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The Committee for the Protection of Human Subjects (IRB)

Date: Tue Jun 8 11:01:10 EDT 2010
To: Sean O'Neill
CC: Mary Ann DiLiberto
From: Mark Schreiner, M.D., Chair, Committees for the Protection of Human Subjects
Re: IRB# IRB 08-005894_CR1 , **Protocol Title:** Efficacy of enteral opioids for prevention of opioid withdrawal in the pediatric intensive care unit when transitioning from an intravenous opioid infusion: a retrospective review
Sponsor: Children's Anesthesiology Associates

IRB CONTINUING REVIEW: NOTICE OF IRB APPROVAL

Final Approval Date: 6/7/2010
Expiration Date: 6/6/2011

Approved Document:

- Protocol dated 2/13/08

Performance Sites:

- CHOP and affiliated sites

Thank you for submitting the progress report for the above-named study. A member of the CHOP IRB reviewed and approved the continuing review via expedited review with the following determinations:

Expedited Category: 45 CFR 46.110, Category 5.

Subpart D Determinations: 45 CFR 46.404.

This study experienced a lapse in IRB approval between March 16, 2010 and June 7, 2010. The IRB approved the continuing review with the understanding that no study activities took place during the lapse in approval. If this is not the case (and study activities were ongoing), please contact the IRB.

Please note the following conditions for conducting this study:

1. **CONDITIONS OF APPROVAL:** None.
2. **REPORTABLE EVENTS:** On-site reportable events such as serious adverse events, Protocol Deviations/Violations, or any unanticipated problem involving risk to subjects or others, or non-compliance that occurs in relation to this study must be reported to the IRB in a timely manner, as outlined in the CHOP investigator instructions (http://stokes.chop.edu/forms/InvestigatorResponsibilitySheet.pdf).
3. **RENEWAL (Continuing Review/Progress Reports):** Approval is valid until the expiration date for your protocol shown above. The IRB must review and approve all human subject research studies at intervals appropriate to the degree of risk, but not less than once per year, as required by 45 CFR 46 / 21 CFR 50, 56. To avoid lapses in study approval and suspension of study procedures, please submit the application for continuing review at least 45 days before the expiration date for your protocol. This will provide the IRB will sufficient time to review your study. As a courtesy, the IRB will send you a reminder; however, it is your responsibility to ensure that you submit the continuing review application on time.
4. **WAIVER OF CONSENT/HIPAA AUTHORIZATION:** A waiver of consent has been approved per 45 CFR 46.116(d) and a waiver of HIPAA authorization has been approved per 45 CFR 164.512(i)(2)(ii).
   The IRB notes that this study is closed to enrollment.
5. **CHANGES/AMENDMENTS/MODIFICATIONS/REVISIONS** : You must obtain IRB review and approval under 45 CFR 46 and 21 CFR 50, 56, if you change any aspect of this study, including but not limited to study procedures, consent form(s), co-investigator, study staff, advertisements, protocol document or procedures, investigator drug

brochure or accrual goals. Implementation of these changes cannot occur until you receive the IRB Approval notice.

6. **COMPLETION OF STUDY:** Notify the IRB when your study is completed. Neither study closure by the sponsor nor the investigator removes your obligation for submitting a timely continuing review or a final report.

Thank you for your cooperation in protecting human research subjects.

DHHS Federal Wide Assurance Identifier: FWA0000459

***** This memorandum constitutes official CHOP IRB correspondence. *****

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