Dear Editors,

I am writing to address the request for proof of informed consent in relation to our retrospective study conducted as per the guidelines and ethical considerations of our study, I would like to bring to your attention that a waiver for informed consent was already provided and approved.

The retrospective nature of our study necessitated the collection and analysis of pre-existing data, which could not be feasibly obtained through prospective consent procedures. In recognition of this unique circumstance, our study underwent a thorough review by the appropriate ethical review board at the University of Kentucky. Subsequently, we were granted a waiver for informed consent based on the following justifications:

Retrospective Study Design: The study was designed to analyze existing data from medical records, surveys, or other archived sources. The identification and contact of individual participants for consent were unfeasible due to the retrospective nature of the study.

Preserving Anonymity and Confidentiality: Measures were implemented to ensure strict confidentiality and anonymity of all collected data. Identifying information was appropriately de-identified or anonymized to protect the privacy of individuals involved.

Minimal Risk and Benefit: The study posed minimal or negligible risk to participants, as it involved the analysis of data that had already been collected for clinical or administrative purposes. Additionally, the potential benefits of this study include valuable insights that may contribute to improved healthcare practices.

The University of Kentucky's ethical review board meticulously evaluated our study proposal and concluded that obtaining informed consent was neither practical nor necessary given the retrospective nature of our research. This determination was made in adherence to the ethical principles outlined in the Belmont Report and the applicable regulations governing human subjects research.

We kindly request that you consider the provided waiver for informed consent as sufficient evidence of our compliance with ethical standards. We assure you that our study was conducted with the utmost regard for the rights and well-being of the individuals whose data were analyzed.

Please feel free to contact me at should you require any additional information or clarification. Thank you for your attention to this matter.

Sincerely,

Moammen Gabr, MD
Director of Third Space Endoscopy
Department of Advanced Endoscopy, Beth Israel Deaconess Medical Center. Boston, MA.