

**CCCWFU CCOP RESEARCH BASE
PROTOCOL AMENDMENT CHANGE FORM**

Study Title: Phase III Double Blind, Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients

Protocol #: 91105
IRB Number: 0000551

Date of Submission to IRB: 9/21/09
IRB Approval Date: 10/06/09

Principal Investigator: Stephen Rapp. PhD **Protocol Amendment # 8**

Brief description of each change in the study protocol and rational. (Additional pages may be used as needed):

1. Header: Deleted Am7/date and added Am 8.
2. Title page: Added 'Amendment 8' Updated NCI version date: 09/16/09
3. Title Page: Added CTSU logistical information and contact information
4. Page x: Updated Table of Contents; Added "Appendix 17: CTSU Procedures"
5. Section 4.2.2: Added "Assessing Participant Emotional Distress....Note occurrence on PHQ Summary Sheet." PI contact information added per NCI request.
6. Section 4.3.1: Added: 'However, if the patient is experiencing insomnia on the 5mg or 10mg dose, the donepezil dose can be taken in the morning, at the physician's discretion.'
7. Section 12: End of section: added "CTSU Participants...enrollment instructions."

Consent Form Changes

Brief description of each change in the consent form and rational.

1. Version Number: Deleted 5 and added 6
2. Disclosure and Confidentiality Section: Added "the Cancer Trials Support Unit (CTSU)...access to cancer trails."

Appendices Changes

Brief description of each change in the appendices.

2: Eligibility Checklist: Added CTSU information to header; Added "CTSU Participants...protocol for details."
12, 13, 14: Baseline, 12, and 24 Week Testing Booklet: Added PHQ Assessment Instructions and PHQ Summary Sheet to each booklet. PI contact information added per NCI request. Patient Information table at the bottom of each page was updated to reflect correct testing booklet week.
16: Histology Form: "or PCI" added to first point, Who Grade 3 and 4 expanded to seven histology