

**nPOD Project Addendum Form**

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| **Approved nPOD project title** |  |
| 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** |  |
| **Addendum title** |  |
| **Specific objectives** |  |

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| 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** | **Number of donors** |
| **[ ]  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: |

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| 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.

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| 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. |
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| **SPECIFIC AIMS** |
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| Background and hypothesis |
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| reason for addendum |
| Please select which best describes the reason for your new request (check as many as apply): |
| [ ]  Continue current study | [ ]  Expand current study |
| [ ]  Explore a new direction | [ ]  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. |
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| progress report |
| Please include supporting data documenting progress made in your original nPOD project that would justify this new request.  |
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| Experimental Approach |
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| figures/Tables |
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| 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. |
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| 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) |
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| 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) |
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| References |
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| data sharing plan |
| 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: |
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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:

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