" of IRB review. In these situations, SCH and UW must each establish its own arrangement with the other IRB or conduct its own IRB review. Examples:
 - UW routinely cedes review of industry-initiated-and-funded research to an independent IRB;
 - UW routinely cedes review of most oncology research that involves interaction with subjects to the Fred Hutchinson Cancer Research Center's Cancer Consortium IRB.
- b. Research engaging other organizations for which SCH or UW may be the IRB of record but that are not included in the definitions of the institutions above or listed on the SCH or UW FWA as a component.

3. Determining the Reviewing Institution

This section describes the default basis for determining which institution's IRB shall conduct the review, for research in which both SCH and UW are engaged. If this information is not sufficient for determining the Reviewing Institution for a specific study or there are extenuating circumstances, individuals with appropriate delegated authority in each institution's Human Research Protection Program (HRPP) office may be consulted, and may consult with each other, to identify the most appropriate IRB to conduct the review.

Each institution reserves the right to require review by its own IRB, or by another IRB that is not party to this Agreement Supplement, so long as that preference is documented and provided to each HRPP office. This Agreement Supplement does not preclude either institution from participating in any other IRB reliance agreements.

The circumstances of the research determine which institution will serve as the Reviewing Institution, as described in the table below. When the principles described in the table are not sufficient to clearly identify the Reviewing Institution, the two HRPP offices shall mutually determine which institution will conduct the IRB review.

Research Circumstances	Reviewing Institution
Supported by external funding	The institution that is the direct recipient of the funding
Not supported by external funding AND involves interaction with human participants	The institution at which the majority of the research procedures will occur
Not supported by external funding AND solely involves the use of identifiable specimens and/or data that were not collected from subjects specifically for the purposes of the research	The institution at which the majority of the research activities (e.g., data or specimen analyses) will occur

4. Responsibilities of the Reviewing Institution

The Reviewing Institution shall fulfill the responsibilities described for reviewing institutions in the Smart IRB Master Reliance Agreement, with the following additions or changes:

- a. Documentation to proceed with review. The Reviewing IRB will not complete the approval of a study in which the Relying Institution is engaged without first receiving documentation that the Relying Institution has provided a written acknowledgment ceding review of the study to the Reviewing IRB.
- b. Flexibility of review. While each institution generally applies the Common Rule to all human subjects research, the terms of each institution's FWA allow the Reviewing IRB to adopt flexibility by substituting specific equivalent protections to non-federally-funded research.
- c. HIPAA authorization. When serving as the Reviewing IRB for the other institution, neither the UW nor SCH will review HIPAA authorization forms or allow HIPAA authorization language to be embedded within the consent form. The PI will be expected to use an institutionally-approved template.
- d. Federal Certificate of Confidentiality or Certificate of Privacy. The Reviewing Institution shall ensure that the Relying Institution is informed of any federal Certificate of Confidentiality or federal Certificate of Privacy that applies to a study it has reviewed on behalf of both institutions, except when the Relying Institution is the prime awardee of a federal grant that supports the research and for which a Certificate is one of the terms of the award.

- e. Prisoner certification. The Reviewing Institution shall obtain and maintain prisoner certification and concurrence from OHRP on behalf of both institutions, for research governed by 45 CFR 46 Subpart C.
- f. Genomic Data Sharing certification. The Reviewing Institution shall provide certification of genomic data for both institutions, for submission of a study's data to national databases such as the National Institutes of Health dbGaP database.
- g. Notification of IRB decisions, changes, lapses in approval. Section 5.9 of the Master Reliance Agreement specifies the obligation of the Reviewing Institution to promptly notify the overall principal investigator (PI), site investigator(s), and the Relying Institution of IRB decisions, changes, lapses in approval and any applicable corrective action plans. With this Agreement Supplement, SCH and UW agree to the following revision of Section 5.9, for the actions and events described in that Section:

The Reviewing IRB shall promptly notify:

- The PI (as listed on the IRB application) of its determinations or review decisions regarding the Research (e.g., approval, disapproval, required modifications); of changes in the Research reviewed and approved by the Reviewing IRB after initial approval; and of lapses in IRB approval and any applicable corrective actions;
- The Relying Institution of any applicable correction actions.

It is the responsibility of the PI to ensure that all members of the study team at both institutions are informed of all IRB determinations, decisions, and requirements.

5. Responsibilities of the Relying Institution

The Relying Institution shall fulfill the responsibilities described for relying institutions in the Smart IRB Master Reliance Agreement.

6. Joint Responsibilities

Each institution retains responsibility for ensuring that appropriate ancillary reviews are conducted for each study reviewed under this Agreement. This includes (as applicable): Radiation Safety, Institutional Biosafety Committee review, and Embryonic Stem Cell Research Oversight Committee (ESCRO) review.

7. General Terms and Conditions

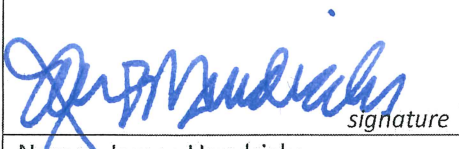

This Agreement Supplement becomes effective upon the date of the last signature by the Institutional Officials below and will be continuous, but it may be revised upon submission of written notice 30 days in advance of the effective amendment or termination date to ensure appropriate reviews and signatures from both institutions are obtained.

Following termination of this Agreement Supplement, each institution agrees to provide continued IRB oversight of ongoing research for the reasonable time necessary to appropriately transfer oversight of the protocol(s) to the Relying Institution's IRB.

This document must be kept on file at both institutions and will be provided to OHRP and/or the Food and Drug Administration (FDA) upon request.

This Agreement Supplement may be executed in any number of counterparts, either in original, printable document file (PDF) or faxed form.

8. Signatures

Authorized Official of Seattle Children's		Authorized Official of the University of Washington	
 signature	14 Feb 19 date	 signature	1/25/19 date
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