Phase 1 Clinical Trial of a Q GRFT Nasal Spray

NCT05180500

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Magee-Womens Hospital
of University of Pittsburgh Medical Center
300 Halket Street Pittsburgh, PA 15213-3180

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Study Title	Phase 1 Clinical Trial of a Q GRFT Nasal Spray [PREVENT COVID 101]		
Consent Version	7.0 07Jul2022	**Protocol Version**	5.0 07Jul2022
Principal Investigator	Katherine Bunge, MD, UPMC Magee-Womens Hospital		
Researcher's phone #	412-641-4242		
Funding agencies	National Cancer Institute		

********************************KEY INFORMATION************************************

You are being asked to take part in a research study. Participation is voluntary. The study involves evaluating the safety of an investigational Q-GRFT nasal spray being studied as a potential future prevention of SARS-CoV2 (COVID) infection. Q-GRFT nasal spray has not been Food and Drug Administration (FDA) approved. Approximately 45 evaluable participants will take part in this study at UPMC Magee-Womens Hospital.

If you are a healthy individual between 18-55 years of age and are fully vaccinated (does not include booster vaccine) for SARS-CoV-2, you may be eligible to participate. If you decide to screen for the study, you are under no obligation to enroll even if you are eligible. You may also withdraw from the study at any time, for any reason.

The study consists of seven visits over approximately 6-8 weeks:

V	Visit Type	Brief description
1	Screen	to assess eligibility, includes COVID testing
2	Enrollment	to confirm eligibility, first dose of nasal spray administered by a clinician; optional sample collection between 1 - 12 hours post dose
3	24 hour post dose	safety assessments
4	Start multi-day dosing	begin daily use of nasal spray (for total of 13 days)
5	Multi-day dosing cont'd	dispense second week of study medication
6	Safety assessment	24 hours after last dose, optional rectal swab for drug levels
7	Final visit	safety labs, drug levels

You cannot take part in this study if you are a pregnant or breastfeeding, you are using nasal products, or you are participating in another investigational research study. There may be other reasons you cannot participate, which will be explained to you by study staff.

There are risks associated with participation in any research study. There may be risks that are unknown and possibly life threatening. The table below outlines the most common risks.

Study procedure	Risk
Use of study medication (Q-GRFT nasal spray)	• This intranasal (used in the nose) spray has been tested for safety in one (single-dose) study. Our study will look at multi-day dose (daily for 14 days) use of the intranasal formulation • As with any nasal product, the following nasal side effects are possible with the study products (Q-GRFT nasal spray or placebo spray containing no active drug): congestion, burning, irritation, increased mucus, dryness, sneezing, coughing, sore throat, nosebleed, redness, ulceration, interference with taste and smell, headaches • Rare risks include a hypersensitivity to the product, including local reaction or rash • As the drug is intended to work locally, systemic side effects are presumed to be exceptionally unlikely • Rare but potentially life-threatening risk of exposure is anaphylaxis (life-threatening allergic reaction), but risks will be mitigated by using the first dose in the clinic and staying for approximately one hour
SARS-CoV-2 testing	• A positive test result could impact social and work schedule • A positive test result will be reported to Allegheny County Health Department

There may be no direct benefit to participate, but some individuals may appreciate the opportunity to contribute to the body of knowledge in the field of SARS-CoV-2 (COVID) research.

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INTRODUCTION/REASON FOR STUDY

This study is a randomized, placebo-controlled study of nasal Q-GRFT spray being done at a single site, UPMC Magee-Womens Hospital. Q-GRFT is derived from Griffithsin and is obtained from Nicotiana benthamiana plants. Q-GRFT has demonstrated an ability to inactivate viruses, including the SARS-CoV-2 virus which causes COVID. It has demonstrated excellent safety in prior laboratory, animal studies in three species, and preliminarily in human rectal studies as an HIV prevention product. This study is the first multi- day dose clinical trial of the intranasal (used in the nose) formulation and is being studied for safety. Additional effective antiviral products are needed for the current COVID pandemic and in the event of the emergence of new coronaviruses. This study will help to understand the safety of Q-GRFT spray and it's potential to be studied more in the future as a prevention for SARS-CoV-2 infection.

PARTICIPATION

You have been asked to join this study because you are a healthy individual, 18 to 55 years old, who is fully vaccinated for SARS-CoV2. Your participation is voluntary. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision and discuss with others if needed.

By participating in this study, you will be asked to use a nasal spray (two sprays in each nostril) a total of 14 times. You will be randomly assigned to use either Q-GRFT nasal spray or a placebo nasal spray (contains no active drug). For every two participants that are assigned to Q-GRFT nasal spray, one will be assigned to placebo nasal spray which equates to 30 participants in the active Q-GFRT group and 15 participants in the placebo group. You will not get to pick your group, nor will you (or the research staff) know which nasal spray you will be assigned to as both will be packaged identically. Both groups are important to the study.

The nasal spray comes in a spray pump bottle with a rounded tip that is gently inserted into each nostril to administer the spray. The first dose will be administered by a research clinician at V2. You will get to practice handling and using the nasal spray at V2 by spraying the product into a paper towel. Later in the study (V4), you will be asked to use the assigned nasal spray for 13 additional doses. Written and verbal instructions will be provided to you. You will be followed for safety, by having repeat questionnaires, exams and safety labs performed as described below.

OVERVIEW OF STUDY DETAILS

VISITS →	**Screening**	**Enrollment**	**Follow up**				**Final**
	V1	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**
Timing of Visit →		Within 60 d of V1	24 hrs after V2	5-49 d after V3	7 d after V4	24 hrs after last dose	28 d after V4
Approx. length of visit	45 mins	1 ½ hrs	30 mins	1 hr	30 mins	30 mins	30 mins
Informed consent	x						
Eligibility	x	x					
Contact information	x	x	x	x	x	x	x
Visit questionnaire	x	x	x	x	x	x	x
Quality of Life Survey		x		x	x	x	x
Medical history	x	x	x	x	x	x	x
Medication review	x	x	x	x	x	x	x
Physical exam, vitals	x	x	x	x	x	x	x
SARS-CoV-2 Testing*	x						
Urine pregnancy test*	^	^		^		^	^
Blood safety labs*	x	x	x	x	x	x	x
Blood drug levels		x	x	x		x	x
Blood drug antibody levels		x				x	x
Respiratory Samples**		x	x	x		x	x
Smell test		x	x	x	x	x	x
Acceptability Questions			x			x	x
Study medication		x		x	x		
Study medication log				x	x		
One hour observation+		x					
Optional sample collection		Respiratory samples				rectal swab	
Visit payment	30	80+OS	60	60	60	60+RS	60

x Required procedure ^ As necessary procedure *The results of tests will be given to you

OS= $40 for 1 hour optional sample collection timepoint and $80 for 2-12 hour optional sample collection timepoints

RS= $20 for optional rectal swab collection

+ procedures performed approximately one hour after first dose administered include repeat blood draw, targeted physical examination, blood pressure and repeat smell test

**Respiratory samples include: nasal, throat and nasopharyngeal (area just behind your nose that goes into the throat area)

Additional details of each visit are listed below. Procedures common to each visit include:

- Contact information (phone number, email, alternate contacts) will be collected/reviewed
- Visit Questionnaire: medical history, medication use and any issues/concerns
- Quality of Life survey will be done at V2, V4, V5, V6 and V7
- Next appointment will be scheduled, as applicable
- Reimbursement for the visit (amounts for each completed visit listed in table above)

- Counseling about protocol procedures
- Reminder to call research staff with issues/concerns

V1: SCREENING VISIT - the following will be conducted/performed/collected:
- Review eligibility
- SARS-CoV-2 test: nasopharyngeal (NP; the area behind your nose that goes into the throat area) sample collected by using a narrow Q-tip like swab. If your test is positive, you can enroll 14 days after the positive test result as long as you remain symptom free. If you test positive and then develop symptoms, you can enroll 14 days after the start of symptoms as long as you do not have a fever for at least 24 hours.
- Full physical exam: height, weight, blood pressure; exam of nose (by using an instrument to shine a light up your nose), throat, heart, lungs, abdomen
- Urine pregnancy test, as applicable
- Blood draw (approx. 1 ½ tsp) for safety labs: blood count, liver and kidney functions

V2: ENROLLMENT VISIT - the following will be conducted/performed/collected:
- Confirm eligibility
- Urine pregnancy test, as applicable
- Targeted physical exam (exam of nose and throat using a small light to see clearly) and blood pressure
- Smell test: scratch and sniff test to identify certain smells
- Blood draw for baseline drug level and anti-drug antibody testing. This test will be done to check if there is any anti Q-GRFT antibodies generated in your body. (less than 1 tsp)
- Collection of respiratory samples (nose, throat, and NP) for drug levels
    - Nose sample: collected with a cotton Q-tip like swab from inside the nostril
    - Throat sample: collected with a cotton Q-tip like swab from the back of the throat
- Random assignment to Q-GRFT nasal spray or placebo nasal spray
    - Administered by a clinician
    - Participant will practice using by spraying into a paper towel
    - Wait in clinic for one hour after product administration
- Approximately one hour following dosing, the following will be performed:
    - Blood draw (less than 3 tsp): safety labs and drug level
    - Repeat targeted physical exam and blood pressure
    - Repeat smell test
- OPTIONAL SAMPLE COLLECTION: single timepoint between 1 - 12 hours post product administration (as time permits); respiratory samples (nose, throat and NP) for drug levels
    - Nose sample: collected with a cotton Q-tip like swab from inside the nostril
    - Throat sample: collected with a cotton Q-tip like swab from the back of the throat

Following V2, safety will be assessed at each visit by asking questionnaires (i.e. changes in medical history, medication use, any issues/concerns). Urine pregnancy tests will be performed throughout the study, as applicable. The study visits include the following:

V3: FOLLOW-UP VISIT – the following will be conducted/performed/collected:
- *NOTE: timing of this visit is 24 hours after V2 dosing*
- Acceptability questionnaire: questions about how you feel about the nasal spray

- Blood draw (less than 3 tsp): safety labs and drug level
- Respiratory samples (nose, throat and NP) for drug levels
- Targeted physical exam and blood pressure
- Smell test

V4: START MULTI- (THIRTEEEN) DAY DOSE – the following will be conducted/performed/collected:
- Blood draw (less than 3 tsp): safety labs and drug level
- Urine pregnancy test, as applicable
- Respiratory samples (nose, throat and NP) for drug levels
- Targeted physical exam and blood pressure
- Smell test
- Provide one week supply of study product with instructions on use
- First dose of nasal spray administered by participant in clinic; followed by daily dosing at home
- Record date and time of study product administration on provided study medication log
- Contacted between V4 and V5 to assess safety (e.g. any new issues or concerns)

V5: PROVIDE SECOND WEEK OF PRODUCT - the following will be conducted/performed/collected:
- Return 1st bottle of study product and completed study medication log
- Blood draw (approx. 1 ½ tsp) for safety labs: blood count, liver and kidney function
- Targeted physical exam and blood pressure
- Smell test
- Provide second week of study product for daily dosing at home and study medication log
- Contacted between V5 and V6 to assess safety (e.g. any new issues or concerns)

V6: FOLLOW-UP VISIT - the following will be conducted/performed/collected:
- *NOTE: timing of this visit is 24 hours after the last self-administered 13th dose. If there is an issue with you coming the day after the 13th dose, the window allows for you to come 24 hours after the 12th dose (essentially skipping the 13th dose)*
- Return 2nd bottle of study product and completed study medication log
- Blood draw (less than 3 tsp): safety labs, drug level, and anti-drug antibody testing
- Acceptability questionnaire
- Urine pregnancy test, as applicable
- Respiratory samples (nose, throat and NP) for drug levels
- Optional rectal swab for drug levels: collected using a cotton Q-tip like swab/sponge
- Targeted physical exam and blood pressure
- Smell test

V7: FINAL VISIT - the following will be conducted/performed/collected:
- Acceptability questionnaire
- Blood draw (less than 3 tsp): safety labs, drug level, and anti-drug antibody testing
- Urine pregnancy test, as applicable
- Respiratory samples (nose, throat and NP) for drug levels
- Targeted physical exam and blood pressure
- Smell test

Unscheduled Visits

Unscheduled visits may occur at any time during the study, for instance if you are having side effects, you have concerns, or to follow up on an abnormal test result. At those visits, any of the above study procedures may be repeated as clinically indicated.

WITHDRAWING FROM THE STUDY

You may stop taking part in this study at any time, for any reason; you can also withdraw your authorization for us to use your identifiable medical information. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh or UPMC.

If you decide to stop participating in the study, we encourage you to talk with the study doctor and your regular doctor first and continue with any safety follow-up, even if you did not complete all the days of study medication.

The study doctor or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you have a bad reaction to the study medication) or because the entire study is stopped. The sponsor, the study doctor or Institutional Review Board may stop the study at any time.

LAB TESTING OF SAMPLES

Some of the respiratory and blood collected from you will be used for research tests to determine the amount of study drug in these samples and the presence of anti-drug antibodies in the blood. The results of these respiratory/blood tests are useful only for research purposes and will not be available to you or your health care provider. These specimens will be sent to an outside testing laboratory. The specimens will not be labeled by your name or other identifying information but rather by a unique study identifier. Personnel at the testing laboratory will not know your identity. Your research information and bio-specimens may be shared with investigators conducting other research, including the University of Louisville who will have access to specimens/specimen data. Specimens will only be kept until study completion.

Blood samples to test the health of your blood, liver and kidney function and SARS-CoV-2 testing will be sent to the clinical lab associated with Magee. They will also be sent by your study number, however the results of these tests will be given to you. At screening, abnormal test results could prevent you from participating. If abnormal labs are identified during the course of the study, they may be repeated as clinically appropriate and/or you may be referred to your own doctor for additional evaluations.

If you test positive for SARS-CoV-2, the Commonwealth of Pennsylvania requires that your name be given to the Allegheny County Health Department.

This study does not include whole genome sequencing (DNA testing).

CLINICAL TEST RESULTS

You will receive your results from the tests performed in this study that are conducted/processed in a certified clinical laboratory. This includes urine pregnancy test results (as applicable), clinical blood tests

and SARS-CoV-2 testing. You will not receive results of the testing conducted for study drug levels/research only laboratory testing. There is no plan to provide participants with the overall study results when completed.

PROTECTION OF CONFIDENTIALITY AND PERSONAL HEALTH INFORMATION

Identifiable medical information may be collected as part of this study and will be made available to members of the research team for an indefinite period of time. Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the Food and Drug Administration, National Cancer Institute, and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and address billing and operational issues. Results from this research may also be shared with other investigators, however this information will be de-identified.

To protect your confidentiality we will use a number instead of your name on all the forms for the study, and we will store your data in password protected files located on secure computers. If information from this study is shown publicly or published in a journal, we will not mention your name, or anything else that could identify you.

We will make every attempt to protect the privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records once your personal information is disclosed to others outside UPMC or the University. This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

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.

Your data or specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or outside agencies may receive.

Per University of Pittsburgh policy all research records must be maintained for at least 7 years following final reporting or publication of a project. In unusual cases, the investigators may be required to release your identifiable research information (which may include your identifiable medical record information) in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action,

suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings;) if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

RISKS AND DISCOMFORTS FROM TAKING PART IN THIS STUDY

As with any research study, there may be adverse events or side effects for you that are currently unknown and certain of these unknown risks could be permanent, severe or life-threatening.

This is a phase 1 trial. The first human tests of investigational drugs or therapies occur in Phase 1 trials. Phase 1 trials are designed to determine the best dose of the study drug and to check for any potential side effects. These trials usually involve small numbers of volunteers. Because some Phase 1 trials use study treatments that have never been tested in humans, they may involve significant risks.
Q-GRFT (the study drug) has been tested for safety in one human study using a single dose of the nasal spray. The risks are unknown. There is a chance that drugs like Q-GRFT may cause a hypersensitivity reaction.

Studies in animals did not show any significant harmful effects from administration of the study drug. The study drug was given to animals nasally at up to 3 times the human dose. The animal studies did not show any major risk associated with the study drug, although animal studies are not always able to predict what will happen in humans.

As with any intranasally (used in the nose) administered product, study products (active or placebo) may cause nasal congestion, nasal discharge, nasal burning, nasal irritation, increased mucus, nasal dryness, sneezing, coughing, pharyngitis (sore throat), nose bleed, mucosal erythema (redness in the lining of the nose), nasal ulceration, interference with taste and smell, ringing in the ear(s) and headache are potential risks. Hypersensitivity reactions (including contact dermatitis and rash) are rare risks with any product. As the drug is intended to work at the mucosal surface, systemic side effects are presumed to be exceptionally unlikely. Nonetheless, safety labs will be checked before and after study medication use.

A rare but potentially life-threatening risk of exposure to nasal spray containing Q GRFT or the placebo spray would be anaphylaxis (life-threatening allergic reaction). You will be asked to stay in the clinic for 1 hour after application. In the unlikely event of a reaction, the study team, including licensed physicians are available to care for you. Medications for allergic reactions as well as a team of medical staff are available at the location of your study visit (UPMC Magee Womens Hospital CTRC).

Persons who are pregnant or breastfeeding may not participate in this research study. If you are pregnant or become pregnant, your unborn child may suffer harms that we have not seen before. If you become pregnant while in this study, the sponsor may ask to follow the outcome of the pregnancy. Before starting this research study, persons of pregnancy potential will have a pregnancy test. Testing positive for pregnancy may cause anxiety. There is a risk that your unborn baby could be harmed if you become pregnant during your participation in the study. There is currently no data about this drug related to pregnancy.

Nasal exam may cause discomfort. Nasal specimen collection may cause mild discomfort and/or nasal spotting. Oropharyngeal (throat) swab collection may induce a gag reflex and cause mild discomfort. Nasopharyngeal (NP) swabs may cause discomfort, eyes to water, coughing/gagging.

Drawing blood may lead to excessive bleeding, discomfort, feelings of dizziness or faintness, and/or bruising, swelling and/or infection.

Collecting a(n optional) rectal swab may cause discomfort.

As part of the study, you will be screened for SARS-CoV-2 at the screening visit. Anxiety and depression surrounding a positive result is a risk. A positive test result will necessitate that the Allegheny County Health Department be notified, which would likely result in a period of self-quarantine and disruption to your daily life.

Performing the smell test can cause stress or anxiety if you are unable to detect a smell. Some of the smells may be unpleasant.

Participation in clinical research includes the risks of loss of confidentiality and discomfort with personal nature of questions. Answering research questionnaires and completing study medication logs may be inconvenient.

GENERAL RISKS:
You will be asked to provide personal/protected health information (PHI). All attempts will be made to keep your PHI confidential within the limits of the law. However, there is a chance that unauthorized persons will see your PHI. All paper records will be kept in a locked file cabinet or maintained in a locked room at Magee. Electronic files will be password protected. Only people who are involved in the conduct, oversight, monitoring, or auditing of this study will be allowed access to the PHI that is collected. Any publications from this study will not use information that will identify participants by name. Organizations that may inspect and/or copy research records maintained at the participating sites for quality assurance and data analysis include groups such as the National Cancer Institute or its designee and the US Food and Drug Administration (FDA).

BENEFITS TO TAKING PART IN THIS STUDY
Participation may have no direct benefit. All participants will receive a SARSCoV-2 test, which some may consider a benefit. Some participants may have the opportunity to access expedient treatment and decreased morbidity due to early diagnosis and treatment of abnormalities in blood count, liver or kidney function tests that would have otherwise not been detected. Lastly, you may appreciate the opportunity to contribute to the body of knowledge in the field of SARS-CoV-2 research. However, there is no guarantee that volunteers will receive any of these benefits.

ALTERNATE CHOICES TO PARTICIPATION
You do not have to take part in this study.

COST
There will be no costs to you for being in this study and there are no anticipated expenses related to your participation. You will not have to pay to receive the study medication in this study. There are no costs for the physical examinations, laboratory testing, or clinic visits. They will be included as part of the study.

During the study, should you test positive for SARS-CoV-2, the study will not be responsible for expenses such as lost wages from having to miss work/quarantine.

STUDY PAYMENT FOR PARTICIPATION

There is no cost to you to participate. You will receive the payments as listed in the tables above for each visit/procedure that is completed.

Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the Accounting Office. Your study payments will be loaded onto a UPMC cash card at the completion of each visit. All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099-Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research but the IRS requires that 26% of the payment be sent by the institution to the IRS for "backup withholding", thus you would only receive 74% of the expected payment

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. If you withdraw from this study, already collected data may not be removed from the study database. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator (study doctor), Dr. Katherine Bunge, and/or research staff at 412-641-4242.

You will be told of any significant new findings which develop during the study which may affect your willingness for you to participate in the study. You may be asked to sign a revised consent form if this occurs.

REMOVAL FROM THE STUDY

Investigators (study doctors), the Institutional Review Board (a committee at the University of Pittsburgh charged with protecting the safety and rights of people taking part in research studies), or the National Cancer Institute can remove you from the research study without your approval. Reasons why this may occur include that you are unable to fulfill the requirements of the study.

If you decide to stop participating in the study, or if your participation is ended, the study doctor or study staff may ask you some questions about being in the study. Any time a participant is permanently discontinued from study medication you may be asked to complete the procedures listed under the study visits described above.

RESEARCH-RELATED INJURY

If you believe that participating in this study has resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this

time, there is no plan for any additional financial compensation. You do not waive any legal rights by signing this form.

PROBLEMS OR QUESTIONS
If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

VOLUNTARY PARTICIPATION
Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for your participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

PLEASE INITIAL YOUR CHOICE FOR THE FOLLOWING OPTIONAL PROCEDURES:

Optional Procedure	Visit	INITIAL if you agree	INITIAL if you do not agree
Collection of Nasal, Throat and Nasopharyngeal samples for study drug levels between 1-12 hours post-dose	Enrollment, Visit 2		
Collection of a rectal sample using a cotton swab for study drug levels	Follow-up, Visit 6		

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VOLUNTARY CONSENT FOR PARTICIPANTS

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified member of the research team or by the Principal Investigator listed on the first page. I understand that I may always request that my questions, concerns or complaints be addressed by the Principal Investigator. At any time, I may also contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form, I agree to participate in this research study for the purposes described above. A copy of this consent form will be offered to me.

_____

Printed Name of Participant

_____ _____ _____

Participant Signature Date Time (am/pm)

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research to the above individual and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about the study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed name of Person Obtaining Consent Role in Research Study

_____ _____ _____

Signature of Person Obtaining Consent Date Time (am/pm)