PRINCIPAL INVESTIGATOR: Sarthak Gupta, MD

STUDY TITLE: Study of the Natural History, Pathogenesis and Outcome of Melorheostosis – A Rare Osteosclerotic Disease

STUDY SITE: Clinical Center

Cohort: Standard Consent

Consent Version: 08/05/2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

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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?

You have been referred to the NIH for evaluation of possible melorheostosis. Melorheostosis is a rare disease that causes bone thickening which may lead to pain, deformities, nerve impingement (compression of nerves by bone) and contractures (limitations in joint movement). In some patients, melorheostosis is caused by a change in the genes in the bone, but not in the genes of the entire body. We would like to offer our knowledge and expand our experience in the care of the disease. We want to understand more about how your disease progresses because very little is known. Therefore, we invite you to participate in this study, which consists of applying current standards of medical care to the diagnosis and treatment of melorheostosis. The goal of the study is to see what happens to patients with melorheostosis over time and understand the cause(s) of the disease. This is done by following patients over a number of years, paying careful attention to certain parts of the bone which are affected by melorheostosis. We hope this study will give us the information needed to help doctors predict which parts of the bone with melorheostosis will remain unchanged, which ones will get worse, which ones will need to be treated and which ones can just

be watched. After the first visit in this study, you will be invited to stay on this study and may return for check-ups. You do not have to do any of these things if you do not want to.

This study does not use medications that are experimental. We may talk to you about starting new medications that could help you. An example of this would be medications for pain like anti-inflammatory or medications known to work for neuropathic pain. These medications and treatments are not for research but are for your clinical care. We will fully explain these to you so you can decide if you want to begin the new treatments at NIH or wait until you talk to your local health care provider. Any medications and treatments started at the NIH will need to be prescribed by your local health care provider for your long term care.

WHAT IS INVOLVED IN THE STUDY?

An individual examined and treated under this study will be cared for on an inpatient or an outpatient basis usually for approximately one week. We will employ only accepted standard of care medical testing and procedures in your diagnosis and treatment.

As part of the diagnostic work-up, you will undergo a medical history, physical examination, blood drawing and urine collections. Imaging studies like X-ray, CT scan, MRI scans and bone scans may be obtained if clinically indicated. Other specialized diagnostic tests which are part of good and accepted medical practice may also be recommended and these will be explained to you on an individual basis.

Blood and Urine Tests

Blood will be drawn from a vein in your arm with a small needle. The amount of blood taken will be about two tablespoons, and will not be more than the limit set by the NIH.

You will be asked to give a sample of urine.

Photography

Following your disease through pictures helps us learn what happens over time. For this reason we may take pictures. You may be asked to remove your clothes except your underwear during these pictures. You will be asked to sign a standard NIH photography consent form if you agree to allow us to take these pictures. These photographs may be published in medical journals without identifying you as the subject. We will make every attempt to preserve your anonymity by not including or blocking out your face or eyes while still providing the visual information needed to support the research being published. You may decline to be photographed or place restrictions on the use of photographs. We encourage you to talk to us about any concerns you have related to photography.

Skin Biopsy (taking a piece of skin)

We may ask you to have two skin biopsies performed. There will be a separate permission form. One biopsy will be for skin lesions potentially related to melorheostosis, and a second skin biopsy of an area of unaffected skin likely from the opposite forearm. You will need to undergo both biopsies for the procedure, so that the normal skin can be compared to the abnormal skin under a

microscope, and so that cells from normal and abnormal areas can be grown in the lab and compared. Samples will be compared to each other and sent for pathology, genetic testing and cell culture. Skin biopsy will not be offered if you decline genetic testing.

Here is a brief description of the skin biopsy procedure. An area of affected skin on top of the bone with melorheostosis, or based on the location of suspicious lesions found on your physical exam by the dermatologist will be selected. The area will be thoroughly cleansed with alcohol. A small quantity of anesthetic (numbing medicine) will be injected into the skin to be sampled at the site of the lesion. For a punch biopsy, a small circle of skin (about half as big around as a pencil eraser) will be removed on each side with a surgical instrument designed for this purpose. For a shave biopsy, a scalpel is used to shave off the top of a lesion. The procedure will be repeated on an area of normal skin on the opposite arm. If your affected skin is in the hand, the normal skin will be taken from the forearm, not the opposite hand. The procedure takes approximately ten minutes in total. Discomfort at the biopsy site is usually mild and short-lived. This can be treated with routine medications such as Tylenol. Normally, the risks include a reaction to the local anesthetic and a low likelihood of local bleeding or bacterial infection. A small scar may be visible at the sites of the biopsy.

Consultations

If during your evaluation we uncover something new about your disease that we do not know much about or if we want another person's recommendations about that aspect of the disease, we may ask another health care expert at NIH to look at you and/or your test results. This is called a consultation.

Questionnaire(s)

We may ask you to fill out questionnaires to assess "quality of life", pain or function. These questionnaires attempt to assess how you are dealing with the disease.

Genetic Testing

Every cell in your body contains your genetic code spelled out in DNA, designated by the letters A, T, C, and G. All people have very similar genomes (genetic material) – about 99.6 percent identical – consisting of over three billion letters, with two copies in each cell. However, everyone is unique and between any two people there could be approximately 24 million places where the spelling is different. The genomes of related family members are usually more similar than the genomes of unrelated people.

By looking at your genome from affected bone and comparing it to the genome of your unaffected bone, we may be able to identify places where the genomes don't match-up. These newly identified places could be associated with melorheostosis. We also want to see if any of these genetic changes are present in your blood and skin.

A new technology, genomic sequencing, is being used that may help find the cause(s) we haven't been able to find using past methods. Older research methods looked at one or a few genes at a time. Genomic sequencing goes further by looking at most of the genes at once. Genes are the instructions our body uses to function. We all have thousands of them. We can look for changes, or variants in the genes. We each have many variants and most do not cause disease. It's difficult

to identify the few variants that do. Although the goal of this research is to find new gene changes that lead to melorheostosis, it may take years and may not be successful. In some cases, at the investigators' discretion, unaffected adult family members of subjects with melorheostosis may be asked to enroll in the study to help us identify the genetic cause(s) of the disease. We expect no immediate clinical benefits to you or your family, as it can take many years to find the cause for melorheostosis.

One of the aims of this study is to identify the genetic cause(s) for melorheostosis. Genetic studies will not be done unless you agree to have these done specifically as described below. Both traditional genetic testing and whole exome sequencing as detailed below are optional and done specifically for research purposes. You will be asked to sign a separate consent to review the risks of bone and skin biopsy.

DNA/Genetic Samples from Blood and Skin

DNA can be taken from your bone specimen(s), blood and/ or skin specimen(s) if you agree. The samples will be studied for specific mutations related to melorheostosis.

Genetic Testing:

The sample from blood (skin if obtained) will be used to isolate DNA for genetic tests performed now, or stored for use in future genetic studies. By studying your genes, we can test for particular misspellings in genes that we know are already associated with bone diseases, or we can check the entire spelling (sequence) of one or more of these genes. We will try to correlate any differences we find in these genes with your symptoms. Genetic testing results will be used in our research but may also provide clinical information about your disease. If we do identify any genetic mutations related to bone disease that may affect how you are treated, these findings will be shared with you and, if you wish, with your health care provider outside of the NIH who will direct further evaluation and make any necessary changes in your treatment plan.

Whole Exome Sequencing:

In addition to standard genetic tests which will be done on all patients who undergo genetic testing in this study, we may want to perform whole exome sequencing of your DNA. Since this is a special test, we are asking you separately if you are willing to participate in this part of the study. If you decide not to participate in this part of the study, your decision will not affect your participation in other parts of the study or your medical care while at the NIH. Traditional genetic tests look for common misspellings at specific places on your genome. Usually these places have already been identified as being associated with a particular disease or condition, such as bone diseases. Traditional genetic tests will look for misspellings in genes that we already know are associated with bone health and disease. We will study whether any misspellings in these genes may cause your bone disease. However, if we want to find additional genes that are associated with disease, we need to perform whole exome sequencing. Your genome consists of genes, which include short segments of DNA that encode exons that code for proteins, and many long segments of DNA that do not contain genes. Scientists use the term 'exome' to represent all of the exons, or protein-coding regions, of the genome. Whole exome sequencing looks at the gene regions of the genome.

We may not sequence your exome immediately, but instead may do this at some point in the future as needed. In most cases, if we do perform this test it will be done within a few years of obtaining the sample. However, in some cases there may be a longer period of time before sequencing is performed.

At the conclusion of your stay, we will schedule you for a wrap-up visit to review the results of all the testing and evaluation performed and available thus far. You have the opportunity to review all of your results (except research results) through the NIH Patient Portal. NIH offers free online access to key medical information regarding the care you received at the Clinical Center including test results through this portal.

We will also obtain research data from you through this study. If you withdraw from this study, the associated research data will also be destroyed, except for medical data that are contained within the official medical record and data that were deposited in a de-identified fashion within public databases.

Experimental treatments are not covered in this study.

In case we find something on exam or testing unrelated to bones but which could be potentially important for your health, we will share the information with you and your local provider if you like. However, ongoing care including confirmatory testing for such findings will not be provided through this protocol. If there is a protocol at NIH related to the finding, we will gladly share the information with you.

TESTING FREQUENCY

Subjects may be asked to follow-up approximately every 2 to 3 years, or as needed. At these follow-up visits, the following tests will be carried out for research purposes:

- Blood and urine tests as at the initial visit

ADDITIONAL TESTING /PROCEDURES

Other tests/procedures not discussed in this consent may be done for clinical purposes if other conditions are found or suspected. You will be told about this and may decide not to do the tests/procedures.

WHAT ARE THE RISKS OF THE STUDY?

Risks and discomforts you could experience during this study include:

Skin Biopsy

The minimally invasive biopsy includes the administration of a local anesthetic, could leave a tiny scar, and might rarely be associated with infection or a bad reaction to the local anesthetic. There will be a small amount of bleeding which can usually be controlled with a Band-Aid and pressure. Discomfort at the biopsy site is usually mild and can be treated with Tylenol.

Blood Collection

There may be some physical discomfort when we collect your blood with a needle. There is a small chance that you will develop a bruise, feel lightheaded, faint, or develop an infection at the needle

site. The amount of blood drawn will be less than 8 tablespoons (tbs.) per admission. (More will be drawn only if it is necessary for your medical care.) This volume of blood (8 tbs.) is less than one-fourth the amount that is taken when blood is donated, e.g., through the Red Cross.

Photographs

Taking pictures of the face and body may be embarrassing to some patients. You may be asked to remove your clothes, except your underwear, during these pictures. The photographs may be published in medical journals, without identifying the patient. There is a risk of loss or theft of the images that may cause the patient to be identified by people not connected with the protocol.

Risks and Discomforts from Genetic Testing and Whole Exome Sequencing

I. The discomfort of blood draw and skin biopsy as described above.

II. The risk of diagnosing a genetic condition unrelated to melorheostosis. Should we uncover incidental or secondary genetic findings that are of significant importance to your health, we will inform you. Confirmation and further evaluation of genetic results, genetic counseling, and any treatment that is required, will need to be done by your health care providers outside the NIH at your own cost.

III. **The unwanted possibility of discovering that parental relationships in a family are not true genetic relationships:** In these cases, we will not perform any additional testing to determine explicit genetic relationships, and we do not plan to inform you of the unproven possibility of mistaken family relationships. Due to the possibility of mistaken family relationships, we may also decide not to include you and/or your family members' data in the research study.

IV. The possibility that people outside of the study may gain access to your personal information. The study has extensive safeguards in place to prevent this from happening. If we become aware that your personal information has been compromised, we will inform you as soon as possible.

V. **The possibility that diagnosis of a genetic disorder could affect your insurability:** You may be concerned that our establishing or confirming such a diagnosis would limit your eligibility for life or health insurance. If you sign a waiver on an insurance application, we would be obliged to divulge the results of tests pertaining to you to the insurance company. We would be happy to discuss these issues in more detail now or after learning the results of your genetic testing, if you so desire.

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.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Other Considerations for Whole Exome Sequencing:

There are several aspects of whole exome sequencing that you should consider before agreeing to participate.

1. Genetics is a fast moving field and new findings for a wide range of diseases are announced every day. By sequencing your entire exome, we may discover possible misspellings in genes not currently recognized as being associated with bone diseases. These are called incidental or secondary findings. Since we are looking exclusively for exome regions associated with bone diseases, we will not intentionally look for incidental misspellings and will generally not inform you of any we find. However, in cases where we happen to find specific gene variants that we think are urgently important to your health, we will inform you. We expect this type of situation to be very uncommon. We will periodically recheck your exome sequence as new information related to bone diseases becomes available and may report our findings back to you. We may not find changes in your genes for many months or even years because of the amount of time it takes to complete our genetic studies.

2. Your exome sequence contains a very large amount of data, which will be stored in a centralized database maintained by the National Institutes of Health (NIH) according to NIH guidelines. In addition to your exome sequence data, clinical information about you – such as your disease history, your symptoms, laboratory test results, and general statistical information about you (for example, your age, sex, and ethnicity) – may also be included in the database.

Your data will be assigned an identifier number and any personal information that could connect you to your data (such as your name, address, or social security number) will be removed from the database. Any of your personally-identifiable information collected for the study will be kept by the study investigators at the NIH in files separate from the database. The study investigators will be the only ones with access to your personal information and who could connect you to your database identifier number.

In addition, only medical scientists with legitimate research interests will be allowed access to your data for analysis purposes. Most of these medical scientists will be investigating bone conditions. However, your data could be made available to medical scientists pursuing research unrelated to bone conditions.

The systems holding your data and personal information have extensive safeguards to prevent unauthorized access. But even with the best safeguards, there is always the possibility of a breach of security in the database and the possibility that someone could deduce your identity by comparing your sequence data to DNA sequence information they may have collected about you. Also, your data and personal information could be released to authorities in response to a legal subpoena. If at any time you would like us to remove your sequence data and/or clinical information from the database, please let us know in writing and we will pull your data from the database. We will not be able to remove your information from studies that are already completed or have been published in a journal prior to your written request.

Reporting of Genetic Information

You may participate in the study even if you do not consent to genetic testing. Genetic testing in this study will be performed for research purposes only. Although we plan to study genetic findings related to bone diseases, we may by chance find other genetic abnormalities unrelated to bone health. We will not routinely report results of any genetic tests to you or to the doctor who regularly cares for you. However, if we believe a genetic test result is medically important for you to know and that preventative actions or treatment can be taken, we will share this information with you, and if you desire, with the doctor who regularly cares for you.

Confirmation and further evaluation of genetic results, genetic counseling, and any treatment that is required, will need to be done by your health care providers outside the NIH. This applies to results obtained from either traditional genetic testing or whole exome sequencing.

By agreeing to participate in this study, you do not waive any rights that you may have regarding access to and disclosure of your records. For further information on those rights, please contact Sarthak Gupta, MD, Phone: 301-443-8541.

Please initial below at the appropriate space if you agree to have genetic testing performed.

_____I agree to have genetic testing performed.

_____I do NOT agree to have any genetic testing.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Your participation in this study may be of no direct benefit to you but may benefit others with melorheostosis in the future. We would be willing to provide information about diagnosis and prognosis as well as recommendations for management to your local physician. You will be able to ask questions and learn more about your disease. We will inform you of new findings from the study that may relate to your safety. We will also release those results upon your signed request. However, many of these results will be of unknown clinical value to you and should be interpreted with caution.

WHAT ARE MY OTHER OPTIONS?

You do not have to participate in this study if you do not want to. Participation in this study is voluntary; you may choose not to participate. You also have the right to refuse any procedure or treatment. Treatment recommendations provided by the research team are based on the premise that the potential benefits outweigh the risks. You should feel free to discuss our recommendations or any other alternative treatments with your primary care doctor or other specialist doctors.

In this study, we collect information about melorheostosis in a standardized fashion to better understand what goes on in the different bones involved in the disease. You will not receive continuous medical care under this study. You should continue your routine care with your primary care and/ or specialist doctor. Whether you decide to participate or not to participate in this study does not influence the clinical care you receive at the NIH or at home with your primary care doctor.

WHAT IF I CHANGE MY MIND?

You may stop participating in this study at any time. You have the right to stop the study at any time. If the doctor feels that it would not be good for you to continue this study he/she may take you out of the study without your permission. If at any time in the future you do not want your research samples used here at NIH, please let us know in writing and we will destroy your research sample. If the sample has been shared with a collaborator outside of the NIH, we will forward your request for its destruction to the outside investigator but will not be able to confirm that this was completed.

WHAT WILL HAPPEN TO THE SAMPLES AND INFORMATION THAT ARE COLLECTED DURING THIS STUDY?

We plan to store blood or skin samples you donate indefinitely. These specimens will be coded for reference purposes. Genetic testing will only be performed if you consent for it. If you do not consent for genetic testing, the stored blood and skin sample will be used for non-genetic research testing. We will inform you and your physician of any findings that would be helpful to you or your family, and will help to arrange for genetic counseling if that is needed.

We may provide a sample of your blood or skin to other collaborators to conduct studies related to this protocol, and, as previously stated, your personal information will never be provided with these samples, which will be coded. Collaborators will sign agreements with NIH to specify how your samples and data may be used for research. If samples will be sent for unrelated purposes, they will be completely anonymized, that is, there will be neither any personal information nor code associated with the sample. The information obtained in other laboratories may provide knowledge that is useful for the analysis of other illnesses but any results would not be transmitted back to you, as your sample would not be identifiable. By agreeing to participate in this study, you do not waive any rights that you may have regarding access to and disclosure of your records. For further information on those rights, please contact Sarthak Gupta, MD, Phone: 301-443-8541.

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.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

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.

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

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

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

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, Sarthak Gupta, MD, Phone: 301-443-8541, Email: guptas3@mail.nih.gov . Other researchers you may call are: Timothy Bhattacharyya, MD, Phone: 301-443-8388, Email: timothy.bhattacharyya@nih.gov and Nancy Ann Spencer, RN, MSCN, Phone 301-435-8434, Email: nancy.spencer@nih.gov.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: _____.