Children's Mercy Hospital Pediatric Institutional Review Board

NOTIFICATION OF INITIAL APPROVAL

1/2/2013 2:58 PM

From:	Office of Research Integrity
To:	Amanda Deacy , Principal Investigator
CC:	Nancy Lathrom
IRB#:	12100473
Study Title:	Preliminary Evaluation of Clinical Outcomes in the Multidisciplinary Abdominal Pain Clinic (APC): A Retrospective Review
Funding:	Gastroenterology
Protocol Name/#:	Clinical Outcomes

Dear Dr. Deacy,

On 1/1/2013, the CMH Pediatric IRB reviewed the above-titled new study by **expedited review** under 45 CFR 46.110 Category (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.

The IRB approved the submission from **1/1/2013** to **12/31/2013**. The IRB will have the authority to suspend or terminate approval of research that is not being conducted in accordance with applicable policies and procedures or that has been associated with unexpected serious harm to subjects.

The IRB approved the MARS application as of 1/1/2013 which included the following study documents:

Name	Modified	Version
Protocol 12.11.12	**12/11/2012 11:51 AM**	**0.01**
IT Database for Clinical Tracking	**11/28/2012 5:39 PM**	**0.01**
SPSS APC Chart Review	**12/11/2012 11:56 AM**	**0.01**

Approved Permission/Assent/Consent Process(es):

A Waiver of Informed Consent has been granted for the above referenced protocol. This waiver was reviewed under 45 CFR 46.116(d). The approval is granted based on a determination that:

- The risk to subject involves no more than minimal risks;
- The waiver of informed consent will not adversely affect the rights and welfare of the subject;
- The investigator has provided assurance that additional pertinent information will be provided to subjects whenever appropriate; and
- The research could not be practicably conducted without this waiver of informed consent.

Approved HIPAA Authorization Process(es):

A Waiver of HIPAA Authorization is approved in accordance with 45 CFR 164.512. This waiver was reviewed and approved under expedited review procedures. The approval is granted based a determination that the risk to the privacy of individuals is minimal based on:

- The investigator's plan to protect the identifiers from improper use or disclosure;
- The investigator's plan to destroy the identifiers at the earliest opportunity consistent with the research; and
- The investigator's written assurance that the PHI identified will not be reused or disclosed outside CMH, except as detailed in the request for waiver of authorization.

It has been determined that the research could not be practicably conducted without this waiver of authorization or without the PHI identified in the MARS application.

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 **12/31/2013** 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).

Please do not hesitate to contact the Office of Research Integrity with questions or for further assistance.

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