BENAROYA RESEARCH INSTITUTE Virginia Mason	SOP No.	CRPA SOP-045
	Revision No.	01
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RESPONSIBLE DEPARTMENT: Clinical Research Program Administration (CRPA)		
TITLE: Clinical Research During a Pandemic		
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APPROVAL SIGNATURES	
	Signature/Date
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PURPOSE

This document provides guidelines for clinical research during a pandemic or other urgent situation in which immediate changes in the conduct of study procedures may be necessary to protect the safety of research staff and participants and to maintain study integrity. Any changes would be in effect during the urgent situation, with the understanding that re-assessment will occur to reflect an evolving situation

SCOPE

Applies to all workforce members involved in the implementation and coordination of clinical research at Benaroya Research Institute and Virginia Mason.

DEFINITIONS

The following definitions apply to terms used in this policy:

Interventional Studies: Studies that involve the administration or use of a medical product in the treatment of the individual.

Non-Interventional Studies: A variety of studies that do not involve administration of or use of a medical product for treatment, (e.g., registries, repositories, or observational).

ROLES AND RESPONSIBILITIES

Institution: Benaroya Research Institute (BRI) at Virginia Mason and/or Virginia Mason Medical Center (VM)

Must/Will: Indicates that staff must comply with the action(s) described or defined.

Should/May: Indicates that staff may use his/her own judgment regarding compliance with the actions described of defined.

Workforce Members: Employees and non-employees which may include volunteers, visiting scientists, students, contractors, agency employees, and VM Principal Investigators conducting research under the auspices of BRI.

PROCEDURE

1. Use of Guidelines

Federal, state, local, and institutional guidelines will be used to determine what changes, if any, must be made to clinical research at BRI and Virginia Mason. These guidelines may include but are not limited to: the IRB of record, the study sponsor, Department(s) of Health, Centers for Disease Control, Food and Drug Administration, National Institutes of Health. Research directly related to the pandemic or other urgent situation may be exempt from these guidelines.

2. Changes to Study Procedures for both Non-Interventional and Interventional Studies

2.1. The site will follow sponsor and institutional directives regarding new study enrollment, continued subject participation and/or treatment.

2.2. For studies in which the sponsor is allowing new enrollment and/or continued study procedures for previously enrolled subjects, a risk/benefit analysis at the study and subject levels will be conducted to guide study procedures.

2.3. Consider modification of study procedures (including consenting) to protect staff and participants. For example, phone, virtual, email assessments should replace in person visits. Consider shipment of study drugs directly to subjects when possible.

2.4. If agreed to, study procedures may be conducted by clinical staff during a clinical visit to reduce risk to study staff.

2.5. Depending on institutional and other guidelines outlined above, collection of biological samples, e.g., blood, tissue, saliva, etc., by research staff may be transiently suspended. Periodic re-evaluation of a suspension should occur, as the risk-benefit analysis changes.

2.6. Consult with the study sponsor and IRB of record to guide approval and documentation of study procedure changes.

2.7. Document the decision-making process for each study and each subject, whether to continue, modify, or halt participation. The PI’s involvement should be clearly documented in anticipation of sponsor and regulatory agency reviews.

3. Study Monitoring/Oversight by Sponsor

On-site monitor visits should be cancelled or postponed. Where possible, remote monitoring should be scheduled. Most contracts allow for this possibility, but some may require a revision or amendment.

4. Communications

BRI and CRPA will communicate relevant information to study sponsors, IRBs of record, and study teams. Study teams will communicate relevant information to their study subjects. Other communications as necessary can and should occur.

TRAINING REQUIREMENTS

The training policy outlined in section 2.6 of CRPA-SOP-01 will be followed. The procedure will be posted on BRINet Policy and SOP Center.

REFERENCES

- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic (March 18, 2020)
- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic (March 27, 2020)
- NOT-OD-20-087 Guidance for NIH-Funded Clinical Trials and Human Subjects Studies Affected by COVID-19 (March 16, 2010)
- Risk/Benefit Tool
- Guide to Risk / Benefit Analysis Table

ATTACHMENTS

- NONE

NEXT REVIEW DATE: **4/1/2023**

This procedure will remain in effect until the next version is reviewed and approved.

REVISION HISTORY

Revision Level	Effective Date	Description of Changes
00	3/25/2020	Initial Version of Document
01	4/1/2020	Removed procedural specific items and simplified tool