



INSTITUTIONAL REVIEW BOARD

Initial Approval Notice

OFFICE OF SPONSORED RESEARCH • 11188 Anderson Street • Loma Linda, CA 92350
(909) 558-4531 (voice) • (909) 558-0131 (fax)

IRB# 58178

To: **Ejike, Janeth Chiaka**
Department: **Pediatrics**
Protocol: *Validation to the standard optimal volume for measuring intra-abdominal pressure*

The protocol and consent form for this study were reviewed and approved by the IRB at a regularly scheduled meeting on 09-Jul-2008. This decision included the following determinations:

Risk to research subjects: **Minor increase over Minimal**
Approval period begins **09-Jul-2008** and ends **08-Jul-2009**
Stipulations of approval:

Consent Form

The attached consent form has been specifically approved by the IRB, as indicated by the affixed IRB approval stamp. This now becomes your official consent form for the dates specified and should be used as a master for making the necessary copies.

Adverse Events / Protocol Changes

The IRB should be notified in writing of any modifications to the approved research protocol. All adverse effects, anticipated or not, should be reported to the IRB: serious events should be reported within seven days; all others within 15 days.

Protocol Review

Your protocol is tentatively scheduled for review and renewal at a meeting of the IRB before **08-Jul-2009**. To assure uninterrupted approval of this project, you will be sent a status report form to complete and return prior to this date. In addition to reporting the number of subjects enrolled, you may close the study or request renewal at this time.

Records

All records relating to this project, including signed consent forms, must be kept on file for three years following completion of the study.

Please note the PI's name and the IRB number assigned to this IRB protocol (as indicated above) on any future communications with the IRB. Direct all communications to the IRB c/o the Office of Sponsored Research.

Thank you for your cooperation in LLU's shared responsibility for the ethical use of human subjects in research.

Signature of IRB Chair/Designee: _____

Date: _____

9/4/08 RLR
~~9/4/08~~

Loma Linda University Adventist Health Sciences Center holds Federalwide Assurance (FWA) No. 6447 with the U.S. Office for Human Research Protections, and the IRB registration no. is IORG226. This Assurance applies to the following institutions: Loma Linda University, Loma Linda University Medical Center (including Loma Linda University Children's Hospital, LLU Community Medical Center), Loma Linda University Behavioral Medicine, and affiliated medical practices groups.

IRB Chair:

Rhodes L. Rigsby, M.D.
Department of Medicine
(909) 558-2341, rrigsby@ahs.llumc.edu

IRB Administrator:

Linda G. Halstead, M.A., Director
Office of Sponsored Research
Ext 43570. Fax 80131, lhalstead@univ.llu.edu

IRB Specialist:

Mark Testerman
Office of Sponsored Research
Ext 43042. Fax 80131, mtesterman@llu.edu



LOMA LINDA UNIVERSITY CHILDREN'S HOSPITAL

*11234 Anderson Street
Loma Linda, California 92354
(909) 825-KIDS (5437)*

Title: Validation of the standard optimal volume for measuring intra-abdominal pressure.

Assent Information (Child 7-12 years old)

Doctors need to learn more about pressures in the tummy and you can help us because you already have a tube in your tummy. We can use this tube to measure those pressures. If you agree to help us do this study, here is what will happen:

You probably have had a urine tube before. If you do not already have a urine tube in place, a urine tube will be put in your bladder. The doctors will use the urine tube and the tube already in your tummy to measure the pressures in your tummy. The study will take 2-4 hours if your tummy tube is used for dialysis. If your tummy tube was placed for draining unwanted fluid it will take 24 hours.

When we place the urine tube you may feel uncomfortable and it might even hurt but only for a few minutes. If you feel uncomfortable in any way while we are doing these things, you can tell us so. You can even tell us to stop if you are really bothered.

We hope this study will help other children like you in the future. It will not be helpful to you right now.

You get to choose if you want to take part in this study or not. You may choose not to take part or may leave the study at any time. Leaving the study will not affect your medical care. However if you decide to stop taking part in the study we encourage you to talk to your regular doctor and the research doctor first.

If you want to say "yes" to be part of the study just sign your name on the line below.

Thank you.

Child's signature _____ (7-12yr) Date _____

Loma Linda University
Advocate Health Sciences Center
Institutional Review Board
Approved 9/4/08 Void After 7/8/2009
58178 Chair R J. Riquelme

