PRINCIPAL INVESTIGATOR: David S. Schrump, MD, MBA

STUDY TITLE: Adjuvant Tumor Lysate Vaccine and Iscomatrix™ with or without Metronomic Oral Cyclophosphamide and Celecoxib in Patients with Malignancies Involving Lungs, Esophagus, Pleura, or Mediastinum

STUDY SITE: NIH Clinical Center

Cohort: Affected Patients

Consent Version: 03/03/2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

David S. Schrump, MD, MBA, by phone at 240-760-6239 or email at schrumpd@mail.nih.gov

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

Research in our lab has shown that certain types of lung, esophageal, or thymic cancers, sarcomas and malignant pleural mesothelioma (MPM) have specific antigens (protein molecules) on their surfaces. We want to see if giving a vaccine that contains antigens similar to these may cause an immune reaction that could prevent the tumors from coming back in patients with these tumors as well as in patients with tumors that have arisen elsewhere in the body but have spread to the chest

that have already had their tumor removed or treated with standard therapy so that there is no or very little disease left. Studies that we have done in the lab have shown that causing an immune response to tumor cells may be a way to keep tumors from growing. At this time there is no way to measure whether or not the vaccine will prevent your cancer from growing. We can measure your immune response to the vaccine and that is what we will use to see if you are responding to the vaccine; but we do not know if this will prevent your tumor from growing.

This vaccine is made from the H1299 cancer cell line, a cluster of lung cancer cells that have been grown and divided many times in the laboratory, and ISCOMATRIX, which is used to help boost your immune system's response to the antigen from the cell line. No vaccines containing ISCOMATRIX have been approved by the United States Food and Drug Administration; however, it has been used in vaccines for nearly 2000 patients and healthy volunteers in clinical trials with only 1 serious side effect, a cardiac arrest, which may have been related to the use of the adjuvant. The H1299 cell line has not been used in humans or in animals; however other cell lines used as vaccines have been well tolerated with no serious side effects.

About half of the subjects participating in the study will also receive 2 medications, cyclophosphamide and celecoxib, with the vaccine. As part of the study, we will test whether the addition of these medications allow the vaccine to work better. Cyclophosphamide is a common chemotherapy drug that prevents the bone marrow from producing white blood cell. When cyclophosphamide is given in very low doses (as in this protocol) it seems to decrease the number of a specific type of white blood cell which may allow the vaccine to work better. Research has shown that celecoxib may also have an effect on the immune system and may allow for a better immune reaction, particularly in patients with lung cancer.

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS STUDY?

You have lung, esophageal or thymic cancer, chest sarcoma, malignant pleural mesothelioma (MPM) or a tumor that has spread to your chest cavity that has been removed and/or treated with standard therapy. Although you have no or very little evidence of remaining disease, there is still a chance that your cancer could come back. We would like to see if giving you this vaccine will cause an immune reaction and whether the addition of chemotherapy improves the immune reaction. We can measure this using blood tests.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 60 patients will be enrolled in this study.

DESCRIPTION OF RESEARCH STUDY

Before you begin the study

Before you can enroll on the study, we will review your medical records and imaging studies to determine if you are eligible for this study. We will ask you questions over the telephone, other NIH approved remote platforms or in person about your medical history. You will need to have certain studies done in order to determine whether you meet the criteria to participate in this study. Any tests or procedures done specifically to evaluate if you are eligible for this study will be explained to you by your doctor under a separate protocol (06C0014, "Prospective Evaluation of Genetic and Epigenetic Alterations in Patients with Thoracic Malignancies").

In order to complete these tests and procedures, you will also be asked to co-enroll on our 06C0014 screening and tissue collection protocol.

A pregnancy test will be performed if you are a female who is capable of having children.

You will not be allowed to participate if we find that you are not eligible.

During the study

Patients on this study will be selected by a computer to participate in one of two treatment arms on a 1:1 basis. This means that there is a 50% chance that you will be assigned to one arm or the other.

Patients on the vaccine plus chemotherapy treatment arm will receive the H1299 vaccine as well as cyclophosphamide and celecoxib. Patients on the vaccine alone treatment arm will receive H1299 vaccine without additional chemotherapy. In both arms, study treatment will be divided into cycles, each lasting 28 days (4 weeks). The vaccine will be given on Day 1 (+/- 5 days) of a cycle.

Vaccine and chemotherapy arm only

If you are assigned to the vaccine plus chemotherapy arm, seven days before your first vaccine, you will be given celecoxib and cyclophosphamide to take twice a day at home for seven days. After you have received your vaccine, you will be given a medication schedule and a supply of cyclophosphamide and celecoxib to take at home. You will take celecoxib every day and the cyclophosphamide every day during Week 2 (Days 8-14) and Week 4 (Days 22-28). You will need to bring any unused pills with you at each visit.

Every 6 months during study treatment, we will also ask you to complete a fecal (stool) test to check for signs of small and/or hidden internal bleeding for your safety.

Both study arms

Patients on both arms will come to the clinic to receive the experimental vaccine. It will be given in your thigh (or your arm if necessary) and will be given in 2 shots. You will need to stay in the clinic for about 4 hours after the first vaccine and for about 1 hour after the second and third vaccine. Before you go home, the nurse will give you a diary to keep track of any side effects that you may have from the study medications. You will need to bring the diary with you to each visit. For the first 3 months of treatment, you will need to have additional blood tests (~ 2 tablespoons) done between clinic visits; every week for the first month and every 2 weeks for the next 2 months. These may be done through your home oncologist with results faxed to Thoracic Oncology Service. You may need more tests if your doctor feels it is in your best interest.

One month after the 6th vaccine we will run blood tests for our research to find out if your body is responding to the vaccine (refer to the section titled "Tests conducted for research" below). Results from these tests are available within 8-12 weeks. You will not take any study medication while waiting for the results. If the blood tests show that your body is responding to the vaccine, we will let you know, and you resume your study therapy and will return to the clinic every 3 months (Cycles 9 and 12) for 2 additional vaccines. You will have a physical exam and lab tests (~2.5 tablespoons) before each vaccination. If we find that your body is not responding to the vaccine, we will take you off the study and refer you back to the care of your local physician.

Tests conducted for research

In addition to the tests that we will conduct to determine whether you are having side effects or if you are responding to the study therapy, we will also collect samples from you for purposes of research only. These studies include:

- Before you have received any study medications, we will collect blood (~2 tablespoons) in order to develop cell lines.
- Before you have received any study medication and at the end of Cycle 3 and Cycle 7, we will collect blood (~3.5 tablespoons) from you so that we can study the different types of immune cells present in your blood.
- We will also collect blood to store for future use.
- Up to one month before you have had your first vaccine and, if you have shown a response to study therapy, within 12 weeks after Cycle 6 and Cycle 12, we will ask you to undergo leukapheresis.
    - Leukapheresis is a procedure that allows us to remove certain types of blood cells from you and return the rest of your blood. It is a very common procedure that is done routinely here with very few risks. During leukapheresis, blood is removed from you through a needle in your arm, circulated through a machine that divides whole blood into red cells, plasma (the serum part), and lymphocytes (or white cells), and then the plasma and red cells are returned to you through a second needle in your other arm. The white blood cells will be saved so we can do tests to see how your body reacts to the vaccines.

When you are finished taking the treatment

If your body is responding to the vaccinations, after you have completed the experimental vaccine treatments you will return to clinic for a physical examination and lab tests every 3 months for one year and then every 6 months for up to 4 years or until such time as your body stops responding to the vaccinations. If you are unable to come to the Clinical Center for these visits, we will contact you by phone, secure videocall, or other NIH approved remote platforms.

BIRTH CONTROL

If you are a woman who is breast feeding or pregnant, you may not take part in the study because we don't know how this medicine would affect your baby or your unborn child. 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, during study treatment, and for four 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.

Effective forms of birth control include:

- abstinence
- intrauterine device (IUD)
- hormonal [birth control pills, injections, or implants]
- tubal ligation
- vasectomy

RISKS OR DISCOMFORTS OF PARTICIPATION

What side effects or risks can I expect from being in this 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.
- You may be asked sensitive or private questions which you normally do not discuss.

The vaccine and chemotherapy 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).

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.

Below we 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.

Vaccine plus chemotherapy arm only

Possible Side Effects of Cyclophosphamide

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cyclophosphamide, more than 20 and up to 100 may have:
• Hair loss • Nausea, vomiting, loss of appetite • Sores in mouth • Infection, especially when white blood cell count is low • Absence of menstrual period which may decrease the ability to have children • Blood in urine

COMMON, SOME MAY BE SERIOUS
In 100 people receiving Cyclophosphamide, more than 20 and up to 100 may have:
OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving Cyclophosphamide, from 4 to 20 may have:
• Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions • Loss or absence of sperm which may lead to an inability to father children • Stuffy nose • Fluid around the heart
RARE, AND SERIOUS
In 100 people receiving Cyclophosphamide, 3 or fewer may have:
• Severe skin rash with blisters and peeling which can involve mouth and other parts of the body • Damage to the heart or heart failure which may cause shortness of breath, swelling of ankles, cough or tiredness • A new cancer including cancer of bone marrow (leukemia) caused by chemotherapy • Swelling of the body including the brain which may cause dizziness, confusion • Scarring of the lungs

Possible Side Effects of Celecoxib (Celebrex)

COMMON, SOME MAY BE SERIOUS
In 100 people receiving Celecoxib (Celebrex), more than 20 and up to 100 may have:
• None

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving Celecoxib (Celebrex), from 4 to 20 may have:
• Abnormal heartbeat which may cause fainting • Blockage of the airway which may cause shortness of breath, cough, wheezing • Diarrhea, nausea • Headache • High blood pressure which may cause dizziness, blurred vision • Kidney damage which may cause swelling, may require dialysis • Sores in stomach which may cause belly pain • Stroke which may cause paralysis, weakness • Swelling of the stomach

RARE, AND SERIOUS In 100 people receiving Celecoxib (Celebrex), 3 or fewer may have:
• Heart attack which may cause chest pain • A tear or a hole in the stomach which may cause belly pain or that may require surgery • Internal bleeding which may cause belly pain, black tarry stool, or blood in vomit • Blood clot • Hepatitis which may cause yellow eyes and skin, tiredness • Liver damage which may cause yellowing of eyes and skin, or swelling • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Severe skin rash with blisters and can involve inside of mouth and other parts of the body • Swelling and redness of the skin • Enlarged heart

Both study arms

Possible Side Effects H1299 Vaccine

Likely:

The most common side effects seen from this type of vaccine include

- Redness, swelling, pain, bruising, and bumps where you have received the injections
- Swollen glands near the injection site
- Fever, chills, rash, headache and tiredness

Rare but Serious:

Rarely, patients can have a more severe allergic reaction to the vaccine.

Cardiac arrest occurred in 1 patient using ISCOMATRIX based vaccine.

Although it is extremely unlikely, this experimental treatment could cause your cancer to get worse or your death.

Research Procedure Risks

Blood Draw

Risks of blood sampling include pain and bleeding at the site where the blood is collected, lightheadedness, and rarely, fainting. When large amounts of blood are collected, low red blood cell count (anemia) can develop. Rarely, there is also a risk of infection at the needle site.

Urine Collection

There are no physical risks or discomforts associated with urine collection.

Fecal Occult Blood Test

There is no physical risk or discomforts associated with fecal collection for this test.

Electrocardiogram (EKG)

This procedure is associated with minimal discomfort.

Leukapheresis

The risks of leukapheresis include pain, bruising, lightheadedness or dizziness, nausea, vomiting and chills. Bruising may last up to 72 hours.

Tingling around the mouth, fingers, or toes and mild muscle cramps may develop from slight lowering of the blood calcium by the blood thinner used during the procedure. These symptoms can be treated by either temporarily stopping the procedure or by giving a calcium pill. Leukapheresis uses a completely closed sterile system. The risk of infection is minimized by cleaning the skin before the needle stick. No infections from leukapheresis have been noted in thousands of such procedures performed over the last 10 years at the NIH.

Rarely, there can be a malfunction of the apheresis machinery that might prevent the return of your blood being processed in the machine. The amount of blood lost would be very small and not harmful. It is also rare for people to faint, have seizures, or have air trapped in the bloodstream.

Temporary or permanent nerve damage may occur at the needle placement sites. This is very rare. At the NIH, to this point, there have been no cases of permanent nerve damage with leukapheresis.

During the leukapheresis procedure, your platelet count may decrease because platelets are collected with the white blood cells. Platelets are cells that help your blood to clot. Taking aspirin in combination with a lowered platelet count may increase your chance of developing bleeding. Therefore, you should not take aspirin or aspirin-containing drugs for 2 weeks after the procedure without physician approval.

POTENTIAL BENEFITS OF PARTICIPATION

Are there benefits to taking part in this study?

The aim of this study is to see if this experimental treatment will cause an immune reaction and possible to decrease the chance of your cancer coming back. We do not know if you will receive personal, medical benefit from taking part in this study. Because there is not much information about the experimental treatment's effect on your cancer, we do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have cancer.

ALTERNATIVE APPROACHES OR TREATMENTS

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

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

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly. Instead, it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to your doctor about these and other options.

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 your immune system does not respond to the 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
- if he/she decides to close the study

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. 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 can**not** be recalled and destroyed.

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.

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

The National Institutes of Health and the research team for this study have developed a process to make your vaccine being used in this study. This study also uses ISCOMATRIX™ adjuvant developed by CSL Limited through a joint study with your researchers and the company. The company also provides financial support for this study.

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 the specimens and data that we collect and use them for future research. 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 remain 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.

PAYMENT

Will you receive any type of payment for taking part in this study?

You will not receive any payment for taking part in this study.

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

On this study, the NCI will reimburse the cost for some of your expenses such as those for hotel, travel, meals. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. The amount and form of these payments are determined by the NCI Travel and Lodging Reimbursement Policy. You will be given a summary of the policy which provides more information.

If your travel to the NIH Clinical Center (e.g. flight, hotel) is arranged and paid for by the NIH, the agency making the reservations and their representatives will have access to your identifiable information.

COSTS

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

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

- If some tests and procedures are performed outside the NIH Clinical Center, 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 NIH Clinical Center.
- Once you have completed taking part in the study, medical care will no longer be provided by the NIH Clinical Center.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your 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. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor, Center for Cancer Research, or their agent(s)
- Qualified representatives from CSL Behring, the pharmaceutical company which manufactures ISCOMATRIX adjuvant.

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those

disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH 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 NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

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. David S. Schrump, MD, MBA, schrumpd@mail.nih.gov, 240-760-6239. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

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

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.