

> 655 West Baltimore Street, 13-013 BRB Baltimore, MD 21201-1559

Phone: (800) 847-1539 | (410) 706-1755

Fax: (410) 706-2128

Email: btbumab@som.umaryland.edu Researchers www.btbank.org Families www.btbankfamily.org

We want to thank you for your support of University of Maryland Brain & Tissue Bank. Each registration represents a great gesture of care and concern for future generations.

As you know, one of the most vital aspects of a tissue donation is advance preparation. The successful donation rests on swift and thorough communication between many professionals and family members. If we have no prior notice, or if we are not called until after the donor has passed away, we may not be able to Join forces quickly enough to retrieve the tissue. All tissue must be retrieved within a twenty-four-hour period, the ideal period being under eight hours. After the passing of a day, the tissue has lost its usefulness for research. Considering the depth of thought and commitment that goes into a decision to donate, and the unique and irreplaceable nature of donated tissue, each lost donation is a blow to research and humanity which is difficult to measure. For these reasons, we emphasize the importance of advanced planning and immediate notification in cases of death or illness.

At times, some interested donors are ineligible for donation. The exclusions include but are not limited to any individual who has a history of cancer, communicable diseases (i.e. hepatitis, HIV, tuberculosis), and any undiagnosed illnesses.

Included in this packet you will find several forms related to tissue donation. What follows is a description of each and its relationship to tissue donation.

THE RESEARCH CONSENT FORM; This form must be signed in order for the Brain and Tissue Bank to be able to collect any tissue from a donor. It should be noted that the donor holds the right to withdraw consent for donation for any reason prior to tissue recovery. This form must be returned to the Brain and Tissue Bank for the registration to be in effect. Feel free to retain a copy for your records.

HIPAA Authorization Form & ATTACHMENT A (MEDICAL RECORDS CONSENT FORM); As you can imagine, researchers who use tissue need to have some background of the donor's illness, such as date of diagnosis, duration of illness and severity of symptoms. In some cases, this information may be collected by the Brain and Tissue Bank from the registered donor's primary physician well in advance of the time of death. Please remember that all information passed along to researchers is done so confidentially without personal identifiers.

THE REGISTRATION FORM AND QUESTIONNAIRE: The registration and questionnaire forms, which is part of the attached packet, supplies us with some much-needed information. This information is not asked for on any of the other forms. Please complete the registration form and send this in to us; please return this form as soon as the decision to register as a donor has been made.

Please note that only the brain and affected organs can be donated. This is not a whole-body donation program. The University of Maryland Brain Bank is responsible for all costs related to tissue donation but does not cover funeral expenses.

We hope that this information is clear to you. Please remember we are always available, no matter how small the question or concern. Advanced planning, we have learned, is very important to the success of a tissue donation, but communication and trust are even more important.

Our telephone number is: 1-800-847-1539.

UNIVERSITY OF MARYLAND BRAIN AND TISSUE BANK - An Affiliate of the NIH NeuroBioBank: https://neurobiobank.nih.gov

OMAS G. BLANCHARD Ph.D. LING LI, M.D RUDY J. CASTELLANI, MI ANTHONY WELDON, JE

Neuropathologists

JOHN COTTRELL, MS, PA, ASCP

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**Project Coordinators** 

Tissue Coordinators





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> > Researchers www.btbankerg Famil'os www.btbanklamily.org

# **Donor Registration Form**

The University of Maryland Brain and Tissue Bank for Developmental Disorders

TISSUE DONOR	NEXT OF KIN	
TRST NAME:	NAME:	
MIDDLE NAME:	RELATIONSHIP TO DONOR:	
AST NAME:		
STREET ADDRESS:	STREET ADDRESS:	
CITY:	CITY:	
STATE: ZIP CODE:	STATE: ZIP CODE:	
PHONE:	PHONE:	
DATE OF BIRTH: PLACE OF BIRTH:	FAX:	
MALE   FEMALE	EMAIL:	
RACE/ETHNICITY (PLEASE CIRCLE ONE): African American Caucasian Asian Hispanic Other	OTHER:	
NAME OF DISORDER:	DATE DIAGNOSES:	

UNIVERSITY OF MARYLAND BRAIN AND TISSUE BANK - An Affiliate of the NIH NeuroBloBank: https://neuroblobank.nih.gov

H. RONALD ZIELKE, PhD Director RUDY J. CASTELLANI, MD ANA RUBIO, MD, PhD Neurocathologists ANTHONY WELDON, JR.
Project Coordinator

JOHN COTTRELL, MS, PA, ASCP ROBERT M. JOHNSON, BS Tissue Coordinators

wish to register myself (or dependent minor) as a tissue

KIMBERLY ANDERSON Research Specialist, Clinical





## RESEARCH CONSENT FORM

**Protocol Title:** 

University of Maryland Brain and Tissue Bank

- Autopsy Consent

Study No.: 00042077

Principal Investigator: Thomas G. Blanchard, Ph. D. 410-706-1755

Sponsor: National Institutes of Health

This is a research study. Your participation is voluntary and is based on your decision to participate. The staff of the University of Maryland Brain and Tissue Bank is available at all times to answer questions regarding the project and your participation.

Under certain circumstance you may be giving consent for someone other than yourself to participate in this project, for example a child or someone unable to provide consent themselves or someone who is deceased. Then the word "you" in this consent form means that person.

#### PURPOSE OF STUDY

- Human tissue is required for studies that may lead to development of new treatments, testing, and prevention of neurologic and developmental disorders. The University of Maryland Brain and Tissue Bank was established by the National Institutes of Health to serve as a repository of rare tissues collected at the time of death.
- The Brain and Tissue Bank collects and distributes tissue from individuals of any age as part of its role as a member of the NIH NeuroBioBank network.
- The purpose of the Brain and Tissue Bank is to systematically collect, store, and distribute brain and other tissues to researchers worldwide who are dedicated to improving the understanding, care and treatment of individuals with developmental and neurological disorders.
- Any individual who has such a disorder, or is related to someone with such a disorder, is
  eligible to donate tissue. In addition, individuals without any disorder may donate tissue
  to serve as control tissue.
- You are being invited to donate tissue and be one of approximately 5000 participants in this tissue donation program at the University of Maryland.





#### **PROCEDURES**

- At or near the time of death, the next of kin or a designated person contacts the Brain and Tissue Bank by telephone to inform the Bank that the tissue donor is near death or has died. The recovery of tissue will be arranged by the staff of the Brain and Tissue Bank through medical institutions and funeral homes once consent for tissue donation has been received. There is no cost to the tissue donor and/or family for donation of tissue.
- The tissue to be collected may include the brain, portions of body organs such as heart, liver, kidney, lung, spine and other tissues affected by the disorder. A skin biopsy may also be recovered to develop fibroblast cell cultures that could be stored frozen for use in the future.
- If there are any tissues/organs that you do not want to donate, please list the tissues/organs

  \_\_\_\_\_\_. If there are no restrictions to what tissue may be collected, then write "None" on the following line:\_\_\_\_\_\_.
- Tissue collection will be arranged within 24 hours. The legal next of kin will be notified if a longer time period is needed.
- Since the Bank depends on the availability of pathologists near the site of the deceased, the Bank cannot give assurance that they will be able to find a pathologist for all cases.
- The tissue will be stored and distributed to qualified researchers by the Bank located at the University of Maryland, Baltimore. The National Institutes of Health may designate successor banks to receive the tissue.
- Donors are de-identified and assigned unique identification numbers. The identity of the
  donor is retained by the Bank. The legal next of kin may request that the tissue be
  disposed of by appropriate and legal processes. Likewise, on the request of the legal next
  of kin, all medical records will be destroyed. the tissue will be disposed of by appropriate
  and legal processes.
- The tissue will be used solely in medical research related to the disorder of the donor. The specific research projects may be microscopic examination of the tissue, analysis of RNA, DNA or proteins. The studies are designed by the researchers requesting the tissue, although the staff of the Brain and Tissue Bank review the projects for feasibility and evaluate the credentials of the researcher. The use of donated tissue may include,
  - Analyzing cells or tissue for genetic information using sequencing or other techniques. Such information may be restricted to specific genes or may include the sequencing of the donor's entire genome.
  - Treating some cells so that they can grow forever in the laboratory and can be studied for many years. Cells may be stored indefinitely, and some may also be





transformed into different kinds of cells. For example, skin cells could be transformed into nerve cells or stem cells. These transformed cells are important to medical research; however, they would not be transplanted into anyone or used for commercial purposes.

- De-identified data collected from this research will be shared in publicly accessible
  scientific databases that anyone can access. These databases will be kept for a long
  time and researchers around the world will use these data sets for countless future
  studies. The results of research using the donated tissue may be also shared on public
  scientific websites, in scientific meetings, and in scientific journals.
- This authorization means that your family member's genetic information and related data may be shared with other researchers, but this will not include any information that could personally identify you or your family member. It is possible that your family member's genetic information could be used to identify him/her when combined with information from other sources, but we believe this is unlikely to happen. We do not think that there will be further risks to your privacy by sharing your family member's genetic data with these databanks; however, we cannot predict how genetic information will be used in the future.
- It is not possible to predict how soon the tissue will be used for research since it depends on when sufficient number of cases for a particular disorder become available and when a researcher requests tissue from the Bank. Therefore, the Bank is not able to track research results for tissue from a particular donor and provide those results to the family.

#### WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

• If you take part in this research, the next of kin or the person with power of attorney will be responsible to notify the Bank at or near the time when a tissue donor dies. The Bank will also ask for access to medical records that related to the disorder of the donor.

#### POTENTIAL RISKS/DISCOMFORTS:

- Tissue donation after death is not considered to inflict pain or risk to the decedent.
- Tissue donation does not interfere with a normal viewing.
- All costs related to tissue recovery are paid by the Bank.





- There is a psychological risk in that the donor may not meet the criteria of the project such as an extended time period after death, or that the donor has developed complicating illnesses that would interfere in the research on the tissue, or the inability of the staff of the Bank to recruit a pathologist to recover the tissue.
- Loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet. Electronic data will be password-protected.
- There may be risks in this study which are not yet known.

#### POTENTIAL BENEFITS

- You will receive no direct benefit from participation in this tissue donation program. However, your participation may help the investigators better understand the underlying basis for developmental disorders. There also will be no direct benefit to the donor of the tissue. However, research findings may benefit the health of future generations.
- If the tissue donor is your child, that you need to decide if your child's participation in this research study is in your child's best interest.

### ALTERNATIVES TO PARTICIPATION

• This is not a treatment study. Your alternative is to not take part. If you choose not to take part and if you are a patient at the University of Maryland, Baltimore, your healthcare at University of Maryland, Baltimore will not be affected.

#### **COSTS TO PARTICIPANTS**

• It will not cost you anything to take part in this study. The Bank will pay all charges related to tissue recovery.

#### CONFIDENTIALITY AND ACCESS TO RECORDS

• Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. If NIH transfers the responsibility of the Brain and Tissue Bank to another organization, the confidential records will also be transferred. That organization is expected to agree to the same confidentiality rules as the University of Maryland, Baltimore site



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• The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

#### RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Thomas G. Blanchard, Ph.D., 410-706-1755.
- If you withdraw from this study, already collected data may not be removed from the study database. For example, if you donated surgical specimens and then withdraw your consent for donating autopsy tissue, data obtained with the surgical tissue will be retained.
- You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

#### CAN I BE REMOVED FROM THE RESEARCH?

• The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to sign tissue donation form, access to medical records form, or if you develop additional complicating disorders that diminishes the value of the tissue for research. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

#### UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

• The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.



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- The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.
- If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine Human Research Protections Office BioPark I 800 W. Baltimore Street, Suite 100 Baltimore, MD 21201 410-706-5037





Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign below.

If Participant is a living adult who is registering as a future tissue donor, please complete section 1.

If Participant is a living minor child or dependent adult, whose parent or guardian is registering the participant as a future tissue donor, please complete section 2.

If Participant is deceased, please complete section 3.

tion 1:			
Name of Participant (Print)	_		
Signature of Participant	Date	Phone Number	of Participant
Witness (Print)	Witness Sig	nature	Date
ephone Number of Witness			







Name of Minor Child or Dependent Adult Particip	oant (Print)	Date of Birth
Name of Parent/Guardian (Print)		Relation to Participant
Signature of Parent/Guardian (Print)	Date	Telephone number of Parent/Guardian
Section 3:		
Name of Deceased Participant (Print)		_
Name of Kin/Guardian (Print)	Relation to Deceased Partici	
Signature of Kin/Guardian	Date	
Telephone number of Kin/Guardian		
Investigator or Designee of the Brain and Tissue	Bank Obta	ining Consent Signature
Date:		

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Section 2:



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# ATTACHMENT A TO THE HIPAA AUTHORIZATION FORM

As a means to better understand and evaluate the causes of carious developmental disorders, the University of Maryland Brain and Tissue Bank requests your permission to abstract and/or copy information from your medical records. Please provide the necessary contact information.

NAME OF PHYSICIAN:		
PHYSICIAN ADDRESS:		4,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
PHYSICIAN ADDRESS:		
CITY:	STATE:	ZIP:
PHONE:	FAX:	
NAME OF PHYSICIAN:		
PHYSICIAN ADDRESS:		
PHYSICIAN ADDRESS:		
CITY:	STATE:	ZIP:
PHONE:	FAX:	
NAME OF PHYSICIAN:		
PHYSICIAN ADDRESS:		
PHYSICIAN ADDRESS:		
CITY:	STATE:	ZIP:
PHONE:	FAX:	
NAME OF DONOR:		
SIGNATURE OF DONOR OR GUARDIAN	<u>l:</u>	
RELATIONSHIP TO DONOR:		, <u>() - () ) () () () () () () () () () () () (</u>
DONORS DATE OF BIRTH:		

ALL INFORMATION WILL BE KEPT CONFIDENTIAL. NEITHER THE DONOR NOR THE PHYSICIAN'S NAME WILL BE PROVIDED TO RESEARCHERS.

UNIVERSITY OF MARYLAND BRAIN AND TISSUE BANK - An Affiliate of the NIH NeuroBioBank: https://neurobiobank.nih.gov

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SHRA LAWSON, BA

ALEXANDRA LEFEVRE, MS, PA, ASCP Research Specialist Clinical

Director

Project Coordinators

Tissue Coordinators



# Health Insurance Portability and Accountability Act (HIPAA) AUTHORIZATION TO OBTAIN, USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Volunteer:			
Date of Birth:	Medical Record Number:		
Name of this Research Study:	University of Maryland brain and tissue bank		
UMB IRB Approval Number:	HP-00042077		
Researcher's Name:	THOMAS BLANCHARD, PH.D.		
RESEARCHER'S CONTACT INFORMATION:	Department of Pediatrics  University of Maryland School of Medicine (UMSOM) 655 W. Baltimore St., Rm. 13-013 BRB 1-800-847-1539; 410-706-1755		

This research study will use health information that identifies you/your child. If you/your child agree to participate, this researcher will use just the health information listed below.

# THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- Medical records and clinical test results.
- School records pertaining to clinical tests.

Federal laws require this researcher to protect the privacy of this health information. He/she will share it only with the people and groups described here.

# PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. Blanchard and his research team.
- The sponsor of the study, or its agents, such as data repositories or contract research organizations.
- Organization that will coordinate health care compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); and the University of Maryland Medical System (UMMS).

# THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.

To revoke this Authorization, send a letter to this researcher stating your decision. He/she will stop collecting health information about you/your child. This researcher might not allow you/your child to continue in this study. He/she can use or share health information already gathered.

# Health Insurance Portability and Accountability Act (HIPAA) AUTHORIZATION TO OBTAIN, USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

#### ADDITIONAL INFORMATION:

• You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you/your child receive at:

o University Physicians, Inc. (UPI)

o University of Maryland Medical System (UMMS)

It will not cause any loss of benefits to which you/your child are otherwise entitled.

 Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, UPI, or UMMS to give it to them.

• This researcher will take reasonable steps to protect your/your child's health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, UPI, or UMMS.

Except for certain special cases, you/your child have the right to a copy of your/your child's health
information created during this research study. You may have to wait until the study ends. Ask this
research how to get a copy of this information from him/her.

My signature indicates that I authorize the use and sharing of my/my child's protected health information for the purposes described above. I also permit my doctors and other health care providers to share my/my child's protected health information with this researcher for the purposes described above.

Signature:	Date:
Name (printed)	
Privacy Questions? Call the UMSOM Privacy Official rights and protections under privacy rules.	(410-706-0337) with questions about your/your child's
Other Questions? Call the researcher named on this for	rm with any other questions.



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#### **Adult Questionnaire:**

Today's Date:		
Donor's Name:	Andrew Province and the second	<del></del>
Date of Birth:		
Name of person completing this:		
Relationship to donor:	Phone Number:	
Address:		
ddress:		<del></del>
onfirmation of Donor's Dia	agnosis:	
What is the donor's diagnosis?		
When was the Diagnosis made? Ye	ar	
How old was the donor at diagnosis	?years	
Who made the diagnosis?	N	
Was the donor followed by a specia	alist?	
What were the doctors' names who	are/were taking care of the donor?	
Did the donor have tests to confirm	the diagnosis?	
If yes, what were those tests?		
harden de		
is there anyone else in the family wit	ih a similar condition? Yes	No If yes
please list the relationship of th	nose individuals to the donor:	
**************************************		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
How old was the donor when he/she	nacead away?	
What were you told was the cause of		

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ALEXANDRA LEFEVRE, MS, PA, ASCP

Resenreh Specialist Clinical

Neuropathologists

Project Coordinators

Tissue Coordinators



How well did you know the donor? Interacted with donor:			
m viii)	Annuaily	Did the	
donor have any history of: Cancer:	Yeş	No	Do not know
High blood pressure:	Yes	No	Do not know
Diabetes:	Yes	No	Do not know
If yes, did the donor take a pill or use insulin?	<u> </u>		Dan et les aux
Stroke:	Yes Yes	No No	Do not know  Do not know
Heart disease:	Yes	No	Do not know
Seizures or epilepsy:	Yes	No	Do not know
Migraines:	Yes	No	Do not know
Communicable or infectious diseases:	Yes	No	Do not know
Seasonal or environmental allergies:		Yes	No
Was the donor seeing a doctor for any of these medical conditions?		162	NO
n yes, which conductors		the dono	 r have anv othe
edical conditions? Yes No			•
If yes, what were they?			
Did the donor have any surgeries?		Yes	No
If yes, what were they and when did they occur?			• • • • • • • • • • • • • • • • • • • •
And what conditions were the medications being taken for?			
Did the donor have any allergies?		Yes	No
If yes, what were they?			
Was the donor taking any non-prescription dietary supplement		Yes	No
yes, please list			
Did the donor smoke cigarettes?		Yes	No
If yes, how many packs per day? For how many	years?_	***************************************	
Did the donor drink alcohol?		Yes	No
If yes, how many drinks? Circle one:			
One drink/mo. One drink/week One drink/day	2-3 drini	ks/day	More
Did the donor drink alcohol to excess? If yes, estimate h	ow much	: <u></u>	·
Did the donor use "illegal drugs" such as cocaine/heroin/etc.?		Yes	No
If yes, what substances did the donor take?			
Has the donor been in the hospital as a patient in the last 10 years.	ears?	Yes	No
If yes, what for and when?			
Did the donor have any childhood illnesses? If yes, what were			
Did tile deliet tidae milk ettiminen ittionnen. it keel titiet tiete	···-//		What kind of

was the donor in school? Circle One:

Ave	rage Good Stru	ggie			
Did the dono	r have help like an IEP (indi	vidual Educational Plar	i)? Yes	No	
Did the dono	Did the donor graduate from high school?		Yes	No	
Did the dono	Did the donor graduate from college?  Yes  How many years of school/education after high school?			No	
How many y					
What educat	ional degrees did the donor	achieve?			
What did the	donor do for a living or wha	t profession did he/she	have?		
lf m	ore than one profession, list	here and how many ye	ears in each:		•
	r lose any cognitive abilities		Yes	No	<del></del>
If ye	es, which abilities or skills we	ere lost?			<b></b>
	Did the donor receive disability? Yes If yes, for what?				if there is a
nlly history of:					
Cancer	Heart disease	Stroke Seizures I	ligh blood pres	sure	Diabete
Migraines	Learning disabilities	Autism	Birth defects	Pregn	ancy loss
Condition sin	nilar to that of the donor	Other			
is the donor	a veteran?			Yes	No
lf ye	s, which branch of service?	Marine Ma			
Did the dono	Did the donor have a history of psychiatric or mental illness?			Yes	No
Did the donor	Did the donor have a history of mood problems?			Yes	No
	If yes, please elaborate:				
Was the done	Was the donor taking any medications for mood or behavior?			Yes	No
lf ye	s, please list:				
Is there a fan	Is there a family history of mental illness or substance abuse?		Yes	No	
If ye	s, please list:				<del></del>
Is there any	thing else about the donor's	history that is importar	it or that you thi	ink we sh	ould know
					<del>,</del>
h					Thank y

for taking the time to complete this.

## Please return the completed form to:

University of Maryland Brain and Tissue Bank Department of Pediatrics 655 W. Baltimore Street, Rm. 13-013 BRB Baltimore, MD 21201