UNIVERSITY OF MICHIGAN
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To: Dr. Sachin Kheterpal

FROM:

Michael Geisser
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Cc:

Sachin Kheterpal
Shelley Vaughn
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Nirav Shah

Subject: Scheduled Continuing Review [CR00085608] Approved for [HUM00025285]

SUBMISSION INFORMATION:
Study Title: Multicenter Perioperative Outcomes Group (MPOG) and Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) Performance Site
Full Study Title (if applicable): Multicenter Perioperative Outcomes Group (MPOG) and Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) Performance Site
Study eResearch ID: HUM00025285
SCR eResearch ID: CR00085608
SCR Title: HUM00025285_Continuing Review - Tue Oct 27 08:12:41 EDT 2020
Date of this Notification from IRB: 12/15/2020
Date Approval for this SCR: 12/15/2020
Review: Expedited
Expiration Date: Approval for this application expires on **11:59 p.m. on** 12/14/2021
UM Federal Assurance: FWA00004969 (For the current FWA expiration date, please visit the UM HRPP Webpage)
OHRP IRB Registration Number(s): IRB00000244

Continuing Review Required: Yes

NOTICE OF IRB APPROVAL AND CONDITIONS:
The IRBMED has reviewed and approved the scheduled continuing review (SCR) to the study referenced above. The IRB determined that the proposed research continues to conform with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

APPROVAL PERIOD AND EXPIRATION:
The approval period for this study is listed above. Please note the expiration date. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

RENEWAL/TERMINATION:
The IRB has determined that annual review and approval is required for this research. At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

The U-M research leadership has now developed protocols and procedures to safely re-engage in-person human research activity. The process will utilize four Activation Tiers as determined by the U-M Human Research Activation Tier Framework.

Apply for Activation Committee Approval by following the UMOR guidelines.

Please refer to the Research Re-engagement website (https://research.umich.edu/covid-19/research-reengagement) for up-to-date information or email humanresearch-activation@umich.edu with questions about the activation process.

The Activation Approval should be provided to IRBMED via the Post Correspondence activity (in eResearch main study workspace) by selecting "IRBMED" as a recipient. Do not create an Amendment or ORIO for this purpose.

APPROVED STUDY DOCUMENTS:
You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the "Currently Approved Documents" section on the "Documents" tab.

AMENDMENTS:
All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects or others. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:
You must inform the IRB of adverse events (AEs) and other reportable information and occurrences (ORIOs) according to your IRB's required reporting timetable (IRBMED and IRB-HSBS/Flint/Dearborn).

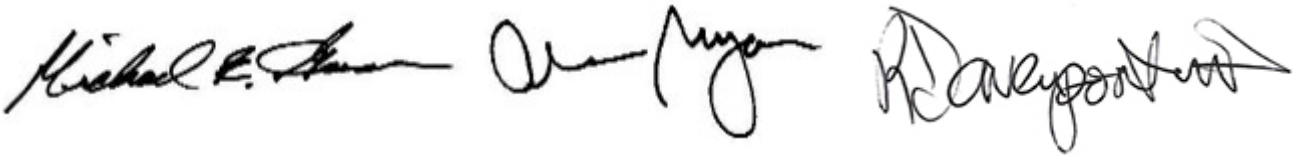
UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS (UPIRSOs or UaPs)
Investigators must continue to inform the IRB via eResearch submission of any potential Unanticipated Problems (UaPs or UPIRSOs) that come to the attention of the study team. Unanticipated Problems meet all of the following criteria:

1. **Unexpected** (in terms of nature, severity, or frequency);
2. **Related or possibly related to participation in the research**; and
3. Suggests that the research places subjects or others at **a greater risk of harm** than was previously known or recognized.

See U-M HRPP Operations Manual Part 12.III.B.1.a. Routine AEs and ORIOs after Termination need not be reported.

SUBMITTING VIA eRESEARCH:
You can access the online forms for continuing review, amendments, and AE/ORIO reporting in the eResearch workspace for this approved study, referenced above.

MORE INFORMATION:
You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: http://research-compliance.umich.edu/human-subjects.



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