# NRG ONCOLOGY

# NRG-GU003

*(ClinicalTrials.gov NCT #:* **03274687***)*

## A RANDOMIZED PHASE III TRIAL OF HYPOFRACTIONATED POST-PROSTATECTOMY RADIATION THERAPY (HYPORT) VERSUS CONVENTIONAL POST-PROSTATECTOMY RADIATION THERAPY (COPORT)

**Amendment 1: April 26, 2019**

**NRG-GU003 Consent Form**

**Study Title for Study Participants:** Testing reduced duration radiation therapy versus standard duration radiation therapy for prostate cancer

**Official Study Title for Internet Search on http://www.ClinicalTrials.gov**
NRG-GU003: A Randomized Phase III Trial of Hypofractionated Post-Prostatectomy Radiation Therapy (HYPORT) versus Conventional Post-Prostatectomy Radiation Therapy (COPORT)

## What is the usual approach to my prostate cancer?

You are being asked to take part in this research study because you have prostate cancer treated with surgery and 1) not all of the cancer was removed with surgery or 2) your prostate specific antigen level (PSA) level indicates your cancer has persisted or returned. People who are not in a study are usually treated with radiation therapy for seven weeks with or without and hormonal drugs. For patients who receive the usual approach for this cancer, on average 65 patients out of 100 are free of cancer at five years.

## What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above without being in a study
- you may choose to take part in a different study, if one is available
- or you may choose not to be treated for cancer

## Why is this study being done?

The purpose of this study is to compare any good and bad effects of using radiation therapy at a higher dose given with each radiation treatment (fraction) for a shorter length of time, called hypofractionated radiation therapy, to radiation therapy given for the standard length of time. The study will compare side effects of the study radiation given at a higher dose for a shorter length of time with those of the usual radiation treatment. The study will also compare how well the cancer is controlled between the two treatments. This study will allow the researchers to know whether this study approach is the same or worse than the usual approach. The study approach is considered the experimental treatment in this study. There will be 282 people taking part in this study.

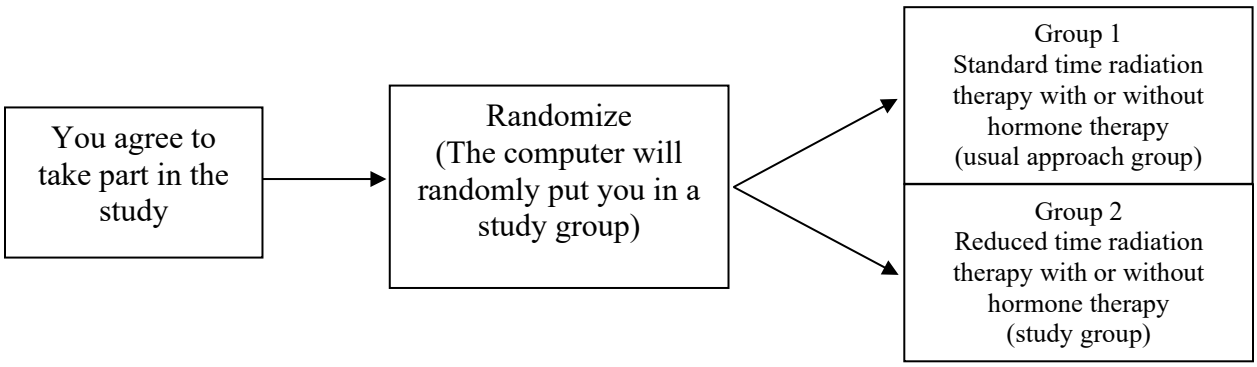
## What are the study groups?

This study has two study groups.

- Group 1 will get radiation therapy for the usual length of time (7 weeks) at the usual radiation dose with each treatment (fraction). People in Group 1 also may receive hormone therapy if their doctor recommends for up to 6 months.
- Group 2 will get radiation therapy for a shorter length of time (5 weeks) at a higher radiation dose with each treatment (fraction). People in Group 2 also may receive hormone therapy if their doctor recommends for up to 6 months.

A computer will by chance assign you to a treatment group in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the other. Neither you nor your doctor can choose which group you will be in. You will have an equal chance of being placed in either group.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.




## How long will I be in this study?

You will receive the study treatment for about 7 weeks if you are in Group 1 and for 5 weeks if you are in Group 2. If your doctor recommends hormone therapy, you will receive the hormone therapy for up to 6 months. After you finish the study treatment, your doctor will continue to watch you for side effects and follow your condition indefinitely.

## What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are two quality of life questionnaires that you will need to complete to take part in this study.

Before you begin the study:
You will be asked to fill out two forms with questions about general quality of life and your urinary and bowel habits, as well as your sexual function and hormonal function, like regulating weight, strength and muscle tone, mood, and sex drive. You may feel uncomfortable answering some of the questions, and you can skip any you do not want to answer. Each form will take about 15 minutes to complete. Researchers will use this information to better understand how patients feel during treatments and what effects the treatments are having.

After you complete radiation therapy:
You will be asked to fill out the two forms about your symptoms at five more times:

- When you finish radiation therapy
- At 6 months from the start of treatment
- At 1 year from the start of treatment
- At 2 years from the start of treatment
- At 5 years from the start of treatment

Neither you nor your health care plan/insurance carrier will be billed for your participation in the quality of life questionnaires.

If you agree to the optional tissue, blood, and urine collection for biobanking as described later in this form, you will be asked to submit tumor tissue from your previous biopsy. Also, you will be asked to submit urine and have blood drawn before, during and after treatment. This is described in detail in the section on optional studies.

## What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- The study approach may not be better, and could possibly be worse, than the usual approach for your cancer.
- You may lose time at work or home and spend more time in the hospital or doctor's office than usual.
- You may be asked sensitive or private questions which you normally do not discuss.

The radiation therapy with or without hormone therapy used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the radiation therapy with or without hormone therapy.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study treatment to try to reduce side effects.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Study Group 1 and Group 2 - Possible side effects of conventional radiation therapy, the usual radiation therapy used for this type of cancer and of hypofractionated radiation therapy, the research radiation therapy used in this trial:

Possible Side Effects of Prostate Radiation (excluding pelvis)

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving prostate radiation, more than 20 and up to 100 may have: |
|---|
| • Need to urinate more often<br>• Urgency with urination<br>• Slower urinary flow |

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving prostate radiation, more than 20 and up to 100 may have: |
|---|
| • Pain, including with urination and/or bowel movements<br>• Hair loss in the treatment area, may be permanent<br>• Tiredness<br>• Abnormal sexual function, may be permanent |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving prostate radiation, from 4 to 20 may have: |
|---|
| • Chronic bowel/bladder symptoms as described above<br>• Blood in urine<br>• Inability to control urine, inability to control bowel movements<br>• Diarrhea<br>• Bleeding of the rectum<br>• Swelling, redness, rash, skin changes, or itching in the area of radiation |

| **RARE, AND SERIOUS**<br>In 100 people receiving prostate radiation, 3 or fewer may have: |
|---|
| • Blockage of internal organs that may require surgery<br>• Damage to or bleeding of the rectum requiring surgery<br>• A new cancer resulting from treatment of earlier cancer |

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

*Reproductive risks:* You should not father a baby nor donate sperm while in this study. The radiation therapy with or without hormone therapy used in this study could be very damaging to an unborn baby. If your partner becomes pregnant while you are participating in this study, immediately notify your study doctor. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

## What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if radiation therapy given at a higher radiation dose with each treatment (fraction) over a shorter length of time (5 weeks) is better than the usual approach of radiation therapy given at a lower radiation dose with each treatment (fraction) over the standard length of time (7 weeks). This study may or may not help you. This study will help researchers learn things that will help people in the future.

## Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

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

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest

- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

## What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

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

## What are the costs of taking part in this study?

You and/or your health plan/insurance company will need to pay for the radiation therapy, hormone therapy (if given), and all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

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

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

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

## Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- NRG Oncology
- Other organizations in the National Clinical Trials Network (NCTN): Alliance for Clinical Trials in Oncology (ALLIANCE), ECOG-ACRIN Cancer Research Group (ECOG-ACRIN), SWOG, and IROC

- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

## Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

## Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

## ADDITIONAL STUDIES SECTION:

## This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say 'no' to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

## Optional Sample Collections for Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part, a sample of tissue from your previous biopsy will be collected. Also, samples of blood and urine taken before, during, and after your treatment on the study will be collected. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by NRG Oncology and supported by the National Cancer Institute.

## WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) A sample from the tissue that was collected at the time of your surgery will be sent to the Biobank.
2) About 2-3 tablespoons of blood will be collected from a vein in your arm at three times: before, at the end of radiation treatment, and 1 year after you receive treatment.
3) A urine sample will also be collected at two times: before and at the end of radiation treatment
4) Your sample and some related health information may be stored in the Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
5) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
6) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
7) 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.

## WHAT ARE THE POSSIBLE RISKS?

1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
2) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
3) 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.]*.

## HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to you name will be kept separate from your sample and health information. Any Biobank and NRG Oncology staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom NRG Oncology sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

## WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

## ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

## WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

## WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

Please circle your answer to show whether or not you would like to take part in each option (*include only applicable questions)*:

**SAMPLES FOR FUTURE RESEARCH STUDIES:**

My samples and related information may be kept in a Biobank for use in future health research.

YES NO

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

## My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional studies where I circled 'yes'.

Participant's signature_____

Date of signature_____

Signature of person(s) conducting the informed consent discussion_____

Date of signature_____