Benaroya Research Institute
Virginia Mason

COVID-19 CRP/IRB memo and FAQs to researchers

March 13, 2020

Dear Clinical Researchers,

In recent days there have been many questions regarding recent events surrounding COVID-19, and how researchers should consider these issues related to the conduct of their research. We are writing to provide guidance regarding BRI and VM clinical trials and other studies involving human research participants as we consider preparedness and response to COVID-19. Protecting the safety and welfare of our volunteer research participants is our top priority. Additionally, we must maintain compliance with human research requirements to support both the protection of participants and the scientific integrity of our protocols. Lastly, we are committed to protecting the safety and welfare of our research staff. With these goals foremost in mind, we have adopted the following checklist to assist in planning for disruption resulting from COVID-19:

- Ensure VM procedures to screen research participants have been followed;
- If possible incorporate telephone screening in lieu of on-site visits by patients or external visitors (e.g., sponsor monitors);
- Ensure you have up-to-date contact information for research staff; and develop a back-up plan in case of absences;
- Enable staff to remote in whenever possible; identify data files that can be put into BOX for central access;
- If possible, pause enrollment and delay initiation of new studies; for example, BRI investigators have paused enrollment in non-interventional studies to avoid bringing healthy individuals into the hospital;
- Consider an alternative to the clinical research center (CRC) in the event it becomes unavailable for research;
- Assess whether the study puts research personnel at unacceptable risk (e.g., in ICU, acute care, or ER settings);
- Check with the IRB of record to report any changes or additional requirements to protocols; and finally
- If continuation of a protocol becomes impracticable for any reason, **always do what is best for the patient**.

Please contact us if you have any questions about your research program. BRI is prepared to assist PIs in contacting Sponsors and external IRBs about current conditions if that is helpful to you in delaying enrollment or stopping a study. Also, please be aware that you always have the option to modify a protocol “without” IRB approval in order to mitigate new risks to subjects. Please review the attached FAQ if you have questions about IRB requirements or patient safety monitoring during this complicated time.

Thank you for all that you are doing to advance our mission and to keep our participants safe and research staff safe.

Neil Hanson, MD Chair BRI IRB

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Frequently-Asked Questions for Researchers

What do I do if a participants cannot come to your study location?

Some study participants may not be able to come to hospitals, clinics, or other study locations because of infection, self-isolation, travel restrictions, facilities restrictions, or being in a COVID-19 high risk group. Study teams should plan for this possibility and submit an Amendment for any alternatives to mitigate risks to study participants. See below FAQ for what requires an Amendment to mitigate immediate hazards to subjects.

What changes require submitting an Amendment or Report to the IRB?

Amendments or notifications are NOT REQUIRED if you are halting, rescheduling, or delaying study enrollment UNLESS those actions are at the request of the funding agency, study sponsor, or data & safety monitoring group.

Amendments are REQUIRED and IRB approval must be obtained before you change study procedures (including consenting processes) for new or existing participants. Example: You want to administer new and follow-up study questionnaires over the phone instead of in-person, or you want to do an in-home visit for assessment of surgical recovery instead of having participants come into the clinic.

There are some limited exceptions to the requirement for an Amendment: For IRB-approved applications that do not specify whether a procedure is remote versus in-person, you do not need to submit an Amendment.

Check with the IRB@benaroyaresearch.org if you have questions. Include the following information:

- Potential impact on subject safety and protections
- Potential impact on scientific integrity and/or benefits of the study
- Plan for how existing subjects will be notified (if their participation will be affected by the changes)
- Number of existing participants affected by the proposed change (if any)
- Date of proposed change implementation

Will the BRI IRB Remain Fully Operational?

The Research Protection Department is fully functional and operating at our standard capacity. All IRB staff are able to work from home, and will be available on-site as needed to for specific needs (e.g. running skype committee meetings) All IRB email addresses continue to be monitored with the same or greater frequency. Contact Chris Weir directly at cweir@BenaroyaResearch.org or (206-661-1960) if you have an emergency need. https://www.benaroyaresearch.org/our-research/research-protections/contact-rpd

Participant Safety Monitoring

Some clinical studies require in-person study visits in order to conduct safety monitoring of the participants. For example, participants in a drug treatment study may need to have regular examinations, interviews, or laboratory tests for specific possible side effects.

Researchers should plan for alternatives to in-person monitoring visits, if possible. For example, interviews could be conducted by phone or email. Visits to participants' homes might be an alternative location for examinations or specimen collection. Or, perhaps the schedule of monitoring could be safely modified or delayed.

These modifications to safety monitoring procedures should be approved in advance by the IRB, except when necessary to eliminate apparent hazards to a participant and there is not sufficient time to obtain IRB approval. Consult with the IRB@benaroyaresearch.org if you have questions. If you do need to change an approved monitoring procedure to eliminate immediate possible danger, please report it to BRI IRB as soon as possible after you have mitigated the hazard with as much detail as possible.

Modifying Study Procedures to Occur Remotely

Many studies are modifying their procedures, to replace in-person study visits with “remote” options for questionnaires, surveys, check-ins, screening, and consenting. Remember these changes must be approved in advance by the IRB as a Modification to the study, unless they are necessary to eliminate immediate apparent hazards to participants. If you have any questions about whether a remote option is possible or approvable (especially for consent), contact you’re the IRB. BRI IRB will prioritize these modifications when notified.

Single Patient Emergency Use

The procedure for Single Patient Emergency Use of an experimental drug or device remains the same during the COVID-19 situation. Contact the Clinical Research Program directly at CRP@benaroyaresearch.org or IRB@benaroyaresearch.org.

What about Coordination of COVID-19 Research?

If you have any plans to conduct clinically-relevant COVID-19 research that may in any way interface with VM/BRI patients/persons under investigation/providers or their information, please contact the Clinical Research Program directly at CRP@benaroyaresearch.org or IRB@benaroyaresearch.org.

COVID-19-Related Activities That May Not Be Research

BRI IRB is ready to assist researchers and clinical care providers who are planning COVID-19-related activities that may intersect or overlap with public health authority activities and/or FDA emergency authorizations for diagnostics. In some cases, IRB approval will not be required. Contact Chris Weir at cweir@BenaroyaResearch.org or (206-661-1960) if you have an emergency need. https://www.benaroyaresearch.org/our-research/research-protections/contact-rpd