October 21, 2021

MOHAMED OTHMAN BAYLOR COLLEGE OF MEDICINE MEDICINE: GASTROENTEROLOGY



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## H-50836 - APPENDICEAL ORIFICE POLYPS MANAGEMENT WITH ENDOSCOPIC MUCOSAL RESECTION (EMR) AND ENDOSCOPIC SUBMUCOSAL DISSECTION (ESD)

## APPROVAL VALID FROM 10/21/2021 TO 10/21/2026

Dear Dr. OTHMAN

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 10/21/2021 by Board 2.

The study **does not require continuing review** but will require a 5 year renewal check in with the IRB Office. 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 be submitted to the IRB as an amendment for 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.

Research that has been approved by the BCM IRB may be subject to further appropriate review and approval or disapproval by officials of the institution(s) where the research will be conducted. However, those institutional officials may not approve the research if it has not yet been approved by the IRB.

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.

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JULIE KATKIN, M.D., B.A.

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

