



The University of Oklahoma
Health Sciences Center
INSTITUTIONAL REVIEW BOARD

IRB Number: 14566
Approval Date: March 26, 2009

April 10, 2009

Sheryl Buckner, R.N.
College of Nursing Building
1100 N. Stonewall, CNB 418
Oklahoma City, OK 73117-1297

RE: Observational Study of Healthcare Worker-Assisted Positioning Frequency for Limited Mobility Patients

Dear Ms. Buckner:

On behalf of the Institutional Review Board (IRB), I have reviewed and granted expedited approval of the above-referenced research study. This study meets the criteria for expedited approval category 4. It is my judgment as Chairperson of the IRB that the rights and welfare of individuals who may be asked to participate in this study will be respected; that the proposed research, including the process of obtaining informed consent, will be conducted in a manner consistent with the requirements of 45 CFR 46 or 21 CFR 50 & 56 as amended; and that the research involves no more than minimal risk to participants.

This study meets the criteria for waiver of informed consent and is approved to be conducted without obtaining consent.

This letter documents approval to conduct the research as described:

Priv - Waiver of Auth Dated: April 08, 2009
Survey Instrument Dated: March 09, 2009 Turning Observational Tool
Protocol Dated: March 09, 2009
IRB Application Dated: March 09, 2009

As principal investigator of this protocol, it is your responsibility to make sure that this study is conducted as approved. Any modifications to the protocol or consent form, initiated by you or by the sponsor, will require prior approval, which you may request by completing a protocol modification form. All study records, including copies of signed consent forms, must be retained for three (3) years after termination of the study.

It is a condition of this approval that you report promptly to the IRB any serious, unanticipated adverse events experienced by subjects in the course of this research, whether or not they are directly related to the study protocol. These adverse events include, but may not be limited to, any experience that is fatal or immediately life-threatening, is permanently disabling, requires (or prolongs) inpatient hospitalization, or is a congenital anomaly, cancer or overdose. For multi-site protocols, the IRB must be informed of serious adverse events at all sites.

The approval granted expires on February 28, 2010. Should you wish to maintain this protocol in an active status beyond that date, you will need to provide the IRB with an IRB Application for Continuing Review (Progress Report) summarizing study results to date. The IRB will request an IRB Application for Continuing Review from you approximately three months before the anniversary date of your current approval.

If you have questions about these procedures, or need any additional assistance from the IRB, please call the IRB office at (405) 271-2045 or send an email to irb@ouhsc.edu. Finally, please review your professional liability insurance to make sure your coverage includes the activities in this study.

Sincerely yours,

Martina Jelley, M.D., M.S.P.H.
Chair, Institutional Review Board



**Request for Waiver or Alteration of Authorization to
Use or Disclose Protected Health Information in Research**

1. Principal Investigator: Sheryl Buckner

2. Protocol Title: **Observational Study of Healthcare Worker-Assisted Positioning
Frequency for Limited Mobility Patients**

3. Type of Waiver Requested:

- Complete Waiver Alteration (Partial Waiver)

4. Regulatory Criteria for Waiver or Alteration of Authorization:

4.1 Briefly describe the health information to be used/disclosed without authorization.

Demographics, nursing care

4.2 Briefly describe how this information will be used/disclosed.

NA

4.3 Will the use/disclosure involve more than a minimal risk to privacy?

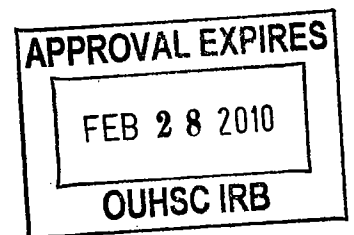
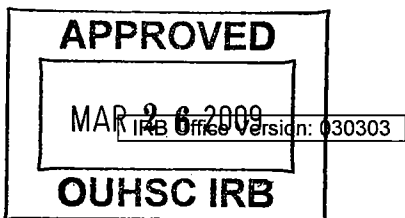
- No.
 Yes.

A. What is the plan to protect the identifiers from improper use and disclosure?

Subject numbers assigned, log with patient names will be retained at participating agencies by site PIs. Patient data will be de-identified to PI as only a subject number.

B. What is the plan, if any, to destroy the identifiers?

Each participating agency will follow their established procedure for storage and destruction of PHI



C. Will the information be reused or disclosed to any other person or entity?

- No.
- Yes. If yes, describe (i) when and under what circumstances; and (ii) how others will be required to protect the privacy and confidentiality of the information:

4.4 Is it practicable to conduct the research without the waiver/alteration?

- Yes.
- No. If no, why not: We are asking for waiver of informed consent as the informed consent process has the potential to alter patient and/or staff behavior related to the planned observation.

4.5 Is it practicable to conduct the research without access to and use of the protected health information?

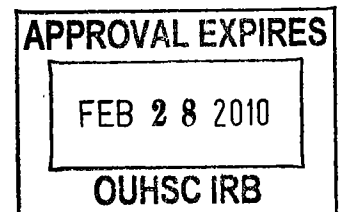
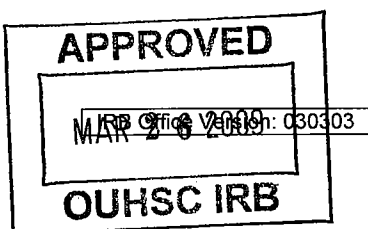
- Yes.
- No. If no, why not: It is necessary to only know the patient's age and Braden Scale score to know if they meet inclusion or exclusion criteria. Name and room number are only needed by the site PI to assure the same patient is observed hourly for the 13 hour period. Only site PI will have the PHI, the primary PI only needs a subject number to enter data and will not collect any PHI.

5. Signature of Principal Investigator

Sheryl Zimmerman
Signature of Principal Investigator

4/8/9
Date

IRB No.: [Provide IRB Number]



**APPROVAL RECORD
FOR IRB USE ONLY**

IRB No.: HS106

Reviewed by: Convened IRB
 IRB Chair or Vice Chair pursuant to expedited procedures

1. The use or disclosure of protect health information involves:

- MINIMAL RISK to individual privacy
- MORE THAN MINIMAL RISK to individual privacy

2. There IS
 IS NOT

an adequate plan to protect identifiers from improper use/disclosure.

3. There IS
 IS NOT

an adequate plan to destroy identifiers at the earliest opportunity.

4. There ARE
 ARE NOT

adequate written assurances that information will not be reused/redisclosed.

5. The research COULD NOT
 COULD

practicably be conducted without the waiver or alteration.

6. The research COULD NOT
 COULD

practicably be conducted without the protected health information.

The request for waiver or alteration of authorization is:

- Not Approved
- Approved as a Waiver (the first box must be checked for all elements above)
- Approved as an Alteration (*description of nature of alteration required*):

Signature of IRB Chair or Vice Chair

Print Name

Date

M. Jolly

4-9-09

APPROVED

MAR 26 2009
IRB Office Version: Q30303

OUHSC IRB

APPROVAL EXPIRES

FEB 28 2010

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