# Listening to Mom in the Neonatal Intensive Care Unit (NICU): Neural, Clinical and Language Outcomes

Informed Consent Form

NCT02847689

November 30, 2020

Please check all that are applicable:

☐ I am an adult participant in this study.

Print your name here:

_____

☐ I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward.")

Print child's name here:

_____

Are you participating in any other research studies? _____ Yes _____No

## INTRODUCTION TO RESEARCH STUDIES

You and your child are being asked to consent to participate in a research study. Your participation in this research study is completely voluntary. The purpose of this study is to examine how sounds from a mother's voice may affect brain and language development in babies born preterm. If you decide to allow your child to participate in this study, s/he will be randomly assigned to one of two study groups. Your baby has a 1/2 (50%) chance of being assigned to the group that will listen to a recording of your voice and a 1/2 (50%) chance of being assigned to the group that will not be played voice recordings. We will get a recording of your voice by having you read a set of children's stories. If you agree to participate, we will examine your child's electronic medical records so that we can monitor your child's health, brain and language development. At or around the time of your child's first birthday, we will contact you to see if you are willing to bring your child back to Stanford to obtain an MRI scan for research purposes. At these visits, we will also perform tests to assess your child's language development. We do not yet know whether playing recordings of your voice will benefit your child's brain or language development. This study does not change the routine care for your child.

## PURPOSE OF RESEARCH

You and your child have been invited to participate in a research study on how sounds from a mother's voice may affect health outcomes and brain development in babies born preterm. We hope to learn whether playing a recording of a mother's voice to her baby in the hospital nursery may have added benefits beyond current standard of care for improving health and neural outcomes in babies born preterm. In the long-term, we hope to learn whether this treatment may also be useful for improving language skills in preterm babies as they continue to develop.

Your child was selected as a possible participant in this study because your child was born preterm (less than 32 weeks gestation) and is scheduled for a neonatal brain MRI at Lucile Packard Children's Hospital prior to discharge.

If you decide to terminate your participation in this study, you should notify Katherine Travis, PhD at 650-498-7690.

This project is funded by the National Institutes of Health. This research study is looking for 80 infants born preterm (less than 32 weeks gestation). Stanford University expects to enroll 80 (100%) research study participants.

## VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your child's medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you and your child are entitled. If you decide to terminate your participation in this study, you should notify Katherine Travis, PhD at 650-498-7690.

## DURATION OF STUDY INVOLVEMENT

This research study will last for 18 months and will consist of three Test Points, near-term birth, age 12 months and age 18 months. In between discharge from the hospital and the 12 month Test Point, we may contact via you phone/text/email to assess study interest and maintain up-to-date contact information.

(1) Near-term birth Test Point: While your child remains hospitalized in the Neonatal Intensive Care Unit your child may be played a sample of your voice depending on treatment group to which s/he is assigned. For each day that your child remains in the hospital nursery, s/he may hear recordings of your voice

played during the nighttime for up to 4 hours. Voice recordings will end at the time your child receives brain MRI imaging prior to hospital discharge. MRI scans collected prior to hospital discharge are part of routine clinical care for infants born less than 32 weeks gestational age. Your consent to participate in this study will grant us access to these brain scans.

(2) 12 Month Test Point: You and your child will be asked to return to Stanford for a MRI brain scan for research purposes. MRI scans will be performed during the evening when your baby is asleep. No sedation will be used. MRI scanning is expected to last < 1 hour. We may ask that you and your child visit our laboratory to assess your child's language development. Language testing is expected to last no longer than 2 hours.

(3) 18 Month Test Point: You and your child will be asked to return for a visit to our laboratory to perform behavioral tests to measure your child's language development. Language testing is expected to last no longer than 2 hours.

## PROCEDURES

If you choose to participate, the Dr. Travis and her research study staff will ask that you and your child do the following:

**Near Term Test Point Procedures**

**Mother's Voice Recording:** You will be asked to read aloud children's storybooks that we will provide to you. If you are unable to read these stories we will ask you to describe the story in your own words. Your voice will be recorded using a digital voice recorder. The purpose of this recording is to obtain a sample of your voice that may be played to your child depending on the treatment group to which s/he is assigned. Recording sessions take approximately 30 minutes. Voice recordings may be played at scientific meetings; recordings will not be saved for future research and will ultimately be erased and/or destroyed.

**Voice Treatment/ Standard Treatment:** Your child will be randomly assigned to 1 of 2 study groups. Your child will have a 1/2 chance of being placed in study group 1 (voice recording treatment) versus study group 2 (standard care). For each day that your child remains in the hospital nursery, s/he may hear recordings of your voice played during the nighttime for up to 4 hours. We will also record sounds that your child may hear to in the nursery using a digital voice recorder.

**Vital Sign Monitoring Sessions:** We will record your baby's vital signs during a 30-60 minute session in which we will play recordings of your voice to your baby. These sessions will take place at the beginning and end of the treatment period. Vital signs will be digitally recorded on to a computer that is connected to the monitors that continuously measure your baby's heart and lung function.

**12 month and 18 month Test Point Procedures**

**MRI (Magnetic Resonance Imaging) – 12 Month Test Point ONLY:** MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. During the scan your child will be asked to lie on a long narrow couch for approximately 30-60 minutes while the machine gathers information. MRI scans will be performed during the evening when your baby is asleep. MRI scanning is expected to last < 1 hour. During this time your child will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which your child will not feel. Your child will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that your child will be required to wear. Scanning will immediately cease if your child awakens during the scanning procedure. A research staff member will be with your child at all times during the scanning procedure. You will have the option to remaining in the MRI scanning room with your child and will be given hearing protection.

**Language Assessments (12 and 18 month):**
Task 1: For this task, your child will look at colorful pictures on a video screen while listening to recorded speech referring to the pictures. We may vary factors in the speech stimuli such as word familiarity or sentence structure to learn more about the development of language understanding. Your child is seated on your lap throughout the session. From the video recording, we can later look at your child's gaze patterns in response to speech.

Task 2: For this task, we observe children interacting with a staff member in the playroom. In these game-like activities, your child may be asked to play with toys, name or point to pictures, repeat sequences of words or sentences, tell stories, imitate hand movements, or solve puzzles. These observations help us understand how language development relates to other types of cognitive activities in children at different ages.

Task 3: For this task, we observe how children interact spontaneously in a less structured situation. In some cases, we observe you as you play with your child in our playroom. We will provide you with a selection of toys appropriate to your child's age, and ask you to engage with your child as you would at home. From

these observations, we learn how children at different ages respond to language in the context of social interaction.

**Procedures for all Test Points (near-term, 12 and 18 months)**

**Family Questionnaires:** You will be asked to fill out questionnaires and answer questions about your family's health, education, and language backgrounds. You may refuse to answer any individual question on these questionnaires. Time to complete questionnaires is expect to take approximately 30 minutes.

**Parent Language Sample:** We will record your voice and any sounds that your child makes or hears using a digital voice recorder (e.g., LENA voice recorder and/or Starling device). The purpose of this recording is to obtain a sample of the language(s) and words that your child may hear in the hospital and in your home. Voice recordings may be played at scientific meetings. These recordings may be saved for future research. Upon completion of this study, recordings will ultimately be erased and/or destroyed.

**Medical Chart Review:** We will review your child's medical records, including your child's routine MRI scan and previous neuroimaging (ultrasounds and CT-scans). Medical record review is to review for possible brain injuries and others conditions that might affect how your child responds to treatment.

**Future Use of Private Information**

Research using private information is an important way to try to understand human disease. You are being given this information because the investigators want to save private information for future research.

Your information will be stored on password protected and encrypted computer servers. Any information relating to your child's medical history, brain or language development will be linked using a unique study identification code and will not contain any personally identifiable information.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

## PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.

- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

## WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your child's participation at any time. Your decision will not affect your ability to receive medical care for your child and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Katherine Travis at 650-498-7690.

If you withdraw from the study, or the study treatment is stopped for any reason,

- There are no anticipated negative consequence of terminating study voice treatment
- You must return any study-related supplies (e.g., voice recording devices)

The Protocol Director may also withdraw you from the study and the study voice treatment will be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- It would not be safe for your child to have a MRI scan.
- Your child needs treatment not allowed in the study.
- The study is cancelled or other administrative reasons.
- Unanticipated circumstances.

## POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

**Risks of Mother's Voice Treatment**: This procedure is considered to be non-invasive. There is minimal risk that your child may experience minor discomfort from listening to recordings of your voice. For example, your child may become upset if woken by voice recordings. Your child's health will be monitored regularly as per routine care in the hospital nursery. This will ensure that voice recordings do not affect your child's health.

**Risks of MRI Scanning**:
Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you or your child have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your or your child's body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed, so it is very important that you notify the operator.

There is a possibility that your child will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs. There is also a possibility of tinnitus (ringing in the ears) after the MRI.

Some of the radio frequency imaging coils, imaging software and devices being used in your scan are not approved by the FDA but are similar to counterparts that have been approved by the FDA. There is a small risk of heating from the cables associated with these devices. Please report any heating sensation immediately. Dizziness or nausea may occur if you or your child move your or her/his head rapidly within the magnet.

**IF YOU FEEL YOUR CHILD IS EXPERIENCING DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.**

The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and Stanford are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact

you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and Stanford are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

**Risks of Language Assessments:** There are no physical risks of assessing your child's language development. You may feel uncomfortable when you are observed interacting with your infant.

**Risks of Voice Recording:** You may have concerns regarding privacy during recording or feel uncomfortable interacting with your infant or bedside nurse at this time. Recording will be kept confidential and only reviewed for word count by study personnel. Members of your infant's care team will not hear the recording nor will recordings be made public.

**Risks of Vital Sign Recording Sessions**: We do not expect any risks of monitoring vital signs while playing sound recordings to babies. Vital sign recording sessions will take place during the day, with permission of the attending physician and nurse to make sure baby is not distressed and does not interfere with routine care procedures or family visits.

**Risks of Questionnaires and Collecting Personal Information**: One potential risk is breach of confidentiality related to the collection of sensitive medical information. Several precautionary steps are made to ensure the protection of confidential information and to minimize the possible breach of confidentiality. Furthermore, since personal information is gathered, there exists the risk of possible invasion of privacy. However, since informed consent is obtained, the likelihood of invasion of privacy is minimal.

**Overall discomforts and inconveniences** include travel to Stanford for follow-up MRI and testing, anxiety and other emotions.

**Unforseeable Risks:** The procedures in the present study may involve risks to your child that are currently unforeseeable.

## POTENTIAL BENEFITS

There is the potential for voice treatment to lead to improvements in your child's health.

Infants assigned to the control group (study group 2) will receive standard of care. There may be no direct benefit to your child if s/he is assigned to this group.

**We cannot and do not guarantee or promise that your child will receive any benefits from this study**.

## ALTERNATIVES

Choosing not to be a participant in this study is an alternative to entering this study.

## PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your child or your willingness to continue participation in this study.

## ClinicalTrials.gov

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 your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your child's identity and/or your child's personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

We will keep *your child's* study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as suspected child abuse or neglect, suspected elder or dependent abuse or neglect, or intent to harm yourself or others.

**CERTIFICATE OF CONFIDENTIALITY**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

# Authorization To Use Your Health Information For Research Purposes

Because information about your child and your child's health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

**What is the purpose of this research study and how will my health information be utilized in the study?**

This is a research study designed to examine whether playing sounds from a mother's voice may be a useful treatment for improving health and brain development in babies born preterm. Information that we learn from this study will help us to determine whether voice treatments may also be helpful for improving language skills in preterm babies as they continue to develop. Your child's medical records, including results from MRI brain scans will be used to determine if there may be certain health factors that may affect how well your child may respond to voice treatment. Your child's health information may be used in scientific publications and scientific presentations. We will not reveal your child's identity in association with this information.

**Do I have to sign this authorization form?**

You do not have to sign this authorization form. But if you do not, your child will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

**If I sign, can I revoke it or withdraw from the research later?**

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your child's health information (and to discontinue any other participation in the study) at any time. After any revocation, your child's health information will no

longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Katherine Travis, 300 Pasteur Drive Grant Bldg S-224 Stanford, CA 94305 ktravis1@stanford.edu

**What Personal Information Will Be Obtained, Used or Disclosed?**
Your child's health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to birth weight, gestational age at birth, congenital disorders, medical health complications related to preterm birth, including those related to a neurological condition. Information about your child's family history, including history of neurological and language disorders, parental education background, number and types of languages spoken at home, and number of siblings. MRI/DTI scans, voice recordings, vision and hearing screenings. We will also review progress and discharge notes to assess the impact of the language intervention in relation to clinical and neural outcomes. We will ask for contact information, such as address, phone number, email address.

**Who May Use or Disclose the Information?**
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director: Katherine Travis, PhD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

**Who May Receive or Use the Information?**
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

- The National Institutes of Health (NIH)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will my authorization expire?**
Your authorization for the use and/or disclosure of your health information will end on February 28, 2050 or when the research project ends, whichever is earlier.

**Will access to my medical record be limited during the study?**
To maintain the integrity of this research study, you may not have access to any of your child's health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about your child (e.g., if included in your official medical record).

_____ _____
Signature of Parent, Guardian or Conservator Date

_____
Print Name of Parent, Guardian or Conservator

_____
Authority to Act for Participant
(Parent, guardian or conservator)

## FINANCIAL CONSIDERATIONS

Payment/Reimbursement
You will receive compensation in a form of a $20 gift card for your time spent performing voice recordings and completing questionnaires about your child's health history.

At 12 month visit you receive compensation in the for of a $50 gift card for you time spent for the MRI and a $25 gift card for time spent performing language assessments.

At 18 month visit you receive compensation in the for of a $25 gift card for your time spent performing language assessments.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs
There is no cost to you for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits.

Sponsor
The National Institutes of Health (NIH) is providing financial support and/or material for this study.

## COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, your child might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist your child in obtaining appropriate medical treatment. In the event that your child has an injury or illness that is directly caused by your child's participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist

you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

## CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Katherine Travis at 650-498-7690. You should also contact her at any time if you feel you have been hurt by being a part of this study.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Katherine Travis at 650-498-7690.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact [redacted] at ([redacted]).

## EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant your child has the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;

- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

Signing your name means you agree to be in this study and that you were given a copy of this signed and dated consent form.

_____ _____
Signature of Parent, Guardian or Conservator Date

_____
Print Name of Parent, Guardian or Conservator

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Print Name of Parent, Guardian or Conservator

_____
Authority to Act for Participant

The Institutional Review Board (IRB) determined that the permission of one parent is sufficient in accordance with 45 CFR 46.408(b).

**I give consent to have my voice recorded during this study:**
*Please initial:* ____ Yes ____ No

**I give consent for recordings of my voice to be used for scientific meetings:**
*Please initial:* ____ Yes ____ No

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness

*(e.g., staff, translator/interpreter, family member)*

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*