

July 9, 2019

Type of Review: Initial

Project Title: Accuracy of a negative Video Capsule Endoscopy in cases of gastrointestinal bleeding, a retrospective analysis at Einstein Medical Center

Investigator: Naemat Sandhu

IRB ID: IRB-2019-195

Funding: Department Funded/Supported

Sponsor/Grant ID: None

IND or IDE: None

Documents Reviewed:

- Protocol (5/17/18)
- Data Collection form

Dear Naemat Sandhu ,

The referenced protocol and the supporting materials were reviewed using the expedited process and approved by the IRB from July 9, 2019 to July 8, 2020 inclusive. A Privacy representative also reviewed the materials and approved the HIPAA Waiver of Authorization for Research.

Please note:

- *This approval expires on the expiration date unless suspended or terminated earlier by action of the IRB.*
- *At least 45 days prior to the study expiration date or within 45 days of study close, whichever is earlier, you are to complete a Continuing Review or Study Completion eIRB submission, whichever is applicable along with the required attachments to request continuing approval or study closure.*
- *If continuing review approval is not granted before the noted expiration date, approval of this research will automatically expire which means no further research-related activities can take place, and you will be considered a restricted investigator until the continuing review/study completion materials have been approved.*

As Principal Investigator, you are responsible for ensuring that this project is conducted in compliance with all applicable federal, state and local laws and regulations, as well as, the requirements listed in the *Investigator Manual*.

Sincerely,
Beth Lynch, CIP
Senior IRB Analyst