Benaroya Research Institute
Virginia Mason

Risk/Benefit Tool

This tool may be helpful to guide enrollment of new subjects and management of currently enrolled subjects.

A. Considerations for Enrollment of New Subjects

1.	☐ Yes	☐ No	Is the study sponsor allowing continued enrollment? If Yes, complete the rest of this section. If no, skip to section B.
2.	☐ Yes*	☐ No	The intervention may provide direct health benefit, or there is serious risk to subjects if study interventions are stopped
3.	☐ Yes*	☐ No	Does the potential benefit justify the potential risk of ongoing participation??

B. Considerations for Continued Treatment of Current Subjects

1.	☐ Yes	☐ No	Is the study sponsor allowing the continuation of treatment in current study subjects?
2.	☐ Yes*	☐ No	The intervention may provide direct health benefit, or there is serious risk to subjects if study interventions are stopped
3.	☐ Yes*	☐ No	Does the potential study treatment justify the potential risk of ongoing participation?

C. Considerations for All Subjects: Procedure Modifications

- Modify visits and data collection to limit face to face contact (i.e. email, phone, virtual visits)
- Limit in person visits, prioritizing visits to ensure participant safety (i.e. safety labs, EKG, physical exam)
- Consider shipment of study drugs and other study materials directly to the participant
- Consult with the study sponsor and IRB of record when making changes to study procedures
- Document everything

Investigator Signature:_____ Date:_____