



The
UNIVERSITY
of **VERMONT**

Committees on Human Subjects
Serving the University of Vermont
and Fletcher Allen Health Care

RESEARCH PROTECTIONS OFFICE
213 Waterman Building
85 South Prospect Street
Burlington, Vermont 05405
(802)656-5040 ph
www.uvm.edu/irb/

Approved Protocol FAHC Billing Plan Transmittal Form

Only to be used when a billing plan is required, and all other IRB issues are resolved.

PI: Brendan Everett

IRB #: CHRMS: 15-134

Study Title: Demographics and Characteristics of Patients Who Follow Up for Outpatient Endoscopy Following Hospital and ICU Admissions for Gastroesophageal Variceal Bleeding

Sponsor: Internal Funding

The IRB has scanned and attached the following to Compliance@vtmednet.org with cc to denise.quint@vtmednet.org.

☒ Assurance (approval)


☐ Consent Form(s)

☒ Protocol version # or Version Date (if applicable) 9/8/2014

☐ HIPAA Authorization Form

☒ Other material that the PI needs back to begin the research (list):

Waiver of Consent and Authorization approved.

Date approval released to FAHC Compliance: 10/01/14 

Note to FAHC Compliance

After FAHC Billing Plan Approval, please forward final approval documents to the PI and Contact as listed below.

PI Name: Brendan Everett

PI Email: Brendan.Everett@uvm.edu

Contact Name: Steven Lidofsky

Contact Email: Steven.Lidofsky@uvm.edu



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Memorandum

TO: Brendan Everett
FROM: Gale Weld
DATE: 29-Sep-2014
SUBJECT: CHRMS: 15-134
Demographics and Characteristics of Patients Who Follow Up for Outpatient
Endoscopy Following Hospital and ICU Admissions for Gastroesophageal Variceal
Bleeding

Attached is a signed assurance form which certifies this application has been reviewed and approved.
Also attached is the IRB's list of key personnel for this protocol.

This project has been approved for a waiver of informed consent and, if applicable, waiver of individual
authorization for disclosure of protected health information.

As the Principal Investigator of this approved protocol you have specific responsibilities. Please refer to
the Research Manual, Section 9. Submission of Materials After Initial Approval is Obtained and Section
10. Investigator Responsibilities to review these responsibilities and obtain further guidance.

cc: Steven Lidofsky



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CHRRS: 15-134

Protection of Human Subjects Assurance

Title: Demographics and Characteristics of Patients Who Follow Up for Outpatient Endoscopy Following Hospital and ICU Admissions for Gastroesophageal Variceal Bleeding

Principal Investigator: Brendan Everett,

Institution: University of Vermont and State Agricultural College, Burlington, VT 05405

This institution has an approved assurance of compliance on file with the Department of Health and Human Services which covers this activity.

University of Vermont and State Agricultural College: FWA 00000723 Expiration Date: Nov 12, 2018

Fletcher Allen Health Care, Inc.: FWA 00000727 Expiration Date: April 18, 2019

IRB number 00000485


Certification of IRB Review

This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts; and, when applicable, with the requirements of 21 CFR 50 and 21 CFR 56.

Date of approval SEP 24 2014 Date of expiration SEP 23 2015

IRB Review Type: Expedited review

Institutional Signature/Date: _____

 9/24/14

Name and Title of Official: David A. Kaminsky, M.D., Associate Chair,
Committee on Human Research in the Medical Sciences

Personnel Roster At Time of Initial Approval

TO: Brendan Everett

FROM: IRB Staff

DATE: 24-Sep-2014

SUBJECT: Key Personnel Listing

CHRRMS: 15-134

Demographics and Characteristics of Patients Who Follow Up for Outpatient Endoscopy Following Hospital and ICU Admissions for Gastroesophageal Variceal Bleeding

Below is the IRB's list of key personnel at the time of protocol approval. To update the roster, you must submit a [Request for Change in Key Personnel form](#).

Thank you for contacting the Committee.

Name

Everett, Brendan

Lidofsky, Steven D.