CARILION CLINIC

September 3, 2015

Approval Date: September 3, 2015
Continuing Review Due Date: September 2, 2016
Expiration Date: September 3, 2016

Marrieth Rubio, MD
Dario Sorrentino, MD
Department of Gastroenterology
Carilion Clinic

re: Fecal Lactoferrin to Quantify Mucosal Inflammation in Inflammatory Bowel Disease

Dear Dr. Rubio and Dr. Sorrentino:

I am pleased to inform you that the Carilion Institutional Review Board (IRB) has reviewed the above-mentioned protocol in an expedited manner according to 45 CFR 46.110 and 21 CFR 56.110. The research project was determined to present no more than minimal risk to human subjects and was found to have appropriate protections so that risks related to breach of confidentiality are no more than minimal. This research project met the expedited criteria outlined in 63 FR 60364-60367, category (5): Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

According to 45 CFR 46.111, the following requirements were satisfied in order for approval to be granted:

- risks were minimized;
- risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and to the importance of the knowledge that may reasonably result from the study;
- selection of the subjects was equitable given the purpose of the research;
- informed consent will be sought from and documented for each prospective subject unless the conditions for a waiver of documentation for consent were met;
- when appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure safety of subjects; and
- adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data were made.

The following research team members have received IRB approval to participate in the above-mentioned study: Dr. Marrieth Rubio, Dr. Dario Sorrentino, Dr. Vu Nguyen, Dr. Doug Grider, and Kristin Knight.

The following documents are IRB-approved: IRB Application (version submitted 9/3/15), Data Collection Tool (submitted 8/11/15).

The total number of approved subjects and/or medical records for this study is approximately 300. The IRB requires that only minimum necessary data be collected for

research. Data must be collected and stored according to the IRB-approved protocol.

We have waived the requirement of informed consent as outlined in 45 CFR 46.116 (d). To meet the provisions of the waiver, the IRB has determined the research involves no more than 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.

The Carilion IRB has granted a Waiver of Authorization to use and access protected health information for the above-mentioned study. The IRB has determined that the Waiver of Authorization satisfies the following criteria outlined in 45 CFR 164.512(i)(2)(A):

- The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on the presence of the following elements:
  - An adequate plan to protect the identifiers from improper use and disclosure
  - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, and
  - 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 by this subpart
- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted without access to and use of protected health information

The waiver of authorization has been reviewed and approved under expedited review procedures and applies only to the data outlined in your application/protocol.

Approval to the study is granted for a period of twelve months, effective today. Approval of your research by the Carilion IRB provides the appropriate review as required by federal and state laws governing human subjects' research. IRB approval does not apply to research activities including data analysis that take place prior to the date of this letter. **This letter conveys IRB approval only and does not grant institutional approval. If your research involves any Carilion facilities, then separate arrangements must be made with the Department of Research & Development and appropriate hospital or medical staff, departments or committees.**

Additionally, the following documentation must be provided to the Carilion IRB:

- Continuing Review Application 30 days prior to the expiration date, providing a summary of the project to date and requesting continuation of the original project. If the original project is discontinued the IRB must be notified within seven business days.

- Serious adverse events and unanticipated problems that are unexpected and related, as outlined in the IRB Guidelines, within seven business days of the investigator becoming aware of them.

- Copies of reports from Data Monitoring Committees or auditing/monitoring reports from a sponsor are to be sent to the IRB Research Compliance Officer within seven business days.

- Any unplanned protocol variance that could adversely affect the safety or welfare of subjects, or the integrity of the research data, within ten days of becoming aware of the variance. Other unplanned variances may be recorded on a log and submitted with continuing review reports. Any changes to the research study must receive IRB approval before those changes can be implemented unless subject safety is directly affected.

Also, please find attached a form titled, "Carilion Clinic IRB Research Organization Checklist." The IRB is distributing this tool to provide guidance on maintaining research documentation for investigator-initiated studies.

The Carilion IRB would like to thank you for allowing us the opportunity to review this project. We look forward to learning of your results.

Sincerely,

Charles A. Hite, MA, CIP
Human Protections Administrator

cc: Daniel Harrington, MD, VP, Academic Affairs
Charles J. Schleupner, MD, Chair, Carilion IRB
Michelle Rothrock, Research & Development
Angela Steele, HIM
Mattie Tenzer, Director, Clinical Integration and Analytics
Mary Potter, Privacy and Information Security Officer
Paul Yeaton, MD, Section Chief, Gastroenterology
IRB files