PATIENT INFORMED CONSENT

Title of Research: Phase 1 Trial of Engineered HSV G207 in Children with Recurrent or Refractory Cerebellar Brain Tumors

VUMC IRB #: 212015

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Sponsor: UAB Department of Pediatrics, Division of Pediatric Hematology and Oncology
Supported By: U.S. Food and Drug Administration, Cannonball Kids' cancer Foundation, Treovir
Sponsor Protocol #: UAB 18113

Summary Table:

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to test the safety of study drug G207 alone or combined with a single dose of radiation and see what effects (good or bad) it has on you (or your child) and your (their) brain tumor.
Duration & Visits	After receiving study drug G207, you will be in this study for clinical evaluations at 7, 14, and 28 days; 3, 5, 7, 9, 12, 18 and 24 months; and yearly thereafter for up to 15 years. Patients who are unable to follow-up in person will be contacted by telephone on a yearly basis to monitor for delayed events.
Overview of Procedures	This study will include periodic blood samples/tests, small sample of your saliva and fluid that lines the eyelid, MRI scans, neurosurgical procedures (biopsy and placement of up to 4 catheters), CT scan(s), 6 hour 35 minute infusion of G207, single dose of radiation, and optional quality of life questionnaires.
Risks	The most common risks/side effects include headache, nausea, vomiting, decreased appetite, dizziness, increased seizure activity, fever, fatigue, and temporary increase in the tumor size on MRI due to treatment.
Benefits	You may or may not have a direct medical benefit from participating in this study. If you respond to this therapy, your tumor may shrink and your symptoms from the tumor may improve.
Alternatives	If you do not want to take part in the study you have other options that include other research studies, treatment that is not part of a research study (surgery, chemotherapy, radiation), and treatment to make you comfortable without anti-cancer therapy.
Disclosure	Two UAB institutional officials, Drs. James Markert and Richard Whitley, have significant financial interests in Treovir, the/a sponsor of this study. UAB has prohibited their involvement in the design, conduct, and reporting of this study and from oversight of all personnel on the study.

Purpose of the Research Study:

This is a Phase 1 study of an experimental new drug called HSV G207. A Phase 1 study is a clinical trial designed primarily to determine the safety of the drug. You are being asked to participate in a clinical trial (a type of a research study) of an investigational product called G207 that is being tested as a possible treatment for patients with brain tumors. G207 is an experimental herpes simplex virus (HSV). HSV causes cold sores and, rarely, causes a severe brain infection. G207 has been genetically changed and weakened, in the hope that only cancer cells will be infected and killed by the virus, without harming normal brain tissue. G207 is currently in clinical development and has not been approved by the Food and Drug Administration (FDA). You are being invited to take part in this study because you (or your child) have a progressive or recurrent brain tumor despite radiotherapy and/or chemotherapy.

We are using HSV G207 because it has been shown to be safe in Phase 1 trials in adults with brain tumors and some adults responded to the treatment. The goal of this study is to determine the highest safe dose (maximum tolerated dose) without causing severe side effects. During your participation in this study, some participants will also receive a single dose of radiation within 24 hours of receiving G207 to see if that helps the virus kill cancer cells. We want to find out if giving you an experimental virus treatment alone or with the radiation therapy is safe and of benefit. The purpose of this study is to test the human safety of G207 alone or combined with a single dose of radiation and see what effects (good or bad) it has on you (or your child) and your (their) brain tumor. It is anticipated that a maximum of 24 patients will take part in the study.

The study is planned to enroll three patients in each of 4 groups (cohorts). The first three patients will receive G207 at a starting dose of 1 x 10^6 plaque-forming units (infectious virus particles). If serious side effects occur in two patients at this starting dose, patients will be treated at a lower dose of 1 x 10^5 plaque-forming units. If no severe side effects occur at the starting dose, groups 2 will receive the same dose of G207 (1 x 10^6) combined with a single low dose of radiation (5 Gy) within 24 hours of receiving G207. If no dose-limiting, severe side effects are seen, group 3 will receive 1 x 10^7 plaque-forming units of G207 plus the single dose of radiation therapy, and group 4 will receive 1 x 10^8 plaque-forming units of G207 plus the single dose of radiation.

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child; "we" means the doctors and other staff. It is important that you understand the study, including the possible benefits and risks, before you decide to participate. This form gives you detailed information about the study. Please take your time to read it carefully and discuss it with your physician. Ask your physician if there is anything that is unclear or if you would like to receive further information. In addition, you may take home a copy of this information and discuss it with your relatives and friends. You will receive a signed copy of this form, should you decide to participate.

Study Participation & Procedures

If you agree to join the study, you will first have tests and procedures to see if you meet the requirements to receive G207. Many of the types of testing and procedures conducted are similar to what you would likely receive as normal standard of care with your physician or if you chose to participate on a different research study. The timing and frequency of the tests and procedures and dosages of radiation may be different because you are joining this research study. The test and exams are not experimental. These tests include a medical history and a physical exam. Your vital signs (temperature, heart rate, breathing rate and blood pressure) will be measured. Urine will be checked to make sure your kidneys are working. About 3-4 tablespoons of your blood will be collected by putting a needle into your vein or port, and that blood will be tested to check your general state of health, to make sure that you are not pregnant (if applicable), and to see if you have any unknown infections (including HIV infection). As part of this study, you will be tested for HIV. If the results show that you are positive for HIV, the study staff will tell you the results and you will be told where to obtain counseling and you will be referred to your primary care physician or the state health department. Some of that blood will also be used to see if you have ever had a herpes virus infection before. A small sample of your saliva and

conjunctival fluid (white surface of the eye) that lines the eyelid will be collected by brushing a sterile cotton-tipped swab in your mouth and along the eyelid to see if you have a herpes virus infection right now. Lastly, a magnetic resonance image (MRI) of your head will be done to see how big your brain tumor is right now and its precise location. During part of the MRI procedure, a dye will be injected into your vein so that the tumor can be better seen. By the time the study is over, you will have up to 11 different MRIs. The estimated amount of time for the first clinic visit is 3-4 hours.

If you qualify for this study, you will be taken to the operating room and receive anesthesia to put you to sleep. After you are asleep, you will have a metal frame placed around your head to help determine the exact site for virus infusion. The neurosurgeon will make an opening in the skin over your skull and will cut a small hole in the bone to access the recurrent tumor. Pieces of the tumor will be removed and specimens will be sent so that the neuropathologist can determine if the tumor is growing back. For larger tumors, portions of the tumor may be removed. If the tumor is growing back, then the neurosurgeon will place one to four catheters (flexible tube) into the remaining tumor which will come outside the scalp through the surgical opening and the skin will be closed around it. The placement of catheters is considered experimental and will add an estimated 45 minutes to the surgery. Most often one hole (the same hole made to take tumor pieces) will be used for the catheters but based on the location of the tumor and depending on the number of catheters placed, up to 4 small holes may be made in the skull. A postoperative CT scan will be obtained to confirm the location of each catheter within the tumor. If needed, the neurosurgeon will adjust the position of the catheter tip by withdrawing it to a more desirable location. Based on the location of the catheter, the neurosurgeon will decide on whether to repeat a head CT scan. The catheter(s) will be hooked up to a syringe pump and G207 will be pumped in during a 6 hour infusion. After the infusion, the catheters will be removed. If G207 given alone is shown to be safe, subsequent participants on this study will receive a single dose of radiation at the UAB Hazelrig-Salter Radiation Oncology Center or UAB Comprehensive Cancer Center within 24 hours of the virus infusion. The radiation will be directed to the tumor and any other areas in the brain or spine where tumor is present and growing by a trained Radiation Oncologist. The radiation treatment is expected to take 10-30 minutes. If there are no complications after you recover, you will remain in a regular hospital room for an estimated 2-3 days to be watched, to monitor you for any side effects.

After leaving the hospital, you must call the clinic immediately if there are any problems. After the treatment, you will be required to return to the clinic for evaluation at 7, 14, and 28 days; 3, 5, 7, 9, 12, 18 and 24 months; and yearly thereafter for up to 15 years. Each time, you will have many exams and tests repeated, including a physical exam, blood tests and MRI scans, and your doctor will ask about side effects and about medications you may be taking. The estimated amount of time per clinic visit is 2-4 hours. After 24 months, patients who are unable to follow-up in person will be contacted by telephone on a yearly basis to monitor for delayed events.

During this study blood samples will be taken at each visit to check your blood, test your immune system and general state of health. Swabs of your saliva and conjunctiva will also be

collected at each visit. These tests will be performed to see if any virus is present in those locations.

If you stop the study early, we will also keep track of how you are doing from time to time, for as long as possible. Therefore, we will keep your current address on file and you should be sure to tell us if you change your address. Should you die, no matter what the cause, permission from your family for an autopsy (after death medical examination) will be requested, unless you tell us that you would not want an autopsy done.

The main period of follow-up for this study is two years; however, we would like to continue evaluations for up to 15 years. You may leave the study at any time, for any reason. However, if you consider stopping, we encourage you to talk to your doctor first. Your doctor may take you out of the study (even if you do not want to stop) if he or she feels that it is not safe for you to continue.

Risks and Discomforts:

G207 has been tested on very few people (less than 50), and little is known about side effects in humans. You may have some of the side effects mentioned below and you should discuss these with the study doctor and/or your regular doctor. There may also be side effects that we cannot predict. Many side effects will be of short duration, but in some cases side effects can be serious or long lasting or permanent.

Possible side effects from the infusion procedure, and from taking blood for special tests include:

- Bleeding or bruising
- Discomfort or pain
- Rarely infection or thrombosis (blood clot)
- Lowered blood pressure resulting in lightheadedness, dizziness or fainting
- Allergic reactions to topical cleansing agents, G207, other chemicals, medical tape, or band aids
- Damage to blood vessels

Potential side effects from the tumor biopsy and catheter(s) placement and removal include:

- Allergic reaction to the anesthesia
- Skin irritation or allergic reaction at or near the surgical site
- Discomfort or pain, which may be severe and require strong pain medication, after the procedure
- Infection at the surgical site
- Spinal fluid leak
- Bleeding into the tumor
- Bleeding into the brain
- Swelling of the brain or brainstem
- Weakness
- Paralysis

- Coma
- Death

Side effects that have been seen in patients shortly after experimental treatment with G207 so far include:

- Headache
- Nausea
- Vomiting
- Diarrhea
- Decreased appetite
- Weakness
- Drowsiness
- Seizure
- Low red blood cell count
- Low platelet count
- Low white blood count
- Fever
- Fatigue
- Confusion
- Increased liver enzymes
- Skin infection
- Shingles
- Temporary increase in the tumor size on MRI due to treatment

Although not reported, side effects could include more severe reactions such as:

- Viral infections with flu-like symptoms and allergic reactions to G207, ranging from itching and hives to difficulty breathing
- Development of irritation or swelling of the brain including swelling due to HSV infection (encephalitis) and/or inflammation of the liver. Brain swelling could be severe and even fatal. If there is concern for encephalitis, a CT scan or MRI scan will be performed and the antivirus drug acyclovir started. Surgical biopsy may be necessary. If there is concern for significant swelling at the tumor site that cannot be controlled with medications, a CT scan or MRI scan may be performed and surgery may be recommended to remove dead tumor tissue and any residual tumor or to remove skull bone to relieve pressure from the swelling.

Potential side effects from CT scan:

You will receive a head CT scan to confirm placement of the catheters and if you are receiving radiation therapy, before radiation therapy. The total radiation from each CT scan is approximately equal to five years of exposure to natural background radiation. Background radiation is radiation normally received from sources such as cosmic rays and natural

radioactivity in building materials and the ground. There is a small risk that the radiation may cause cancer or other radiation effects in several years.

To prepare you for your CT scan, a liquid called a “contrast dye” may be injected into your veins to improve the quality of the image. There is a small possibility that you could have a severe allergic reaction to this dye that could cause injury or death. If you have any kidney problems, the dye may cause other medical problems.

• If you have any kidney problems or have ever had an allergic reaction to contrast dye, you must let the study physician know as soon as possible.

Potential side effects from MRI scans:

MRI is a test that uses magnetic fields and radio waves to generate images of the inside of your body. You will be placed inside a scanner and asked to lie still for approximately 30-60 minutes. This is a noisy exam; you will be given earplugs to protect your hearing. During the scan, a liquid will be injected into your vein to improve the quality of the scan.

MRI has negligible risks for most people; however, if you have any metal objects in your body MRI may not be safe for you and you will not be allowed to take part in this study.

To prepare you for your MRI exam, a liquid called a “contrast dye” may be injected into your veins to improve the quality of the image. There is a small possibility that you could have a severe allergic reaction to this dye that could cause injury or death. If you have any kidney problems, the dye may cause other medical problems such as a rare disease called Nephrogenic Systemic Fibrosis. If you have any kidney problems or have ever had allergic reactions to contrast dye, you must let the study physician know as soon as possible.

Potential side effect from radiation therapy:

If you receive radiation therapy, the amount of radiation is much less than what is normally used to kill tumors. However, it can still damage normal tissue. To prevent this, the doctors will design the radiation therapy to avoid the most sensitive parts of the brain.

Common side effects include:

- Fatigue
- Hair loss
- Skin changes
- Swelling/edema
- Nausea
- Vomiting
- Sexual effects (reduced desire)
- Blood clots

Less common but more serious side effects include:

- Neurologic deficits (this usually depends on the area of the brain being treated)
- Post-radiation swelling can cause weakness, numbness, difficulty

walking, and seizures
- Cognitive problems
- Seizures
- Headaches
- Additional cancers later in life

Another risk in this study is loss of confidentiality. The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Confidentiality will be protected to the extent that is allowed by law.

For more information about risks and side effects, speak with your doctor or ask the doctor in charge of the study: Dr. Gregory Friedman at 205-638-9285.

Information for Women of Childbearing Potential, Nursing Mothers, and/or Men Capable of Fathering a Child:

Boys and girls that are able to have babies must take special care:

- Mothers may not breast-feed during the study
- Patients and partners of patients must practice an effective double-barrier (condom plus a second type of contraception prevention) method of birth control for a minimum of 2-months after G207 administration. There could be unknown risks to an unborn child or to the patient should pregnancy occur. If you are pregnant, you may not participate in this study.
- Patients may not donate sperm or eggs for 2 months following the G207 administration
- Patients should avoid intimate contact (including kissing, body fluid exchange, and sexual activity) for 2 weeks following infusion with G207. Close contact with pregnant women, infants and young children, elderly people, and those with weak immune systems (for example, those with HIV or AIDS), should also be avoided during this time period.

Benefits:

Your participation in this study may not be of any direct medical benefit to you. If you respond to this therapy, your tumor may shrink and your symptoms from the tumor may improve. We hope that information learned from this study may help patients with brain tumors in the future.

Alternatives:

Instead of being in this study, you have these options:

- Other research studies that your doctor may be aware of for the treatment

of your type of cancer
- Treatment with therapies such as surgery, chemotherapy, or radiation (not part of a research study).
- Treatment to make you comfortable without any anti-cancer therapy. The investigator will discuss these options with you.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes:

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient), results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record. If you have never received care within this health system (outpatient or inpatient), a medical record will be created for you to maintain results of research tests or procedures. Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

A description of this clinical trial will be available on 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 this website at any time.

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?

All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

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

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

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

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research study.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically. The use of your personal health

information will continue until you cancel your permission.

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 study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

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

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal:

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study drug and referred for follow-up care. Contact the study doctor if you want to withdraw from the study.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation:

We will cover the costs of all evaluations and scans required by the study that are not part of your routine treatment and disease management. We will cover the costs of the placement and removal of the catheters, G207 and the infusion of G207. Either you or your insurance company will be billed in the usual manner for routine medical care, tests, and for problems that are unrelated to your being in this study. This includes routine blood tests, x-rays, scans, medications you currently take or are prescribed and physician charges. The cost to you should not be more than it would be if you were not in this study. Financial assistance may be available, and we have a social worker who can work with you if needed.

Payment for Participation:

UAB and Children's of Alabama have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge. Your doctor will arrange for the proper care and

treatment for any injury resulting directly from being in this study.

Payment for Research-Related Injuries:

UAB and Children's of Alabama have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings:

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Optional Research:

Future Research Use of Private Information and/or Biospecimens

We would like your permission to keep your private information (data containing personal information) and biospecimens (*study blood and tumor tissue*) collected in this study for future research. The future research may be similar to this study or may be completely different. About 1 teaspoon of additional blood will be collected at each visit by a phlebotomist or nurse. The collection of blood will occur at the same time as routine blood draws. The tumor tissue will be collected by a neurosurgeon. Your private information and biospecimens will be stored indefinitely or until used. Your private information and biospecimens will be labeled with a code that only the study doctor can link back to you. Results of any future research will not be given to you or your doctor.

You can take part in this study even if you decide not to let us keep your private information and biospecimens for future research. If you give us permission now to keep your private information and biospecimens, you can change your mind later and ask us to destroy it. However, once we have analyzed your private information and biospecimens, we may not be able to take it out of our future research.

We may share your private information and biospecimens, so that others can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your private information and biospecimens with other researchers, we will not be able to get it back.

Future research use of your private information and biospecimens will be conducted in compliance with applicable regulatory requirements. You will not find out the results of future research on your private information and biospecimens. Allowing us to do future research on your private information and biospecimens will not benefit you directly.

Initial your choice below:

_____ I agree to allow my private information and biospecimens (study blood) be collected

and to be kept and used for future research on malignant brain tumors and/or immunotherapy.

_____ I do not agree to allow my private information and biospecimens (study blood) be collected to be kept and used for future research on malignant brain tumors and/or immunotherapy.

_____ I agree to allow my private information and biospecimens (tumor tissue) be collected and to be kept and used for future research on malignant brain tumors and/or immunotherapy.

_____ I do not agree to allow my private information and biospecimens (tumor tissue) be collected to be kept and used for future research on malignant brain tumors and/or immunotherapy.

Quality of Life and Parental Stress Assessments

We would like the patient and the parent/guardian to be participate in the quality of life and parental/family stress assessments. Both the patient and the parent or legal guardian would be considered participants. We would like to learn more about the quality of life (physical, emotional, and social well-being) of children that are receiving G207 therapy and the quality of life of their siblings and parent(s). This is an optional consent. If you agree to take part in these assessments, you and/or your child will be asked to complete up to 5 surveys. These are expected to take less than 30 minutes and can be completed during a routine clinic visit. You will be asked to complete these surveys prior to receiving G207 therapy, and then 1, 3, 5 and 12 months after completing therapy. You do not have to do these optional research surveys if you do not want to, and you can still be in the study if you do not want to do these surveys.

Initial your choice below:

_____ My child and I agree to participate in quality of life and parental/family stress assessments.

_____ My child and I do not agree to participate in quality of life and parental/family stress assessments.

Questions:

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Gregory Friedman at 205-638-9285 or after hours by paging him at 205-638-9100.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Legal Rights:

You are not waiving any of your legal rights by signing this consent form.

Signatures for Participants Age 18-21:

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

I have carefully explained the purpose and procedures of this study to the patient. I certify by my signature that, to the best of my knowledge, the patient understands the nature, demands, risks and benefits involved by their participation in this study.

_____

Signature of Principal Investigator Date

_____

Signature of Person Obtaining Consent Date

Signatures for Research Involving Children:

You are making a decision whether or not to have your child participate in this study. Your signature indicates that you have read (or been read) the information provided above and decided to allow your child to participate. You will receive a copy of this signed consent form.

_____

Signature of Participant 14-17 Years of Age Date

_____

Signature of Parent or Guardian of Participants 3-17 Years of Age Date

I have carefully explained the purpose and procedures of this study to the patient. I certify by my signature that, to the best of my knowledge, the patient understands the nature, demands, risks and benefits involved by their participation in this study.

_____

Signature of Principal Investigator Date

_____

Signature of Person Obtaining Consent Date

Waiver of Assent:

The assent of _____ (name of child/minor) was waived because of:

Age_____ Maturity_____ Psychological state of the child_____