MC1821 / 19-010887

Randomized Phase II Study of Standard Chemotherapy with Docetaxel with or without Bintrafusp Alfa in Patients with Advanced NSCLC after Progressing on a Combination of Anti-PD-1/PD-L1 Agents and Chemotherapy

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1821 – Randomized, Phase II Study of Standard Chemotherapy with Docetaxel with or without Bintrafusp Alfa in Patients with Advanced NSCLC after Progressing on a Combination of Anti-PD-1/PD-L1 Agents and Chemotherapy

IRB#: 19-010887

Principal Investigator: Dr. Alex A. Adjei and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.

It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to test an investigational drug called bintrafusp alfa for the treatment of advanced non-small cell lung cancer (NSCLC). You have been asked to take part in this research because you have lung cancer that has gotten worse after treatment.

What's Involved	Study participation involves: • a biopsy before you start treatment • treatment with chemotherapy alone or with bintrafusp alfa • a biopsy after one cycle of treatment to see how the drug is working • continued treatment with bintrafusp alfa You may receive treatment on this study until your cancer gets worse or you have side effects that are intolerable are unsafe for you to continue.
Key Information	All patients will receive docetaxel. This study involves randomization; there is a 50 percent chance that you will receive bintrafusp alfa. You will need to return to Mayo Clinic every 3 weeks to receive study treatment. This study will take about the same amount of time as regular care for your cancer. The biggest risks to consider are the risks of the study drug (bintrafusp alfa) and the risks of the biopsies. The side effects of bintrafusp alfa are not well known, and these side effects may be mild (nausea) or rarely life threatening (kidney injury or lung disease). Though the risks from biopsies are low, there is still a risk of infection, or bleeding, and both of these risks could be life threatening. The risks associated with study participation are completely described later in this form, be sure to review them carefully. This study is not the only option you have for treatment of NSCLC. If you decide not to take part in this study, you will still be able to receive medical care. The research team will discuss other treatment options with you. While our study is research and not guaranteed to offer help, you may benefit from the treatment if it works.

Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigators:** Alex A. Adjei, M.D., Ph.D. (MN) Yanyan Lou, M.D., Ph.D. (FL) Panayiotis S. Savvides, M.D., Ph.D. (AZ) **Phone:** MN: (507) 284-2511 FL: (904) 953-2000 AZ: (480) 301-8000 **Institution Name and Address:** Mayo Clinic 200 First St SW Rochester, MN 55905 Mayo Clinic 4500 San Pablo Road Jacksonville, FL 32224 Mayo Clinic 5777 E Mayo Boulevard Phoenix, AZ 85054
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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.

A description of this research study will be available on http://www.clinicaltrials.mayo.edu. This website will not include information that can identify you. You can search this website at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this study because you have advanced non-small cell lung cancer (NSCLC) which has progressed on prior therapy with anti PD-1/PD-L1 agents combined with chemotherapy.

The plan is to have about 80 people take part in this study at Mayo Clinic.

Why is this research study being done?

This study is being done to find out more about the anti-cancer effects of an investigational drug called "bintrafusp alfa." About half the people enrolled in this study will receive bintrafusp alfa which is still experimental and isn't approved by the U.S. Food and Drug Administration (FDA). However, the FDA has allowed the use of this drug in this research study. We don't know all the ways that this drug may affect people.

There may be additional chemotherapy drugs available for treatment of your cancer that may provide clinical benefit. Before enrolling in this study, you should discuss all other options with your doctor before making a decision.

Information you should know

Who is Funding the Study?
EMD Serono is funding this study. EMD Serono will pay Mayo Clinic to cover costs related to running this study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will receive treatment in this study as long as your cancer does not get worse and you are not having bothersome side effects. After you stop treatment, we will follow your health for up to 5 years after you start this study.

What will happen to you while you are in this research study?

Before starting this study, you will need to have the following tests to see if you are eligible:

- Medical history and physical exam including measurements of your vital signs (pulse, blood pressure, temperature), and your height and weight
- Routine blood tests
- Electrocardiogram (also called ECG or sometimes EKG) to see how your heart is working
- Routine imaging of your tumors to determine their size and location before starting the study (usual imaging methods may include CT, MRI, PET/CT, or ultrasound)
- Pregnancy testing if you are a able to become pregnant

These exams, tests or procedures are part of regular clinical care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This decision will be up to the study doctor.

If you agree to be in this study and sign this consent form you will have the following tests and procedures:

- Research biopsy of your cancer for research testing on your tumor(s)
- Blood draw for research testing

If you are eligible for the study, we will assign you by chance (like a coin toss) to the bintrafusp alfa plus docetaxel group or the docetaxel alone group. Neither you nor the study doctor can choose your study group. You will have an equal chance of being assigned to the bintrafusp alfa plus docetaxel group.
Docetaxel is a standard chemotherapy agent used for many types of cancer.

Bintrafusp alfa is an investigational agent which is being tested in this study.

If you start this study you will be given docetaxel plus bintrafusp alfa, or docetaxel alone by intravenous (IV) infusion once every three weeks. This three week period is called a “cycle.”

If you are randomized to docetaxel plus bintrafusp alfa, you will receive docetaxel plus bintrafusp alfa for up to four cycles followed by bintrafusp alfa alone for up to two years.

If you are randomized to docetaxel alone, you will receive docetaxel until your cancer gets worse or you cannot tolerate the side effects. If your cancer gets worse, you may be given the option to get bintrafusp alfa alone for up to two years.

After your first treatment, you will have a research biopsy about 3 weeks later, before you have the second cycle of treatment. This biopsy will obtain tumor tissue to see how the tissue is responding to the treatment.

You will continue to come back about once every three weeks to receive treatment and have the following tests and procedures:

- Physical exam including measurements of your vital signs (pulse, blood pressure, temperature), and your weight
- Routine blood tests

After Cycle 2 and Cycle 4 of treatment, you will have standard imaging of your cancer to see whether the cancer has gotten better or worse. If your cancer is stable or improving, you will

continue your assigned treatment. You will have regular imaging of your cancer to make sure it is not getting worse.

If your cancer appears to be getting worse at any time, your treatment with docetaxel may be stopped. If you were originally assigned to the group that received docetaxel alone, you may be given the option to crossover and receive bintrafusp alfa alone for up to 2 years, as long as you and your doctor agree.

Tissue and blood specimens are required for this study. You will be asked to have biopsies to collect tissue, and blood draws (taken at the same times as your clinical blood tests) for this study. These specimens help us see how the study drug affects cancer.

Below is a table that shows the procedures and study visits.

Time	What will happen
Pre-Study	• Tumor biopsy • Routine physical exam • Routine blood tests • Measurement of your tumors by imaging • Electrocardiogram • Research blood collection
Cycle 1, Day 1	• Docetaxel plus bintrafusp alfa or docetaxel alone by IV into a vein or port if you have one
Day 8 of every cycle during treatment with docetaxel	• Routine blood tests (may be done at local lab and submitted to Mayo Clinic)
End of Cycle 1, before starting Cycle 2	• Research blood collection • Research tumor biopsy
At the end of each cycle (every 3 weeks or 21 days)	• Routine physical exam • Routine blood tests • Research blood collection at the end of Cycle 2 and Cycle 4
Cycle 2, Day 1 Cycle 3, Day 1 Cycle 4, Day 1	• Docetaxel plus bintrafusp alfa or docetaxel alone by IV into a vein or port if you have one
Every other cycle starting at the end of Cycle 2 (then end of Cycle 4, Cycle 6, etc.)	• Imaging scans to document tumor size and location about every 6 weeks
Day 1 of every cycle starting with Cycle 5	• If you were randomized to docetaxel alone you will continue to get docetaxel by IV into a vein or port if you have one,

Time	What will happen
	until your cancer gets worse or you cannot tolerate the side effects • If you were randomized to the combination, you will continue to receive bintrafusp alfa alone by IV into a vein or port if you have one for up to 2 years
At time of disease progression	• If you were assigned to the docetaxel alone arm, you may be eligible to crossover to bintrafusp alfa alone • Routine physical exam • Routine blood tests • Imaging scans to document tumor size • Research blood collection • Research tumor sample only if clinical biopsy is done at this time
Crossover for patients in the docetaxel alone group at the time of disease progression	• Discuss crossover with your study doctor, if you both agree, you will continue to have visits every three weeks according to the schedule above • You may receive bintrafusp alfa alone by IV into a vein or port every 3 weeks for up to 2 years
Follow-up after treatment discontinuation	• After you stop the study medication (bintrafusp alfa), you will need one more safety visit about 30 days after your last dose to make sure you do not have residual effects from the drug • After that visit, you may be contacted by the study team during a clinic visit or by telephone every 6 months for a maximum of 5 years after you start this study

You will be informed of any clinically relevant research results. Any results reported to you individually, will also be placed in your medical record. Study results will be reported on ClinicalTrials.gov after the study is completed.

What are the possible risks or discomforts from being in this research study?

Bintrafusp alfa (M7824)
Bintrafusp alfa has been tested in over 650 patients as of April 2019.

The risks and discomforts of bintrafusp alfa include the following frequently reported events:

- Decrease in red blood cells (anemia)
- Bleeding from nose (epistaxis) or other soft tissues (mucosal bleeding)
- Not feeling hungry, not wanting to eat (decreased appetite)
- Fever (pyrexia)
- Fatigue
- Weakness (asthenia)
- Loose stools (diarrhea)
- Hard stools (constipation)
- Belly pain (abdominal pain)
- Nausea
- Vomiting
- Feeling short of breath, trouble breathing (dyspnea)
- Cough
- Rash
- Itching (pruritis)
- Changes in liver enzymes as seen on a blood test (AST)
- Headache
- Swelling in arms and hands or legs and feet (edema)

Blood Draws
The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

Biopsies
Biopsies are normally performed under the guidance of an imaging technique (such as ultrasound, x-ray, or CT). Each procedure requires a separate clinical consent prior to the biopsy.

The risks of biopsies may include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site
- Tenderness at the biopsy site
- Scarring at the biopsy site
- Rarely, an infection at the biopsy site

Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These complications might require additional surgical intervention.

Radiation risk from biopsies
Biopsies may be performed using CT guidance. You will be exposed to radiation during these tests. The amount of radiation you would get has a low risk of harmful effects.

Genetic Information Nondiscrimination Act (GINA)
The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or employment discrimination based on genetic information.
The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law also will not help you get other types of insurance (such as: life, disability or long-term care).

Risks Associated with Genomic Testing
Despite the GINA protections and the best efforts of the research team, there may still be a risk if information about you were to become known to people outside of this study.

Genetic information is unique to you, even without your name or other identifiers. For this reason, genetic information like DNA may be used to identify you and possibly your family members. We have procedures (such as, labeling your biospecimens with a password protected code known only to select research staff) to prevent people working with your DNA from discovering if it belongs to you. However, there is the risk this can happen as new ways of tracing genetic information are being developed that may make re-identification of genetic information possible.

Pregnancy
It is not known if the study drugs may affect an unborn or nursing baby or if the study drugs have an effect on sperm. Chemotherapy can cause harm to an unborn child. If you are pregnant, trying to become pregnant or breast-feeding, you may not be in the study. The study doctor will perform a blood or urine pregnancy test before the start of and during the study, if you are able to have a baby. If the test is positive, you will not be able to be in the study.

For persons able to become pregnant
If you are sexually active and able to become pregnant, you must agree to use birth control. You should discuss appropriate birth control methods with your doctor. Acceptable methods are listed below:

- Intrauterine device (IUD)
- Vasectomy in male partner
- Contraceptive rod implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Cervical cap with spermicide or contraceptive sponge (only if you've never been pregnant)
- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or injection
- Abstinence (no sex) if that is your preferred and usual lifestyle

You must use birth control for the entire study and for at least 180 days after your last dose of study drug.

If you miss a period, or think you might be pregnant during the study, you must tell the study doctor immediately. The study doctor may ask for your permission to collect information about the outcome of your pregnancy and your newborn.

For persons able to father a child
If you have a partner who is able to become pregnant, you must agree to use birth control. You should discuss appropriate birth control methods with your doctor. (Acceptable methods for you and your partner are listed above.)

You must use birth control for the entire study and for at least 90 days after your last dose of study drug.

Unforeseeable Risks
Many side effects go away shortly after the study drugs are stopped, but in some cases side effects can be serious, long lasting, or may never go away. There may be a risk of death. Some side effects may not be known. Side effects may range from mild to life-threatening. Other drugs may be given to make side effects less serious and less uncomfortable. Talk to the researcher and/or your healthcare provider about side effects and ask any other questions.

This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). This testing may include whole genome sequencing (mapping your entire genetic code). You will not be notified of the genetic test results and they will not be put into your medical record.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop.

In addition, the Principal Investigator, the study sponsor, or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
EMD Serono will offer to pay for medical treatment of research-related injuries directly resulting from the proper application of the study drug/procedure. EMD Serono may decide not to pay for several reasons. EMD Serono may not pay if EMD Serono concludes the injury happened because you did not follow the study directions or the injury resulted from your actions. EMD Serono may not consider the worsening of an existing health condition to be a research-related injury. In the case of injury resulting from your participation in this study, you do not lose any of your legal rights to seek payment by signing this form. Contact the Principal Investigator, who can help you obtain this reimbursement.

What are the possible benefits from being in this research study?

This study may not make your health better. However, if the study treatment is effective you may benefit by having your tumors get smaller which may help you live longer and improve any symptoms you may be experiencing as a result of the tumor. Researchers may also gain knowledge from this study that may help other patients in the future.

What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. Your other choices may include other chemotherapy, other clinical trials or no treatment for your disease. Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- The study drug, bintrafusp alfa, and its administration
- Research biopsies prior to treatment on this study and at the end of Cycle 1 (including imaging to obtain the biopsy tissue)
- Research testing on blood and tissue

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures include:

- Regular chemotherapy with docetaxel, and its administration
- Regular physical exams
- Regular blood testing
- Regular scans or imaging of your cancer (such as by MRI, CT, PET/CT, X-ray, etc.)

You and/or your insurance will need to pay for all other tests and procedures that are part of this research study because they are part of care for your cancer. You might also have to pay for other drugs or treatments given to help control side effects. Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. You will have to pay for any costs not covered by your insurance. You will also be responsible for any co-payments or deductibles.

If you have questions about any costs to you that may result from taking part in the research, please speak with the Principal Investigator. If you wish, arrangements can be made for you to speak with someone in Patient Financial Services about these costs.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

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

There is a very small chance that some commercial value may result from the use of your donated samples. This could include new products like a drug or a test to diagnose a disease. If that happens, you won't be offered a share in any profits.

Will your information or samples be used for future research?

Your information and samples will be sent to the Sponsor, Mayo Clinic. The Sponsor can use your data and samples for research purposes only as described in the research study. Your data and samples will be sent to the Sponsor in a coded format, which protects your identity. Mayo Clinic may destroy the samples at any time without telling you. We will test your tissue and blood as part of this study. In addition, we would like to keep your study information and samples for future research. You can still take part in this study without giving permission to use your data and samples for future research. If you agree to give your sample, it will be the property of Mayo Clinic.

Researchers who aren't involved with this study may ask to use your sample for future research. Researchers at other institutions may also ask for a part of your sample for future studies. Your sample will be sent to researchers in a coded format, which protects your identity.

Some future studies may examine your DNA, which is the genetic information you inherited from your parents (genetic testing). If there are findings which may be useful for your health care, the researchers may contact Mayo Clinic, so Mayo Clinic can give you the option of learning the results. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.
To support future research, de-identified genetic information may be placed in databases accessible by the internet. Some of the information may be available to anyone using the internet, and some will be released only to approved researchers. Combined study information (including genomic summary results) may be published, but the information will not identify you.

Even though information traditionally used to identify you will not be shared, people may develop ways in the future to allow someone to link your genetic information back to you. For this reason, confidentiality cannot be guaranteed. It is also possible that re-identified information could be used in discriminating ways, and there could be additional unknown risks. We will make every effort to protect your confidentiality.

Please read the following statements and mark your choices:

1. I permit my information and samples to be stored and used in future research to learn about, prevent or treat cancer:

   ☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my information and samples to be stored and used in future research to learn about, prevent, or treat any other health problems (for example: causes of diabetes, heart disease, and Alzheimer's, or genetic links to alcoholism):

   ☐ Yes ☐ No Please initial here: _____Date: _____

3. I agree to have my coded genetic information and coded medical information placed in password-protected secured databases for research analyses.

   ☐ Yes ☐ No Please initial here: _____Date: _____

4. I agree that my study doctor, or someone on the Mayo Clinic study team, may contact me to see if I wish to participate in other research in the future.

   ☐ Yes ☐ No Please initial here: _____Date: _____

You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved. Because we cannot predict how your sample will be used in the future, we cannot promise that samples can be retrieved and destroyed.

It is possible that information identifying your samples or your data could be removed. These samples and data will no longer be linked to you. If that were to happen, the samples and data could be used for future research studies or given to another researcher without asking for your permission.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. All of your research samples transferred to the Mayo Clinic or designee will be labeled with a code number and kept in locked storage. Only your study doctor will be able to link your samples with your identity. No one working with your samples will know your identity. If the results of the research are made public, information that identifies you will not be used.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Mayo Clinic, the sponsor of this study and the people or groups hired by the sponsor to help perform this research.

- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media) information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

	/ /	AM/PM
Printed Name	Date (mm/dd/yyyy)	Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	AM/PM
Printed Name	Date (mm/dd/yyyy)	Time (hh:mm am/pm)

Signature