

**nPOD New Project / Addendum Application**

Text boxes are expandable. There is no word limit, but please be concise.

|  |  |
| --- | --- |
| 1. **APPLICATION TYPE** | |
| **Proposal Type** | PROJECT  ADDENDUM TO APPROVED PROJECT |
| **Submission Type** | NEW APPLICATION  REVISED APPLICATION |
| **Project Title** |  |
| **Specific Objectives** |  |
| **If Addendum proposal, list title of approved parent project below:** | |
|  | |

|  |  |
| --- | --- |
| reason for addendum, IF APPLICABLE | |
| Please select which best describes the reason for your new request (check as many as apply): | |
| Advance study to next stage/request more samples | Expand scope of study to explore a new, related direction or question |
| Add a donor group to the study | Add a co-Investigator |
| Change Institution | Other |
| 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. | |
|  | |

|  |  |  |
| --- | --- | --- |
| 1. **PROJECT CATEGORY:** Please select only **ONE** category | | |
| Beta Cell Physiology & Dysfunction | Beta Cell Development, Differentiation, & Regeneration | Immunology |
| Novel Biomarkers | Novel Technologies | Exocrine Pancreas |
| Pathology | T1D Etiology & Environment | Other (list): |

|  |  |  |
| --- | --- | --- |
| 1. **ORIGIN OF PROPOSAL** | | |
| Single Investigator | Multiple Investigators (up to 2) | **Working Group**  Autoimmunity Group  Extra-Cellular matrix Group  Islet Cell Dysfunction  Virus Group  Other Group \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FILL out IF PROPOSAL IS FROM a SINGLE or MULTIPLE Investigator/S (up to 2) | | | | | | | | | | | | | | | | | |
| **PI Last Name** |  | | | | **First Name** | | | |  | | | | | **Degree(s)** | | |  |
| **Email** |  | | | | | | | | **Phone** | | | | |  | | | |
| **Institution** |  | | | | | | | | | | | | | | | | |
| **Department** |  | | | | | | | | | | | | | | | | |
| **Address** |  | | | | | | | | | | | | | | | | |
| **City** |  | | **State** | |  | **ZIP** | | |  | | | **Country** | | | |  | |
| **Co-PI Last Name** |  | | | | **First Name** | | | |  | | | | | **Degree(s)** | | |  |
| **Email** |  | | | | | | | | **Phone** | |  | | | | | | |
| **Institution** |  | | | | | | | | | | | | | | | | |
| **Department** |  | | | | | | | | | | | | | | | | |
| **Address** |  | | | | | | | | | | | | | | | | |
| **City** |  | **State** | |  | | | **ZIP** | | |  | | | **Country** | |  | | |
| **CURRENT AND PENDING GRANTS SUPPORTING THE PROPOSED STUDIES OF nPOD SAMPLES** | | | | | | | | | | | | | | | | | |
| **Grant Title** | | | | | | | | **Agency and Award ID** | | | | | | | | | |
|  | | | | | | | |  | | | | | | | | | |
|  | | | | | | | |  | | | | | | | | | |
|  | | | | | | | |  | | | | | | | | | |
|  | | | | | | | |  | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FILL OUT THIS FORM IS THIS IS A WORKING GROUP PROPOSAL | | | | | | | | | | |
| **CONTACT PI Last Name** |  | | **First Name** | | |  | | **Degree(s)** | |  |
| **Email** |  | | | | | **Phone** | |  | | |
| **Institution** |  | | | | | | | | | |
| **Department** |  | | | | | | | | | |
| **Address** |  | | | | | | | | | |
| **City** |  | **State** |  | **ZIP** | |  | **Country** | |  | |
| **CURRENT AND PENDING GRANTS SUPPORTING THE PROPOSED STUDIES OF nPOD SAMPLES** | | | | | | | | | | |
| **Grant Title** | | | | | **Agency and Award ID** | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |

|  |  |
| --- | --- |
| 1. **WORKING GROUP MEMBERS ACTIVELY PARTICIPATING IN THE STUDY (BY PERFORMING STUDIES ON TISSUES, BY SHARING REAGENTS, BY CONTRIBUTING TO STUDY DESIGN, OR BY CONDUCTING DATA ANALYSIS OR OTHER FUNCTIONS) – list in alphabetical order** | |
| **Last Name, First Name** | **Institution** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Add rows if needed or duplicate table in next page**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| lab contact & shipping information(NOTE: For studies with human islets, pancreas slices or other fresh tissue, we require additional shipping information for weekend and holiday delivery) | | | | | | | | | | | | | | | | | |
| **Lab Contact Person** |  | | | | | | | **Cell Phone** | | | | |  | | | | |
| **Email** |  | | | | | | | **Lab Phone** | | | | |  | | | | |
| **FedEx Acct** |  | | | | | | | **Lab Fax** | | | | |  | | | | |
| **FedEx Shipping Address** |  | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| **City** |  | | | **State** |  | | | | | **ZIP** |  | | | **Country** | |  | |
| **Shipping Instructions** |  | | | | | | | | | | | | | | | | |
| **LAB CONTACT & SHIPPING INFORMATION FOR WEEKENDS AND HOLIDAYS** | | | | | | | | | | | | | | | | | |
| **Weekend/Holiday Contact Name** | |  | | | | | | | **Cell Phone** | | |  | | | | | |
| **Email** | |  | | | | | | | **Lab Phone** | | |  | | | | | |
| **FedEx Account** | |  | | | | | | | | | | | | | | | |
| **Weekend/Holiday Shipping Address** | |  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **City** | |  | **State** | | |  | **ZIP** | | | |  | | | | **Country** | |  |
| **Shipping Instructions** | |  | | | | | | | | | | | | | | | |

**If samples should be sent to more than one lab, please duplicate the table.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 type. | | | | |
| **DONOR TYPE** | **SPECIFIC FEATURES AND/OR CASE ID #** | | **TOTAL # OF DONORS** | |
| **No Diabetes (control)** |  | |  | |
| **No Diabetes** **Autoantibody Positive** |  | |  | |
| **Type 1 Diabetes** |  | |  | |
| **Type 1 Diabetes Medalist** |  | |  | |
| **Type 1 Diabetes Pancreas Transplant Recipients** | Native Pancreas  Transplanted Pancreas | |  | |
| **Type 2 Diabetes** |  | |  | |
| **Other (**[**https://www.jdrfnpod.org/for-investigators/donor-groups/**](https://www.jdrfnpod.org/for-investigators/donor-groups/)**)** |  | |  | |
| Please visit our website to review donor groups and the current number of donors per group (<https://www.jdrfnpod.org/for-investigators/donor-groups/>).  For additional information about donor characteristics and for guidance in selecting specific donors, please contact [Gina Aulisio](mailto:gaulisio@ufl.edu). | | | | |
| **DONOR DEMOGRAPHICS REQUESTED:** | | | | |
| **Age** | Any | Specific ages (list): | | |
| **Gender** | Any | Female only | | Male only |
| **Ethnicity** | Any | Specific ethnicity (list): | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Sample TYPES AND QUANTITIES 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” **Note:** Typically, requests for tissue slides are limited to 10/block. You may request slides or tissue from different regions of the pancreas (head, body and tail). Requests that exceed this limit/block or exceed a total of 300 slides require truly compelling justification. Please be conservative and order the minimum number of slides or specimens required to complete your assay(s). | | | | | | | |
| **SAMPLE TYPE** | | **PANCREAS** | **PLN** | **SPLEEN** | | **NON-PLN** | **OTHER, LIST:** |
| **Paraffin Slides** | |  |  |  | |  |  |
| **Frozen OCT Slides** | |  |  |  | |  |  |
| **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\*\*** | | | | | | | |
| **Other (please describe):** |  | | | | | | |
| \*\*Estimated cells (millions) needed per donor | |  | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **REQUEST FOR ISOLATED ISLETS FROM THE nPOD-IIP\*** | | | | |
| **Donor Type** | | **Number of IEQ Requested** | **Minimum IEQ Necessary**  (if low yield distributions must be prioritized) | **Isolated islets types of samples** |
| **Islets from T1D donors** | |  |  | Fresh Islets  Exocrine tissue  **SPECIAL REQUESTS**  (will be honored if possible)  Frozen Islets  Islet Supernatant  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Islets from AAb+ donors** | |  |  |
| **Special Instructions** |  | | | |

\*nPOD-IIP (Islet Isolation Program): A request for applications (RFA) to study pancreas islets was released in 2018. Additional applications that have not been submitted in response to this RFA may be supported based on scientific merit and on the ability to obtain a sufficient number of isolated islets. Applicants planning to apply for pancreatic islets are strongly encouraged to contact nPOD to discuss their projects prior to applying.

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **REQUEST FOR LIVE PANCREAS SLICES\*** | | | |
| **Donor Type** | **Ideal number of Pancreas Slices Requested (Maximum of 20)** | **Minimum # of Pancreas Slices Necessary** | **Pancreas Slices types of samples** |
| **Slices from T1D donors** |  |  | Fresh Slices  **SPECIAL REQUESTS**  (will be honored if possible)  Frozen Slices  Supernatant  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Slices from AAb+ donors** |  |  |
| **Slices from nondiabetic donors** |  |  |
| **Special Instructions** |  | | |

\*A request for applications (RFA) to study pancreas slices was released in April 2019. Applications that have not been submitted in response to this RFA may be supported based on scientific merit and on the ability to generate a sufficient number of pancreas slices. Applicants planning to apply for pancreas slices are encouraged to contact nPOD to discuss their projects prior to applying.

**EXPERIMENTAL PLAN**

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 proposed project in about 300 words. It will be published on the nPOD website once your project is approved. This will help our current and future Investigators better understand your work and facilitate collaboration, and the general public can learn about the important research being pursued by nPOD Investigators. |
|  |

|  |  |
| --- | --- |
| SPECIFIC AIMS | |
|  | |
| Background and hypothesis | |
|  | |
| Preliminary Data |
| Please pay special attention to demonstrate feasibility of your methods, keeping in mind that 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. We strongly encourage potential Investigators to show feasibility of their methods, assay or staining validation, etc., on nPOD control tissues **BEFORE** submitting your application. Please contact [Gina Aulisio](mailto:gaulisio@ufl.edu) to learn more about this opportunity. |
|  |

|  |
| --- |
| Experimental Approach |
| Projects are often approved in a “step-wise” fashion, with release of samples based on the data generated at each step (i.e., control and then T2D samples released before the rare T1D and AAb+ samples). It is helpful to structure your experimental approach accordingly. |
|  |

|  |
| --- |
| FIgures/Tables |
| In addition to including any figures and tables needed to illustrate your preliminary data and experimental approach, we encourage potential investigators to fill out a table illustrating the 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** | | *EXAMPLE* | *Ab 1* | *Dapi* | *GCG (Rb, Dako)* | *INS (GP, Dako)* | *CD45 (Rat, BD)* | | *Ab 2* | *N/A* | *Dkey anti Rb 488* | *Dkey anti GP 594* | *Dkey anti-Rat 647* | | Combination #1 | Ab 1 |  |  |  |  | | Ab 2 |  |  |  |  | | Combination #2 | Ab 1 |  |  |  |  | | Ab 2 |  |  |  |  | | Combination #3 | Ab 1 |  |  |  |  | | Ab 2 |  |  |  |  | |

|  |
| --- |
| 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 donors 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 the nPOD biorepository, we strongly encourage potential Investigators to consult with nPOD OPPC’s Director ([Dr. Irina Kusmartseva](mailto:%20inkusmartseva@ufl.edu?subject=nPOD%20application%20pre-submission%20inquiry)) before submitting the application, in order to verify specific tissue availability and discuss project needs. |
|  |
| 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. |
|  |

|  |
| --- |
| 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](mailto:scechin@med.miami.edu). Please describe how your proposed studies can be relevant to existing working groups and which ones. |
|  |
| REFERENCES |
|  |

|  |
| --- |
| 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 [Gina Aulisio](mailto:gaulisio@ufl.edu) 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: |
| 1. **PUBLICATION POLICY AGREEMENT** |
| We ask all nPOD Investigators to become and remain familiar with the [nPOD Publication and Presentations Policies.](http://www.jdrfnpod.org/wordpress/wp-content/uploads/2014/07/SOP-4-Publications-and-Presentations.pdf) 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**](http://www.jdrfnpod.org/wordpress/wp-content/uploads/2014/07/SOP-4-Publications-and-Presentations.pdf)**.** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. **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](https://www.jdrfnpod.org/wordpress/wp-content/uploads/2018/02/nPOD-IRB201600029-approval-letter_.pdf) 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. | | | | | |
| 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 | | |
| MATERIAL TRANSFER AGREEMENT | | | | | |
| nPOD samples and their derivatives remain the property of nPOD. Investigators may not share nPOD samples or their derivatives without nPOD approval. Please contact nPOD if you have unused samples at the end of your study.Approved Investigators may only use nPOD samples for the intent 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.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>. 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 [Gina Aulisio.](mailto:gaulisio@ufl.edu) | | | | | |
| **I have read and agree to the terms of the nPOD MTA, and will provide a copy signed by myself and my institution.** | | | | | |

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.

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. Signed 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).