To whom it my concern:

This letter is to update you on several recent changes made to the following study offered through the Comprehensive Cancer Center of Wake Forest University CCOP Research Base:

"Phase III Double Blind, Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients" (#91105)

As you will recall, this study is testing if the acetylcholinesterase inhibitor, donepezil, can improve the overall cognitive functioning (primary outcome) and specific cognitive functioning, mood, quality of life and fatigue (secondary outcomes) among adult patients who are at least 6 months post partial or whole brain irradiation.

To facilitate and simplify enrollment we made several important changes to the protocol including:

- Adding a $40 gift for participating (2, $20 Wal-Mart cards offered after the first and last assessment)
- Simplifying and reducing medication exclusions. Patients are eligible if they are on:
    - Stable or decreasing dose of steroids, anti-cholinergics, anti-epileptics, anti-depressants, sedatives / benzodiazepines
    - Stable and/or prn dose of narcotic analgesics
    - Stable dose of methylphenidate or dextramphetamine
- Permitting hormonal therapy for patients with breast or prostate cancer
- Allowing enrollment of patients who have received single fraction stereotactic radiosurgery (SRS) in addition to whole or partial brain irradiation
- Allowing patients who have received prophylactic cranial irradiation
- Allowing patients who have received Gliadel Wafers in addition to brain irradiation (but not GliaSite or other brain brachytherapy)
- Patients are eligible as soon as they complete chemotherapy
- Opening the window for latest allowable MRI (WHO Grade 1: w/in 1 yr. prior to enrollment; Grade 2: w/in 6 mo.; Grade 3/4: w/in 3 mo.)

When considering patients for **91105** please remember that they can be years post brain irradiation. Thus, many patients you follow, including former pediatric brain tumor patients, are eligible. Enrollees must only be at least 6 months post irradiation without an upper limit.

We have also developed efficient training methods for your research nurse to become skilled in the administration of our simple battery. We use a web-based training video, self-study and face-to-face experiential methods that can be arranged conveniently at your site. Please contact June Fletcher-Steede (jsteede@wfubmc.edu) for training information.

This study is among several with neurocognitive endpoints we plan to offer through the CCCWFU CCOP Research Base in the coming years, so now is an excellent time to prepare your clinic to become involved. If you or your staff have any questions regarding the study please feel free to contact me

(srapp@wfubmc.edu), Ed Shaw, MD (Co-PI) (eshaw@wfubmc.edu) or Robin Rosdhal, RN (rosdhal@wfubmc.edu) directly for more information.

Thanks for supporting cancer the WFUCCC Research Base studies and the many patients who benefit!

Sincerely,

Steve Rapp, PhD (PI, 91105)
Professor
Department of Psychiatry and Behavioral Medicine and
WFUCCC Research Base
Wake Forest University Health Science
Medical Center Blvd.
Winston-Salem, NC 27157
Email: srapp@wfubmc.edu
Ph: (336) 716-6995
Fax: (336) 716-6830