



## Research Institute

May 1, 2007

(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 F. Ph.D.: Quality of Life Outcomes in Neurological

Disorders

Amendment #4, dated March 22, 2007

Dear Dr. Cella:

The Research Institute received your request for a revision of the above-referenced research protocol on 4/24/2007. The revision has been reviewed in the Research Institute and by a member of the Institutional Review Board (IRB) of Evanston Northwestern Healthcare. The above referenced revision qualifies for expedited review because the addition of an online panel organization for recruitment does not change the risk of the study.

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

Your request for a waiver of the requirement for written documentation of consent has been granted since the study poses no more than minimal risk and the research involves procedures that do not require written consent when performed outside of a research setting. The IRB is aware that this waiver applies to procedures to be followed in addition to the previously approved consent process.

It is noted that this amendment did not require a change in the existing consent forms.

Sincerely yours,

Douglas E. Merkel, M.D.

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Chairman, Institutional Review Board

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cc:

Frederick E. Miller, M.D. Leopold G. Selker, Ph.D. Robert Stanton, J.D. Ye (Juliette) Song