NATIONAL TEMPORAL BONE DONOR PROGRAM

DONOR ENROLLMENT PACKET

NIDCD National Temporal Bone,
Hearing & Balance Pathology Resource

REGISTRY

Instructions
for Completing the National Temporal Bone Donor Program Enrollment Packet

1. These forms should be completed by the person wishing to make an anatomical gift of his/her temporal bones and/or brain (in order to study brain pathways associated with hearing and balance).

2. Each form should contain information on one person only. Should other family members or friends wish to become temporal bone donors, please either photocopy this form, print out another copy, or request additional copies from the Registry.

3. The confidential medical information form provides the Registry with some of your medical history pertinent to your ear disorder. Many of the questions have a box (☐) next to them. Check the box if the answer is yes. Leave the box blank if the answer is no. Insert a question mark (?) if you do not know or are unsure of the answer. The more information you can provide, the more valuable your anatomical gift will be. If necessary, use additional pages to explain your ear disorders.

4. This confidential medical information form along with a signed donor consent form, and signed donor's Next of Kin consent form complete your bequest. The donor consent form requires your signature and the signatures of two witnesses, the donor's Next of Kin consent form requires your signature and the signature of your delegated Next of Kin.

5. Please return all forms to the Registry at the address below. You will then receive a wallet-sized donor card with the telephone number to be called at the time of your death.

6. The scientific value of your temporal bones and brain tissues is greatly enhanced if accompanied by up-to-date medical records. Donors will be contacted every 3-5 years to update their records.

If you have any questions, please contact us:

NIDCD National Temporal Bone, Hearing & Balance Pathology Resource Registry
Massachusetts Eye & Ear
243 Charles Street
Boston, MA 02114-3096
(800) 822-1327 Toll-Free
(617) 573-3711 (Voice)
(617) 573-3838 (Fax)
www.tbregistry.org

Subject Identification

Protocol Title: NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry

Principal Investigator: Felipe Santos, MD

Site Principal Investigator:

Description of Subject Population: Subject with or without various hearing and/or vestibular deficits

Collection of Samples and Health Information for Research

About this consent form

Please read this form carefully. It tells you important information about the collection and storage of tissue samples for research. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to give your permission. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead, we may ask the person's authorized representative to give consent.

The word "you" means the person who wishes to make an anatomical gift of his/her temporal bones and entire brain if indicated on his/her Donor Consent Form. The words "we" or "National Temporal Bone Registry" mean the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry **("Registry"),** which is administered by the Massachusetts Eye and Ear.

Key Information

We are asking you to make an anatomical gift of your temporal bone and brain (if applicable), genetic information (if applicable) and related demographic and medical information so that it may be included in the NIDCD National Temporal Bone, Hearing & Balance Pathology Resource **Registry**, and to be used for future research.

The **Registry** is a nonprofit organization established by the National Institute of Deafness and Other Communication Disorder to provide information about temporal bone donation and research. Thanks to those who contributed their temporal bones in the past, many advances in understanding and treating ear disorders have been made.

This form will tell you what you should expect if you agree to be became a donor. If you are not a patient at Mass General Brigham in Boston, Massachusetts, some parts of this consent form may not apply to you.

It is your decision whether to become a donor. You can become a donor if you have hearing or balance impairment, as well as if you do not have any of these problems. You will not be paid for your anatomical donation to the Registry.

Researchers will study each temporal bone to learn more about the ear structure and causes of the donor's ear problem. With this knowledge, researchers can develop new ways to diagnose and correct ear disorders in others.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

If you have any questions before you sign this consent form or after you join the study, please feel free to call Temporal Bone Registry **24/7** at our toll-free number, **(800) 822-1327,**
Or email us to:
tbregistry@meei.harvard.edu

The person in charge of the Registry is **Dr. Felipe Santos, MD.**

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

What will happen if you take part in this research tissue bank?

You are making the anatomical gift of your temporal bone and brain (if applicable), genetic information (if applicable) and related demographic and medical information so that it may be included in the NIDCD National Temporal Bone, Hearing & Balance Pathology Resource Registry, and to be used for future research.

I, (Please type or print name) ____, hereby make this anatomical gift of my temporal bones to National Temporal Bone Registry.

Optional Brain Donation:

☐ **Yes,** In addition to the anatomical gift of my temporal bones, I also make the anatomical gift of my entire brain, in order to study brain pathways associated with hearing and balance.

☐ **No**, I am not interested in participating in optional brain donation.

Optional Donation of DNA from Buccal (Cheek) Swabs:

The value of your bequest can be enhanced even further by combining the histopathological studies (the examination of the cells and structure of the hearing and balance organs) of your temporal bones and brain pathways with DNA studies of genes involved in hearing and balance. DNA is the material that makes up your genes and is an “instruction manual” programmed into your cells. DNA is the material that makes up your genes and is an “instruction manual “programmed into your cells. The functions of hearing and balance are controlled and determined by a large number of genes. Estimates range from 200 to more than 1,000 genes.

Please consider donating a sample of your DNA obtained via cheek swabs. The Registry will send you a DNA collection kit with detailed instructions, a separate consent form to sign and provide a prepaid mailer to return the swabs back to Registry. The procedure is as simple and painless as brushing your teeth. You will apply the sterile brush at the end of the swab against the inside of your cheek and rub it back and forth several times. Your donation of DNA is entirely optional. You may choose not to donate your DNA from the cheek swab, and instead only donate your temporal bones and brain.

☐ **Yes,** I am interested in participating. Please send me the cheek swabs.
In addition to the sharing of my demographic and medical information, I also authorize the collection, storage, and use of my DNA/genetic information for inclusion in the National Temporal Bone Bank Repository

☐ **No**, I am not interested in participating in the DNA cheek swab program.

Medical Record Release:

By signing this document,
I, (Please type or print name) ____,

hereby authorize the release of my past and future medical records, pertaining to ear disorders, including results of post-mortem examination from the doctors, individuals and facilities, involved in my medical care to the NIDCD National Temporal Bone, Hearing & Balance Pathology Resource Registry, or its collaborating laboratories, for the purposes of including my information in the Registry's research repository.
This authorization includes any examinations, tests and review of medical history necessary to assure medical acceptability of the donated tissues.

Upon your death your temporal bones (only the part containing the middle and inner ear) and brain (if applicable), will be surgically removed by any medical doctor, coroner or other qualified person without cost to your estate, your family or your friends.

After Registry receives your anatomical gift, it will be coded and the Registry will keep the key code linking your identity to the study identifier in a secure file.

Your DNA sample, (if applicable), obtained using cheek swabs will be coded and the Registry will keep the key code linking your identity to the study identifier in a secure file.
Then the swabs will stored in a freezer at -80°C. You may choose not to donate your DNA from the cheek swab, and instead only donate your temporal bones and brain.

Researchers may study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes may be analyzed and used by researchers to study links to hearing or balance disorders.

The scientific value of your temporal bones and brain tissues is greatly enhanced if accompanied by up-to-date medical records. In order to administer, track, and use your planned and actual anatomical gift and related demographic, medical and genetic information (if applicable) from the time of your consent, during your life, and following your death we need to be able to collect, use and share your protected health information.

We plan to continue to review your medical record to update your health information in the Registry database. Donors and /or their medical provider may be contacted every 3-5 years to update the donor records.

How are your samples stored?

The purpose of the Registry is to create a registry of temporal bone and brain tissue, and related demographic, medical and genetic information that may be used for future research. Results of this research may be presented or published for use by the medical or scientific community

After Registry receives your anatomical gift, it will be coded and the Registry will keep the key code linking your identity to the study identifier in a secure file.

Your DNA sample, (if applicable), obtained using cheek swabs will be coded and the Registry will keep the key code linking your identity to the study identifier in a secure file.

Your medical information submitted to Registry by you, or your medical providers will be stored in the secure location.

Which researchers can use your samples and what information about you can they have?

The Registry may share your data and /or samples with researchers at Mass General Brigham institutions, as well as non-Mass General Brigham academic institutions. Occasionally, your data and or samples may be shared with for-profit companies that are working with Mass General Brigham researchers on a specific research project.

- As described above, all of the data/samples stored in the Registry are labeled with a code number that connects the sample to medical information related to the sample. The key to the code that links the samples and information to a specific individual will only be available to the Registry staff and will be securely stored.
- We may share information that identify you with researchers at Mass General Brigham institutions, at non-Mass General Brigham institutions or with for-profit companies that are working with Mass General Brigham researchers only if they have the approval of Mass General Brigham ethics board.
- Any actual use or sharing of your anatomical gift and related protected health information for a specific research study will be subject to applicable rules in effect at the time of the proposed research
- The results of this research study may be published in a medical book or journal or used to teach others. However, your name or other identifying information **will not** be used for these purposes.

For what type of research will your samples be used?

Millions of people are affected by hearing loss or other ear problem. Hearing and balance organs are fond deep within the skull, and it is not easy to examine these hidden organs directly in living people. So, studying donated temporal bones after death is one of the best ways to learn about the causes of ear disorders and to device new treatment and cure.

How long will your samples and information be kept?

Since the purpose of the Registry is to create a registry of temporal bone and brain tissue, and related demographic, medical and genetic information that may be used for future research, this authorization has no expiration date.

In the case the Registry was not able to arrange for the removal of your temporal bones and brain if indicated, we will permanently destroy all protected health information and your DNA sample, that we have gathered about you, or to the extent that we are unable to reasonably destroy the protected health information, we will protect it to prevent its future use or disclosure.

Can you stop allowing your samples and information to be stored and used for research?

Yes. If you change your mind later and do not want to make an anatomical gift upon your death of your temporal bones (and if applicable, the entire brain), or do not want us to collect, use or share your protected health information to administer, track, and use your planned anatomical gift and related demographic, medical and genetic (if applicable) information, you need to send a letter to the Registry at the address listed below. The letter needs to say that you have changed your mind and do not want to make an anatomical gift upon your death of your temporal bones (and if indicated, the entire brain) or do not want us to collect, use or share your protected health information to administer, track, and use your previously planned anatomical gift. In this case, promptly following receipt of your request, and to the extent reasonable, we will permanently destroy all protected health information that we have gathered about you, or to the extent that we are unable to reasonably destroy the protected health information, we will protect it to prevent its future use or disclosure. However, the requested revocation will not affect any uses or sharing of your protected health information that has been used or shared prior to the receipt of the revocation request.

Following your death and anatomical gift, your legal representative may request that your protected health information be removed from the Registry. In this case the Registry will permanently destroy all protected health information that we have gathered about you, or to the extent that we are unable to reasonably destroy the protected health information, we will protect it to prevent its future use or disclosure. However, the requested revocation will not affect any uses or sharing of your protected health information that has been used or shared prior to the receipt of the revocation request.

Address to inform the Registry that you have changed your mind:
National Temporal Bone Registry
Care of the Massachusetts Eye and Ear
243 Charles Street
Boston, Massachusetts 02114

Will you get results of research done using your samples?

No. Temporal bone and brain (if applicable) donation are done post-mortem. No information about the final results of your participation in NIDCD National Temporal Bone, Hearing & Balance Pathology Resource Registry will be given to your family or your doctor.

During your lifetime, you can choose to receive the Registry Newsletter, released quarterly, that will tell you about the research studies we are doing. This newsletter will not announce your results or anyone else's, but it will tell you some information about what we are learning about hearing and balance disorders studying donor's anatomical gifts bequeathed to Registry.

☐ **Yes,** I am interested in receiving the Registry Newsletter.

What are the risks?

The main risk of allowing us to use your anatomical gift and health information for research is a potential loss of privacy. We protect your privacy by coding your samples and health information and following the rules of the Mass General Brigham ethics board and applicable federal laws.

What are the costs to you to take part in the research tissue bank?

There are no costs to you to participate in Registry. Upon your death, the temporal bones and brain (if applicable) will be removed by a qualified person without cost to your estate, your family or your friends.

Will you be paid for your samples?

You will not receive payment for your anatomical gift bequeathed to Registry.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

Can you still get medical care within Mass General Brigham if you don't take part in this research tissue bank or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now, or have a right to receive.

Taking part in the bank is up to you. You can decide not to allow your samples and information to be placed in the bank. If you decide to take part now, you can change your mind and drop out later.

What happens if you are injured as a result of taking part in this research study?

Your temporal bones ad brain (if applicable) will be removed **only upon your death.**

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information simply as "identifiable information."

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Mass General Brigham research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Mass General Brigham who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Mass General Brigham ethics board that oversees the research and the Mass General Brigham research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

By signing this document you have agreed to:

- Make an anatomical gift of your temporal bones and if indicated the entire brain upon your death,
- Contribute and provide access to your:
  - Demographic and medical information, and
  - To the extent that you indicated also DNA/genetic information.

You understand that this gift (temporal bones, brain, and DNA from cheek swab if applicable) is made to the National Temporal Bone Donor Program of the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry for the purpose of the creation of a research database and repository for future access by investigators for research purposes. You understand that these tissues will be removed by any medical doctor, coroner or other qualified person without cost to your estate, your family or your friends. You also authorize the release of your medical records including results of post-mortem examination to the Registry. This authorization includes also any examinations, tests and review of medical history necessary to assure medical acceptability of the donated tissues.

If you **sign** this form, you are giving us permission to collect, use and share your protected health information. If you decide not to sign this form, you cannot make an anatomical gift of your temporal bones (and if applicable, the entire brain) upon your death to the National Temporal Bone Donor Program of the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry. You need to sign this form in order to make the anatomical gift(s) upon your death.

The Registry Coordinator will give/mail you a signed copy of this form upon your request.

Whatever decision you make about making the anatomical gift(s), and allowing the collection, use and sharing of your protected health information with National Temporal Bone Donor Program of the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry will not affect your access to medical care.

Informed Consent and Authorization for Collection of Samples and Health Information for Research

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Donor:

I, (donor name) ____________________________ **give my consent** to take part in the National Temporal Bone Donor Program of the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry.

____________________________________ _____________ _____________
(Donor's Signature) (Date signed) (Time/optional)

____
(Address)

____
(City, State, Zip Code)

Witness #1:

(Signature of First Witness) (Date signed) (Time/optional)

(Print Names)

(Address)

(City, State, Zip Code)

Witness #2:

(Signature of Second Witness) (Date signed) (Time/Optional)

(Print Names)

(Address)

(City, State, Zip Code)

Signature of Guardian or Authorized Representative for Adult:

I, (print or type name)___________________________________ give my consent for the person I am authorized to represent to take part in the National Temporal Bone Donor Program of the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry as described above.

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

____ _________________
Signature Date/Time

Relationship to Subject:____

Consent Form Version: September 12, 2022

Mass General Brigham

Research Consent Form

Research Tissue Bank
Version Date: February 2022

Subject Identification

Protocol Title: NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry

Principal Investigator: Felipe Santos, MD

Site Principal Investigator:

Description of Subject Population: Subject with or without various hearing and/or vestibular deficits

National Temporal Bone Donor Program Consent of Next of Kin

The word "donor" means the person who wishes to make an anatomical gift of his/her temporal bones and entire brain if indicated on his/her Donor Consent Form to the National Temporal Bone Donor Program of the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry.
The words "you" and "Next of Kin" means the close blood relative of the donor or a person with connection to donor as defined under the "Uniform Anatomical Gift Act" and similar law. The words "we" or "National Temporal Bone Registry" mean the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry **("Registry"),** which is administered by the Massachusetts Eye and Ear.

Key Information

The Registry is a nonprofit organization established by the National Institute of Deafness and Other Communication Disorder to provide information about temporal bone donation and research. The Registry enlists people with or without ear disorders to be donors of their temporal bones and if indicated by the donor on the donor consent form, also their brain after their death. By signing this document, we are asking you to indicate that you have agreed to the removal of these tissues upon the death of the donor.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

If you have any questions before or after you sign this consent form, please feel free to call Temporal Bone Registry **24/7** at our toll-free number, **(800) 822-1327), or**
by calling 617 573 3711

Or email us to:
tbregistry@meei.harvard.edu

The person in charge of the Registry is **Dr. Felipe Santos, MD**.
The Registry Coordinator will give/mail you a signed copy of this form upon your request.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

What will happen in this study?

Donor is making the anatomical gift of his/her temporal bone and brain (if applicable), genetic information (if applicable) and related demographic and medical information so that it may be included in the NIDCD National Temporal Bone, Hearing & Balance Pathology Resource Registry, and to be used for future research.

Researchers will study each sample to learn more about the ear structure and causes of the donor's ear problem. With this knowledge, researcher can develop new ways to diagnose and correct ear disorders in others.

Samples of the donor tissue, bequeathed to the Registry will be made available to researchers at Mass General Brigham institutions, as well as non-Mass General Brigham academic institutions. Occasionally, the donor's samples may be shared with for-profit companies that are working with Mass General Brigham researchers on a specific research project. Donor's samples will not be sold to anyone for profit. The tissue bank will usually provide samples with limited information.

Will you get the result of the research done on the donor's samples?

No. No information about the result of the donor participation in NIDCD National Temporal Bone, Hearing & Balance Pathology Resource Registry, will be given to the donor or his family.

What are the costs to you or your family?

There is no cost to donor, donor's family or to you, as the Registry arranges for the donation. We may use donor's samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if the donor's samples or information are used for this purpose.

How will we protect the donor's privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information simply as "identifiable information.". In this study we will collect health information from past, present and future medical records of the donor.

Who may see, use, and share the donor's identifiable health information and why they may need to do so:

- Mass General Brigham research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Mass General Brigham who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Mass General Brigham ethics board that oversees the research and the Mass General Brigham research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to donor or others, we may need to report this, as required by law)

Some people or groups who get donor's health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. We share donor's health information only when we must, and we ask anyone who receives it from us to take measures to protect his/her privacy.

Mass General Brigham

Research Consent Form

Research Tissue Bank
Version Date: February 2022

Subject Identification

Informed Consent and Authorization of Next of Kin

I, ____________________________________, am the Next of Kin of donor
(Please type or print of Next-of-Kin name)

______________________________________,
(Please type or print donor's name)

who is pledging the future donation of his/her **temporal bones**, and if indicated on the donor consent form, his/her **entire brain** made to **the National Temporal Bone Donor Program of the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry.**

I do hereby agree to the removal of these tissues upon the death of this donor, as he/she has pledged. I understand that the Registry arranges for the donation and these tissues will be removed by any medical doctor, coroner or other qualified person without cost to donor's estate, donor's family or donor's friends.

I will instruct the doctor in charge, the person taking care of the donor at the time of his/her death or the coroner either before or immediately after the donor's death to notify the NIDCD National Temporal Bone Registry day or night by telephone **(800-822-1327 or 617-573-3711)** for instruction regarding the removal and preservation of these tissues. I understand that I will incur no cost in fulfillment of this anatomical gift.

Under the Uniform Anatomical Gift Act and similar laws, the legal next of kin is defined as below. In order of priority the legal next of kin shall be:

☐ The spouse
☐ An adult son or daughter,
☐ Either parent,
☐ An adult brother or sister,
☐ Court-appointed Guardian
☐ Health Care Proxy
☐ Durable Power of Attorney
☐ Family Member/Next-of-Kin

Please indicate your relationship to the Donor by **circling one of the six categories above**.

Subject Identification

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- I understand the information given to me.

Signature of Next of Kin:

I, (Print/ type name) ___________________________________ give my consent to the removal of a temporal bones and brain (if applicable) of the donor taking part in the National Temporal Bone Donor Program of the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry.

___________________________________ ______________ ______________
(Signature of Next of Kin) (Date signed) (Time/optional)

____
(Address)

___________________________________ ______________________________
(City, State, Zip Code) (Email address and/or phone)

Donor:

___________________________________ ______________ ______________
(Signature of the Donor) (Date signed) (Time/optional)

____
(Print/type Name of the Donor)

Consent Form Version: 12/12/2022

The National Temporal Bone Donor Program
Confidential Medical Information Form

(Please type or print)

The “donor” is the individual making the anatomical gift to the National Temporal Bone Donor Program.

DONOR:

Name: ____

Home Address: ____

City, State, Zip: ____

Email Address: ____

Home Telephone: (____)____

Date of Birth: ____

Occupation: ____

Today’s Date: ____

Preferred Method of Contact: ____

1. What is the exact diagnosis (or diagnoses) of your hearing or balance disorder(s)?

____
____
____
____
____

2. Describe your ear disorder(s) in your own words, giving onset, duration, treatment and cause (e.g., “I started losing hearing slowly in both ears at age 25. Hearing tests were done and I was diagnosed as having otosclerosis. I underwent a successful stapedectomy in my right ear at age 35...”).

____
____
____
____
____
____
____
____
____
____
____

3. Do you currently have, or have you ever had, any of the following symptoms? Please check the boxes that apply, and indicate right or left ear, if appropriate. If you are not sure, please place a question mark (?) in the appropriate box. Use the space under question 5 to give details of each item marked.

	Right Ear	Left Ear
☐ Hearing loss	________	________
☐ Ear drainage (pus)	________	________
☐ Tinnitus (noises, ringing, etc.)	________	________
☐ Ear pain	________	________
☐ Ear pressure or fullness	________	________
☐ Facial nerve paralysis	________	________
☐ Dizziness or vertigo	________	________

4. Have you ever had any of the following? If so, check the appropriate box, and use the space below to give details of the item checked.

☐ Exposure to loud noises (e.g., gunfire, military service, jackhammer at work, etc.)
☐ Ear surgery (if yes, please list operations below)
☐ Drug treatment that resulted in hearing loss (e.g., chemotherapy, lasix, gentamicin, etc.)
☐ Neurological illness (e.g., seizures, stroke, tumor, infection, etc.)
☐ Ear infections (bacterial or viral)
☐ Injury to ear (skull fracture, etc.)
☐ Meningitis
☐ Radiation therapy to head, face or neck
☐ I wear a hearing aid

5. Please provide explanations or details on any of the boxes you marked in questions 3 or 4.
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6. List all non-ear problems or illnesses that you have (e.g., diabetes, hypertension, rheumatoid arthritis, etc.) and non-ear surgery that you have had. Include a list of medications you have taken to treat these problems.
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7. Is there a **family history** (parents and their brothers and sisters, grandparents, your brothers and sisters, etc. **not** your relatives by marriage) of any of the following? Check all appropriate boxes.

- ☐ Hearing loss in old age
- ☐ Otosclerosis
- ☐ Balance (equilibrium) disorders
- ☐ Hearing problems in childhood or as an adult
- ☐ Deformity of the ear at birth
- ☐ My parents or grandparents are/were related by blood (brother and sister, first or second cousins, etc.)
- ☐ A certain kind of hearing loss runs in my family

8. Please provide explanations or details below on any of the boxes checked in question 7.

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9. Please provide the name(s), addresses and telephone number(s) of your ear, nose, and throat (ENT) doctor(s) and others who have treated you for ear disorders.

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10. Please provide the name(s), addresses and telephone number(s) of your hearing aid dealer(s) and audiologist(s).

11. Please list any facility (e.g., hospital, clinic, etc.) where you have had hearing or balance tests, X-rays (e.g., CT Scan, MRI Scan) of your ears, or ear surgery. Indicate which tests or procedures were done and when.

12. Please choose your ethnic and racial category:

Ethnic Categories:

☐ Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term “Spanish origin” can also be used in addition to “Hispanic or Latino.”
☐ Not Hispanic or Latino

Racial Categories (choose one or more):

☐ American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

☐ Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

☐ Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.”

☐ Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

☐ White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.