INFORMED CONSENT FORM

Official title: A novel approach for reducing hyperoxaluria and kidney stone risk.

NCT number: NCT06481150

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Title of Study: A novel approach for reducing hyperoxaluria and kidney stone risk

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center

Key Information about this Study

You are being asked to take part in a research study because you are considered a healthy adult. We are proposing to test whether the FDA-approved drug Tenapanor (a drug that is currently approved for irritable bowel syndrome with constipation in adults and adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy) will block intestinal oxalate absorption.

The prevalence of kidney stones is increasing in the United States where over two-thirds of kidney stones are primarily composed of calcium oxalate the most common type of kidney stones. One of the main risk factors for calcium oxalate formation is elevated urine oxalate (hyperoxaluria). Many cases of hyperoxaluria are due to excess absorption of dietary oxalate associated with gastrointestinal disease and/or surgery. There are no currently available therapies and treatment options are mostly confined to management through dietary manipulations, which are not always feasible or effective.

Tenapanor (the study drug) was designed as a non-absorbable inhibitor of the intestinal sodium/proton exchanger which is responsible for sodium and water absorption. In 2019, it was approved for the treatment of constipation associated with irritable bowel syndrome (IBS-C) and marketed as Ibsrela. Pre-clinical studies also discovered Tenapanor blocks phosphate absorption by the intestine and in October 2023 it was approved for treating hyperphosphatemia in patients with chronic kidney disease (CKD), being sold as Xphozah.

Healthy adults with normal kidney function and no history of kidney stones or gastrointestinal disease will be recruited into this study. If you decide to participate in this study, you will take:

- 50 mg Tenapanor twice a day, or
- Placebo pill. A placebo is an inactive, harmless substance that looks like the other study drugs.

While you are taking part in this study, you will be asked to attend approximately three (3) visits with the researchers or study staff. It will be necessary for you to return to the clinic every 5-7 days. You will be in this study for 17 days.

This is a two-phase study, and each phase is 5 days in duration.

Phase 1: You will consume a frozen oxalate-rich metabolic diet for 5 days while taking 50 mg Tenapanor or Placebo twice a day just prior to the morning and evening meals. On days 4 and 5 you will collect two 24-hour urines for measurement of urine oxalate and stone-risk profile.

Washout: You will undergo a 7-day washout period.

Phase 2: You will consume a frozen oxalate-rich metabolic diet for 5 days while taking 50 mg Tenapanor or Placebo twice a day just prior to the morning and evening meals. On days 4 and 5 you will collect two 24-hour urines for measurement of urine oxalate and stone-risk profile.

There are no significant risks of participating in this study. The most common risk associated with use of the study drug is diarrhea. The information obtained from this study may contribute to generalizable knowledge and may help patients who have hyperoxaluria from absorbing too much dietary oxalate and who are at risk of forming kidney stones. However, there is no benefit to you for taking part in this study.

Your participation is completely voluntary. You do not have to participate if choose not to. The alternative to taking part in this study is deciding not to participate.

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Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you. Please tell the researchers or study staff if you are taking part in another research study.

Your doctor is a research investigator in this study. He is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Jonathan Whittamore, Ph.D, with The Charles and Jane Pak Center for Mineral Metabolism and Clinical Research (CMMCR) department at UT Southwestern Medical Center.

Funding
Funding for this study is received from the National Center for Advancing Translational Sciences of the National Institutes of Health under the UTSW Center for Translational Medicine's (CTSA) award. The National Institutes of Health is a federal agency that promotes scientific research. This organization is providing money to UTSW so that the researchers can conduct research studies.

Purpose – "Why is this study being done?"

This pilot and feasibility study is being done to see whether the drug Tenapanor will block intestinal oxalate absorption and thus reduce the amount of oxalate excreted in the urine of normal, healthy subjects receiving a standardized high-oxalate diet. Many cases of hyperoxaluria are due to excess absorption of dietary oxalate associated with gastrointestinal disease and/or surgery and currently there are no available therapies for reducing oxalate absorption by the intestine.
Tenapanor (XPHOZAH or IBSRELA) has been approved by the by the U.S. Food & Drug Administration (FDA) to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis and for treatment of irritable bowel syndrome with constipation (IBS-C) in adults.

Investigational Use of Drug

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This study involves the use of an investigational drug called Tenapanor. "Investigational" means that the drug has not yet been approved by the U.S. Food & Drug Administration (FDA) for treating elevated urine oxalate (hyperoxaluria).

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.

Information about Study Participants – "Who is participating in this research?"

You are being asked to take part in this study because you are a normal, healthy volunteer.

This study will enroll approximately 10 study participants from UT Southwestern Medical Center.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately three (3) visits with the researchers or study staff. It will be necessary for you to return to the clinic every 5-7 days.

Screening – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study, this is called screening. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study.

You will be told which results we will obtain for this research study and which procedures will not have to be repeated.

Screening Procedures
To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgical procedures you have had. It will take approximately 30 minutes of your time to complete the screening visit.

You may also have to fill out certain forms or have the following exams, tests or procedures all for research:
- Physical exam;
- Social and medical history;
- Vital signs;
- 24-hour urine collection;
- Blood draw; (1 mL) for a comprehensive metabolic panel and cystatin C
- Stool sample for fecal calprotectin a marker of intestinal inflammation
- Demographic information (age, gender, ethnic origin);
- Personal information (name, date of birth, address, telephone number, emergency contact)

1) The results of the physical examination done as part of your standard care may be used.
2) A Chart review of your past medical history, past family history, social history, and medications will be conducted.
3) Detailed questionnaires may be completed online or in person.
4) The urine and stool containers may be sent to you by mail.

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you.

After it is determined that you are eligible for the study, you will be randomly assigned to receive either the study drug or placebo in Phase 1.

You will have a 50 % chance of receiving the placebo. A placebo is an inactive, harmless substance that looks like the study drug.

You will not know whether you are receiving the study drug or a placebo. The researchers will know which you are taking.

Study Procedures - as a participant, you will undergo the following procedures:

Study Medication/Intervention (Research)

If you decide to participate in this study you will take:

- 50 mg Tenapanor twice a day.
- Placebo pill.

Procedures and Evaluations (Research)

This is a two-phase study, and each phase is 5 days in duration.

Phase 1: You will consume a frozen oxalate-rich metabolic diet for 5 days while taking 50 mg Tenapanor or Placebo twice a day just prior to the morning and evening meals. On days 4 and 5 you will collect two 24-hour urines for measurement of urine oxalate and stone-risk profile.

Washout: You will undergo a 7-day washout period.

Phase 2: You will consume a frozen oxalate-rich metabolic diet for 5 days while taking 50 mg Tenapanor or Placebo twice a day just prior to the morning and evening meals. On days 4 and 5 you will collect two 24-hour urines for measurement of urine oxalate and stone-risk profile.

Procedures for storing of extra or left over samples:

- Extra urine samples may be stored for reanalysis until the sample is used up.
- Extra stool sample may be stored for future analysis.

- All data and samples will be de-identified and kept secure in the Mineral Metabolism Lab.
- Study data will be kept indefinitely.

- Only Mineral Metabolism Lab personnel will have access to the samples.

How long can I expect to be in this study?

The duration of this study is 17 days. You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician.

Risks – "What are the risks of participation in the research?"

The investigators have designed this study to learn how well this new drug treatment for patients with chronic kidney disease can also reduce urine oxalate.

Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

The following section will describe the risks related to your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

The study drugs may cause some, all, or none of the side-effects listed below.

Tenapanor (Ibsrela/Xphozah)
Common:
In 100 people, approximately 43-53 may experience mild to moderate diarrhea that resolves with time.

Rare and Serious:
In 100 people, approximately 5 may experience severe diarrhea.

Confidentiality
Any time information is collected there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

Risks to Sperm, Embryo, Fetus or Breast-fed Infant

After oral administration, Tenapanor is essentially non-absorbed, therefore its use is not expected to result in any unsafe exposures.

Females: If you are part of this study while pregnant or breast-feeding an infant, it is possible that you may expose the unborn child or infant to risks. For that reason, pregnant and breast-feeding females cannot participate in the study. If you can become pregnant, a urine pregnancy test will be done and it must be negative before you participate in this study. If you take part in this study and you are sexually active, you and any person that you have sex with must use medically acceptable birth control (contraceptives) during the study. Medically acceptable birth control (contraceptives) includes:

(1) surgical sterilization (such as hysterectomy or "tubes tied"),
(2) approved hormonal contraceptives (such as birth control pills, patch or ring; Depo-Provera, Implanon),
(3) barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm),
(4) an intrauterine device (IUD).

If you think you might have become pregnant while you are in this study, you must tell one of the study doctors right away so that management of the pregnancy and the possibility of stopping the study can be discussed.

If you are a woman who is pregnant or could be pregnant, you cannot take part in this study because we do not know how the procedures might affect a developing fetus. We will do a pregnancy test before you start the study to make sure you are not pregnant.

There are no known risks to men with use of the study drug and pregnant partners of male participants may not have any known side effects with the study drug.

Other Risks

You may experience psychological distress and minor discomfort due to the urine and stool collection.

There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?

Being in more than one research study at the same time may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

How will risks be minimized or prevented?

We will ask for your consent prior to your participation in the study. All efforts will be utilized to ensure subject privacy and all data will be held confidentially. Your study participation will be monitored for any unexpected side effects and the investigators will be alerted immediately in the case of any patient concerns. Participation in the study will be terminated if you request to withdraw.

What will my responsibilities be during the study?

While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Store study materials in a secure place at home away from anyone who is unable to read and understand labels, especially children.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem or something purchased over the counter.
- Tell your regular doctor about your participation in this study.
- Report to the researchers any injury or illnesses while you are on study even if you do not think it is related.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?
If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the last page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking, including any medications you are taking for this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study is that it may contribute to generalizable knowledge to help other patients in the future.

There is no guarantee or promise that you will receive any benefit from this study.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

The alternative to taking part in this study is to decide not to participate.

Payments – Will there be any payments for participation?

You will be paid $250 after the end of the study using the UT Southwestern Greenphire ClinCard if you complete all the study visits. But if you stop taking part in this study or are withdrawn by the research team, you will receive payment for only the visits you have completed. The payments in the study for the visits are, you will be paid $50 for screening, $100 for completing phase 1 of the study, and $100 for completing phase 2.

If you live more than 25 miles away, you may be reimbursed for travel expenses at the current reimbursement rate of 62.5 cents per mile up to $15.00 per visit.

There are no funds available to pay for parking expenses, lost time away from work and other activities, lost wages, or childcare expenses.

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of the study visit. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. Your social security number is needed to process your payments. Study payments are considered taxable income and are reportable to the IRS. Should you decide not to provide your social security number, or your social security number does not match the name on file with the IRS, your study participation payment will be decreased in accordance with the current IRS tax rate. All information will be stored in a secure fashion.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year unless it's a reimbursement.

Costs – Will taking part in this study cost anything?

There are no costs to you or your insurance company for participating in this research study.

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as a physical exam for your standard care. It is important to understand that some insurance companies do not cover some costs (for example, approved drugs used in a way different from the package instructions). If your insurance company does not cover these treatments or procedures, you will be required to pay for them.

Confidentiality – How will your records be kept confidential?

The information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Certificate of Confidentiality:
To help us further protect your information, the investigators will obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

How will my information and/or tissue samples be used?
With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

By agreeing to participate in this study, your information or samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. The information

that identifies you will first be removed from your information or tissue samples. If you do not want your information or tissue samples to be used for future research studies without your consent, you should not participate in this study.

Research policies require that private information about you be protected, and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:
Your medical history, information you give us during your participation in the study such as during interviews or from questionnaires, results of tests; demographic information.

We will get this information by completing chart reviews, speaking to your doctor, and lab and urine analysis we obtain as part of your participation in the study. We might ask you to complete an 'Authorization to Disclose Protected Health Information' form to obtain medical records from facilities outside of UT Southwestern as part of your enrollment in this study.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- CTSA Program at UT Southwestern.
- The National Institute of Health, a federal agency that is funding this study.
- The Center for Mineral Metabolism and Clinical Research (CMMCR). This includes any people, entities, groups or companies working for or with CMMCR or owned by CMMCR. The PI and CO-Investigators will receive written reports about your participation in the research and may look at your health information to assure the quality of the information used in the research.
- The members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the UT Southwestern Medical Center.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of CMMCR for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. Jonathan Whittamore
Charles and Jane Pak Center for Mineral Metabolism and Clinical Research
5939 Harry Hines Blvd.,
Dallas, Texas 75390

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information– Who can you contact if you have questions, concerns, comments or complaints?
If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact the PI listed below:

Primary contact (PI):
Jonathan Whittamore, Ph.D at 214-648-9792

If primary is not available, contact the Co-I:
Naim Maalouf, MD at 214-648-2954

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

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Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:
By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM