[redacted]

[redacted]

Patient information flip chart

Protocol [redacted]

[redacted]

This flip chart has been designed as a tool to facilitate the informed consent process, for use when describing the [redacted] Clinical Trial to potential participants.

The flip chart will help you:

- Explain the key facts of the [redacted] Clinical Trial
- Describe what will happen and when

The flip chart should be placed in the center of the table, with this side facing you (the trial staff) and the other side facing the potential participant. Please discuss each topic in detail and encourage participants to ask questions at any time during the conversation.

This flip chart does NOT replace the informed consent form. You will still work through the informed consent form with interested participants, and the informed consent form must be signed before screening can begin.

[redacted]

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What is a clinical research trial?

- Explain what a clinical research trial is and why trials are conducted
- Discuss how many people around the world volunteer to take part in clinical research trials
- Explain that all clinical research trials are reviewed by regulatory bodies (e.g., government health authorities, institutional review boards, and ethics committees)
- Clarify that during a clinical research trial, doctors and scientists regularly check the health of each participant, and the participant will be removed from the trial if there are any serious issues

What is a clinical research trial?

- A clinical research trial is a scientific trial done with the help of people who volunteer to participate
- The goal of clinical trials is to determine how safe a trial medication or treatment is and how well it works (its effectiveness)
- Through clinical research trials, doctors can find new and better ways to prevent, detect, diagnose, and treat illnesses
- All clinical research trials are carefully monitored and regulated to protect participants

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What is the purpose of the [redacted] Clinical Trial?

- Explain why the [redacted] Clinical Trial is being conducted:
  - To evaluate the safety and effectiveness of an investigational chimeric antigen receptor (CAR) T cell therapy in individuals with active systemic lupus erythematosus (SLE), including lupus nephritis (LN)
  - In CAR T cell therapy, autologous T cells are removed from your blood and then introduced to a CAR that teaches them to target and attack the cause of disease symptoms. Next, these T cells, now called CAR T cells, are multiplied in a lab and then returned to the bloodstream through an infusion.
  - Researchers believe that, when used to address SLE, CAR T cell therapy may help the body destroy malfunctioning immune cells and potentially lead to SLE improvement
- Explain the trial, including the potential risks and benefits
- Explain what happens after the trial is over or if the patient stops participating in this trial
- Clarify that during the [redacted] Clinical Trial, the doctors regularly check the health of each participant; if any problems occur, the participant may be removed from the trial
- Explain that participation is voluntary, and a participant may choose to leave the trial at any time. If participants choose to leave the trial early, they will be asked to come for a follow-up visit to check on their health.

[redacted]

The [redacted] Clinical Trial

The purpose of this trial is:

- To evaluate the safety and effectiveness of an investigational chimeric antigen receptor (CAR) T cell therapy in individuals with active systemic lupus erythematosus (SLE), including lupus nephritis (LN)

The trial doctor will explain the trial, including its potential risks and benefits.

- Participation is voluntary, and whether you participate in this trial is up to you
- You may choose not to take part, or you can change your mind and drop out at any time
- If you choose to leave the trial early, you will still be asked to come for a follow-up to check on your health

After the trial is over, or if you decide to stop your participation in this trial:

- You will be asked to attend several follow-up visits so that your health can be monitored
- Tell the trial doctor if you have any side effects after receiving the investigational therapy. The trial doctor may add that to your trial record.
- If you decide to stop the trial early, you are agreeing that we can still use your trial information that has already been collected

The trial doctor has the right to remove you, the trial participant, from the trial at any time, with or without your agreement. This decision will be made if:

- It is in your best medical interest to stop participation
- You do not follow instructions
- The trial is canceled

Participation in this trial is voluntary, and you may choose to leave the trial at any time. If you choose to leave the trial early, you will be asked to come back for a follow-up visit to check on your health.

[redacted]

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What will happen in the trial?

- In order to participate in this trial, potential participants must be 16 years of age or older and weigh 88 lbs. (40 kg) or more have a diagnosis of SLE (including LN), and have taken steroids and at least 2 immunosuppressants (1 of which is a biologic therapy consistent with treatment guidelines), but have not had a good response. There are other inclusion criteria as well.
- Explain the design of the trial
  - The trial lasts for about 5 years and is divided into 3 periods: pre-treatment, treatment, and post-treatment follow-up
  - After participants are screened and enroll in the trial, they will undergo leukapheresis and pre-treatment evaluation. Once the trial treatment period begins, they will have lymphodepleting (LD) therapy administered and then receive the investigational therapy.
    - **Leukapheresis:** You will be connected to a machine by 2 intravenous (IV) lines that are placed into your body. One IV line will take your blood, which is then circulated in the machine to collect the T cells, and the second IV will carry your blood back to your body. The collected T cells will be genetically modified and then returned to your bloodstream at a later point. This procedure may take a few hours and will prepare your body for the investigational therapy.
    - **LD therapy:** This is administered to reduce certain white blood cells in the body so that they do not attack the CAR T cells that are introduced during the investigational therapy infusion.
  - Following infusion of the investigational therapy, participants will remain at the hospital for 10 days to be monitored
  - There will be will be 17 follow-up visits over about 5 years
  - Additionally, there will be a long-term follow-up (LTFU) under a separate protocol.

Trial design

Individuals who are at least 16 years of age and have a diagnosis of SLE, including lupus nephritis (LN), may qualify to participate in the [redacted] Clinical Trial.

The trial will last about five years and is divided into the following periods:

- **Pre-treatment period:** You will attend one screening visit. At this screening, certain tests and procedures may be done to make sure the trial is a good match for you. If you are eligible and decide to enroll, you will then undergo a procedure called leukapheresis before the treatment period begins. This is all done after you sign the informed consent form (ICF).
  - During **leukapheresis**, you will be connected to a machine by two intravenous (IV) lines that are placed into your body. One IV line will take your blood, which is then circulated in the machine to collect the T cells, and the second IV will carry your blood back to your body. The collected T cells will then be genetically modified at a [redacted] laboratory before they are returned to your bloodstream at a later time (it may take a few weeks before the new T cells are ready to be returned back into your bloodstream). This procedure may take a few hours and will prepare your body for the investigational therapy.
- **Treatment period:** You will undergo lymphodepleting therapy and then receive a single infusion of the investigational therapy, [redacted]. Following this, you may remain in the hospital for 10 days to be monitored and undergo procedures such as vital sign measurements, physical exams, and blood and urine sample collections. After being discharged, you will attend four additional trial visits.
  - **Lymphodepleting (LD) therapy** is administered to reduce certain white blood cells in the body so that they do not attack the CAR T cells that are introduced during the investigational therapy infusion. This helps prepare the body for the trial treatment.
  - You will be contacted by an experienced CAR T health care provider via phone call every day that you are not in the hospital or visiting the trial site, until the end of the first four weeks.

[redacted]

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What will happen in the trial?

- In order to participate in this trial, potential participants must be 16 years of age or older and weigh more than 88 lbs. (40 kg), have a diagnosis of SLE (including LN), and have taken steroids and at least 2 immunosuppressants (1 of which is a biologic therapy consistent with treatment guidelines), but have not had a good response. There are other inclusion criteria as well.
- Explain the design of the trial
  - The trial lasts for about 5 years and is divided into 3 periods: pre-treatment, treatment, and post-treatment follow-up
  - After participants are screened and enroll in the trial, they will undergo leukapheresis and pre-treatment evaluation. Once the trial treatment period begins, they will have lymphodepleting (LD) therapy administered and then receive the investigational therapy.
    - **Leukapheresis:** You will be connected to a machine by 2 intravenous (IV) lines that are placed into your body. One IV line will take your blood, which is then circulated in the machine to collect the T cells, and the second IV will carry your blood back to your body. The collected T cells will be genetically modified and then returned to your bloodstream at a later point. This procedure may take a few hours and will prepare your body for the investigational therapy.
    - **LD therapy:** This is administered to reduce certain white blood cells in the body so that they do not attack the CAR T cells that are introduced during the investigational therapy infusion.
  - Following infusion of the investigational therapy, participants will remain at the hospital for 10 days to be monitored
  - There will be will be 17 follow-up visits over about 5 years

[redacted]

Trial design (cont'd)

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NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What will happen during the trial?

- Review of medical history and medications
- Review of side effects
- New malignancy surveillance
- Complete physical exam, including weight, height, and vital signs
- Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) assessment
- Electrocardiogram (ECG)
- Echocardiogram (ECHO)
- Pregnancy test (if applicable)
- Urine and blood sample collections
- Leukapheresis
- Lymphodepleting (LD) therapy
- Bridging therapy/rescue therapy (optional)
- Investigational CAR T therapy infusion
- Questionnaires
- Lupus disease assessments

Trial visits

Below is a list of all the assessments that will happen during the trial. There is also a table called "Schedule of Activities" that shows what will be done at each visit. After enrolling in the trial, you will receive a visit guide that goes over the trial assessments on a day-to-day basis and an appointment reminder card to inform you of your next trial visit and what trial assessments will be completed at that particular visit.

Please review the following list of procedures that are a part of the trial and ask the trial team any questions you may have.

- Review of medical history and medications
- Review of side effects
- New malignancy surveillance
- Complete physical exam, including weight, height, and vital signs
- Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) assessment
- Electrocardiogram (ECG)
- Echocardiogram (ECHO)
- Pregnancy test (if applicable)
- Urine and blood sample collections
- Leukapheresis
- Lymphodepleting (LD) therapy
- Bridging therapy/rescue therapy (optional)
- Investigational CAR T therapy infusion
- Questionnaires
- Lupus disease assessments

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What will happen throughout the trial?

Time and events schedule

What will happen throughout the trial.

Procedure	Pre-treatment	Treatment	Post-treatment follow-up
Informed consent	X		
Review eligibility criteria	X	X	
Review of medical history and current medications	X		
Tuberculosis testing	X		
Review of side effects	Continuously		
New malignancy surveillance	Continuously		
Physical exam	X	X	X
Vital signs	X	X	X
ICANS assessment		X	X
ECG	X		
ECHO	X		
Pregnancy test (if applicable)	X	X	X
Blood sample collection	X	X	X
Urine sample collection	X	X	X
LD therapy		X	
Investigational CAR T therapy infusion		X	
Leukapheresis	X		
Bridging therapy/rescue therapy (optional)	X		
Questionnaires	X	X	X
Lupus disease assessments	X	X	X

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What are the requirements of the trial?

Explain to the participants that they must:

- Discuss with the trial doctor all of the medications they are currently taking, including herbal remedies, over-the-counter medications, and vitamins
- Stop taking any medications that are NOT prescribed or recommended by the trial team (like herbal preparations and over-the-counter medications)
- Attend all of their appointments and follow all instructions given to them by the trial team
- Tell their trial team if they can't make an appointment
- Tell their trial doctor about any side effects or discomforts that they experience
- Talk to their trial team before starting any new medications or treatments (like elective surgery)
- Tell their trial team if they change their address, telephone number, or other contact information
- Inform any medical care providers they see outside of the trial that they are in a trial

It is important that participants always carry their Subject Alert Card (SAC) with them. It will be given to them at the beginning of this trial. The SAC will help explain this trial to any other doctor or health care professional who may become involved in their care (like emergency room doctors or family doctors).

[redacted]

Trial requirements

As a participant in this trial, you must:

- Discuss with your trial doctor all of the medications you are currently taking, including herbal remedies, over-the-counter medications, and vitamins
- Stop taking any medications that are NOT prescribed or recommended by your trial team (like herbal preparations and over-the-counter medications)
- Attend all of your appointments and follow all instructions given to you by the trial team
- Tell your trial team if you can't make an appointment
- Tell your trial doctor about any side effects or discomforts that you experience
- Talk to your trial team before starting any new medications or treatments (like elective surgery)
- Tell your trial team if you change your address, telephone number, or other contact information
- Inform any medical care providers you see outside of the trial that you are in a trial

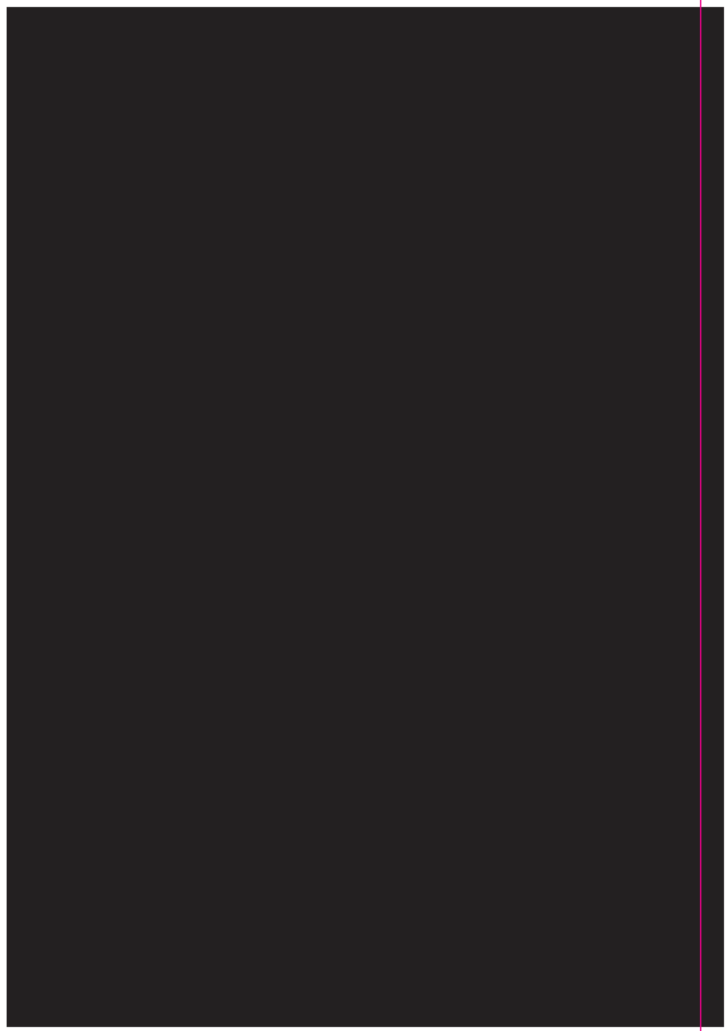
It is important to know that you must always carry your Subject Alert Card (SAC) with you. It will be given to you at the beginning of this trial. The SAC will help explain this trial to any other doctor or health care professional who may become involved in your care (like emergency room doctors or family doctors).

[redacted]

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What are the risks of participating in this trial?

- Explain possible side effects and risks associated with medicines being used in this trial and explain that not all risks are currently known
- Explain side effects specific to LD therapy (e.g., cyclophosphamide, fludarabine) and CAR T cell therapy (e.g., cytokine release syndrome [CRS], neurologic toxicities, low blood cell counts, etc.)
- List the risks, such as allergic reactions, that can occur with antibodies and explain that participants may have an allergic reaction where the investigational therapy is infused into the body
- List the possible side effects associated with the procedures being done in this trial
- In order to participate in this trial, individuals of childbearing potential must not become pregnant. Males (as assigned at birth) must use barrier contraception to prevent pregnancies in a female (as assigned at birth) partner.



Risks

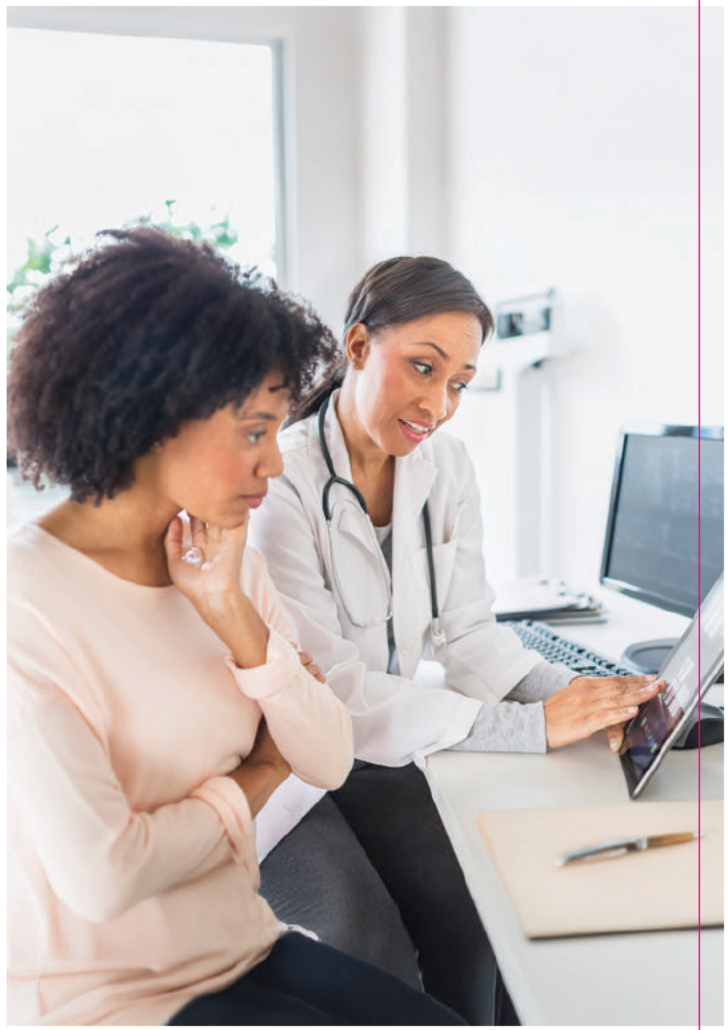
The possible discomforts, side effects, and risks related to the investigational therapy are not all known. Please refer to the informed consent form for a complete list of all side effects.

Pregnant individuals and individuals who are breastfeeding cannot participate in this trial. Individuals of childbearing potential must have a blood test when beginning this trial that shows they are not pregnant. It is very important that participants enrolled in this trial do not become pregnant or get a partner pregnant during the trial.

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What are the benefits of this trial?

- Mention that it is possible that the patient may not personally benefit from participating; however, the knowledge gained from a patient's participation in this trial may help other patients in the future
- A possible benefit is improvement in the patient's SLE symptoms, though this is not guaranteed



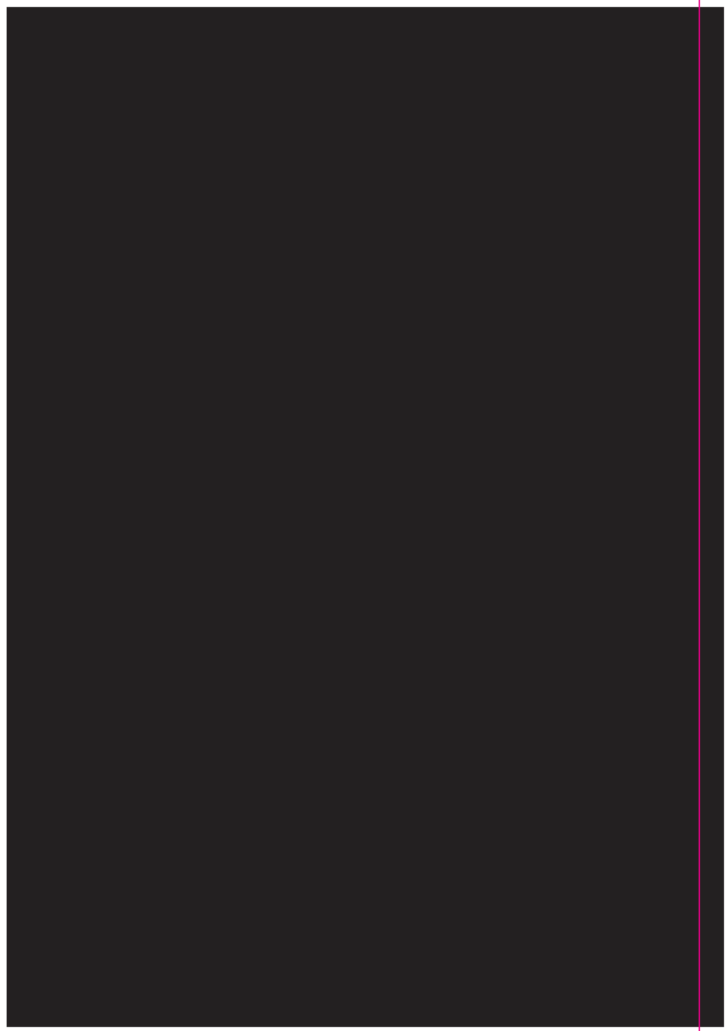
Benefits

Taking part in this trial may improve your condition, but that is not guaranteed. There may be no benefit to you. While you are in this trial, the trial doctor will follow your condition closely. By taking part in the trial, you may help future patients with SLE and the autoimmune disease community at large.

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: Is reimbursement for participating in this trial available?

- Explain that there is no payment for participating in this trial, though reimbursement for travel and time may be available
- Explain that the investigational therapy and most trial-related medical tests, which are not considered standard of care, will be provided at no cost



Costs and reimbursement

Care and tests:

- You will receive the investigational therapy and most trial-related medical tests, which are not considered standard of care, at no cost
- The sponsor will not pay for doctor visits or other medications or tests that are not related to this trial

Reimbursement for this trial:

- Please speak with the trial team to learn about how you may be reimbursed for trial-related costs, including time, travel, trial visits, and parking

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What happens to the samples collected throughout the trial?

- Define what a sample is (e.g., blood, urine, tissue)
- Explain what samples are used for during the trial
- Explain that the results of any additional scientific research done on a participant's samples will not be used for their medical care
- Samples collected in this trial may be stored in a secure facility for up to 20 years after the trial is completed. If required by a regulatory agency, there is a chance that samples may be stored for longer than 20 years.

Collected samples

Samples are any fluid (e.g., blood, urine) or tissue collected from you in this trial. Your samples may be used for the following scientific research only:

- To understand how the investigational therapy works or why it may cause side effects
- To better understand SLE
- To identify how people may respond to the investigational therapy (e.g., side effects, allergic reactions)

The results of any scientific research done on your samples will not be used for your medical care. If you leave the trial early or your participation stops for any reason, your samples will still be used to complete the testing and analysis required for the trial and to satisfy regulatory requirements.

NOTES FOR INVESTIGATOR/TRIAL COORDINATOR

Q: What are some frequently asked questions about this trial?

Talk through the following questions:

Q: Will I get the investigational therapy?

A: Yes, all participants who enroll in this trial will receive the investigational therapy.

Q: Will I experience side effects from being in the trial?

A: There is a chance you could experience side effects. Please refer to the section of the informed consent form titled "Risks and Benefits" for details. If you do have any side effects, it will be important to let the study team know.

Q: How long will I be in the trial?

A: You will be in the trial for just over 5 years. At the end of the trial, you will be asked to join a long-term follow-up period for up to 15 years. You should join the trial only if you are willing and able to stay in the trial until the end.

Q: Can I withdraw from the trial?

A: Yes, you can leave the trial at any time. You do not have to give a reason. However, you should inform the trial doctor as soon as possible if you decide to leave the trial. There is no charge or penalty for quitting. If you stop the trial, you will be asked to come in again to monitor your health.

Q: Can the trial team remove me from the trial?

A: Yes, the trial doctor or the trial team can remove you from the trial at any time.

[redacted]

Informed consent form summary

- **Will I get the investigational therapy?**
  Yes, all participants who enroll in this trial will receive the investigational therapy.

- **Will I experience side effects from being in the trial?**
  There is a chance you could have side effects. Please refer to the section of the informed consent form titled "Risks and Benefits" for details. If you do have any side effects, it will be important to let the study team know.

- **How long will I be in the trial?**
  You will be in the trial for just over five years. At the end of the trial, you will be asked to join a long-term follow-up period for up to 15 years. You should join the trial only if you are willing and able to stay in the trial until the end.

- **Can I withdraw from the trial?**
  Yes, you can leave the trial at any time. You do not have to give a reason. However, you should inform the trial doctor as soon as possible if you decide to leave the trial. There is no charge or penalty for quitting. If you stop the trial, you will be asked to come in again to monitor your health.

- **Can the trial team remove me from the trial?**
  Yes, the trial doctor or the trial team can remove you from the trial at any time.

[redacted]

[redacted]

Thank you for your time.

[redacted]

[redacted]