University Hospitals
Cleveland Medical Center

IRB ADMINISTRATION OFFICE
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IRB APPROVAL NOTIFICATION

****Approval by the IRB does NOT mean that you have permission to start your study. Prior to starting your study, you may be required to obtain (1) a coverage analysis for studies that involve patient care, regardless of source of funding, and/or (2) a contract with the Sponsor of your study or an agreement with any third party collaborator that may receive UH patient information in any format. Please ensure that all required approvals are obtained before initiation of research activity.****

The University Hospitals Institutional Review Board (IRB) has reviewed the following submission:

Principal Investigator: Erin Crawford
Protocol Title: Comparing outcomes, efficiency and cost effectiveness of pediatric endoscopic procedures at tertiary care centers vs satellite centers
UHCMC IRB number: 02-18-50

Submission Type: Initial Review Submission Form

Review Type: Expedite

As such, the UHCMC IRB has determined that with respect to the rights and welfare of the individuals, the appropriateness of the methods used to obtain informed consent and the risks and potential medical benefits of the investigation, the current submission is acceptable under Federal Human Subject Protection regulations promulgated under 45 CFR 46 and 21 CFR 50 and 56.

Date of Approval: 03/08/2018

The current expiration date for this study is: **03/07/2020**
(The expiration date is the last day that a protocol has IRB approval)

- Per Federal regulation, changes MAY NOT be made to any element of the current research without prior IRB approval, except to eliminate an immediate and apparent hazard to subjects enrolled in the trial.
- Per Federal regulation, the research may not continue without IRB approval. You must submit a request for continuation at least 6-8 weeks prior to the expiration date noted above. Once the study is complete, the IRB requires prompt notification of study closure.
- Failure to retain current IRB approval may result in archiving of the current study and human subjects non-compliance allegations.

Documents reviewed and/or approved as part of this submission:

Title	Version Number	Version Date
Application	Version 1.2	03/05/2018
Personnel Table	Version 1.0	03/01/2018
Crawford	Version 1.0	03/08/2018
endoscopy2	Version 1.0	03/07/2018
Endoscopy1	Version 1.0	03/07/2018

Human Risk Determination: Not Greater than Minimal Risk

If you have any questions or concerns, please contact the UHCMC IRB office at (216) 844-1529. The UHCMC IRB appreciates your commitment towards the ethical conduct of human subjects research.