

**nPOD New Project/Investigator Application**

|  |
| --- |
| Principal investigator/co-investigator Information |
| **PI Last Name** |  | **First Name** |  | **Degree(s)** |  |
| **Email** |  | **Phone** |  |
| **Institution** |  | **Department** |  |
| **Address** |  |
| **City** |  | **State** |  | **ZIP** |  | **Country** |  |
| **Co-PI Last Name** |  | **First Name** |  | **Degree(s)** |  |
|  | **First Name** |  | **Degree(s)** |  |
| **Email** |  | **Phone** |  |
| **Email** |  | **Phone** |  |
| **Project title** |  |
| **Specific objectives** |  |
| **CURRENT AND PENDING GRANTS SUPPORTING THE PROPOSED STUDIES OF nPOD SAMPLES** |
| **Grant title** | **Agency and award ID** |
|  |  |
|  |  |

|  |
| --- |
| **PROJECT CATEGORY:** Please select only ONE category |
| [ ]  Beta Cell Physiology & Dysfunction | [ ]  Beta Cell Development, Differentiation & Regeneration | [ ]  Bone Marrow Studies | [ ]  Bone Marrow Studies |
| [ ]  Core Lab | [ ]  Immunology | [ ]  Novel Biomarkers | [ ]  Novel Technologies |
| [ ]  Pathology | [ ]  T1D Etiology & Environment | [ ]  Other (list):  |
| lab contact & shipping information |
| **Lab contact person** |  | **Cell phone** |  |
| **Email** |  | **Lab phone** |  |
| **FedEx acct** |  | **Lab fax** |  |
| **FedEx shipping address** |  |
|  |
| **City** |  | **State** |  | **ZIP** |  | **Country** |  |
| **Shipping instructions** |  |
| Donor Requests (check appropriate donor categories by double-clicking on gray box and selecting the option “checked”) |
| **Diagnosis** | **Specific features or desired case IDs** | **Total # donors/group** |
| **[ ]  No diabetes (control)** |  |  |
| **[ ]  Autoantibody positive only** |  |  |
| **[ ]  Type 1 diabetes** |  |  |
| **[ ]  Type 1 diabetes Medalist** |  |  |
| **[ ]  Type 2 diabetes** |  |  |
| **[ ]  Other** |  |  |
| **Demographics** |
| **Age** | [ ]  Any | [ ]  Specific ages, list |  |
| **Gender** | [ ]  Any | [ ]  Female only | [ ]  Male only |
| **Ethnicity** | [ ]  Any | [ ]  Specific ethnicity, list |  |
| Sample Requests: Indicate the number of slides, cryovials, cells or other specific amount required – DO not enter “x” |
|  | **Pancreas** | **PLN** | **Spleen** | **Non-PLN** | **Other, list:** |
| **[ ]  Paraffin slides** |  |  |  |  |  |
| **[ ]  Frozen OCT slides** |  |  |  |  |  |
| **[ ]  Snap frozen cryovial** |  |  |  |  |  |
| **[ ]  Snap frozen cryovial**  |  |  |  |  |  |
| **[ ]  Snap frozen in RNAlater** |  |  |  |  |  |
| **[ ]  Cryopreserved cells\*\*** | N/A |  |  |  |  |
| **[ ]  Fresh (minced in media)** | N/A |  |  |  |  |
| **[ ]  Serum/Plasma** | If yes, Volume (µl) needed per donor |  |
| [ ]  **PBMC\*\*** |
| \*\*Estimated cells (millions) needed per donor |  |
| **Special Requests:** |  |

**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.

|  |
| --- |
| PROJECT SUMMARY |
| In non-technical language, please describe your project in about 300 words. This will help our current and future investigators better understand your proposed work and facilitate collaboration. It will be published on the nPOD website once your project is approved. |
|  |
|

|  |
| --- |
| **SPECIFIC AIMS** |
|  |

 |
| Background and hypothesis |
|  |

|  |
| --- |
| Preliminary Data |
| Please pay special attention to demonstrate feasibility of your methods. For example, while we can help you with control tissue to validate a new staining technique, we would not immediately provide tissues from patients in your desired donor groups if that technique is not well established. Remember that you are requesting precious tissues and nPOD needs to ensure the best possible use. |
|  |
| Experimental Approach |
|

|  |
| --- |
| figures/Tables |
|  |

 |
| 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; in other words, have to be 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) for projected tissue availability. 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, please contact the nPOD OPPC at npod@pathology.ufl.edu for further inquiry about specific tissue availability. We strongly encourage investigators to consult with nPOD OPPC’s Director (Dr. Irina Kusmartseva) before submitting the application. |
|  |
| 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 (<http://www.jdrfnpod.org/publications/current-npod-projects/>) for a list of projects currently supported by nPOD. 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. (Maximum 200 words) |
|  |
| 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, and more are being formed. A focus group is centered on the study of nPOD pancreas transplant donors. Updated Working Group information is maintained on the nPOD website. 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. (Maximum 200 words) |
|  |
| 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 scientific forums and inclusion of the data in the nPOD DataShare. Upon becoming an approved nPOD investigator you may request a DataShare account, so you can access the system. Please contact Dr. John Kaddis to set up an account. As nPOD members, investigators are also expected to share reagents, methods, strategies, and when appropriate samples 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: |
| 1. **INSTITUTIONAL REVIEW BOARD/ETHICAL BOARD APPROVAL**
 |
| The nPOD ethical approval from the University of Florida can be [found by clicking here](http://www.jdrfnpod.org/wordpress/wp-content/uploads/2014/06/IRB2014.pdf) and could expedite your own ethical approval for this research. **Current** Institutional Review Board/Ethical Board approval is *required* to be on file with nPOD before any tissue samples from the nPOD biobank can be distributed. * 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.
 |
| [ ]  IRB/Ethical Board **Approval** required | [ ]  IRB/Ethical **Approval** documentation attached | [ ]  IRB/Ethical **Approval** pending |
| [ ]  IRB/Ethical Board **Exempt** | [ ]  IRB/Ethical **Exemption** documentation attached | [ ]  IRB/Ethical **Exemption** pending |
| [ ]  IRB/Ethical Board review **‘Not Required’** | [ ]  IRB/Ethical Board review **‘Not Required’** documentation attached |
| References |
|  |
| 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 advancing 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 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. For example, 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 $25,000, 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 JDRF 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 $25,000 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:**
 |
| BUDGET FOR PILOT (UP TO $25,000 + 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). **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:**  |
| **PI** |  |
| **Personnel** |  |
| **Supplies** |  |
| **Other** |  |
| **Travel (limited $1,000 to present at the annual nPOD meeting** |  |
| **TOTAL DIRECT COSTS** |  |
| **INDIRECT COSTS (up to 10%)** |  |
| **TOTAL COSTS** |  |
| BUDGET JUSTIFICATION |
| **PI and personnel cost:** **Supplies:****Other:****Travel:**  |

1. **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 1diabetes.

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

PI Signature: Date:

Attach the following files: 1) NIH-formatted Biographical Sketch (PI and up to 2 co-investigators), 2) IRB approval or exemption letter copy 3) nPOD Material Transfer Agreement.

Following completion, email application and required files to npod@pathology.ufl.edu.

Scan & Email/Fax a copy of the PI signature (current page) to:

npod@pathology.ufl.edu

Fax: (352) 273-9370