NDRI Private Donor Program: Accelerating Biomedical Research via Private Donation

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Webinar Objectives

- NDRI Overview
- Private Donor Program Overview
- How to work with NDRI
- Current project highlights
Why Partner with Us

35 years of experience working with:

• national network of accredited organ/tissue procurement organizations and professionals

• the research community to develop customized projects to meet current scientific needs

• Partner with highly skilled professionals to help champion the wishes of NDRI’s registered participants
NDRI’s History and Overview
Mission Statement

To advance disease research through the procurement, preservation and distribution of human cells, tissues and organs.
Who We Are

NDRI was founded in Philadelphia in 1980

What you should know about NDRI

- A 501c3 corporation
- Governed by a board of directors
- NIH funded
- Support for over 30 years by the National Institutes of Health
- 29,000 biospecimens
- Provided to biomedical scientists per year
- Publishing
- 200 hundred publications annually
Funded by the National Institutes of Health
For over 30 years

NIH – Office of the Director (ORIP)
Additional Funding

Corporate

- Pharma / Biotech Industry

Special Initiatives

- Cystic Fibrosis Foundation Collaboration
- Genotype-Tissue Expression Project (GTEx)
- ATSDR/Boston VA ALS Projects
- Joslin Medalist Diabetes Project
- Children’s Tumor Foundation Project
NDRI’s Reach and Network
Nationwide Procurement Network

- **Organ Procurement Organizations**: 56
- **Tissue Banks**: 23
- **Hospitals**: 43
- **Eye Banks**: 37
- **Recovery Personnel**: 150
  - Forensic Pathologist
  - Hospital Pathologist
  - Medical Examiners
  - Pathology Assistants & Dieners

Advancing Medical Research through Organ and Tissue Donation
Biospecimen Donor Profiles

- Deceased Transplant Donors
- Living Donors
- Pre-registered Research Donors

Organ / Tissue / Eye
Standard Authorization / Consent

Protocol approved by University of Pennsylvania IRB

Authorization for general research including:
- For profit
- Therapeutics and diagnostics
- Genome sequencing

Potential access to complete health record

No payment to donor or family decision maker
Expanded Authorization / Consent

- Project specific IRB approval
- Incorporates additional objectives (e.g. product development)
- Right to withdraw limits
- Addresses risks associated with loss of identity (genotyping)
- Unknown future uses
- Cell line development (unlimited future use)
NDRI’s Fulfillment Department

24/7 Call Center
Key Metrics

58,000 Donation Opportunities Nationally

NDRI 24 / 7 Call Center

29,000 Tissues Placed

4,600 Diseased Tissues / 82 Diseases

500 Researchers Served
Experimental Aim Diversity

Human Tissues and Organs for:

- Physiology and Functional Analysis
- Pathophysiology Studies
- Gene Expression/ Biomarkers screening
- Assay Development
NDRI's Private Donor Program

Advancing Medical Research through Organ and Tissue Donation
The Private Donor Program

A program that gives individuals and their families an opportunity to leave a meaningful legacy for their loved ones by providing a simple system through which organs and tissues can be donated for research after death.

NDRI works with patients and Next-of-Kin to obtain authorization for donation and takes care of recovering tissues and providing them to approved researchers.

To coordinate these recoveries, NDRI partners with Organ Procurement Organizations (OPO), tissue banks, hospitals, pathologist, medical examiners, tissue recovery specialist, and funeral homes.
Benefits to the donor and family

- Donation is the decedents last wishes
- Family member will be able to leave a meaningful legacy for their loved one
- NDRI coordinates all donor recovery process
- Recovery cost is covered by NDRI
What to expect from NDRI

- Obtaining authorization from Next-of-Kin & donation discussion
- Tissue Procurement Form (TPF) & Recovery Work Instructions
- Packing & Shipping Materials
- Transportation of the body (if needed)
- NDRI project examples
Authorization for Research Donation

- NDRI will obtain the authorization and medical & social history from the Next-of-Kin
- Authorization for general research will include:
  - For profit and non-profit agency authorization
  - International distribution authorization
  - Therapeutic & diagnostic authorization
  - Genome sequencing
  - Release of medical records
  - Serological testing
Topics Covered with the Family

1. Tissues requested
   - Potential tissues will be explained to the family, including the recovery process
   - Some tissues requested are disfiguring
     - Disfiguring tissues will only be requested if the family is comfortable with the recovery and that it will be a direct cremation with no viewing
     - Reconstructive material will be provided by NDRI (if needed)
# Tissue Protocols

## Donor Recovery Form

**Print Date/Time:** 2/2/2015 at 2:30:15PM

**To Be Completed by NDRI**

<table>
<thead>
<tr>
<th>Donor #</th>
<th>Age/Race/Sex</th>
<th>Consent Verified</th>
<th>Tissues Authorized for research:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td>Kidney, Skin, Eyes, Pancreas, Heart, Abdominal Aorta.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Tumor, additional (see authorization form).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Recovery Tissue:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Recovery Location:</td>
</tr>
</tbody>
</table>

**To Be Completed by Recovery Tech**

<table>
<thead>
<tr>
<th>Date and Time of Recovery Initiation:</th>
<th>Date and Time of Recovery Completion:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HFP - Hours Past to Preservation, DTD - Days to Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney - Diabetic - Type I</td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>Procurement Instructions:</td>
</tr>
<tr>
<td>DONOR CONTRAINDICATIONS:</td>
</tr>
<tr>
<td>Screening Notes: Tissue must be delivered to the researcher within 45 hours post-mortem.</td>
</tr>
<tr>
<td>Protocol Groupings: N/A</td>
</tr>
<tr>
<td>Procurement: Recover a whole kidney.</td>
</tr>
<tr>
<td>Preservation: Place the sample and place each kidney in a separate rigid storage container with PBS and antibiotics.</td>
</tr>
<tr>
<td>Packaging: Please label container with project code, tissue, time, preservation, recovery location (left or right) and donor number.</td>
</tr>
<tr>
<td>Short-term Storage: Samples must be stored at 4°C within a refrigerator or on wet ice until shipment.</td>
</tr>
<tr>
<td>Shipping: Post procurement an NDRI coordinator will provide you with the paperwork for shipment. Samples are to be shipped on wet ice. Contact NDRI immediately following procurement.</td>
</tr>
</tbody>
</table>

| Preservation: Number of Tissues Recovered: Location of Recovery: Recovery Comment: |
|--------------------------------------|---------------------------------|-----------------|
|                                      |                                 |                 |

<table>
<thead>
<tr>
<th>Slims - Full Thickness - Diabetic - Type I</th>
<th>5x3 CM 2</th>
<th>Fresh PBS + antibiotics</th>
<th>DEBC1 002 003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procurement Instructions:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DONOR CONTRAINDICATIONS:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screening Notes: Tissue must be delivered to the researcher by 10 hours post-mortem.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol Groupings: N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procurement: Recover a random sample of full thickness skin. Notes the recovery location on the Tissue Recovery Log (TRL).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preservation: Place the specimen in a sterile rigid container filled with PBS and antibiotics.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Packaging: Please label each container with project code, tissue, time, preservation, donor number and recovery location.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term Storage: Samples must be stored at 4°C within a refrigerator or on wet ice until shipment.</td>
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<tr>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Preservation: Number of Tissue Recovered: Location of Recovery: Recovery Comment: |
|--------------------------------------|---------------------------------|-----------------|
|                                      |                                 |                 |
Tissue Protocols

Tissue Procurement Form (TPF) Includes:

- Hours post to preservation (HPP)
- Hours post to delivery (HPD)
- Media Preservation
- Tissue Requested
- Amount of tissue requested
- Researcher Code
- Procurement Instructions
Recovery Work Instructions

- Detailed recovery work instructions
  - Step by step process of the recovery
  - Packaging instructions
  - Shipping instructions
Private Donor Program

Expectations of recovery partners
Recovery Partners Expectations

• Professional & accountable
• Flexible availability (nights and weekends)
  • Timely recovery to meet timely tissue constrains and funeral arrangements
• Appropriate contact information & documents
  • Signed NDRI contract agreement & Completed W9
  • Updated resumes, CV’s, training documents, and insurance coverage
• Workers comp is not covered by NDRI
Recovery Partners Expectations

- Possess the proper tools for organ & tissue recovery
- Possesses the ability to store the recovery kit, including transport media
- Clear understanding of tissues requested
- Has access to dry ice for freezing tissues
- Demonstrates proficiency with prosthetics
Private Donor Project Examples

Type 1 Diabetes

• Funded by the Joslin Diabetes Center

• Patients identified and consented by collaborators

• Nationwide recoveries using NDRI Private Donor Program
  ➢ Tissue recovered from >50yr T1D patients
  ➢ Collects kidneys, pancreas, eyes, heart, aorta, skin, and long bone (femur or tibia)
  ➢ Recoveries completed < 24 hours *post mortem*
Private Donor Project Examples

Amyotrophic Lateral Sclerosis

• Two funded projects
  ➢ ATSDR / McKing Corporation
  ➢ Boston VA

• Patients identified and consented by collaborators

• Nationwide recoveries using NDRI Private Donor Program
  ➢ Collects brain, spinal cord, CSF, bone and skin
  ➢ Recoveries completed < 24 hours post mortem
Private Donor Project Examples

HIV

• Funded by NIAID

• Patients identified and consented by NDRI

• Nationwide recoveries using NDRI Private Donor Program
  ➢ Collects brain (cortex & frontal lobe), CSF, liver samples, blood (blood & plasma), lymph nodes, kidney cortex, adipose, lung samples, spleen, bone marrow, thymus
  ➢ Recoveries completed < 24 hours post mortem
Bench to Bedside Success

Cystic Fibrosis

- Explanted lungs recovered from CF patients undergoing transplant
- NDRI provided 200 CF lungs for Cystic Fibrosis Foundation-funded scientists
- Two new drugs developed
  - Kalydeco FDA approved, and
  - VX809/Kalydeco in Clinical Trials
Private Donor Program Summary

- Established nationwide network
- Pre-registered donors
  - Authorization
  - Customized donation plans
- Fulfill patients last wishes
- Help cure common and rare diseased through research donation
Thank you!

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