VTC Virginia Tech Carilion
School of Medicine and Research Institute

CARILION CLINIC

October 18, 2018

Carilion Clinic
3 Riverside Circle, 3rd Floor
Roanoke, VA 24016
United States

Re: Manuscript Submission 42710

Dear Editors:

Please see the original attached Institutional Review Board approval for our study. This study was exempt from requirements for informed consent, as no identifiable patient information was used in the final analysis, and all data that was collected was retrospective and did not affect patient outcomes.

Sincerely,

Maithili Chitnavis, MD
Assistant Professor, Gastroenterology

University of Virginia
Institutional Review Board for Health Sciences Research
Protection of Human Subjects Approval
Assurance Identification/Certification/Declaration
(Common Federal Rule)

HSR # 16221

Event:	Type:	Sponsor(s):
Approval Protocol Modification - Expedited	Protocol	Sponsor Protocol #:
		Principal Investigator: Justin Crocker

Title: Chronic narcotic use in IBD and IBD with an FGID. Is there a difference

Assurance: Federal Wide Assurance (FWA)#: 00006183

Certification of IRB Review: The IRB-HSR abides by 21CFR50, 21CFR56, 45CFR46, 45CFR160, 45CFR164, 32CFR219 and ICH guidelines. This activity has been reviewed and approved by the IRB in accordance with these regulations.

Approval Date: 09/23/13

Protocol Expiration Date: 04/25/14

Approved to Enroll 3000 **subjects.**

HSR Protocol Version Date: 09/18/13

Current Status: Closed to Enrollment, Performing Data Analysis

Consent Version Dates:

Committee Members (did not vote):

Comments: Modification Expedited-Minimal Risk/Minor Changes.
Revised IRB protocol includes the following key changes:
1) Increase enrollment from 2000 to 3000 to allow for a better analysis of the data. Enrollment change form is on file.
2) Extend the follow-up period from 2014 to 2017
3) Add in the analysis of patients based upon their weight
4) Title updated.
5) Administrative and grammatical changes.

This study was previously granted waiver of documentation of consent. No changes were made to the verbal consent script.

The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.

Name: Lynn R. Noland , RN PhD	Name and Address of Institution:
Title: Vice Chair, Institutional Review Board for Health Sciences Research	Institutional Review Board for Health Sciences Research PO Box 800483 University of Virginia Charlottesville, VA 22908
Phone: 434-924-9634 Fax: 434-924-2932	

Signature: Lynn R. Noland **Date:** SEP 26 2013