



Biospecimens for Research Project Guide



BEFORE YOU BEGIN

About the Biospecimens for Research Project Guide

This guide provides an overview of current research projects requiring donated organs and tissues (biospecimens).

Definitions

Each audience LifeNet Health team members communicate with requires different information to best understand the significance of our research projects. The levels of detail and their audiences are listed below:

- (1) **Community Education Level** – This language is intended to explain research projects to potential donor families and the community at large. This overview includes less medical and technical details to explain the projects.

Audience: Donor Center, Family Approach Team, and Donor Family Services

- (2) **Intermediate Level** – This language is intended to explain projects to external partners such as other Organ Procurement Organizations (OPOs), funeral home staff, etc.

Audience: Clinical Recovery Account Managers (CRAMs), Donor Relations Account Managers (DRAMs), OPO team, and Tissue Recovery teams

- (3) **Comprehensive/Technical Level** - This language is intended to be used for technical communication with physicians and medical examiners.

Audience: CRAMs, Tissue Recovery, DRAMs, Donor Center, and OPO team members

- (4) **Project Details** – This section identifies specific needs for each research project such as supplies, training needed, and target partners. This information will assist in completing projects in a timely manner, maximizing current partner potential research donors, and identify new key partners to aid in research project completion.

Audience: CRAMs, Tissue Recovery, DRAMs, Donor Center, and OPO team members



Using the Research Guide

Determine what type of research project is of interest to you. Select a heading or sub-heading from the table of contents to jump to that section.

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BRAIN PROJECTS

Non-diseased Controls

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others and meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

Non- Disease or control brains help the research team identify differences between a healthy, or unaffected donor with those who suffer from specific disease processes like “the target project name”. This allows the team to compare and identify differences in order to study what may be different in those instances and considered a critical part of any study so that a baseline can be established.

- One brain can potentially help in providing information in hundreds of studies. The number of people helped by your participation is countless as the information provided is invaluable.
- These research projects are in need of donors without disease from people of all different ethnicities, genders, geographical location, and sexual, orientation. Therefore, your loved one has such an important opportunity to donate.

Applications

Non-Disease donors may be able to help people who suffer from significant medical conditions. Some examples of how your loved one may help are, Alzheimer’s, Lew body dementia, frontotemporal disorders, mixed dementia, Parkinson’s, Huntington’s disease, Autism, trauma, and stroke.

(2) Intermediate Level

Introduction

Brain donation helps researchers study brain disorders, such as Alzheimer’s disease/related dementias, Traumatic Brain Injuries, PTSD, Autism, and other brain injuries that affect millions of people. One donated brain can make a huge impact, potentially providing information for hundreds of studies. But many brains are needed from diverse populations and ages to help researchers investigate the causes of disease and to develop more effective therapies that can then be applied broadly.

Summary

People choose to donate their brains after death for various reasons, but one thing is true for everyone: Brain donation for research is truly a generous gift. A critical method for researchers is to compare healthy brains to those affected by neurodegenerative disease, in order to learn more about the underlying biology that causes brain disease. Researchers learn the most from the brains of people who have participated in studies while they’re still alive. This allows researchers to track changes in memory, thinking, language, and behavior

over time and to gather information on environmental and biological factors. The more researchers know about a brain donor, the more they can learn about the relationships among cognitive test results, biomarkers such as blood tests and brain scans, and the changes detected in the donor brain tissue. All of this information helps them gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

LifeNet Health works closely with many organizations currently studying brain diseases and injuries including: The Center for Neuroscience and Regenerative Medicine (CNRM), The Uniformed Services University, and the National Institute of Health. As a company, we are committed to collaborating and working towards cures and therapies for those affected by the various ailments.

Applications

Non-Diseased control brains to assist research into PTSD, TBIs, Alzheimer's Disease & related dementias, Autism and other brain/neurological disorders and diseases.

(3) Comprehensive/Technical Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For others, the main goal is to have a positive impact on their community and future generations through scientific studies. Sometimes, family members want to know, for certain, whether their deceased loved one had Alzheimer's disease or if something else caused the dementia. Currently, it is still true that only by examining the brain after death under a microscope is a full diagnosis of Alzheimer's or another disorder possible. When donating their brain, there is no cost to the individual's family for the donation procedure.

One significant benefit of brain donation often catches families by surprise, and that is a sense of solace. Despite losing a loved one, some are comforted by knowing that this action may have a broad, positive impact on public health, disease research and wellness for years to come.

Whatever the reasons, one thing is true for everyone: Brain donation is a generous gift. Researchers use donated brain tissue to study brain diseases that affect millions of people and include Alzheimer's disease, Lewy body dementia, frontotemporal disorders, mixed dementia, Parkinson's, and Huntington's disease, Autism, as well as brain injuries such as trauma and stroke.

Researchers learn the most from the brains of people who have participated in studies while they're still alive. This allows researchers to track changes in memory, thinking, language, and behavior over time and to gather information on environmental and biological factors. The more researchers know about a brain donor, the more they can learn about the relationships among cognitive test results, biomarkers such as blood tests and brain scans, and the changes detected in the donor brain tissue. All this information helps them gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

Brain donation helps researchers study brain disorders, such as Alzheimer's disease and related dementias, that affect millions of people. This project will help you learn about why people donate their brains, the process of brain donation, and how you can enroll to help make this generous gift.

Our brains are amazing and intricate networks that help us think, love, and breathe. But sometimes things go awry and cause brain disorders, such as Alzheimer's disease, related dementias, PTSD, Autism, or injuries from traumatic brain injuries. By studying the brains of people who have died, both those who had a brain disorder and those who were healthy during life, researchers learn more about how types of dementia affect the brain and how we might better treat and prevent them. Brain donation provides the opportunity to help researchers better understand these disorders, which can lead to improved treatments for future generations.

While many people think that signing up to be an organ and tissue donor includes donating their brain, the purpose and the process of brain donation are different. Rather than helping to keep others alive through kidney or heart donation, brain donation helps advance scientific research. One donated brain can make a huge impact, potentially providing information for hundreds of studies. Many brains are needed from diverse populations and ages to help researchers investigate the causes of disease and to develop more effective therapies that can then be applied broadly.

Summary

Provide a baseline for disease research and allow for a greater understanding of brain function and biomarker discovery. Both healthy brains and brains affected by diseases and injuries are needed for research. Comparing healthy brains to those affected by neurodegenerative disease/injury is a critical method for researchers to learn more about the underlying biology that causes brain damage and disease. It is important to receive brain donations from people who have a brain disorder and those with healthy brains. In fact, both are needed for this important research. Donations from people without symptoms of brain disease/damage provide all-important insights into what's considered normal aging of the brain and certain brain mechanisms that may protect against disease. Put simply, healthy brains provide researchers with critical models for comparison in understanding what's gone wrong in cases of disease.

Researchers also need brains from a diverse group of people representing, for example, different races and ethnicities, genders, geographic locations, and sexual orientations.

Applications

Non-Diseased control brains to assist research into PTSD, TBIs, Alzheimer's Disease & her related dementias, Autism and other brain/neurological disorders and diseases.

(4) Project Details

Estimated Length of Project	5+ years
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	n/a
Number of Donations Needed	Varies depending on researcher needs
Target Partners	Medical Examiners/Coroners General Hospitals Specialized Hospitals such as VA Hospice
External OPOs:	Experienced and Non-experienced
Materials Required:	yes
Recovery Supplies:	May vary
Training Materials/Recovery Protocols:	Recovery Spec Sheets, training videos, training sign-off sheets
Education	Understanding of the end use and recovery parameters
Recovery Parameters	
Postmortem Interval/Delivery Time:	If they're fixed it'll be 24 hours. Fresh brains are generally to be recovered and delivered by the 36-hour mark
Institutional Review Board (IRB)	Duke and CNRM
Department-specific	n/a

Traumatic Brain Injury

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others. They meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

Traumatic Injury project allows the research team to find way to improve the lives of members who have suffered a Traumatic Brain Injury (TBI). This study allows the team to evaluate the cells of a brain exposed to blast injuries with military members that did not suffer a blast injury to better identify and treat those who affected.

Applications

- One brain can potentially help in providing information in hundreds of studies. The number of people helped by your participation is countless as the information provided is invaluable.
- This project partners with other researching agencies to maximize the opportunity for evaluation and data sharing. This allows your loved one the ability to help more people by providing information on multiple levels.
- Traumatic brain injuries affect the mood and behavior of over 260,000 service men and women and your loved one has the ability to help others in the future by recognizing, preventing, and/or treating in new ways.
- The brain of a person suffering from a TBI secondary to a blast injury is very different than a person suffering from a TBI from another mechanism. This may be unique to our military members and this project is crucial to understand the differences on multiple levels.
- Learn more about this project at www.researchbraininjury.org

(2) Intermediate Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For others, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research, and wellness for years to come.

Researchers use donated brain tissue to study brain diseases that affect millions of people such as traumatic brain injuries or other injuries such as trauma and stroke.

Researchers learn the most from the brains of people who have participated in studies while they're still alive. This allows researchers to track changes in memory, thinking, language, and behavior over time and to gather information on environmental and biological factors. The more researchers know about a brain donor, the more they can learn about the

relationships among cognitive test results, biomarkers such as blood tests and brain scans, and the changes detected in the donor brain tissue. All this information helps them gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

Summary

LifeNet Health has collaborated to help conduct over 135 studies and enrolled over 9,000 research participants directly related to the study of TBIs. This is especially important when considering the number of veterans who are affected by brain injuries sustained in combat, which currently affect the mood and memory functions of more than 260,000 servicemen and women. Effects like these often disrupt their ability to maintain a job, reenter the community or even reconnect with their family.

Applications

Improving the lives of service members with TBI isn't a solo effort. It requires a comprehensive approach among investigators and staff; among partners within the Department of Defense (DoD) and the Department of Health and Human Services (HHS); and, most importantly, among the individuals who volunteer to participate in our studies. Together, we can all make a difference in the lives of service members with TBI.

The Center for Neuroscience and Regenerative Medicine's Brain Tissue Repository was established to help better understand traumatic brain injury (TBI), the most common wound of recent wars, and a huge burden for many returning servicemembers and families. Through the repository, scientists and physicians will use innovative approaches to help better understand how to care for our military personnel after a head injury.

The U.S. Department of Defense has established a brain tissue repository as an important resource to advance traumatic brain injury research. Comparing injured and uninjured brain tissue will allow scientists and physicians to learn ways to prevent and possibly treat the effects of this injury. This kind of brain injury affects the mood and memory of more than 260,000 servicemen and women, often disrupting their ability to maintain a job, reenter the community, even reconnect with their family.

Department of Defense research project that will advance knowledge regarding traumatic brain injury and may lead to treatment and cures.

(3) Comprehensive/Technical Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For others, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research, and wellness for years to come.

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Summary

These projects are sponsored by the Center for Neuroscience and Regenerative Medicine (CNRM.) The Center for Neuroscience and Regenerative Medicine (CNRM). They are a federal military traumatic brain injury (TBI) research program organized as a partnership between the Uniformed Services University (USU) and the National Institutes of Health (NIH). Their mission is to conduct cutting-edge science that improves the lives of service members with TBI and perform a range of robust research—with an emphasis on clinical trials—that studies military-related TBI and its comorbidities. The overall goal is to build a substantial evidence base that will enhance the Department of Defense’s (DoD) current guidelines for TBI diagnosis and treatment.

Since inception, there has been over 135 studies conducted and over 9,000 research participants have been enrolled. Results from these studies have generated conclusive results that have laid a strong foundation for present efforts.

The research team is comprised of over twenty senior scientific investigators and fifty dedicated staff members including in-house:

- Clinical Trials Unit
- Research Support Cores: Biomarkers and Biospecimen Repository; Informatics; and a TBI Study Opportunities Registry for prospective study participants
- Translational Research Division
- Neuropathology-Neuroradiology Integration Core
- Operational Research Division
- Program Management and Administrative team

The team is serious about their work and are honored to have the opportunity to give back to those who serve our country. They are committed to a set of values that guide their decisions, actions, and relationships.

- Urgency: Working swiftly and diligently to improve outcomes for service members with TBI
- Solutions-focused: Focusing on research that makes a difference in the lives of service members with TBI
- Collaboration: Partnering with other renowned TBI research groups
- Transparency: Publishing and disseminating all study findings, regardless of the outcome
- Fiscal Responsibility: Generating real-world value for taxpayer money

Applications

Improving the lives of service members with TBI isn’t a solo effort. It requires a comprehensive approach among investigators and staff; among partners within the Department of Defense (DoD) and the Department of Health and Human Services (HHS); and, most importantly, among the individuals who volunteer to participate in our studies. Together, we can all make a difference in the lives of service members with TBI.

The Center for Neuroscience and Regenerative Medicine's Brain Tissue Repository was established to help better understand traumatic brain injury (TBI), the most common wound of recent wars, and a huge burden for many returning servicemembers and families. Through the repository, scientists and physicians will use innovative approaches to help better understand how to care for our military personnel after a head injury.

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Department of Defense research project that will advance knowledge regarding traumatic brain injury and may lead to treatment and cures.

(4) Project Details

Estimated Length of Project	18 months to 2 years
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	MUST HAVE MEDICAL DIAGNOSIS OF PTSD. Bipolar disease or personality disorder with PTSD IS acceptable. Alzheimer's disease/dementia with PTSD IS acceptable. PTSD with depression IS acceptable. Increased risk donors are acceptable. IV drug use and drug use IS acceptable. Parkinson's disease, Huntington's disease, and Multiple sclerosis with PTSD IS acceptable. Schizophrenia or schizoaffective disorders with PTSD IS acceptable.
Number of Donations Needed	75 to 100
Target Partners	Medical Examiners/Coroner's General Hospitals Specialized Hospitals such as VA Hospice
External OPOs:	Experienced and Non-experienced
Materials Required	yes
Recovery Supplies:	Packaging, shipping and labeling supplies. Surgical recovery supplies.
Training Materials/ Recovery Protocols:	Recovery Spec Sheets specific to the research project
Education	Connect to purpose of research project (why we are recovering these specific tissues)
Recovery Parameters	
Postmortem Interval/Delivery Time:	One active project PMI 36 hours
Institutional Review Board (IRB)	
Department-specific	n/a

Post-Traumatic Stress

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others and meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

The PTSD study allows the research team to study the cells of an individual suffering from PTSD against cells from a donor with no PTSD to help better understand this disease process. This study helps analyze cells from other individuals who have suffered from PTSD and other related depression disorders. This will help with treatment options, better understanding, and better support for individuals in the future.

Applications

- One gift of brain donation can potentially help in providing information in hundreds of studies. The number of people helped by your participation is countless as the information provided is invaluable.
- PTSD develops after experiencing a traumatic event. Not everyone who experiences a traumatic event is diagnosed with PTSD.
- Some examples of PTSD related experience are when a person hears, sees, or an event that happens directly to the person:
 - Combat exposure
 - Child sexual or physical abuse
 - Sexual or physical assault
 - Terrorist attack
 - Serious accident, like a car wreck
 - Natural disasters, like a fire, tornado, hurricane, flood, or earthquake.

(2) Intermediate Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For other, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research and wellness for years to come.

Researchers use donated brain tissue to study brain diseases that affect millions of people such as traumatic brain injuries or other injuries such as trauma and stroke.

Researchers learn the most from the brains of people who have participated in studies while they're still alive. This allows researchers to track changes in memory, thinking, language, and behavior over time and to gather information on environmental and biological factors. The more researchers know about a brain donor, the more they can learn about the

relationships among cognitive test results, biomarkers such as blood tests and brain scans, and the changes detected in the donor brain tissue. All this information helps them gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

Summary

LifeNet Health has collaborated to help conduct over 135 studies and enrolled over 9,000 research participants directly related to the study of PTSD and TBIs. This is especially important when considering the number of veterans who are affected by brain injuries sustained in combat, which currently affect the mood and memory functions of more than 260,000 servicemen and women. Effects like these often disrupt their ability to maintain a job, reenter the community or even reconnect with their family.

Applications

Currently the only true diagnostic is through autopsy at the time of death. Donated human brains will enable the exploration into new diagnostic tools and therapies. Access to these important donations will enable open exploration into the development of better treatments for patients suffering PTSD and other TBI related neurologic diseases.

(3) Comprehensive Technical Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For other, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research and wellness for years to come.

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Summary

PTSD can occur after experiencing a traumatic event. A traumatic event is something terrible and scary that you see, hear about, or that happens to you, examples include:

- Combat exposure
- Child sexual or physical abuse
- Sexual or physical assault
- Terrorist attack

- Serious accidents, like a car wreck
- Natural disasters, like a fire, tornado, hurricane, flood, or earthquake

During a traumatic event, you think that your life or lives of others are in danger. You may feel afraid or feel that you have no control over the events happening around you. Most people have some stress-related reactions after a traumatic event; but not everyone gets PTSD. If your reactions don't go away over time and they disrupt your life, you may have PTSD.

Applications

Brain donation supports the scientific study of the pathophysiology of mental illness for both PTSD and related depression disorders. Donated human brains are critical to understand disease progression and potential therapeutic approaches for successful treatment.

(4) Project Details

Estimated Length of Project	18 months to 2 years
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	MUST HAVE MEDICAL DIAGNOSIS OF PTSD. Bipolar disease or personality disorder with PTSD IS acceptable. Alzheimer's disease/dementia with PTSD IS acceptable. PTSD with depression IS acceptable. Increased risk donors are acceptable. IV drug use and drug use IS acceptable. Parkinson's disease, Huntington's disease, and Multiple sclerosis with PTSD IS acceptable. Schizophrenia or Schizoaffective disorders with PTSD IS acceptable.
Number of Donations Needed	20-25
Target Partners	Medical Examiners/Coroner's General Hospitals Specialized Hospitals such as VA Hospice
External OPOs:	Experienced and Non-experienced
Materials Required	yes
Recovery Supplies:	Packaging, shipping and labeling materials Surgical recovery supplies
Training Materials/ Recovery Protocols:	Recovery Spec Sheets specific to research project
Education	Connect to purpose of research project (why we are recovering these specific tissues)
Recovery Parameters	
Postmortem Interval/Delivery Time:	One active project PMI 36 hours
Institutional Review Board (IRB)	Yes
Department-specific	n/a

Alzheimer's Disease

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others and meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

The Alzheimer's project will evaluate how this disease affects the brain on a cellular level in hopes of finding a better understanding and furthering treatment options. One brain can potentially help in providing information in hundreds of studies. The number of people helped by your participation is countless as the information provided is invaluable.

Alzheimer's is a progressive neurologic disorder causing brain cells to shrink causing a decline in cognitive and behavioral skills. This means that over time, people with Alzheimer's have changes with normal day activities and behavior that make it difficult to function independently. This is the most common cause of dementia.

Applications

This research opportunity would include individuals

- People with dementia who are Asian, African American, Hispanic, Native American and/or Pacific Islander
- People diagnosed with non-Alzheimer's dementias such as Lewy body dementia and frontotemporal disorders
- People with early onset Alzheimer's disease
- Those with Down syndrome because they are at a higher risk for Alzheimer's disease
- People who have dementia and have a family history of dementia
- People who have helped with clinical trial and other research on Alzheimer's disease and related dementias.

(2) Intermediate Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For other, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research and wellness for years to come.

Researchers use donated brain tissue to study brain diseases that affect millions of people such as traumatic brain injuries or other injuries such as trauma and stroke.

Researchers learn the most from the brains of people who have participated in studies while they're still alive. This allows researchers to track changes in memory, thinking, language, and behavior over time and to gather information on environmental and biological factors. The

more researchers know about a brain donor, the more they can learn about the relationships among cognitive test results, biomarkers such as blood tests and brain scans, and the changes detected in the donor brain tissue. All this information helps them gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

Summary

LifeNet Health helps support Alzheimer's research by studying the different regions of the brain in adults with clinical diagnosis for advanced Alzheimer's disease. The examination of brain tissue can contribute to research about Alzheimer's disease and other dementias, including research into new treatments. Brain donations are essential to furthering these research advancements. Advanced planning will help in this process of giving the ultimate gift.

Applications

The following are high priority for researchers studying these diseases

- People with healthy brains, including younger and older donors.
- Asian, Black/African American, Hispanic/Latino, Native American/Pacific Islander.
- People diagnosed with any type of dementia or frontotemporal disorders.
- People with Down Syndrome.
- People with a diagnosis of dementia who also have a family history of dementia.
- Participants in clinical trials and other research related to dementia.

(3) Comprehensive/Technical Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For other, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research and wellness for years to come.

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Summary

Our goal is to support Alzheimer's research by studying the different regions of the brain in adults with clinical diagnosis for advanced Alzheimer's disease. The examination of brain tissue can contribute to research about Alzheimer's disease and other dementias, including research into new treatments. Brain donations are essential to furthering these research advancements. Advanced planning will help in this process of giving the ultimate gift.

Applications

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The following are high priority for researchers studying Alzheimer's disease and related dementias:

- People with healthy brains, including both younger and older people
- Those who are Asian, Black/African American, Hispanic/Latino, Native American and/or Pacific Islander, including both healthy donors and those with dementia
- People diagnosed with non-Alzheimer's dementias, such as Lewy body dementia and frontotemporal disorders
- People with early-onset Alzheimer's disease
- Those with Down syndrome, who are at higher risk for Alzheimer's disease
- People with a diagnosis of dementia who have a family history of dementia
- Participants in clinical trials and other research on Alzheimer's disease and related dementias

(4) Project Details

Estimated Length of Project	2-4 years
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	Must specify Alzheimer's or may be included if donor has Alzheimer's.
Number of Donations Needed	125-175
Target Partners	Medical Examiners/Coroner's General Hospitals Specialized Hospitals such as VA Hospice
External OPOs:	Experienced
Materials Required	yes
Recovery Supplies:	Packaging, shipping and labeling materials Surgical recovery supplies
Training Materials/ Recovery Protocols:	Recovery Spec Sheets specific to research project
Education	Connect to purpose of research project (why we are recovering these specific tissues)
Recovery Parameters	
Postmortem Interval/Delivery Time:	18 to 36 hours PMI
Institutional Review Board (IRB)	Yes
Department-specific	n/a

Autism and related spectrum disorders

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others. They meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

Autism and related spectrum disorders project allows the research team to study individual cells and how they function in relation to genes. This project can only be accomplished after someone has passed and provides enormous opportunity to learn more about Autism and spectrum disorders in new ways. Hundreds of genes have been associated with these disorders with many different symptoms. Cells from different types of affected donors are in great need.

Currently there are no treatment options for people with Autism and spectrum disorders. However, your family has the opportunity to change that in the future by helping with this project. Your loved one will provide crucial information needed to identify new treatment options and improve the quality of life for them and their family.

Applications

One brain can potentially help in providing information in hundreds of studies. The number of people helped by your participation is countless as the information provided is invaluable. There is no cost to the family to participate in these projects. Autism spectrum disorder is a condition related to brain development that interferes in a variety of ways for a person affected from communication challenges, social challenges, repetitive behaviors, and more. Autism and Spectrum disorders usually begins in early childhood and can range in severity. There is no cure for these disorders and more information is needed to understand these spectrum diseases more thoroughly.

(2) Intermediate Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For others, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research, and wellness for years to come.

Researchers use donated brain tissue to study brain diseases that affect millions of people, such as traumatic brain injuries or other injuries such as trauma and stroke.

Researchers learn the most from the brains of people who have participated in studies while they're still alive. This allows researchers to track changes in memory, thinking, language, and behavior over time and to gather information on environmental and

biological factors. The more researchers know about a brain donor, the more they can learn about the relationships among cognitive test results, biomarkers such as blood tests and brain scans, and the changes detected in the donor brain tissue. All this information

helps them gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

Summary

Scientists can study the living human brain using neuroimaging techniques such as MRIs and EEGs, but these methods do not allow them to see the individual brain cells that form the brain tissue, or the molecules that signal the cells development and functions. Brain donation is critical to these studies as it allows scientists to study the cells on a microscopic level, as well as molecular pathways and patterns of gene activity.

Applications

No pharmacological intervention is currently available to address the core symptoms associated with ASD. Through a better understanding of the changes in brain tissue, autism researchers may help identify targets for new treatments that could improve the quality of life of individuals with autism and their families.

(4) Comprehensive/Technical Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For others, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research, and wellness for years to come.

Researchers use donated brain tissue to study brain diseases that affect millions of people such as traumatic brain injuries or other injuries such as trauma and stroke. Researchers learn the most from the brains of people who have participated in studies while they're still alive. This allows researchers to track changes in memory, thinking, language, and behavior over time and to gather information on environmental and biological factors. The more researchers know about a brain donor, the more they can learn about the relationships among cognitive test results, biomarkers such as blood tests and brain scans, and the changes detected in the donor brain tissue. All this information helps them gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

Summary

One further challenge of studying the autism brain is that ASD is a very complex condition. Hundreds of genes have been associated with ASD, and many different clinical manifestations have been observed. The only way to understand this genetic and behavioral diversity is to examine many cases, but unfortunately, brain donations are not common. No pharmacological intervention is currently available to address the core symptoms associated with ASD. Through a better understanding of the changes in brain tissue, autism researchers may help identify targets for new treatments that could improve the quality of life of individuals with autism and their families.

Applications

There is still much to learn about how the human brain works and the differences in how the brain of a person who has Autism or a related neurodevelopmental condition works. Scientists can study the living human brain by using neuroimaging techniques such as magnetic resonance imaging (MRI) and electroencephalography (EEG). But these methods do not allow seeing the individual brain cells that form the brain tissue or studying the molecules that signal how these cells develop and function. Neuroimaging techniques do not give scientists enough information to understand how genetic changes affect brain tissue at the microscopic level. Thus, it is extremely important to examine the postmortem human brain to study individual brain cells, as well as molecular pathways and patterns of gene activity.

(4) Project Details

Estimated Length of Project	5+ years
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	Project 1 – Autism Control Donation Autism Control. No autism diagnosis. No trauma to the brain. Will accept donor if has had history of developmental delay, Special Ed classes or repetitive behaviors. Project 2 Autism Spectrum No trauma to the brain. Will accept if DRAI states autism or autism spectrum without medical diagnosis.
Number of Donations Needed	20-25
Target Partners	Medical Examiners/Coroner's General Hospitals Specialized Hospitals such as VA Hospice
External OPOs:	Experienced
Materials Required	yes
Recovery Supplies:	Packaging, shipping and labeling materials Surgical recovery supplies
Training Materials/ Recovery Protocols:	Recovery Spec Sheets specific to research project
Education	Connect to purpose of research project (why we are recovering these specific tissues)
Recovery Parameters	
Postmortem Interval/Delivery Time:	Postmortem Interval (PMI) is 27 hours
Institutional Review Board (IRB)	No
Department-specific	n/a

Parkinson's Disease

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others and meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

Individuals and families can support Parkinson's Disease research through the gift of brain donation. Donations are used to further research into the causes of Parkinson's Disease, the development of new treatment options, and the improvement of current therapy options. By choosing to participate, donors and their families will provide hope to others impacted by this devastating diagnosis.

Applications

This research opportunity would include individuals

- People with dementia who are Asian, African American, Hispanic, Native American and/or Pacific Islander
- People diagnosed with non-Parkinson's dementias such as Lewy body dementia and frontotemporal disorders
- People with early onset Parkinson's disease
- Those with Down syndrome because they are at a higher risk for Parkinson's disease
- People who have dementia and have a family history of dementia
- People who have helped with clinical trial and other research on Parkinson's disease and related dementias.

(2) Intermediate Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For others, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research and wellness for years to come.

Researchers use donated brain tissue to study brain diseases that affect millions of people such as autism as well as traumatic brain injuries, or other injuries such as trauma and stroke.

Researchers learn the most from the brains of people who have participated in studies while they're still alive. This allows researchers to track changes in memory, thinking, language and behavior over time and to gather information on environmental and biological factors. The more researchers know about a brain donor, the more they can learn about the relationships among cognitive test results, biomarkers such as blood tests and brain scans, and the changes detected in the donor brain tissue. All this information helps them gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

Summary

LifeNet Health helps support Parkinson's research by studying the different regions of the brain in adults with clinical diagnosis for advanced Parkinson's disease. The examination of brain tissue can contribute to research about Parkinson's disease and other dementias, including research into new treatments. Brain donations are essential to furthering these research advancements. Advanced planning will help in this process of giving the ultimate gift

Applications

The following are high priorities for researchers studying these diseases

- People with healthy brains, including younger and older donors.
- Asian, Black/African American, Hispanic/Latino, Native American/Pacific Islander.
- People diagnosed with any type of dementia or frontotemporal disorders.
- People with Down Syndrome, who are at higher risk for Parkinson's disease.
- People with a diagnosis of dementia who also have a family history of dementia.
- Participants in clinical trials and other research related to dementia.

(3) Comprehensive/Technical Level

Introduction

People choose to donate their brains after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for diseases or disorders. For others, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research and wellness for years to come.

Researchers use donated brain tissue to study brain diseases that affect millions of people such as autism as well as traumatic brain injuries, or other injuries such as trauma and stroke.

Researchers learn the most from the brains of people who have participated in studies while they're still alive. This allows researchers to track changes in memory, thinking, language and behavior over time and to gather information on environmental and biological factors. The more researchers know about a brain donor, the more they can learn about the relationships among cognitive test results, biomarkers such as blood tests and brain scans, and the changes detected in the donor brain tissue. All this information helps them gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

Summary

Our goal is to support Parkinson's research by studying the different regions of the brain in adults with clinical diagnosis for advanced Parkinson's disease. For example, a factor believed to play a fundamental role in the development of Parkinson's research involves abnormalities of a protein called alpha-synuclein. In the normal brain, alpha-synuclein is located in nerve cells in specialized structures called presynaptic terminals. Evidence suggests the buildup of excessive and abnormal alpha-synuclein plays a key role in the development of Parkinson's Disease.

The examination of brain tissue can contribute to research about Parkinson's Disease and other dementias, including research into new treatments. Brain donations are essential to furthering these research advancements. Advanced planning will help in this process of giving the ultimate gift.

Applications

The following are high priority for researchers studying Parkinson's disease and related dementias:

- People with healthy brains, including both younger and older people
- Those who are Asian, Black/African American, Hispanic/Latino, Native American and/or Pacific Islander, including both healthy donors and those with dementia
- People diagnosed with non- Parkinson's dementias, such as Lewy body dementia and frontotemporal disorders
- People with early-onset Parkinson's disease
- Those with Down syndrome, who are at higher risk for Parkinson's disease
- People with a diagnosis of dementia who have a family history of dementia
- Participants in clinical trials and other research on Parkinson's disease and related dementias

(4) Project Details

Estimated Length of Project	2 to 4 years
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	Must specify Parkinson's or may be included if donor has Parkinson's.
Number of Donations Needed	125 to 175
Target Partners	Medical Examiners/Coroner's General Hospitals Specialized Hospitals such as VA Hospice Extended OPO's Hospice
External OPOs:	Experienced
Materials Required	Yes
Recovery Supplies:	Packaging, shipping and labeling materials
Training Materials/ Recovery Protocols:	Recovery Spec Sheets specific to research project
Education	Connect to purpose of research project (why we are recovering these specific tissues)
Recovery Parameters	n/a
Postmortem Interval/Delivery Time:	Postmortem Interval (PMI) is 18 to 36 hours
Institutional Review Board (IRB)	Yes
Department-specific	n/a

DORSAL ROOT GANGLIA (DRG) PAIN RESEARCH PROJECTS

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others and meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

The Dorsal Root Ganglia (DRG) Pain Research Project is investigating a new way to treat severe and ongoing pain by changing how the body sends pain signals. Researchers are attempting to influence the sending of pain signals in the body with a new type of medication that will block the path of pain.

This is a new approach to treating pain with specialized medications that would give doctors a better option than prescribing strong pain medications aimed to numb the body. These strong medications commonly leave some patients feeling unwell while leading other patients down a path of addiction. It is hoped that this new type of medication will be able to block the pain signals from reaching the brain without the side effects that strong numbing pain medications currently cause.

Applications

Poorly managed pain can lead to a significant decrease in quality of life. It's often associated with complications, such as sleep interruption, limited movement, inability to work, and mental health disorders like major depression. Opioids are a strong type of pain medication generally prescribed for acute pain but are often unsuitable for chronic use. Anti-inflammatory drugs like prednisone can be used for both acute (sudden and severe) and chronic (on going) pain, but their use is limited due to side effects. Beyond these approaches there are limited options and there have not been any major innovations in pain treatment for decades. There is a significant unmet need for new treatments that can be effective for various types of pain.

(2) Intermediate Level

Introduction

The Vertex DRG project is focused on researching and discovering medicines aimed at selectively targeting the underlying cause of pain response, including acute or chronic severe pain caused by a variety of conditions.

Summary

Pain has many faces: it can occur at any moment, affect any system, can vary in its intensity and duration, and has the potential to impact a person's quality of life to a significant extent.

Although pain is one of the most common reasons for a doctor visit, there has not been any major breakthroughs in treatment for decades. The management of pain continues to be limited to a handful of opioids and anti-inflammatory drugs. Currently, we are unable to prevent the initiation of pain, however, we can influence how the body processes pain signals

in an effort to ease the impact of pain. Through voltage-gated sodium channels (NaV), the nervous system is responsible for how the body senses, transmits, and interprets pain. Specific channels, like NaV 1.7 and 1.8, which have been validated through human genetics, play an important role in transmitting pain signals from peripheral sensory neurons to the central nervous system.

Applications

The Vertex approach is to focus on researching and discovering medicines which target specific sodium channels in the NaV family that have been validated by human biology in an effort to develop new potential treatment options for those suffering from the many faces of pain.

(3) Comprehensive/Technical Level

Introduction

The Vertex DRG project is focused on researching and discovering medicines aimed at selectively targeting the underlying cause of pain response, including acute or chronic severe pain caused by a variety of conditions.

Summary

Although the role of voltage-gated sodium channels like NaV 1.7 and 1.8 in human pain sensation has been understood since the cloning of the NaV channels in the 1980s, no one has successfully developed a treatment that selectively uses these mechanisms to treat pain. Because of the significant prevalence of pain across the world and the complications it may cause, the Vertex organization believes there is a significant unmet need for potential new treatments.

Vertex is investigating an approach to treat pain by targeting specific sodium channels in the NaV family that have been validated by human biology. Their goal is to interrupt pain signals and prevent them from traveling from the sensory nerves to the brain. Vertex continues to discover, research, and develop a portfolio of small molecule medicines as potential medicines for the treatment of both acute and chronic pain, including chronic neuropathic pain. By inhibiting the specific channels validated by human biology, they hope to alleviate pain.

Applications

Vertex has three Phase 2 proof-of-concept studies that validated their approach. Based on the results of these trials, they are continuing to pursue potential small molecule inhibitors that meet the criteria for evaluation in clinical trials.

(4) Project Details

Estimated Length of Project	1 year to 18 months
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	<ol style="list-style-type: none"> 1. No Neurological disease 2. Donor serology results must be negative for HBV, HCV, HIV. Donor must have < 30min downtime. Exclude all donors who have had chemo or radiation. Exclude damaged, bruised or bloodied DRGs. 3. Exclude donors undergoing chemotherapy. Exclude donors undergoing radiation therapy in the region where DRG are to be recovered. Exclude Diabetes Type I, Diabetes Type II. Exclude DRGs which are bruised or damaged. Exclude donors where COD is due to asphyxiation as well as cardiac arrest/downtime being unknown. Exclude donors where CPR initiated was more than 15 min after start of cardiac arrest. Total cardiac arrest/downtime greater than 45 minutes.
Number of Donations Needed	10 to 20
Target Partners	Medical Examiners/Coroner's General Hospitals Specialized Hospitals such as VA Hospice
External OPOs:	Experienced and Non-experienced
Materials Required	
Recovery Supplies:	LNH may supply Stryker saws if it does not impact other research tissue recovery.
Training Materials/ Recovery Protocols:	Recovery spec sheets, training videos, training sign off sheets
Education:	Understanding of the end use and recovery parameters
Recovery Parameters	
Postmortem Interval/Delivery Time:	6-10 hours PMI with a delivery time of ≤ 24 hours from time of recovery.
Institutional Review Board (IRB)	No
Department-specific	n/a

KIDNEY PROJECTS

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others and meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

Donating your loved one's kidneys allows researchers to investigate how kidney disease worsens over time and to develop as well as improve treatment options that can slow or stop kidney disease from progressing and delay or prevent the need for a kidney transplant. By doing this research, better treatments can be found that will ultimately prevent kidney failure.

The kidneys are two bean-shaped organs. Each kidney is about the size of a fist. Your kidneys filter extra water and wastes out of your blood and make urine. Kidney disease means your kidneys are damaged and cannot filter blood the way they should. You are at greater risk for kidney disease if you have diabetes or high blood pressure. If you experience kidney failure, treatments include kidney transplant or dialysis. Kidney diseases and other kidney problems include acute/chronic diseases, diabetic kidney disease, acute kidney injury, kidney cysts, kidney stones, polycystic kidney disease, and kidney infections.

Applications

A new trend within the scientific community is research to predict how safe and how well new drugs work by using the individual cells of the kidney and exposing these cells to new drugs in order to better understand which drugs are safe and most effective in preventing kidney failure.

(2) Intermediate Level

Introduction

Kidney disease is a leading cause of death in the US and the world, yet treatment options for kidney disease patients are limited to dialysis and kidney transplantation with no current pharmacological options available that directly target the kidney. Dialysis is associated with a significant decrease in life quality, and transplantation, although highly successful, is limited by availability of donor organs. Development of pharmacologic treatments has been an area of focus for years but remains a challenge partly due to the unavailability of reliable renal systems for pharmacological evaluation both in-vitro and in-vivo. Walden has two programs targeting two kidney specific pathways. In support of translating these programs into the clinic, obtaining organs that cannot be transplanted would allow for isolation of functional human kidney cells that can be used to evaluate pharmacological effects as well as further knowledge and validation of the molecular mechanisms involved in regulation of kidney health and disease.

Another important aspect of kidney research relates to improvements in transplant kidney preservation. There are numerous cold preservation technologies and emerging trends toward the further development and improvement of normothermic mechanical pump methodologies. Donated human kidneys for research allow for continuous improvements in this technology.

Summary

You are at greater risk for kidney disease if you have diabetes or high blood pressure. If you experience kidney failure, treatments include kidney dialysis or transplant. Kidney diseases and other kidney problems include acute/chronic diseases, diabetic kidney disease, acute kidney injury, kidney cysts, kidney stones, polycystic kidney disease, and kidney infections.

Donated kidneys for research allow researchers to investigate disease progression and develop improved treatment option to either slow or stop disease progression and ultimately eliminate risks associated with kidney failure.

Other emerging trends within the scientific community is the development of laboratory models to predict new drug safety and efficacy. The individual cells of the kidney can be isolated and used to construct living cellular models that can be exposed to new drugs to aid in understanding how human cells will react to these new treatment options, thus vastly improving our understanding of which drugs are safe or not.

Applications

Donating your kidneys to research allow researchers to investigate disease progression and develop improved treatment option to either slow or stop disease progression and ultimately eliminate risks associated with kidney failure.

Other emerging trends within the scientific community is the development of laboratory models to predict new drug safety and efficacy. The individual cells of the kidney can be isolated and used to construct living cellular models that can be exposed to new drugs to aid in understanding how human cells will react to these new treatment options, thus vastly improving our understanding of which drugs are safe or not.

New technologies for normothermic kidney preservation will improve the successful outcomes of kidney transplantation.

(3) Comprehensive/Technical Level

Introduction

Kidney disease is a leading cause of death in the US and the world, yet treatment options for kidney disease patients are limited to dialysis and kidney transplantation with no current pharmacological options available that directly target the kidney. Dialysis is associated with a significant decrease in life quality, and transplantation, although highly successful, is limited by availability of donor organs. Development of pharmacologic treatments has been an area of focus for years but remains a challenge partly due to the unavailability of reliable renal systems for pharmacological evaluation both in-vitro and in-vivo. Walden has two programs targeting two kidney specific pathways. In support of translating these programs into the clinic, obtaining organs that cannot be transplanted would allow for isolation of functional human

kidney cells that can be used to evaluate pharmacological effects as well as further knowledge and validation of the molecular mechanisms involved in regulation of kidney health and disease.

Another important aspect of kidney research relates to improvements in transplant kidney preservation. There are numerous cold preservation technologies and emerging trends toward the further development and improvement of normothermic mechanical pump methodologies. Donated human kidneys for research allow for continuous improvements in this technology.

Summary

You are at greater risk for kidney disease if you have diabetes or high blood pressure. If you experience kidney failure, treatments include kidney transplant or dialysis. Kidney diseases and other kidney problems include acute/chronic diseases, diabetic kidney disease, acute kidney injury, kidney cysts, kidney stones, polycystic kidney disease, and kidney infections.

Research kidneys provide important insight into understanding kidney disease and the progression of various disease states. This allows for the development of diagnostic, disease modeling, and therapeutic approaches for various kidney diseases.

Advancement in kidney preservation methods improve the clinical outcomes for transplant patients and rely on research kidneys.

Applications

Donating your kidneys to research allow researchers to investigate disease progression and develop improved treatment option to either slow or stop disease progression and ultimately eliminate risks associated with kidney failure.

Other emerging trends within the scientific community is the development of laboratory models to predict new drug safety and efficacy. The individual cells of the kidney can be isolated and used to construct living cellular models that can be exposed to new drugs to aid in understanding how human cells will react to these new treatment options, thus vastly improving our understanding of which drugs are safe or not.

New technologies for normothermic kidney preservation will improve the successful outcomes of kidney transplantation.

(4) Project Details

Estimated Length of Project	18 months to 2 years
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	1. Donors MUST have lupus 2. Must have a Creatinine level <3.0 on last labs report. 3. Donors with diagnosis kidney disease, any reference to End-stage or Chronic kidney disease (without specific renal disease diagnosis eGFR <60%; serum creatinine >1.5mg/dL), history of diabetes or cardiovascular disease.
Number of Donations Needed	20 to 25 donors needed, Total for 6 projects
Target Partners	Medical Examiners/Coroner's General Hospitals Specialized Hospitals such as VA Hospice
External OPOs:	Experienced and Non-experienced
Materials Required	
Recovery Supplies:	LNH may supply Stryker saws if it does not impact other research tissue recovery.
Training Materials/ Recovery Protocols:	Recovery spec sheets, training videos, training sign off sheets.
Education	Understanding of the end use and recovery parameters
Recovery Parameters	
Postmortem Interval/Delivery Time:	1 to 24 hour PMI
Institutional Review Board (IRB)	No
Department-specific	n/a

LIVER PROJECTS

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others and meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

The liver acts as a filtering system for the body. Understanding the effects and possible toxicity of medications we take can greatly enhance the understanding of how the liver processes these drugs. 60% of the cells in the liver are hepatocyte cells. The researcher needs to be able to view the hepatocytes as a whole cell versus a mere slice of the cell. If I hold up a ball of yarn in front of you, it looks like a circle. Intellectually, you know it's more than a flat circle, but without being able to manipulate the yarn- you can't be sure. Enhancing cellular observation from 2-D to 3-D allows the researcher to gain invaluable knowledge regarding the function of the hepatocyte cell.

Applications

We are asking for your loved one to participate in liver research to help all who take medication on a regular basis. This project allows the researcher to transition from studying a 2- dimensional model to a 3-dimensional model, greatly enhancing the understanding of how these cells work in the liver when processing medications. The difference between these models is like comparing a photo of a car (a 2-dimensional model) to a toy model of the same car (a 3-dimensional model).

(2) Intermediate Level

Introduction

One of the tissues that may be recovered for research purposes is the liver. While whole liver biospecimens may be sent to researchers for further examination, including cell isolation and DNA sequencing.

Summary

The primary objective of the LifeSciences division at LNH is to offer cell solutions as human hepatocyte for a range of research applications, as hepatocytes make up approximately 60% of all cells within the liver and perform multiple functions including protein synthesis and storage, carbohydrate metabolism, lipid metabolism, and detoxification. Primary human hepatocytes are the gold standard for metabolism, drug-drug interaction, and toxicity studies. Hepatocytes can also be genotyped for these studies. Genotyping information is important in experimental designs for compound discovery and development. It can be applied to studies of metabolism rates, drug-drug interactions, disease models, diversity in preclinical investigations, and 3D model and co-culture systems.

Applications:

- Metabolic clearance
- Drug-Drug interaction
- Disease modeling
- Transporter assays
- Pharmacogenomics studies
- 2D and 3D cell culture

(3) Comprehensive/Technical Level

Introduction

One of the tissues that may be recovered for research purposes is the liver. While whole liver biospecimens may be sent to researchers for further examination, including cell isolation and DNA sequencing.

Summary

While whole liver biospecimens may be sent to researchers for further examination, including cell isolation and genomic and proteomic testing, the primary objective of the LifeSciences division at LNH is to offer cell solutions as human hepatocyte for a range of research applications including metabolic clearance, drug interaction studies, disease modeling, and pharmacogenomic studies. Genotyping information is important in experimental designs for compound discovery and development. It can be applied to studies of metabolism rates, drug-drug interactions, disease models, diversity in preclinical investigations, and 3D model and co-culture systems.

Applications

- Metabolic clearance
- Drug-Drug interaction
- Disease modeling
- Transporter assays
- Pharmacogenomics studies
- 2D and 3D cell culture

(4) Project Details

Estimated Length of Project	5 years and longer – Total Active Projects: 4 length of 1-6 years
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	<p>4 active case disease process criteria: XCLUDE donors with a history of autoimmune disorders and/or current or past history of positive viral antigen tests for known infectious bloodborne pathogen(s) that would require BSL3 practices including viral hepatitis (HAV, HBV, HCV). Exclude positive toxoplasmosis, RPR, HIV, HCV, and HBV.</p> <p>DONOR MUST BE HBcAb (+) & HbsAg (+) Negative for Hep B/C, RPR, and HIV. Positive toxoplasmosis is a rule out.</p> <p>Increased risk donors on case by case basis. BMI < 35, but can be reviewed on a case by case basis.</p> <ul style="list-style-type: none"> • Brain Death or DCD donors acceptable • Unacceptable: Positive serological tests: Toxoplasmosis, HBsAg, Hep B Total Core, HIV I/II Ab, Hep C Ab, Positive Hep B, C or HIV NAT, RPR with positive confirmatory test • Unacceptable: Hepatocellular or cholangiocarcinoma (Liver carcinoma) • Unacceptable: Serological results from hemodiluted sample • Unacceptable: No DRAI • Unacceptable: Current or untreated systemic infection or meningitis • Unacceptable: Current Alcohol Use: Current use of more than 6 drinks per day: 6 pack of beer or 6 glasses of wine or 6 shots of liquor or any combination for 10 years regardless of age of the donor. <p>0 - 70 years old, male or female, any race</p> <ul style="list-style-type: none"> • Brain Death or DCD donors: Visual acceptable
Number of Donations Needed	Total from all 4 active projects 275 recovered to date 133
Target Partners	Medical Examiners/Coroner's General Hospitals

	Specialized Hospitals such as VA Hospice
External OPOs:	Experienced and Non-experienced
Materials Required	
Recovery Supplies:	No
Training Materials/ Recovery Protocols:	Recovery spec sheets, training videos, training sign off sheets.
Education	Understanding of the end use and recovery parameters
Recovery Parameters	
Postmortem Interval/Delivery Time:	72 PMI hours
Institutional Review Board (IRB)	No
Department-specific	n/a

LUNG PROJECTS

(5) Community Education Level

Introduction

We are reaching out to you about this donation opportunity because your loved one has the potential to make a lasting impact through participation in a lung research project. This contribution can help advance scientific understanding and improve treatments for respiratory conditions. Please know that recovery does not interfere with family viewing plans. Our recovery teams are committed to honoring your wishes and treating every donor with the utmost dignity and respect.

Summary

The lungs are vital organs responsible for oxygen exchange and are composed of a complex network of specialized cells. Understanding how these cells function—especially in the context of diseases like asthma, COPD, pulmonary fibrosis, and lung cancer—is essential for developing better treatments. A key focus of this research is isolating and studying specific lung cell types, such as alveolar epithelial cells, which play a critical role in gas exchange and immune defense.

To truly understand how these cells behave, researchers need access to whole, intact cells through whole lung donation. Imagine holding a sponge in your hand, it looks like a flat shape from one angle, but only by examining in three dimensions can you appreciate its full structure and function. This shift from 2-D to 3-D cellular observation allows scientists to gain deeper insights into how lung cells interact, respond to injuries, and regenerate.

One set of lungs can potentially provide critical insight for dozens, even hundreds, of research studies. The number of people helped through your loved one's contributions is immeasurable, as the knowledge gained is invaluable.

Applications

We are asking for your loved one to participate in lung research to find treatments and cures for patients whose lives are affected by lung injuries or chronic respiratory diseases. This project enables researchers to move beyond traditional 2-D models and work with 3-D lung cell systems. The difference is like comparing a photograph of a tree to a miniature model of the tree—you can see the branches, the depth, and how everything connects. This enhanced perspective is crucial for developing more effective therapies and understanding how lung cells function in health and disease.

(6) Intermediate Level

Introduction

Donated human lungs support many research applications and studies. While whole lung biospecimens may be sent to researchers for further examination, a key focus is the isolation of specific lung cell types for advanced studies, including genetic, protein, and metabolism analysis. Donations for lung research can also help in the advancements of regenerative medicine technologies to create tissue-engineered lungs for transplantation.

Summary

The primary objective of the LifeSciences division at LNH is to offer lung biospecimens for

research and cellular solutions such as primary human lung cells for a wide range of research applications. These include alveolar epithelial cells, bronchial epithelial cells, and other specialized lung cell types that play critical roles in gas exchange, immune defense, and tissue repair. These cells are essential for studying respiratory diseases such as asthma, COPD, pulmonary fibrosis, cystic fibrosis, COVID related complications, and lung cancer.

Primary human lung cells are considered the gold standard for modeling lung function, disease progression, and drug response. They can also be genotyped to support pharmacogenomic studies. Genotyping data enhances experimental design for compound discovery and development, and supports research into disease mechanisms, drug interactions, and personalized medicine approaches using both 2-D and 3-D culture systems.

Applications:

LNH works with many organizations currently studying lung diseases and injuries, including academic medical centers, government agencies, and biotechnology partners. We are committed to advancing therapies that improve lives through multiple applications including but not limited to:

- Respiratory disease modeling
- Drug response and toxicity testing
- Inflammatory and fibrotic pathway studies
- Transporter and barrier function assays
- Drug discovery and personalized medicine
- 2D and 3D cell culture systems

(7) Comprehensive/Technical Level

Introduction

Lung donation provides a foundation for disease research and biomarker discovery. These donations allow investigators to conduct detailed analysis, including the isolation of specific lung cell populations and advanced genomic and proteomic testing.

Both healthy and diseased lungs are necessary to understand how respiratory diseases develop and to identify what normal lung structure and function looks like. Non-diseased lungs offer researchers a vital comparison point, showing how lung aging and resilience vary, and what protective mechanisms might exist.

Donations from individuals without lung disease offer insight into what's considered normal and help identify early changes before disease begins. This is essential in developing early detection tools and preventive therapies.

Summary

The LifeSciences division at LNH focuses on providing high-quality primary human lung cells for use in a variety of research applications. These include metabolic and toxicological studies, disease modeling, and pharmacogenomic investigations. Lung cell types such as Alveolar Type I and II epithelial cells, bronchial epithelial cells, and fibroblasts are isolated and characterized for use in both 2D and 3D culture systems.

Genotyping of these cells support precision medicine research by enabling scientists to correlate genetic profiles with cellular behavior, drug metabolism, and disease susceptibility. These models are critical for understanding lung-specific responses to therapies, environmental exposures, and infectious agents.

Applications

Researchers need lung donations from diverse individuals of all races, genders, geographic locations, and identities to ensure findings are accurate, inclusive, and impactful across populations. These donations can be utilized for a wide variety of applications including:

- Drug discovery
- Respiratory disease modeling (e.g. asthma, COPD, fibrosis)
- Drug metabolism and toxicity screening
- Transporter and permeability assays
- Inflammatory response and immune cell interaction studies
- Drug discovery and genetic diversity research
- 2D monolayer and 3D organoid/co-culture systems

(8) Project Details

Estimated Length of Project	Multiyear projects
Target Donors	Control and diseased donors
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	<ul style="list-style-type: none"> • Donor must be NEGATIVE for Hep B, Hep C, RPR, and HIV. • Increased risk donors acceptable on a case by case basis. • Brain Death or DCD donors acceptable • Preliminary blood cultures and sputum cultures needed for screening • Final blood and sputum cultures required post recovery after organ import
Number of Donations Needed	Ongoing: at minimum 12 a year
Target Partners	Medical Examiners/Coroner's General Hospitals

	Specialized Hospitals such as VA Hospice
External OPOs:	Experienced and Non-experienced
Materials Required	
Recovery Supplies:	Standard lung recovery supplies
Training Materials/ Recovery Protocols:	Recovery spec sheets, training videos, training sign off sheets.
Education	Understanding of the end use and recovery parameters
Recovery Parameters	
Postmortem Interval/Delivery Time:	44 hours
Institutional Review Board (IRB)	No
Department-specific	n/a

MULTIPLE TISSUE PROJECTS

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others and meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

The goal of Multiple Tissue research is to utilize multiple types of donated human tissue in order to conduct scientific research and reduce the use of animal testing. When a patient donates multiple tissues, this helps researchers study many different projects. For instance, a research study may need three separate donors who each gift one tissue sample from different areas of their body. By using donated human tissues, research can be done using species-specific testing which means that the outcomes have already been tested on human tissue. In particular, these research projects can investigate the use of medication and how they impact tissues such as tumors and inflammation as well as how they impact viruses and bacteria. With human donated tissues, researchers can study more effectively how medications can influence the level of anti-bodies and toxicity in tissues.

Applications

Animal tissues help researchers begin to understand the impacts of medications on tissues like tumors and inflammation as well as how they impact viruses and bacteria, but the results are limited because they originate from tissues of a different species. Utilizing donated human tissues can provide a relevant species-specific result reducing and eventually eliminating the use of animals for testing. The regulatory and research industry as a whole will be required to stop using animals for testing in the next decade. Shifting to human tissue studies now is both proactive and innovative.

(2) Intermediate Level

Introduction

Some research projects require the recovery of multiple tissue samples from a single donor. Sample requests for multiple tissue project can include brain, intestines, kidneys, liver and other organs. All samples must come from an individual donor so each tissue is represented in the scientific analysis. The types of studies support genomic, proteomic toxicology and biomarker discovery programs.

Summary

Two areas of interest relate to gene expression and FDA safety studies. An example of a gene expression study is the National Institutes of Health Genotype Tissue Expression project (GTEx). The goal of GTEx was to extensively genotype 30+ tissue types from a single donor and create a database of a large cohort for gene expression studies. The GTEx project was extremely successful and recovered almost 1,000 donors.

There are a few research projects requesting multiple tissue samples. The types of samples requested include brain, intestines, kidneys, liver and other organs.

Applications

Multi-tissue experiments are ideal for comparative studies across many different tissue types. These studies are important to gene expression and safety assessments. This will help researchers understand a disease state, support therapeutic discovery, and aid in drug safety, prevention of adverse events, and identify biomarkers for drug discovery.

(3) Comprehensive/Technical Level

Introduction

Some research projects require the recovery of multiple tissue samples from a single donor. Sample requests for multiple tissue project can include brain, intestines, kidneys, liver and other organs. All samples must come from an individual donor so each tissue is represented in the scientific analysis. The types of studies support genomic, proteomic toxicology and biomarker discovery programs.

Summary

Two areas of interest relate to gene expression and FDA safety studies. An example of a gene expression study is the National Institutes of Health Genotype Tissue Expression project (GTEx). The goal of GTEx was to extensively genotype 30+ tissue types from a single donor and create a database of a large cohort for gene expression studies. The GTEx project was extremely successful and recovered almost 1,000 donors.

FDA guidance also requires multiple tissues from a single donor and identifies that research studies should facilitate the timely conduct of clinical trials, reduce the use of animals in accordance with the 3Rs (reduce/refine/replace) principles and reduce the use of other drug development resources. FDA recommends that Multi-tissue studies from a single donor should be considered for in vitro alternative methods for safety evaluation. These methods, if accepted by all ICH regulatory authorities, can be used to replace current standard methods and harmonize the nonclinical safety studies to support the various stages of clinical development among the regions of European Union (EU), Japan, and the United States. The present addendum represents the consensus that exists regarding the safety evaluation of biotechnology-derived pharmaceuticals.

The FDA recommends a number of factors should be taken into account when determining species relevancy, requiring in vitro assays to make qualitative and quantitative cross-species comparisons of relative target binding affinities and receptor/ligand occupancy and kinetics. Assessments of functional activity are also recommended. Functional activity can be demonstrated in species-specific cell-based systems and/or in vivo pharmacology or toxicology studies. Modulation of a known biologic response or of a pharmacodynamic (PD) marker can provide evidence for functional activity to support species relevance. Consideration of species differences in target binding and functional activity in the context of the intended dosing regimen should provide confidence that a model can demonstrate potentially adverse consequences of target modulation. When the target is expressed at very low levels in typical healthy preclinical species (e.g., inflammatory cytokines or tumor antigens), binding affinity and activity in cell-based systems can be sufficient to guide species selection. Assessment of tissue cross reactivity (see Note 1) in animal tissues is of limited value for species selection. However, in specific cases (i.e., where the approaches described above cannot be used to demonstrate a pharmacologically relevant species) tissue cross-reactivity (TCR) studies can be 2 Contains Nonbinding Recommendations used to guide selection of toxicology species by

comparison of tissue binding profiles between those human and animal tissues where target binding is expected. As described in ICH S6, when no relevant species can be identified because the biopharmaceutical does not interact with the orthologous target in any species, use of homologous molecules or transgenic models can be considered. For monoclonal antibodies and other related antibody products directed at foreign targets (i.e., bacterial, viral targets etc.), a short-term safety study (see ICH S6) in one species (choice of species to be justified by the sponsor) can be considered; no additional toxicity studies, including reproductive toxicity studies, are appropriate. Alternatively, when animal models of disease are used to evaluate proof of principle, a safety assessment can be included to provide information on potential target-associated safety aspects. Where this is not feasible, appropriate risk mitigation strategies should be adopted for clinical trials. Species selection for an antibody-drug/toxin conjugate (ADC) incorporating a novel toxin/toxicant should follow the same general principles as an unconjugated antibody

Applications

Multi-tissue experiments are ideal for comparative studies across many different tissue types. These studies are important to gene expression and safety assessments. This will help researchers understand a disease state, support therapeutic discovery, and aid in drug safety, prevention of adverse events, and identify biomarkers for drug discovery.

(4) Project Details

Estimated Length of Project	18 months to 2 years
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	n/a
Number of Donations Needed	50 to 75 donors needed, Total for 4 projects
Target Partners	Medical Examiners/Coroner's General Hospitals Specialized Hospitals such as VA Hospice
External OPOs:	Experienced and Non-experienced
Materials Required	
Recovery Supplies:	May vary
Training Materials/ Recovery Protocols:	Recovery spec sheets, training videos, training sign off sheets.
Education	Understanding of the end use and recovery parameters
Recovery Parameters	
Postmortem Interval/Delivery Time:	Within 24 hours
Institutional Review Board (IRB)	No
Department-specific	n/a

SKIN PROJECTS

(1) Community Education Level

Introduction

We are inquiring with you about this donation option because your loved one has an opportunity to make a difference in the lives of others and meet the criteria necessary to be invited to participate in this research project. Recovery does not interfere with family viewing plans. Our recovery teams take great care in making sure your family has the services you want and treats every donor with dignity and respect.

Summary

Skin donation can help researchers develop new medicines to treat skin conditions and also improve environmental safety. Researchers are studying new ways to administer medicine through the skin. Donated skin can help researchers identify other medications that can be given through the skin and also new ways to deliver those medications through the skin.

Transdermal means through the skin. You might recognize this type of medication given as a patch, like a nicotine patch, but transdermal can also mean medicines administered through ultrasound or microneedling.

First generation research focuses on transdermal patches, like the nicotine patch. This project studies new medications that can be used in patch form.

Second generation research investigates the types of medicines that can be given through ultrasound technology. This project studies how we can better deliver medications through the skin, without damaging the deeper layers.

Third generation research investigates the types of medicines that can be given through microneedling and microdermabrasion. This project also investigates the types of medicines that can be administered in this way, using these different technologies.

Applications

Skin is one of the most important and largest organs of the human body. We use skin donations to prevent skin diseases and conditions, such as skin cancer, psoriasis, acne, eczema, shingles, hives, and rosacea.

The average adult has 22 square feet of skin. Skin is our first layer of protection from disease, infection, and the environment. Environmental safety includes things like what happens to our skin and our bodies when a substance gets on our skin.

(2) Intermediate Level

Introduction

Skin recovered for research can be used to study and better understand a multitude of skin conditions and/or diseases.

People choose to donate their skin after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for skin diseases or disorders. For others, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health, disease research and wellness for years to come. LifeNet Health is committed to supporting donors and their families who choose research donation.

Researchers use donated skin to study integumentary diseases that affect millions of people such as psoriasis, acne, eczema, shingles, hives, sunburn, dermatitis rosacea, athlete's foot, and basal cell carcinoma. Many skin conditions have mild to moderate adverse effects, but some like basal cell carcinoma present significant threats to health and wellbeing. Whether symptoms are mild to severe it is extremely important to maintain healthy skin, since it is our first layer of protection from disease, infection, and the environment. Donated human skin can greatly improve treatments, enable the development of better skin protection medicines, and improve our understanding of environmental safety.

Other types of integumentary research include transdermal skin assays for the evaluation of drug delivery and chemical toxicity testing. Transdermal delivery represents an attractive alternative to oral delivery of drugs and is poised to provide an alternative to hypodermic injection. For thousands of years, people have placed substances on the skin for therapeutic effects and, in the modern era, a variety of topical formulations have been developed to treat local indications. The first transdermal system for systemic delivery—a three-day patch that delivers scopolamine to treat motion sickness—was approved for use in the United States in 1979. A decade later, nicotine patches became the first transdermal blockbuster, raising the profile of transdermal delivery in medicine and for the public in general. It is estimated that more than one billion transdermal patches are currently manufactured each year.

Summary

Donated research skin is important to study many diseases including psoriasis, acne, eczema, shingles, hives, sunburn, dermatitis rosacea, athlete's foot, and basal cell carcinoma. Skin is also used to study alternative routes of administration for different medicines. There are also studies on the viability of vaccine delivery via the transdermal route. Access to donated skin for research is critical to the development of new therapies and drug and vaccine administration.

Applications

The recovered skin will be used to aid in the discovery of new treatments and therapies for all the above ailments. Transdermal delivery of vaccines would not require higher level medical providers to administer. This would allow delivery on a much broader scale.

The donation of human skin to support research investigating new treatments for skin diseases and other studies exploring transdermal drug and vaccine delivery will significantly reduce the effects of skin diseases and improve the efficacy of drug and vaccine delivery. All this information helps gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

(3) Comprehensive/Technical Level

Introduction

People choose to donate their skin after death for various reasons. For some, the primary motivation is to help scientists discover new treatments and prevention for skin diseases or disorders. For others, the main goal is to have a positive impact on their community and future generations through scientific studies. Despite losing a loved one, some families are comforted by knowing that this action may have a broad, positive impact on public health,

disease research and wellness for years to come. LifeNet Health is committed to supporting donors and their families who choose research donation.

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Summary

Skin is one of the most important tissues of the human body. Human skin can be used to study various skin conditions/diseases as well as approaches to prevent skin conditions/diseases like cancer. Also, Transdermal drug delivery provides several advantages over oral and hypodermic injections e.g., when the liver prematurely metabolizes drugs reducing first pass results, reduced pain and is non-invasive and can be self-administered and can allow for drugs to be released over long periods of time.

Applications

The recovered skin will be used to aid in the discovery of new treatments and therapies for all the above ailments. Transdermal delivery of vaccines would not require higher level medical providers to administer. This would allow delivery on a much broader scale.

The donation of human skin to support research investigating new treatments for skin diseases and other studies exploring transdermal drug and vaccine delivery will significantly reduce the effects of skin diseases and improve the efficacy of drug and vaccine delivery. All this information helps gain a better understanding of disease causes, progression, and treatment options. Ultimately, this knowledge will help researchers better target and test treatments in clinical trials.

(4) Project Details

Estimated Length of Project	2-4 years
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	CAUCASIAN ONLY No skin diseases. No scars, splits, or hair thicker than down. No reddish or darkened skin (suntan okay), and no internal bleed.
Number of Donations Needed	75-100 donors needed
Target Partners	Medical Examiners/Coroner's General Hospitals Specialized Hospitals such as VA Hospice
External OPOs:	Experienced and Non-experienced
Materials Required	
Recovery Supplies:	No
Training Materials/ Recovery Protocols:	Recovery spec sheets, training videos, training sign off sheets.
Education	Understanding of the end use and recovery parameters
Recovery Parameters	
Postmortem Interval/Delivery Time:	72 PMI hours
Institutional Review Board (IRB)	No
Department-specific	n/a

THYROID PROJECTS

(1) Community Education Level

Summary

Thyroid gland: A gland that makes and stores hormones that help regulate the heart rate, blood pressure, body temperature, and the rate at which food is converted into energy. Thyroid hormones are essential for the function of every cell in the body.

The project will provide invaluable testing of a 3D culture model of the human thyroid. For the researcher, changing from a 2D model to a 3D model is like studying a picture of a baseball and then someone hands you an actual baseball. Your perspective and appreciation of the ball completely changes as does our researcher's when he/she is given a 3D model of the human thyroid.

Applications

This study helps identify what amounts of toxins are found in everyday items such as food preservatives, cosmetics, and household cleaners to determine the impact these chemicals have on our thyroid.

(2) Intermediate Level

The US Environmental Protection Agency (EPA), in partnership with LifeNet Health, has invested efforts into developing an in vitro human thyroid microtissue 3D model that is physiologically relevant to humans and capable of examining thyroid hormone production to effectively identify hazards to thyroid function.

Summary

This product addresses the absence of human endocrine cell models for use in toxicology studies. Current challenges in toxicity testing are:

- 1) Too many chemicals and not enough data.
- 2) A broad range of chemical categories: pesticides, cosmetics, drugs, food additives, production, and industry chemicals.
- 3) Over 65,000 chemicals exist with more than 46,000 having no toxicity data of any kind.

LifeNet Health has been supporting the EPA's development of a thyroid chemical screening model over the last three years by providing thyroid tissues. Cell Biologists for the EPA's National Center for Computational Toxicology with the support of LNH tissue recovery and scientific team, has developed a 3D culture model of the human thyroid that could satisfy the EDSPs requirements for a high-throughput and cost-effective model that screens for potential endocrine effects.

Applications

Now that model development is nearing completion, there is a significant need to ramp up testing for evaluating assay predictivity and performance. The EPA has expressed preference for LifeNet Health to be the provider of thyroid tissue through the remainder of the project.

(3) Comprehensive/Technical Level

As part of the Endocrine Disruptor Screening Program (EDSP), the US Environmental Protection Agency (EPA), in partnership with LifeNet Health (LNH), has invested efforts into developing an in vitro human thyroid microtissue model that is physiologically relevant to humans and capable of examining thyroid hormone production to effectively identify hazards to thyroid function.

LifeSciences division is to offer human cell solutions for a range of research applications. Genotyping information is important in experimental designs for compound discovery and development. It can be applied to studies of metabolism rates, drug-drug interactions, disease models, diversity in preclinical investigations, and 3D model and co-culture systems.

Summary

LNH has been supporting the EPA's development of a thyroid chemical screening model over the last three years by providing thyroid tissue and thyroid epithelial cells (thyrocytes). Dr. Chad Deisenroth, Cell Biologist for the EPA's National Center for Computational Toxicology with the support of LNH tissue recovery and scientific team, has developed a 3D culture model of the human thyroid that recapitulates thyroid hormone biosynthesis and provides initial evidence that an in vitro assay could satisfy the EDSP's requirements for a high-throughput and cost-effective model that screens for potential endocrine effects. Now that model development is nearing completion, there is a significant need to ramp up testing for evaluating assay predictivity and performance. Dr. Deisenroth has expressed his preference for LNH to be the provider of thyrocytes through the remainder of the project and has agreed to support the technology transfer of the thyrocyte manufacturing process.

The thyrocytes provided to the EPA in the past have been fresh isolations with which the EPA has expanded, aliquoted, and cryopreserved for use in future experiments. LifeNet Health will develop a cryopreserved primary thyroid assay utilizing thyrocytes at passage 1-2 for the EPA and agro-chemical and general chemical companies, including chemical safety groups and toxicologists for compound risk assessment studies. This product addresses the absence of human endocrine disruption cell models for use in toxicology studies. Current challenges in toxicity testing are 1) too many chemicals and not enough data, 2) a broad range of chemical categories: pesticides, cosmetics, drugs, food additives, production and industry chemicals, and 3) over 65,000 chemicals exist with more than 46,000 having no toxicity data of any kind.

The process outlined above is a result of the following chemical testing regulations.

2009 (EU): Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

- Places responsibility on industry to manage the risks from chemicals and provide safety information on the substances
- Manufacturers and importers required to gather information on the properties of their chemical substances and to register the information in a central database in the European Chemicals Agency (ECHA) in Helsinki

2016 (USA): The Frank R. Lautenberg Chemical Safety for the 21st Century Act

- Amendment of the Toxic Substances Control Act (TSCA), the nation's primary chemical management law.

- Mandatory requirement for EPA to evaluate existing chemicals, establish risk-based safety standards, increase public transparency for chemical information, and provide consistent source of funding for EPA to carry out responsibilities in the law.

The National Research Council's 2007 report titled Toxicity in the 21st Century: A Vision and Strategy highlights the future trends in toxicity testing as 1) reduction and refinement of animal-based studies, 2) an increase in human cell-based testing, 3) an increase in high-throughput screening models, 4) the integration of molecular biology into toxicity testing, and 5) incorporation of elements of population and exposure into risk assessment. Additionally, a message from the EPA Administrator, Andrew Wheeler, in September of 2019 stated the EPA's commitments to reduce requests and funding of mammal studies by 30% by 2025 and eliminate all mammal study request and funding by 2035. The offering of human primary thyrocytes by LifeNet Health will be an essential requirement for the reported future trends in toxicology testing to be carried forward.

Applications

The end resulting product would be used in research laboratories for the purposes of toxicity testing, food, cosmetic and chemical safety, drug development, and disease modeling.

(4) Project Details

Estimated Length of Project	5 years and longer
	Total active projects: 2 from 1 to 6 yrs.
Target Donors	
Type:	Clinical & Research Organ and Tissue Donor
Conditions or Diagnosis:	No hypothyroidism (Hashimoto's thyroiditis), hyperthyroidism (Grave's disease), Goiter, Thyroid cancer. No thyroidectomy. Have currently or ever taken Thyroxin medication. Exclude donors with severe atherosclerotic disease.
Number of Donations Needed	50 to 75 Donors
Target Partners	Medical Examiners/Coroner's General Hospitals Specialized Hospitals such as VA Hospice
External OPOs:	Experienced and Non-experienced
Materials Required	No materials required for the above targeted partners.
Recovery Supplies:	Materials may be required in the future.
Training Materials/Recovery Protocols:	Recovery spec sheets, training videos, training sign off sheets. Understanding of the end use and recovery parameters
Recovery Parameters	
Postmortem Interval/Delivery Time:	2 to 3 hours PMI
Institutional Review Board	No Institutional Review Board (IRB)
Department-specific	n/a

Not seeing what you need?

If you have questions you can contact:

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