Click for IRB help/forms
Click for IT help

ID: NA_00041583

1 - General Information

1.0 * **Principal Investigator (PI)**

*Click **Select** to choose PI:*

Steven Brant

2.0 * **Will the PI obtain consent for this study?**

Yes

3.0 * **Indicate the PI's primary affiliation:**

(Select "Other (Affiliation Not Listed)" if the PI's primary affiliation is not listed)

Gastroenterology & Hepatology

4.0 * **Title of study:**
Johns Hopkins Crohn's Disease and Ulcerative Colitis Study

5.0 * **Provide a BRIEF statement of your research question and plan:**

Inflammatory bowel disease (IBD), including Crohn's disease (CD) and ulcerative colitis (UC), is a idiopathic, chronic and frequently disabling inflammatory disorder of the intestines characterized by a dysregulated mucosal immune response that affect more than a million Americans. This current protocol was established in 1996 with the goal of identifying the genetic and environmental components that contribute to the development of IBD, especially in families.

6.0 * **Select type of review requested:**

- [ ] **Convened**
- [x] **Expedited**
- [ ] **Exempt/Not Human Subjects Research (NHSR)**
- [ ] **Planning Phase**

7.0 **Is this a resubmission of an expired, terminated, withdrawn or disapproved application?**

No

8.0 **Is this a conversion of a currently active paper study, Suburban Hospital study or Sibley Memorial Hospital study?**

Yes

9.0 * **Enter prior application number:**

96-01-31-06

10.0 * **Progress Report:**

*Click **Add** to upload a new document. Click **Upload Revision** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*
{rpgress Repo(0.01)

Office of Human Subjects Research
Institutional Review Boards

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
410-955-4367 Fax
e-mail: jhmirb@jhmi.edu

Date: July 5, 2011

NEW APPLICATION APPROVAL

Review Type:	Expedited
PI Name:	Steven Brant
Study #:	NA_00041583
Study Name:	Johns Hopkins Crohn&#65533;s Disease and Ulcerative Colitis Study
Committee Chair:	Beryl Rosenstein
Committee:	JHM-IRB 1

Date of review: June 28, 2011

Date of approval: June 28, 2011

Date of expiration: June 27, 2012

The JHM IRB approved the above-referenced New Application.

Approval includes:
Protocol, dated 4/28/2011
Consent Forms
Research Assent Form
HIPAA Form 4
Telephone Screening Script
Questionnaires/Supplemental Study Documents
eProgress Report

The Board approved the application, but the final stamped versions of the consent forms, research assent form, and telephone screening script will not be released until you submit an eIRB Change in Research application with the Certificate of Confidentiality information.

45CFR46.404 and/or 21 CFR 50.51: This study has been approved for the inclusion of children as 'research not involving greater than minimal risk'. The permission of one parent is required.

45CFR46.204 This study has been approved for the involvement of pregnant women and fetuses prior to delivery.

Date of Approval and Expiration Date: The approval and expiration date for this research are listed above. If the approval lapses, the research must stop and you must submit a request to the IRB to determine whether it is in the best interests of individual participants to continue with treatment interventions.

Changes in Research: All proposed changes to the research must be submitted using an eIRB Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Continuing Review: Continuing Review Applications should be submitted at least 6 weeks prior to the study expiration date. Failure to allow sufficient time for review may result in a lapse of approval. If the Continuing Review Application is not submitted prior to the expiration date, your study will be terminated and a New Application must be submitted to reinitiate the research.

Unanticipated Problems: You must inform the IRB of any unanticipated problems involving risks to participants or others.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

Study documents:

Written Consent:

Only consent forms with a valid approval stamp may be presented to participants. All consent forms signed by subjects enrolled in the study should be retained on file. The Office of Human Subjects Research conducts periodic compliance monitoring of protocol records, and consent documentation is part of such monitoring.
FINAL_Brant NA_00041583 Consent Form_Multiple_062811 NoLogo.doc
FINAL_Brant NA_00041583 Consent Form_Single_062811 NoLogo.doc
FINAL Brant_NA_00041583 MouthwashConsent_062811 NoLogo.doc
FINAL_Brant NA_00041583 Consent Form_Anti-TNF_062811 NoLogo.doc

Written Assent:
FINAL_Brant NA_00041583 Research Assent Form_062811 NoLogo.doc

Recruitment Materials:
FINAL_Brant NA_00041583 Telephone Screening Script_062811 NoLogo.doc

HIPAA Form 4:
Final_Brant_NA_00041583_HIPPA Form 4_06282011_NoLogo.doc

Additional Supplemental Study Documents:
Family Study UA QX.doc
FamilyStudyIBDQX.doc

eFormA:
eFormA_Family Study_NA00041583

Study Team Members:
Patricia Ushry, Theodore Bayless, Christopher Bach, Vivian Abadom, Chengrui Huang, Carmelo Cuffari, Lisa Datta, Christina Ha, AHARON FELDMAN, Xuhang Li, Mary Harris, WARREN STROBER, Sharon Dudley-Brown, Vinzella Spears, Maria Oliva-Hemker, BOBBY BROOKE HERRERA, THEMISTOCLES DASSOPOULOS, Ming-Hsi Wang, Mark Lazarev, Miguel Ramos, Florin Selaru, MICHAEL YAO

Office of Human Subjects Research
Institutional Review Boards

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
410-955-4367 Fax
e-mail: jhmeirb@jhmi.edu

Date: October 19, 2017

CHANGE IN RESEARCH APPROVAL

Review Type:	Expedited
Principal Investigator:	Florin Selaru
Number:	NA_00041583 / CIR00030715
Title:	Johns Hopkins Crohn's Disease and Ulcerative Colitis Study
Committee Chair:	Howard Lederman
IRB Committee:	IRB-1

Date of approval: October 18, 2017

Date of Expiration: April 3, 2018

The JHM IRB approved the above-referenced Change In Research.

Approval includes:

1. Revised eForm A (dated: 10/12/2017).
2. One revised consent form.
3. One revised assent form.
4. Revised consent process.
5. Revised recruitment process.
6. Revised telephone screening script.
7. Two revised supplemental study documents.
8. Revised HIPAA Form 4.
9. Study team member changes:

-A change in PI from Dr. Steven Brant to Dr. Florin Selaur.
-A role change for Dr. Steven Brant.
-The removal of Feng Zhou, Bobby Brooke Herrera, George Salem, Tara Dhingra, Vinzella Spears, Ming-Hsi Wang, Faradia Kernizan, Aharon Feldman, Matthew Pfeffer, Ferdouse Begum, Christina Ha, Chengrui Huang, WeiWei Jiang, Miguel Ramos, Matthew Marcetich, Patricia Ushry, Elie Al Kazzi, & Christopher Bach.

45CFR46.404 and/or 21 CFR 50.51: This study has been approved for the inclusion of children as 'research not involving greater than minimal risk'. The permission of one parent is required.

Study Team Members:
This approval includes study team member changes. See below for a list of approved study team members.

There is an institutional policy which governs the participation of post-doctoral fellows in research. Please see: http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/post_doc.html. You are responsible for ensuring that any post-doctoral fellows on the study team meet all criteria for participation pursuant to this policy.

Carmelo Cuffari, Jennifer Yeh, Eboselume Akhuemonkhan, Sharon Dudley-Brown, Lysandra Voltaggio, CLAIRE SIMPSON, Joanna Melia, Mary Harris, WARREN STROBER, Gilad Halpert, MICHAEL YAO, Jairo Ortiz Ortiz, Reezwana Chowdhury, Mohammed Razvi, Cynthia Sears, Abhijit Date, Ellen Stein, Vivian Abadom, THEMISTOCLES DASSOPOULOS, Martin Everson, Theodore Bayless, Lisa Datta, Maria Oliva-Hemker, Mark Lazarev, Alyssa Parian, Berkeley Limketkai, Xuhang Li, Brindusa Truta, Barbara Slusher, Laura Ensign-Hodges, Taarika Babu, Elizabeth Mann, Steven Brant

The JHMIRB is constituted to meet the requirements of the Privacy Rule at section 45 CFR 164.512(i)(1)(i)(B) and is authorized and qualified to serve as the Privacy Board for human subjects research applications conducted by Hopkins' faculty members. The JHM IRB reviewed your request to waive authorization the above-referenced project. The IRB determined that all specific criteria for a waiver of authorization were met, as follows:
(A) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;
(1) An adequate plan to protect the identifiers from improper use and disclosure;
(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted;
(B) The research could not practicably be conducted without the waiver or alteration; and
(C) the research could not practicably be conducted without access to and use of the protected health information.

Office of Human Subjects Research
Institutional Review Boards

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
410-955-4367 Fax
e-mail: jhmeirb@jhmi.edu

Date: February 12, 2020

CONTINUING REVIEW APPROVAL

Review Type:	Expedited
Principal Investigator:	Florin Selaru
Number:	CR00030585 / NA_00041583
Title:	Johns Hopkins Crohn's Disease and Ulcerative Colitis Study
Committee Chair:	Howard Lederman
IRB Committee:	IRB-1

Date of Approval: February 11, 2020

Date of Expiration: February 10, 2021

The JHM IRB approved the above-referenced Continuing Review.

Approval includes: a progress report.

Enrollment is active.

45CFR46.404 and/or 21 CFR 50.51: This study has been approved for the inclusion of children as 'research not involving greater than minimal risk'. The permission of one parent is required.

45CFR46.204 This study has been approved for the involvement of pregnant women and fetuses.

If this study is a clinical trial and data collection is complete for the prespecified primary outcome, Section 801 of the Food and Drug Administration Amendments Act requires reporting of summary results information at http://www.clinicaltrials.gov. Reporting must be done within 12 months of completing data collection for the prespecified primary outcome, regardless of sponsor or funding source. Failure to comply with this law may result in civil penalties. For more information on results reporting go to http://www.clinicaltrials.gov. If the study is registered with Clinicaltrials.gov and is closed to recruitment and enrollment, the record must be updated within 30 days to reflect the study's enrollment status. See http://clinicaltrials.gov/ct2/manage-recs/how-edit for more information. Questions can be directed to register@clinicaltrials.gov.

Expiration Date: The expiration date for this research is listed above. If a continuing review application is required for this research and the approval lapses, the research must stop and you must submit a request to the IRB to determine whether it is in the best interests of individual participants to continue with protocol-related procedures.

Changes in Research: All proposed changes to the research must be submitted using a Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Continuing Review/Progress Report: Continuing Review/Progress Report Applications should be submitted at least 6 weeks prior to the study expiration date.

If a progress report is required, failure to submit a progress report in the time period requested will result in your inability to submit any further study actions other than a progress report until your progress report is submitted and acknowledged.

If a Continuing Review application is required, failure to allow sufficient time for review may result in a lapse of approval. If the Continuing Review Application is not submitted prior to the expiration date, your study will be terminated and a New Application must be submitted to reinitiate the research.

Unanticipated Problems: All unanticipated problems must be submitted using a Protocol Event Report.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.