MaGil IRB
INTEGRITY IN HUMAN RESEARCH
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CERTIFICATE OF IRB APPROVAL

Study Sponsor: Lawrence J. Wurn
44215 NW 39th Ave., Ste 2-2
Gainesville, FL 32606
USA

PI: Lawrence J. Wurn
44215 NW 39th Ave., Ste 2-2
Gainesville, FL 32606
USA

Study Title: The Impact of Small Bowel Obstruction (SBO) on Quality of Life (QOL); the efficacy of a manual physical therapy to improve QOL in subjects with a history of SBO

Protocol Number: **SBO-C2015-005**

Date: 18Dec2015

The study named above was reviewed by MaGil IRB via **expedited review** on ***18Dec2015*** This letter serves as proof the study meets all criteria for approval and was approved, at that time, with no additional restrictions on the conduct of the study. This study has been approved to be conducted ***in English only*** at the following site:

Clear Passage Physical Therapy
4421 NW 39th Ave. Ste 2-2
Gainesville, FL 32606
USA

As a condition of MaGil IRB's approval, you are required to use and abide by the enclosed, approved documents stamped with "Approved MaGil IRB."

- ***SBO-C2015-005 - protocol version 1.0 - APPROVED 18Dec2015***
- ***SBO-C2015-005 - ICF version 1.0 - APPROVED 18Dec2015***
- ***SBO-C2015-005 - initial survey version 1.0 - APPROVED 18Dec2015***
- ***SBO-C2015-005 - followup survey version 1.0 - APPROVED 18Dec2015***
- ***SBO-C2015-005 - study webpage version 1.0 - APPROVED 18Dec2015***
- ***SBO-C2015-005 - social media Ad version 1.0 - APPROVED 18Dec2015***

The IRB has determined that your study is of ***Minimal Risk*** and has been assigned an approval period of ***12 months (365 days)***. Please be aware that this study's IRB approval will therefore expire on ***15Dec2016.*** As a reminder, you will receive a Continuing Review Report Form (CRRF) approximately sixty days before the study's IRB approval period ends. The sponsor and/or designee is responsible for completing the CRRF and returning it to MaGil IRB along with the necessary materials for a continuing review re-approval prior to the due date printed on the CRRF.

PLEASE NOTE:

- ***The CRRF must be received by the due date printed on your form to allow sufficient time for our IRB panels to review your study for continuing review approval before your initial or most recent approval expires.***
- ***If the CRRF is not received and reviewed before the study's approval expiration date, your study's approval will have expired, barring continuation of the study until a new approval is issued.***
- ***Continuing research after expiration of IRB approval is a violation of federal law.***
- ***Missed CRRF submission deadlines are the sole responsibility of the Sponsor and/or designee regardless of whether or not the IRB notifies you.***

You are obligated to notify MaGil IRB of the following occurrences:

- Any and all amendments or changes to the protocol, investigator guide, or consent/assent scripts (all changes must receive IRB approval before implementation.
- Any and all changes to the protocol that are implemented without prior IRB approval to eliminate an apparent immediate hazard to subjects – *must be reported within 24 business hours of implementation*
- Related (Possible, Probable or Likely) Serious Adverse Events and unexpected and related Adverse Events – *must be reported within 5 business days from the date of discovery*
- Significant Protocol Deviations/Violations – *must be reported within 5 business days from the date of discovery*
- Unanticipated Problems involving risks to subjects or others – *within 5 business days of discovery*
- All materials used to recruit study subjects – *these items must receive IRB approval before being used*
- Any and all changes in the research activity

The Principle Investigator (PI) is bared from making any changes in research, without prior approval of MaGil IRB, except when it is necessary to eliminate immediate risk to study subjects. In addition, it is the responsibility of the PI to uphold the following three ethical principles outlined in the Belmont Report throughout the entire conduct of this study:

- **Respect for Persons** – individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
- **Beneficence** – maximize possible benefits and minimize possible harms.
- **Justice** – benefits and burdens of research should be distributed equally.

MaGil IRB is a resource to assist you in protecting research subjects and carrying out ethical research. Please don't hesitate to contact us for help.

MaGil IRB, Inc. provides ethical review and support services to principle investigators (PIs), institutions, contract research organizations (CROs), and sponsors of human subjects research. MaGil IRB, Inc. is duly constituted, has written procedures for initial, continuing and expedited review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with the requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference of Harmonization (ICH) E6, Good Clinical Practice (GCP), as applicable. MaGil IRB, Inc. is registered with OHRP/FDA with IRB registration number: IRB00007218 and its parent organization number: IORG0005985.

Signature: Reid Simon
Reid Simon (Dec 21, 2015)

Email: rsimon@magilirb.com

Title: Panel Member

Company: MaGil IRB, Inc.