INSTITUTE: National Cancer Institute

STUDY NUMBER: 09-C-0214 PRINCIPAL INVESTIGATOR: James H. Doroshow, MD

STUDY TITLE: A Multi-Histology Phase II Study of 5-Fluoro-2-Deoxycytidine with Tetrahydrouridine (FdCyd + THU)

Continuing Review Approved by the IRB on 06/11/18
Amendment Approved by the IRB on 05/31/18 (X) Date Posted to Web: 06/22/18
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.

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team.

If you have any questions, you can ask your study doctor for more information. You are being asked to take part in this study because you have a cancer that has not responded to standard treatments or for which no standard treatments have been identified.

Why is the study being done?

This research study includes patients with advanced non-small cell lung cancer, breast cancer, bladder cancer, and head and neck cancer. You are being asked to volunteer to take part in this research study because you have advanced cancer that has progressed after receiving standard treatment or for which no effective therapy exists. We are doing this study to try to develop better treatments for cancer. On this study, two experimental drugs, FdCyd (also called 5-fluoro-2'-deoxcytidine), and THU (also called tetrahydrouridine), will be given to you. The purpose of this study is to see if the drugs work together to control your tumor growth. FdCyd is thought to work by changing how genes work in cancer cells. THU does not have any anticancer effects on its own, but it helps keep the other drug, FdCyd, from being broken down by your body. These drugs have been given to more than 170 patients as of February 2016. The two drugs have some side effects that will be reviewed with you by your medical team before you sign the consent form.

How many people will take part in this study?

Up to 165 patients will take part in this study across 6 centers in the United States.

What will happen if I take part in this study?

If you are accepted and you choose to take part, you will begin receiving FdCyd and THU. Please see the Study Chart below for more details. You will also have tests and procedures done because you are in the study to see how FdCyd and THU are affecting your body. This will include repeating some of the imaging studies (e.g., CT scans, a computerized x-ray examination) to find out if your cancer has responded. Descriptions of the tests and procedures that will be performed during the study are listed below.

FdCyd and THU will be given in cycles. Each cycle is 28 days long. You will receive FdCyd and THU on days 1-5 and 8-12 of each cycle. You may continue to receive FdCyd and THU if your cancer does not grow, if you do not have too many side effects, and if you are willing to do so.

Clinical Center Visits: FdCyd and THU will be given through a vein each day on days 1-5 and 8-12 of each cycle. We will ask that you come to the Clinical Center on these days during each cycle. While you are at the Clinical Center we will perform study tests and procedures to see how the study drugs are affecting your body. So, for each cycle you will be coming to the

Clinical Center for at least 12-14 days. If you develop any side effects, you may be asked to visit more often.

Standard procedures being done because you are in this study; these may be done more often because you are in the study:

- **Clinic visit:** to ask how you are feeling and to evaluate you with a physical examination every week during Cycle 1, and then at the beginning of each cycle.
- **Vital signs and physical examinations:** will be performed during the clinic visits.
- **Blood tests:** Measurement of your white blood cells, red blood cells, and platelets and measurements of your blood sugar and electrolytes and of how your liver, kidneys, and blood clotting work will be done every week during Cycle 1, and then before treatment on weeks 1 and 2 of all other cycles. Approximately 1 tablespoon (15 mL) of blood will be drawn per visit.
- **Urine test:** Depending on the results of blood tests, you may be asked to collect your urine for 24 hours for further testing.
- **CT scans** or other imaging tests such as ultrasound (an examination using sound waves) or MRI (an examination using magnetic field and radio waves) that detect your tumor will be done before the study and every 8 weeks while you are receiving study drugs (less often if you have been on study for more than one year). This is done so that any benefit of the treatment can be determined, and if your cancer is not responding to the treatment, the study team can tell you and discuss other treatment options (discussed further below).

Tests and procedures that are either being tested in this study or being done to see how the drug is affecting your body:

- **Measurement of FdCyd and THU in your blood:** We will collect blood samples from some patients to measure the amount of study drugs in the blood and to help us find out how the body handles the drugs. Blood will be collected during Cycle 1 only, on day 1 before the drugs are given, at multiple time points while the drugs are being given, at several times up to 6 hours after the drugs are given, and then once before treatment on days 2, 3, 4, and 5. The total blood for all these tests will be about 3 tablespoons (45 mL).
- **Other research blood samples:** We will also be collecting blood samples to find out the effects of the drugs on cells in your blood. Blood samples will be collected on days 1, 2, and 12 in Cycle 1, on day 1 of Cycle 2 and every subsequent cycle, on day 12 in Cycles 2, 4, and 6, and, if your disease comes back, at the time that your disease comes back. The total blood for all these tests will be about 1/2 a cup (about 115 mL).
- **Measurement of FdCyd and THU in your urine:** We will collect urine samples from some patients to measure the amount of study drugs in the urine. Urine will be collected before the study drugs are given and for 24 hours after the drugs are given on Cycle 1, day 1.

- **Tumor biopsies:** After you are accepted to take part in the study, you will be asked to have a biopsy of your tumor (removal of a small bit of tissue for examination under a microscope) once before you receive study drugs and a second time after you complete Cycle 2. We are collecting biopsy samples to study how the drugs affect your tumor. Biopsies are a very important part of this trial and are done for research purposes. Tumor biopsies are optional, and no more than two biopsy procedures will be performed during the study. You may choose not to have tumor biopsies, and this will not affect your taking part in this study. If you decide not to have tumor biopsies, you will still receive study drugs and have other tests that are part of the study.

  Tumor biopsies are only collected by trained personnel. Biopsies are collected using a small core needle under imaging guidance (CT, MRI, or ultrasound as considered appropriate by the interventional radiologist performing the biopsy). Imaging helps the specialized radiologist know that the needle has been placed into the tumor mass.

  Typical risks of biopsy collection include, but are not limited to, bleeding, infection, pain, and scarring. If you experience any complications from the biopsy, medical care will be offered to you. You will be counseled in more detail about biopsies, and you will be asked to sign a separate consent form that will describe the procedures and risks at that time. Your safety is the most important thing at all times. If upon attempting the first biopsy, no tissue can be obtained or it has caused you harm, the second biopsy procedure will not be done. After you are enrolled in this study, if for any reason the biopsies cannot be done safely, you may still receive the study drugs but the biopsies will not be done.

  I agree to allow biopsies for research purposes Yes____ No____
  Initials_____

Study Chart

The drugs are given over 28-day periods of time called cycles. FdCyd and THU are given through a vein for about 3 hours each day on days 1-5 and 8-12 of each cycle. The days you receive study drugs may change by up to 1 day for scheduling reasons (for example, weekends, holidays, or for your convenience), but FdCyd and THU will only be given for 5 days in week 1 and 5 days in week 2.

The chart below shows what will happen to you during Cycle 1 and future cycles after you sign the consent and start the study. Each cycle is numbered. The left-hand column shows the day in the cycle, and the right-hand column tells you what will happen on that day.

Day	What to do and what will happen to you
Before starting study drug	• Have a history taken of how you feel and undergo a physical examination by a Health Care Provider (HCP) • Get routine blood tests • CT scan will be done • Tumor biopsy may be performed (optional, see above)
Cycle 1 onwards, Day 1	• Have a history taken of how you feel and undergo a physical examination by a HCP • Get routine blood tests • FdCyd and THU will be given through a vein for 3 hours • Blood draws for research will be obtained • Urine samples for research will be obtained over a 24-hour period (Cycle 1 only)
Cycle 1 onwards, Days 2, 3, 4, 5	• FdCyd and THU will be given through a vein for 3 hours • Blood draws for research will be obtained (Cycle 1 only)
Cycle 1 onwards, Days 6, 7	• No treatment
Cycle 1 onwards, Day 8	• Have a history taken of how you feel and undergo a physical examination by a HCP (Cycles 1 and 2 only) • Get routine blood tests • FdCyd and THU will be given through a vein for 3 hours
Cycle 1 onwards, Days 9, 10, 11	• FdCyd and THU will be given through a vein for 3 hours
Cycle 1 onwards, Day 12	• FdCyd and THU will be given through a vein for 3 hours • Blood draws for research will be obtained (Cycles 1, 2, 4, and 6)
Cycle 1 onwards, Days 13-28	• No treatment • On approximately days 15 and 21, you will have a physical examination and blood draws for routine blood tests (Cycle 1 only)
Cycle 3 onwards	• CT scans to determine how your tumor is responding to the treatment will be done every 2 cycles (every 3 cycles if you have been on the study for more than a year or every 4 cycles if for more than 3 years) • Tumor biopsy may be performed (at the end of Cycle 2/prior to start of Cycle 3 only; optional, see above) • Blood draw for research will be obtained if your disease comes back

Are there reasons that my taking part in this study may end early?

Your study doctor will be watching you and your cancer while you are receiving FdCyd and THU. If your cancer is worsening, the study doctor will suggest that you stop taking the drugs and she or he will discuss other options with you. Also, if you are having side effects from the drugs which are dangerous to your health or too difficult for you to tolerate, you and the study team may decide that you should stop taking the drugs. The study doctor may stop you from taking part in this study at any time if he or she believes it is not in your best interest, if you do not follow the study rules, or if the study is stopped.

Stopping Therapy

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease comes back during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if new information shows that another treatment would be better for you

In this case, you will be informed of the reason therapy is being stopped.
You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.
If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to the Cancer Therapy Evaluation Program (CTEP) at the National Cancer Institute (NCI) or designated representatives. If you withdraw your consent and leave the trial, any samples of yours that have been obtained for the study and stored at the NCI can be destroyed upon request. However, any samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases **cannot** be recalled and destroyed.

What side effects or risks can I expect from being in the study?

If you choose to take part in this study, there is a risk that you may:

- Lose time at work or home and spend more time in the hospital or doctor's office than usual
- Be asked sensitive or private questions which you normally do not discuss

The agents 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(s)/study approach. Here are important points 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 interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The 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 that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Risks and side effects related to FdCyd with THU may include:

COMMON, SOME MAY BE SERIOUS In 100 people receiving FdCyd/THU, more than 20 and up to 100 may have:
• Anemia which may require blood transfusion • Diarrhea, nausea, vomiting • Tiredness • Bruising, bleeding • Infection, especially when white blood cell count is low • Loss of appetite

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving FdCyd/THU, from 4 to 20 may have:
• Abnormal heartbeat • Bloating, constipation, heartburn, passing gas • Pain • Dry mouth, skin • Sores in mouth which may cause difficulty swallowing • Chills, fever • Swelling of arms, legs • Weight loss • Dehydration

- Muscle weakness
- Dizziness, headache
- Changes in taste
- Numbness, tingling or pain of the arms and legs
- Cough, shortness of breath
- Nose bleed
- Hair loss, itching, rash
- Increased sweating
- Redness, pain or peeling of the palms and soles
- Low blood pressure which may cause feeling faint

THU has no expected side effects at the dose used in this study, but THU may make the side effects of FdCyd worse.

Blood draws for routine laboratory tests may result in bruising, infection, and minor pain or discomfort comparable with a needle prick. When the medication is put through a vein in your arm, you may experience a moment of pain. In addition, there is the discomfort of having the catheter taped to your arm. Other risks include bleeding, bruising, temporary clotting of the vein, and infection.

The removal of tumor tissue for research biopsies can cause pain, bruising, and possibly infection at the site where the biopsy was taken. The biopsy procedure will be discussed in detail with you, including side effects, and we will ask you to sign a separate consent form before to the procedure.

Reproductive Risks: Because the drugs in this study can possibly affect unborn babies and infants, you should not become pregnant, father a baby, or breastfeed while you are on this study. Women of childbearing potential will be required to have a pregnancy test. If you are a woman who can become pregnant, or are the partner of a woman who can become pregnant, you will need to practice an effective form of birth control before starting study treatment and for 3 months after you finish study treatment. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once. Avoiding sexual activity is the only certain method to prevent pregnancy. But, if you choose to be sexually active, you should use an appropriate "double barrier" method of birth control (such as female use of a diaphragm, intrauterine device (IUD), or contraceptive sponge, in addition to male use of a condom) or the female should be using prescribed "birth control" pills, injections, or implants. Male participants must also use adequate contraception. If you choose to be sexually active during this study, you understand that even with use of these birth control measures pregnancy could still result. Some methods might not be approved for use in this study. Ask about counseling and more

information about preventing pregnancy. For more information about risks and side effects, ask your study team.

Potential Risks Related to Research-Related Imaging Studies:

This research study involves exposure to radiation from up to 2 CT scans (used in biopsy collections). This radiation exposure is not required for your medical care and is for research purposes only. The amount of radiation you will receive in this study is 1.6 rem, which is below the guideline of 5 rem per year allowed for research subjects by the NIH Radiation Safety Committee. The average person in the United States receives a radiation exposure of 0.3 rem per year from natural sources, such as the sun, outer space, and the earth's air and soil. If you would like more information about radiation, please ask the investigator for a copy of the pamphlet, An Introduction to Radiation for NIH Research Subjects.

While there is no direct evidence that the amount of exposure received from participating in this study is harmful, there is indirect evidence it may not be completely safe. There may be a very slight increase in the risk of cancer.
Please tell your doctor if you have had any radiation exposure in the past year, either from other research studies or from medical tests or care, so we can make sure that you will not receive too much radiation. Radiation exposure includes x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body.

If you are pregnant you will not be permitted to participate in this research study. If you are breast feeding and the protocol involves injection of radioactive material you will not be permitted to participate. It is best to avoid radiation exposure to unborn or nursing infants since they are more sensitive to radiation than adults.

Are there benefits to taking part in this study?

Taking part in this study may or may not make your health better. While doctors hope the combination of FdCyd and THU will be useful against your cancer, there is no proof of this yet. You should discuss other treatment options with the study team and your home doctor before deciding to take part in this study. We do know that information from this study will help doctors learn more about the combination of FdCyd and THU as a treatment for cancer. This information will also help future cancer patients.

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

Talk to your doctor about your choices before you decide if you will take part in this study. Your other choices may include:

- Getting other therapies that, although might not improve survival, may have other benefits, such as delaying disease progression.
- Taking part in another study.
- Getting no treatment.
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.
Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people.

- Designated investigators from other cancer centers participating in this study, including the City of Hope National Medical Center; the City of Hope Medical Group, Pasadena; the University of Southern California/Norris Comprehensive Cancer Center; and the University of California, Davis Cancer Center.

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

What are the costs of taking part in this study?

The study agents, FdCyd and THU, will be provided free of charge while you are participating in this study. Even though it is unlikely, there is a possibility that at some point the supply of study agent may run out necessitating taking you off-study. While taking part in the study, costs of your medical care and the costs of the laboratory and radiographic studies carried out at the Clinical Center, NIH, will be at no charge to you. We cannot, however, assume the cost of your overall medical care. Any studies done outside of the NCI may require you or your insurance company to cover the costs of the service. You will not be paid for taking part in this study. For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site. Another way to get information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

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

Taking part in this study is your choice. You may choose either to take part or not to take part in this study. If you decide to participate, 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 regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution if you are eligible and choose to participate in another trial. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at: 1-800-4-CANCER (1-800-422-6237). You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

Use of Specimens and Data for Future Research

We would like 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 identified by a number and not your name. Your specimens and data will be used for research purposes only and will not benefit you. Researchers use specimens and data stored in scientific databases to advance science and learn about health and disease. 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 decide now that your specimens and data can be kept for research and shared, you can change your mind at any time. Just contact us 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.

Please read the sentence below and think about your choice. After reading the sentence, circle and initial the answer that is right for you. No matter what you decide to do, it will not affect your care.

My specimens and data may be kept and shared for use in research to learn about, prevent, or treat cancer or other health problems.

Yes No Initials_____

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should also know that there are several circumstances in which the Certificate does not provide coverage. These include when information:

- will be used for auditing or program evaluation internally by the NIH; or
- must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA).
- is necessary for your medical treatment and you have consented to this disclosure;

- is for other research.

In addition, identifiable, sensitive information protected by this Certificate cannot be admissible as evidence or used for any purpose in any action, suit, or proceeding without your consent.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

Conflict of Interest

1. The National Institutes of Health 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 additional information or a copy of the Protocol Review Guide.

2. One or more investigators participating in this study may have less than $15,000 of stock in the manufacturer of the product(s) used in this study. Under federal regulations, however, this is permissible and does not create a conflict of interest.

3. This protocol may have investigators who are not NIH employees. Non-NIH investigators are expected to adhere to the principles of the Protocol Review Guide but are not required to report their personal financial holdings to the NIH.

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, Dr. James H. Doroshow or Dr. Alice Chen, 31 Center Drive, Bldg 31 Room 3A44, Bethesda, MD, Telephone: [*redacted*]. If you have any questions about the use of your tissue for future research studies, you may also contact the Office of the Clinical Director, Telephone: 240-760-6070. You may also call the Clinical Center Patient Representative at (301) 496-2626.

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

COMPLETE APPROPRIATE ITEM(S) BELOW:	
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.	**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.)
Signature of Adult Patient/ Legal Representative _____ Date _____ Print Name _____	Signature of Parent(s)/Guardian _____ Date _____ Print Name _____
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. Signature of Parent(s)/Guardian _____ Date _____ Print Name _____	
THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM JUNE 11, 2018 THROUGH JUNE 10, 2019. Signature of Investigator _____ Date _____ Signature of Witness _____ Date _____ Print Name _____ Print Name _____	