

August 24, 2020



VINITHA SHENAVA  
BAYLOR COLLEGE OF MEDICINE  
ORTHOPEDIC SURGERY

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

**APPROVAL VALID FROM 8/24/2020 TO 5/26/2021**

Dear Dr. SHENAVA

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was reviewed and approved by Expedited procedures on 8/24/2020 by Board 6.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Flor Munoz-Rivas".

FLOR MUNOZ-RIVAS, M.D., M.S.

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

