Additional COVID-19 Guidance from UW Hospital and Clinics

Hello Research Community,

As you may be aware, the Office of the Vice Chancellor of Research and Graduate Education required a temporary hiatus from all in-person interactions on research studies except those that are related to therapeutics or are deemed critical to participants’ safety and well-being until at least April 10, 2020.

Additional guidance about specifics related to clinical research are outlined below.

General Human Subjects Research Guidance

- At this time we are asking research teams to limit in-person contact to only those activities related to treatment of patients (for example Oncology treatment trials) and activities that are critical to the health and safety of the participant.

- In-person enrollment activities for non-treatment trials should be temporarily suspended. This would include in-person enrollments for observational studies, biomarker collections outside of treatment protocols, survey studies etc.. This temporary suspension of enrollment activities will not require an IRB modification but may require us to notify sponsors/funders.

- For follow-up visits or other activities for patients already enrolled in research, please consider using alternative methods (phone, telehealth etc.) or delaying these visits when possible. Please remember that these changes to established protocols require IRB approval and possibly exemption requests from sponsors.

- Many industry sponsors are international and are having difficulty getting supplies and lab processing for FDA-regulated studies in the US. If you have patients on treatment studies and sponsors reach out to you for possible alternatives for lab processing etc., please reach out so we may assist you.

Monitoring, Site Selection, Site Initiation Visits

In consideration of CDC guidance related to COVID-19, and in an effort to slow its spread and protect our community, our caregivers, and our patients, UW Health is cancelling all community events, including meetings with vendors, consultants and external guests at our facilities until further notice. In compliance with this action, the UW Health and SMPH are cancelling all existing in person monitoring visits, site selection visits and site initiation visits from any agent external to the UW System. Virtual meetings are highly recommended for purposes of performing site initiation visits and site selection visits, however remote monitoring is not fully possible at this time. We can work with sponsors for alternative monitoring if it is deemed critical to the research study.

These are challenging times and we are here to provide you with assistance to ensure your study remains in compliance and ready to open again.