IRB Approval – Expedited Review of Continuing Review

To: James Trotter, MD

Copy to: Angela Smith, James Trotter, MD, Sharon Primeaux

Date: July 09, 2018

Re: 009-279
Protocol to conduct a broad range of retrospective data reviews on liver transplant, kidney transplant and hepatology
Reference Number: 313349

Your request for continuing review 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 non-research purposes (such as medical treatment or diagnosis)

This review included the following components:

Submission Components		
Form Name	Version	Outcome
Continuing Review Submission Form	Version 4.1	Approved as Presented
Review Response Submission Form	Version 1.0	Approved as Presented
Study Application - Review by BSWRI IRB	Version 1.5	Approved as Presented

Study Document			
Title	Version #	Version Date	Outcome
Protocol V.5_20JUL2017	Version 5.0	07/20/2017	Approved

Your submission has been approved. The approval period begins on 07/06/2018 and expires on 07/05/2019. Your next continuing review is scheduled for 05/05/2019.

This study is approved to be conducted at the following locations:
Baylor University Medical Center, Sammons Outpatient Cancer Center, BUMC-Sammons Outpatient Cancer Center
Sammons Transplant Institute, Sammons Cancer Center, Suite 950

The following individuals are approved as key study personnel:
Alsahhar, Jamil Sami, MD; Asrani, Sumeet, MD; Bizzarri, Daniel; Bommisetty, Deepak, MD; Boutte, Jodi; Collinsworth, Ashley, MPH; Gautam, Manjushree, MD; Goel, Ajay, PhD; Gonzalez, Stevan, MD, MS; Griffin, Connor, MD; Guo, Linsheng, MD; Hall, Lauren; Idriss, Rajab; Jamil, Aayla; Lepe-Suastegui, Maria Rita, MD; Loyd, Niechelle; Mehta, Ashwini, MD; Modi, Apurva, MD; O'Connor, Maria; Peattie, Jennifer Victoria; Perrillo, Robert, MD; Primeaux, Sharon; Rahimi, Robert, MD; Ramsay, Michael A. E., MD; Sam, Teena; Saracino, Giovanna, MS; Sarmast, Naveed, MD; Smith, Angela; Spak, Cedric, MD; Trotter, James, MD; Voigt, Lisa, MD

Based on the information provided in your submission, the IRB has determined that this study qualifies for a waiver of informed consent in accordance with 45 CFR 46.116 (d) and a waiver of HIPAA Authorization 45 CFR 160 and 164.

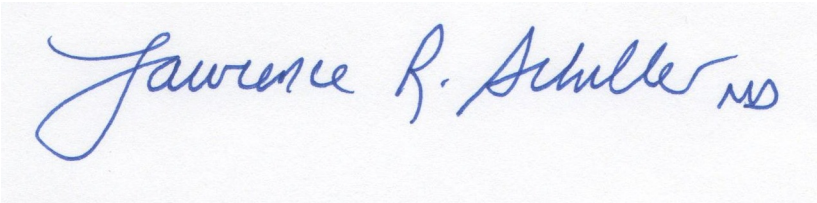
All events that occur on this study including protocol deviations, serious adverse events, unanticipated problems involving risks to subjects/others, subject complaints or other similar events must be reported to the IRB in accordance with the respective policies.

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.

If you need additional assistance, please contact the IRB Specialist at 214-820-9692 (NTX) 254-771-4869 (CTX).

Sincerely,



Signature applied by Lawrence R. Schiller on 07/09/2018 03:17:07 PM CDT