

Cooperative IRB Reliance Agreement

Institution: Kaiser Permanente Foundation Health Plan of Washington
Federal wide Assurance (FWA) #: FWA00002344
IRB Registration #: 00010902

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

Kaiser Foundation Health Plan of Washington (KPWA) and the University of Washington (UW) share a mutual concern for safeguarding the rights and welfare of human subjects involved in non-exempt research activities conducted by their respective institutions. Both institutions also seek to provide high-quality efficient Institutional Review Board (IRB) review for their investigators. This Agreement establishes the terms by which one institution may rely on the IRB review conducted by the other institution, for research studies that engage both institutions. This Agreement sets forth the respective authorities, roles, and responsibilities of each party in such reliance arrangements. This agreement meets federal requirements for designation of another institution's IRB as the Reviewing IRB.

1. Definitions

- a. **Employee or agent.** As defined by OHRP, this refers to individuals who (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally-designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. For the purpose of this Agreement and for the purpose of identifying institutional engagement in collaborative research, KPWA and UW agree that:
 - i. **KPWHRI investigators who are affiliate or clinical UW faculty.** Individuals who are identified as investigators at Kaiser Permanente Washington Health Research Institute (KPWHRI) and who have UW affiliate faculty or clinical faculty appointments are considered to be employees/agents of KPWA (not UW) when they conduct research, except when the research is externally funded and the UW is the direct recipient of the external funding. In such circumstances the investigator is considered to be an employee/agent of both institutions.
 - ii. **KPWHRI investigators who are research or regular UW faculty.** Individuals who are identified as investigators at KPWHRI and who have appointments as UW research faculty or UW regular faculty (i.e., not research, not clinical, not affiliate) conduct research, the circumstances of the research (as evaluated by the KPWA and/or UW IRB office) shall dictate whether the individual is considered to be an employee/agent of KPWA, UW, or both for the purposes of the specific study.
- b. **Engagement.** This term refers to a set of criteria used by OHRP to determine whether an institution is involved in non-exempt human subjects research and must therefore obtain IRB review. The criteria consider whether an institution's employee/agent is conducting specified activities related to the research. KPWA and UW use this concept to identify collaborative research that is appropriate for the cooperative review arrangement described in this Agreement.

- c. **Kaiser Permanente Washington (KPWA).** For the purposes of this Agreement the KPWA institution is defined as all components of the Kaiser Foundation Health Plan of Washington as well as Columbia Medical Associates and Washington Permanente Medical Group (WPMG, the physicians practice group for KPWA).
- d. **Relying institution.** The institution (KPWA or UW) that cedes IRB review to the other institution, as described in this Agreement.
- e. **Reviewing institution.** The institution (KPWA or UW) whose IRB conducts the IRB review on behalf of both institutions.
- f. **Reviewing IRB.** The IRB at KPWA or UW, when it conducts IRB review on behalf of both institutions.
- g. **University of Washington (UW).** For the purposes of this Agreement, the UW institution is defined as all components listed on the UW Federal-wide 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.

2. Scope of the Agreement

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

- a. Industry-sponsored-and-initiated clinical trials
- b. Determinations about whether an activity (1) meets the definition of "human subjects research"; (2) qualifies for exempt status; or (3) engages the other institution.
- c. Research in which both institutions are engaged but for which KPWA or UW intends to cede review to an IRB at a third institution; i.e., this Agreement does not allow for "daisy chaining" of IRB review. In these situations, KPWA and UW must each establish its own arrangement with the other IRB or conduct its own IRB review.

3. Criteria for Determining the Reviewing IRB

This section describes the default basis for determining which institution's IRB shall conduct the review of research in which both KPWA and UW are engaged. However, individuals with appropriate delegated authority in each institution's IRB office may consult and mutually agree to apply different criteria for selecting which IRB will conduct the review, on a study-specific basis. Each institution reserves the right to require review by its own IRB, or another IRB that is not party to this Agreement, so long as that preference is documented and provided to each IRB office. This Agreement 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 IRB offices shall consult with each other to 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 external 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 from which the majority of the specimens or data are being obtained

4. Responsibilities of the Reviewing Institution and Reviewing IRB

Applicable regulations. The IRB review will be conducted in accordance with all applicable human subjects regulations. This may include, for example: the Common Rule (45 CFR Part 46); Food and Drug Administration (FDA) regulations (21 CFR Parts 50, 56, 312, 812), HIPAA (45 CFR 164); RCW 70.02, and additional regulations and requirements of specific federal funding agencies (e.g., Department of Defense, National Institutes of Health).

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 appropriate flexibility in the application of the Common Rule to research that is not subject to federal regulations (e.g., research that is not federally-funded and not subject to FDA regulations).

Acknowledgment of reliance. When KPWA is the Reviewing IRB, it will not grant final IRB approval of the UW's engagement in a collaborative study until the KPWA IRB has received a written Acknowledgement of Ceding Review (provided by the UW IRB office to the UW PI) as part of the IRB submission.

Specific additional responsibilities of the Reviewing Institution and Reviewing IRB include:

- **Local context.** Consider local context issues as identified by the Relying Institution/PI.
- **Financial Conflict of Interest.** Consider Financial Conflict of Interest management plans developed by the Relying Institution for its investigator(s). Ensure that any disclosures to subjects required by the Plan and that are approvable by the Reviewing IRB are included in the approved informed consent form(s) for the Relying Institution. The Reviewing IRB retains the authority to impose additional prohibitions or conflict management requirements more stringent or restrictive than proposed by the Relying Institution if necessary to approve the research. In the extraordinary circumstance that the Reviewing IRB is unable to implement/approve the Relying Institution's prohibitions or management plans, the Reviewing IRB will inform the Relying Institution.
- **Provide documents and records.** Upon request, provide the Relying Institution with:
 - IRB membership roster
 - IRB Standard Operating Policies and Procedures
 - Relevant minutes of IRB meetings
 - Relevant file documents and/or the entire study file
- **Authority to review.** Notify the Relying Institution immediately of a change in the IRB's authority to review, including but not limited to: restriction, suspension, termination, or expiration of its FWA; or failure to maintain registration of its IRB(s).
- **Required reporting.** Promptly notify the IRB office of the Relying Institution of any determinations that require reporting to institutional officials and/or regulatory agencies under 45 CFR 46.103(b)(5), 21 CFR 56.108(b) and 56.113, 45 CFR 46.400-414, and WA RCW 70.02. Submit required reports to relevant federal regulatory agencies (e.g., OHRP, FDA, OCR), after making best efforts to provide the Relying Institution an opportunity to review and provide input on any reports prior to transmission to regulatory agencies. Submit required reports to funding agencies, when the Reviewing Institution is the primary recipient.
- **Audits, investigations.** Promptly notify the Relying Institution with respect to which it is conducting an audit or investigation of an allegation or matter relating to the ceded review, and report its findings to the Relying Institution within a reasonable timeframe. Alternately, the Reviewing IRB may request the Relying Institution to conduct its own audit/investigation and report its findings back to the Reviewing IRB, or the two institutions may work cooperatively to conduct an audit/investigation. Neither

institution is obligated to provide to the other its communications, analyses, or other information subject to attorney-client privilege or other privilege or rule of confidentiality.

- Certificate of Confidentiality. Ensure that the Relying Institution is informed of any federal Certificate of Confidentiality or federal Certificate of Privacy that applies to a study 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.
- Prisoner certification. Obtain and maintain prisoner certification and concurrence from OHRP on behalf of both institutions, for research governed by 45 CFR 46 Subpart C.
- Genomic Data Sharing Certification. Provide federally-mandated certification of genomic data for submission to national databases such the National Institute of Health dbGaP database, for any specimens held by the Reviewing Institution.
- HIPAA waiver. Grant waivers of HIPAA authorization for research use of Protected Health Information, as necessary and allowable for specific studies. The Reviewing IRB may choose to require the investigators to obtain HIPAA authorization (if not waived) separately from consent; if so, then the investigators and their respective institutions are responsible for using a HIPAA authorization form that contains all applicable federal and state elements of authorization.

5. Responsibilities of Reviewing Site Investigator

It is considered the responsibility of the study investigator/team at the Reviewing Institution to inform the study investigator/team at the Relying Institution of all IRB determinations, decisions, and requirements.

6. Responsibilities of the Relying Institution

Confidentiality Laws and Regulations. Compliance with confidentiality laws and regulations, including HIPAA and state law requirements, is considered a local institutional issue, except that the Reviewing IRB may grant waivers of HIPAA authorization for records at both institutions. The Relying Institution remains responsible for how compliance with confidentiality requirements is implemented at the institution.

Specific additional responsibilities are:

- Local context. Provide the Reviewing IRB with the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors that would affect the approval or conduct of the research at the Relying Institution. This includes any site-specific consent form requirements, such as appropriate subject injury language. Upon request, provide a local context consultant or reviewer who has knowledge of the local research context that would assist the IRB in its review.
- Conflicts of interest. Review and monitor individual and institutional conflicts of interest per the relying Institution's own policies and procedures.
- Research oversight. Oversight of the performance of the research at the relying institution, including any post-approval monitoring according to the policies of the relying institution.
- Assistance and cooperation. Assist as needed, and cooperate, with the management and resolution of serious adverse events, unanticipated problems, noncompliance, and complaints/inquiries.
- Ability to conduct the research. Promptly notify the reviewing institution if the relying institution becomes aware of events or circumstances that may change the ability of the relying institution or PI to conduct the research (e.g., suspension of the institution's FWA; FDA audit findings of PI's research program; serious investigator noncompliance).
- Local contact persons. Ensure prompt availability to the reviewing IRB of local contact persons who have the authority to communicate on behalf of the relying institution (e.g. the local IRB Director);

7. Responsibilities of Relying Institution Investigator

Serious Adverse Events and Other Unanticipated Problems. It is the responsibility of the investigator at the Relying Institution to identify and report Serious Adverse Events and/or Other Unanticipated Problems in accordance with the reviewing IRB's reporting policy. The investigator is also responsible for reporting any breaches involving data or specimens from/held by the Relying Institution to the Relying Institution's IRB.

8. Responsibilities of Both Institutions

Confidentiality. Each institution agrees to treat exchanged information as confidential and will not disclose such information without prior written approval. Notwithstanding the foregoing, nothing in this Agreement shall be construed to restrict an institution from disclosing confidential information as required by law, subpoena, court order, business need, or other governmental order or request. This section shall survive the termination of this Agreement.

Ancillary reviews. Each institution retains responsibility for ensuring that appropriate ancillary reviews are conducted for each study. This includes, for example: radiation safety, institutional biosafety committee review, embryonic stem cell oversight review (ESCRO), etc.

9. General Terms and Conditions

Additional specific operating procedures to implement and support this agreement may be developed, as needed, by the IRB Directors, in cooperation with appropriate institutional officials.



This Agreement becomes effective upon the date of the last signature by the Institutional Officials below and will be continuous, but it may be revised by either party upon submission of written notice 30 days in advance of the effective amendment or termination date.

Following termination of this Agreement, 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. Additional terms and responsibilities are outlined on the attachment and shall be deemed incorporated herein by reference.

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

10. Signatures

Authorized Official of Kaiser Foundation Health Plan of Washington		Authorized Official of the University of Washington	
 signature	4/10/18 date	 signature	4/12/2018 date
Name: Eric Garcia		Name: Joe Giffels	
title: National Research Compliance Officer Director, National Compliance In Research Support		Title: Associate Vice Provost for Research	

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