NCI Community Oncology Research Program – Kansas City (NCORP-KC)

NRG-GU002 Consent Form

Study Title for Study Participants: Testing if radiation, hormone therapy, and docetaxel versus radiation and hormone therapy after prostectomy decreases cancer recurrence

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
NRG-GU002: Phase II-III Trial Of Adjuvant Radiotherapy and Androgen Deprivation Following Radical Prostatectomy With or without Adjuvant Docetaxel

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 that was surgically removed, but you have certain risk factors for which additional therapy with radiation and androgen deprivation therapy (hormonal therapy to decrease testosterone levels) is routinely given. People who are not in a study are usually treated following surgery with radiation therapy and hormonal therapy. There are several FDA-approved chemotherapy drugs that are commonly used along with the radiation therapy but not as part of routine care for people with prostate cancer such as yours which has not metastasized (spread to other sites in your body). For patients who receive the usual approach for this cancer, about *33* out of 100 are free of cancer at three 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
- you may choose to take part in a different study, if one is available
- or you may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

Why is this study being done?

The purpose of this study is to compare any good and bad effects of using docetaxel *along with* the radiation therapy and hormone suppression therapy to using radiation and hormone suppression therapy alone in men with a high chance of prostate cancer recurrence after surgically removing the prostate. Docetaxel is FDA-approved for prostate cancer that has spread and does not respond to hormone suppression. In this study, docetaxel is being used off-label. Off-label means that the FDA has not yet approved docetaxel for this type of prostate cancer that has not spread. The addition of docetaxel to the usual *radiation and hormone suppression therapy* could shrink your cancer or prevent it from returning but it could also cause side effects. This study will allow the researchers to know whether this different approach is better, the same, or worse than the usual approach. To be better, the study approach should decrease the chance of your cancer progressing by 30% or more compared to the usual approach. There will be about 612 men taking part in this study.

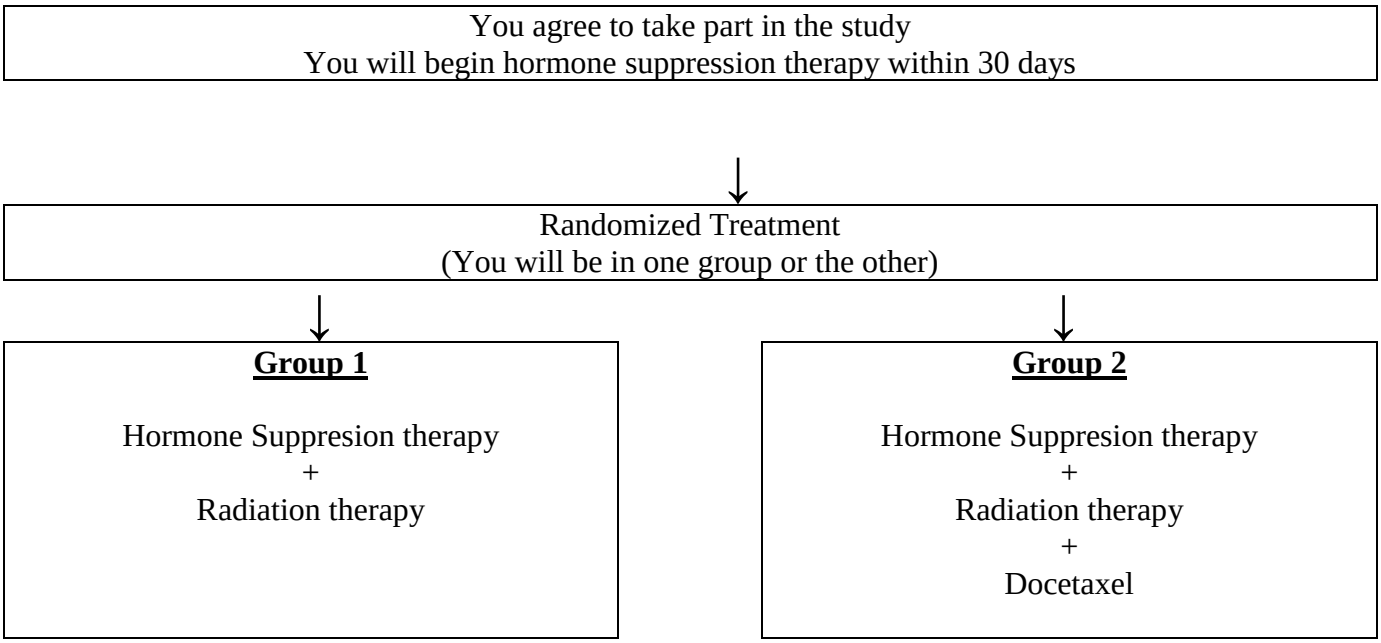
What are the study groups?

All study participants will begin hormone suppression therapy within 30 days from study enrollment. Hormone suppression requires that you receive two drugs, an LHRH analog and an antiandrogen, for 6 months in order to decrease the level of male hormones. There are a variety of LHRH drugs that are given in different ways and at different doses. Your study doctor will discuss the different LHRH options with you and select the drug best for you. The antiandrogen drug, bicalutamide, is a pill taken by mouth once a day. If a dose is missed, you will not make it up. You will complete a Patient Pill Diary to help you and your study doctor keep track of the doses you take to ensure accurate dosing. After you begin hormone suppression, you will be assigned to one of two study groups.

This study has two study groups.

- Group 1 will continue to receive hormone suppression therapy and will get the usual radiation therapy used for this type of cancer
- Group 2 will continue to receive hormone suppression therapy and will get the usual radiation therapy used for this type of cancer **followed by** 6 doses of the chemotherapy drug, docetaxel. Docetaxel begins 4-6 weeks after the end of radiation therapy and will be given IV (through a vein) over the course of 1 hour every 3 weeks.

A computer will by chance assign you to treatment groups 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. You will have an equal chance of being placed in either group.



How long will I be in this study?

You will receive hormone suppression therapy for a total of 6 months, starting within 30 days after study enrollment. You will begin the radiation therapy about 8 weeks after the start of hormone suppression therapy. You will receive radiation for 7 1/2 weeks. If you are assigned to Group 2, you will begin docetaxel 4-6 weeks after the end of radiation therapy. You will receive docetaxel every 3 weeks for a total of 6 doses. You will be

seen by your doctor weekly while you are receiving radiation therapy and before each chemotherapy treatment. After you complete treatment, you will be seen by your doctors every 3 months for 2 years, then every 6 months for 3 years, and then yearly.

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 some extra tests that you will need to have if you take part in this study.

Before you begin treatment on the study:
Small pieces of cancer tissue removed at the time of your surgery will be taken for the study *before you begin treatment on this study.* This sample is required in order for you to take part in this study because the research on the sample is an important part of the study. Your study doctor will need to send this tissue to a central pathology site. There, the tumor tissue from your previous biopsy will be tested for certain genetic markers. The result of this test is called the DECIPHER POST-OP score. This score may provide useful information about your response to the treatment. The DECIPHER score does not impact the treatment you will receive for your cancer during the study. Your doctor will receive these results and will discuss them with you. *If any of the tissue is left over and you chose to give your consent, it will be stored for biobanking. Biobanking will be discussed in the section on optional studies.*If your doctor already sent your tumor tissue for this test and you have a Decipher risk score, the Decipher risk score report will need to be submitted for review. A tissue sample is not required if you already have a Decipher risk score.

Before you begin, during, and after you finish treatment on this study:
If you consent to optional biobanking, blood and urine will be collected. Biobanking will be discussed further in the section on optional studies.
Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information.

Neither you nor your health care plan/insurance carrier will be billed for the collection of the tissue that will be used for this study.

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:

- 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 study approach may not be better, and could possibly be worse, than the usual approach for your cancer.
- There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. (For non-U.S. participants, please verify the existence of such laws before including the following sentence.) There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

- There can also be a risk in finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study.

The radiation therapy and drugs 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 and study approach.

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 drugs to try to reduce side effects.

In addition, some medications or herbal supplements (for example, St. John's wort) that you are taking may impact how well the study medications work. It is important that you give your study doctor a complete list of your medications, including herbal supplements, prior to beginning study treatment. Some medications may need to be delayed while you are receiving the study treatment.

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 Groups 1 and Groups 2: Possible side effects of prostate radiation (excluding pelvis), **which is the usual approach for this type of cancer:**

COMMON, SOME MAY BE SERIOUS In 100 people receiving prostate radiation, more than 20 and up to 100 may have:
• Need to urinate more often • Urgency with urination • Slower urinary flow • Pain, including with urination and/or bowel movements • Hair loss in the treatment area, may be permanent • Tiredness • Abnormal sexual function, may be permanent

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

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

Study Groups 1 and Group 2 - Possible side effects of hormone suppression therapy, **which is the usual approach for this type of cancer:**

Hormone suppression therapy requires that you receive two types of drugs. There are a number of different drugs that can be used for hormone suppression therapy. You and your doctor will choose the two drugs best for you. The risks below describe the side effects of hormone suppression therapy, in general. Your study doctor will discuss any side effects specific to the drugs selected for your hormone suppression therapy.

COMMON, SOME MAY BE SERIOUS In 100 people receiving hormone suppression therapy, more than 20 and up to 100 may have:
• Hot flashes • Abnormal sexual function • Change in sexual desire • Tiredness • Breast tenderness or enlargement • Diarrhea • Loss of bone tissue

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving hormone suppression therapy, from 4 to 20 may have:
• Anemia, which may require blood transfusions • Headache • Pain • Liver damage which may cause yellowing of eyes and skin • Swelling of the body • Infection • Nausea • Bruising, bleeding • Mood swings, depression • Increased urination • Weight gain • Shrinkage of the testis • Broken bone

RARE, AND SERIOUS In 100 people receiving hormone suppression therapy, 3 or fewer may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Heart attack, heart failure which may cause shortness of breath, swelling of ankles, and tiredness • Diabetes

Study Group 2 - In addition to side effects outlined above, people who are in Group 2 may also experience the possible side effects of docetaxel listed below

COMMON, SOME MAY BE SERIOUS In 100 people receiving Docetaxel, more than 20 and up to 100 may have:
• Swelling of the body • Hair loss • Change in nails • Rash, itching • Vomiting, diarrhea, nausea, constipation • Sores in mouth which may cause difficulty swallowing • Infection, especially when white blood cell count is low • Anemia which may require blood transfusions • Bruising, bleeding • Tiredness • Numbness and tingling of the arms and legs • Fever • Absence of menstrual period* • Swelling and redness of the arms, leg or face • Pain • Watering, itchy eyes

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Docetaxel, from 4 to 20 may have:
• Severe skin rash with blisters and peeling which can involve inside of mouth and other parts of the body • Belly pain • Kidney damage which may require dialysis • Blood clot which may cause swelling, pain, shortness of breath • Abnormal heart rate • Shortness of breath, wheezing • Chest pain

RARE, AND SERIOUS In 100 people receiving Docetaxel, 3 or fewer may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Cancer of bone marrow (leukemia) caused by chemotherapy

**Not applicable to this study*

Patients should be aware that docetaxel may cause them to become intoxicated from the alcohol it contains. Patients should avoid driving, operating machinery, or performing other activities that are dangerous within one to two hours after the infusion of docetaxel. In addition, some medications, such as pain relievers and sleep aids, may interact with the alcohol in the docetaxel infusion and worsen the intoxicating effects.

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 while in this study. The *radiation therapy and drug 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.

Risks associated with DECIPHER POST-OP testing:
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. Please see **What are the possible risks?** section under **Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies.**

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

It is not possible to know at this time if the study approach is better than the usual approach so 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 Central Institutional Review Board at 888-657-3711.

What are the costs of taking part in this study?

You and/or your health plan/insurance company will need to pay for all of the 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. There are no costs to you or your insurance company for the Decipher testing. 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:

- The study sponsor, 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), and SWOG
- 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.
- GenomeDx Biosciences

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 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 you or 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 Laboratory Studies and/or 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, leftover tumor tissue, blood and urine will be collected. If your tumor sample was submitted for a Decipher risk score as part of the main study, any leftover tissue will be collected. If your tumor sample was not submitted as part of the main study, leftover tissue from your cancer surgery (biopsy) 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) About *4 1/2* tablespoons of blood will be collected from a vein in your arm and sent to the Biobank at three times at the same time that blood is collected as part of your participation in the main part of this study: (1) Before your start treatment, (2) during week 4 of your treatment, and (3) at your first follow-up visit after you complete treatment.
2) About 2 tablespoons of urine will be collected and sent to the Biobank at three times at the same time that urine is collected as part of your participation in the main part of this study: (1) Before your start treatment, (2) during week 4 of your treatment, and (3) at your first follow-up visit after you complete treatment.
3) Any leftover tissue from your biopsy after performing the required DECIPHER test also will be sent to the Biobank. If you already had a DECIPHER test and did not submit tissue as part of the main study, leftover tissue from your biopsy will be collected and sent to the Biobank.

4) Your samples 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 your study doctor.

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 your 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:

SAMPLES FOR FUTURE RESEARCH STUDIES:

I agree to have my blood, urine, and tissue specimens collected. I agree that the leftover tissue after the post-operative testing can be sent to the Biobank. If I already had a DECIPHER test, I agree to have the leftover tissue from my original biopsy be stored in the Biobank. I agree that my specimen sample(s) 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.

Release

By signing this form you authorize NCORP-KC to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

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

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'.

Print patient's name_____

Patient's signature_____

Date of signature_____

Print name of person(s) conducting the informed consent discussion

_____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature_____