RESEARCH SUBJECT CONSENT FORM AND HIPAA AUTHORIZATION – PHAGE STAGES 2a/2b

TITLE: A Phase 1b/2, Multi-Centered, Randomized, Double-Blind, Placebo-Controlled Trial of the Safety and Microbiological Activity of a Single Dose of Bacteriophage Therapy in Cystic Fibrosis Subjects Colonized with *Pseudomonas aeruginosa* (PHAGE)

PROTOCOL NO.: 20-0001
WCG IRB Protocol # 20210887

SPONSOR: National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID)/Division of Microbiology and Infectious Diseases (DMID)

<<CF-Main Header Block - Investigator>>

INVESTIGATOR: Name
Address
City, State, Zip Code
Country

Study-Related Phone Number(s): <<CF-Main User Defined #1>>
Phone Number
Phone Number (24 hours)

For Stage 2a/2b subjects only

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a study that involves research. A person who consents to a research study (takes part in a research study) is called a research subject, or research participant. The research study is called the Phage Study (from this point it will be called "the study" or "this study"). The first section of this document (consent summary) provides a brief summary of the study. It describes the key information that we believe most people need to decide whether to participate. Later sections of this document will provide all relevant details.

The sponsor is paying for this research study. Your study doctor will be paid by the sponsor.

What should I know about this study?

- Someone will explain this study to you.
- Taking part in this study is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this study?

We expect that your taking part in this study will include coming into the clinic (5 visits) and one (1) virtual visit for a total of six (6) visits spread out over around forty-four (44) days.

Why is this study being done?

The main purpose of this study is to see how safe and how well a one-time dose of an experimental study "medication" works in adult patients who have cystic fibrosis and whose lungs have bacteria called *Pseudomonas aeruginosa*. "Experimental" means that the study medication is currently being tested. It is not approved by the U.S. Food and Drug Administration (FDA). The name of the "medication" is called "bacteriophages". The short name for bacteriophages is "phage(s)". Phages are viruses that, when injected into your blood, can kill some types of bacteria inside your body.

The study will see how well the phages work in decreasing the amount of *Pseudomonas aeruginosa* from your lungs. The study will also see how your body tolerates the phages up to thirty-seven (37) days after you receive the phage.

What happens to me if I agree to take part in this study?

If you decide to take part in this study, and sign this informed consent form, the procedures will include a screening visit in order to see if you qualify to participate in this study.

The screening visit will include a physical exam and a review of your medical history. During this visit we will check your lungs to see how well you are able to breathe. The study team will also collect some blood and sputum samples from you for testing during this period. Sputum is a mix of coughed-up saliva and mucus.

If you qualify for study participation, you will return to the clinic one (1) to seven (7) days later and you will receive a dose of phage, or a placebo. A placebo is a liquid that will look exactly like phage, but it will not have any active "medicine" (actual phage dose not given). After this visit you will then return to the clinic (3 visits) and one (1) virtual visit for a total of four (4) study visits to see how you are doing. If there is a medical reason (illness), where you cannot come in-person, please contact your study doctor at the number on page 1 of this consent to see if a virtual visit can be done instead.

Could being in this study hurt me?
Phage/placebo will be given to subjects using what is called a peripheral intravenous catheter (IV catheter). An IV catheter is a small, flexible hollow tube that is inserted into a vein of your arm with the use of a needle. Placement of IV catheters that will be used in this study can cause discomfort, minor bleeding, and infections from bacteria that live on the skin. You may feel dizzy or you may faint.

The scientific literature regarding the use of phages has not indicated any clear safety risks. Some of the potential risks may include hypotension (low blood pressure), shortness of breath and feeling sweaty or flushed. Other potential risks from phage could include worsening of respiratory conditions, inflammatory or allergic reactions caused by endotoxins (the product left after bacteria are destroyed), or temporary elevation of liver enzymes. These have all been temporary reactions that have gone away quickly. While phages have been studied, not all is known about their effects and it is possible you could experience a reaction to the phage. The study team will monitor you during the time you receive the phage or placebo and up to about thirty-seven (37) days after you receive the phage or placebo.

Will being in this study benefit me?
It is unknown if the study medication will benefit you. It may decrease the amount of a single type of bacteria, *Pseudomonas aeruginosa,* in your lungs while you are in this study. There are no benefits to your Cystic Fibrosis from taking part in this study. However, there are societal (within society) benefits with study participation. The information gathered from this trial will further advance the science of phages and could benefit future patients with infections from *Pseudomonas aeruginosa*.

What other choices do I have besides taking part in this study?
Instead of being in this study, you may choose not to participate in the study. The choice on whether to participate or not in this study is up to you. You will continue to receive clinical care as you normally would, without penalty, whether or not you choose to participate in this study. Your study doctor will discuss other options, and their risks and benefits, with you.

What else should I know about this study?
This is a phase 1b/2 study, which means it is early in the development process and we will be collecting safety information about you. Study visits will take place in an outpatient setting, which means you do not need to be admitted to the hospital (you can go home on the days of the visits).

There are no study related costs to you for participating in this study other than your time to meet with the study team during the six (6) study visits. The estimated time required for each visit is: Visit 1: 2-3 hours; Visit 2: 6-8 hours; Visit 3: 2 hours; Visit 4: 2 hours; Visit 5 (virtual visit): 1 hour; Visit 6: **will not occur in Stage 2**; Visit 7: 2 hours. Your study team may ask you to come in for one or more Unscheduled Study Visits. If requested, this visit would take around 1-2 hours. If necessary, some of these visits can be virtual.

If you are a person who is capable of having children/giving birth, you will have to use an effective method of birth control while in the study.

If you are in the process of receiving, or are planning to receive (in the next 30 days) the COVID-19 vaccine(s), you may be asked to wait before you start the study. The amount of time you may be asked to wait is at least 2 weeks after you finish your final COVID-19 vaccine. The COVID-19 vaccine is a shot that is given to people to help them not get sick from the Corona Virus.

If you participated in this study in the past you will not be able to participate again.

The information and samples collected for this study may be used for future, currently unknown, research. This future research may include such things as additional work on phages, cystic fibrosis, and infections of the blood, lung, skin, or other parts of the body. While this short list does not describe every possible use of your samples, it does show the likely types of future research that your information and samples will be used in.

In these future research studies, your information and/or samples will be coded (with a number). This means that the people who will use your information and/or samples for future research studies will not be given information to directly identify you. Any future

research using your information and samples will be performed without obtaining additional consent from you.

DETAILED RESEARCH STUDY CONSENT

What should I know about this study?

- Someone will explain this study to you.
- This form sums up that explanation.
- Taking part in this study is voluntary. Whether you take part is up to you.
- You can choose not to participate. There will be no penalty or loss of benefits to which you are otherwise entitled. The quality of your medical care will not be affected if you choose not to participate.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.
- Take as much time as you need to think about whether or not you want to participate. If you wish, you may discuss this study with your family and friends.

Why is this study being done?

The purpose of this study is to study a new investigational drug to see how well it is tolerated and to see if it will help reduce bacteria that is commonly found in the lungs of people who have cystic fibrosis. This study is also being done to see how much drug will be absorbed by the body and how fast it will be absorbed after it is given to subjects. These types of studies are called "PK studies" (Pharmacokinetics studies).

Cystic fibrosis is a disease primarily impacting the lungs. Patients who have cystic fibrosis have difficulties breathing because their lungs make extra-thick, sticky mucus. The mucus builds up in the airways of the lungs, which can lead to an infection of the lungs by bacteria.

The name of the investigational drug that is being used in this study is called "bacteriophages". The short name for bacteriophages is "phage(s)". Phages are viruses that, when injected into your blood, can kill some types of bacteria inside your body. The name of the bacteria that this study is aiming to reduce in your lungs is called *Pseudomonas aeruginosa.*

The phage that is being used in this study is investigational. This means that the use of phage in humans is not approved by the Food and Drug Administration (FDA).

The reason why this part of the study (Stage 2) is being done is to continue to see how safe phage is and how well your body will tolerate the dose (amount) of phage you may receive. It will also help us understand how well phage work to kill bacteria called

Pseudomonas aeruginosa, and will help determine the ideal phage dose to use for patients like you.

How long will I be in this study?
The actual number of days that will be required for you to come into the clinic or be seen virtually is six (6) days, but taking into account the number of days in between the visits, the total number of days you participate in the study will be up to approximately forty-four (44) days.

What happens to me if I agree to take part in this study?
This study is divided into different parts that are called Stages. The main stages are Stage 1 and Stages 2a/2b. Stage 1 of the study has been recently completed or will be completed soon. The goal of Stage 1 was to try to understand how safe phage is. A total of six (6) study participants are in Stage 1. The people in charge of this study confirmed that, from information obtained during Stage 1, the study is safe to continue. Therefore, they agreed that Stage 2 of the study may begin.

You are being asked to participate in one of the two stages listed below. Your study team will inform you which stage you are being asked to participate in.

- Stage 2a: This is a randomized, double-blind, placebo controlled stage. What this means is that those who volunteer for Stage 2a will receive one of three phage doses (low, medium or high amount), or they will receive a placebo. You will have a 3 out of 4 chance to receive phage and 1 out of 4 to receive placebo.
- Stage 2b: This will also be a randomized, double-blind, placebo controlled stage. Those who volunteer for Stage 2b will receive one dose of phage (the dose that performed the best in Stage 2a), or they will receive a placebo. You will have an equal chance to receive phage or placebo.

Whether you receive active phage or the inactive placebo will depend on a computer program. Neither you or your study team (other than the pharmacist who will prepare the products) will know if you will be assigned to phage or placebo because all final prepared products will look exactly the same. Your study doctor can find out in case of an emergency. "**Phage/placebo**" will be used in this consent form to describe the phage **or** placebo.

About thirty-two (32) study participants will participate in Stage 2a and about twenty-four (24) to thirty-four (34) study participants will participate in Stage 2b. Overall up to seventy-two (72) study participants in the United States will be enrolled in this study.

If you agree to be part of this study, you will be asked to come in to the clinic/hospital/medical facility for 5 visits and do 1 virtual visit, a total of six (6) visits:

- Visit #1 (up to 7 days before Visit #2) - Screening Visit to see if you qualify.
- Visit #2 (Day 1) -- The day you will receive phage/placebo.
- Visit #3 (Day 2) – A check-up visit.
- Visit #4 (Day 3 to Day 7) – Another check-up visit.
- Visit #5 (Day 8 to Day 11) – A virtual check-up visit.
- Visit #6 **This visit will not occur in Stage 2**.
- Visit #7 (Day 23 to Day 37) - Another check-up visit. This will be the final visit.

It is not expected that you will be required to stay in the hospital overnight (be hospitalized) as a result of participating in this study. All visits outlined in this consent will be done on an outpatient basis, which means you will be allowed to go home. The details of each visit are listed in the next sections.

Screening Visit (1 to 7 days before you receive phage/placebo)

The Screening Visit is expected to take around 2-3 hours. The study doctor or the study team will first explain the study to you and they will give you an opportunity to ask questions about phage/placebo and any details of the study. You will also be given an opportunity to think about whether or not you will want to participate. If you agree to be in this study you will be asked to sign this consent form. The informed consent explains what you can expect during the course of the study.

Once the consent form is signed, you will start the screening visit so that the study team can determine if you will be able to continue to participate in the study (be enrolled and receive phage/placebo). A copy of the signed consent form will be given to you.

The screening activities include:

- A review by the study team of the study requirements to be sure you qualify to participate in the study.
- If you are a person who is capable of having children/giving birth, a blood pregnancy test will be done. The total amount of blood collected during this visit for the pregnancy test is about 5 mL (1 teaspoon). The study team will make every effort to collect blood work with no more than one blood draw (“stick”), but this may not be possible if it will be difficult for the study team to find an accessible vein.
    - You will not be able to participate in the study if you are pregnant, planning to become pregnant, or are breastfeeding.
    - If you are a person who is capable of having children/giving birth, you must agree to use an effective method of birth control while in the study.

  - If you become pregnant while you are in the study, the study team will ask to check on you after the birth of your baby. The pregnancy outcome and the health status of you and your baby will be documented. Your baby's date of delivery, sex, and weight will be collected. You will also be followed for 8 weeks after you give birth to your baby, or after the pregnancy is terminated (either naturally or by choice).
- Demographic information (age, gender, race, ethnicity).
- Height and weight measurement.
- A medical history and medication history. The medication history that will be collected will be from the past 30 days to present day. You will also be asked about your routines as they relate to your respiratory system.
- A review of your medical systems. This means that you will be asked about your general well-being and if you have problems with your vision, hearing, balance, mental health, dizziness, breathing, nausea, vomiting, etc.
- A complete physical examination.
- Vital signs (blood pressure, heart rate, breathing rate, and body temperature).

If a physical exam or vital signs were done as part of your normal medical care within three (3) days before the Screening Visit, then these results may be used and another physical exam and/or vital signs will not be required at the Screening visit.

- Blood will be collected for these tests: liver function. The total amount of blood collected during this visit will be about 2 mL (about 1/2 of a teaspoon).
- A spirometry test. This is a test to check your lungs and to see how well you are able to breathe.
- Sputum collection (to confirm you have *Pseudomonas aeruginosa* bacteria in your lungs). The study team will likely perform the spirometry test before this sputum sample is collected. The study team will try to do this whenever the spirometry test will be needed for the study. If it will be difficult for you to provide a sputum sample at this or at any other visit (where sputum will be needed), you may be asked to have what is called a hypertonic saline treatment, or another procedure that may help you cough up sputum. Hypertonic saline treatment is done by breathing in vapors (through a mask that will cover your nose and mouth) that originate from a liquid made of sterile water mixed with salt. You can also use your home airway clearance devices like a vest or flutter valve to help produce sputum. The total amount of sputum you will be asked to provide during this visit is about 2 mL (about 1/2 of a teaspoon).

After the screening visit is done and you've returned home, the study team will let you know (likely over the telephone) if you qualify to continue in this study. If the study team tells you that you qualify to participate in this study, you will then make a decision about

whether you will want to continue or not continue your participation in this study. The study team will schedule a time for you to come in for the next visit, but only if you choose to continue in the study.

Baseline/Dosing Visit (Day 1)

If you agree to continue in the study, you will return to the clinic for the Baseline/Dosing Visit. The Baseline Visit is expected to take around 6-8 hours. The following activities will be done:

- The study team will check a second time to make sure you still meet the study requirements.
- If you are a person who is capable of having children/giving birth, a urine pregnancy test will be done. In order to do this test, you will be asked to provide about one-half (1/2) cup of urine. The result of this test must be negative before you receive phage/placebo.
- A review of your medical systems.
- You will be assigned to receive one of the following products:

For Stage 2a Subjects	
Product that you could be assigned to:	**What's the chance of being assigned to each group?**
Phage at the lowest possible dose, or	1 in 4 chance (or 25%) (like drawing straws)
Phage at a medium dose, or	1 in 4 chance (or 25%) (like drawing straws)
Phage at the highest possible dose, or	1 in 4 chance (or 25%) (like drawing straws)
Placebo	1 in 4 chance (or 25%) (like drawing straws)

For Stage 2b Subjects	
Product that you could be assigned to:	**What's the chance of being assigned to each group?**
Phage (at the dose/amount that performed the best in Stage 2a) or	1 in 2 chance (or 50%) (like a coin toss)
Placebo	1 in 2 chance (or 50%) (like a coin toss)

- Your study team will give you the experimental phage, or placebo. Phage/placebo will be given through an IV catheter. An IV catheter is a small, flexible hollow tube that is inserted into a vein of your arm. This tube will remain in your arm after you receive phage/placebo. Inserting an IV catheter requires a needle that can cause discomfort at the location where it is inserted. You are not likely to feel discomfort while phage/placebo is given through the IV catheter, but you will be asked to keep your arm still and remain in a resting position while the

study team gives you phage/placebo. It is expected that about thirty (30) minutes will be needed in order to finish giving you phage/placebo, and up to another 30 minutes to flush the IV catheter.

- A review of the medications you are taking.
- A physical examination will be done before phage/placebo is given and thirty to sixty (30-60) minutes after your study team finishes giving you phage/placebo. This will not be a complete physical exam, but it will be what is called a symptom directed physical exam, which is an exam that will focus on areas of your body that may be affected by phage/placebo. The exam will check your general appearance and your lungs. Other body systems may also be examined depending on your symptoms at the time of the physical exam.
- Vital signs. These tests will be done before phage/placebo is given and about thirty to sixty (30-60) minutes after your study team finishes giving you phage/placebo.
- Spirometry tests. These will be done before phage/placebo is given and may also be done after your study team finishes giving you phage/placebo.
- Sputum collection (to be collected after spirometry, if the study doctor thinks spirometry will help increase sputum production) will be done before and about one to three hours after your study team finishes giving you phage/placebo. The total amount of sputum you will be asked to provide during this visit is at least 4 mL and up to 8 mL (about 1/3 to 1/2 of a tablespoon). Any left-over sputum (remaining after testing) will be stored and used for future research studies. Your left-over sputum will not be able to be linked back to you and no human genetic testing will be performed on it. The use of these samples will proceed without any additional consent from you. Note: this will apply to this and all other study visits that require collection of sputum.
- Serum PK collection (for PK studies) – Blood will be collected at the following times:
    - Before phage/placebo is given
    - Approximately 30 minutes, 1 hour, 1.5 hours, 2 hours, 2.5 hours, 3 hours, and 3.5 hours after your study team finishes giving you phage/placebo.
- Other blood tests called: clinical chemistry, hematology, and liver function test will be collected before phage is given. If these tests were done within seven (7) days before the Baseline Visit, then the results of the tests may be used and blood collection will not be required for these other blood tests during the Baseline Visit.

  In order to collect blood for these blood tests and Serum PK, you will have another IV catheter inserted into the arm that was not used to give you phage/placebo. So, in total, you will have two IV catheters inserted during this visit. The total amount of blood collected during this visit for all these samples will be about 31 mL (about 2 tablespoons). Any left-over blood obtained for

serum PK (remaining after PK testing) will be stored and used for future research studies. Note: this will apply to this visit and Visit 3, the visits that require collection of blood for serum PK.

- Cystic Fibrosis Questionnaire Revised (CFQ-R) will be done before phage/placebo is given. The CFQ-R is a questionnaire that measures how cystic fibrosis has an impact on your overall health and daily life. Every time you are asked to do this questionnaire, you will be asked to write your answers directly on paper that will be provided at the clinic.
- Cystic Fibrosis Respiratory Symptom Diary (CFRSD) will be done before phage/placebo is given. CFRSD is a questionnaire that asks questions about your health and how you felt over the last 24 hours. Every time you are asked to do this questionnaire, you will be asked to write your answers directly on paper that will be provided at the clinic.
- A study clinician (such as a doctor or other qualified medical worker) will check to see if you experienced any side effects or worsening respiratory symptoms.

Visit 3 (Day 2):

After completing the Baseline/Dosing Visit, you will return to the clinic for three (3) more follow-up visits and 1 virtual visit. Although it is preferred these occur in-person, should there be any issues preventing you from coming to the clinic in-person, you can discuss with your study team if a virtual visit is an option. The first follow-up visit will be done one (1) day after you receive phage/placebo. The purpose of this visit is to see how you are doing and if anything has changed since the last visit. Visit 3 is expected to take around 2 hours.

The following activities will be done:

- A review of your medical systems.
- A review of the medications you are taking.
- A symptom directed physical examination.
- A spirometry test.
- Vital signs.
- Sputum collection (to be collected after spirometry, if the study doctor thinks spirometry will help increase sputum production). The total amount of sputum you will be asked to provide during this visit is at least 2 mL and up to 4 mL (about 1/2 to 3/4 of a teaspoon).
- Blood will be collected for these tests: serum PK, clinical chemistry, hematology, and liver function. The total amount of blood collected during this visit will be about 10 mL (almost 3/4 of a tablespoon). Note: Blood will not be collected if this is a virtual visit.
- Cystic Fibrosis Respiratory Symptom Diary (CFRSD).

- A study clinician will check to see if you experienced any side effects or worsening respiratory symptoms.

Visit 4 (Day 3-7):
After completing Visit 3 you will return to the clinic between three (3) to seven (7) days after you receive phage/placebo. The purpose of this visit is to see how you are doing and if anything has changed since the last visit. Visit 4 is expected to take around 2 hours.

The following will be done during this final visit:
- A review of your medical systems.
- A review of the medications you are taking.
- A symptom directed physical examination.
- A spirometry test.
- Vital signs.
- Sputum collection (to be collected after spirometry, if the study doctor thinks spirometry will help increase sputum production). The total amount of sputum you will be asked to provide during this visit is at least 2 mL and up to 4 mL (about 1/2 to 3/4 of a teaspoon).
- Blood will be collected for these tests: clinical chemistry, hematology, and liver function. The total amount of blood collected during this visit will be about 7 mL (about 1/2 of a tablespoon). Note: Blood will not be collected if this is a virtual visit.
- Cystic Fibrosis Respiratory Symptom Diary (CFRSD).
- A study clinician will check to see if you experienced any side effects or worsening respiratory symptoms.

Visit 5 (Day 8-11):

This is a virtual visit.
After completing Visit 4 you will have a virtual visit between eight (8) to eleven (11) days after you receive phage/placebo. The purpose of this visit is to see how you are doing and if anything has changed since the last visit. Visit 5 is expected to take around 1 hour.

The following activities will be done:
- A review of your medical systems.
- A review of the medications you are taking.
- Sputum collection (to be collected after spirometry, if the study doctor thinks spirometry will help increase sputum production). The total amount of sputum you will be asked to provide during this visit is about 2 mL (about 1/2 of a

teaspoon). A sputum collection kit, shipping materials, and instructions for shipping the sputum to the central lab will be provided to you prior to the visit. You will be provided with the closest FedEx location so you can drop off the sputum sample within 3 hours of collection.
- Cystic Fibrosis Respiratory Symptom Diary (CFRSD).
- A study clinician will check to see if you experienced any side effects or worsening respiratory symptoms.

Note: If you do not have the equipment necessary for a virtual visit, Visit 5 can be done in-person.

Visit 6: This visit will NOT occur in Stage 2

Visit 7 (Day 23-37):
After completing Visit 5 you will return to the clinic between twenty-three (23) to thirty (37) days after you receive phage/placebo. This will be the final visit. The purpose of this visit is to see how you are doing and if anything has changed since the last visit. Visit 7 is expected to take around 2 hours.

The following activities will be done:
- A review of your medical systems.
- A review of the medications you are taking.
- A symptom directed physical examination.
- A spirometry test.
- Vital signs.
- Sputum collection (to be collected after spirometry, if the study doctor thinks spirometry will help increase sputum production). The total amount of sputum you will be asked to provide during this visit is at least 2 mL and up to 4 mL (about 1/2 to 3/4 of a teaspoon).
- Blood will be collected for these tests: clinical chemistry, hematology, and liver function. The total amount of blood collected during this visit will be about 7 mL (about 1/2 of a tablespoon). Note: Blood will not be collected if this is a virtual visit.
- Cystic Fibrosis Questionnaire Revised (CFQ-R).
- Cystic Fibrosis Respiratory Symptom Diary (CFRSD).
- A study clinician will check to see if you experienced any side effects. If you experience any serious side effects, the study clinician will continue to contact you until they resolve.

Early Termination Visit

Your study doctor or sponsor may withdraw you from the study without your consent. Some possible reasons include, but are not limited to: 1) You no longer qualify to be in the study; 2) You do not follow the instructions of the study team; 3) You develop a medical condition which, in the opinion of your study doctor, may interfere with your ability to finish the study; 4) The study team can't locate you/contact you.

You can also voluntarily choose not to participate in the study. If at any time you decide to no longer participate in the study or are withdrawn from the study before the final visit (Visit 7, Day 23-37), the study team will ask that you return to the clinic for an Early Termination Visit. If you are too ill to attend an in-person or a virtual Early Termination Visit, this visit may be conducted by telephone call and you will be asked about your health, medications and any side effects. The physical exam, spirometry test, vital signs, and blood collections will only be done if you come into the clinic.

The purpose of this visit is to make sure you are doing okay and to help you withdraw safely. The Early Termination Visit is expected to take around 1-2 hours. What will be done during this visit is similar to what is done during other visits. The activities include:

- A review of your medical systems.
- A review of the medications you are taking.
- A symptom directed physical examination.
- A spirometry test.
- Vital signs.
- Sputum collection (to be collected after spirometry, if the study doctor thinks spirometry will help increase sputum production). The total amount of sputum you will be asked to provide during this visit is at least 2 mL and up to 4 mL (about 1/2 to 3/4 of a teaspoon).
- Blood will be collected for these tests: clinical chemistry, hematology, and liver function. The total amount of blood collected during this visit will be about 7 mL (about 1/2 of a tablespoon). If this visit occurs 7 or less days after your previous visit, blood test results from that visit may be used. Note: Blood will not be collected if this is a virtual visit.
- Cystic Fibrosis Respiratory Symptom Diary (CFRSD).
- A study clinician will check to see if you experienced any side effects or worsening respiratory symptoms (if this visit occurs prior to Visit 5). If you experience any serious side effects, the study clinician will continue to contact you until they resolve.

Virtual Study Visits

Virtual study visits will be allowable instead of in-person study visits for circumstances that would keep you from attending in-person visits (e.g., a COVID-19 diagnosis,

fractured bone(s)). Prior to conducting a virtual visit, the reason for the requested virtual visit should be reviewed and approved by your study doctor. You will need access to a computer or tablet so that your virtual visit can occur by video conference (e.g. Zoom, WebEx).

Note: Visit 5 (Day 8-11) will always be conducted virtually without the need for prior approval by the protocol PI.

Virtual study visits will only be allowed for follow-up visits (Visit 3, 4, or 7) or an Early Termination Visit. Virtual Study Visits will not be allowed for the Screening (Visit 1) or Baseline/Dosing visit (Visit 2) or for an Unscheduled visit, if this is needed for a side effect from the study drug.

The following will be collected during the Virtual Study Visits:

- A review of your medical systems
- A review of the medications you are taking
- Sputum collection. The total amount of sputum you will be asked to provide during this visit is at about 2 mL (about 1/2 of a teaspoon). You will be allowed to use your normal airflow clearance device or sputum induction method if needed to produce sputum. A sputum collection kit, shipping materials, and instructions for shipping the sputum to the central lab will be provided to you prior to the visit. You will be provided with the closest FedEx location so you can drop off the sputum sample within 3 hours of collection.
- Cystic Fibrosis Questionnaire Revised (CFQ-R) (Only for Visit 7).
- Cystic Fibrosis Respiratory Symptom Diary (CFRSD).
  The CFRSD and CFQ-R (Visit 7 only) will be provided to you and you will be asked to complete and mail them back to your study doctor.
- A study clinician will check to see if you experienced any side effects or worsening respiratory symptoms (if this visit occurs prior to Visit 5).

This virtual study visit should take about 1 hour.

Unscheduled Study Visits

Your study doctor may decide you should come in for one or more Unscheduled Study Visits. If done, this visit would occur in between the expected scheduled study visits. The most likely reason why you may be asked to come in for an Unscheduled Study Visit is if you develop a side effect that your study doctor will want to follow-up on. If done, each Unscheduled Study Visit is expected to take around 1-2 hours.

The following would be done during these visits:

- A review of your medical systems.
- A review of the medications you are taking.

- A symptom directed physical examination.
- A spirometry test.
- Vital signs.
- Sputum collection (to be collected after spirometry, if the study doctor thinks spirometry will help increase sputum production). The total amount of sputum you will be asked to provide during this visit is at least 2 mL and up to 4 mL (about 1/2 to 3/4 of a teaspoon).
- Blood will be collected for these tests: clinical chemistry, hematology, and liver function. The total amount of blood collected during this visit will be about 7 mL (about 1/2 of a tablespoon). If this visit occurs 7 or less days after your previous visit, blood test results from that visit may be used. Note: Blood will not be collected if this is a virtual visit.
- Cystic Fibrosis Respiratory Symptom Diary (CFRSD).
- A study clinician will check to see if you experienced any side effects or worsening respiratory symptoms (if this visit occurs prior to Visit 5).

What are my responsibilities if I take part in this study?
If you take part in this study, you will be responsible to take an active role in the study, attend all study related visits, undergo all study related procedures, and follow the instructions given to you by the study team. You also need to commit to keeping in contact with your study team and let them know of questions you may have. You will be responsible to inform the study team of new medications you take and to tell your study team about new medical issues/injuries you may experience. If you are taking medication (such as inhaled antibiotics) that is on a cyclic dosing schedule (example: 28 days on medication/28 days off medication), you must be willing to keep these medications constant (no days off) through the final study visit. If you are taking antimicrobial medication for a chronic illness (illness that is long lasting or is constantly recurring), you must be willing and able to continue taking this medication through the final study visit. If you think you have a reaction to the phage/placebo, please notify the study team immediately. Seek immediate medical attention when needed. Your study team may ask you to come back to the clinic for an unplanned/unscheduled study visit. If this is the case, please make all efforts to return to the clinic when the study team tells you to return.

The effects of phages on the unborn child are not known. For this reason, if you are a person who is capable of having children/giving birth, you will have pregnancy tests done before you receive phage/placebo. You must also agree to use an effective method of birth control for the duration of the study. Examples of effective birth control include: (a) abstinence (not having sexual intercourse) (b) vasectomy (operation done in men to prevent pregnancy), (c) intrauterine devices (birth control devices inserted into the uterus of women) (d) hormonal implants, or (e) other methods to include birth control pills, birth control injections, patches, and vaginal rings. Periodic abstinence

(having sex from time to time) without the use of effective birth control, using the "withdrawal" method, or using the "rhythm" method are not effective methods of birth control. If you have questions about effective methods of birth control, please ask your study staff.

Could being in this study hurt me?
The most important risks or discomforts that you may expect from taking part in this study include possible bruising, irritation and redness, and discomfort at or near the site of the vein used to collect periodic blood samples. There may be risk of infection. There are similar risks associated with the site or near the site of the vein that is used to give you phage/placebo. These risks include site discomfort from the placement of an IV catheter, minor bleeding and infections caused by the bacteria found in your skin.

Excess bleeding, blood clotting or fainting due to a temporary lowering of blood pressure are also possible, but not likely.

Other potential risks could include worsening of respiratory conditions, inflammatory or allergic reactions caused by endotoxins (the product left after bacteria are destroyed), or temporary elevation of liver enzymes.

The total amount of blood required for this study is about 62 mL (approximately 4 and 1/4 tablespoons). This amount is not enough to make you anemic if your blood production is normal.

The risks noted are similar to what you might experience with routine clinical care and steps will be taken by the study team to lessen these risks.

In addition to these risks, taking part in this study may harm you in ways that are not known.

The effects of the phages on the unborn child are not known. Taking part in this study may hurt a pregnancy, nursing infant, or fetus in unknown ways. These may be minor or so severe as to cause death. Because of the unknown effects of phages on the unborn child, you are advised to avoid becoming pregnant by using an effective method of birth control throughout the study.

There is the possibility that you might experience an allergic reaction or a new symptom because you received phage. Please tell your study team as soon as possible if you believe you are having such an event. Earlier studies using phages have shown that people sometimes experience any of the following:

- Temporary increases in liver enzymes that are not associated with any discomfort.

- Temporary shortness of breath or wheezing.
- Temporary decrease in blood pressure.
- Temporary feeling of being flushed or sweaty.
- Development of fever
- Temporary increase in heart rate

Additionally, your bacteria may become resistant to the phage that is administered as part of this trial. In the future, if you are treated with phage therapy, different phage may need to be used as the phage administered in this trial may no longer be effective.

Participation in this study may involve some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information will be viewed by individuals involved in this study and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be disclosed (given out) if required by law.

Participation in this study will require in-person visits with your study staff. This will involve exposing yourself to current public health threats like, for example, Coronavirus (COVID-19). Please speak with your study team on how you can best protect yourself from such health threats prior to coming in for your study visits and during the study visits.

Will it cost me money to take part in this study?
There are no anticipated costs to you with study participation other than your time involved with the study. You or your insurance company may have to pay for routine care you would receive whether or not you are in the study. You may talk to the study staff and your insurance company about what is covered.

Will being in this study benefit me?
It is unknown if the study medication will benefit you. It may decrease the amount of a single bacteria, *Pseudomonas aeruginosa,* in your lungs while you are in this study. There are no benefits to your Cystic Fibrosis from taking part in this study. We cannot promise any benefits to you or others from your taking part in this study. However, there are societal (in society) benefits with study participation. For example, the information gathered from this trial may help doctors further understand of the use of phages. This, in turn, could potentially benefit future patients with cystic fibrosis.

It is not known if the phage used in this study will be available at the end of the study and it is not known if there will be an extension study or follow-up to this study. Therefore, there is no guarantee that you will have access to phage used in this study

after you complete this study. If there will be another study you may qualify for and wish to partake in, you will be asked to sign another informed consent. Note, this may only occur after you complete this study, are withdrawn from this study, or you withdraw your consent to participate in this study.

What other choices do I have besides taking part in this study?
You have the option to not participate in this study. Your participation is strictly voluntary and no one will try to influence you to participate in this study. You will continue to receive clinical care as you normally would, without penalty, whether or not you choose to participate in this study. There may also be other research studies available to you that you may qualify to participate in. Please speak with your study doctor and/or team about this option as well as any other options, and their risks and benefits.

Confidentiality
If you sign this consent form and join in this study, you are giving permission for your health information to be collected, used and disclosed as described in this consent form. The study site and all physicians and health care providers, nurses, scientists and other study staff including the study doctor involved in this study (collectively the "study team") will use this information to find out the benefits or risks of phages. Your identifiable health information is protected by law, including the Health Insurance Portability and Accountability Act (HIPAA). By signing this consent form, you give permission for your health information to be collected, used and disclosed in the United States (U.S.) and outside the U.S. for research involving phages and for other purposes described in this consent.

The information that will be collected could be a part of your medical record filed at the study site. You have the right to review and copy your health information. However, to maintain the integrity of this study, you generally will not have access to your health information related to this study until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that the study site maintains in a designated record set, which means a set of data that includes medical or billing records or other records used in whole or in part by your doctors or other health care providers at the study site to make decisions about you. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by the study site. If it is necessary for your care, your health information will be provided to you or your doctor.

Your agreement to allow the study site and the study team to use and disclose (release) your information begins when you sign this document. Access to your health information (e.g. your medical record) will expire at the end of the study.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin this authorization will expire on 31Dec2070.

There is no expiration of this authorization except for research conducted in the states listed above.

What happens to the information collected for this study?
If you participate in this study you will be assigned a unique code number. Your health information will be associated with that number and not your name or other identifying information for this study to help ensure confidentiality. Your health information will be collected, used and disclosed for this study. This information includes, but is not limited to the following:

- Laboratory results from blood, sputum and urine samples.
- Any medications you are taking.
- Your medical history.
- Your demographics (age, gender, race, ethnicity).
- Results of your physical examinations.
- Vital signs (blood pressure, heart rate, breathing rate, and temperature).
- Results of pregnancy tests.
- Any changes in your medical condition or problems you may have.
- Details about any doctor or clinic/hospital/medical facility visits you have while in the study.
- Medical records (from any doctor, hospital or other healthcare provider)

Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours.

The study site and the study team will use and disclose your health information to treat you and for research purposes. Medical information about you will be combined with information about other people in the study. This study information will be used to learn about the phages, prepare research publications, make submissions to government agencies, monitor your safety and the safety of others participating in the study and as otherwise permitted by law.

You should know that by signing this form, you are also giving permission for the entities and persons listed below to see your health information that is disclosed under this consent form. This makes it possible for your safety to be assured, for the research procedures and result of the study to be verified as reliable, to ensure that the study is being run properly, to report adverse events (negative effects of the phage or other drugs), to obtain marketing approval for new products resulting from this research and

to locate you as necessary to follow up on your condition. To the extent that the law allows, your original medical record/health information or copies may be given to, used by, and/or shared by the following groups:

- The research sponsor [National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID)/Division of Microbiology and Infectious Diseases (DMID)] and its affiliates (such as monitors and auditors).
- Individuals who work with the research sponsor, including the Antibacterial Resistance Leadership Group (ARLG) at Duke Clinical Research Institute (DCRI)/Duke University, ARLG/DCRI/Duke University affiliates, The University of California, San Diego, Walter Reed Army Institute of Research (WRAIR), and Adaptive Phage Therapeutics (APT).
- Government agencies, such as the FDA. The FDA is the agency that oversees the conduct of the study; for this reason it is important that this agency is given access to your health information when needed.
- A Data Safety Monitoring Board (DSMB), which is an independent group of qualified professionals who will review and interpret the study data and will monitor the data for safety.
- Any health care providers, professionals or agencies who have provided you with health services or treatment, such as physicians, clinics, hospitals, home health agencies, diagnostics centers, laboratories, treatment or surgical centers or government health agencies.
- Any agencies that provide payment for health care, such as insurers or government agencies.
- Investigator(s) listed on this consent form as well as the supporting study team.
- Institutional Review Boards (IRB's)/Ethics Committees (EC's), which is responsible for reviewing studies to protect research participants. The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects.<<CF-Main SMO Company 1>><<CF-Main Affiliated IN Language 1>>
- The Duke University Health System IRB as it is also responsible for reviewing this study.
- Future researchers who are not part of this study but who may appropriately obtain the study data and/or samples (sputum, blood). These future research studies will be performed without additional consent from you.

By signing this form you will authorize the organizations listed above access to your study records.

We protect your information from inappropriate disclosure to others to the extent required by law, but we cannot promise complete secrecy of your personal information.

If your health information is re-disclosed by the above recipients, it may no longer be protected by federal privacy laws.

Your health information may be further shared by the groups above. If shared by them, the information will no longer be covered by this Authorization. Those persons who receive your health information may not be required by federal privacy laws (such as the HIPAA Privacy Rule) or state law to protect it and may share your information with others without your permission, if permitted by laws governing them; however, it is possible to use or share your information in a way that will not identify you or anyone else individually in the study.

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.

We may publish the results of this study. However, we will keep your name and other identifying information confidential.

Your health information (data) and/or samples (blood and sputum) collected in this study will have your identifiable private information removed. After removal, and only after additional IRB review and approval, the data and/or samples may be used for future research or distributed to another investigator for future research without the need for your additional consent. You should not expect to receive any results from any future research that may use your data and/or samples (specimens).

You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

You may withdraw your permission to use and disclose your health information at any time. You can do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in the research study.

Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

Information and samples collected for future research

The information and samples collected for this study may be used for future, currently unknown, research. Any future research using your information and samples will be performed without obtaining additional consent from you. This future research may include such things as additional work on phages, cystic fibrosis, and infections of the blood, lung, skin, or other parts of the body. The research may also include, but is not limited to, profiling various phages and the bacteria the phage infect, determining the body's response to phage (did the body make antibodies to the phage?), and looking at the impact on other bacteria in the lungs, after phage is given. While this short list does not describe every possible use of your samples, it does show the likely types of future research that your information and samples will be used in.

In these future research studies, your information and/or samples will be coded. The staff at your research site may keep a code key (with your name) but do not give it to other researchers. Future research studies will not directly identify you. Also, your medical records will not be needed to conduct future research studies. We will only use the information and samples collected from this study.

No human genetic testing or sequencing of human DNA will be performed using your samples. This means that we will not be looking at any genes that could describe you or your family members.

Your samples will be stored in the ARLG Biorepository until they are needed for the future research studies. Those who will use your samples (in the USA or internationally) include, but are not limited to: other researchers, other institutions, and others in industry.

Your information and samples may be used by future researchers to create, test, or perform research on products that may be sold for commercial profit, but you will not share in this profit.

While the use of samples (for future research) will proceed without any additional consent from you, you should know that you may withdraw your consent for storage and use of your samples at any time by contacting your research site. Only the samples that have not been released for future research can be destroyed.

How will my privacy be protected?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this study and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests and procedures may be reported to the DMID at National Institute of Allergy and Infectious Disease (NIAID) and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the FDA, representatives and affiliates of the DMID at NIAID, the Duke Institutional Review Board (IRB), and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

A copy of this consent form will go in to your medical record. This will allow the doctors caring for you to know what study medication or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study.

If you want to participate in this study, you have to sign this document to allow access to your medical records. You have the right to not sign the document. If you choose not to sign it, you are still able to receive your medical treatment not related to the study. You will be given a copy of this document. If you do sign it, you can change your mind later by writing a letter that states you are taking back your permission. Stopping your authorization will prevent sharing of information in the future, but will not affect any information that has already been shared.

The Department of Health and Human Services (DHHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

- There is a law that requires disclosure (such as to report child abuse or communicable disease but not for legal proceedings);
- You have consented to the disclosure, including for your medical treatment; or
- The research information is used for other scientific research, as allowed by federal regulations protecting research subjects/study participants.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the FDA.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this study. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Who can answer my questions about this study?
If you have questions, concerns, or complaints, or think this study has hurt you or made you sick, talk to the study team at the phone number listed above on the first page.

This study is being overseen by an IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-855-818-2289 or Researchquestions@wcgirb.com if:

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

What if I am injured because of taking part in this study?
If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide medical treatment or refer you for treatment. Your insurance may be billed for this treatment. Immediate necessary medical care is available at the study site in the event that you are injured as a result of your participation in this study. However, there is no commitment by the study site or the study doctor, Duke University (including Duke Clinical Research Institute) or the NIH to provide monetary compensation or free medical care to you in the event of a study-related injury. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government. If your insurance is billed for this medical care, you may be required to pay deductibles and any co-payments that apply. You should check with your insurance company about any such payments.

For questions about the study or research-related injury, contact the study doctor at the phone number listed above on the first page.

Can I be removed from this study without my approval?
You may be removed from this study by the study doctor or sponsor without your approval at any time. Possible reasons for removal include:

- If your doctor/study investigator determines it is in your best interest to stop study participation.
- You have a side effect that requires stopping your participation.
- You need a treatment that is not allowed in this study.
- You become pregnant.
- The research is canceled by the FDA or the sponsor.
- You are unable to take the research medication.
- You are unable to follow instructions or keep your scheduled appointments.
- New risk/safety information becomes available that may warrant study discontinuation.

We will tell you as soon as we can about any new information that may affect your health, welfare, or choice to stay in this study.

What happens if I agree to be in this study, but I change my mind later?
Your participation in this study is voluntary; therefore, you can withdraw from this study at any time, and your clinical treatment will continue without penalty.

If you decide to leave this study, please contact the study team so that the investigator and study personnel can schedule you for one last visit to make sure you are doing okay and help you withdraw safely. The procedures expected to be done on the last visit are:

- A review of your medical systems.
- A review of the medications you are taking.
- A physical examination. This will not be a complete physical exam, but it will be what is called a symptom directed physical exam, which is an exam that will focus on areas of your body that may be affected by phage/placebo.
- Vital signs (blood pressure, heart rate, breathing rate, and body temperature).
- Cystic Fibrosis Respiratory Symptom Diary (CFRSD).
- A study clinician will check to see if you experienced any side effects.

Will I be paid for taking part in this study?
<<CF-Main Payment for Part. Paragraph>>In exchange for your time and effort to participate in the study, you may be paid for each completed <<in-person or virtual>> study visit. You will not be paid in a lump sum, but instead your payment will be distributed and paid as follows:

Visit 1	**Visit 2**	**Visit 3** <<in-person	**Visit 4** <<in-person

		or virtual>>	or virtual>>
$ XX Paid after completion of Visit 1	$ XX Paid after completion of Visit 2	$ XX Paid after completion of Visit 3	$ XX Paid after completion of Visit 4
Visit 5 <<virtual>>	**Visit 6**	**Visit 7** <<in-person or virtual>>	
$ XX Paid after completion of Visit 5	**This visit will not occur in Stage 2**	$ XX Paid after completion of Visit 7	

The amounts noted above will only be paid after completion of each noted study visit. If you do not finish the study, you will be paid only up until the last visit you attend. For example, if you only complete Visits 1 and Visit 2, you will be paid for those visits and will not be paid for Visit 3 through 7. If you come in for an Unscheduled Visit, or if you finish the study early (Early Termination Visit), you will be paid the following amount:

Unscheduled Visit/ Early Termination Visit <<in-person or virtual>>
$ XX paid after completion of visit

Note: If the Early Termination Visit coincides with one of the six visits (Visits 1, 2, 3, 4, 5, or 7), you will only be paid the amount listed for one visit. For example, if your Early Termination Visit coincides with Visit 3, you will be paid the amount that is paid for Visit 3; you will not be paid for completing Visit 3 plus what is paid for the Early Termination Visit.

OR You will not receive any payment for taking part in this research study.

<<CF-Main Financial Disclosure>>

Reimbursement for your travel expenses may be available if you live more than 50 miles from <<study site name>>. You can discuss if you are eligible for reimbursement of your travel expenses with your study team.

STATEMENT OF CONSENT

The purpose of this study, the procedures to be followed and the study's risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to talk about problems, concerns, or suggestions related to the research or to obtain information or offer input about the research. I have read this consent form (or it has been read to me), and I agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form and HIPAA Authorization<<CF-Main California Bill of Rights>> and that a copy of this form will become part of my medical record.

I authorize the use and disclosure of health information from my medical record to the people or groups identified in this consent form for the purposes described in this document.

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Your signature below documents your consent to take part in this research study.

_____
Printed name of adult subject capable of consent

_____ _____
Signature of adult subject capable of consent Date

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date

<<CF-Main California HIPAA>>

CALIFORNIA HIPAA AUTHORIZATION

****This HIPAA section will be for sites that are only located in CA****

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

WHAT INFORMATION MAY BE USED AND SHARED?

The study doctor and study staff will use and share your health information as part of this research study. Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours.

Examples of the information that may be used are:

- Medical records (from any doctor, hospital or other healthcare provider)
- Information created or collected during the research. This could include your medical history, and dates or results from any physical exams, laboratory tests or other tests.

WHO WILL RECEIVE INFORMATION ABOUT YOU?

The study doctor and study staff will share your personal health information with:

- the sponsor, including persons or companies working for or with the sponsor
- Institutional Review Board (IRB)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- other regulatory agencies

WHY WILL THIS INFORMATION BE USED AND/OR GIVEN TO OTHERS?

The sponsor and the groups above will use your health information:

- to complete this research
- to evaluate the results of the study
- to check that the study is being done properly
- to obtain marketing approval for new products resulting from this research

IS MY HEALTH INFORMATION PROTECTED AFTER IT HAS BEEN GIVEN TO OTHERS?

Your health information may be further shared by the groups above. If shared by them, the information will no longer be covered by this Authorization. These groups are committed to keeping your health information confidential.

WHAT IF I DECIDE NOT TO ALLOW THE USE OF MY HEALTH INFORMATION?

You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

MAY I WITHDRAW OR REVOKE (CANCEL) MY PERMISSION?

YES. You may withdraw your permission to use and disclose your health information at any time. You can do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in the research study.

WHAT HAPPENS IF I WANT TO WITHDRAW MY AUTHORIZATION?

Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

WILL MY AUTHORIZATION EXPIRE?
If you do not withdraw this Authorization, it will remain in effect.

This Authorization will expire December 31, 2070, unless you withdraw it in writing before then.

MAY I REVIEW OR COPY THE INFORMATION OBTAINED OR CREATED ABOUT ME?
YES. You have the right to review and copy your health information. However, your access to this information may be delayed until the study is complete.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

AUTHORIZATION
By signing this form, I allow the use or disclosure of my health information. I will receive a signed and dated copy of this Authorization.

_____

Printed Name of Subject

_____

Signature of Subject **Date**