

**Institutional Review Board (IRB)**  
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[www.bostonchildrens.org/research/irb](http://www.bostonchildrens.org/research/irb)

**Principal Investigator** Florence Bourgeois, MD  
**Protocol Number** IRB-P00035935  
**Protocol Title** Establishment of a repository for international pediatric data on COVID-19  
**Date:** July 22, 2020

### **NOTICE OF EXPEDITED APPROVAL**

<b><u>IRB Approval Date:</u></b>	<b><u>7/21/2020</u></b>
<b><u>IRB Activation/Release Date:</u></b>	<b><u>7/22/2020</u></b>
<b><u>IRB Expiration Date:</u></b>	<b><u>7/20/2021</u></b>

Please Note: The initiation or continuation of clinical research activities must follow the Boston Children's Hospital (BCH) advisories or policies. The IRB is continuing to review protocols; **however BCH is currently restricting the conduct of clinical research in response to the COVID-19 crisis.** Details of these restrictions and an IRB Q&A document are available at <http://www.childrenshospital.org/research/IRB> and both will be updated as changes are implemented. Please contact the IRB Office with any questions you may have.

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The Institutional Review Board has approved the above referenced protocol through expedited review procedures. We are now able to release this approval to you since you have adequately responded to the IRB's questions and concerns. It was determined this protocol will require continuing review in the future.

Risks were determined to be minimal with no potential for direct benefit.

The IRB has determined that you have met the waiver of informed consent regulatory requirements.

The occurrence of unanticipated problems should promptly be reported to this office. Any revisions, amendments, or changes to the protocol require prior IRB approval. The IRB has asked this office to notify investigators that clinical investigation protocol files are subject to audits at some future time.

Sincerely,



Theresa Williams, IRB Administrator  
For the Institutional Review Board

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