APPENDIX 2

CONSENT FORMS

Information to Patients
Selenoproteins and antioxidants in pathogenesis of Alzheimer's disease

Purpose of Research and Benefits

The clinical study in which your participation is proposed aims to evaluate the role of selenoproteins and antioxidants in preventing the pathogenesis of Alzheimer’s/neurological/neurodegenerative diseases. It is expected that you would be benefited by knowing your selenoprotein and antioxidant status which will help the physician and also you to plan a balanced nutrient diet and also therapeutic supplements.

Possible Risk

About 25 - 30 number of healthy control subjects aged above 40 will be included in this study along with the blood samples from the patients with Alzheimer’s and vascular dementia. Blood sample of 10ml and CSF (4ml) will be drawn from these subjects. Since blood/CSF collection will be made through trained personnel using disposable syringes there is no specific risk involved.

Study Procedures

The blood sample will be taken and processed to assess the following:

Antioxidants: Endogenous antioxidant enzymes namely catalase, superoxide dismutase, glutathione, Peroxidase, lipid peroxidation product, glutathione reductase and glucose 6 phosphate dehydrogenase
Selenoproteins: Selenoprotein P, GSH-Px, Thioredoxin reductase, and Selenium
Apo E polymorphism, Amyloid and tau

Confidentiality

Your medical records will be treated with confidentiality and will be revealed only to scientists of this study. The results of this study may be published in a scientific journal but you will not be identified by name.

Your participation in the study and your rights

Your participation in this study is voluntary and please tell about your decision to the hospital doctor. In any case, you will receive appropriate treatment for your condition.

For any further questions which you may have, please contact the following persons

1. Dr. R.M. Bhoopathy, Head, Institute of Neurology, Madras Medical College, Chennai
2. Dr P.Rani, Associate Professor, Department of Biotechnology, PSG College of Technology, Coimbatore-641 004
Patient Consent Form

Selenoproteins and antioxidants in pathogenesis of Alzheimer's disease

Name of the Subject: ..................................... Investigator’s Name: .............................
Name of the Institution/Location: .............................................................
Name of the sponsor:

For the Subject:

I ........................................ exercising my free power of choice, hereby give my consent to be included as a subject in the clinical study of “Selenoproteins and antioxidants in pathogenesis of Alzheimer’s disease”. I am over 18 years of age, I understand that I will be giving a sample of venous blood (10ml/CSF 4 ml). I have been informed to my satisfaction by my attending physician about the purpose of this study. I have been given a full explanation by the supervising doctor of the nature and purpose of the study and what I will be expected to do. The information sheet given to me is attached. I hereby give permission to the doctors in charge of this study to release the information regarding or obtained as a result of my participation in this study to national and international regulatory bodies and Government agencies and allow them to inspect all my medical records. I understand that medical records that reveal my identity will remain confidential except that they will be provided as noted above or as may be required by law.

Signature/thumb impression of the Patient  Signature/thumb impression of the Guardian

Signature of Impartial Witness*                  Date:.....................

I confirm that I have explained the nature and purpose of the above study to Mr./Mrs......

Signature of the Investigator: .......................... Date: ..................

* Signature of impartial witness required if patient is illiterate. Impartial witness will read the patient information sheet and patient consent form in a language understood by the patient