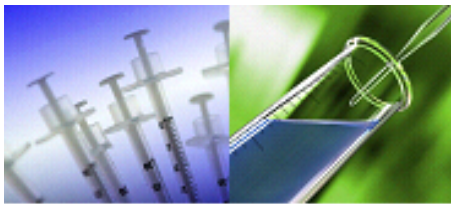


Before filling out the form, please check the [JDRF nPOD site](#) to make sure you are using the current form.



## nPOD Project Addendum Form

<b>Approved nPOD Project Title</b>	
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### PRINCIPAL INVESTIGATOR/CO-INVESTIGATOR INFORMATION

<b>PI Last Name</b>		<b>First Name</b>		<b>Degree(s)</b>	
<b>Email</b>			<b>Phone</b>		
<b>Institution</b>			<b>Department</b>		
<b>Address</b>					
<b>City</b>		<b>State</b>		<b>ZIP</b>	
				<b>Country</b>	
<b>Co-PI Last Name</b>		<b>First Name</b>		<b>Degree(s)</b>	
		<b>First Name</b>		<b>Degree(s)</b>	
<b>Email</b>			<b>Phone</b>		
<b>Email</b>			<b>Phone</b>		
<b>Addendum Title (if any)</b>					
<b>Specific Objectives</b>					

### CURRENT AND PENDING GRANTS SUPPORTING THE PROPOSED STUDIES OF nPOD SAMPLES

<b>Grant Title</b>	<b>Agency and Award ID</b>

Before filling out the form, please check the [JDRF nPOD site](#) to make sure you are using the current form.

**PROJECT CATEGORY:** Please select only ONE category

<input type="checkbox"/> Beta Cell Physiology & Dysfunction	<input type="checkbox"/> Beta Cell Development, Differentiation & Regeneration	<input type="checkbox"/> Bone Marrow Studies	<input type="checkbox"/> Bone Marrow Studies
<input type="checkbox"/> Core Lab	<input type="checkbox"/> Immunology	<input type="checkbox"/> Novel Biomarkers	<input type="checkbox"/> Novel Technologies
<input type="checkbox"/> Pathology	<input type="checkbox"/> T1D Etiology & Environment	<input type="checkbox"/> Other (list):	

**LAB CONTACT & SHIPPING INFORMATION**

<b>Lab Contact Person</b>				<b>Cell Phone</b>			
<b>Email</b>				<b>Lab Phone</b>			
<b>FedEx Acct</b>				<b>Lab Fax</b>			
<b>FedEx Shipping Address</b>							
<b>City</b>		<b>State</b>		<b>ZIP</b>		<b>Country</b>	
<b>Shipping Instructions</b>							

**LAB CONTACT & SHIPPING INFORMATION FOR WEEKENDS AND HOLIDAYS**

<b>Weekend/Holiday Contact Name</b>				<b>Cell Phone</b>			
<b>Email</b>				<b>Lab Phone</b>			
<b>FedEx Account</b>							
<b>Weekend/Holiday Shipping Address</b>							
<b>City</b>		<b>State</b>		<b>ZIP</b>		<b>Country</b>	
<b>Shipping Instructions</b>							

Before filling out the form, please check the [JDRF nPOD site](#) to make sure you are using the current form.

### DONOR TYPES REQUESTED:

Select all donor types being requested, then **clarify specific donor features**/case ID numbers, and the **total number of donors** needed per donor.

DONOR TYPE	SPECIFIC FEATURES OR CASE ID #	TOTAL # DONORS/TYPE
<input type="checkbox"/> No diabetes (control)		
<input type="checkbox"/> Autoantibody Positive Only		
<input type="checkbox"/> Type 1 Diabetes		
<input type="checkbox"/> Type 1 Diabetes Medalist		
<input type="checkbox"/> Type 2 Diabetes		
<input type="checkbox"/> Other <a href="https://www.jdrfnpod.org/for-investigators/donor-groups/">(https://www.jdrfnpod.org/for-investigators/donor-groups/)</a>		

### DONOR DEMOGRAPHICS REQUESTED:

<b>Age</b>	<input type="checkbox"/> Any	<input type="checkbox"/> Specific ages, list:	
<b>Gender</b>	<input type="checkbox"/> Any	<input type="checkbox"/> Female only	<input type="checkbox"/> Male only
<b>Ethnicity</b>	<input type="checkbox"/> Any	<input type="checkbox"/> Specific ethnicity, list:	

Before filling out the form, please check the [JDRF nPOD site](#) to make sure you are using the current form.

### SAMPLE TYPES REQUESTED:

Select all sample types being requested, then indicate the **specific number** of slides, cryovials, cells or other specific amount required – **do not enter “x”**

SAMPLE TYPE	PANCREAS	PLN	SPLEEN	NON-PLN	OTHER, LIST:
<input type="checkbox"/> Paraffin Slides					
<input type="checkbox"/> Frozen OCT Slides					
<input type="checkbox"/> Snap Frozen Cryovial					
<input type="checkbox"/> Snap Frozen in RNAlater					
<input type="checkbox"/> Cryopreserved Cells**	N/A				
<input type="checkbox"/> Fresh (minced in media)	N/A				
<input type="checkbox"/> Serum/Plasma	If yes, Volume (µl) needed per donor				
<input type="checkbox"/> PBMC**					
**Estimated cells (millions) needed per donor					

### ISOLATED ISLET TYPES REQUESTED

Donor Type	# of IEQ Requested	Minimum IEQ Necessary (should an isolation produce a low yield and distributions must be prioritized)	Form of IEQ
<input type="checkbox"/> Isolated Islets from donors with T1D			<input type="checkbox"/> Fresh Islets <input type="checkbox"/> Cryopreserved Islets <input type="checkbox"/> Supernatant
<input type="checkbox"/> Isolated Islets from Aab+ donors			<input type="checkbox"/> RNA <input type="checkbox"/> DNA <input type="checkbox"/> Exocrine tissue

### SPECIAL REQUESTS

Before filling out the form, please check the [JDRF nPOD site](#) to make sure you are using the current form.

## **EXPERIMENTAL PLAN**

Please limit sections A-E to *no more* than 3 pages of text, excluding references, figures/tables. Be sure to read the **highlighted text**, which provides instructions/clarification for some sections. Please insert text in the boxes; the boxes will expand as you type in.

### **A. PROJECT SUMMARY**

In non-technical language, please describe your proposed project in about 300 words. It will be published on the nPOD website once your project is approved. This will not only help our current and future Investigators better understand your work and facilitate collaboration, it will also help the general public better understand the important work our Investigators are doing.

### **B. SPECIFIC AIMS**

### **C. BACKGROUND AND HYPOTHESIS**

Before filling out the form, please check the [JDRF nPOD site](#) to make sure you are using the current form.

#### D. REASON FOR ADDENDUM

Please select which best describes the reason for your new request (check as many as apply):

- |  |   |
|--|---|
| <input type="checkbox"/> Continue current study  | <input type="checkbox"/> Expand current study |
| <input type="checkbox"/> Explore a new direction | <input type="checkbox"/> Other                |

Please explain in greater detail the reason for your new request. Be sure to specify in which ways your proposed addendum is related to your original project. If your request is not related to the original project, it may have to be submitted as a new project. Remember that you are requesting precious tissues and nPOD needs to ensure the best possible use.

#### E. PROGRESS REPORT

Please include supporting data documenting progress made in your original nPOD project that would justify this new request.

#### F. EXPERIMENTAL APPROACH

Before filling out the form, please check the [JDRF nPOD site](#) to make sure you are using the current form.

## G. FIGURES/TABLES

In addition to including any figures and tables needed to illustrate your progress and experimental approach, we encourage Investigators to fill out a table illustrating any new antibody combinations proposed per slide (template below), which helps to accurately estimate the number of slides needed. We further encourage staining for multiple markers simultaneously, as this not only tends to be more informative, but also reduces the total number of slides needed.

Table 1: Antibody combinations to illustrate the markers studied per slide					
ANTIBODY COMBINATION		MARKER A	MARKER B	MARKER C	MARKER D
<i>EXAMPLE</i>	<i>Ab 1</i>	<i>Dapi</i>	<i>GCG (Rb, Dako)</i>	<i>INS (GP, Dako)</i>	<i>CD45 (Rat, BD)</i>
	<i>Ab 2</i>	<i>N/A</i>	<i>Dkey anti Rb 488</i>	<i>Dkey anti GP 594</i>	<i>Dkey anti-Rat 647</i>
Combination #1	Ab 1				
	Ab 2				
Combination #2	Ab 1				
	Ab 2				
Combination #3	Ab 1				
	Ab 2				

## H. JUSTIFICATION FOR THE TISSUES REQUESTED

Please provide justification for each type of tissue you request, as well as for each donor type (control, new onset T1D, etc.), and the number of specimens/donors. Specify if different types of tissues have to be matched (i.e., from the same donor). Please explain any other special requirements. Consider that tissues from new onset T1D and autoantibody-positive patients are particularly rare and valuable; therefore you need to provide strong justification to receive them. While preparing this application, please make sure to check the nPOD Online Pathology Database (password required) to review basic morphology and staining. More information on the nPOD Online Pathology database can be found here: <http://jdrfnpod.org/online-pathology.php>. Once you have reviewed nPOD's biorepository, **we strongly encourage potential Investigators to consult with nPOD OPPC's Director (Dr. Irina Kusmartseva) before submitting the application, in order to verify specific tissue availability.**

Before filling out the form, please check the [JDRF nPOD site](http://www.jdrfnpod.org) to make sure you are using the current form.

## **I. EXPECTED OUTCOME AND SIGNIFICANCE FOR THE ADVANCEMENT OF KNOWLEDGE ABOUT HUMAN T1D AND A POTENTIAL CURE**

Please check the Current Projects page of the nPOD website for a list of projects currently supported by nPOD (<http://www.jdrfnpod.org/publications/current-npod-projects/>). Please note any potential scientific overlap with ongoing projects. While overlap does not necessarily preclude approval, it does help if your project can be synergistic and provide additional information with limited overlap. When projects have similar or overlapping approaches, nPOD tries to encourage collaboration and data/sample sharing among investigators. Data generated by nPOD Investigators from the study of nPOD tissues will contribute to developing a comprehensive view of human T1D, as Investigators study different aspects of the same specimens. For example, while independent Investigators will separately study T cell responses and the presence of viruses, sharing of data will shed light on where there is a correlation of a virus with a particular immune response. Ultimately, nPOD Investigators participate in a collaborative effort to characterize human T1D.

## **J. PARTICIPATION AND RELEVANCE TO nPOD WORKING GROUPS**

nPOD is evolving from Investigator-initiated projects to a model of coordinated team science and collaboration. We believe that collaboration and working groups can lead to more impactful discoveries. Several working groups are operational: the nPOD-Virus group, the nPOD-Autoimmunity group (T cell, TCRs, B cells, etc.), the nPOD-Extracellular Matrix group, nPOD-Omics group, nPOD-Transplant, nPOD-Slice, nPOD-IIP, and more are being formed. Updated Working Group information can be found at <http://www.jdrfnpod.org/publications/npod-working-groups/>. Support will be made available for specific research initiatives designed by a given group. For any questions regarding Working Groups, please contact [Sirlene Cechin](#). Please describe how your proposed studies can be relevant to existing working groups and which ones.



## K. REFERENCES

## L. DATA SHARING

Investigators approved to study nPOD tissues become members of the nPOD Consortium and may perform independent studies. However, nPOD aims at developing a comprehensive understanding of the abnormalities associated with T1D. Thus, nPOD studies will be coordinated to promote sharing of information and to reach the best possible understanding of T1D from the collective study of human tissues. Sharing of research data among nPOD Investigators is of critical importance to the project and will be accomplished in a variety of ways, including regular working group meetings, scientific forums and inclusion of the data in nPOD DataShare. Furthermore, studies performed as part of nPOD Working Groups will be coordinated to regulate samples utilization by employing careful samples allocation, assays that spare material, and sharing of information learned from these precious and rare samples.

Upon becoming an approved nPOD Investigator you may request a DataShare account, so you can access the system. Please contact [Amanda Myers](#) to set up an account. As nPOD members, Investigators are also expected to share reagents, methods, and strategies with other members of the Consortium. Sharing and collaboration will be implemented in a way that preserves publication and other rights of consortium members. Please check the box and type your name below to agree on sharing data generated in this project using nPOD samples. Again, this is part of the nPOD mission to generate a comprehensive analysis of human Type 1 Diabetes.

**I Agree to the nPOD Data Sharing policy.**

**My name (Please type):**

For the purpose of helping you set up your DataShare account, please specify what type of data you will share by checking the boxes below:

- IHC images, I can scan whole slides: Yes , No
- Fluorescent images, I can scan whole slides: Yes , No
- Sequencing data
- Gene expression data
- Proteomics data
- Flow Cytometry data
- PCR data
- Other - Please specify:

## M. PUBLICATION POLICY AGREEMENT

We ask all nPOD Investigators to become and remain familiar with the [nPOD Publication and Presentations Policies](#). This policy document includes acknowledging statements, governs the use of the nPOD images in publications, explains how to identify nPOD samples in your work, and provides other guidelines related to presentations and publications. As an approved nPOD Investigator, you are responsible for abiding by the guidelines and requirements of this document. Additional information on image terms of use, acknowledging statements, nomenclature, logos and more can be found at <http://www.jdrfnpod.org/publications/policies/>.

I have read and Agree to the terms of the [nPOD Publication and Presentation Policies](#).  
**My name (Please type):**

#### N. INSTITUTIONAL REVIEW BOARD/ETHICAL BOARD APPROVAL

nPOD is required to have a **current** Institutional Review Board (IRB)/Ethical Board approval on file for each approved Investigator before any tissue samples from the nPOD biobank can be distributed. The nPOD ethical approval from the University of Florida can be [found by clicking here](#) and could expedite your own ethical approval for this research. Please indicate the nature of your IRB/Ethical Board review below.

- If your institution requires full ethical review board approval, please forward the submitted protocol, as well as the protocol approval letter for this study to be kept in your nPOD investigator file.
- If your institution provides exemption for “Non-human subject” research studies, please provide the exemption letter from your ethical board to be kept in your nPOD investigator file.

**IF YOUR INSTITUTION DOES NOT REQUIRE EITHER APPROVAL OR EXEMPTION, PLEASE PROVIDE A LETTER INDICATING THAT YOUR ETHICAL BOARD DOES NOT REQUIRE DOCUMENTATION FOR “NON-HUMAN SUBJECTS” RESEARCH STUDIES ON INSTITUTIONAL LETTERHEAD TO BE KEPT IN YOUR NPOD INVESTIGATOR FILE.**

<input type="checkbox"/> IRB/Ethical Board <b>Approval</b> required	<input type="checkbox"/> IRB/Ethical <b>Approval</b> documentation attached	<input type="checkbox"/> IRB/Ethical <b>Approval</b> pending
<input type="checkbox"/> IRB/Ethical Board <b>Exempt</b>	<input type="checkbox"/> IRB/Ethical <b>Exemption</b> documentation attached	<input type="checkbox"/> IRB/Ethical <b>Exemption</b> pending
<input type="checkbox"/> IRB/Ethical Board review <b>‘Not Required’</b>		<input type="checkbox"/> IRB/Ethical Board review <b>‘Not Required’</b> documentation attached

#### O. MATERIAL TRANSFER AGREEMENT

nPOD samples and their derivatives remain the property of nPOD.

Approved Investigators may only use nPOD samples for the use approved by the Tissue Prioritization Committee, and may not make any additional use of the material without prior consent.

We understand that scientific goals often evolve; in that event, please submit an addendum application to update your research plan, report progress, request more specimens, or request the reallocation of specimens to a different use that is still related to the original scope of the work. Should you wish to reallocate samples to a different and new project, you may have to submit a new project application.

We encourage you to check with us so we can advise on the best course of action to expedite and facilitate a request.

Investigators may not share nPOD samples or their derivatives. Unused samples should be returned to nPOD.

To this end, nPOD is required to execute a Material Transfer Agreement (MTA) for each approved Investigator. A blank copy can be found here: [HTTPS://WWW.JDRFNPOD.ORG/WORDPRESS/WP-CONTENT/UPLOADS/2017/11/NPOD-MTA-BLANK-04-19-17.PDF](https://www.jdrfnpod.org/wordpress/wp-content/uploads/2017/11/npod-mta-blank-04-19-17.pdf). The MTA is designed to be very simple and non-restrictive by University of Florida legal counsel and is considered non-negotiable. The MTA needs to be signed by someone with signing authority from your institution as the “Recipient”, and by the prospective PI of your project as the “Recipient Scientist”. Please submit this agreement with your application, and a completed copy will be returned to you after your application has been approved. Please send any questions regarding the specific language of the MTA to Investigator Coordinator, [Amanda Myers](#).

**I have read and agree to the terms of the nPOD MTA, and will provide a copy signed by myself and my institution.**

#### **P. CONSIDERATION FOR PILOT FUNDING THROUGH THE HELMSLEY CHARITABLE TRUST GEORGE S. EISENBARTH nPOD AWARD FOR TEAM SCIENCE**

The Leona M. and Harry B. Helmsley Charitable Trust is partnering with the JDRF nPOD to support research on nPOD donors and help advance research about the causes of human Type 1 Diabetes. The generous funding provided by the Trust has been named the Helmsley Charitable Trust George S. Eisenbarth nPOD Award for Team Science to honor the memory of the late George Eisenbarth, a true pioneer in diabetes research who also was instrumental in the creation of nPOD. You may qualify for support through the pilot funding program as outlined below:

##### **Pilot Program**

The spirit of the pilot program is to support Investigators in initiating innovative research using nPOD specimens. There are some criteria that help qualify a study for nPOD pilot funding:

1. **Conceptual Innovation:** the scope of the work is innovative, by testing a novel hypothesis which is not been pursued by other nPOD Investigators (please check projects summaries on the nPOD site; if in doubt, please contact us ahead of the submission)
2. **Methodological Innovation:** the work is based on developing and validating novel methodological approaches that have not yet seen application to the study of the pancreas or Type 1 Diabetes (e.g., these would include methods that allow improved analytical ability, sensitivity, utilize less tissue, and more)
3. **Lack of Dedicated Funding:** the Investigator has no specific grant support for this project
4. **Relevance to nPOD Main Research Themes/Working Groups:** while not an absolute requirement, pilot studies that can later find application or further development in the context of

working groups, or can provide methodological advances that can facilitate the progress of working groups, are encouraged

From time to time, we may identify specific areas of study or methodologies for which nPOD has programmatic interest in supporting, but applications can be submitted on any topic, any time. Overall project approval and funding approval are not necessarily linked. A project may be approved, but not necessarily receive direct funding. **Pilot funding requests are limited to \$50,000, plus 10% indirect cost.** The typical turnaround time for reviewing pilot applications is less than 60 days, depending on when the application is submitted in relation to review meetings, which on average take place every 2 months.

If awarded, a progress report would be expected at least yearly and at the completion of the study. Data generated shall be deposited in the nPOD DataShare system, while Investigators retain full right to publication. At the completion of the study Investigators should also present their results at the annual nPOD meeting or during an nPOD Webinar. **Publications should acknowledge support from the JDRC nPOD and the Helmsley Charitable Trust George S. Eisenbarth nPOD Award for Team Science.**

Prospective or approved nPOD Investigators can also obtain support through participation in nPOD Working Groups. Contact [Sirlene Cechin](#) to inquire.

Please check this box if you wish to be considered for pilot funding. Requests up to \$50,000 will be considered, **but you can request less**. If you checked the box, please provide narrative to address all of the 4 points above and provide a simple budget. (Maximum 600 words for topic 1-4 below)

**1. Conceptual innovation:**

**2. Methodological innovation:**

**3. Lack of dedicated funding:**

**4. Relevance to nPOD main research themes/working groups:**

#### **Q. BUDGET FOR HELMSLEY PILOT FUNDING (UP TO \$50,000 + 10% indirect cost)**

Please calculate your budgets in U.S. \$ based on the following criteria:

Budgets should be calculated based on the actual project cost independent of time (because studies may be performed over very variable periods based on availability of donor tissues relevant to the study).

Before filling out the form, please check the [JDRF nPOD site](#) to make sure you are using the current form.

**PI and personnel cost:** please estimate the effort based on projected actual time required for the project, not as annual percent effort (for example, 50 hours at a \$50 salary rate = \$2,500; if staining 10 slides and the procedure requires 4 hours of actual work, then it would be cover 4 hours).

**Technical supplies:**

<b>PI</b>	
<b>Personnel</b>	
<b>Supplies</b>	
<b>Other</b>	
<b>Travel (limited \$1,000 to present at the annual nPOD meeting)</b>	
<b>TOTAL DIRECT COSTS</b>	
<b>INDIRECT COSTS (up to 10%)</b>	
<b>TOTAL COSTS</b>	

**R. BUDGET JUSTIFICATION**

**PI and personnel cost:**

**Supplies:**

**Other:**

**Travel:**

Before filling out the form, please check the [JDRF nPOD site](#) to make sure you are using the current form.

## S. nPOD User's Agreement

I acknowledge that the conditions for use of this research material are governed by the University of Florida Institutional Review Board (IRB) or the Principal Investigator's IRB in accordance with Department of Health and Human Services regulations at 45 CFR 46 and the nPOD Material Transfer Agreement.

I acknowledge that I have read and understand the data sharing plan and confirm my willingness to share data with nPOD, again as a part of its mission to generate a comprehensive analysis of human type 1 diabetes.

I acknowledge that I have read and agree to the terms of the nPOD MTA.

By my signature below, I agree to the terms set forth above:

PI Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Along with your nPOD Project Application, please provide the following files:**

1. NIH-formatted Biographical Sketch for the PI and any Co-PIs
2. IRB approval or exemption letter copy
3. nPOD Material Transfer Agreement
4. nPOD User's Agreement (current page)

Following completion, email the application and required files to [npod@pathology.ufl.edu](mailto:npod@pathology.ufl.edu).