UNIVERSITY OF MICHIGAN
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Medical School Institutional Review Board (IRBMED) • 2800 Plymouth Road, Building 520, Suite 3214, Ann Arbor, MI 48109-2800 • phone (734) 763 4768 • fax (734) 763 9603 • irbmed@umich.edu

To: Dr. Douglas Colquhoun

From:

Michael	Geisser
Amy	Filbrun
Robertson	Davenport

Cc:

Sachin	Kheterpal
Douglas	Colquhoun
Nora	Alrubaie
Shelley	Vaughn
Nicole	Eyrich
Victoria	Lacca
Nirav	Shah

Subject: Scheduled Continuing Review [CR00109928] 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: CR00109928
SCR Title: HUM00025285_Continuing Review - May 2025
Date of this Notification from IRB:5/14/2025
Review: Expedited
Date Approval for this SCR: 5/13/2025
Current IRB Approval Period: 5/13/2025 - 5/12/2026
Expiration Date: Approval for this expires **at 11:59 p.m. on 5/12/2026**
UM Federalwide Assurance:FWA00004969 (For the current FWA expiration date, please visit the UM HRPP Webpage)
OHRP IRB Registration Number(s): IRB00001996

Approved Risk Level(s) as of this Continuing Report:

Name	Risk Level
HUM00025285	

NOTICE OF IRB APPROVAL AND CONDITIONS:
The IRBMED has reviewed and approved the scheduled continuing review (SCR) submitted for 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 DATE:
The updated 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 or others. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

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.

In accordance with 45 CFR 46.111 and IRB practice, consent document(s) and process are considered as part of Continuing Review to ensure accuracy and completeness. The dates on the consent documents, if applicable, have been updated to reflect the date of Continuing Review approval.

RENEWAL/TERMINATION:
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.

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 continue to inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or others.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (https://az.research.umich.edu/medschool/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-other), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate hazards to the subject, implement the change and report via an ORIO and/or amendment submission within 5 calendar days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

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.

Michael Geisser
Co-chair, IRBMED

Amy Filbrun
Co-chair, IRBMED

Robertson Davenport
Co-chair, IRBMED