RUSH UNIVERSITY MEDICAL CENTER
1653 WEST CONGRESS PARKWAY, CHICAGO, ILLINOIS, 60612-3833
RUSH UNIVERSITY

RUSH UNIVERSITY MEDICAL CENTER

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

RESEARCH AND CLINICAL TRIALS ADMINISTRATION OFFICE
312.942.5498
312.942.2874 (FAX)

Rush Institutional Review Board
FWA #: 00000482

Notification of Expedited Continuing Review Approval

The following research activity has been re-reviewed and re-approved by the Institutional Review Board (IRB) at Rush University Medical Center in accordance with the Common Rule (45CFR46, December 13, 2001) and any other governing regulations or subparts. The Institutional Review Board at Rush also confirms that the project still meets the following categories under 45CFR46.110 for expedited review:

Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).	45CFR46.110 Category 5

The following documents were reviewed and approved by the committee:

Continuing Review Application

Please note the date for continuing review. Although you will be notified near the time for continuing review, it is your responsibility to assure that your project receives ongoing IRB approval.

ORA Number: 12021511-IRB02-CR01
Principal Investigator: Ece Mutlu, M.D.
Project Title: Hepatitis B in IBD Patients

Date of approval: 3/19/2013

Due for continuing review: 3/19/2014

It is your responsibility to follow the guidelines below:

- Conduct the study in accordance with the relevant, current protocol and only make changes in the protocol after notifying the IRB, except when necessary to protect the safety, rights or welfare of subjects.
- Record and track number of subjects accrued as well as information regarding study drop-outs or withdrawals.
- Provide brief updates on the changing scientific literature as that literature pertains to the efficacy and safety of the specific procedure or intervention under study.
- Report any complaints from subjects as well as any and all serious or unexpected adverse events related to this study to the IRB.
- Maintain and use copies of the currently approved consent document related to this project (if applicable).
- Maintain a file of the consent documents bearing the signature of the subjects enrolled in this study.

{The below is a representation of an electronic record that was signed electronically and is the manifestation of the electronic signature.}

Stephanie Pittman
3/20/2013 3:02 PM
Signing for Mary Jane Welch

Mary Jane Welch, DNP, APRN, BC
Director, Human Subjects Protection
Research and Clinical Trials Administration Office

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Institutional Review Board #1
FWA #: 00000482

Expedited Review Initial Approval Notification

The following research activity has been reviewed and approved by the Institutional Review Board (IRB) at Rush University Medical Center. In accordance with the Federal Regulations found at 45 CFR 46.110, this review was *conducted on an expedited basis:*

Research involving materials (data, documents, records, or specimens) that have been collected or will *be collected solely for nonresearch purposes (such as medical treatment or diagnosis).*	Category 5

Please note the date for continuing review. Although you will be notified near the time for continuing review, it is your responsibility to assure that your project receives ongoing IRB approval.

ORA Number: 12021511-IRB02
Principal Investigator: Ece Mutlu, M.D.
Project Title: Hepatitis B in IBD Patients

Date of approval: 4/27/2012
Due for continuing/annual review: 4/27/2013

New Project Application

Waiver of Written or Signed Consent (i.e. Information Sheets, telephone consent, verbal script): 45 CFR 46.116 (d): The research involves no more that minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver or alteration; and, whenever appropriate, the subjects will be provided with additional pertinent information after participation.

HIPAA Waiver of Authorization

Study Protocol

Data Collection Tool: Hepatitis B Data Sheet

{The below is a representation of an electronic record that was signed electronically and is the manifestation of the electronic signature.}

Stephanie Pittman
4/30/2012 2:01 PM
Signing for Mary Jane Welch

Mary Jane Welch, DNP, APRN, BC
Director, Human Subjects Protection
Research and Clinical Trials Administration Office