PARTNERS HEALTHCARE | FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

March 18, 2020

Dear Industry Sponsors:

Partners HealthCare and our affiliated hospitals are committed to the integrity and continuity of our research projects. We are first and foremost committed to the health and safety of our patients, research subjects, and our employees. The current situation related to the COVID-19 pandemic is rapidly evolving. We support social distancing for individual and public health reasons, thus many research study staff have been instructed to work remotely. Partners research leadership along with the Partners IRB has developed a policy on the safe conduct of human subject research, including new and ongoing clinical trials. The following apply to any research conducted at a Partners HealthCare site regardless of the IRB that reviews the research:

- Therapeutic research may continue for currently enrolled subjects if investigational product, other necessary supplies, and appropriate staffing can be maintained. Recruitment of new subjects is restricted to those studies that have the potential to be lifesaving or is disease-altering AND there are no appropriate alternative clinical treatments for the patient OR all study visits and recruitment activities can be conducted completely remotely.
    - Research teams have been instructed to prepare should subjects need to be transitioned to clinical care.
    - Sponsors should confirm with their Partners HealthCare site the availability of investigational product and identify any barriers to study continuity.
- All non-therapeutic research is suspended except for recruitment and study visits that can happen completely remotely.
- Review of new research by the Partners IRB is suspended. Requests to rely on a commercial or other outside IRB will be considered on a case-by-case basis and only for those studies that meet the requirements for research above. Please be sure to check with any outside IRB to see if they have any restrictions for review of protocols in place.
- Any study initiation visits for research already approved and in the process of opening must occur remotely and all sponsor monitoring may only occur remotely.
- These restrictions do not apply to COVID-19 related research.

We understand there maybe circumstances that require changes to study protocols and timelines. The Partners IRB has provided guidance to our research teams with regard to what changes require amendments or other notices to the IRB and have specifically clarified that some changes may be made to address immediate hazards without prior IRB approval. Please be in touch with the PI/study team you have been working with to discuss specific study related issues.

The Clinical Trials Office at Partners HealthCare is currently operating remotely, but at full staff. We remain committed to the high-quality support you have come to expect from us and the Partners clinical research community. The office will prioritize COVID-19 related projects and modifications to ongoing projects but will also continue to support new projects.

Please feel free to contact us with any specific questions related to PHS guidance, office operations, or specific contracts and budgets after conferring with the study team.

Sincerely,

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