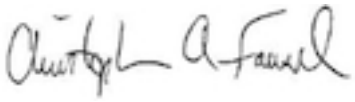
INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

Office of Research Compliance

To: Kamal Abulebda
PED-PULMONARY INTENSIVE CARE

From:



Chair - IRB-05
Human Subjects Office
Office of Research Compliance – Indiana University

Date: February 23, 2017

RE: **NOTICE OF EXPEDITED APPROVAL - RENEWAL**

Protocol Title: Retrospective Practice Analysis in Pediatric Procedural Sedation

Study #: 1204008435R003

Funding Agency/Sponsor: N/A

Review Level: Expedited

Status: Approved | Submitted to IRB

Study Approval Date: February 23, 2017

Study Expiration Date: February 22, 2019

The Indiana University Institutional Review Board (IRB) IRB00004961 | IRB-05 recently reviewed the renewal associated with the above-referenced protocol. In compliance with (as applicable) 21 C.F.R. § 56.109 (e) and 46 C.F.R. § 46.109 (d), this letter serves as written notification of the IRB's determination.

The study is approved under Expedited Category (5) Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**, with the following determinations, as applicable:**

Approval of this study is based on your agreement to abide by the policies and procedures of the Indiana University Human Research Protection Program and does not replace any other approvals that may be required. Relevant policies and procedures governing Human Subject Research can be found at: http://researchcompliance.iu.edu/hso/hs_guidance.html.

As a reminder, IRB approval is required prior to implementing any changes or amendments in the protocol, regardless of how minor, except to eliminate immediate hazards to subjects. No changes to the informed consent document may be made without prior IRB approval.

If you submitted and/or are required to provide participants with an informed consent document, please ensure you are using the most recent version of the document to consent subjects.

The approval period is noted above. Failure to receive notification from the Human Subjects Office will not relieve you of your responsibility to ensure compliance with Federal Regulations regarding annual review [as applicable, 21 C.F.R. § 56.109(f) and 45 C.F.R. § 46.109(e)].

You should retain a copy of this letter and all associated approved study documents for your records. Please refer to the assigned study number and exact study title in future correspondence with our office. Additional information is available on our website at at http://researchcompliance.iu.edu/hso/.

If your source of funding changes, you must submit an amendment to update your study documents immediately.

If you have any questions or require further information, please contact the Human Subjects Office via email at irb@iu.edu or via phone at (317)274-8289 (Indianapolis) or (812) 856-4242 (Bloomington).