Children's Mercy Hospital Pediatric Institutional Review Board

NOTIFICATION OF INITIAL APPROVAL

12/28/2013

From:	Office of Research Integrity
To:	Nadia Hijaz , Principal Investigator
CC:	Shawna Ricks Thomas Attard
IRB#:	13080263
Study Title:	Comparison of the use of Wireless Capsule Endoscopy with Magnetic Resonance Enterography in Children with Inflammatory Bowel Disease
Funding:	Gastroenterology
Protocol Name/#:	Capsule Endoscopy

Dear Dr. Hijaz,

The CMH Pediatric IRB reviewed the above-titled new study at the convened IRB meeting on 11/21/2013 at which time the committee voted to **approve with contingencies**. Your response to contingencies were subsequently reviewed and approved on **12/27/2013**.

The IRB has approved this study from **12/27/2013** to **11/20/2014** and determined that the appropriate child risk classification for this study is category 2 for research involving greater than minimal risk, but presenting a prospect of direct benefit to individual subjects.

The IRB approved the MARS application as of 12/27/2013 which included the following study documents:

- protocol 12.6.13.doc MARS ver. 0.05
- pre-screen log.xlsx MARS ver. 0.02
- Advertisement 12.3.13.doc MARS ver. 0.02
- phone script 12.3.13.docx MARS ver. 0.02
- Capsule Endoscopy Data collection form clean 12.3.13.docx MARS ver. 0.02
- Study Schedule for subjects 12.3.13.docx MARS ver. 0.03
- WCE subject instructions - 12.3.13.doc MARS ver. 0.02
- master subject log.xlsx MARS ver. 0.02
- results database.xlsx MARS ver. 0.01
- P-A capsule endoscopy 12.4.13.docx MARS ver. 0.05

Approved Permission/Assent/Consent Process(es):

Written informed permission/consent by parent(s) or legal guardian(s) of pediatric subjects
Written informed assent of pediatric subjects

If a written or verbal permission/assent/consent process has been approved as part of this study, ***you must use the stamped versions of the forms located under the "Documents" tab in MARS.***

Approved HIPAA Authorization Process(es):

Full written HIPAA Authorization wrapped into permission/assent/consent form(s)
Partial waiver of HIPAA Authorization (i.e., waiver for recruitment purposes only)

Additional Determination(s):

- The IRB determined that the medical device that will be used in this research meets the FDA *Non-Significant* risk definition.

Reminder of Principal Investigator Responsibilities:

- You are required to submit a continuing review report within MARS *30 days prior to your expiration date*. If continuing review approval is not granted before the expiration date of **11/20/2014** approval of this protocol expires on that date.
- Notify the IRB immediately upon termination of the project and/or departure of the Principal Investigator from the institution or project.
- **Report any changes or deviations** in the protocol to the IRB **prior to implementation**.
- Report any unexpected significant adverse events or problems related to your study promptly to the IRB.
- Maintain copies of all pertinent information related to research activities, including copies of all signed informed consent agreements obtained from participants (if applicable).

Sincerely,

Doug Swanson, M.D.
Co-Chair, CMH Pediatric Institutional Review Board

Dane Sommer, D.Min.
Co-Chair, CMH Pediatric Institutional Review Board

Rebecca A. Ballard, J.D., M.A.
Director, Office of Research Integrity

Office of Research Integrity
Children's Mercy Hospitals & Clinics
Phone: (816) 701-4358 Fax: (816) 701-4357 Email: MARSAdmin@cmh.edu