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of Research Subjects

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7/6/2007

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IRB Protocol Number: STU00001168
Meeting/Review Date: 7/5/2007
Review Type: Full IRB Review
Protocol Sites:

Rehabilitation Institute of Chicago (RIC)

Sponsor Information:

There are no items to display

Protocol Document:

: Lubiprostone (Amitiza) Compared to Standard Care in the Treatment of Postoperative Opioid-Induced Constipation in Inpatient Rehabilitation Patients Following Orthopedic Procedures.	0.02
Amitiza study7-1-07.doc	0.01

Protocol Title: Lubiprostone (Amitiza®) Compared to Standard Care in the Treatment of Postoperative Opioid-Induced Constipation in Inpatient Rehabilitation Patients Following Orthopedic Procedures.

Submission(s) Considered: New Project
Status: APPROVED **Expiration of IRB approval: 6/20/2008**

The Institutional Review Board considered and approved your submission referenced above through 6/20/2008.

Approved Consent Forms:

NU Consent Form and Authorization for Research version 7-01-07	0.01

Survey/Questionnaires:

Data collection 0.01

IRB approval is granted with the understanding that the investigator will:

- Change neither the procedures nor the consent form without prior IRB review and approval of those changes. (Changes in the approved research may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.) Proposed changes must be submitted to the IRB as a Revision.
- Promptly report any unanticipated problems involving risks to subjects or others to the IRB. (See http://www.northwestern.edu/research/OPRS/irb for additional guidance on reporting of UPIRSOS)
- Submit a continuing review applications 4 - 6 weeks prior to the expiration of IRB approval. If IRB re-approval is not obtained by the expiration date indicated above, all research related activities shall shall stop and no new subjects may be enrolled (See http://www.hhs.gov/ohrp/humansubjects/guidance/contrev2002.htm for guidance on continuing subjects when it may be in their best interest to continue reserach participation during a lapse in IRB approval).

For more information regarding OPRS submissions and guidelines, please consult http://www.northwestern.edu/research/OPRS/irb.
This Institution has an approved Federalwide Assurance with the Department of Health and Human Services: FWA00001549.