Boston Children's Hospital
Until every child is well

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

Monday, March 16, 2020

Dear Research Colleagues:

This document is a continuation and update of the guidelines we communicated to you last week related to clinical research activities at BCH. This specific communication is focused on Clinical Research Activities. A separate communication will be distributed for Basic/Translational Researchers.

It was announced today that Boston Children's Hospital will begin cancelling non-urgent and non-emergent surgeries, procedures, admissions, clinic and research visits at all of our locations. Staff and employees were directed to start immediately on this work with the plan that by Wednesday, March 18, all procedures and processes will be in place. The institution will evaluate this decision every 2 weeks.

BCH will continue to care for Urgent, and Emergent patients during this critical time. Investigators will need to determine which encounters can be cancelled or completed via Telehealth and be responsible for communicating any changes to study subjects and families. Please provide clear directions for how to contact you as the investigator or a member of your study team should they have any questions. The use of virtual visits and/or phone check-ins when possible is encouraged—you can find more information as well as how to manage these changes with the IRB here. Zoom is a HIPAA compliant option.

The current situation with COVID-19 is being monitored closely, and the institution cannot currently commit to when our patients/study subjects can be rescheduled, for non-urgent and non-emergent study visits. While current guidelines are for the next 2 weeks and the institution will be reviewing recommendations constantly, **it is recommended that you not reschedule any patients/study subjects for at least 6 weeks.**

Any ongoing clinical research activities may continue only if they are commensurate with the BCH policy regarding staffing and remote work requirements and clinical care guidelines to ensure to the extent possible the safety of our staff and investigators. These activities cannot violate current BCH guidelines for research staffing and clinical activities in general.

These requirements apply regardless of the IRB that oversees the ethical and regulatory conduct of these studies (including other institutional IRBs and commercial IRBs.) Researchers should follow the policies and procedures of the IRB that oversees the ethical and regulatory requirements of their research regarding how to report changes or obtain approval for changes that are needed to comply with the requirements below.

1. **Interventional Research** (if there is potential for direct benefit to subjects through therapeutic intervention)
    a. Recruitment of new subjects may continue ONLY if the following conditions are met
        i. Research has the potential to be lifesaving or disease-altering and there are no appropriate alternative clinical treatments for the patient.
        ii. You can ensure both adequate investigational drug supplies and staffing, including the PI (in accordance with BCH general clinical care policies in place).
        iii. The PI must confirm there will be a sufficient number of trained study staff to support

the conduct of the study considering staff workloads and any requirement to work remotely or to cover other hospital needs.

iv. Any COVID-19 research must be reviewed and approved by CSO and EVP for Health Affairs.

b. Active therapeutic studies may continue for subjects already enrolled in the study under the following conditions:

i. The PI is available to maintain appropriate oversight including from a remote location should that be required and there will be a sufficient number of trained study staff to support the conduct of the study considering staff workloads and any requirement to work remotely or to cover other hospital needs.

ii. The PI can confirm there are adequate supplies available including the treatment itself and all additional supplies to administer and monitor the study treatment and study-specific procedures to maintain the safety of subjects can be continued (labs, exams, etc.).

c. Research that includes placebo arms and continues to require visits to the hospital (for example infusions) that cannot be replaced by remote interactions/ assessments must be discussed on an individual basis with the IRB.

2. **Non-interventional Research** (no direct benefit to subjects through therapeutic intervention

a. Recruitment of new subjects and ongoing conduct may continue only if all of the following conditions are met:

i. Recruitment occurs completely remotely (e.g. by phone, videoconference).

ii. The study activities are currently approved to be conducted remotely or may easily be transitioned to remote activities (e.g. an internet-based survey study.

iii. In-person interactions with potential subjects are not required.

iv. The PI is available to maintain appropriate oversight from a remote location.

v. There will be a sufficient number of trained study staff to support the conduct of the study remotely and considering staff workloads and any requirement to work remotely or to cover other hospital needs.

We recognize that the determination as to which category many protocols fall may be complex. **You are urged to work with your colleagues in your Departments and Divisions to review ongoing activities to clarify and obtain a consensus if needed as to which protocol meets the criteria for continued activities.**

Please note: The IRB staff is continuing to work remotely and is fully operational, but the IRB will be prioritizing COVID-19 clinical research efforts. This includes new protocols and amendments to existing protocols. Expanded access and emergency use of drugs and devices will also take priority.

Continuing reviews for all protocols even if temporarily paused need to continue to be submitted to remain in compliance with the regulations.

New protocol submissions will be accepted but it is possible protocols not related to COVID may be triaged with the expectation that the turn-around times may be markedly extended. The IRB staff will communicate with you regarding these matters. Please note even when approvals are granted for new research activities you must follow the above guidelines and you may not be able to begin the research until some of these restrictions are lifted.

Any studies that were in the process of review with the IRB at the time of this notice will continue through the review process only as time allows considering other priorities. Studies that are approved are still required to follow the requirements above with regard to recruitment limitations and conduct of research.

Sincerely,

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