University of Pennsylvania
Office of Regulatory Affairs
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INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

04-May-2015

Mark Seamon
Andrew.Nunn@uphs.upenn.edu

PRINCIPAL INVESTIGATOR	: Mark Seamon
TITLE	: Emergency Department Thoracotomy Occupational Blood Exposure
SPONSORING AGENCY	: NO SPONSOR NUMBER
PROTOCOL #	: 822393
REVIEW BOARD	: IRB #7

Dear Dr. Seamon:

The above referenced protocol was reviewed and approved by the Executive Chair (or her authorized designee) using the expedited procedure set forth in 45 CFR 46.110, category 5,7, on 30-Apr-2015. This study will be due for continuing review on or before 29-Apr-2016.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study. Principal investigators are responsible for assuring final approval from other applicable school, department, center or institute review committee(s) or boards has been obtained. If any of these committees require changes to the IRB-approved protocol and informed consent/assent document(s), the changes must be submitted to and approved by the IRB prior to beginning the research study.

If this protocol involves cancer research with human subjects, biospecimens, or data, you may not begin the research until you have obtained approval or proof of exemption from the Cancer Center's Clinical Trials Review and Monitoring Committee.

For Physician Survey ONLY: The IRB reviewed and approved a waiver of written documentation of consent as per HHS 45 CFR 46.117(c)(2) or FDA 21 CFR 56.109(c)(1): That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context {e.g. Telephone survey}.

The waiver of informed consent and HIPAA waiver of authorization were reviewed as authorized by 45 CRF 46.116 (d) and 45 CFR 164.512 (i), respectively, and approved on 30-Apr-2015.

An expedited review procedure was used for the HIPAA authorization waiver because the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought.

The protected health information for which use or access has been determined to be necessary is as follows:

For Medical Chart Review ONLY:

Direct identifiers:
-Used/collected:
---Medical record numbers

-Disclosed:
---No direct identifiers will be disclosed

Indirect identifiers:
-Used/collected:

---All elements of dates (except year) for dates directly related to an individual (e.g. date of birth/death, dates of admission/discharge etc.)

-Disclosed:
---No indirect identifiers will be disclosed

Documents submitted for review:
-HS ERA Initial Application, confirmation code: biabdgjj, submitted 4.28.15
-Cover Letter, dated 3.26.15
-Study Protocol, uploaded 3.25.15
-Ed Thoracotomy Risk Assessment, uploaded 4.28.15
-IRB Request for Waiver of HIPAA Authorization Form, uploaded 4.27.15

The review of the research has determined the following:

- An adequate plan has been presented to protect the identifiers from improper use and disclosure;
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research exists, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and,
- An adequate written assurance has been provided that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted under the law.
- That the research cannot practicably be conducted without the waiver to access and use of the protected health information.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/IRB/directory.

Thank you for your cooperation.

Sincerely,

Heather Emery

IRB Administrator

Digitally signed by Heather Emery
DN: cn=Heather Emery, o=ORA, ou=IRB, email=heathern@upenn.edu, c=US
Reason: I attest to the accuracy and integrity of this document
Date: 2015.05.05 13:07:00 -04'00'