

MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY <ul style="list-style-type: none"> • Adult Patient or •Parent, for Minor Patient
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INSTITUTE: National Cancer Institute

STUDY NUMBER: 17-C-0088 PRINCIPAL INVESTIGATOR: John Glod, M.D., Ph.D.

STUDY TITLE: A Phase II Trial of the DNA Methyl Transferase Inhibitor, SGI-110 (Guadecitabine), in Children and Adults Wild Type GIST, Pheochromocytoma and Paraganglioma Associated with Succinate Dehydrogenase Deficiency and HLRCC-Associated Kidney Cancer

Continuing Review Approved by the IRB on 02/11/19

Amendment Approved by the IRB on 11/5/19 (B)

Date posted to web: 11/14/19

Standard

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

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If you are signing for a minor child, “you” refers to “your child” throughout the consent document.

What is the usual approach to my diagnosis?

You are being asked to participate in this study because you have one of the following 3 disorders:

- Wild-type gastrointestinal stromal tumor (GIST) (this means there is no mutation in *KIT* or *PDGFRA*);
- Pheochromocytoma and paraganglioma (PHEO/PGL); or
- Kidney cancer related to a disorder called hereditary leiomyomatosis and renal cell carcinoma (HLRCC).

GIST is a type of cancer that occurs in the gastrointestinal tract (esophagus, stomach or intestines) which does not respond well to standard chemotherapy or radiation therapy. A targeted therapy used to treat most patients with GIST is called imatinib (Gleevec®), but in many children with GIST, imatinib may not work. This may be because children with this type of cancer do not have the same permanent alteration in their genes (mutation in *KIT* or *PDGFRA*) that is often seen in adults with the same cancer. Most GIST in pediatric patients have a deficiency in an enzyme called succinate dehydrogenase or SDH.

This SDH deficiency is also seen in some patients (about 10-30%) with PHEO/PGL. The only treatment to cure PHEO/PGL is surgery, although both chemotherapy and radiation therapy are used to treat patients with PHEO/PGL.

Kidney cancer in patients with HLRCC is often treated with surgery. If the cancer has metastasized outside of the kidney, the most common treatment is chemotherapy. Many patients with HLRCC have mutations in a different enzyme called FH (fumarate hydratase).

SGI-110 is a small molecule that is derived from decitabine that acts as a DNA methyltransferase (DNMT) inhibitor. Its specific properties appear to work in laboratory tests in disorders that have the types of enzyme deficiencies seen in GIST, PHEO/PGL or HLRCC.

What are my other choices if I do not take part in this study?

You will only be eligible for this trial if the other known treatments for your disorder, such as surgery, radiation therapy or chemotherapy, have not proven effective treatments for you. Alternatives to this experimental regimen may include partial surgical removal of your tumor, other experimental therapies, or chemotherapies you have not yet tried, or you may decide not to receive any treatment directed at shrinking your tumor(s) at this point in time.

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Please talk to your doctor about these and other options.

Why is this study being done?

The purposes of this research study are:

1. To assess if SGI-110 is helpful in the treatment of your type of tumor(s) (causes your tumor to shrink or slow down the growth).
2. To study how SGI-110 acts in the body (pharmacokinetics, also known as PK) in children and adults.
3. To study the DNA methylation (the process that cells use to control gene expression) and gene expression in your tumor (the genetic instructions the tumor uses to create proteins) in response to treatment with SGI-110.

Studies in animals and other types of cancer have shown that SGI-110 can shrink tumors in some types of cancer. There are several clinical studies using SGI-110 including studies in patients with leukemia, liver cancer, ovarian cancer, melanoma, colorectal cancer and myelodysplastic syndrome (this refers to a group of bone marrow disorders in which the bone marrow does not make enough healthy blood cells). Many of these studies are ongoing.

Up to 70 patients may take part in this study.

What are the study groups?

All study participants will get the same study intervention. There will be three groups of study participants based on your tumor type:

- Wild-type gastrointestinal stromal tumor (GIST);
- Pheochromocytoma and paraganglioma (PHEO/PGL); or
- Kidney cancer in patients with a disorder called hereditary leiomyomatosis and renal cell carcinoma (HLRCC).

You will come to the NIH and be given an injection of SGI-110 under the skin (subcutaneously), usually in your abdomen, every day for 5 days. This will be repeated every 28 days.

We will help treat any symptoms that you may have as a result of the study medication. Some helpful hints include:

- We will inject the study medication slowly (up to one minute) to minimize any discomfort.

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- We will apply ice to the skin where we plan to inject the medication before and after the injection.
- If you still have pain, tell your study team and they may give you something to reduce the discomfort.

If you experience side effects that are too distressing, the dose of the SGI-110 can be reduced.

How long will I be in this study?

You will have the injections every day for 5 days, which will be repeated every 28 days as long as you do not have unacceptable side effects or your tumor(s) do not get worse. If you have side effects the dose of SGI-110 may be held for a short time and the dose may be reduced to prevent return of the side effect. Two dose reductions are allowed on this study. If the side effect(s) is too severe, or side effect(s) recur after two dose reductions, SGI-110 may need to be stopped.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer, such as physical examination, laboratory testing and scans and x-rays. However, there are some extra tests and procedures that you will need to have if you take part in this study. You will not be billed for any extra tests or procedures.

Before you begin the study

You will need to have the following extra tests to find out if you can be in the study:

- Pregnancy test (if you are a woman who could have children)
- CT Scan, MRI scan and/or FDG-PET scan of your tumor(s).

During the study

- Questionnaires to evaluate the effects of SGI-110 on your pain and quality of life at baseline and then at the end of cycle 4, and then every 4 cycles thereafter, and at the time you stop SGI-110 treatment. Everyone will be asked to complete a quality of life and pain evaluation.
- Biopsy of your tumor (take a small piece of your tumor tissue using a large needle) if you are 18 years of age and older and a have a tumor that can be safety biopsied (this tumor biopsy is optional). We will ask you to allow us to do one biopsy your tumor at some

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point during the treatment with SGI-110. This tissue will be studied for the effects of SGI-110 on your tumor DNA and if your tumor has a protein called NY-ESO-1 or not.

- Blood samples for special research tests (mandatory):
 - Pharmacokinetics (called PK studies), to see how much SGI-110 is in your blood. About 3 mL of blood (~1/2 teaspoon) will be collected before your first dose of SGI-110 and then after the first dose at ½ hr, 1, 2, 4, 6, and 24 hours after the first dose.
 - Pharmacodynamics (called PD studies) to study the effects of SGI-110:
 - A urine sample will be taken to study the metabolites in the urine. We will ask for a urine sample before your first dose, and on days 7, 14 and 28 of cycle 1.
 - Blood samples will be taken at the same time as the urine samples to study the metabolites in the blood (3 mL of blood or ~1/2 teaspoon), before your first dose, and on days 7, 14 and 28 of cycle 1.
 - Blood samples (3 mL of blood or ~1/2 teaspoon) will be taken to study the demethylation activity in response to SGI-110 before the first dose and one additional time while you are receiving SGI-110.

The total volume of blood obtained for the research studies outlined above (PD and PK) will be about 40 mL [8 teaspoons] over 1 month. Your doctor will discuss these tests in detail with you and make sure that all blood draws combined do not exceed a safe volume.

For specific research tests, your tissue and blood will be sent to other laboratories in the NIH for testing. Your name will not be attached to your tissue or blood; it will be identified using a study number. Only the investigator and research team will have access to the information that links your personal information to your tissue and blood samples.

When you are finished taking the drugs (treatment)

At the end of treatment with SGI-110 you will have an evaluation at the NIH which will include a final evaluation of your pain and quality of life.

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A study calendar that shows how often these tests and procedures will be done is attached.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that the SGI-110 (guadecitabine) may not be as good as the usual approach for your cancer or condition at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The SGI-110 (guadecitabine) used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug/ study approach.

Here are important points things to know about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may make it hard for you to have children.
- Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

<p>COMMON, SOME MAY BE SERIOUS</p> <p>In 100 people receiving SGI-110 (guadecitabine), more than 20 and up to 100 may have</p> <ul style="list-style-type: none"> • Tiredness

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| <ul style="list-style-type: none"> • Swelling and redness at the site of the medication injection • Bruising, bleeding |
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| <p>OCCASIONAL, SOME MAY BE SERIOUS</p> <p>In 100 people receiving SGI-110 (guadecitabine), from 4 to 20 may have:</p> |
| <ul style="list-style-type: none"> • Anemia which may require blood transfusion • Infection, especially when white blood cell count is low • Constipation, diarrhea, nausea, vomiting • Sores in the mouth which may cause difficulty swallowing • Fever • Pain • Loss of appetite • Dizziness, headache • Difficulty sleeping • Shortness of breath • Nose bleed • Rash |

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|---|
| <p>RARE, AND SERIOUS</p> <p>In 100 people receiving SGI-110 (guadecitabine), 3 or fewer may have:</p> |
| <ul style="list-style-type: none"> • Swelling of the eye • Swelling of the face • Kidney damage which may require dialysis |

You may experience diarrhea with this treatment and should record the number of stools and associated symptoms. If you develop diarrhea you should inform the study doctor. You may take a dose of loperamide after the first episode of unformed, loose stool. After discussion with the study doctor, loperamide can be continued until you are diarrhea-free for at least 12 hours. You should contact the study doctor or study nurse if you develop persistent diarrhea, diarrhea complicated by vomiting or fever, abdominal pain, or inability to take oral liquids.

Reproductive Risks: You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on

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this study. Both male and female participants must use effective birth control measures while participating in this study and for at least six months after the last dose of study drug. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. Optional birth control methods include, but are not limited to, abstinence, oral birth control pills, an IUD, or condoms with spermicide. If you are a woman and become pregnant or suspect you are pregnant while participating in this study, please inform your treating physician immediately. A patient who becomes pregnant while on study drug will immediately be taken off study.

Questionnaires: You will be asked to complete 2 questionnaires that take 7-12 minutes each to complete. Completion of the questionnaires may become uncomfortable for some participants, either due to boredom or due to the personal nature of the questions. Tell the health care provider if you are uncomfortable and do not wish to complete a questionnaire.

What possible benefits can I expect from taking part in this study?

SGI-110 may cause your tumor(s) to stop growing or shrink or it may lessen the symptoms, such as pain, that are caused by the tumor. However, because there is not much information about the drug's effect on your type of tumor, we do not know if you will benefit from taking part in this study, although the knowledge gained from this study may benefit others. Your samples may be helpful to research. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization helping the investigator run the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB (the Institutional Review Board) or FDA (U.S. Food and Drug Administration). The sponsor is the company or organization, in this study it is Cancer Therapy Evaluation Program or CTEP, that is responsible for

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overseeing the study. CTEP works with the drug company making SGI-110 and makes it available for this study.

What are my rights?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

What are the costs of taking part in this study?

If you choose to take part in the study, the following will apply, in keeping with the NIH policy:

- You will receive study treatment at no charge to you. This may include surgery, medicines, laboratory testing, x-rays or scans done at the Clinical Center, National Institutes of Health (NIH), or arranged for you by the research team to be done outside the Clinical Center, NIH if the study related treatment is not available at the NIH.
- There are limited funds available to cover the cost of some tests and procedures performed outside the Clinical Center, NIH. You may have to pay for these costs if they are not covered by your insurance company.
- Medicines that are not part of the study treatment will not be provided or paid for by the Clinical Center, NIH.
- Once you have completed taking part in the study, medical care will no longer be provided by the Clinical Center, NIH.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. Please see **Other Pertinent Information** on page 14 of 15, item 2 for more information.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the

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researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor and any drug company supporting the study.
- The IRB is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the National Cancer Institute in the U.S.

Your individual genomic data and health information will be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database have agreed not to attempt to identify you.

Where can I get more information?

You may visit the NCI Web site at <http://cancer.gov/> for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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 website will include a summary of the results. You can search this Web site at any time.

Conflict of Interest

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a Protocol Review Guide. You may ask your research team for a copy of the Protocol Review Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines but they do not need to report their personal finances to the NIH.

Additional Studies Section

Tumor Biopsy (optional)

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If you are 18 years of age or older and have a tumor that can be safely biopsied with a needle, we will ask that you undergo a biopsy after receiving SGI-110. This biopsy is optional.

What is involved?

A doctor will use a hollow needle attached to a syringe to enter a tumor, then withdraw (aspirate) a small amount of tissue from the tumor. The doctor may use a scan or ultrasound to guide the needle directly to the tumor. Depending upon the location of the tumor, the doctor may use numbing medicine (called local anesthetic) to numb the area before the biopsy.

What are the possible risks?

Biopsies are very common procedures that have few risks. The risks will be explained to you fully in a different consent. In general, the risks include bleeding, pain, scarring and infection. If there is bleeding under the skin, a hematoma or collection of blood at the biopsy site may occur. Other risks depend on the location of the tumor being sampled. The doctor will discuss these specific risks with you before the procedure. We have successfully performed hundreds of tumor biopsies in the POB without major complications or side effects.

How will information about me be kept private?

Your tumor samples will be identified and stored using a number and not your name. Only the study investigator and research team taking care of you on this study will have access to your name.

What are the possible benefits?

The use of your biopsy specimens will be for research purposes only and will not benefit you. Results of research done on your tumor specimens will not be available to you or your doctor, but it will help us better understand how this study drug works on tumors, and it might help people who have these types of tumors in the future.

Are there any costs or payments?

There are no costs to you. You will not be paid for your tissue. The cost of storage and testing will be paid by the study investigators or collaborators in this study.

What if I change my mind?

If you decide now that you will undergo the biopsy, you can change your mind at any time. Just let us know at the time of the biopsy or contact us (office of Dr. Glod, Principal Investigator: 240-760-6194) and let us know that you do not want to have the biopsy.

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What if I have more questions?

If you have additional questions, please contact the office of Dr. Glod, Principal Investigator: 240-760-6194.

Use of Specimens and Data for Future Research

To advance science, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. A researcher who wants to study the information must apply to the database and be approved. Researchers use specimens and data stored in scientific databases to advance science and learn about health and disease.

We plan to keep some of your specimens and data that we collect and use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These specimens and data will be stripped of identifiers such as name, address or account number, so that they may be used for future research on any topic and shared broadly for research purposes. Your specimens and data will be used for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used.

Results of research done on your specimens and data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

If you do not want your stored specimens and data used for future research, please contact us in writing and let us know that you do not want us to use your specimens and/or data. Then any specimens that have not already been used or shared will be destroyed and your data will not be used for future research. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

Study Calendar

Test/Procedure	Pre-treatment	During Cycle 1 (28 days)	During Cycles 2 through end of treatment	Completion/Stopping treatment
Medical history, Physical exam, vital signs	X	Before starting cycle 1	At the beginning of each cycle	
Standard blood tests	X	Before starting cycle 1	At the beginning of each cycle	
SGI-110 injection under the skin (subcutaneously), once		Day 1 through Day 5	Day 1 through Day 5	

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a day for 5 days; record in the diary				
Blood & urine samples for special research tests		On days 1, 7, 14 and 28 of cycle 1		
Tumor biopsy (optional if you are 18 years of age or older)			During treatment	
Pregnancy test (in women who can get pregnant)	X		At the beginning of each cycle	
Tumor evaluations may include CT scan, FDG PET scan and/or MRI	X		Prior to cycle 2, 4, 6, 8, 10, 12, etc.	
Quality of life and distress thermometer	X		At the end of cycle 4, and then after every 4 cycles (i.e. end of cycle 8, 12, 16, etc)	X

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OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, John Glod, M.D., PhD., Building 10, Room 1-3940, Telephone: 240-760-6194. You may also call the Clinical Center Patient Representative at 301-496-2626. If you have any questions about the use of your specimens or data for future research studies, you may also contact the Office of the Clinical Director, Telephone: 240-760-6070.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

PATIENT IDENTIFICATION	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY (Continuation Sheet) • Adult Patient or •Parent, for Minor Patient NIH-2514-1 (07-09) P.A.: 09-25-0099 File in Section 4: Protocol Consent
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COMPLETE APPROPRIATE ITEM(S) BELOW:			
<p>A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.</p>	<p>B. Parent's Permission for Minor Patient. I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)</p>		
<p>_____ Signature of Adult Patient/ Legal Representative</p>	<p>_____ Date</p>	<p>_____ Signature of Parent(s)/ Guardian</p>	<p>_____ Date</p>
<p>_____ Print Name</p>	<p>_____ Print Name</p>		
<p>C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study.</p>			
<p>_____ Signature of Parent(s)/Guardian Date Print Name</p>			
<p>THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM FEBRUARY 11, 2019 THROUGH FEBRUARY 25, 2020.</p>			
<p>_____ Signature of Investigator</p>	<p>_____ Date</p>	<p>_____ Signature of Witness</p>	<p>_____ Date</p>
<p>_____ Print Name</p>	<p>_____ Print Name</p>		