Children's Mercy Hospital Pediatric Institutional Review Board

NOTIFICATION OF INITIAL APPROVAL

6/3/2014

From:	Office of Research Integrity
To:	Katherine Sturgeon, Principal Investigator
CC:	Nancy Lathrom
	Seth Septer
IRB#:	14010042
Study Title:	The therapeutic effect of Melatonin in pediatric patients with functional dyspepsia
Funding:	Gastroenterology - Chairman's Award - Partial
Protocol Name/#:	Melatonin/FD

Dear Dr. Sturgeon,

The CMH Pediatric IRB reviewed the above-titled new study at the convened IRB meeting on 5/15/2014 at which time the committee voted to **approve with contingencies**. Your response to contingencies were subsequently reviewed and approved on **6/3/2014**.

The IRB has approved this study from **6/3/2014** to **5/14/2015** and determined that the appropriate child risk classification for this study is category 1 for research not involving greater than minimal risk.

The IRB approved the MARS application as of 6/3/2014 which included the following study documents:

- FD-Melatonin 05.22.14 MARS ver. 0.01
- FDA Response Melatonin
- Web-MD Melatonin Overview
- 510K Letter MARS ver. 0.01
- Melatonin Prescreen Log MARS ver. 0.01
- FD-Melatonin Telephone Script MARS ver. 0.01
- Melatonin/Fd Recruitment Letter MARS ver. 0.01
- FD-Melatonin Data Collection MARS ver. 0.01
- FD-Melatonin Eligibility and Medical Form MARS ver. 0.01
- FD-Melatonin Sleep Diary MARS ver. 0.01
- melatonin FD Adverse Event Form MARS ver. 0.01
- Melatonin FD End of Study Form MARS ver. 0.01
- Melatonin-FD Prescription MARS ver. 0.01
- FD-Melatonin Database MARS ver. 0.01
- FD-Melatonin Master List MARS ver. 0.01
- FD-Melatonin 05.22.14 MARS ver. 0.01

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 **5/14/2015** 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

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