Institutional Review Board Office
Northwestern University

Biomedical IRB
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Social and Behavioral Sciences IRB
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3/14/2012

Dr. Sarah Kinsinger
Gastroenterology and Hepatology Division
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Chicago, IL 60611
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IRB Project Number: CR2_STU00026087
Project Title: Characterizing psychosocial symptoms and treatment outcome in gastroenterology patients referred for psychological treatment.
Project Sites:

Northwestern Medical Faculty Foundation (NMFF)
Northwestern University (NU)

Submission Considered: Continuing Review **Submission Number:** CR2_STU00026087
Submission Review Type: Expedited as per 45 CFR 46.110(b)1
Review Date: 3/14/2012
Status: APPROVED **Approval Period:** (3/15/2012 - 3/14/2013)

Dear Dr. Kinsinger,

The IRB considered and approved your submission referenced above through 3/14/2013 . As Principal Investigator (P.I.), you have ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of human subjects. You are required to comply with all NU policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

- Not changing the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).
- Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.
- Promptly reporting unanticipated problems involving risks to subjects or others, or promptly reportable non-compliance in accordance with IRB guidelines.
- Submit a continuing review application 45 days prior to the expiration of IRB approval. If IRB re-approval is not obtained by the end of the approval period indicated above, all research related activities must stop and no new subjects may be enrolled.

IRB approval includes the following:

Waiver of Consent: A Waiver of Consent was granted for this project in accordance with section 45CFR46.116d(1-4)

HIPAA: A HIPAA Waiver of Authorization was granted for this project in accordance with section 42CFR 164-512 (I) 2(ii) of the HIPAA Privacy Rule and with Northwestern University's HIPAA Research Policy.

Protocol: Chart Review Protocol Template 3.12.10.doc

Survey/Questionnaires:

FACT-C_us[1].doc
NewPatientForm_EE_1.28.10.pdf
NewPatientForm_Esophageal_1.28.10.pdf
NewPatientForm_v3_Bowel_1.28.10.pdf
QOLRAD new layout.docx
Termination_EE_1.28.10.pdf
Termination_Esophageal_1.28.10.pdf
Termination_v3_bowel.pdf
