

Cooperative IRB Reliance Agreement

between

Benaroya Research Institute at Virginia Mason (BRI)
Federalwide Assurance (FWA) #: FWA00001994 and FWA00001995
IRB Registration #: 00000057

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

The University of Washington (UW) and Benaroya Research Institute at Virginia Mason (BRI) share a mutual concern for safeguarding the rights and welfare of human subjects involved in research activities conducted under the

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. As such, it is the responsibility of the Principal Investigator to contact his/her IRB Office to familiarize himself/herself with current cooperative review procedures and requirements.

This overarching Cooperative Agreement becomes effective upon the date of the last signature by the Institutional Officials below and will be continuous, but 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 upon request. Additional terms and responsibilities are outlined on the attachment and shall be deemed incorporated herein by reference.

The Officials signing below agree that this agreement applies to all non-exempt human subject research in which both institutions are engaged, as described above and in the attachment.

Maintain an IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;

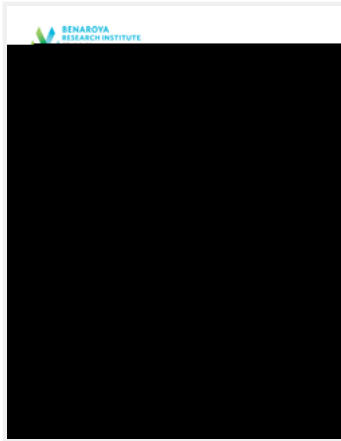
Make available the roster of IRB membership, the IRB Standard Operating Policies and Procedures (SOPs), as well as applicable IRB application files, IRB approval documents, and IRB minutes to the Relying Institution, upon its request;

Ensure all IRB members receive orientation and continuing education on topics relevant to human subjects protection;

Ensure the IRB has adequate meeting space and sufficient staff to support the IRB's review and recordkeeping duties;

Notify the Relying Institution immediately if there is ever a suspension or restriction of IRB authorization to review a study; and

Notify the Relying Institution of any changes in the IRB of record's SOPs that might affect the











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