Study Participant Consent Addendum

A study comparing stereotactic radiosurgery, a type of targeted radiation therapy, to whole brain radiotherapy (using a technique that avoids the hippocampus) with memantine in people with cancer that has spread to the brain.

A PHASE III TRIAL OF STEREOTACTIC RADIOSURGERY COMPARED WITH HIPPOCAMPAL-AVOIDANT WHOLE BRAIN RADIOTHERAPY (HA- WBRT) PLUS MEMANTINE FOR 5-15 BRAIN METASTASES

Trial Code: **CE.7**

Sponsor: Canadian Cancer Trials Group

Background Information

You are taking part in a clinical trial which is looking at cancer somewhere else in your body that has spread to your brain.

Before beginning this research study, you signed an Informed Consent Form describing the study and your rights as a research participant. At that time, we explained that we would tell you about any new information that might affect your health, welfare, or willingness to stay in the trial. Since that time, new information has become available.

There are no other changes to the information in the consent form you previously received.

New Information

The new information relates to changes to the handling of blood and urine samples in this study.

Initially we told you that the researchers doing this study need to do tests on samples to better understand the nature of your cancer, and to see how patients respond to treatment.The purpose of this sample collection is to look for markers that might help predict which patients are most likely to be affected by the study treatment. This is called biomarker research (small “signature” molecules or indicators in your samples).

The researchers are also interested in examining the genes (DNA) found in your blood. The study of genes (DNA) is often called **genetic research**. Genes carry information about features, such as hair or eye colour. Researchers are interested in the way that changes in the genes found in your blood affect how your body responds to treatment. They may look at this DNA to learn about changes in the body that happen after you were born (**non-inherited**). For example, being in the sun too much can cause changes in cells that lead to skin cancer. Hereditary genetic testing (to find out if cancer runs in your family) will not be done on these samples.

We also told you that the samples of your tumour and blood would be sent to a laboratory at Queen's University, Kingston, Ontario and then onwards to another laboratory in Canada where they will be examined.

However, as the scientific knowledge and technology for this testing has improved, some of the tests are best conducted in specialized laboratories. If planned testing cannot be done at Queen's University, it may be done in another laboratory outside of Canada with the specific expertise needed but only under the direction of The Canadian Cancer Trials Group. Samples sent to another laboratory will only include a unique tumour bank code that is assigned upon receipt at the lab at Queen's University. The samples will not include participant study ID or initials and will be used completely, destroyed or returned to Queen's University. Personal information about you will not be sent with the samples and all results will be returned to The Canadian Cancer Trials Group.

We are therefore seeking your additional permission to send the samples of your tumour and blood to these laboratories if the planned testing cannot be done at Queen's University, or at another laboratory in Canada.

Contacts

If you have questions about taking part in this study, or if you suffer a research-related injury you should talk to your study doctor. Contact information for your study doctor is listed on the consent cover page.

For questions about your rights while in this study, call the Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

Signatures

- All of my questions have been answered.
- The new information has been fully explained to me.
- I agree to continue taking part in this study.

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)
(Required for initial consent only)