

Health Sciences Campus Institutional Review Board

NOTICE OF NEW STUDY APPROVAL – EXPEDITED

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IRB #: 11348
Protocol Title: High flow nasal cannula during sedation for endoscopy procedures

Date of IRB Review: 7/1/2014
Date of IRB Approval/Anniversary Date: 7/1/2014
IRB Approval Valid Until: 6/30/2015

Protocol approved: Version received: 27 June 2014

FOR ANY FUNDED STUDY: THIS RESEARCH MUST NOT BE INITIATED WITHOUT AUTHORIZATION FROM EITHER THE OFFICE OF RESEARCH ADMINISTRATION OR THE GRANTS AND CONTRACTS OFFICE.

- This study was reviewed and approved via expedited review procedures in accordance with 45 CFR 46.110(b)(5).
- In accordance with the Health Insurance Portability and Accountability Act (HIPAA), the IRB granted a HIPAA waiver of research authorization for this project. The Principal Investigator must fulfill the accounting requirements associated with the granting of the HIPAA waiver.
- This study is approved to review a total of 200 records.

Informed Consent Form (ICF): Waived in accordance with 45 CFR 46.116(d).

Human Protection Form for Funding Agency: Not required

Regulations regarding your research protocol:

1. The approval is valid for one year from the date of approval (unless otherwise stipulated by the IRB).
2. Unanticipated problems are to be reported to the IRB within five business days. Other internal SAEs and any external SAEs requiring protocol and/or ICF changes are to be reported to the IRB within fifteen business days. All other external SAEs and internal non-serious situations may be summarized and submitted at continuing review. Details may be found in the Unanticipated Problem and Adverse Event Reporting policy on the IRB website.
3. Any change to the protocol or ICF must be reviewed and approved by the IRB prior to implementation.
4. Do not use the ICF or any other study document until it has been approved and validated by the IRB.
5. If HIPAA applies to your research, the Security Rule also applies. If you create, receive, store, or transmit electronic PHI you must meet institutional Security Rule standards. Contact your HIPAA Privacy Officer for Research for more information.

THIS NOTICE MUST BE RETAINED WITH YOUR RESEARCH FILES.

7/7/14
Date


Signature of Chair/Vice Chair