

IRB APPROVAL NOTIFICATION

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

Principal Investigator: Ashima Das

Protocol Title: Characterization of the process of death following withdrawal of support in the Pediatric Intensive Care Unit (PICU) at Rainbow Babies and Children's Hospital.

UHCMC IRB number: 12-13-12

Submission Type: Continuing Review

Review Type: Expedite

Expedited Review Category: Expedited Approval per: 45 CFR 46.110 (b) (1)/ 21 CFR 56.110 (b) (1)

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).

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: 12/30/2014

The current expiration date for this study is: 12/29/2015

(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 1.1	12/23/2014
Peds Review Committee Approval 12-13-12	Version 1.0	12/11/2014
Personnel Table	Version 1.0	12/23/2014

Human Risk:

- [Risk for adults] Not Greater Than Minimal Risk
- [Risk for minors] Not greater than minimal risk (45 CFR 46.404/ 21 CFR 50.51)

Vulnerable populations approved for inclusion: Minors

Funding Source: None

Other information: Retrospective Chart Review

- Waiver of consent approved under 45 CFR 46.116 / 21 CFR 56.109
- Waiver of assent approved under 45 CFR 46.408 / 21 CFR 50.55
- Waiver of HIPAA Authorization for Research under 45 CFR 160 and 45 CRF 164

Approval Signature:



UHCMC IRB Chairperson
(Signature was applied by the IRB Administration Office)

The UHCMC IRB operates under the HHS Federal Wide Assurance of Compliance number 00003937 and IRB registration numbers 00000684, 00001691 and 00008600