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MEMORANDUM

TO: VINITHA SHENAVA
ORTHOPEDIC SURGERY

FROM: FLOR MUNOZ-RIVAS, M.D., M.S.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

DATE: August 24, 2020

RE: **H-47568 - TILLAUX FRACTURES IN PEDIATRIC PATIENTS: EPIDEMIOLOGY AND MANAGEMENT**

The IRB, through expedited procedures has approved on 8/24/2020, a consent procedure which waives the requirement to obtain informed consent/HIPAA authorization for this research, and hereby describes how both of the following are found and documented in this protocol:

Waiver of consent and HIPAA authorization has been approved for the research as described here: This is study includes chart review of retrospective subjects. Therefore, the waiver is requested for the chart reviews. The study will i) initially identify the subjects who meet criteria for the retrospective part of the study which requires readily available data; and ii) identify the subjects to be approached to complete the survey. The retrospective data are already available and the chances of reaching every subject are low. As such a waiver is needed to complete the retrospective aspect of the study, and those whom we are able to reach will be consented for the completion of the survey.

a) The research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals because:

   This study entails retrospective review of clinical records and prospective enrollment and review of records for future patients/ patients currently ongoing treatment. We will protect patient confidentiality by using unique identifiers and storing all patient information in a password-protected electronic database. The use of PHI will only be used to gather necessary clinical data.

   1. An adequate plan exists in order to protect health information identifiers from improper use and disclosure, because:

      All data will be stored in locked filing cabinets and on secured computer spreadsheets on a secured server. Each participant will be identified using only an assigned unique study identification number. The identification number itself will not include PHI and the participant identification key list will be stored in a separate password protected file. Only personnel associated with this study will have access to the data.

   2. An adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so), because:

      Data collected will only be harvested until the completion of the study. An adequate plan exists in order to destroy

identifiers at the earliest opportunity consistent with the conduct of the research (absent a health or research justification retaining them or a legal requirement to do so). The data will be destroyed in a secure manner.

3. Adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) 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 the PHI would be permitted under the Privacy Rule, because:

   Adequate written assurances are in place so that protected health information will not be reused or disclosed to any other person or entity except when required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted under the Privacy Rule.

b) The informed consent waiver will not adversely affect the rights and welfare of the subjects, because:

   The waiver will not adversely affect the privacy rights nor the welfare of the research subjects because there is no risk, other than the very remote risk of loss of confidentiality. In order to safeguard against loss of confidentiality, multiple steps will be taken to ensure proper protection of patient information. Research personnel will store all research related data in a secure manner.

c) The research could not practicably be carried out without the waiver or alteration, and the research could not practicably be conducted without access to and use of the requested information because:

   The research cannot practicably conducted without access to protected health information because we need to assess the clinical course of each patient. Additionally, it would not be practical to contact the anticipated number of patients given the fact that a majority of them were treated years ago and some have since been lost to follow up. The scientific validity of the study would therefore be compromised if consent were required,as the sample of patients providing consent would be limited and not accurately represent the population at large.

d) The research could not practicably be carried out without using identifiable private information and/or identifiable biospecimens because:

   N/A

e) Informed consent is being waived, and providing participants with additional pertinent information after participation is not appropriate, because:

   This is a retrospective chart review of a condition the patient has already received treatment for; further information from this study would not be pertinent.

The following is a brief description of the PHI and the specific subject identifiers for which the IRB has determined use or disclosure to be necessary:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)

Given the assurances provided above, this memorandum serves as documentation that the BCM IRB has approved a waiver of consent/HIPAA authorization and has determined that all requirements are met by this protocol in order to grant the waiver.