

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 HIPAA authorization will complete your bequest. The consent form requires your signature and the signatures of your next-of-kin and two witnesses. 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.
5. 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

Signing the following and the attached HIPAA authorization authorizes the release of your medical records for purposes of including the information in the NIDCD National Temporal Bone, Hearing & Balance Pathology Resource Registry.

MEDICAL RECORDS RELEASE

I hereby authorize the release of my medical records from the doctors, individuals and facilities listed above 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. I also authorize the release of any future medical records pertaining to ear disorders to the Registry.

(Donor's Signature)

(Date Signed)

(Donor's Name)

NATIONAL TEMPORAL BONE DONOR PROGRAM DONOR CONSENT FORM

I, (Please type or print name) _____, hereby make this anatomical gift of my temporal bones.

Optional Brain Donation:

Yes ☐ No ☐ 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.

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, which are estimated to range from 200 to more than 1,000 genes. DNA is the material that makes up your genes and is an “instruction manual” programmed into your cells. It is difficult to extract DNA for genetic studies from temporal bones and related brain tissue; the DNA is often fragmented and contaminated during tissue processing. Therefore, it would be very valuable to obtain the DNA from a clean and uncontaminated sample to enhance the value of the temporal bone studies.

Please consider donating a sample of your DNA obtained via cheek swabs. 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. After replacing the brush back in the sterile container, you can then mail the brushes to the Registry in the prepaid mailer provided. The risks of obtaining the cheek swab are minimal. The procedure is as simple and painless as brushing your teeth. Your cheek swabs will be coded with a random study identifier and the Registry will keep the key code linking your identity to the random study identifier in a secure file. Then the swabs will be stored in a freezer at -70°C. Results of this research may be presented or published for use by the medical or scientific community, but your identity will not be disclosed in publications. Your donation of DNA is entirely optional. You may choose not to donate your DNA from the cheek swab, and instead to only donate your temporal bones and brain.

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

☐ 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.

This gift (temporal bones, brain, and DNA from cheek swab as 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. I understand that these tissues will be removed by any medical doctor, coroner or other qualified person without cost to my estate, my family or my friends. I also authorize the release of all of my medical records including results of post-mortem examination to the Program. This authorization includes any examinations, tests and review of medical history necessary to assure medical acceptability of the donated tissues.

(Donor's Signature)

(Date signed)

(Address)

(City, State, Zip Code)

Witnesses:

(Signature of First Witness)

(Signature of Second Witness)

(Print Names)

(Print Name)

(Address)

(Address)

(City, State, Zip Code)

(City, State, Zip Code)

This is a legal document under the Uniform Anatomical Gift Act or similar laws.
(A copy of this form will be sent to you for your will or funeral instructions)

NATIONAL TEMPORAL BONE DONOR PROGRAM

CONSENT OF NEXT OF KIN

I, _____, am the next of kin of _____
(Please type or print name) (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. I do hereby agree to the removal of these tissues upon the death of this person, as he/she has pledged. I will instruct the doctor in charge, 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.

(Signature of Next of Kin)

(Address)

(Date Signed)

(City, State, Zip Code)

Email address

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:

- (1) the spouse
- (2) an adult son or daughter,
- (3) either parent,
- (4) an adult brother or sister,
- (5) a guardian,
- (6) any other person authorized or under obligation to make funeral arrangements for the deceased.

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

**National Temporal Bone Registry
Massachusetts Eye and Ear
243 Charles Street
Boston, Massachusetts 02114-3096**

**THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)
AUTHORIZATION FORM**

PROTOCOL TITLE: NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry

PROTOCOL NUMBER:

PRINCIPAL INVESTIGATOR: Felipe Santos, M.D.

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” and “NTBR” or “National Temporal Bone Registry” mean the NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry, which is administered by the Massachusetts Eye and Ear.

What is the purpose of using and sharing my protected health information?

You have agreed to:

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

You are making the anatomical gift and sharing the information described above (“protected health information”) so that it can be included in a registry of temporal bone and brain tissues associated with hearing and balance, and related demographic, medical and genetic information that is intended to be used for future research. In order to administer, track, and use your planned and actual anatomical gift and related demographic, medical and genetic information 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.

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.

What protected health information about me will be collected, used and shared with others for purposes of participating in the National Temporal Bone Registry?

We will request the release of your medical records from your health care providers and collect, use and share health information that identifies you, (your “protected health information”) including the following:

- Your demographic information, including, but not limited to, your name, date of birth, date of death, addresses, telephone numbers, and the name, address, telephone number and relationship to your next of kin,

- Medical information, including information provided directly by you and information contained in your medical records from your healthcare providers, including but not limited to physicians, hospitals, laboratories, and audiologists, and
- To the extent that you indicated on the Donor Consent Form, DNA / genetic information.

Who will use or share protected health information about me?

We will use and share your protected health information with:

- People at the NTBR or at institutions contracted by the NTBR to administer the NTBR now or in the future, including individuals who administer and provide oversight of the registry, such as, but not limited to registry managers and support staff, physicians, and oversight committees,
- Institutions or laboratories collaborating with the NTBR for purposes of carrying out the functions of the NTBR, and
- External entities responsible for the regulation, oversight and/or funding of the NTBR.

Some of these people may share your health information with someone else. If they do, the same laws that the NTBR must obey may not apply to those people, and may not protect your health information.

For how long will protected health information about me be collected, used or shared with others?

Since the purpose of the NTBR 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.

Can I change my mind?

If you change your mind later and do not want to make an anatomical gift upon your death of your temporal bones (and if indicated on the donor consent form, 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 information, you need to send a letter to the NTBR 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 on the donor consent form, 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 NTBR. In this case the NTBR 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 NTBR that you have changed your mind:
National Temporal Bone Registry
Care of the Massachusetts Eye and Ear
243 Charles Street
Boston, Massachusetts 02114

If you have any questions, 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

If you'd like to speak to someone **not** involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at **(857) 282-1900**.
The NTBR Coordinator will give you a signed copy of this form.

Summary of privacy rights:

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 indicated on the donor consent form, the entire brain) upon your death to the NTBR. You need to sign this form and the attached donor consent form in order to make the anatomical gift(s) upon your death. Whatever decision you make about making the anatomical gift(s), and allowing the collection, use and sharing of your protected health information for this purpose, will not affect your access to medical care.

AUTHORIZATION, SIGNATURE, DATE, AND IDENTITY OF PERSON SIGNING

The person signing below authorizes the release of his or her medical records by his or her healthcare providers and the collection, use and sharing by the NTBR of his or her protected health information including his or her demographic, medical, and to the extent indicated on the Donor Consent Form, DNA / genetic information.

(Donor's Signature)

(Date signed)

(Donor's Name)

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...”).

[illegible]

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
<input type="checkbox"/> Hearing loss	_____	_____
<input type="checkbox"/> Ear drainage (pus)	_____	_____
<input type="checkbox"/> Tinnitus (noises, ringing, etc.)	_____	_____
<input type="checkbox"/> Ear pain	_____	_____
<input type="checkbox"/> Ear pressure or fullness	_____	_____
<input type="checkbox"/> Facial nerve paralysis	_____	_____
<input type="checkbox"/> 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.

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.

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.

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.

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.

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MEDICAL RECORDS RELEASE

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(Donor's Signature)

(Date Signed)

(Donor's Name)