



PREDICTING SEVERE PNEUMONIA IN THE EMERGENCY DEPARTMENT

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Dear PERN pneumonia collaborators,

We hope that you and your loved ones are staying healthy and safe during these incredibly challenging times. We wanted to continue to provide this newsletter as an update on our study progress with PERN pneumonia. While we know that all of our colleagues are working extra hard through this pandemic, we also know that research teams are wanting to continue their important work. As such, we've made modifications to the PERN pneumonia study procedures to allow for enrollment by telephone, eliminating the need for enrollment to occur in the ED. Our research coordinators have started this "no contact" enrollment with much success.

We sent an email on 11Apr2020 with information about no contact procedures and the PERN-COVID-19 arm of the PERN study. We included the updated PERN protocol (v1.21) to allow for "no contact" enrollment and an amendment to allow for PERN-COVID-19 enrollment for sites that are participating in this study, in addition to updated CRFs for paper enrollment, as well as CCHMC's IRB approval letter for this amendment. Please review those documents and submit these materials to your ethics committee as soon as possible.

We understand the difficulties many of our colleagues are facing and hope that the CCHMC IRB waiver of documentation of consent and HIPAA authorization will allow for us to continue making positive changes in child health through discovery in these unprecedented times. For PERN pneumonia, we are still requesting KAPPA inter-rater assessments to be conducted on 5-10% of PERN enrollments—instead of an in-person exam, the kappa form will occur by a 2nd chart reviewer independently reviewing the medical record and completing the KAPPA form. For missed eligible patients, a patient is considered a missed eligible if they were eligible to be contacted by telephone but were unable to be contacted or enrolled.

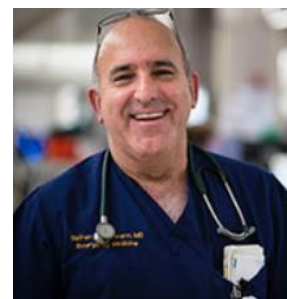
As a reminder, all sites should continue to be in contact through PERN@cchmc.org for any questions specific to the PERN pneumonia study. Any operational questions specific to PERN-COVID-19 should be sent to pern.covid19@albertahealthservices.ca. If your question is related to both studies, please email both.

Yours in collaboration and appreciation,

Todd Florin & Nate Kuppermann



Todd Florin, MD, MSCE (PI)



Nathan Kuppermann, MD, MPH (Co-PI)



Predicting Severe Pneumonia in the Emergency Department: A Global Study of the Pediatric Emergency Research Networks (PERN)

Top Enrolling Sites as of April 30, 2020

Enrollment
Total: 2156

(as of 04/30/20)

Site	Enrolled Total
Hospital Nacional de Ninos "Dr. Carlos Saenz Herrera"	143
Cruces University Hospital	137
Childrens National Medical Center	116
PRONTO SOCCORSO PEDIATRICO - A.S.S.T. Spedali Civili di Brescia	91
Washington U / St. Louis Childrens Hospital	79
Wayne State University (Childrens Hospital of Michigan)	77
Perth Childrens Hospital (previously Princess Margaret Hospital)	57
Columbia - Morgan Stanley Childrens Hospital of NY-Presbyterian	56
Complejo Hospitalario Universitario Insular - Materno Infantil	54
Childrens Hospital Los Angeles	49
Policlinico Umberto I	49

SITE REPORT CARDS!

We have sent enrolling site PIs a report card with insights into study recruitment, query resolution, kappa participation, and subject follow-ups. Please reach out to us with any questions, suggestions, or comments at PERN@cchmc.org.

The report card includes the following site-specific metrics:

- Number of subjects enrolled
- Comparison with other sites in their network
- Number of follow-up calls completed
- Number of queries still open
- Number of missed eligibles

Study-Wide Query Metrics (Compared to Last Month)

of Open Queries:

152
(+0)



of Resolved Queries:

151
(+0)



Average Time for Query Resolution:

46 days
(+1)



IRB Renewals and Protocol v1.21

We have recently sent out a new copy of the protocol to all participating sites, adding a PERN-COVID study arm. Please refer to the email that was sent on **11Apr2020** for details, and the attached protocol and PERN-COVID specific CRFs and supplemental documents.

If your site is using a Local IRB, please follow your local procedures regarding protocol amendments.

IRB Renewals

We have come across some sites that might have reached their IRB expiration dates. Emails have been sent out to confirm continued site participation and warn of potential IRB expiration.

If your site has an expired IRB approval, please cease all study related activity and reach out to PERN@cchmc.org. Otherwise, please be mindful as we are reaching the 12 months of participation for many sites.



PERN PEDIATRIC EMERGENCY RESEARCH NETWORKS



Predicting Severe Pneumonia in the Emergency Department: A Global Study of the Pediatric Emergency Research Networks (PERN)

Study Reminders!

- ❖ If a participant is **enrolled** and the PI later determines the subject is **ineligible**, please let the PERN Pneumonia study team know at PERN@cchmc.org and update the *Screening and Demographics* form if needed.
- ❖ If your site is using **paper forms**, please be sure to input the information into REDCap **monthly**.

Study SharePoint Site

An important source of study information is the study SharePoint site (<http://portal.cchmc.org/sites/PERNpna>) – you should have received log-in information for this site where all study documents, including PERN-COVID related documents, are stored for your reference. Please feel free to reach out to us at PERN@cchmc.org for any study related questions that you cannot find in the newsletter or the study SharePoint site. Any other PERN-COVID questions should be sent to pern.covid19@albertahealthservices.ca

FREQUENTLY ASKED QUESTION (FAQ) OF THE MONTH



1. Can you delete subjects that were erroneously entered into the database after finding later that they were, in fact, not meeting eligibility criteria?
2. If a subject is eligible to both PERN and PERN-COVID, which database do I add them to?
3. If my IRB approval letter is expired for PERN, can I still participate in PERN-COVID?



1. No, we cannot delete subject data, however, please update the Screening and Demographics form to indicate the subject as ineligible and they will be excluded from study analysis.
2. If a participant is eligible for both studies, they should be entered in both study databases. If paper copies are being used, this information should be uploaded monthly.
3. No, sites expired in PERN will not be able to participate in PERN-COVID. If there is a regulatory issue, please contact PERN@cchmc.org.

Guidance for completing Screening & Eligibility Form and Missed Eligible Form

Scenario	Forms to Complete
Patient approached, eligible & consents to participate	Arm 1: ALL FORMS
Patient approached, eligible & does not consent	Arm 1: Screening & Demographics form ONLY & Arm 2: Missed Eligible
Patient approached, has pneumonia, but meets one or more exclusion criteria	Arm 1: Screening & Demographics form ONLY
Patient approached, does not have pneumonia	No Forms
Patient not approached and appears eligible by record review	Arm 2: Missed Eligible



PERN PEDIATRIC EMERGENCY RESEARCH NETWORKS

