PRINCIPAL INVESTIGATOR: Deborah Citrin, M.D.

STUDY TITLE: A Phase I Trial of Highly Conformal, Hypofractionated, Focally Dose Escalated Post-Prostatectomy Radiotherapy

STUDY SITE: NIH Clinical Center

Cohort: Affected patient

Consent Version: 05/08/2023

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal investigator:

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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.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. 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). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

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?

Prostatic Specific Antigen (PSA) is usually measured after surgical removal of the prostate to determine if the tumor is returning. In cases when PSA is rising and there is no evidence of spread of prostate cancer to areas outside of the pelvis, the standard treatment is radiation to the area where the prostate was located before surgery, which is also known as the prostate bed. Radiation is a commonly used treatment for prostate cancer that has returned after prostatectomy. Radiation kills prostate cancer cells and can be very effective. This treatment is most commonly given as a short daily treatment, five days per week, for 6-7 weeks. This treatment can offer the chance of

cure and can provide PSA control in most of the patients who receive the treatment, but may have side effects.

In this study, we are trying to understand if a shortened, or compressed, radiation treatment schedule can be as effective as standard treatments with similar or reduced side effects. We plan to deliver the radiation dose in progressively shorter total treatment times, with the goal of reducing the length of treatment from the currently used 6-7 weeks to 2, 3, or 4 weeks. Because the radiation treatment is given over a shorter total time, it is delivered in higher than standard dose fractions.

The goal of this study is to find the most compressed radiation schedule that people can tolerate without strong side effects.

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

You are being asked to participate in this study because you have had a prostatectomy and have reasons that radiation is being recommended, such as a detectable PSA or worrisome findings on pathologic review of the tumor that was removed at the time of surgery.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

A maximum of 48 patients who need to receive radiation after prostatectomy for prostate cancer will be included in this study.

DESCRIPTION OF RESEARCH STUDY

Before the study

Before you begin this study, you will need to have exams and tests to make sure you are eligible for this study. The exams and tests are usually part of regular cancer care. These tests will be done under a separate consent. We will collect the records about your medical history, diagnosis, and this screening testing for the study.

During the study

Before the start of radiation treatment we will perform:

- Physical examination, including vital signs, review of your symptoms and your ability to perform your normal activities.
- Routine blood tests to find out if you are anemic, have low blood counts, the status of your immune system and if your liver, kidneys, and other organs are working well. Up to 1 tablespoon of blood may be collected.
- Blood tests to evaluate PSA and testosterone levels. Up to half a tablespoon of blood may be collected.

Radiation treatment

Radiation will be administered in daily fractions Monday through Friday except in the case of machine malfunction or federal holiday.

Depending on when you enter the study, treatment may last 2, 3 or 4 weeks.

Research tests

We are planning to collect blood and urine samples from you for purposes of research only. These samples will be used to study your response to treatment, including evaluation of cancer cell death and damage to normal cells:

- Blood and urine samples will be drawn before you start the treatment, within 24 hours after the last dose of irradiation, at 1, 3, 6, 9, 12, 15, 18, 21, 24 months after completion of treatment. Up to 3 and a half tablespoon of blood may be collected at each visit.
- If available, we will ask you to provide tissue sample from prostatectomy or biopsy for research purposes.
- You also will be asked to complete questionnaires to determine you general well-being and function - before you start the treatment and every 6 months after completion of treatment for 2 years. It will take you about 20 minutes and will only be done if you can complete the surveys in English.
- You will be asked to have a magnetic resonance imaging (MRI) that uses a magnetic field to produce an image of your prostate bed 6 month after completion of your treatment.
- Genetic testing – Your tissue samples contain genes, which are made up of DNA (**d**eoxyribo**n**ucleic **a**cid) which serves as the "instruction book" for the cells that make up our bodies. We will use the tissue samples and blood you provided to learn about how the genes in your tumor compare to genes in normal tissue. Your tissue will help us study how genes might play a role in prostate cancer and other diseases. We will not share the results of these research tests with you.

When we are conducting the above genetic tests, it is possible that we could identify changes in other parts of your DNA that are not related to this research. These are known as “incidental medical findings”.

However, the analyses that we perform in our laboratory are for research purposes only; they are not nearly as sensitive as the tests that are performed in a laboratory that is certified to perform genetic testing. Changes that we observe unrelated to our research may or may not be valid. Therefore, we do not plan to inform you of the results of testing on your tissue and blood that is performed in our research lab. There may be exceptions to what we share with you and this is described later in this consent form in the section for “Return of research results.”

WHEN YOU ARE FINISHED WITH RADIATION TREATMENT

About 4 – 5 weeks after you have finished radiation treatment, you will be asked to return for a safety follow up visit. At this visit, we will ask questions about your health, perform a physical exam and collect blood for research.

After the safety visit, we will ask you to come for follow up visits on months 3, 6, 9, 12, 15, 18, 21 and 24. At these visits, your will be asked questions about your health and any other medications you may have taken. During some of these visits you will have PSA, testosterone level tests, immune system testing (white blood cells), blood and urine collected for research purposes, one MRI (6 months after treatment) and we will ask you to complete questionnaires assessing your well-being.

If you are unable to return for these visits, we will obtain the information from you by telephone, email, video call or refer you to your local provider.

STANDARD OF CARE TREATMENT

Treatments covered under this study may include a single medication or a combination of medications, surgery or radiation to treat your cancer. These treatments will not be experimental. Your doctors will describe your treatment plan to you in detail before asking you to sign this consent form. You may be asked to sign a separate consent form for any treatment procedures not outlined in this consent.

BIRTH CONTROL

If you 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 4 months after you finish radiation treatments. If you think that your partner is pregnant, you should tell your study doctor or nurse at once. Your partner may be asked to enroll on a separate research study so that she can be followed for the duration of the pregnancy to better understand the potential effects of the treatment on pregnancy outcomes.

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 radiation used in this study may affect how different parts of your body work.

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.

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 any symptoms.
- 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.

Risks from radiation

Overall radiation risk

During a year in this research study, if your tumor is visible in imaging assessments, you may be exposed to up to approximately 60.4 Gy of radiation in 20 treatment sessions, or up to 54.6 Gy in 15 sessions or up to 47.1 Gy in 10 sessions. If your tumor is not visible in imaging assessments, you may be exposed to up to 56.4 Gy in 20 treatment sessions, or 51.2 Gy in 15 sessions, or 44.2 Gy in 10 sessions. This radiation has been reviewed by the NIH Radiation Safety Committee and deemed appropriate for this study.

Radiation treatment risk

It is impossible to predict exactly what side effects and individual may have during or after a radiation treatment, but, in general, radiation side effects are usually limited to the part of the body being treated. Radiation can have side effects that occur during or shortly after the treatment, and a separate set of side effects that can happen month to years later. The side effects listed below are seen after radiation to the same area of the body with more prolonged treatments. It is not known if the risks of these side effects will be similar for this compressed treatment. During or shortly after the treatment:

- Common: mild fatigue, burning with urination, more frequent urination (including urinating at night), more frequent bowel movements, more urgent bowel movements, hemorrhoid irritation, mild irritation or dryness of skin in the area being treated, thinning of hair in the area being treated.
- Uncommon: decreased blood count that could lead to infection or bleeding, mild aching in the area treated.

Months to years after the treatment:

- Common: increased frequency or urgency of urination, increased feelings of gassiness, decreased ability to have or maintain an erection, more frequent or urgent bowel movements.
- Uncommon: bleeding from the bladder, bleeding from the rectum, decreased urinary control (increase in leakage).
- Rare: Severe damage to bladder or bowel that could require a surgery to correct.
- Extremely rare: cancer caused by radiation.

Risks from MRI

The main discomfort of an MRI is lying still on the scanning table for up to 60 minutes. Some people are bothered by the repetitive thumping noise of the MRI machine (ear plugs will be provided). Some people feel claustrophobic inside the narrow scanning machine. Cool circulating air and soft lighting helps to ease these feelings. If you are very claustrophobic, you may ask your physician for a mild sedative for the procedure, but you must not drive a vehicle until the sedative wears off. MRI scans cannot be done on people who have metal implants, including cardiac pacemaker, neural pacemaker, surgical clips in the brain or blood vessels, or other implanted metal objects.

Risks from MRI Gadolinium

The risks of an IV catheter include bleeding, infection, or inflammation of the skin and vein with pain and swelling.

Mild symptoms from gadolinium infusion occur in fewer than 1% of those who receive it and usually go away quickly. Mild symptoms may include coldness in the arm during the injection, a metallic taste, headache, and nausea. In an extremely small number, fewer than one in 300,000 people, more severe symptoms have been reported including shortness of breath, wheezing, hives, and lowering of blood pressure. You should not receive gadolinium if you previously had an allergic reaction to it. You will be asked about such allergic reactions before gadolinium is given.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis (NSF)". This condition always involves the skin and can also involve the muscles, joints and internal organs. NSF has resulted in a very small number of deaths. A blood test of your kidney function may be done within the month before an MRI scan with gadolinium contrast. You will not receive gadolinium for a research MRI scan if your kidney function is below the safe level.

Most of the gadolinium contrast leaves the body in the urine. However, the FDA has issued a safety alert that indicates small amounts of gadolinium may remain in the body for months to years. The long-term effects of the retained gadolinium are not unknown. Some types of gadolinium contrast drugs are less likely to remain in the body than others. In this study, we will use the gadolinium contrast drugs that are less likely to remain in the body. We will also give you additional information called a "Medication Guide." Upon request, we will give you individual information about retained gadolinium we see on your studies.

Risks from blood draws

- pain at the needle site
- bruising
- possible dizziness if you stand up quickly
- possible inflammation of the vein or infection at the needle site.

POTENTIAL BENEFITS OF PARTICIPATION

Are there benefits to taking part in this study?

The aim of this study is to determine how rapidly radiation can be safely delivered after a prostatectomy. We do not know if you will receive personal, medical benefit from taking part in this study. Potential benefits could include long term suppression of your PSA level and potentially curative treatment of the remaining prostate cancer. Radiation is a potentially curative treatment when used in your situation.

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, including receiving standard radiation over 6-7 weeks
- Taking part in another study

Please talk to your doctor about these and other options.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

In this study, we will use a test that looks at all or most of your genes or DNA. This test may find gene changes that are not related to what is being studied in this research. These are called "secondary findings". Most of the time when we look for these, we do not find anything. If we were to look for them in 100 people, we would expect them in only about 2 to 4 of those people.

If we discover a secondary finding that might be important to you or your family's health, we plan to tell you about this. However, before we can tell you, we may need to do the test again in another laboratory to be sure that the result is correct. To do so, we may need to ask you to submit another sample for testing. Once these results are available, we will invite you to schedule a visit, in person (at our expense) or remote so that you we can give you more information about this result and to help you seek follow-up care outside of the NIH if it is needed. If you are unable to see us, we will provide a referral to a local genetic healthcare provider. The NIH will not generally provide any further follow-up testing or care for this condition for you or your family.

We will not be testing the samples we have collected from you for several years. Because of this, just because you have not heard from us, you should not assume that you do not have any gene changes that might be important for your health.

We also do not know all the gene changes that cause can cause health problems. We could learn later that some gene changes that now we do not think cause health problems are of concern. We

will look for gene changes only once and will look for those that are known to cause problems at the time we are looking. We do not plan to look again at a later time for new secondary findings.

It is up to you if you want us to tell you about any secondary findings. At any point you can tell us that you do not want to us to contact you or tell you about any secondary findings.

We can only provide these results to you. If you want us to tell anyone else, then you must provide us with a signed written release of medical information request.

It is very important for you to keep us updated on how to contact you. If we do not have up to date information, we will not be able to get in touch with you to collect an additional sample or tell you about a secondary finding. If your contact information changes, providing us with the new information is your responsibility. To tell us of your new contact information, by reaching out to your study doctor and/or study Principal Investigator.

If you have questions or concerns about learning this kind of genetic information, please speak with someone from the study team

Risks of returning secondary genetic findings

- The evaluation for unexpected gene changes is limited and may not be as complete as clinical genetic testing that might be available to you outside of the research study.
- If an unexpected gene change result is confirmed, then that test result will go into your NIH medical record. These documents are confidential, but other NIH investigators can see them.
- Learning about the changes in your genes could mean something about your family members and might cause you or your family distress. Before joining the study, it may be helpful to talk with your family members about whether they want you to share your results with them.
- If a gene change is found, it may reveal whether a particular parent passed on the change to a biological child.
- You may receive a result for an unexpected gene change that turns out not to cause that health condition. This may cause you unnecessary distress or lead to unnecessary medical testing risks and costs.

Benefits of returning secondary genetic findings

An unexpected gene change result may be useful because you may be able to do something about it to protect your health or to help you plan for your future.

Protections against misuse of genetic information

This study involves genetic testing on samples. Some genetic information can help predict future health problems of you and your family and this information might be of interest to your employers or insurers. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care

insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component.

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 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 the investigator decides to end 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. However, according to FDA guidelines, information collected on you up to that point may still be provided to 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 can**not** be recalled and destroyed.

CONFLICT OF INTEREST (COI)

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI 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.

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.

These specimens and data will be used for future research and shared with other researchers. We will not contact you to ask about each of these future uses. These specimens and data will be stripped of identifiers such as name, address or account number, so that they may be used for future research on any topic and shared broadly for research purposes. Your specimens and data will be used for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used. Results of research done on your specimens and data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

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

Genomic Data Sharing

As part of this research study, we will put your genomic data in a large database for broad sharing with the research community. These databases are commonly called data repositories. The information in this database will include but is not limited to genetic information, race and ethnicity, and sex. If your individual data are placed in one of these repositories, they will be labeled with a code and not with your name or other information that could be used to easily identify you, and only qualified researchers will be able to access them. These researchers must receive prior approval from individuals or committees with authority to determine whether these researchers can access the data.

Summary information about all of the participants included in this study (including you) is being placed in a database and will be available through open access. That means that researchers and non-researchers will be able to access summary information about all the participants included in the study, or summary information combined from multiple studies, without applying for permission. The risk of anyone identifying you with this information is very low.

NIH policies require that genomic data be placed in a repository for sharing. Therefore, we cannot offer you a choice of whether your data will be shared. If you do not wish to have your data placed in a repository, you should not enroll in this study.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

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

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

On this study, the NCI will cover the cost for some of your expenses. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. Someone will work with you to provide more information.

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 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

Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you.

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)

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, Deborah Citrin, Citrind@mail.nih.gov, 301-496-5457. 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

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

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: _____.