

**CONSENT AND RESEARCH AUTHORIZATION TO DONATE [SELECT ALL THAT APPLY: TISSUE/BIOLOGICAL SPECIMEN/RESEARCH DATA] FOR FUTURE RESEARCH PURPOSES
YALE UNIVERSITY SCHOOL OF MEDICINE**

INSTRUCTIONS: THIS TEMPLATE IS DESIGNED TO PROVIDE GUIDANCE IN THE DEVELOPMENT OF A COMPOUND CONSENT/RESEARCH AUTHORIZATION FORM FOR PROTOCOLS WHICH AIM TO DEVELOP A REPOSITORY OF DATA OR BIOLOGICAL SAMPLES. ITALICIZED SECTIONS IN SQUARE BRACKETS MUST BE EDITED FOR YOUR SPECIFIC PROTOCOL. NOT ALL SECTIONS WILL APPLY TO YOUR PROTOCOL THEREFORE DELETE THOSE WHICH DO NOT APPLY. DELETE THIS INSTRUCTION PARAGRAPH PRIOR TO SUBMISSION TO THE HIC.

Title:

Principal Investigator:

Funding Source:

[Tissue/Biological Specimen/Research Data] Donation

You are invited to donate your *[tissue/biological specimen/research data]* to a research *[tissue/specimen/data]* database or bank where it can be used for future research projects. The *[tissue/specimen/data]* collected in this bank will be used by researchers *[or specify department, section researchers]* to study *[specify in broad terms what the data will be used for]*:

Examples:

- *neurological diseases, illnesses and conditions.*
- *the biology, pathology, and treatment of cancer.*
- *reasons why people may develop diabetes, how to help treat the disease and ways that may prevent it.*

In order to decide whether or not you wish to donate your *[tissue/biological specimen/research data]* for future research, you should know enough about the risks and benefits to make an informed decision. This form gives you information about the research bank and how the *[tissue/specimen/data]* may be used. Once you understand the *[tissue/specimen/data]* donation and banking process, you will be asked if you wish to take part; if so, you will be asked to sign this form.

How Your [Tissue/Specimen/Data] Gets Into the Databank

The *[tissue/specimen/research data]* that you have donated for this research study will be sent to the *[tissue/specimen/data]* bank along with the following information about you which will be entered into a computer (the database) that is used for *[clinical/research]* purposes.

The following information about you will be entered into the database: *[Specify the data that will be entered. Examples: name, the date that clinical or research procedures were conducted, the*

results from laboratory, x-ray, scanning or other procedures, medical record number, date of birth, race, sex information from medical history and physical examination].

How Your [Tissue/Specimen/Data] Gets Used for Future Research

The researchers who are responsible for entering and protecting your information in the database will use your information to: *[State the research purposes as noted in the first paragraph, i.e., studying neurological diseases].*

Whenever possible, the researchers will use your information in a de-identified manner. De-identified means that the researchers will use your information without knowing your identity. In some cases they may use some identifying information about you for research purposes, subject to an approval process undertaken by the Yale Human Investigation Committee (HIC). (The HIC is an ethics committee that reviews, approves and monitors research on human subjects.) At times the researchers will use your information with a code, instead of your name; the code would allow results of the research to be linked back to you. *[If applicable, indicate any other entities, investigators, or institutions that may have access to the data, for what purposes, under what types of approval, and how the data will be shared with these other entities, investigators, or institutions: identified or de-identified.]*

Risks and Inconveniences

There are no physical risks to you for donating and storing your *[tissue/specimen/data]* for use in future research studies. *[If applicable state whether the subject will or will not be required to give any more (tissue/specimen/data) than that which will be taken during (this research study/for clinical purposes/surgery, etc.)]* In the unlikely chance that your information is viewed by someone outside the research team however, there is a risk of breach of confidentiality (see the Confidentiality section for an explanation of how your information is protected).

[Insert for DNA or other genetic testing: For research conducted on your DNA or other genetic material that has not been de-identified, certain risks can arise if genetic information about you is made known to others.

{Version 1} Risks to you may include discrimination in insurance coverage, employment, or educational opportunities, and if one of your family members also participates in the study, undisclosed family relationships such as different fathers might be found. Also, variation in some genes we will be studying in your DNA may be shown at some point in the future to be related to illness. Since the results of these genetic tests may allow prediction of risk of illness in some cases, we will keep the results confidential (only scientists working on this research project will know the results). We will not make any of our laboratory results available to you, nor will we add them to your medical record. (If you want to know your risks for genetic diseases, we will refer you to a genetic counselor.)]

{Version 2} Known risks may include but are not limited to issues related to insurability or employability, or that family members may become aware of information related to the study and

you, or that you may become aware of information about yourself or family members that you would have preferred not to know.]

Benefits

You will not receive any direct benefit for donating your *[tissue/specimen/data]* for future research use. We hope that the information we learn in future research studies will increase our knowledge of human health and that this information will lead to better prevention, diagnoses and treatments in the future.

Economic Considerations

You will not receive any payments for donating your *[tissue/specimen/research data]* into the research data bank.

[Tissue/Specimen/Data] obtained from you in this research may be used to establish a *[product or information]* that could be patented and licensed by Yale University. If materials from the bank were shared with other investigators, the research and patenting might reach outside Yale University. In either case, there are no plans to provide financial compensation to you should this occur. Your *[Tissue/Specimen/Data]* will not be sold.

Confidentiality

All identifiable information that is obtained in connection with this research study will remain confidential. Information about you will be kept *[specify security measures: Example: in a locked, password-protected computer, not connected to the internet, in a locked cabinet, etc.]*. Only the members of the research *[tissue/specimen/data]* bank staff and researchers who have received the approval of the HIC to use your *[tissue/specimen/data]* will know your identity. *[if applicable, indicate if the information will be shared with other investigators either within Yale or outside of Yale, and if they will have access to confidential and identifiable data.]* When the results of future research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent is obtained.

Representatives from *[indicate what agencies if any will be able to inspect the study records, such as the NIH, or FDA]* and from the HIC may inspect study records during auditing procedures. However, these individuals are required to keep all donor information confidential.

Voluntary Participation and Withdrawal

You are free to choose not to donate your *[tissue/specimen/data]* to research and if you do become a donor you are free to change your mind at any time, but the researchers may still use the information collected before you changed your mind in order to complete the research that has already started. The researchers will anonymize the *[tissue/specimen/data]* by removing and destroying all identifiers and links to identifiers so that it can not be associated with you, but the researchers will not destroy the *[tissue/specimen/data]*.

If you choose not to allow your information/samples to be stored and used, or if you withdraw your permission, this will not harm your relationship with the study doctors, with Yale University or Yale-New Haven Hospital.

This form and your permission will never expire unless you change your mind and withdraw it. To withdraw your permission to use your information, please write to [*Enter name and address of the data repository's principal investigator*] at the Yale University
_____ New Haven, CT 06520.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this donation of information and/or specimens and the consent form carefully – as long as you feel is necessary – before you make a decision.

Privacy Rights

The health-related information that we gather about you in this study is personal. The researchers are required by law to protect the privacy of information known as protected health information (PHI). All reasonable efforts will be made to protect the confidentiality of your PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Despite these protections, there is a possibility that information about you could be used or disclosed in a way that it will no longer be protected.

By signing this form, you give permission for the researchers to store and use and/or disclose the information in this research database. You have a right to refuse to sign this form. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form. Information about you gathered during your clinical care or during this research study [*choose one or both*] will not be placed into the research data bank described in this form or used for future research if you do not sign this form.

Authorization

I have read (or someone has read to me) this Consent and Authorization Form to donate [tissue/specimen/research data] for future research purposes and have decided to donate my [tissue/specimen/data] to the [named Bank]. The general purposes of this donation, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. By signing below, I give permission for the described uses and disclosures of my information. My signature also indicates that I have received a copy of this consent/authorization form.

CHECK ONE: [THIS SECTION IS OPTIONAL]

___ No, I do not wish to donate my [tissue/specimen/research data] to the [named Bank] for research.

___ Yes, I do wish to donate my [tissue/specimen/research data] to the [named Bank] only for the purposes of described above.

___ Yes, I do wish to donate my [tissue/specimen/research data] **that has been de-identified** to the [named Bank] for future, undefined research which must be approved by a research ethics committee.

___ Yes, I do wish to donate my [tissue/research data] for future research, but if the aim of the project is different than the aim of this bank, contact me first for my permission:
Tel. Number: _____.

Signature of Subject or Personal Representative Date

Print Name of Subject or Personal Representative Description of Representative's Authority

Signature of Principal Investigator Date Received

or

Signature of Person Obtaining Consent Date

CONTACT INFORMATION

The contact information of the subject or personal representative who signed this form should be filled in below.

Address:

Telephone:

_____ (daytime)
_____ (evening)

Email Address (optional):

If you have further questions about this project, you may contact the Principal Investigator, [Enter name and Phone number]. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688. If after you have signed this form you have any questions about your rights to confidentiality, please contact the Yale Privacy Officer at (203) 436-3650.

***THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX
HAS BEEN COMPLETED BY THE YALE HUMAN INVESTIGATION COMMITTEE OFFICE***

<p>THIS FORM IS VALID ONLY FROM: _____ THROUGH: _____</p> <p>HIC PROTOCOL #: _____</p> <p>INITIALED: _____</p>

***THE SUBJECT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED
WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.***