NRG ONCOLOGY
Radiation Therapy Oncology Group

RTOG 1114

(ClinicalTrials.gov NCT #: 01399372)

Phase II Randomized Study of Rituximab, Methotrexate, Procarbazine, Vincristine, and Cytarabine With and Without Low-Dose Whole-Brain Radiotherapy for Primary Central Nervous System Lymphoma

Amendment 10: September 19, 2019

RTOG 1114

Informed Consent Template for Cancer Treatment Trials (NCI Template Date: August 2009)
(English Language)

PHASE II RANDOMIZED STUDY OF RITUXIMAB, METHOTREXATE, PROCARBAZINE, VINCRISTINE, AND CYTARABINE WITH AND WITHOUT LOW-DOSE WHOLE-BRAIN RADIOTHERAPY FOR PRIMARY CENTRAL NERVOUS SYSTEM LYMPHOMA

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Participation in this study is entirely voluntary. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have primary central nervous system lymphoma (PCNSL).

Why is this study being done?

PCNSL is a disease that can be cured in less than half of patients with a combination of chemotherapy and standard brain radiation. Unfortunately, the combination of chemotherapy and standard brain radiation may cause serious damage to the brain. When this occurs, patients develop progressive memory and other neurologic problems that can be fatal. Because of this risk, many patients and physicians prefer to avoid radiotherapy. However, this results in higher risks of disease coming back. Many patients end up requiring radiotherapy anyway.

As a new alternative, radiotherapy has been used in significantly lower doses. In a previous study, this seemed to achieve the same rates of cure as full doses of radiotherapy but with much less risk of neurologic side effects.

The purpose of this study is to determine the effects, good and/or bad, of the combination of low-dose whole brain radiation plus chemotherapy on you and your tumor compared with chemotherapy alone, to find out which is better. In this study, you will either get the experimental treatment (chemotherapy plus reduced-dose whole brain radiation) or chemotherapy alone.

How many people will take part in the study?

About 89 people will take part in this study.

What will happen if I take part in this research study?

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

If you are in group 1 (often called "Arm A") …
You will receive chemotherapy with rituximab, methotrexate (MTX), procarbazine, and vincristine. You will receive the chemotherapy for four 28-day cycles (for approximately 4 months total) on several days each cycle as follows:

- Day 1: Rituximab (given by vein, as an outpatient). The first treatment will last approximately 5 hours, but subsequent treatments may be shorter, according to your physician.

- Day 2: MTX and vincristine (vincristine is given during cycles 1 and 2 only). These will be given by vein in the hospital. MTX is given over 2 hours and vincristine is given over approximately one minute. You will need to stay in the hospital for approximately 3-5 days, until the MTX is eliminated from your body.
- Days 2-8: Procarbazine (given by mouth, once a day, on an empty stomach). While you are on procarbazine:
    - You should not to drink alcoholic beverages while you are taking procarbazine since it may cause nausea, vomiting, and serious flushing.
    - You will need to avoid foods with high tyramine content such as wine, yogurt, ripe cheese and bananas.
    - You will need to avoid over-the-counter drug preparations containing antihistamines or sympathomimetic drugs (drugs are used to treat low blood pressure and cardiac arrest, reduce nasal stuffiness, delay premature labor, and treat other things). Ask your physician or pharmacist before using any over-the-counter drug.
    - You will be asked to keep a diary where you will record the number of procarbazine pills you take each day. At your next clinic visit, you will be asked to bring the diary and the procarbazine bottle with the remainder of pills left.
- Day 15: Rituximab (given by vein, as an outpatient)
- Day 16: MTX and vincristine (vincristine is given during cycles 1 and 2 only). These will be given by vein in the hospital, as described above.

When you have finished receiving the four cycles of chemotherapy with rituximab, MTX, procarbazine, and vincristine, you will receive two 28-day cycles (approximately 2 months total) of additional chemotherapy on several days each cycle as follows:

- Days 1 and 2: Cytarabine (given by vein as an outpatient). Cytarabine is given over 3 hours.

If you are in group 2 (often called "Arm B")…
You will receive chemotherapy with rituximab, methotrexate (MTX), procarbazine, and vincristine as described above.

If your tumor has not grown during the chemotherapy, you will then receive the reduced-dose radiation therapy to your brain daily for a total of 13 days. If however your tumor has grown, your doctor will discuss other treatment alternatives with you.

When you have finished the radiation therapy, you will receive chemotherapy with cytarabine as described above.

Before you begin the study …

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- MRI of your brain
- CT scan of your chest, abdomen, and pelvis
- History and physical examination
- Blood tests for bone marrow function, liver function, and renal function
- HIV test
- Pregnancy test (if are a woman of childbearing potential)

In addition, when you enter the study, you will need to agree to permit your doctors to send the block of tumor tissue obtained at the time of your brain tumor surgery to a central pathology site. There, a pathologist will confirm that the tumor is the type of tumor being studied in this trial.

During the study … (1/31/13)

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

Within 2 weeks before starting treatment

- Blood tests for bone marrow function, liver function, renal function, electrolyte levels,
- Urine test
- Chest X-ray
- MRI scan of your brain
- History and physical examination, including neurologic examination, assessment of ability to carry out activities of daily living, and history of corticosteroid use
  An examination by an eye doctor, to see if there are cancer cells in the eyes

Within 6 weeks before starting treatment

- A spinal tap will be required, for examination of the cerebrospinal fluid (a fluid that bathes the brain and the spinal cord). This procedure is routinely done to see if there are cancer cells in cerebrospinal fluid. You will receive local anesthesia for that.
- A bone marrow biopsy will be required, to look for cancer cells in the bone marrow.
- A blood test for hepatitis B screening is recommended.

Every week during treatment with rituximab, methotrexate, procarbazine and vincristine

- Blood tests for bone marrow function

Every 2 weeks during treatment with rituximab, methotrexate, procarbazine and vincristine

- History and physical examination, including neurologic examination
- Blood test to determine the level of methotrexate in your blood (and then daily until the methotrexate is cleared)
- Blood tests for liver function, renal function, and electrolyte levels (and then daily until the methotrexate is cleared)

Every other month during treatment with rituximab, methotrexate, procarbazine and vincristine

- MRI scan of your brain
- Assessment of ability to carry out activities of daily living
- History of corticosteroid use

Every week during cytarabine treatment

- Blood tests for bone marrow function

Every month during cytarabine treatment

- History and physical examination, including neurologic examination
- Assessment of ability to carry out activities of daily living
- Blood tests for liver function, renal function, and electrolyte levels

Once during cytarabine treatment (for patients assigned to Arm B/whole brain radiation treatment)

- MRI scan of your brain
- History of corticosteroid use

When you are finished taking all of the chemotherapy…(1/27/15)

When you are finished with the treatment, you will need to come back to clinic for the following tests and procedures. They are part of regular cancer care:

Every 2 months for the first 2 years, then every 6 months for the next 3 years

- History and physical examination, including neurologic examination
- MRI scan of your brain
- History of corticosteroid use
- Spinal tap (if you previously had cancer cells in the spinal fluid) will be obtained every 2 months until you have 2 MRIs showing no sign of disease
- An examination by an eye doctor, to see if there are cancer cells in the eyes (if you previously had evidence of cancer cells in the eyes)

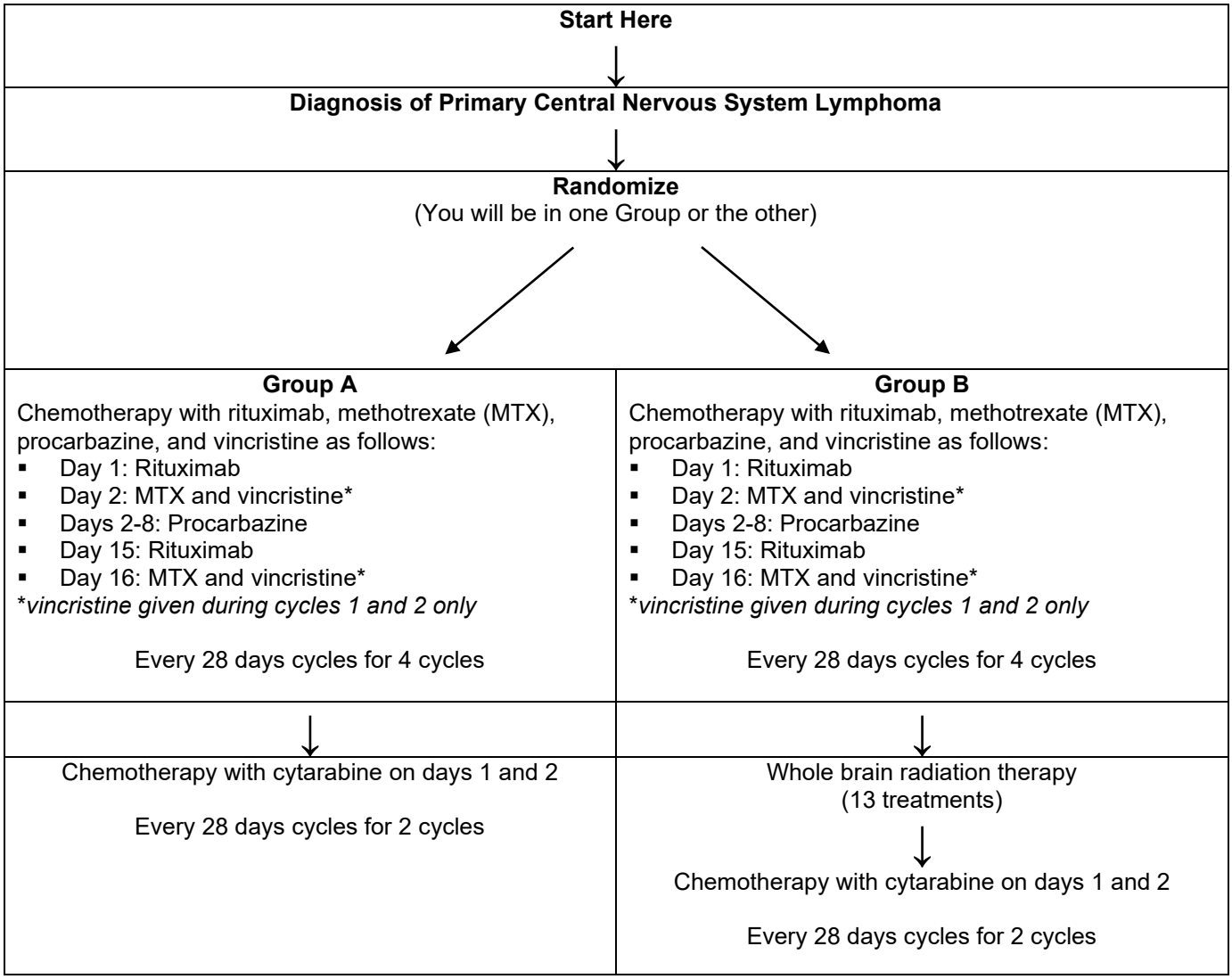
You will need these tests and procedures that are either being tested in this study or being done to see how the study is affecting your body:

Every 2 months for 3 years, starting at the end of the first two years

- Telephone call: a study assistant will call you and ask questions about your disease status and other treatments you have received since your last visit to the doctor, if any. We may collect medical records, if you have received additional treatments.

Study Plan

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



How long will I be in the study?

You will receive treatment for about 6-7 months. You will be seen in follow-up visits beginning 4 weeks after the start of cytarabine. You will be seen every 2 months for the first 2 years and every 6 months for the next 3 years.
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Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the chemotherapy and/or radiation can be evaluated by him/her. Another reason to tell your study doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study? (8/25/15)

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the chemotherapy and/or radiation. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Possible Side Effects of Rituximab (Table Version Date: June 16, 2014)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Rituximab, more than 20 and up to 100 may have:
• Nausea • Chills, fever • Reaction during or following infusion of the drug • Infection, especially when white blood cell count is low • • Numbness and tingling of the arms and legs • Tiredness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Rituximab, from 4 to 20 may have:
• Anemia which may require blood transfusions • Bruising, bleeding • Abnormal heartbeat • Heart attack or heart failure which may cause shortness of breath, swelling of ankles, and tiredness • Sores in eye • A tear or a hole in the stomach that may require surgery • Diarrhea, vomiting • Pain • Swelling of the body • Hepatitis which may cause yellow eyes and skin • Dizziness, headache • Kidney damage which may require dialysis • Cough • Scarring of the lungs • Stuffy nose • Blockage of internal organs which may cause shortness of breath, wheezing, vomiting • Increased sweating • Itching, rash, blisters on the skin • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body • Low blood pressure which may cause feeling faint

RARE, AND SERIOUS In 100 people receiving Rituximab , 3 or fewer may have:
• Damage to the brain caused by a virus which may result in tiredness, weakness, changes in thinking, and disability. This is called progressive multifocal leukoencephalopathy (PML). • Heart stops beating

Additional information

In people who have ever been infected with hepatitis B virus, there is a risk that the virus can flare up during treatment with drugs that affect your immune system, such as rituximab. This could lead to liver failure or even

death. The risk of hepatitis B virus flaring up may continue for several months after you stop taking rituximab. If you become jaundiced (yellowing of the skin and eyes) or develop viral hepatitis while taking rituximab or after stopping treatment, you should tell your study doctor immediately. Your study doctor will discuss this risk with you and explain what testing is recommended to check for hepatitis.

Other symptoms may occur, usually within 30 to 120 minutes of beginning the first infusion, and include nausea, vomiting, itching, hives, swelling of the lips or throat, lowered blood pressure, increased blood pressure, headache, difficulty breathing, throat irritation, running nose, rash, decreased appetite, muscle aches, or dizziness. These symptoms generally improve with each treatment and respond to slowing or interrupting the therapy and treating the symptoms.

Possible Side Effects of Methotrexate (Table Version Date: October 8, 2013)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Methotrexate, more than 20 and up to 100 may have:
• Increased risk of sunburn, rash

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Methotrexate, from 4 to 20 may have:
• Scarring of the lungs which may cause shortness of breath • Fluid around heart • Internal bleeding which may cause belly pain, black tarry stool, blood in vomit • Nausea, vomiting, diarrhea • Sores in mouth which may cause difficulty swallowing • Liver damage which may cause yellowing of eyes and skin • Scarring of the liver • Hepatitis • Hair loss • Bruising, bleeding • Infection, especially when white blood cell count is low • Anemia which may cause tiredness, or may require transfusion • A new cancer resulting from treatment of earlier cancer • Confusion • Seizure • Kidney damage which may require dialysis • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body • Blood clot which may cause swelling, pain, shortness of breath •

RARE, AND SERIOUS In 100 people receiving Methotrexate, 3 or fewer may have:
• Dizziness • Damage to the brain which may cause tiredness, changes in thinking

Possible Side Effects of Procarbazine (Table Version Date: October 8, 2013)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Procarbazine, more than 20 and up to 100 may have:
• Nausea, vomiting

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Procarbazine, from 4 to 20 may have:
• Anemia which may cause tiredness, or may require blood transfusions • Infection, especially when white blood cell count is low

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Procarbazine, from 4 to 20 may have:
• Bruising, bleeding • A new cancer resulting from treatment of earlier cancer • Muscle weakness • Confusion • Sores in mouth which may cause difficulty swallowing • Diarrhea

RARE, AND SERIOUS In 100 people receiving Procarbazine, 3 or fewer may have:
• None

NOTE: You will be required to avoid some foods, such as alcohol, some cheeses and banana that can cause high blood pressure or nausea and vomiting when eaten with procarbazine. You will be given written diet instructions.

Possible Side Effects of Vincristine (Table Version Date: May 28, 2013)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Vincristine, more than 20 and up to 100 may have:
• Constipation • Hair loss • Pain or redness at the site of injection • Numbness and tingling of fingers or toes • Headache, jaw pain and/or muscle pain • Weakness and difficulty walking • Swelling of lower legs

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Vincristine, from 4 to 20 may have:
• Anemia which may cause tiredness, or may require transfusion • Drooping eyelids • Hoarseness

RARE, AND SERIOUS In 100 people receiving Vincristine, 3 or fewer may have:
• Seizure

Possible Side Effects of Cytarabine (Table Version Date: July 27, 2015)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cytarabine, more than 20 and up to 100 may have:
• Blood clot • Rash • Swelling in the rectum which may cause rectal pain • Diarrhea, loss of appetite, nausea, vomiting • Sores in mouth which may cause difficulty swallowing • Anemia which may cause tiredness, or may require blood transfusions • Fever

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cytarabine, from 4 to 20 may have:
• Infection, especially when white blood cell count is low

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cytarabine, from 4 to 20 may have:
• Bruising, bleeding • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Numbness and tingling of the arms and legs • Severe blood infection • Kidney damage which may cause swelling, may require dialysis • Headache • Dizziness • Chest pain • Hair loss • Liver damage which may cause yellowing of skin or eyes • Swelling and redness of the eye

RARE, AND SERIOUS In 100 people receiving Cytarabine, 3 or fewer may have:
• Coma

Possible Side Effects of Whole Brain Radiation

COMMON, SOME MAY BE SERIOUS In 100 people receiving Whole Brain Radiation, more than 20 may have:
• Scalp redness or soreness • Hair loss, which may be temporary or permanent • Short term hearing loss • Tiredness • Temporary increase of brain tumor symptoms such as headaches, seizures, or weakness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Whole Brain Radiation, from 4 to 20 may have:
• Change in thinking patterns • Permanent hearing loss • Cloudiness of the eye, visual disturbancesChange in behavior • Nausea, vomiting • Dry mouth, changes in taste

RARE, AND SERIOUS In 100 people receiving Whole Brain Radiation, 3 or fewer may have:
• Damage to the brainVisual loss • A new cancer resulting from treatment of earlier cancer

Reproductive risks: You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. . A pregnancy test will be required if you are a woman of childbearing potential.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While researchers hope that the addition of whole brain radiation to chemotherapy will be more useful against cancer compared to chemotherapy alone, there is no proof of this yet. We do know that the information from this study will help researchers learn more about radiation and chemotherapy as a treatment for cancer. This information could help future cancer patients.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Talk to your study doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private? (4/17/14)

Data are housed at NRG Oncology Statistics and Data Management Center in a password-protected database. We will do our best to make sure that the personal information in your medical record will be kept private.

However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- NRG Oncology
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[Note to Local Investigators: The NCI has recommended that HIPAA regulations be addressed by the local institution. The regulations may or may not be included in the informed consent form depending on local institutional policy.]

What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

You will not be paid for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, _____ *[investigator's name(s)],* if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call him/her at _____ *[telephone number].*

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

A Data Safety Monitoring Board will be regularly meeting to monitor safety and other data related to phase I, I/II, and II NRG Oncology clinical trials. The Board members may receive confidential patient information, but they will not receive your name or other information that would allow them to identify you by name.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor _____ *[name(s)]* at _____ *[telephone number].*

For questions about your rights while taking part in this study, call the _____ *[name of center]* Institutional Review Board (a group of people who review the research to protect your rights) at _____ *(telephone number). [Note to Local Investigator: Contact information for patient representatives or other individuals in a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can be listed here.]*

Please note: This section of the informed consent form is about additional research that is being done with people who are taking part in the main study. You may take part in this additional research if you want to. You can still be a part of the main study even if you say 'no' to taking part in this additional research.

You can say "yes" or "no" to each of the following studies. Below, please mark your choice for each study.

Consent Form for Quality of Life Study/Neurocognitive Function Study (8/25/15)

We want to know your view of how your life has been affected by cancer and its treatment. This "quality of life/neurocognitive function" sub-study looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities. Patients participating in the main part of the study will be asked to participate by having their symptoms, quality of life, and neurocognitive function evaluated.

This information is very important and will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer.

If you agree to participate in this part of the study, you will be asked to complete a neurocognitive assessment and two quality of life questionnaires at the following times throughout the main part of the study:

- Before you begin treatment;
- During Treatment with R-MP(V) on d28 of cycle 4 and every 6 months for the next 5 years.

The quality of life questionnaires and the symptom assessment will take approximately 30 minutes to complete. If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

If you decide to take part in this sub-study, the only thing you will be asked to do is fill out the questionnaires and undergo the assessment. You may change your mind about completing the questionnaires and undergoing the assessment at any time. You may stop participating in this part of the study at any time without affecting your care or your participation in the main part of the study.

Just like in the main study, we will do our best to make sure that your personal information will be kept private.

Please circle your answer.

I choose to take part in the Quality of Life/Neurocognitive Function Study. I agree to fill out the Quality of Life/Neurocognitive Function Questionnaires.

YES NO

Consent Form for Use of Tissue for Research

About Using Tissue and Other Specimens for Research (1/27/25)

To determine if you have cancer, you have had, or are going to have, the following procedures:

- A biopsy (or surgery) to remove tumor tissue
- A lumbar puncture to remove cerebrospinal fluid
- A bone marrow or eye biopsy to remove tissue

The results of these tests will be given to you by your doctor and will be used to plan your care.

We would like to keep some of the tissue and cerebrospinal fluid that is left over for future research. If you agree, this material will be kept and may be used in research to learn more about cancer and other diseases. An information sheet about using tissue for research is available at http://www.cancer.gov/cancertopics/factsheet/clinicaltrials/donating-tissue-research

As a result of your participation in the trial, you will have blood tests performed before you start treatment. We would like to collect for future research an extra blood sample (about one tablespoon) the next time you have a blood test performed. If you agree, the extra blood sample will be kept and may be used in research to learn more about cancer and other diseases.

In addition, at your next office visit in conjunction with the trial, we would like to collect some cells from inside your cheek. If you agree, the study staff would gently brush the inside of your cheek with a soft toothbrush. The cells will be kept and may be used in research to learn about cancer and other diseases.

The specimens collected from your body may be helpful for research whether you do or do not have cancer. The research that may be done with the specimens is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your specimens will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us keep the specimens for future research is up to you. No matter what you decide to do, it will not affect your care or your participation in the main part of the study.

If you decide now that your specimens can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use the material. You can do so by writing to your study doctor. Then any material that remains will no longer be used for research and will either be returned to the institution that submitted it or will be destroyed.

In the future, people who do research may need to know more about your health. While the doctor/institution may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if your specimens are used for this kind of research, the results will not be put in your health records.

Your specimens will be used only for research and will not be sold. The research done with your specimens may help to develop new treatments for cancer in the future.

Benefits

The benefits of research using bodily specimens include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

Risks (10/28/13)

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included. The samples are given a code to protect your privacy before they are used. Any related information given to researchers will also be coded. Researchers will receive the code instead of any information that might directly identify you.

There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives.

Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded. Research results will not be returned to you or your doctor.

Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, life insurance companies may charge a higher rate based on this information.

Many states have laws to protect against genetic discrimination *[list appropriate state information if your state or locality has such laws]*. Additionally, a federal law called the Genetic Information Non-Discrimination Act, or GINA, is in effect. This law prohibits health insurer or employer discrimination. The law does not include other types of misuse by life insurance, disability, or long term care insurance. To learn more about the GINA Law, please ask *[Note to local investigator: Contact information for patient representatives or other individuals in a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can be listed here.]*

Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at _____ [IRB's phone number].

No matter what you decide to do, it will not affect your care.

1. My specimens may be kept for use in research to learn about, prevent, or treat cancer, as follows:
   - Tumor tissue ☐Yes ☐ No
   - Bone marrow/eye biopsy ☐Yes ☐ No
   - Cerebrospinal fluid ☐Yes ☐ No
   - Blood ☐Yes ☐ No
   - Cells from inside my mouth ☐Yes ☐ No

2. My specimens may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease), as follows:
   - Tumor tissue ☐Yes ☐ No
   - Bone marrow/eye biopsy ☐Yes ☐ No
   - Cerebrospinal fluid ☐Yes ☐ No
   - Blood ☐Yes ☐ No
   - Cells from inside my mouth ☐Yes ☐ No

3. Someone may contact me in the future to ask me to take part in more research.
   ☐Yes ☐ No

Where can I get more information? (4/23/12)

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/

- **For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/**
- **For NCI's general information about cancer, go to http://www.cancer.gov/cancertopics/**

You will get a copy of this form. If you want more information about this study, ask your study doctor.

Signature

I have been given a copy of all _____ *[insert total of number of pages]* **pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.**

Participant _____

Date _____