IRB Approval – Expedited Review of New Study

To: Jennifer Mooney, MD

Copy to: Jessica Fox

Date: April 21, 2026

Re: 026-300
Safety and efficacy of chemoprophylaxis in the presence of spinal epidural hematoma in traumatic spinal injuries
Reference Number: 428703

Your new proposal was reviewed by a designated member of Baylor Scott & White Research IRB Red via expedited review.

This study was determined to be eligible for expedited review as it involves no greater than minimal risk to the subjects and fits into the following category from the 1998 approved list: Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

This review included the following components:

Submission Components			
Form Name		**Version**	**Outcome**
Review Response Submission Form		Version 1.0	Approved
Initial Review Submission Packet		Version 1.1	Approved
Study Application - Review by BSWRI IRB		Version 1.0	Approved
Study Document			
Title	**Version #**	**Version Date**	**Outcome**
EDH spine MCT proposal	Version 1.1	04/15/2026	Approved
EDH Spine_Data Collection	Version 1.0	04/15/2026	Acknowledged

Your submission has been approved. The approval period begins on 4/21/2026 and expires on 4/20/2027. Your next continuing review is scheduled for 3/20/2027.

This study is approved to be conducted at the following locations: Baylor University Medical Center, Main, BUMC-Trauma Center

The following individuals are approved as key study personnel or are acknowledged as study contacts/administrative support/department approvers: Aguirre, Salvador, MD; Fox, Jessica; Gibbs, David, MD; Mooney, Jennifer, MD; Ogola, Gerald O., PhD, MPH

Waiver of consent/authorization: The IRB has waived the requirement for informed consent based on 45 CFR 46.116 (f). The IRB has 1) waived the requirement for authorization based on 45 CFR 164.512 (i) (2) (ii) and 2) determined the use of existing protected health information is necessary to do the research.

All events that occur on this study including protocol deviations, serious adverse events, unanticipated problems involving risks to subjects/others, subject complaints or other similar events must be reported to the IRB in accordance with the respective policies.

Remember that this study is approved to be conducted as presented. Any revisions to this proposal and/or any of the referenced documents must be approved by the IRB prior to being implemented. Additionally, if you wish to begin using any new documents, these must receive IRB approval prior to implementation of them in the study.

IRB approval may not be the final approval needed to begin the study. All contractual, financial or other administrative issues must be resolved through Baylor Scott & White Research Institute prior to beginning your study.

For Investigator Initiated studies that meet the requirements to be posted on www.clinicaltrials.gov; as Principal Investigator, it is your responsibility to ensure that your study is listed prior to enrolling the first subject. Instructions on fulfilling this requirement can be found in iRIS under the "Help" tab.

If you need additional assistance, please contact the IRB Specialist at 254-215-9697.

Sincerely,

Signature applied by Lauren Ellis on 04/21/2026 10:33:11 AM CDT