

Research Institute

August 21, 2006

(224) 364-7100 (847) 570-8011 fax

David F. Cella, Ph.D. Department of Psychiatry Evanston Northwestern Healthcare 1001 University Place #100, CORE Evanston, IL 60201

Re:

EH03-339: Cella, David Ph.D.: Quality of Life Outcomes in Neurological

Disorders

Dear Dr. Cella:

The Periodic Progress Report for your above-referenced project was reviewed by the Research Institute and a member of the Institutional Review Board of Evanston Northwestern Healthcare. This project was originally approved by expedited review and continues to qualify.

The project was reviewed in accordance with the Code of Federal Regulations (45 CFR 46 - as revised and 21 CFR 50, 56, as applicable). The Evanston Northwestern Healthcare Corporation Institutional Review Board has an approved assurance of compliance with OHRP which covers this activity (Federal Wide Assurance: FWA00003000). This project was approved by expedited review on the date of this letter and has IRB approval through 8/20/2007.

In addition, the project fulfills the requirements of 21 CFR 50 and 45 CFR 46, Subpart D, Additional Protections for Children Involved as Subjects in Research. In adherence to section 404 of the subpart, the research does not involve greater than minimal risk to subjects.

Updated Consent Forms are enclosed with this letter. Please make copies of these Consent Forms and use them in your study. All prior Consent Forms are invalid and must not be used. You are required to keep the original signed Consent Forms in your files. As you enroll subjects into this study, copies of the Consent Forms must be sent to the Research Institute.

Your project must be reviewed on a yearly basis. Approximately two months before your approval expires, you will receive an e-mail notice that your project is due for review. Changes in either the experimental protocol or Consent Form must not occur without prior approval of the IRB. Adverse effects must be reported to the IRB. If this project is terminated before its next Annual Review, please notify the Research Institute by completing a Periodic Progress Report.

Thank you for submitting this project.

Sincerely yours,

Douglas E. Merkel, M.D.

Chairman, Institutional Review Board

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cc:

Frederick E. Miller, M.D., Ph.D. Leopold G. Selker, Ph.D.

Robert Stanton, J.D. Jacquelyn George