

NBTF Richard Hollow Quality of Life Grant – 6 Months Progress Report

Project title: Stress reduction program for patients with malignant brain tumors and their family caregivers

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This project has been delayed because of a combination of subjective and objective reasons. First, as the Principal investigator, I take full responsibility for this delay. I was not able to finalize the protocol for this pilot study on a timely basis due to unexpectedly increased workload related to the departure of the study coordinator of my ongoing clinical study, hiring and training of a new post-doctoral fellow in my research lab and a recent month-long absence from work due to personal reasons.

Second, new clinical protocols are currently reviewed and approved through a novel system that adds extra steps in order to obtain approval for beginning the study. The Taussig Cancer Center of the Cleveland Clinic Foundation where the Brain Tumor Institute administratively belongs is being integrated with the Case Comprehensive Cancer Center (of the Case Western Reserve University and the University Hospitals HealthSystem in Cleveland), one of the National Cancer Institute designated cancer centers.

New studies are evaluated first by the joint Protocol Review and Monitoring Committee (PRMC) and when approved by the PRMC, they are submitted for an approval to a new joint Institutional Review Board (IRB). My application to become a member of the Case Comprehensive Cancer Center was approved at the end of November, 2005 and as a result, we will be able to enroll participants from both institutions for the NBTF project. Having a larger pool of eligible patients with malignant brain tumors and their caregivers is likely to shorten the time needed to accrue the proposed number of patient/caregiver pairs for an 8-week long intervention of a stress reduction program.

An additional reason for this delay is related to the fact that this study on yoga-based stress reduction is the first project of this kind to be conducted at the Cleveland Clinic Foundation and Case Comprehensive Cancer Center. To strengthen our case, we were fortunate that two experts joined our study as Co-Investigators (and volunteers as there are no funds to support their efforts). First, Laura A. Siminoff, Ph.D. is a Professor of Bioethics and Family Medicine at Case Western Reserve University, Co-Leader of a scientific program of "Cancer Prevention, Control and Population Research" within the Case Comprehensive Cancer Center and chair of the Behavioral section within the PRMC that is reviewing the clinical protocol for our project. Second, Leo Pozuelo, M.D. is from the Department of Psychiatry and Psychology of the Cleveland Clinic. Besides yoga-based stress reduction and neuro-oncology experts, our project will now have experts for mental health and bioethics-related issues.

This project is currently being reviewed by the PRMC. We will learn about the decision about its approval on March 14, 2006. If approved, it will be submitted to the IRB and hopefully approved within the usual time frame of 2-4 weeks.