



INDIANA UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION

To: VEDA L. ACKERMAN
PED-PULMONARY MED/CRITICAL CARE/ALLERGY

From: IU Human Subjects Office
Office of Research Administration – Indiana University

Date: November 07, 2011

RE: EXEMPTION GRANTED

Protocol Title: A Dedicated Nurse Practitioner Decreases Length of Stay in a Chronic Ventilation Intensive Care Unit

Protocol #: 1110007052

Funding Agency/Sponsor: None

IRB: IRB-01, IRB00000220

Your study named above was accepted on October 27, 2011 as meeting the criteria of exempt research as described in the Federal regulations at 45 CFR 46.101(b), paragraph(s) (4) . This approval does not replace any departmental or other approvals that may be required.

As the principal investigator (or faculty sponsor in the case of a student protocol) of this study, you assume the following responsibilities:

Amendments: Any proposed changes to the research study must be reported to the IRB prior to implementation. To request approval, please complete an Amendment form and submit it, along with any revised study documents, to irb@iu.edu. Only after approval has been granted by the IRB can these changes be implemented.

Completion: Although a continuing review is not required for an exempt study, you are required to notify the IRB when this project is completed. In some cases, you will receive a request for current project status from our office. If we are unsuccessful at in our attempts to confirm the status of the project, we will consider the project closed. It is your responsibility to inform us of any address changes to ensure our records are kept current.

Per federal regulations, there is no requirement for the use of an informed consent document or study information sheet for exempt research, although one may be used if it is felt to be appropriate for the research being conducted. As such, these documents are returned without an IRB-approval stamp. Please note that if your submission included an informed consent statement or a study information sheet, the IRB requires the investigational team to use these documents.

You should retain a copy of this letter and any associated approved study documents for your records. Please refer to the project title and number in future correspondence with our office. Additional information is available on our website at <http://researchadmin.iu.edu/HumanSubjects/index.html>.

If you have any questions, please contact our office at the below address.

Thank you.