NRG ONCOLOGY

NRG-CC007CD

(ClinicalTrials.gov NCT #NCT03860961)

INCREASING THE DOSE OF SURVIVORSHIP CARE PLANNING IN PROSTATE CANCER SURVIVORS WHO RECEIVE ANDROGEN DEPRIVATION THERAPY

Amendment 4 March 24, 2021

Research Study Informed Consent Document – Arm B

Study Title for Participants: Survivorship Care Planning for Prostate Cancer Survivors

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: NRG-CC007CD, "Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy," (NCT# NCT03860961)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you will be receiving prostate cancer treatment at a clinic that has chosen to take part in this study of the effectiveness of survivorship care plans.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials information.

Why is this study being done?

This study is being done to answer the following question:
How can a survivorship care plan be used to improve the monitoring patients receive after finishing radiation treatment, and improve their satisfaction with care?

After patients finish prostate cancer treatment, monitoring by both the cancer specialist (i.e. radiation oncologist) and the primary care provider is needed. This study is trying to improve the use of the survivorship care plan to help patients improve the monitoring patients receive.

What is the usual approach to my prostate cancer after receiving radiation therapy?

The usual approach for participants who are not in this study is to receive a care plan at the end of treatment. This care plan is also sent to the primary care provider.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for your cancer

What will happen if I decide to take part in this study?

As part of this study, you will be receiving a treatment plan from your radiation oncology team at the beginning of treatment, and a survivorship care plan at the end of radiation treatment. You will be asked to meet with your primary care provider to discuss the survivorship care plan. You will also be asked to complete surveys. Two years after radiation treatment is finished, you will have a blood test to check your blood sugar and cholesterol levels.

Your radiation oncology team will review the recommendations on these care plans with you each time, and each plan will be sent to your primary care provider. You can help the researchers understand your care and satisfaction with care after finishing radiation treatment by completing questionnaires.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

There is a risk you may feel uncomfortable being asked about your satisfaction of care.

Benefits

There may not be a direct benefit to you from participating in this study. This study will help the study doctors learn things that will help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your 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.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.

- You do not follow the study rules.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), or study sponsor (NRG Oncology). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to find out if the standard survivorship or if a more intensive survivorship care plan results in better follow-up care by the cancer specialists (i.e. radiation oncologist) and primary care doctors. This study will also assess your heart health. You are enrolled in the more intensive survivorship care plan arm of this trial.

What are the study groups? (20-Oct-2020)

In this study you will communicate more frequently with your doctors during the following times:

- Before you start radiation therapy
- After you end radiation therapy you'll meet with your radiation doctor and your primary care doctor
- Annual updates over two years by your radiation doctor

We will also collect information from your medical records and ask you to complete forms about your ability to understand medical information and satisfaction of care. Two years after radiation treatment is finished, you may be asked to have a blood test to check your blood sugar and cholesterol levels.

There will be about 272 people in this group and a total of 544 people participating in this study.

What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures and you must have a primary care doctor and/or cardiologist. If you do not have one, you must be able to obtain a primary care doctor or cardiologist either before starting radiation therapy or within 2 weeks after starting radiation therapy. If you join the study, you may have one blood draw to monitor your health. Most of these are included in the usual care you would get even if you were not in this study.

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

- Some of your medical records may be looked at. Any data that is used from your medical records will be de-identified and patient confidentiality will be maintained.
- You will be asked to fill out 3 forms with questions about satisfaction of care and your ability to understand written information. Researchers will use this information to learn more about how cancer treatment affects people. You will be asked to fill out all 3 forms

before you begin the study and you will fill out 2 forms 1 and 2 years after completing radiation therapy. Each form will take about 5 minutes to complete for a total of 10-15 minutes to complete the forms each time.
    - Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.
    - The forms will ask about things like care you received by your doctor and your cancer specialist (i.e. radiation oncologist) as well as your ability to understand medical information.
    - You don't have to answer any question that makes you feel uncomfortable.
- You will be asked to release records from your Primary Care Provider (PCP) or cardiologist to the study team.

Option for completing Quality of Life Questionnaires with a personal electronic device

You will have the option of completing the questionnaires by paper or by an electronic device. If you choose to complete the questionnaires with an electronic device, you will enter your answers to the questionnaires via a personal electronic device such as your smart phone or tablet. In some cases, a tablet may be provided to you at your health care institution. The use of your own electronic device on a cellular network may result in a nominal cost to your data plan. Regardless of the device you use, your answers and personal information will not be stored on the device. Your survey answers will be sent to the research database and will be kept private in the same way listed in the later section about who will see your medical records. Your e-mail address will only be used for this survey study and will not be used for mail or marketing purposes. NRG Oncology will not keep your e-mail address.

If you need help using the survey application on your phone or tablet, ask for help at your study site. You don't have to answer any question that makes you feel uncomfortable. Someone may help you enter your answers in the device if you need.

All patients will complete the questionnaires before treatment on paper. After that, you can choose to complete the remaining forms online or on paper. The choice is up to you. If you choose to complete questionnaires using an electronic device, see Appendix I of this document for more information.

Please circle your answer:

I choose to use the electronic software for completing the Quality of Life Questionnaires. I agree to fill out the Quality of Life forms electronically (after treatment has started).

YES NO

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

General Risks

If you choose to take part in this study, there is a risk that you may feel uncomfortable being asked about your satisfaction of care.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.

We will do everything we can to keep your medical information confidential. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are. Any information from this study that is published or presented at scientific meetings, such as your personal information, will not be used.

Risks of venipuncture
The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. Rarely, an infection can occur.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
    - all medications and supplements you are taking
    - any side effects
    - any doctors' visits or hospital stays outside of this study
    - if you have been or are currently in another research study.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your prostate cancer. This includes:

- The costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- Your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or those are covered by the study. These include: completion of surveys. Other exams and tests are expected to be paid by your insurance provider.

You will not be paid for taking part in this study. The research may lead to new procedures. For example, if the study uncovers new heart disease, it is possible that you may need procedures or treatment. If it does, you will not get any payment.

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- NRG Oncology
- The Institutional Review Board (IRB), which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The NCI and the groups it works with to review research.

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.

- You will not get reports or other information about any research that is done using your information.

Where can I get more information? (20-Oct-2020)

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.

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).*

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

My signature agreeing to take part in the 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 and dated copy of this form. I agree to take part in the main study.

Participant's signature _____

Date of signature _____

Signature of person(s) conducting the informed consent discussion _____

Date of signature _____

Appendix I: Patient Instructions for Accessing the Patient Cloud Using Your Personal Device

Downloading the Patient Cloud ePRO App

If you are using your personal device, and you do not have the Patient Cloud ePRO app, use the following instructions. When downloading the app, you must use the Apple ID or Google account associated with the device. If the Patient Cloud ePRO app is already on the device, or if you are using a study team's device, you can skip this section.

You will need an email address that you agree to use for this purpose. The e-mail address is needed to identify you on the Patient Cloud Application and for you to receive notifications to let you know when forms are due. Your e-mail address will only be used for this survey study, and will not be used for mail or marketing purposes.

If you decide to use the electronic method to complete the questionnaires, and do not have an e-mail address, you may sign up for one at no charge at many different websites. A few sites that are commonly used and will allow you to create an email address very easily are Yahoo, Gmail, and Outlook.

For iOS:

1. An Apple ID is required for downloading the Patient Cloud ePRO app.
2. Tap the *App Store* icon.
3. Search for *Medidata Patient Cloud* and follow the installation instructions.

Note: Patient Cloud ePRO is listed as an iPhone App in the App store. When using an iPad, please view the search results under iPhone apps.

For Android:

1. A Google account is required for downloading the Patient Cloud ePRO app
2. Tap the *Play Store* icon.
3. Search for *Medidata Patient Cloud* and follow the installation instructions.

Registering

You must register in order to complete and submit your study forms. When you register, you will create a username, which is your email address, and a password that allows you to log in to the Patient Cloud ePRO app.

Note**:** You must have an activation code to begin this process. If you do not have an activation code, please contact your study team.

There are two possible ways to register. Your study team may have sent you a link to a web address where you may register from any web browser, including the one on your device. The other way to register is on the Patient Cloud ePRO app.

1. If registering from the Patient Cloud app, tap Register on the bottom of the log in page. If registering on the web, open the URL shield.imedidata.com on a web browser.
2. Enter your activation code and tap Activate.
3. On the next page, read the instructions and tap Next.
4. Read the privacy notice and tap I agree. Then tap OK to confirm.
5. Enter and confirm your email address. Tap Next.
6. Enter and confirm your password. Tap Next.
7. Choose a security question by scrolling through the dropdown menu to display the question of your choice.
8. Enter your security question response.
9. Tap Create my account to complete your registration.

If you registered on the Patient Cloud ePRO app, it automatically logs you out. If you registered on the web, you are presented with the option to download the Patient Cloud ePRO app. You can then proceed to log in with the credentials you created.

Logging in to the App

1. Enter your Email and Password that you created during the registration process. (If you previously set a PIN code, just enter your four-digit PIN.)
2. Tap Log in.

Note: If you do not remember your password, tap **Forgot Password**, and follow the instructions provided.

Setting a PIN Code

The first time you log in to the Patient Cloud ePRO app, you are given the option to create a PIN code. A PIN code allows you to bypass the step of entering your email and password every time you need to log in to the Patient Cloud ePRO app. Instead, you can enter a four-digit PIN.

1. If you wish to set a PIN code the first time you log in, tap Yes when prompted.
2. Note: You can also set your PIN at a later time by tapping the options menu on the top left of most pages and selecting Set PIN.
3. Enter a four-digit PIN.
4. Re-enter the four-digit PIN to confirm.

If you forget your PIN code, tap **Forgot PIN** and you can access the app using your email and password. You may reset your PIN by tapping the options menu on the top left of most pages and selecting Set PIN.

Resetting Your Password

You can reset your password by using the options menu at the top left of most pages.

1. Tap the options menu icon.
2. Tap Reset Password.
3. Follow the instructions to reset your password.

Completing and Submitting Forms

Once logged in, forms related to your study display on the Tasks page. If you are enrolled in multiple studies, select the appropriate study first, and then select a form. New forms can appear on the Tasks page at any time, depending on how the study is designed.

There are two types of forms displayed on the Task List page:

- *Scheduled Forms* (with a  icon): These forms have a "Due Date" indicator in them so you are aware of the last day by which you will need to complete the form. If the form is due in less than one day, you will see the due time in hours.
- *Anytime Forms* (with a  icon): These forms have "Last Completed Time" indicator on them which tells the most recent date or time when you completed the form. If you start a form, but do not complete it, you will see an 'Incomplete" status beneath the form name, along with a half-moon icon.

1. Select the appropriate form.
2. Follow the on-screen instructions until you reach the end of the form where you are given the opportunity to review and change your responses prior to submitting.
3. Review your responses by scrolling down the list.
4. If you need to change an answer, tap the question to go back and change the answer.
5. When you are ready to submit, tap Submit Your Data.

Note: Once a form is submitted, you will be unable to edit any of your responses. In some cases, you may be asked to acknowledge your submission by entering your password.

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Amendment 4 March 24, 2021

Research Study Informed Consent Document – Arm A

Study Title for Participants: Survivorship Care Planning for Prostate Cancer Survivors

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: NRG-CC007CD, "Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy," (NCT# NCT03860961)

Overview and Key Information

What am I being asked to do?

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We are asking you to take part in this research study because you will be receiving prostate cancer treatment at a clinic that has chosen to take part in this study of the effectiveness of survivorship care plans.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials information.

Why is this study being done?

This study is being done to answer the following question:

How can a survivorship care plan be used to improve the monitoring patients receive after finishing radiation treatment, and improve their satisfaction with care?

After patients finish prostate cancer treatment, monitoring by both the cancer specialist (i.e. radiation oncologist) and the primary care provider is needed. This study is trying to improve the use of the survivorship care plan to help patients improve the monitoring patients need.

What is the usual approach to my prostate cancer after receiving radiation therapy?

The usual approach for participants who are not in this study is to receive a care plan at the end of treatment. This care plan is also sent to the primary care study team.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.

- You may choose to take part in a different research study, if one is available.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will receive a survivorship care plan from your radiation oncology team at the end of radiation treatment. You will also be asked to complete surveys. Two years after radiation treatment is finished, you will have a blood test to check your blood sugar and cholesterol levels.

Your radiation oncology team will review this care plan with you, and the care plan will be sent to your primary care provider. You can help the researchers understand your care and satisfaction with care after finishing radiation treatment by completing questionnaires.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

There is a risk you may feel uncomfortable being asked about your satisfaction of care.

Benefits

There may not be a direct benefit to you from participating in this study. This study will help the study doctors learn things that will help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your 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.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), or study sponsor (NRG Oncology). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to find out if the standard survivorship care or if a more intensive survivorship care plan results in better follow-up care by the cancer specialists (i.e. radiation oncologist) and primary care doctors You are enrolled in the standard survivorship care plan arm of this trial.

What are the study groups? (20-Oct-2020)

In this study you will get the standard care plan from your doctor after you complete radiation therapy.

We will also collect information from your medical records and ask you to complete forms about your ability to understand written information and satisfaction of care. Two years after radiation treatment is finished, you may be asked to have a blood test to check your blood sugar and cholesterol levels.

There will be about 272 people in this group and a total of 544 people participating in this study.

What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures and you must have a primary care doctor and/or cardiologist. If you do not have one, you must be able to obtain a primary care doctor or cardiologist either before starting radiation therapy or within 2 weeks after starting radiation therapy. If you join the study, you may have one blood draw to monitor your health. Most of these are included in the usual care you would get even if you were not in a study.

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

- Some of your medical records may be looked at. Any data that is used from your medical records will be de-identified and patient confidentiality will be maintained.

- You will be asked to fill out 3 forms with questions about satisfaction of care and your ability to understand written information. Researchers will use this information to learn more about how cancer treatment affects people. You will be asked to fill out all 3 forms before you begin the study and you will fill out 2 forms 1 and 2 years after completing radiation therapy. Each form will take about 5 minutes to complete for a total of 10-15 minutes to complete the forms each time.
    - Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

- The forms will ask about things like care you received by your doctor and your cancer specialist (i.e. radiation oncologist) as well as your ability to understand medical information.
- You don't have to answer any question that makes you feel uncomfortable.

- You will be asked to release records from your Primary Care Provider (PCP) or cardiologist to the study team.

Option for completing Quality of Life Questionnaires with a personal electronic device

You will have the option of completing the questionnaires by paper or by an electronic device. If you choose to complete the questionnaires with an electronic device, you will enter your answers to the questionnaires via a personal electronic device such as your smart phone or tablet. In some cases, a tablet may be provided to you at your health care institution. The use of your own electronic device on a cellular network may result in a nominal cost to your data plan. Regardless of the device you use, your answers and personal information will not be stored on the device. Your survey answers will be sent to the research database and will be kept private in the same way listed in the later section about who will see your medical records. Your e-mail address will only be used for this survey study and will not be used for mail or marketing purposes. NRG Oncology will not keep your e-mail address.

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Please circle your answer:

I choose to use the electronic software for completing the Quality of Life Questionnaires. I agree to fill out the Quality of Life forms electronically (after treatment has started).

YES NO

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

General Risks
If you choose to take part in this study, there is a risk that you may feel uncomfortable being asked about your satisfaction of care.

You also may have the following discomforts:
- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.

We will do everything we can to keep your medical information confidential. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are. Any information from this study that is published or presented at scientific meetings, such as your personal information, will not be used.

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If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- NRG Oncology
- The Institutional Review Board (IRB), which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The NCI and the groups it works with to review research.

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

Where can I get more information? (20-Oct-2020)

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.

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).*

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

My signature agreeing to take part in the 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 and dated copy of this form. I agree to take part in the main study.

Participant's signature _____

Date of signature _____

Signature of person(s) conducting the informed consent discussion _____

Date of signature _____

Appendix I: Patient Instructions for Accessing the Patient Cloud Using Your Personal Device

Downloading the Patient Cloud ePRO App

If you are using your personal device, and you do not have the Patient Cloud ePRO app, use the following instructions. When downloading the app, you must use the Apple ID or Google account associated with the device. If the Patient Cloud ePRO app is already on the device, or if you are using the study team's device, you can skip this section.

You will need an email address that you agree to use for this purpose. The e-mail address is needed to identify you on the Patient Cloud Application and for you to receive notifications to let you know when forms are due. Your e-mail address will only be used for this survey study, and will not be used for mail or marketing purposes.

If you decide to use the electronic method to complete the questionnaires, and do not have an e-mail address, you may sign up for one at no charge at many different websites. A few sites that are commonly used and will allow you to create an email address very easily are Yahoo, Gmail, and Outlook.

For iOS:

1. An Apple ID is required for downloading the Patient Cloud ePRO app.
2. Tap the *App Store* icon.
3. Search for *Medidata Patient Cloud* and follow the installation instructions.

Note: Patient Cloud ePRO is listed as an iPhone App in the App store. When using an iPad, please view the search results under iPhone apps.

For Android:

1. A Google account is required for downloading the Patient Cloud ePRO app
2. Tap the *Play Store* icon.
3. Search for *Medidata Patient Cloud* and follow the installation instructions.

Registering

You must register in order to complete and submit your study forms. When you register, you will create a username, which is your email address, and a password that allows you to log in to the Patient Cloud ePRO app.

Note**:** You must have an activation code to begin this process. If you do not have an activation code, please contact your study team.

There are two possible ways to register. Your study team may have sent you a link to a web address where you may register from any web browser, including the one on your device. The other way to register is on the Patient Cloud ePRO app.

1. If registering from the Patient Cloud app, tap Register on the bottom of the log in page. If registering on the web, open the URL shield.imedidata.com on a web browser.
2. Enter your activation code and tap Activate.
3. On the next page, read the instructions and tap Next.
4. Read the privacy notice and tap I agree. Then tap OK to confirm.
5. Enter and confirm your email address. Tap Next.
6. Enter and confirm your password. Tap Next.
7. Choose a security question by scrolling through the dropdown menu to display the question of your choice.
8. Enter your security question response.
9. Tap Create my account to complete your registration.

If you registered on the Patient Cloud ePRO app, it automatically logs you out. If you registered on the web, you are presented with the option to download the Patient Cloud ePRO app. You can then proceed to log in with the credentials you created.

Logging in to the App

1. Enter your Email and Password that you created during the registration process. (If you previously set a PIN code, just enter your four-digit PIN.)
2. Tap Log in.

Note: If you do not remember your password, tap **Forgot Password**, and follow the instructions provided.

Setting a PIN Code

The first time you log in to the Patient Cloud ePRO app, you are given the option to create a PIN code. A PIN code allows you to bypass the step of entering your email and password every time you need to log in to the Patient Cloud ePRO app. Instead, you can enter a four-digit PIN.

1. If you wish to set a PIN code the first time you log in, tap Yes when prompted.
2. Note: You can also set your PIN at a later time by tapping the options menu on the top left of most pages and selecting Set PIN.
3. Enter a four-digit PIN.
4. Re-enter the four-digit PIN to confirm.

If you forget your PIN code, tap **Forgot PIN** and you can access the app using your email and password. You may reset your PIN by tapping the options menu on the top left of most pages and selecting Set PIN.

Resetting Your Password

You can reset your password by using the options menu at the top left of most pages.

1. Tap the options menu icon.
2. Tap Reset Password.
3. Follow the instructions to reset your password.

Completing and Submitting Forms

Once logged in, forms related to your study display on the Tasks page. If you are enrolled in multiple studies, select the appropriate study first, and then select a form. New forms can appear on the Tasks page at any time, depending on how the study is designed.

There are two types of forms displayed on the Task List page:

- *Scheduled Forms* (with a  icon): These forms have a "Due Date" indicator in them so you are aware of the last day by which you will need to complete the form. If the form is due in less than one day, you will see the due time in hours.
- *Anytime Forms* (with a  icon): These forms have "Last Completed Time" indicator on them which tells the most recent date or time when you completed the form. If you start a form, but do not complete it, you will see an 'Incomplete" status beneath the form name, along with a half-moon icon.

1. Select the appropriate form.
2. Follow the on-screen instructions until you reach the end of the form where you are given the opportunity to review and change your responses prior to submitting.
3. Review your responses by scrolling down the list.
4. If you need to change an answer, tap the question to go back and change the answer.
5. When you are ready to submit, tap Submit Your Data.

Note: Once a form is submitted, you will be unable to edit any of your responses. In some cases, you may be asked to acknowledge your submission by entering your password.