The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**A phase II study of oral Infigratinib in adult patients with advanced or metastatic solid tumors with FGFR1-3 gene fusions or other FGFR genetic alterations**
Principal Investigator:	**Sameek Roychowdhury, MD, PhD**
Sponsor:	**The Ohio State University** **QED Therapeutics, Inc.**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

You are being asked to participate in this clinical study because you have a solid tumor cancer with abnormal changes in the fibroblast growth factor receptor (FGFR) gene family. These gene changes frequently occur in specific types of solid tumor cancers, and physician researchers want to test if using an oral drug inhibiting the function of these abnormal FGFR

genes will prevent your tumor from growing, and whether treatment will help improve your overall quality of life.

If you decide to take part in this treatment, you will first be asked to sign this consent form. You will then be assigned to one of the three study groups, called cohorts, based on the kind of cancer that you have:

- **Cohort 1:** Patients with FGFR gene changes called fusions who have received standard of care (what is usually done) treatments, **but not** treatment with a different FGFR inhibitor drug, and have either progressed or did not tolerate them well.
- **Cohort 2:** Patients with FGFR gene changes called fusions who have received standard of care (what is usually done) treatments, **as well as** treatment with a different FGFR inhibitor drug, and have either progressed or did not tolerate them well.
- **Cohort 3:** Patients who have tumors with different FGFR gene changes than the first two cohorts, and who have not received treatment with a different FGFR inhibitor drug.

During each 28-day cycle, you will be asked to take the study medication which consists of two Infigratinib pill capsules (one 100mg and one 25mg) daily from days 1 through 21. On Days 22-28, you will not take the study medication.

While receiving study treatment, you will be asked to avoid eating grapefruit, grapefruit hybrids, pomegranates, star fruits, pomelos, Seville oranges or products containing the juice of each during the entire study and preferably 7 days before the first dose of study medications, due to potential interaction with the study medications.

While you are on the study, you will need to have medical procedures, including physical exams, CT scans, EKGs, Cardiac imaging, tumor biopsies, and blood draws. These are outlined in the Study Calendar in Section 3, and the risks are explained in Section 6.

You will be able to stay on study treatment until your disease worsens, or you experience too many/severe side effects of the study medication.

Side Effects of the study medication include: temporary phosphorus increase or decrease in your blood, temporary calcium changes in your blood, temporary kidney function changes, muscle weakness, joint pain, sore mouth, Gastrointestinal side effects, dry mouth, taste changes, decreased appetite/weight changes, skin and nail changes, eye problems, hair loss, changes in liver function, decrease in red blood cell count, nose bleed, dizziness, low sodium in blood, and pain in extremities.

These risks are fully outlined in Section 6, and your study doctor will continuously monitor you for any side effects and help you to deal with them.

This study may or may not help you feel better, and may or may not work to shrink your tumors, but the valuable information gained may help other patients with your disease receive better care in the future.

You do not have to take part in this study, even after signing this consent form.

1. Why is this study being done?

You are being asked to participate in this clinical study because you have a solid tumor cancer with abnormal changes in the fibroblast growth factor receptor (FGFR) gene family. These gene changes frequently occur in specific types of solid tumor cancers, and physician researchers want to test if using an oral drug inhibiting the function of these abnormal FGFR genes will prevent your tumor from growing, and whether treatment will help improve your overall quality of life.

This is a clinical research study sponsored by the pharmaceutical company QED Therapeutics, Inc. (QED). It is testing the medicine Infigratinib, which has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of people with your medical condition. Infigratinib is currently not "on the market" (available for you to receive a prescription for and/or to buy) in any country.

2. How many people will take part in this study?

At The Ohio State University, and other major academic centers in the US, will consent up to 88 patients with the goal to enroll/treat 50 people who will take part in this study.

3. What will happen if I take part in this study?

Before you decide to take part in this study, it is important that you understand what the study will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask your doctor if there is anything you do not understand or is unclear or if you would like more information.

The study consists of screening period (to find out if you can be in the study), treatment period (while you are taking the study treatment), end of treatment period and follow-up period (after you have stopped taking study treatment). You will need to have some tests, exams and/or procedures during each of these study periods.

If you decide to take part in this treatment, you will first be asked to sign this consent form. You will then be assigned to one of the three study groups, called cohorts, based on the kind of cancer that you have:

- **Cohort 1:** Patients with FGFR gene changes called fusions who have received standard of care (what is usually done) treatments, **but not** treatment with a different FGFR inhibitor drug, and have either progressed or did not tolerate them well.
- **Cohort 2:** Patients with FGFR gene changes called fusions who have received standard of care (what is usually done) treatments, **as well as** treatment with a different FGFR inhibitor drug, and have either progressed or did not tolerate them well.
- **Cohort 3:** Patients who have tumors with different FGFR gene changes than the first two cohorts, who have not received treatment with a different FGFR inhibitor drug.

Some of the exams, tests, and procedures outlined in the study calendar may be completed via Telehealth visit (phone, video call, or email) if the investigator deems it appropriate. Ask your physician if you have quetsions about Teleheath or Telehealth visits.

Study Treatment:
A treatment cycle consists of 28 days. During each 28-day cycle, you will be asked to take the study medication which consists of two Infigratinib pill capsules (one 100mg and one 25mg) daily from days 1 through 21. On Days 22-28, you will not take the study medication.

You should only take the study treatment as instructed, and should not do anything else with it. Each dose should be taken with a large glass of water, and be taken at about the same time each day. If you forget to take a dose, you can take it if it is within 2 hours of your normal time. Otherwise, skip that dose and continue treatment at your usual time next day. Do not "make up" for the missed dose by taking it the next day.

You will be asked to take your dose in the morning 2 hours after a light meal (for example, non-grapefruit-type juice and toast). After taking your dose, you cannot eat or drink anything for 1 hour. On the days that you come to OSU for clinic visits, you will take the study drugs at the clinic. Afterwards, you will be provided with enough study drug(s) to last you until your next planned clinic visit.

While receiving study treatment, you will be asked to avoid eating grapefruit, grapefruit hybrids, pomegranates, star fruits, pomelos, Seville oranges or products containing the juice of each during the entire study and preferably 7 days before the first dose of study medications, due to potential interaction with the study medications. Oranges and orange juice are allowed.

Phosphate-lowering treatment including low phosphate diet and phosphate binding therapy may be started when study treatment is started and will be adjusted by your doctors as necessary.

Study Calendar:

Before the following takes place, you will be asked to sign this informed consent document.

Within 28 days of signing this informed consent form:

- Your health information will be recorded
- Your current medications will be recorded
- You will complete a physical examination
- Your Vitals, Height, and Weight will be recorded.
- Blood and urine will be collected for standard of care medical testing
- Pregnancy Test (may be a blood or urine test)
- You will have a CT (computed tomography) scan or MRI (magnetic resonance imaging) scan to assess your cancer
- You will have an eye exam
- You will have an ECG (Electrocardiogram) or MUGA (multiple-gated acquisition) scan. MUGA is a form of radionuclide angiography, which measures your heart function using radiation.
- You will have a biopsy, if the doctors cannot use archival tissue for testing

On Day 1 of every cycle, you will:

- You will begin taking the study drug
- Your health information will be recorded
- Your current medications will be recorded
- You will complete a physical examination (including weight and vitals)
- Have your blood drawn
- Take a pregnancy test, if applicable
- You will have an ECG or MUGA scan

Your vital signs will continue to be collected on **Days 8, 15, and 21** of every cycle, and you will also have blood draws on these days.

On Day 15 of Cycle 1, you will:

- Have a physical exam
- Have your vitals taken
- Have an eye exam
- Have your blood drawn
- Your current medications will be recorded
- Have an ECG or MUGA scan

On Day 21 of each cycle, you will:

- Stop taking the study drug for that cycle (you will restart on day one of the following cycle)
- Have your vitals taken

At your End of Study Visit, you will:

- Your health information will be recorded
- Your current medications will be recorded
- You will complete a physical examination
- Have your blood drawn
- Have an eye exam
- Take a pregnancy test, if applicable
- Have an ECG or MUGA scan
- Have a biopsy of your tumor
- Have a CT or MRI Scan, if you have not had one done within 28 days

30 Days after your end of study treatment visit, you will:

- Your health information will be recorded
- Your current medications will be recorded
- You will be asked about any chemotherapies you are taking since stopping study treatment

Eight Weeks after Stopping study treatment:

- You will be followed up with
- you will have a CT or MRI scan to measure your tumor
- You will be asked about any chemotherapies you are taking since stopping study treatment

You will be followed up with every 8 weeks until your disease gets worse, at which point you will be followed up with every 4 months for 1 year.

4. How long will I be in the study?

You will be able to stay on study treatment until your disease worsens, or you experience too many/severe side effects of the study medication. If you decide to withdraw your consent and end your study participation early, you will still be asked to come in for a follow up visit for your safety.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Possible risks of study medication Infigratinib

Frequent, mild to moderate adverse events may include, but not limited to:

- Temporary increases in the mineral phosphorus (P) or phosphate in the blood. Change to your blood phosphorus levels may not cause symptoms or they could lead to calcium deposits in your body, including in your skin, heart, or blood vessels. A blood test will determine if there have been changes in your blood phosphorus levels. If your phosphate level is high, your doctor may decrease your study drug dose or may ask you to take medicine to lower the phosphate level.
- Temporary decreases in the mineral phosphorus (P) in your blood. This is not directly due to Infigratinib, but rather is usually due to medications given to treat increased phosphorous levels, and occurred very commonly in patients treated with Infigratinib.
- Temporary changes in the mineral calcium (Ca) in the blood. Calcium is a mineral found in your body and has important functions such as helping keep your bones healthy. You may not have any symptoms if you have a slight increase or decrease of the calcium level in your blood. In severe cases of high levels of calcium, you might experience kidney problems, irregular heartbeat, or confusion. A blood test will determine if there are changes to your blood calcium levels.
- Temporary changes in measurement of your kidney function which are most frequently seen at the same time as the changes in your phosphorus blood levels. This is a laboratory abnormality that does not result in changes in the ability of your kidneys to work properly.

- Muscle weakness and/or discomfort (asthenia and myalgia) and fatigue
- Joint pain (arthralgia)
- Stomatitis (inflamed and sore mouth)
- Gastrointestinal (GI) side effects including constipation, diarrhea, nausea, vomiting, abdominal pain, heartburn, changes in taste.
- Dry Mouth
- Decreased appetite and weight changes
- Skin and nail changes, including blistering and peeling of the skin on the hands and feet
- Eye related side effects (most frequently dry eye and less frequently corneal or retinal problems, blurry vision, worsening cataracts or conjunctivitis.
- Hair loss (alopecia)
- Temporary, mild changes in blood tests that monitor the ability of your liver to work. These changes are reversed when you stop taking Infigratinib. Changes to liver function are identified based on blood tests that look for the presence of liver enzymes (proteins) in your blood.
- Decrease in red blood cell count that may cause fatigue and shortness of breath
- Changes in appetite and weight
- Skin and nail changes: Redness, peeling, discomfort or numbness in the hands and feet
- Nose bleeds
- Dizziness
- Low sodium in the blood which can lead to weakness
- Pain in extremity which might be at rest or with exercise

Infigratinib has caused mild to moderate visual changes in some patients. While this type of visual impairment may improve, there is a risk that it might continue. Blurred vision and, in some cases, loss of vision have been seen with similar drugs tested in other human studies. All patients will undergo a detailed eye examination at the start of the study and again during the study. If the results of eye exams conducted at screening are abnormal, you will not be able to participate in this study and you may need to discontinue from the study if abnormal changes are found while you are on study. It is important to tell your doctor about any pre-existing eye problems you have and visual changes that occur while taking the study drug as your doctor may decide to change or stop your treatment with the study drug. It is important that you do not drive a car or work with machinery if you begin to experience any visual changes while on the study.

Less frequent, severe/serious adverse events may include, but not limited to:

- Injury to the cornea, which is the transparent, dome-shaped window covering the front of the eye. These changes may be noticed as blurry vision, or may only be found by an ophthalmologist (a doctor that specializes in eye care).
- Changes to your retina (the light sensitive portion of your eye). These changes may be noticed as blurry vision, or may only be found by an ophthalmologist (a doctor that specializes in eye care).
- Liver injury: Changes to the function of your liver that may not be reversible and may impact on the ability of your liver to work.
- Kidney injury: Changes to the function of your kidneys that may not be reversible and may impact on the ability of your kidneys to function
- Increases in the digestive enzymes amylase and lipase without symptoms, which can be related to pancreatic function
- Temporary worsening of measurements of the pumping ability of your heart most often without symptoms and may go away when you stop taking Infigratinib
- Severe changes to the levels of phosphorus and/or calcium in your blood
- Dehydration
- Changes in body's ability to produce hormones
- Headache
- Increases in blood levels of potassium which usually does not cause any symptoms but can cause nausea, palpitations, and low energy

Problems or side effects that are not currently known could also occur. You will be given any new information as it becomes available that can help you choose to continue in the study.

Your doctor can tell you more about management and treatment of any of the above side effects.

Possible risks of taking blood

You will have blood samples taken while you are on study. The risks of taking blood may include fainting, pain and/or bruising. Rarely, there may be a small blood clot or infection where the needle punctures the skin. How many blood draws you have depends on how long you participate in the study, since blood will be taken during each cycle to monitor your safety. The blood pressure cuff may also cause discomfort or bruising of the upper arm.

In rare instances where a nurse, a doctor, or a laboratory technician, is exposed to your blood, tissue, or body fluids by needle stick, cut, or splash to mucosa or damaged skin, it may be necessary to test your blood, tissue, or body fluid sample(s) for certain viral infections, including Hepatitis B and C and HIV on the sample already available. This is to make sure that person can receive appropriate counseling, monitoring, and treatment, if need be. In this

instance the Study Doctor will tell you the results of these tests and advise you on the next steps. State law may require that positive results be reported to the local health authorities. Confidentiality of the results of your tests will still be respected at all times.

CT scan

Procedure: The purpose of a computed tomography (CT) scan is to produce images of internal body parts. It uses x-ray (or ionizing radiation) and a computer to take pictures of the inside of your body. A contrast agent (dye) may be injected into your vein(s) using a small needle, which will help to better define the various organs. You may also be given a substance to drink to further define the different organs. Additional information and instructions will be provided to you by the study staff prior to this procedure.

Risks: You will receive radiation when CT is done. The radiation received during one exam is the same as 2 - 10 years of normal radiation received in everyday life, depending on the body parts included. Although repeated radiation may damage your body tissues and slightly increase your chances of having cancer, you should not expect an increased risk from the imaging being done for this study.

Some people may have a 'closed in' feeling while inside the machine. The injection may make you sick to your stomach, pass out, have pain, warmth, swelling, bruising, or a small blood clot or infection at the injection site. You may get a rash or other signs of allergy from the injection. You should inform the physician or technologist if you have any history of allergies (for example, to seafood or medications), asthma, high blood sugar (or diabetes), heart problems, kidney problems, or thyroid problems, as all of these may increase your chances of having problems with the CT injection. Your physician or technologist can explain the procedure and risks in greater detail and clarify any concerns or questions.

MRI

Procedure: MRI (Magnetic Resonance Imaging) is being done to create images of the inside of your body using a large magnet and a computer. An injection of a solution may be given to obtain better pictures of the inside of your body. More information will be given to you by the study staff before this exam.

Procedure: You may not have an MRI done if you have metal in your body, like some hip replacements, hearing aids, pacemakers, bullets, or jewelry that cannot be removed. You should inform the technologist or physician if you have any metal in your body. During the MRI exam, you may feel some heat and hear banging noises but have no reason to worry. Some people may have a 'closed in' feeling while inside the machine.

The injection may make you sick to your stomach have pain, warmth, swelling, bruising, or small blood clot or infection at the injection site. Rarely, you may get a rash or other signs of allergy from the injection or get a rare disease where some of your body parts get scarred. If you have a history of kidney problems you must inform the technologist or physician as you may not be able to receive an injection during the MRI exam. Your physician or technologist can explain the procedure and risks in greater detail and clarify concerns or questions.

Electrocardiogram (ECG) Risk

ECG leads may cause slight discomfort during placement and removal. Allergic reaction to the gel used to attach the electrodes is possible.

Echocardiogram and MUGA scan

You may have an echocardiogram (heart ultrasound) or multigated acquisition scan (MUGA) scan to make sure that your heart is functioning properly. An echocardiogram does not cause any discomfort and is a standard test that takes "moving pictures" of the heart with sound waves. This is a non- invasive, highly accurate and quick assessment of the overall health of the heart. A gel will be applied to your chest area and then a wand like instrument will be used to detect sound waves.

In the case of a MUGA scan, an intravenous injection of a radioactive isotope (technetium) temporarily "labels" your red blood cells, and a gamma scintillation camera follows the blood moving through your heart. You will lie on an examination table and remain still without speaking during the scanning process. The level of radiation is considered to be very low and is not considered to cause any risks.

Tumor biopsy

Archival tumor biopsy:

There are no risks to you if previous tumor samples are used for testing because the sample was collected in the past.

Tumor biopsy

Tumor biopsies may be collected before, and/or during and/or after study treatment. Your Study Doctor will inform you in detail about the risks associated with the place where your tumor is located, and with the biopsy technique chosen (tumor biopsies can be obtained by different techniques). Biopsies may cause pain, inflammation, bleeding, swelling, and/or

infection at the site of the biopsy. If your doctor decides to use anesthetic, an allergic reaction may also occur.

Eye exams

Eye exams are required during the screening, on treatment, and end of study periods.

Assessment of both eyes will typically include:

- Testing that checks the acuteness or clearness of the vision.
- Testing that measures all areas of your eyesight, including your side, or peripheral, vision.
- An examination of the frontal eye structures of the eye, including the eyelid, sclera (the white of the eye), conjunctiva (a clear mucous membrane that covers the sclera just behind the iris), and the cornea. The instrument used for this test consists of a high-intensity light source that can be focused to shine a thin sheet of light into the eye.
- Fluid pressure inside the eye.
- Assessment of retinal structures. This is a non-invasive, non-contact, transpupillary imaging technology. The anatomic layers within the retina can be differentiated and retinal thickness can be measured.
- An examination of the back of the eye. The test may involve placing drops in the eye in order to dilate (expand) the pupils, which may cause you to experience some light sensitivity for a few hours after this examination. The dilating drops may rarely cause increased pressure in the eye, leading to nausea and pain.

Other examinations may be done if your study doctor believes that they should be conducted.

Risks to your Privacy
In the unlikely event that there is an accidental release of information that can be used to identify you, it may negatively impact your ability to obtain certain types of insurance coverage.

When your health information is released to other researchers, or further disclosed to others who are not required to comply with the federal privacy law called the Health Insurance Portability and Accountability Act (HIPAA), it may no longer be protected by this law, and could possibly be used or disclosed in ways other than those listed here. There may also be additional risks that we do not know about at this time.

Contraception and Pregnancy

Women who are pregnant or nursing a child cannot participate in this trial. You must confirm, to the best of your knowledge, that you are not pregnant, and that you do not intend to become pregnant during the trial.

The risks to an unborn human fetus or a nursing child from the medications in this study are not known.

As a female participant in the study, it is therefore important that you use a barrier contraceptive and second form of highly effective form of birth control method (contraception) during the study and for 3 months after stopping study treatment if you are sexually active and may become pregnant. These highly effective methods of birth control have a less than 1% chance of unwanted pregnancy during one year, if used appropriately according to the instructions of the manufacturer. Please discuss with your Study Doctor the most appropriate birth control method for you in respect of your cultural and religious situation.

- **Total abstinence**, when this is in line with your preferred and usual lifestyle. Periodic abstinence like calendar, ovulation, symptothermal, post-ovulation methods, and withdrawal are not acceptable methods of contraception.
- **Female sterilization**, when you have been already surgically sterilized prior to the study by surgical bilateral removal of ovaries (woman's reproductive system that stores and releases eggs for fertilization and produces female sex hormones), or tubal ligation (getting your “tubes tied”) at least six weeks ago.
- **Your male partner has already been sterilized** with the appropriate documentation. The sterilized male partner should be your sole partner.
- **Use of oral, injected or implanted hormonal methods** of contraception or placement of an intrauterine device (IUD) or intrauterine system (IUS) or other forms of hormonal contraception that have comparable efficacy (failure rate <1%), for example hormone vaginal ring or transdermal hormone contraception

In case of use of oral contraception, you should be stable on the same pill for a minimum of 3 months before taking study treatment.

Hormonal contraception is available in the form of pills which need to be taken every day, injections, which lasts approximately 3 months and as implanted devices. Hormonal methods are associated with some risks like changes in your cycle, nausea, headache, changes in mood, weight gain, breast tenderness, and blood clots.

Implanted devices are inserted into the uterus and can stay there for several years. They can cause cramps, bleeding, and infertility. It is important to know that not all women experience all of the adverse effects listed above.

If you become pregnant or suspect you may be pregnant during study treatment or within 3 months after completing study treatment, you must inform your Study Doctor immediately, and you have to stop ongoing study treatment. You will not be allowed to continue study treatment if you are pregnant. Your Study Doctor will medically follow your pregnancy until delivery to monitor you and your child`s safety.

As a male participant in the study, you must agree to use a condom during intercourse and not to father a child during the study and for the period of 3 months following stopping of study treatment. In addition, it is advised that your female partner uses a highly effective form of birth control method (contraception) if she may become pregnant. Partners of male subjects who become pregnant while the male partner is taking the study drug will be asked for authorization to follow the pregnancy to its outcome.

7. What benefits can I expect from being in the study?

Some potential benefits may include shrinkage of your tumors and improved quality of life leading to you feeling better while on study. However, because there is no reliable method to predict this, you may or may not benefit from being in this study. It is important to know that the information gained from this study may help future cancer patients receive better care.

8. What other choices do I have if I do not take part in the study?

You do not have to take part in this clinical trial. You may take part in another trial, opt to receive additional Standard of Care (what is usually done for your disease) treatment, or receive comfort care (no more treatment for your disease and instead focus on optimizing quality of life).

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

The study drug, Infigratinib, will be provided to you by the sponsor. You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of this research study and are outside the standard of care for your condition.

You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research study. You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner. You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage. You will be responsible for any charges not reimbursed by your insurance company.

Some insurance companies will not pay for routine costs for people taking part in research studies. Before deciding to be in this research study you should check with your insurance company to find out what they will pay for.

10. Will I be paid for taking part in this study?

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

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

You do not give up any legal rights by signing this consent.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to

applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information (and bio-specimens) be used or shared for future research?

No.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;

- Information gathered for this research about:
  - HIV / AIDS
  - Hepatitis infection
  - Sexually transmitted diseases
  - Other reportable infectious diseases
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
  - The diagnosis and treatment of a mental health condition
- Records about any study drug you received

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others: QED Therapeutics, Inc.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;

- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

To withdraw your permission, submit the cancellation in writing to:

Sameek Roychowdhury, MD, PhD
460 W 12th Ave.
996 Biomedical Research Tower
Columbus, OH 432110

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Dr. Sameek Roychowdhury 614-685-6700 (Office Hours) or (614) 293-8000 (24 hours).**

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact:

HIPAA Privacy Manager
The Ohio State University
Medical Center, Suite E2140
600 Ackerman Road, Columbus, OH 43202
614-293-4477

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Sameek Roychowdhury 614-685-6700 (Office Hours) or (614) 293-8000 (24 hours).**

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant** **AM/PM** **Date and time**
Printed name of person authorized to consent for participant (when applicable) **Relationship to the participant**	**Signature of person authorized to consent for participant (when applicable)** **AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent** **AM/PM** **Date and time**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness** **AM/PM** **Date and time**
Printed name of witness	**Signature of witness** **AM/PM** **Date and time**