NORTH
MEMORIAL HEALTH

Date 2/1/2018

To: North Memorial IRB

Re: Request for waiver of consent for study "Chest Tube Use in Trauma: A Western Trauma Association (WTA) Multi-Center Trials Committee (MCTC) Prospective, Observational Study"
(See attached with specifics on the proposed study)

Investigator: Michaela West, MD, PhD, North Memorial Health
Joseph Farhat, MD, North Memorial Health

I am requesting a waiver of authorization of consent because the above-mentioned study satisfies the three criteria of 45 CFR164.512(i)(2) as follows:

A. The use of disclosure of this protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

   1) An adequate plan exists to protect patient identifiers from improper use and disclosure; (see D below).

   2) An adequate plan exists to destroy patient identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

   3) Adequate written assurances have 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 study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

B. The research could not practicably be conducted without the waiver or alteration; and

C. The research could not practicably be conducted without access to and use of the protected health information.

D. Identifiable patient information (name and MR#) that links to the non-identifiable study number will be maintained on a secure, password-protected computer on the North Memorial Health network. No identifying information will exist outside of that list.

Sincerely,

Michaela West

North Memorial Trauma Services

Incl: Research proposal abstract, Chest Tube Study Protocol, WTA Chest Tube Study data collection variables.

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Title: Chest Tube Use in Trauma: A Western Trauma Association (WTA) Multi-Center Trials Committee (MCTC) Prospective, Observational Study

Principle Investigators: Michaela West, MD, PhD, FACS; Joseph Farhat, MD, FACS

Primary objective:
Provide a contemporary description of the current use of chest tubes in hospitalized adult trauma patients, including indications, type of tube, technique of insertion, criteria and technique of removal, complications, and experience/training of individuals performing insertion.

Secondary objective:
Compare use of imaging, duration of chest tube drainage, rate and type of complications, criteria for chest tube removal, hospital LOS, impact of tube size, and a variety of technical factors between institutions.

Study design/Methods:
Prospective, observational study of chest tube use in trauma centers. Proposed timeframe is 5/14/18 to 8/17/18.

Inclusion Criteria:
1. Patients $\geq$ 18 years of age
2. Primary admission diagnosis of traumatic injury
3. Hospital length of stay $\geq$ 2 days
4. Patient had one or more chest tube placed during admission for traumatic injury.

Exclusion Criteria:
1. children < 18 years of age
2. Death within 48 (?) hrs of admission
3. prisoners.

Data Collection
Information will include specifics of insertion location, technique, experience of operator, size of tube, and location. Daily chest tube information will include: volume out, presence of air leak, and number of chest xrays. At the time of removal the technique, experience, followup, and complications will be noted. Additional de-identified patient information will include: hospital length of stay, need for ICU admit, complications, and management of chest tube complications. In addition, descriptive information about each trauma center participating in the project will be obtained.

Participating hospitals will receive a hospital identification number. Each patient enrolled will be numbered sequentially starting with #1. Patient's names and medical record numbers will be kept securely at the local sites, but not forwarded to the data collection center or included in the study database.