Standard Process Description:

Relying IRB Process

Virginia Mason

Quality Check	Safety Precaution	Standard WIP
		

Purpose:
To provide a framework that allows for an external non-profit IRB to be considered as the relying IRB for a study.

Related Policies or Evidence:
IRB Polices and procedures

Roles/Work Units Who Must Adopt This Process:	Takt Time:
Research Protections staff, CRP Managers and their Designees, CRP Administrative Staff	90 Days

STEP Add Quality, Safety or WIP symbols as needed	OPERATOR List role responsible for each task	TASK DESCRIPTION	TOOLS/SUPPLIES REQUIRED -Fill in as needed to explain use of a specific tool or supply -Add photos if valuable to provide clear instructions	CYCLE TIME Add if converting to standard work
1. 	Manager or Designee	Receive communication that a new study requests our site to use their IRB of record (or the terminology may be Reviewing IRB).	Email Phone In-person	**5m**
2. 	Manager or Designee	Documents uploaded to the study management site review (SMS) located on BRI.net, under the Clinical Research Program.	SMS	**30m**
3. 	Manager or Designee	Complete Impact Statement which includes checking the box that this study requires a "Cooperative" review. Once the impact statement is sent, this will initiate a workflow email to the BRI IRB for their review and action.	Impact Statement	**15m**
4. 	IRB Admin Dir or Designee	BRI IRB utilizes Reviewing IRB Checklist to assess if the external IRB will meet the minimum requirements. Go to SMS for documents to review submitted materials. *A conversation with the Reviewing IRB, PI or Site Staff may be necessary to better understand the specifics.*	IRB Shared drive (checklist) SMS Impact Statement	**7d**

5.	IRB Admin Dir or Designee	***If the answer is yes*****,** the IRB staff will complete the Impact Statement under IRB Use Only with next steps, i.e., complete site-specific components, ok to move forward with feasibility. ***If the answer is no*****,** meaning Reviewing IRB does not meet the minimal requirements, the IRB staff will document reason in the Impact Statement and enter the email address so a workflow is generated to the Manager or Designee about concern(s) moving forward and next steps.	SMS Impact Statement	**5m**
6.	-IRB Staff -Manager or Designee	If there are any site-specific questions, the IRB staff will generate a workflow by updating the Impact Statement and filling in the appropriate email address. Once the Manager or Designee has completed their site-specific components, they'll notify the IRB staff by email.	Impact Statement Email	**7d**
7.	CR Contract Administrator	The draft Reliance Agreement is reviewed by CR Contract Administrator for language changes.	SMS	**7d**
8.	IRB Admin Dir or Designee	Once the draft IRB Reliance Agreement is complete, the local IRB sends it to the Reviewing IRB for review. Any suggested revisions may require a phone call or email follow-up.	SMS email	**7d**
9.	-IRB Admin Dir or Designee -CSA	Once the agreement is finalized, it's circulated for signature by the BRI IRB.	Adobe Sign	**7d**
10.	Manager or Designee	Feasibility review can begin prior to full execution of the Reliance Agreement, but approval will be held until the Agreement is fully executed.	SMS In-person Email	

11.	IRB Staff	IRB staff update the Impact Statement when the agreement is fully executed and email address added for Manager or Designee notification and upload the fully executed Agreement to SMS.	SMS Impact Statement	**10m**
12.	-Manager or Designee -CRP staff	Feasibility and other start-up activities are completed per their own standard process.	SMS Email	

BENAROYA RESEARCH INSTITUTE
Virginia Mason

BRI Reviewing IRB Institutional Requirements

(Quality Checklist when BRI is Relying Institution)

This form is used to document the qualifications for an external IRB to serve as the Reviewing IRB (IRB of Record) for research being conducted at Benaroya Research Institute at Virginia Mason (Relying IRB). Reference the SOP titled: *IRB SOP-012 Externa IRBs and Cooperative Research*. BRI requires review and continuing oversight be performed by the Reviewing IRB to meet all human subjects protection requirements outlined on under our 45 CFR 46, 21 CFR 50 & 56, our FWA, and other federal regulations that may apply to the research being reviewed for the Relying Institution. The Reviewing IRB shall follow written procedures for reporting its findings and actions to appropriate officials at the Relying Institution. These procedures and relevant minutes of IRB meetings shall be made available to the Relying Institution upon request. The Relying Institution retains responsibility for ensuring compliance with the Reviewing IRB's determinations and with the terms of its own FWA. The IRB for the Relying Institution maintains its authority to accept or reject the review of the Reviewing IRB.

Reviewing IRB Information:

- Legal name of the External Reviewing IRB/Organization:
- Contact information for the Institutional/Signatory Official:
  - Institutional Official Name:
  - Title:
  - Mailing Address:
  - Telephone number:
  - Email address:
- Contact information for the Human Protections Administrator:
  - Human Protections Administrator Name:
  - Title:
  - Mailing Address:
  - Telephone number:
  - Email address:
- Does the Organization have an active Federalwide Assurance (FWA) on file with the Federal Office for Human Research Protection (OHRP)? ☐ **Yes** ☐ **No**

  *Access the OHRP database and verify [**http://ohrp.cit.nih.gov/search/**]. Document to be stored in BOX folder.*

  - FWA number and expiration date (if one exists):
  - IORG number:
  - IRB name(s) and number(s):
- Does Reviewing Institution have **appropriate insurance,** third-party liability as the IRB? ☐ **Yes** ☐ **No**

- Confirm that the Reviewing Institution has one of the following:
  - ☐ HRPP has undergone accreditation through an external organization (Document to be stored in BOX folder)
    - Accrediting organization:
    - Date received:
  - ☐ HRPP is pursuing accreditation through an external organization
    - Accrediting organization:
    - Status:
  - ☐ IRB(s) has undergone or has initiated OHRP's Quality Assessment Program
    - Date completed:
    - In progress; please describe status:
  - ☐ Other approach, please specify (e.g., recent FDA audits and description of findings):

  (The Reviewing Institution must have an IRB Organization, and must have undergone or have initiated an assessment of the quality of its human research protection program (HRPP). Such assessment must have occurred or have been initiated within the past 5 years at the reviewing institution. The assessment may be accomplished by accreditation through an external organization, through OHRP's Quality Assessment Program, or other equivalent approach.)
- Has the Reviewing IRB received any **FDA warning letters** within the last year? ☐ **Yes** ☐ **No**

  If yes, provide a summary of the issue/corrective action(s) taken and/or provide documentation.

  -FDA website to verify:
https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

  -Attach warning letter (if applicable)
- Has the IRB received any **OHRP Determination letters** within the last year? ☐ **Yes** ☐ **No**

  If yes, provide a summary of the issue/corrective action(s) taken and/or provide documentation.

  -OHRP website to verify:
https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

  -Attach determination letter (if applicable)
- Does the Reviewing IRB have a process/portal in place to notify BRI IRB and the Researcher of its approvals, determinations, reportable events, suspensions, etc. ☐ **Yes** ☐ **No**

  -Summarize this process:

- In the opinion of BRI IRB, CRP, and Administrative leadership, can the Reviewing IRB above fulfill its responsibilities as outlined in the authorization agreement? ☐ **Yes** ☐ **No**

  -Comments:

Reminder for BRI IRB:
- BRI/VM's FWA will need to be updated to notify OHRP of any NEW Reviewing IRB we wish to use. ☐ **Yes**

- It is preferred to use the BRI's Authorization Agreement template to document the reliance on an External IRB.

Relying Organization Information:

- Legal name of Relying Organization: **Benaroya Research Institute at Virginia Mason (BRI)**
- Relying Organization's Federalwide Assurance (FWA) number: **FWA00001994, FWA00001995**
- **Local Context**—There are no local policies, requirements, or unique community attitudes (e.g., religious, ethical, ethnic, or economic) regarding the conduct of human research at the Relying Institution that the Reviewing IRB must account for during its review process. Note: All other study-specific local context will be provided to the Reviewing IRB as applicable.
- **State laws**-- There are no special laws (such as experimental bill of rights, age of majority, laws related to protected health information, or reporting requirements) that govern the conduct of research at the Relying Institution.
- **Relying Institution Policies/Requirements**-- There are no special Relying Institution policies or requirements related to the conduct of human research that the Reviewing IRB must account for during its review process. All policies and procedures are available in a central repository for all staff.
- The name and address of where research activities for this study will take place: **Virginia Mason Medical Center, 1100 Ninth Avenue, Seattle, WA, 98101.**
    - Facilities description:

      Established in 1920, Virginia Mason is a large, multispecialty group practice of more than 500 physicians employed by the organization, offering both primary care and a full range of specialty care. We operate an acute care hospital licensed for 336 beds, including one of the region's busiest emergency departments. We have a network of regional clinics and affiliated health care organizations that utilize our extensive research program, which spans a diverse range of diseases in partnership with Benaroya Research Institute at Virginia Mason.

      The research department includes 3 dedicated research exam rooms, two processing labs and a dedicated research pharmacy.
- **Training**-- All research personnel at our site undergo human subjects protections education using the CITI training program. All documentation is available upon request.
- **Compliance**—The Clinical Research Program (CRP) compliance group oversees the conduct of research at VM/BRI and provides the mechanism for oversight of research, quality assurance and audits at the Relying Institution.
- **Conflict of Interest (COI)**—The COI review process will be managed by the Relying Institution study team and any positive disclosures will be mitigated by the Relying Institution's legal department and submitted to the Reviewing IRB along with any tracked changes to the consent as appropriate.
- **Privacy Board**-- The Relying Institution defers to the Reviewing IRB as the "Privacy Board" for issues regarding HIPAA authorization waivers. All HIPAA-related compliance will be reviewed and managed by the relying institution and conveyed to the reviewing institution as appropriate.
- **HIPAA-covered Entity**-- Virginia Mason Hospital is considered a fully-covered Institution under HIPAA; however, BRI is considered a hybrid HIPAA Institution.

- **Signature Authority**-- The BRI official below may sign on behalf of the Relying Institution t cede oversight to the Reviewing IRB for the review and continuing oversight of its human subject research.

  Institutional Official for Relying Institution:

  Name: Lynn Rose, PhD
  Title: Chief of Scientific Administration
  Phone: 206-287-1085
  Email: lrose@benaroyaresearch.org

  Regulatory contact of Relying Institution for the Reviewing IRB:

  Name: Chris Weir, CIP
  Title: Administrative Director, Research Protections
  Address: 1201 Ninth Ave, Seattle WA 98101
  Telephone: 206-342-6916
  E-mail address: cweir@benaroyaresearch.org

  Administrative contact for Relying Institution for the Reviewing IRB:

  Name: Rainier Reyes, CIP
  Title: Regulatory Specialist
  Address: 1201 Ninth Ave, Seattle WA 98101
  Telephone: 206-342-6917
  E-mail address: irb@benaroyaresearch.org (copy on all ongoing correspondence and approvals)

- **Communication Plan**
  - All Regulatory-specific information should be communicated to the above Regulatory contact.
  - All study-specific content should be communicated directly to the Relying Institution's study team and should copy the Administrative contact above at: irb@benaroyaresearch.org.
- **IRB application** – BRI site-specific: The Relying Institution study team will be requested to be responsible to manage, prepare, and submit the site-specific applications and site-specific amendments to the Reviewing IRB that address site variations in study conduct, informed consent language, HIPAA Privacy Rule requirements, subject identification and recruitment processes (including recruitment materials), and any other applicable components of the research. All email correspondence should copy: irb@benaroyaresearch.org.
- **Ongoing Study Activity**-- Continuing Reviews, BRI specific reportable events (e.g., AEs, unanticipated problems, noncompliance, subject complaints), closures, etc. will be submitted and managed by the Relying Institution study team and submitted to the Reviewing IRB. All email correspondence should copy: irb@benaroyaresearch.org.
- **Centralized Document Storage**—The Relying Institution requires the Reviewing IRB provide universal access to the portal (or the equivalent) where pertinent study documents, agreements and IRB-approved documentation will reside for the life of the study. All email correspondence should copy irb@benaroyaresearch.org.
- **SMART IRB**—BRI has established an agreement and is willing to participate in studies that use the SMART IRB model for IRB oversight and management.

- **BRI standard consent form requirements are listed below.**

1. Document must contain **BRI logo** in the upper left corner of the header:

2. **Footer** must contain: document version number, date of last revision, and page numbers.

3. Preferred **Subject Injury Language** below (or the equivalent if confirmed by the Relying IRB):

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If you get hurt or sick as a direct result of being in this study, the sponsor will pay the costs of reasonable medical treatment directly related to adverse reactions from study drugs, devices, or study procedures (unless the injury is due to the negligence or misconduct of study doctor and/or study staff). To ask questions about this, talk to the study doctor or study staff.

The sponsor's policy does not provide payment for other expenses. You do not give up any of your legal rights by signing this form.

You may have to pay the costs of diagnosing and treating a condition or injury that you or others think is a direct result of your being in the study. This could happen if:

- The sponsor and/or the study doctor do not think the condition or injury is a direct result of your being in the study.
- You have not followed the directions the study doctor or study staff gave you about the study.

4. **HIPAA**—All consent forms must include a minimum of the core HIPAA elements listed below (unless the use of a stand-alone document is mandated by the Reviewing IRB and agreed to by the Relying IRB).
   - A description of the information to be used or disclosed
   - The names of the person(s), authorized to make the requested use or disclosure.
   - The name of the person(s)/entities to whom VM may make the requested use or disclosure.
   - An expiration date/event that relates to the individual or the purpose of the use or disclosure.
   - The individual's right to revoke the authorization in writing.

5. **CONFLICT OF INTEREST (COI):** If a positive disclosure exists, the COI will be identified by the study team at the Relying Institution and tracked into the final site-specific consent prior to submission to the Reviewing IRB.