Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

Harborview Office Tower
19 Hagood Ave., Suite 601, MSC857
Charleston, SC 29425-8570
Federal Wide Assurance # 1888

APPROVAL:
This is to certify that the research proposal **Pro00081854** entitled:
Endoscopic Balloon Dilation, A Safer Route than Surgery for Initial Management of Children with Stricturing Crohn's Disease

and submitted by: **Brianna McSorley**
Department: **Medical University of South Carolina**

For consideration has been reviewed by **IRB-I - Medical University of South Carolina** and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequately methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. Additionally, the Institutional Review Board for Human Research (IRB) recommends approval of the investigator's request for Waiver of Consent pursuant to 45 CFR 46.116(d) because the research involves no more than minimal risk to the subject, the waiver will not adversely affect the rights and welfare of the subjects, and the research could not be practicably carried out without the waiver. The Institutional Review Board for Human Research (IRB) also recommends approval of the investigator's request for a HIPAA Waiver of Authorization, as it appears that the criteria of the Privacy Rule have been satisfied. The HIPAA Waiver of Authorization was reviewed under expedited review procedures. No IRB member who has a conflicting interest was involved in the review or approval of this study, except to provide information as requested by the IRB.

Original Approval Date: **9/19/2018**
Approval Expiration: **9/18/2019**

Type: **Expedited**

Chairman, **IRB-I - Medical University of South Carolina**
Mark Hamner*

Statement of Principal Investigator:

As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this Institution and the project.

* ***Electronic Signature****: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

TO PRINCIPAL INVESTIGATOR

The IRB approval for your study has been released. Please see below for helpful reminders.

IRB POLICIES AND PROCEDURES

The link below will connect you to all IRB all IRB policies and procedures:
http://academicdepartments.musc.edu/research/ori/irb/policies.html
Here you will find important policy information regarding items such as: amendments, continuing reviews, protocol deviations, unanticipated problems and adverse events, etc.

INFORMED CONSENT AND HIPAA

Use only stamped IRB approved consent(s) and HIPAA. As the Principal Investigator, you are also required to make sure each person obtaining consent is approved and listed on your protocol and uses the most currently approved version of the consent(s)/HIPAA.

COMPLIANCE AUDITS FOR HUMAN RESEARCH STUDIES

The MUSC Compliance Office will randomly select human research studies for routine audit. Audits "for cause" will be conducted as necessary. The checklist used by the Compliance Auditor is located on the compliance website at:
http://horseshoe.musc.edu/~/media/files/services-all-files/compliance-files/univ-compliance-files/human-subject-audit-checklist-new-format-762016/human-subject-audit-checklist-12152016.pdf?la=en

SUCCESS CENTER

The SUCCESS Center provides a variety of resources at no charge for PIs and study teams at any point in the research process including individualized training and consultation for regulatory submissions and documentation. Contact SUCCESS at: 843-792-8300 or success@musc.edu
http://academicdepartments.musc.edu/sctr/programs/success_center/index.htm