INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

Office of Research Compliance

**NOTICE OF EXEMPTION - NEW PROTOCOL**

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| **DATE:** | April 03, 2019 |
| **TO:** | Matthew Yuknis, Principal Investigator<br>PED-INTENSIVE AND CRITICAL CARE<br><br>Kamal Abulebda<br>PED-INTENSIVE AND CRITICAL CARE |
| **FROM:** | KRONENBERGER, WILLIAM G.<br>Chair - IRB-01 |
| **RE:** | Protocol #: 1902762162<br>Protocol Type: Exempt<br>Protocol Title: ImPACTS Outpatient<br>Funding Source: None |

In accordance with 45 CFR 46.101(b) and/or IU HRPP Policy, the above-referenced protocol is granted exemption. Exemption of this submission is based on your agreement to abide by the policies and procedures of the Indiana University Human Research Protection Program (HRPP) and does not replace any other approvals that may be required. Relevant HRPP policies and procedures governing Human Subject Research can be found at: https://research.iu.edu/compliance/human-subjects/guidance/index.html.

**Submission and Review Information:**

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| **Type of Submission:** | Initial Protocol Application |
| **Level of Review:** | Exempt |
| **Exempt Category(ies), if applicable:** | Category 2: Research that only includes interactions involving educational tests, survey procedures, interview procedures or observation of public behavior.Category 4: Secondary research uses of identifiable private information or identifiable biospecimens. |
| **Date of Exemption Granted:** | April 03, 2019 |
| **Authorized IRB Signature:** |  <br>Danielle Giltner |

**Regulatory Determinations:**

- The PHI to be used or disclosed is determined to be necessary
- The explanation of how this research involves no more than minimal risk of loss of privacy to the subject is sufficient
- There exists an adequate plan to protect the identifiers from improper use and disclosure
- There exists an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research
- There exist adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule
- The explanation of how this research could not be practicably conducted without waiver of authorization is adequate
- The explanation of how this research could not be practicably conducted without access to and use of the individually identifiable health information is appropriate

- PHI to be used or disclosed:
  - o For collection and use: Data elements include basic demographic data of patients including age and gender, as well as type of medical emergency (respiratory distress, etc) and any difficulties encountered when caring for these patients.

**Documents Approved with this Submission (for Amendments and Renewals, documents appearing in bold were either added or replaced with the submission):**

| **Attachment Type - Document Version #** |
|---|
| Data Collection Instrument - Respiratory Distress Checklist<br>Data Collection Instrument - Seizure Checklist<br>Data Collection Instrument - Readiness Survey Checklist |

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

**The following key personnel are approved to participate in the above titled research activities:**

| **Investigator Name** | **Role** | **Training** |
|---|---|---|
| Matthew Yuknis<br>Kamal Abulebda | Principal Investigator<br>Co-PI Student/Fellow/Resident | Yes<br>Yes |

**Organizations:**

| **Organization** |
|---|
| Riley Hospital for Children at IU Health (Downtown) |

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 https://research.iu.edu/compliance/human-subjects/guidance/index.html.

If you have any questions or require further information, please contact the HSO via email at irb@iu.edu or via phone at (317)274-8289.