University of Virginia
Institutional Review Board for Health Sciences Research
HIPAA Privacy Board

IRB - HSR # 16221		
Event: Approval Protocol Continuation - Expedited	**Type:** Protocol	**Sponsor(s):** **Sponsor Protocol #:** **Principal Investigator:** Brian Behm, MD
Title: Chronic narcotic use in IBD and IBD with an FGID: Is there a difference		
Assurance: Federal Wide Assurance (FWA)#: 00006183 **IRB#00000447**		
Certification of IRB Review: The IRB-HSR/HIPAA Privacy Board abides by 21CFR50, 21CFR56, 45CFR46, 45CFR160, 45CFR164, 32CFR219 and ICH guidelines as compatible with FDA and DHHS regulations. This activity has been reviewed in accordance with these regulations.		
Event Date: 12/14/17 **Protocol Expiration Date:** 12/13/18 **Number of Subjects:** 3000 **HSR Protocol Version Date:** 04/29/15		
Current Status: Closed to Enrollment, Performing Data Analysis		
Consent Version Dates:		
Committee Members (did not vote):		

Comments: Protocol Expedited by Category #5: Research involving materials (data, documents, records or specimens) that have been collected solely for non-research purposes (such as medical treatment and/or diagnosis).

Protocol Expedited by Category #7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Protocol Expedited by Category #8C: Continuing review data analysis only.

Protocol status changed from open to enrollment to closed to enrollment,data analysis per status form.

Modification expedited: minimal risk/minor change: the following personnel change(s) were made per the Status Form/Personnel Change Form on file with this submission: Maithill Chitnavis, removed.

PLEASE REMEMBER:
1. If an outside sponsor is providing funding or supplies, you must contact the SOM Grants and Contracts Office/ OSP regarding the need for a contract and letter of indemnification. If it is determined that either of these documents is required, participants cannot be enrolled until these documents are complete.
2. You must notify the IRB of any new personnel working on the protocol PRIOR to them beginning work.
3. You must obtain IRB approval prior to implementing any changes to the approved protocol or consent form except in an emergency, if necessary to safeguard the well-being of currently enrolled subjects.
4. If you are obtaining consent from subjects, prisoners are not allowed to be enrolled in this study unless the IRB-HSR previously approved the enrollment of prisoners. If one of your subjects becomes a prisoner

after they are enrolled in the protocol you must notify the IRB immediately.
5. You must notify the IRB-HSR office within 30 days of the closure of this study.
6. Continuation of this study past the expiration date requires re-approval by the IRB-HSR.

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

Name: Joanna Faulconer Title: Member, Institutional Review Board for Health Sciences Research Phone: 434-924-9634 Fax: 434-924-2932	Name and Address of Institution: IRB for Health Sciences Research University of Virginia, PO Box 800483 Charlottesville, VA 22908 **OR** IRB for Health Sciences Research One Morton Drive, Suite 400 Charlottesville, VA 22903

Approval: Approved by Joanna Faulconer From IP Address: 172.28.22.113	Date: 12/14/17 at 11:47 AM

UNIVERSITY *of* VIRGINIA

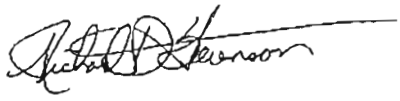
Office of the Vice President for Research
Institutional Review Board for Health Sciences Research

Confirmation of Training in Human Subject Protection

HSR # : 16221 **Title :** Chronic narcotic use in IBD and IBD with an FGID: Is there a difference

This is a certificate confirming that the following personnel have completed University of Virginia Research Training, an on-line tutorial that reviews the core concepts for the responsible conduct of research in a way that is consistent with federal and university requirements. Following each topic summary, the investigator must correctly answer the test question before being allowed to continue. This training is required every three years.

Name	Training	Last Trained	Expires
Patrick Northup	HSR	(HSR CITI - All Researchers) 14-Aug-17	14-Aug-20
Patrick Northup	HSR	(HSR CITI - Update) 14-Aug-17	14-Aug-20
Brian Behm	HSR	(HSR CITI - All Researchers) 10-Apr-16	10-Apr-19
Anna M Arp	HSR	(HSR CITI - All Researchers) 20-Oct-17	20-Oct-20



12/14/2017

Date

Richard Stevenson, MD
Chair, Institutional Review Board for Health Sciences Research
(UVA IRB)

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