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AS MODIFIED
Dec 11, 2023

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Phase Ib, Open Label, Multicenter Study to Determine the Maximum Tolerated Dose (MTD) of PARPi 2X-121 Monotherapy and the MTD of Dovitinib in Combination with 2X-121 in Patients with Advanced Solid Tumors

PROTOCOL NO.: AL-2003

SPONSOR: Allarity Therapeutics, Inc

<<CF-Main Header Block - Investigator>>
STUDY-RELATED PHONE NUMBER(S): <<CF-Main User Defined #1>>
[24 hour number is required]

INTRODUCTION

You are being invited to take part in a clinical research study because you have been diagnosed with an advanced solid tumor. This research study is using an investigational product, 2X-121, as a possible treatment for this diagnosis, both alone and in combination with another investigational product, dovitinib. 2X-121 belongs to a group of drugs called PARP inhibitors (poly [adenosine diphosphate-ribose] polymerase). PARP is an enzyme (a type of protein) found in the cells of your body. In normal cells when DNA is damaged, PARP helps to repair the damage. Dovitinib is a tyrosine kinase inhibitor that exhibits antitumor effects.

For purposes of this research, you will be referred to as “participant”.

Allarity Therapeutics, Inc. is a pharmaceutical company that is supporting this research study by providing funding for this research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

Before you decide to take part in this study, it is important for you to understand why the research is being done and what it will involve.

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PURPOSE OF THE STUDY

This research study is a Phase Ib clinical trial. Phase Ib clinical trials test the safety and efficacy of an investigational drug to determine whether or not the drug works safely to treat a specific disease.

Your study doctor and medical team are conducting a research study with Allarity Therapeutics, Inc. This study will help determine the safety of 2X-121 and dovitinib. The study will help determine a safe and effective dose of 2X-121 alone and a safe and effective dose of dovitinib when given in combination with 2X-121.

[redacted] oth drugs are investigational meaning that the FDA (the U.S. Food and Drug Administration) has not yet approved them as a treatment for any disease. The results of this study and previous studies will be used to design future studies to improve treatment of advanced solid tumors.

There will be two parts of this study. The first part will enroll about 16 participants, and the second part will enroll about 24 participants. The study will take place across up to five study centers.

[redacted]

[redacted]

[redacted]

[redacted]

ALTERNATIVE OPTIONS

Taking part in this research study is voluntary. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor. Other options may include:

- Participating in another research study, if there is one available
- Receive no therapy specific to your cancer
- Comfort care, also called palliative care. This type of care may help to reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to treat the symptoms.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

This research study will involve two parts. Participants in Part 1 will be assigned to receive either 600 mg, 800 mg, or 1000 mg of 2X-121 daily for 28 days. After Part 1, one of these dose amounts will be used in Part 2 of the study. Participants in Part 2 will be assigned to receive the chosen daily dose of 2X-121 as decided after Part 1, along with dovitinib at either a 300 mg, 400 mg, or 500 mg dose once daily for five days followed by 2 days without dovitinib. The 5 days on / 2 days off schedule will repeat for 28 days. Treatment will be allowed to continue as long as your disease does not progress, you do not experience unacceptable toxicity, and you continue to consent to treatment.

Each part of the study will consist of three phases: Screening Phase, Treatment Phase, and Follow-Up Phase. Assessments in each phase are the same in Part 1 and Part 2 unless otherwise noted.

Duration of your participation in this research study will be as follows:

- **Screening Phase**: Up to 28 Days
- **Treatment Phase**:
  - First treatment cycle: 4 weeks
  - Subsequent treatment cycles: you will be eligible to continue treatment as long as you do not experience progressive disease or unacceptable toxicity, and as long as you do not withdraw your consent to participate.
  - End of Treatment (EOT): EOT visit will be conducted approximately one month after the last treatment visit (i.e. after your last dose of 2X-121)
- **Follow-up Phase**: you will be followed up for two years after the EOT visit.

Screening Phase

After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated.

The screening period may last up to 28 days (4 weeks).

[redacted]

[redacted]

Note that all of the procedures listed above may not be done if at any point during the evaluation you fail eligibility. If you are not eligible for the study, your study doctor will explain the reasons and arrange for your prescribed standard care to continue.

At the end of this 4-week period you will be informed if you are eligible to enter the study.

Treatment Phase

The treatment phase will start within 28 days of the screening visit. This phase will be divided into 28-day treatment cycles.

Treatment Cycle 1

[redacted]

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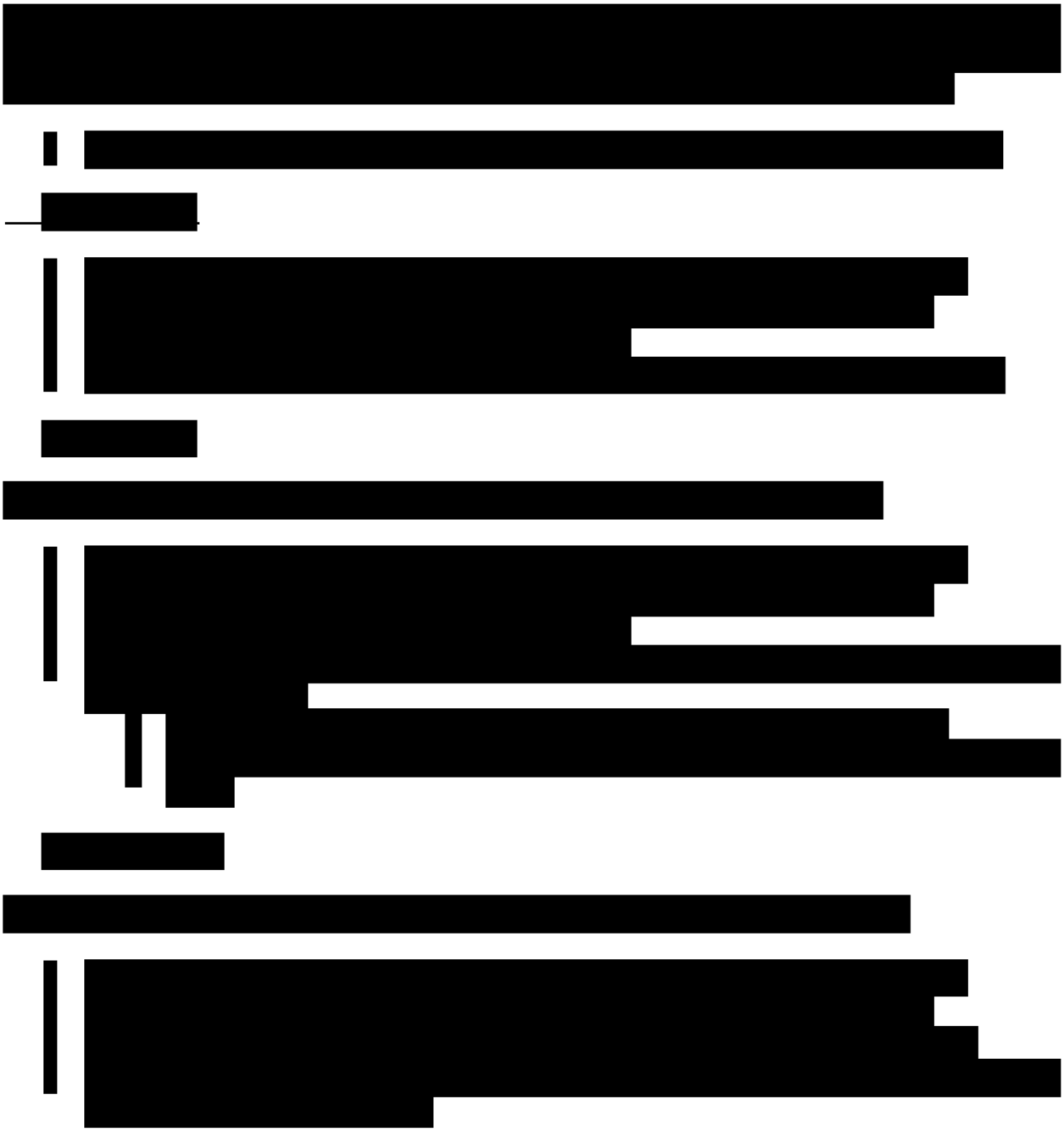

[redacted]

Treatment Cycle 2

[redacted]

[redacted]

Subsequent Treatment Cycles

You will be allowed to continue treatment until your disease progresses, you experience unacceptable toxicity, or you withdraw your consent to participate.

[redacted]

[redacted]

Follow-Up Phase

[redacted]

[redacted]

Unscheduled Visits

If you return to the study clinic at any time other than a regularly scheduled study visit, this will be considered an unscheduled visit. Your study doctor will decide what assessments to perform at these visits.

Genetics Studies:
This research will involve genomic or germline testing.
This research study WILL NOT include whole genome sequencing with the intent to generate the genome or exome sequence of your tumor tissue.

[redacted]

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health and may prevent discrimination by health insurers and employers based on genetic information. GINA is intended to ease concerns about discrimination that might keep some people from getting genetic tests that could benefit their health and enable people to take part in research studies such as this without fear that their DNA information might be used against them by health insurers or their workplace. This protection does not extend to disability or life insurance. Additional information can be found at http://www.genome.gov/10002328.

RISKS OF PARTICIPATION IN THE STUDY

There are risks to taking part in any research study. One risk is that you may get a study drug that does not help treat your disease or that makes your condition or disease worse. Another risk is that there may be side effects.

All cancer treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability among side effects of different cancer treatments and between individuals. In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study drugs to keep track of your blood counts and organ function, particularly your kidney and liver function. If you experience side effects, they may go away after you stop taking the study drug. Some side effects can be mild; but others can be long lasting and may never go away. Some may be life-threatening or fatal.

Since the effect of the study drug taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods that you should avoid while on this research study and your research doctor will review this information with you.

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

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[redacted]

Reproductive Risks:

The drug used in this research study may affect a fetus.

While participating in this research study, you should not:

- become pregnant
- nurse a baby

We can provide counseling about preventing pregnancy for either male or female study participants. Let your doctor know immediately if you become pregnant.

Risks associated with study procedures:

[redacted]

[redacted]

Non-Physical Risks:

Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

The questionnaires used in this study may be upsetting. If you find the questionnaires upsetting, you may speak with the research doctor or ask to be referred for additional emotional support.

BENEFITS OF PARTICIPATION IN THE STUDY

We do not know if taking part in this study will help you. This study may help researchers learn information that could help people in the future.

WILL I BE PAID FOR PARTICIPATION IN THIS STUDY?

You will not be paid for participating in this study.

The study sponsor may reimburse you for qualifying study-related travel costs and/or expenses. Study staff will review the reimbursement plan and any requirements for reimbursement with you.
<<CF-Main Payment for Part. Paragraph>>

ARE THERE COSTS TO PARTICIPATION IN THE STUDY?

Taking part in this research study may lead to added costs to you or your insurance company. This 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 disease. You may:

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

You will not be charged for 2X-121 or dovitinib.

You or your insurance company will be charged for portions of your care during this research study that are considered standard care. Standard of care is the care that you would receive regardless of whether you were enrolled in the study or not. You may be responsible for co-payments, co-insurance, premiums and deductibles that are typical for your insurance coverage. This includes the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests, done for research only, are supplied at no charge.
<<CF-Main Financial Disclosure>>

WHAT HAPPENS IN THE CASE OF INJURY OR ILLNESS DUE TO PARTICIPATION IN THE STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments may be billed to you or your insurance company. You will be responsible for deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

The study sponsor, Allarity Therapeutics, Inc., may pay for the cost of medical treatment. The treating institution and the study sponsor will be responsible for determining what costs may be covered by the study sponsor. You or your insurance company will still be billed for costs that are not covered by the study sponsor.

CONFIDENTIALITY

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration <<CF-Main SMO Company 1>> <<CF-Main Affiliated IN Language 1>>
- The Institutional Review Board (IRB) that reviewed this research

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file. It may also become part of a DF/HCC research database called CORIS.

Participation in this study involves providing a specimen of your tissue; please know that if the research doctor leaves the institution, the research and the tissue might remain at the DF/HCC or might be transferred to another institution.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do additional research.

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.

WHAT WILL HAPPEN TO THE REMAINING BIOMARKER SAMPLES AFTER THE STUDY IS OVER?

After the study is over, Allarity Therapeutics would like to keep any remaining tissue samples for future research and/or the development of biological tests related to the two drugs (2X-121 and dovitinib) or cancer. These samples will be labeled with a unique code and be stored under Allarity control for up to 15 years. The sponsor is responsible for the destruction of the samples at the end of the storage period. Any data generated from the future research studies will belong to Allarity and will not become part of your medical record. You can choose not to have your sample stored for future research and still be a part of this study. You will have the chance to state your choice about this at the end of this form.

WHAT HAPPENS IF NEW INFORMATION BECOMES AVAILABLE?

During the course of a research study, new information may become available about your disease or the treatment that is being studied that might change your decision to be in this study. If this happens, your study doctor will discuss this with you and whether you want to continue in the study. If you decide to withdraw, your study doctor will make arrangements for your prescribed standard care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

In addition, on receiving new information your study doctor might consider it to be in your best interest to withdraw you from the study. Your study doctor will explain the reasons and arrange for your prescribed standard care to continue.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

Once the study has finished, the information will be analyzed and a clinical report will be written to record the results. This process can take about 6 months. Your study doctor will be kept informed of the results from the study, and a paper detailing these results will probably be published in an appropriate medical journal. You can also ask your study doctor for the results of the study.

RESEARCH FUNDING

This study is being funded by Allarity Therapeutics, Inc.

WHAT HAPPENS IF I WANT TO STOP PARTICIPATING?

You may be taken off the research study for any reason including:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- You are a female and become pregnant or plan to become pregnant
- Your condition worsens
- A decision is made to end the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

It is important to tell the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping the study drug.

It is important to note that although you may withdraw from study participation, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from study records.

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WHO DO I CONTACT IF I HAVE QUESTIONS?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

CONSENT

Please do not sign this consent form until you had time to read it thoroughly and have any questions answered. If you choose to participate in this study, please read the following and sign where indicated.

Your signature below means that you have read the above information about this study and have had a chance to ask questions to help you understand what you will do in this study. Your signature also means that all of your questions have been answered to your satisfaction and your signature below means that you are agreeing to participate this research study. You have been told that you can change your mind later if you want to. You will be given a signed and dated copy of this agreement. By signing this consent form you are not giving up any of your legal rights.

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I have also read the part of this form about storing my samples for future research. My choice about having my sample stored and used for future research under the conditions described is (please initial ONE line below):

_____ I refuse to have my sample(s) stored or used for future research and/or the development of biological tests related to these two drugs (2X-121 and dovitinib) or cancer.

_____ I agree to store or use my sample(s) for future research and/ or the development of biological tests related to these two drugs (2X-121 and dovitinib) or cancer.

SIGNATURE OF SUBJECT	DATE

PRINTED NAME OF SUBJECT	TIME

I confirm that a copy of this consent form has been given to this person to read and that this person has been told about the study. The contents of the consent form describing the study has been discussed with this person. All questions have been answered to his or her satisfaction. I have watched this person sign the consent form.

SIGNATURE OF PERSON OBTAINING CONSENT	DATE

PRINTED NAME OF PERSON OBTAINING CONSENT

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---------- Use this witness section only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

Signature of Impartial Witness *Date*

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

Original for researcher; one copy for subject; one copy to be kept with medical records.

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Authorization to Use Your Private Health Information

Title:	A Phase Ib, Open Label, Multicenter Study to Determine the Maximum Tolerated Dose (MTD) of PARPi 2X-121 Monotherapy and the MTD of Dovitinib in Combination with 2X-121 in Patients with Advanced Solid Tumors
Study Part (Phase):	Phase Ib
Protocol Number:	AL-2003
Sponsor:	Allarity Therapeutics, Inc 210 Broadway Cambridge, MA 02139
Protocol Prepared By:	Amarex Clinical Research, LLC. 20201 Century Blvd, Suite # 405 Germantown, MD 20874 USA
Investigator:	[PI name] <<CF-Main Investigator Full Name-Title>>

1. Introduction

This authorization may contain words that you do not understand. Please ask the study doctor or staff to explain any words or information that you do not understand.

The purpose of this form is to explain how details about your health and your personal information that you give us during this study will be used and shared with others.

By signing this form, you allow the study doctor to use and share your personal health information collected during the course of this study. Please read this with the Informed Consent that you already signed for the above-mentioned study. All participation information is explained in that consent form.

If you choose not to sign this authorization, you may not participate in the study.

2. Information that may be used and shared

Information that may be used and given to others may include past, present and future health information collected during this study. Your personal health information includes, but is not limited to your name, address, telephone number, date of birth, government-issued identification number, medical records and charts, including the results of all tests and study related procedures as described in the Informed Consent. [i.e., subject satisfaction questionnaires, photographs, laboratory tests and other study-related materials that are unique and specific to your participation in this clinical study].

Your personal health information will be used to carry out the research, to review records on the information collected in this study, to check how the study was carried out, or for other uses permitted by law.

In addition to collecting your personal health information, your picture may be taken for identification purposes throughout the study and will be stored only within Allarity.

3. This information may be seen by

- The study doctor and staff,
- The study Sponsor, its current or future research partners, collaborators, assignees, licensees or designees,
- WCG IRB,
- The FDA,
- The Department of Health and Human Services,
- Government agencies that require reporting of reportable diseases,
- Governmental agencies in other countries,

- Individuals or companies that monitor the quality of research practice,
- Other individuals and organizations that analyze your health information in connection with this study, such as laboratories and other study sites participating in this study,
- Other individuals and organization that assist in determining your health, vital status or contact information should you withdraw from treatment or are otherwise lost to follow-up.

There may be other information that may be used and given to others that has not been stated above. It is advised that you discuss this with the study doctor or a member of the staff and ask any questions that you may have about the sharing of your health information.

4. How long is this authorization in effect

[This authorization to use and disclose your personal health information does not expire. You must notify the study doctor that you no longer want to share your information. Information collected prior to the termination of your authorization may still be used for study purposes. OR This permission will be good until December 31, 2070.] <<CF-Main User Defined #6>>

If you decide that you no longer wish to have your personal health information shared, you may withdraw at any time. However, once you do so, you can no longer continue to participate in the study.

In addition:

- You must provide a written request to the study doctor, listed on page 1, and tell him or her that you no longer want to share your information. Revoking your authorization and choosing to no longer participate in this study, does not affect your treatment or any other benefits to which you would otherwise be entitled.
- You will no longer be a part of this research study.
- Neither Sponsor, the study doctor or study staff will be able to use or disclose your personal health information generated from this study except to the extent that they or the study Sponsor has already relied on this information to conduct the study.

Once the study doctor has shared your information with someone outside the study, it may no longer be protected. There is a chance that your information will be shared with others in ways that are not listed here and released without your permission.

You have a right to see and copy your information, however, not while the research study is going on.

SIGNATURE OF SUBJECT	DATE
PRINTED NAME OF SUBJECT	TIME
SIGNATURE OF PERSON OBTAINING CONSENT	DATE
PRINTED NAME OF PERSON OBTAINING CONSENT	