BENAROYA RESEARCH INSTITUTE
Virginia Mason

COOPERATIVE RESEARCH STUDIES: GUIDELINES & FAQs

General Guidelines:

Cooperative research studies are collaborative projects between one or more institutions designed to avoid duplicative review when research is conducted at more than one location. This is allowable per the federal regulation per 45 CFR 46.114. *[http://www.hhs.gov/ohrp/policy/engage08.html]*

BRI IRB views studies where BRI IRB is not the IRB of record as a "Cooperative Study". The only exceptions are for contract IRBs *(i.e. WIRB, Quorum, or CIRB)* where BRI has an established agreement in place.

BRI has established overarching cooperative agreements with some local institutions *(i.e. UW, FHCRC)*. These Cooperative agreements are found at: http://www.benaroyaresearch.org/forms-library#IRB BRI may rely on any of these institutions as the IRB of record.

When BRI relies on another IRB as the IRB of record, a Cooperative agreement must be established, and an application must be submitted and approved in eProtocol (https://eprotocol.benaroyaresearch.org/) prior to the conduct of any activity at VM/BRI. The BRI Cooperative IRB application is limited to information about research activity being conducted at VM/BRI and/or with VM subjects.

➢ The following items must be true in order to submit a Cooperative Review in eProtocol for approval:

- There needs to be a VM/BRI investigator willing and interested in supporting/be responsible for the research being conducted at VM/BRI *(i.e. a local VM PI)*.
- The activity being conducted at VM/BRI must be considered "engaged" activity required IRB oversight under the regulations.
- BRI must have or establish a Cooperative IRB Agreement with the IRB of record prior to reviewing the study locally.
- Initial IRB approval must have already occurred at the IRB of record, and BRI must have been added/approved by the IRB of record as a site they have oversite.

➢ The items below must be addressed **before completing** a Cooperative submission in eProtocol:

- BRI IRB will need documentation from the IRB of record citing VM/BRI is "engaged" in research, and has been approved as a site for the conduct of research described in the submission.
- VM/BRI local PI name and phone number needs to be added to the front page of the consent form(s), if there will be any consenting of subjects at VM/BRI. All other VM/BRI site specific consent language/information should also be included as negotiate with the IRB of record and applicable to the study in question.
- VM/BRI has an "**opt-in**" in regard to recruitment strategies for VM patients. VM/BRI study participants may be notified about a study, either in-person or by mail, with the option to contact researchers if they want to participate or want more information. Unless approved in advance, no follow-up phone calls, mailings, etc… may occur if subject choose not to "**opt-in**".

- If any outside personnel will be coming onto VM/BRI campus to directly interact with patients and/or their records, all fit-for-duty requirements must be met before research occurs.

➢ The items below need to be considered **when completing** a Cooperative submission in eProtocol:

- A detailed description of the specific activities and/or procedures that will take place at VM/BRI or with VM/BRI subjects must be described.
- The names and exact duties of outside personnel coming onto campus, either directly interacting with VM/BRI patients, or have access to their PHI must be disclosed.
- The number of VM/BRI subjects expected to be accrued at the end of the study from VM/BRI.
- If VM/BRI participants will be consented at locally, VM/BRI policy does not generally allow the use of gift cards for participant payments. If participants will be monetarily compensated, checks should be used unless a prior exemption was made.
- All study documents submitted per the application must have already been approved by the IRB of record. BRI IRB will not stamp approve any documents since we are not acting as the IRB of record.

For further assistance and clarifications on any of the above items, please contact the IRB for clarification. IRB Contacts