Boston Children's Hospital
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HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

Tuesday, March 24, 2020

Dear BCH community:

This is an update on our previous guidance for the clinical research community COVID-19 BCH Clinical Research Advisory 3.16.20 (click here for the complete Advisory) and specifically addresses clinical research related to the coronavirus and individuals infected (or suspected to be infected) with this virus. First, we want to thank you for your continued dedication and efforts related to keeping our research moving forward even under these extraordinary conditions. This memo has **three important new items**. Please read the entire document.

We are experiencing a rapid increase in the number of research protocols seeking samples from patients who may have coronavirus (or been exposed to individuals with documented infection) and we anticipate even more as time goes on. This includes protocols originating both internal to BCH and many developed outside BCH in which our investigators are being asked to provide samples to a larger network of institutions.

We have thus been developing a plan to manage the implementation of the large number of protocols that are moving through the IRB process.

First, we will implement a Coronavirus Research Oversight Committee (CROC) that will be tasked with providing overall institutional guidance for this clinical research over the next 3 months. These guidelines are for protocols in which direct interaction with patients is required. Protocols that can be implemented entirely remotely, such as patient registries, do not fall under these guidelines.

Guiding principles of this would include:

i. **The care of the patient is the highest priority. Negative impact on patient care and patient flow should be minimized, including prioritization of PPE equipment as needed for essential clinical care.**
ii. ***The safety of personnel is essential; minimal numbers of qualified staff* (see below) that are well trained in PPE should interact directly with study subjects.***
iii. Research in this area is a responsibility of BCH as a leading pediatric research institution and we will make all efforts possible to contribute to new knowledge on the biology and potential new vaccines and treatments for this disease.
iv. Ultimately, implementation after IRB approval will be tailored as needed to each area and will be the responsibility of the faculty lead in collaboration with the CSO and IRB Chairs and with the PIs of each protocol.
v. The experience of many faculty and nursing staff and others is recognized as a resource; the faculty lead can judge the need and institute the assembly of a faculty/investigator/nursing workforce for each sector to help guide decisions and implementation as needed and warranted.

The basic plan is outlined of the plan we are instituting is listed below:

A. The hospital will be divided into three sectors for the purpose of managing clinical research on coronavirus patients in the next months:
    a. ED (future would include ambulatory)

    b. ICUs, including ORs
    c. In-patient

B. Each sector would have a faculty lead and be supported to the extent *needed* and possible by ICCTR. Laboratory Medicine would be involved at the level of potential use of discarded clinical samples and IRB and IBC will be appropriately involved. Areas/lead faculty are listed below:

    a. ED: Mark Neuman
    b. ICU and ORs: Adrienne Randolph
    c. In-patient: Benji Raby
    d. ICCTR support: Andy Place (Chief Medical Officer) and Cindy Williams (nursing)

C. Laboratory Medicine: Orah Platt and Nira Pollock
D. The faculty lead along with the CROC will be tasked with integrating multiple consenting requests (and prioritizing if needed) and ensuring specimen acquisition and distribution in an efficient and fair fashion.
E. The ICCTR will provide logistic support, as needed and as possible given staffing constraints. This may include the deployment of CRNs for consenting and specimen acquisition and retrieval as requested.
F. There will be regularly scheduled meetings of the core group overseeing this process led by the CSO and the process will be modified as evolving events dictate.

Second, in addition, for this acute crisis, we will **replace departmental scientific review of COVID-19 related studies with a centralized scientific review committee (SRC)** which (as we have done in the past for gene therapy and specific areas). All protocols dealing with coronavirus patients or suspected patients will use this mechanism to allow for a more robust and uniform review of the protocols and prioritization and to assist the IRB with scientific expertise. The SRC membership will be broadly based with representatives from across a variety of departments/divisions and include appropriate scientific and clinical trial expertise. This SRC will meet on an *ad hoc* basis for the next 3 months to ensure rapid turnaround on the protocol reviews. This SRC process will be time-limited to the next 3 months unless renewed after that by the appropriate hospital executive committees. As a reminder, research on this virus is done **under BL-2 conditions with enhanced procedures**[1].

Third, during this acute crisis, to optimize infection control we will be **restricting direct in-person access to families/patients for the purpose of clinical research related to COVID-19 to licensed providers only**[2].

This will hopefully reduce any use of PPE to a minimum and provide additional protection to our staff. We realize this will be difficult for some research teams but we think it is justified for both reasons noted above.

We recognize that the situation is fluid and that any additional changes in our normal processes add more strain and even anxiety to all of our efforts. Thus, we are instituting these measures only after careful considerations concerning the principles outlined above.

[1] All laboratory and animal research involving SARS-CoV-2 and COVID-19 human specimens (suspected or confirmed) must be approved by the IBC. The IBC submission and review process has not changed. Our IBC is following both the CDC and BPHC guidelines for this research. As of right now, human specimens from patients are recommended at BSL-2 with enhanced work practices and procedures (e.g. all work is conducted in the Biosafety Cabinet). Isolating or culturing the virus requires BSL-3 containment and a permit from the City of Boston.

[2]Licensed healthcare professionals and caregivers are those who are licensed to practice clinical care.

Licensed healthcare professionals include physicians, nurses, nurse practitioners, physician assistants, and pharmacists. Additional categories of licensed healthcare personnel are social workers, dentists, respiratory therapists, psychologists, physical and occupational therapists and assistants, speech pathologists and diagnostic technicians. **In the setting of clinical research amidst the COVID-19 outbreak** licensed personnel supporting clinical research principally refers to physicians and research nurses, nurse practitioners, and physician assistants. There may be studies where respiratory therapists are engaged in clinical research. Emphasis should be placed where possible on engaging experienced and trained licensed research nurses and staff over clinical nurses or clinical nurse practitioners. There may be some examples of non-licensed personnel such as phlebotomists collecting blood samples engaged in patient-facing COVID-19 research study activities.

Non-licensed clinical research professionals such as study coordinators, research assistants, and research specialists will support non- patient-facing study activities such as IRB submissions, data collection, data entry, drafting study documents, etc. and can be particularly useful remotely.

Sincerely,

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