SWOG | CANCER RESEARCH NETWORK

Version Date: February 23, 2024

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS; CTSU

FROM: SWOG Network Operations Center (E-mail: protocols@swog.org)

RE: **S1914**, "A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT versus SBRT Alone in High Risk, Early Stage NSCLC"
Study Chairs: Drs. [redacted] and [redacted]

REVISION #8

Study Chair: [redacted] M.D.
Phone number: [redacted]
E-mail: [redacted]

Action Codes
(√) Expedited review allowed

Key Updates
(√) Editorial / Administrative changes
(√) Treatment / Study Calendar changes

The protocol and/or informed consent form changes have been approved by the CIRB and must be activated within 30 days of distribution of this notice through the CTSU Bi-Monthly Broadcast email.

REVISION #8

This revision has been prepared to: (1) clarify the study calendar to indicate that magnesium is required for patients on Arm A only, (2) to clarify the off-protocol treatment follow-up period, and (3) to make general administrative edits and clarifications.

Protocol Changes

1. The version date has been updated.

2. Throughout the protocol, formatting, typographical errors, pagination, and cross-references have been corrected as needed.

3. Table of Contents: The table of contents has been updated.

4. CTSU Contact Page: This section has been updated with CTSU template wording.

5. Section 5.1g: This criterion has been revised to specify that an evaluating thoracic surgeon can document the patient as inoperable, medically or surgically, rather than requiring board certified thoracic surgeon.

6. Section 7.2: For the CT chest collection, a ± 14 days window period has been added for the timepoint that occurs at 6-months for patients on both Arms A and B.

7. Section 9.1: A row for magnesium has been added to the study calendar for Arm A. Magnesium is only required to be collected for patients on Arm A at the timepoints specified in the calendar.

8. Sections 9.1 and 9.2, footnotes "G": For the after off treatment prior to progression timepoints, a 14-day window has been added for the timepoints that occur after Week 54.

9. Sections 9.1 and 9.2, footnotes "H": For the tests to be collected after off treatment after progression, the timepoints have been updated to occur less frequently.

10. Sections 9.1, footnote O and 9.2, footnote P: Magnesium has been removed from the chemistry panel footnote.

11. Section 13.2: This section has been updated with CTSU template wording.

12. Section 13.3: The alphabetical list has been updated to reflect the removal of SSN in the prior amendment. No other changes have been made to this section.

13. Sections 14.3a and 14.3e: These sections have been updated with CTSU template wording.

14. Section 14.4j: The reference to the vital status form has been updated to Section 14.4h.

15. Section 14.4k: The follow-up period once off protocol treatment has been updated to occur less frequently to match the change in the study calendar.

16. Section 14.4m: The references to the notice of death and forms has been updated to Sections 14.4h and 14.4k.

17. Section 18.3: The third bullet point under "Onsite Audits" has been revised to indicate that subsequent monitoring visits will be conducted biennially for fewer than five patients per year.

Model Consent Form Changes

1. The version date has been updated. No other changes have been made.

The updated protocol and model informed consent form can be accessed from the CTSU website (www.ctsu.org). Please discard any previous versions of the documents and replace them with the updated versions.

This study has been reviewed and approved by the NCI's Central Institutional Review Board (CIRB).

This memorandum serves to notify the NCI and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE
[redacted], M.D.
[redacted] M.D.
[redacted], M.D.
[redacted], M.D.
[redacted], B.S., R.T.

[redacted] Ph.D.
[redacted], M.D.
[redacted], Ph.D.
[redacted], M.D.
[redacted], M.D.

Research Study Informed Consent Document

Study Title for Participants: Testing the addition of the drug atezolizumab to the usual radiation treatment for patients with early non-small cell lung cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
S1914, "A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC" (NCT#04214262)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. 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 have inoperable, early stage non-small cell lung cancer.

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 and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

Can we extend your life by adding the immunotherapy drug atezolizumab to the usual radiation treatment?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for inoperable, early stage non-small cell lung cancer. The usual approach is defined as care that most people get for inoperable, early stage non-small cell lung cancer (NSCLC).

What is the usual approach to my early non-small cell lung cancer (NSCLC)?

The usual approach for patients who are not in a study is treatment with radiation alone. The use of radiation for early stage NSCLC is not regulated by the FDA.

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 cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for cancer.

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

If you decide to take part in this study, you will either receive 3-8 radiation treatments over a period of a few weeks and the study immunotherapy drug atezolizumab for about six months, or you will receive the 3-8 radiation treatments alone, until your disease gets worse, the side effects become too severe, or you want to stop your participation.

After you finish the study treatment, your doctor and study team will watch you for side effects. Starting 18 weeks after you begin the study, they will check you every 12 weeks for the first year. After that, they will check you every 6 months for 2 years. Then they will check you every 12 months for 2 more years. This means you will keep seeing your doctor for 5 years after you start the study.

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 a few key risks right now. We give you more information in the “What risks can I expect from taking part in this study?” section.

If you choose to take part in this study, there is a risk that the study treatment may not be as good as the usual treatment for your cancer at extending your life.

There is also a risk that you could have side effects from the combination of atezolizumab and radiation or radiation alone. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

Some of the most common side effects that the study doctors know about are:

- Tiredness
- Infection

There may be some risks that the study doctors do not yet know about.

Benefits

There is evidence that atezolizumab, when delivered alone or with chemotherapy, is effective in extending the life of patients with more advanced stages of your type of cancer. It is not possible to know if the atezolizumab will extend your life compared to the usual approach of radiation only. 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. This may mean slowly stopping the study drugs so that there is not a sudden unsafe change, causing risk to your health. 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.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or the study sponsor (the National Cancer Institute [NCI]). The study sponsor is the organization that 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 compare the usual treatment alone to using the immunotherapy drug atezolizumab plus the usual treatment. The addition of atezolizumab to the usual treatment could extend your life. But, it could also cause side effects, which are described in the risks section below.

The immunotherapy drug atezolizumab has not been approved by the FDA to treat this type of cancer.

This study will help the study doctors find out if this different approach is better than the usual approach. To decide if it is better, the study doctors will be looking to see if the atezolizumab increases the life of patients compared to the usual approach.

There will be about 480 people taking part in this study.

What are the study groups?

Patients in this study will be evenly divided into 2 study groups.

- Group 1

  If you are in this group, you will get a study drug called atezolizumab plus the usual radiation treatment used to treat this type of cancer.

  You will get atezolizumab on the first day of each cycle. Each cycle lasts 21 days. This study has 8 cycles. Atezolizumab is given through a vein in your arm (IV). The first time you receive it, the IV will be given over a period of 60 minutes. As long as you do not have any adverse reactions to the IV in cycle 1, in cycles 2 through 8 it will be given over a period of 30 minutes.

  You will visit the radiation treatment facility three to eight times over a period of one to three weeks. Each treatment will take about 20 minutes.

  There will be about 240 people in this group.

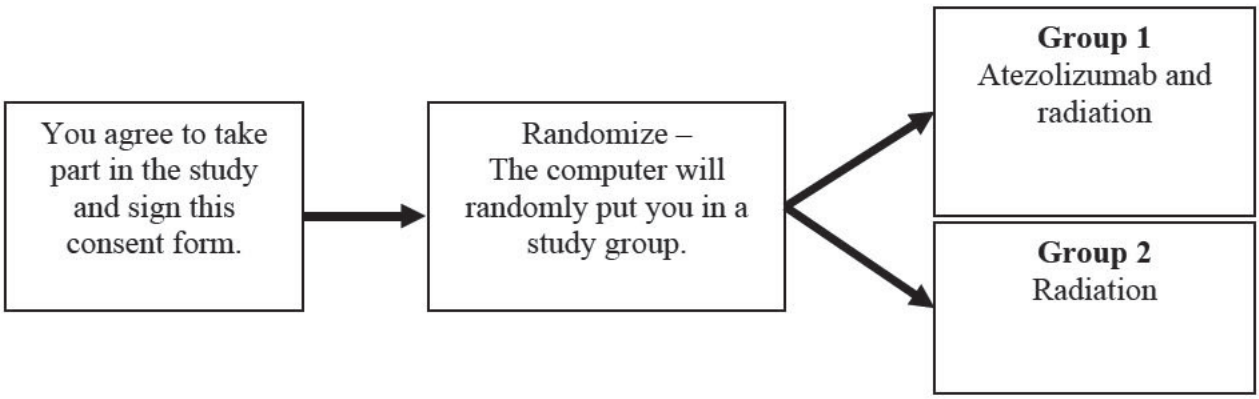
- Group 2

If you are in this group, you will get the usual radiation treatment used to treat this type of cancer. For this, you will visit the radiation treatment facility three to eight times over a period of one to three weeks. Each treatment will take about 20 minutes.

There will be about 240 people in this group.

We will use a computer to assign you to one of the study groups. This process is called "randomization". It means that your doctor will not choose and you cannot choose which study group you are in. You will be put into a group by chance. You will have an equal chance of being in Group 1 or Group 2.

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.



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. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care.

- Blood tests for thyroid function, hepatitis B, and hepatitis C before you begin the 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.

Sample collection

Your study doctor will need to use some of the tissue left over from your biopsy when you were diagnosed with cancer. They will also collect blood from a vein in your arm at the following time points:

- Before you begin the study (about 3 tablespoons)
- One week after you finish radiation treatment (about 3 tablespoons)
- At week 18 (about 3 tablespoons)
- If your disease gets worse (about 1 tablespoon)

Whenever possible, blood will be drawn at the same time as other blood draws being done to monitor side effects. There is a chance that you will have a separate clinic visit and stick to obtain the blood.

These samples are a required part of the study. They will be stored. Storing samples for future studies is called "biobanking". The biobank is being run by SWOG and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what research may be done in the future using your blood and/or tissue samples. This means that:

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

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes. If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

Quality of Life Study

The Quality of Life Study only applies to you if you originally consented to participate after the 12/11/20 version of the study.

If you speak and understand English, French, or Spanish you will fill out 2 forms with questions about your physical and emotional well-being. Researchers will use this information to learn more about how cancer and cancer treatment affects the physical and emotional well-being of patients.

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.

You will fill out these forms at 5 times:

- After study entry within 2 weeks before starting treatment (both Groups)
- Prior to radiation (Group 1)
- Day 43 after starting treatment (Group 2)
- Weeks 30, 54 and 80 from start of treatment (both Groups)

Each form will take about 5-7 minutes to complete for a total of 10-14 minutes to complete the forms each time. You don't have to answer any question that makes you feel uncomfortable.

You will have the option of completing the questionnaires by paper or by an electronic device.

**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, NRG Oncology is working with a company, VisionTree Software, Inc., that has a web site where patients can fill out these forms anywhere there is a computer with Internet access. This option is being offered as some patients may find it more convenient to fill out the forms electronically from any location, including home. When you log on to the web site, it will take you through the process of completing the forms step by step. You will need an e-mail address that you agree to use for this purpose. The e-mail address is needed to identify you on the VisionTree web site and for e-mail reminders that will be sent to you when the forms are due. Your e-mail address will only be used for the purpose of this study, not for mail or marketing purposes. If you are interested in filling out quality of life forms electronically but do not have an e-mail address, you may obtain one (quickly and for no charge at web sites such as Yahoo!, Hotmail, or AOL). You will only be sent e-mail reminders at the time that the forms are due (a maximum of 3 e-mail reminders per time point). Your access to the VisionTree web site is password protected and secure. You can use your e-mail address to retrieve your password if you forget it or lose your login card. You will receive a login card either by regular mail or e-mail, and it will include the information you need to log in to the VisionTree web site the first time.

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, you don't have to answer any question that makes you feel uncomfortable.

Please circle your answer: I choose to use the VisionTree Software. I agree to fill out the Quality of Life forms electronically (after treatment has started) using the VisionTree web site.

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 atezolizumab plus radiation may not be as good as radiation alone at extending your life.

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.
- May not be able to take part in future studies.

The atezolizumab and radiation used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for 5 months after you have completed the study.

This study will use a sample of your tissue. Generally, your hospital will keep some of your tissue. This tissue may be used to help treat your cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.

Blood Draw Risks

Common side effects of a blood draw are a small amount of bleeding at the time of the blood draw, brief pain, and maybe a bruise. Another potential risk of having blood drawn from your arm is infection.

Genetic Testing Risks

The genetic test used in this study will test your tumor for genes associated with development of lung cancer. This change also may be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down."

Since this study is only testing tumor tissue, we will not know if a genetic change in your tumor is also in your normal tissue. If you want to find out if the change is in your normal tissue, then you will need to get other tests done outside of this study.

Side Effect Risks

The radiation treatment and drug 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 test your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study treatment.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

Drug Risks

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

Possible side effects of Atezolizumab (MPDL3280A) (CAEPR Version 2.4, September 14, 2023)

COMMON, SOME MAY BE SERIOUS In 100 people receiving atezolizumab (MPDL3280A), more than 20 and up to 100 may have:
• Tiredness • Infection

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving atezolizumab (MPDL3280A), from 4 to 20 may have:

- Anemia which may require blood transfusion
- Diarrhea, nausea, vomiting
- Difficulty swallowing
- Fever
- Flu-like symptoms including body aches
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Reaction during or following a drug infusion which may cause fever, chills, rash
- Loss of appetite
- Pain in back
- Cough, shortness of breath, stuffy nose
- Itching, acne, rash

Atezolizumab (MPDL3280A) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:

- Hormone gland problems (especially the thyroid, pituitary and adrenal glands, and pancreas). Signs and symptoms may include: headaches that will not go away or unusual headaches, extreme tiredness or changes in mood or behavior decreased sex drive; weight loss or weight gain; excessive thirst or urine; dizziness or fainting.
- Pain in belly
- Pain or swelling of the joints
- Rash that develops on skin, nails, scalp and inside of mouth or vagina that may be painful

RARE, AND SERIOUS

In 100 people receiving atezolizumab (MPDL3280A), 3 or fewer may have:

- Bruising, bleeding

Atezolizumab (MPDL3280A) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:

- Heart problems including swelling and heart failure. Symptoms and signs of heart problems may include: shortness of breath, swelling of the ankles and body.
- A condition with high blood sugar which leads to tiredness, frequent urination or excessive thirst.
- Swelling and redness of the eye
- Intestinal problems (colitis) that can rarely lead to tears or holes in your intestine. Signs and symptoms of colitis may include: diarrhea or increase in bowel movements, blood in your stools or dark, tarry, sticky stools, severe belly pain or tenderness.
- Liver problems (hepatitis) which can cause liver failure. Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes, severe nausea or vomiting; drowsiness; pain in the right upper belly.
- Damage to organs in the body when the body produces too many white cells
- Swelling of the brain (meningitis/encephalitis), which may cause: headache, confusion, sleepiness, seizures, and stiff neck.
- Abnormal movement of the facial muscles
- Swelling of the spinal cord
- Problem of the muscle, including swelling, which can cause muscle pain and severe muscle weakness sometimes with dark urine.
- Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs.
- Kidney problems, including nephritis and kidney failure requiring dialysis. Signs of kidney problems may include: decrease in the amount of urine, blood in your urine, ankle swelling.
- Lung problems (pneumonitis and pleural effusion). Symptoms may include: new or worsening cough, chest pain, shortness of breath.
- Skin: blisters on the skin, including inside the mouth (can be severe), rash with blisters, skin rash developing 1-8 weeks after a drug is given, which may be accompanied by fever, lymph node swelling and organ failure.

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.

Additional Drug Risks

Drug Interactions
Throughout your treatment, you should inform your doctor about any medication changes. Do not receive any live attenuated vaccinations, such as shingles or influenza nasal spray, while you are taking part in this study and for 5 months after your last atezolizumab dose.

Possible Side Effects of Radiation Therapy

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, 20 to 100 may have:
• Reddening, tanning, or peeling of the skin • Mild pain • Cough • Chest wall/rib pain • Tiredness • Anemia

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, 4 to 20 may have:
• Thickening and numbness of the skin • Inflammation of the lung leading to shortness of breath, cough, and fever • Lung scarring • Discomfort with swallowing • Heart injury

RARE, AND SERIOUS In 100 people receiving radiation therapy, 3 or fewer may have:
• Damage to internal organs • Bleeding from airways that may be fatal • Obstruction of airways that may lead to infections • Sores or ulcers on the skin or near the cancer location • Abnormal opening in internal organs which may cause pain and bleeding

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.

For women: Do not get pregnant or breastfeed while taking part in this study and for five months after your last dose of atezolizumab.
For men: Do not father a baby while taking part in this study and for five months after your last dose of atezolizumab.
For men and women: Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 5 months after your last dose of atezolizumab.

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. 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.
- the costs of getting the atezolizumab ready and giving it to you.
- 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 that are covered by the study. These include:

- Sampling of your blood and tumor tissue
- Blood tests for thyroid function, hepatitis B, and hepatitis C before you begin the study

You or your insurance provider will not have to pay for the atezolizumab while you take part in this study.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. 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 or receive copies of some of the information in 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:

- The study sponsor, SWOG Cancer Research Network, and any company supporting the study now or in the future
- The NCI Central 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 FDA and the groups it works with to review research
- The NCI and the groups it works with to review research
- The NCI's National Clinical Trials Network and groups it works with to conduct research including the Imaging and Radiation Oncology Core (IROC)

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records

may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now 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.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

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.

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 ( ) at ( ).

For questions about your rights while in this study, call the Institutional Review Board at xxx.

OPTIONAL ADDITIONAL STUDIES

Optional studies that 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. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading these optional studies hope the results will help other people with inoperable, early stage non-small cell lung cancer in the future. Results will not be added to your medical records and you or your study doctor will not know the results.

Taking part in these optional studies is your choice. You can still take part in the main study even if you say "no" to any or all of these studies. There is no penalty for saying "no." You and your insurance company will not be billed for these optional studies. If you sign up for, but cannot complete any of these 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.

Contact for Future Research

Occasionally, researchers working with SWOG may have another research idea that relates to people who were on a SWOG study. In some cases, to carry out the new research, we would need to contact participants in a particular study. You can agree or not agree to future contact.

I agree that my study doctor, or someone on the study team, may contact me or my doctor 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 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. I also agree to take part in 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 _____