Policies and Procedures for the Integrated Islet Distribution Program (IIDP)

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I. GENERAL POLICIES AND PROCEDURES

1.0 MISSION STATEMENT

The Integrated Islet Distribution Program (IIDP) mission is to work with leading islet isolation centers in the U.S. to distribute high quality human islets, associated tissues, and integrated data to the diabetes research community to advance scientific discoveries.

2.0 IIDP ORGANIZATION

The IIDP, funded by the NIDDK, consists of the NIDDK Project Scientist (PS), the NIDDK Program Officer (PO), the Executive Committee (EC), the Coordinating Center (CC),sub-contracted Islet Isolation Centers (IICs), the Human Islet Phenotyping Program(HIPP) and the Human Islet Genotyping Initiative (HIGI). All participants in this program are bound to the policies and procedures stated in this document.

2.1 IIDP Coordinating Center (CC):

The IIDP CC is housed at the City of Hope in the Department of Diabetes & Cancer Discovery Science and is directed by Joyce C. Niland, Ph.D. as Principal Investigator (PI). Carmella Evans-Molina, M.D., Ph.D. is co-PI of the program. The CC is funded by NIDDK to manage the distribution of human islets for research to approved investigators in the diabetes research community.

2.2 IIDP NIDDK Project Scientist (PS):

Albert Hwa, Ph.D., as the NIDDK Project Scientist (PS), serves as the overseer of all policies and procedures initiated by the IIDP and scientific issues posed by the IIDP. He also acts as a representative for NIDDK with the EC.

2.3 IIDP NIDDK Program Officer (PO)

Thomas Eggerman, M.D., Ph.D., as the NIDDK Program Officer (PO), also has oversight of IIDPpolicies and procedures, as well as budgetary issues. He also serves as a representative for NIDDK with the EC.

2.4 IIDP Human Islet Isolation Centers (IICs):

The IIDP CC subcontracts with an interactive group of academic laboratories as our ten IICs. All centers are bound by the language of the subcontract, its appendices and policies.

The following IIDP isolation centers provide human islets, ancillary tissue and data for distribution through this program:

Center	Director
Columbia University Islet Core	Dr. Xiaojuan Chen
Human Islet Isolation Center, Diabetes Research Institute, University of Miami	Dr. Camillo Ricordi
Imagine Islet Center	Dr. Rita Bottino
Norton Islet Cell Research & Transplant Program	Dr. Balamurugan Appakalai
Prodo Laboratories Human Islet Isolation Center	Dr. David Scharp
So. California Islet Cell Resource Center	Dr. Fouad Kandeel
University of Arizona Institute for Cellular Transplantation	Dr. Klearchos Papas
University of Pennsylvania Islet Transplant Center	Dr. Ali Naji
University of Wisconsin Human Islet Core	Dr. Jon Odorico
VCU Islet Cell Processing Lab	Dr. Mazhar Kanak

2.5 IIDP Approved Investigators:

The investigators approved to have access to IIDP services must meet all eligibility requirements listed in Section II (Human Islets for Research). All procedures for application and review need to be met to qualify for participation in the Program.

II. AVAILABLE RESOURCES

1.0 HUMAN ISLETS

The IIDP offers islets from human cadaveric donors meeting or exceeding the IIDP's minimal donor criteria. Approved researchers are required to complete a study profile detailing the donor and islet processing parameters required by the study, and these parameters will be utilized by the IIDP's Matching Algorithm for Islet Distribution (MAID) when determining islet offer eligibility. The MAID ensures that all eligible islet studies are treated fairly while also ensuring optimal and efficient islet placement for the IIDP's islet isolation centers.

Both viable and flash frozen human islets are available to IIDP researchers with an active subscription. All viable human islets are cultured to allow the islets an opportunity to recover and stabilize following the isolation procedure and are shipped according to the IIDP's standardized packaging and shipping protocol.

2.0 Related Biomaterials

The IIDP also offers non-islet pancreatic tissue (acinar) to active subscribers. Acinar tissue is made available as either fresh or frozen samples. Packaging and shipping protocols for fresh and frozen acinar samples are followed. Donors for IIDP acinar tissue must meet the same minimal criteria as IIDP islets referenced in section II.1.0 above.

3.0 Data

All human islet and related biomaterial shipments to approved IIDP subscribers are accompanied by detailed medical and demographic data of the deidentified donor (no protected health information (PHI) are available) as well as sufficient data defining the tissue processing and shipment procedures. Basic data are available to the researcher prior to acceptance of the tissue offer so that the researcher can make an informed decision. However, in the weeks following the processing and shipping procedures, additional data sources provide comprehensive information regarding donor medical history and other relevant donor factors. All data are made available to recipients of the tissue as the data become available.

Additionally, researchers approved to access the IIDP Research Data Repository (RDR) have access to all data described above f*or all IIDP islet isolations in the IIDP database* as opposed to only the records directly relevant to the researcher's specific tissue shipment history. The RDR can be accessed by logging into the secured IIDP website and clicking on the RDR tile.

III. SUBSCRIBING FOR HUMAN ISLETS, RELATED BIOMATERIALS, AND RELATED DATA FOR RESEARCH

1.0 Eligibility Requirements

Subscribers for IIDP resources must be employed by and perform the proposed study within an institution or government agency, domestic or international, and must also have the expertise to perform the proposed scientific study.

Subscribers for IIDP services typically will be located at not-for-profit institutions. However, for-profit companies also may apply. For-profit companies may receive islets from the IIDP under a differential pricing structure.

2.0 Application and Review

For the requested services, all investigators must complete an application via the IIDP website and submit it electronically to the CC. All applicants will be notified of approval, disapproval, or requests for any supplemental information. The IIDP honors peer reviews conducted by legitimate funding agencies. Applications for projects that have been funded by sources utilizing peer review will be automatically approved by the IIDP. For applicants without prior peer review, IIDP will send the application for external expert review by qualified diabetes researchers.

Approved investigators seeking human islets and/or other tissues from the IIDP will be

required to submit payments for their IIDP subscription. There are no IIDP-imposed limits on the size or frequency of payments. Rather, the investigator may decide on the payment schedule that suits the needs of the project. Upon receipt of payment, the investigator will then be eligible for shipments from all IIDP centers. If partial payments were made for the subscription which do not fully address the entire requirement of the project, the investigator will be alerted prior to reaching their paid limit to assist the investigator in avoiding interruptions to the desired IIDP services.

3.0 ISLET DISTRIBUTION

3.1 Subscriber Responsibilities

To maintain islet and tissue offer eligibility, subscribers must:

1) maintain an active subscription with a sufficient balance to accommodate a shipment of the desired quantity,
2) maintain a study profile that accurately represents the needs of the study,
3) maintain a valid FedEx account to pay for the courier charges associated with the islet or tissue shipment from the distribution site to his/her laboratory,
4) complete User Feedback Forms (UFF) after each shipment to assist the IIDP in monitoring islet and tissue quality as well as protocol compliance by the production center. Part 1 is due 10 days and Part II due 30 days after receipt of islets, and
5) adhere to the guidelines described in section IV. Terms of Acceptance below.

3.2 IIDP Responsibilities

3.2.1 Solicit and Qualify Islet and Tissue Distribution Centers for the IIDP

The IIDP CC has been given the charge to solicit and qualify islet isolation centers to be included by subcontract under the IIDP. The IIDP shall ensure via these subcontracts that quality performance standards are in place and shall provide training for islet isolation center staff to conform to the SOPs of the program in order to meet the demand with high quality islets.

3.2.2 Review of Requests for IIDP Access

CC duties include receipt and data storage of applications and their administrative review. Investigators with peer-reviewed grant funding will be administratively reviewed only. For non-peer reviewed applicants, the application will be sent to IIDP external reviewers for review.

3.2.3 Creation and Maintenance of the IIDP Website

The CC has developed and maintains an electronic communication system that monitors and matches islet availability from production sites with subscriber requirements, automatically notifying production sites of need for islets and subscribers' availability. The system utilizes the subscriber study profile, including approved islet limits, frequency of shipments, quantity of islets per shipment and the purity and viability of islets required, to run the MAID optimization algorithm to prioritize islet distributions.

3.2.4 Maintenance of Databases

The CC maintains the databases necessary to track the shipment and receipt of human islets and other distributed tissues. Data collected consists of basic donor information, islet processing data, and islet quality assessments for the available islets and tissues offered through the IIDP Islet Allocation System (IAS), along with the investigators' requested islet parameters, shipping information, and recipients' islet assessments for quality control purposes. These data are entered into the IAS and subsequently accessible through the secure access IIDP website by both production centers and islet recipients. The CC facilitates contact between investigators and IIDP production facilities, acknowledging that information will remain confidential.

The CC also maintains records of shipments from the production sites to IIDP recipients. The CC evaluates the quantity and quality of shipments as assessed by production sites and recipients and analyzes trends in demand to project future requirements.

The CC is responsible for collecting and tracking payments received. The CC also has established and maintains financial tracking databases to record reimbursements to centers and receivables from IIDP subscribers.

The CC also collects evidence of scientific progress attributable to tissue and data distributed through this program based on manuscripts published. Researchers participating in the IIDP agree to correctly cite the IIDP in these publications using the citation displayed in the IIDP Publications and Presentations Policy.

3.3 Islet Charge Schedule

IIDP investigators may subscribe to any number of islets for which they have been approved. This subscription fee must be paid before any islets are distributed to the investigator. Payments can be made via credit card, check, or automated clearing house (ACH) deposit. Subscriptions will be honored through the end of NIDDK funding of the IIDP.

Current charge rates for various IIDP services are as follows.

IIDP Service	Non-Profit Rate	Corporate Rate
Human Islets (Viable)	$0.15 per IEQ	$0.25 per IEQ (non-diabetic) $0.30 per IEQ (T2D)
Human Islets (Flash Frozen)	$0.15 per IEQ	$0.25 per IEQ (non-diabetic) $0.30 per IEQ (T2D)
Human Pancreatic Acinar Tissue, Blood Plasma, Blood Serum, Spleen, Peripancreatic Lymph Nodes, Frozen Pancreas Pieces, and Pancreatic Ductal Tissue	$250 per Sample	$250 per Sample
Human Duodenal Tissue	$1,000 per Sample	$1,000 per Sample
Histological Slides of Pancreatic Tissue	$15 per Slide	$15 per Slide
Research Data Repository (RDR) Data	N/A	N/A

If a user is dissatisfied with a shipment and can document via digital photograph or other functional assay that the quality is poor, requests for subscription credits for the islet cost will be reviewed and granted according to the IIDP subscription credit policy.

3.4 Material Transfer Agreements (MTAs)

In addition to completing the basic science application, investigators may be required by their institution to complete an MTA with the IIDP supplier and/or the Organ Procurement Organization (OPO) that provided the pancreas. The investigator must comply with all IIDP requirements before the islets can be shipped.

3.5 Shipment Specifications

Prior to islet shipment, the recipient must complete their IIDP study profile which outlines shipment information such as recipient's address, express shipping account number, desired islet parameters and frequency, tissue specifications and other relevant information. The recipient is required to pay shipping costs. The IIDP will send shipments to the user in standardized IIDP packaging.

3.6 Accompanying Islet Data

Limited donor information, isolation data, islet specifications and release criteria will be provided on the IIDP "Tissue Shipment Form" that accompanies each islet or tissue shipment from an IIC. An example of this form is provided in the application. Additionally, the user will be able to obtain islet characterization data online at the time of broadcast, and quality assurance data subsequently at ten days post (preliminary data) and thirty days post (final data). More comprehensive donor data collected by the United Network for Organ Sharing (UNOS) will be made available to IIDP recipients as data become available. Phenotypic data are provided on most isolations since 2016, with the establishment of the Human Islet Phenotyping Program (HIPP) subcontracted to Vanderbilt University. Genetic ancestry and partitioned genetic risk scores for T1D and T2D are provided on most isolations since 2017, with the establishment of the Human Islet Genotyping Initiative (HIGI) subcontracted to Stanford University.

3.7 Islet Assessment by Recipients

The recipient can access a "User Feedback Form" online which is used to convey their level of satisfaction with the quality and quantity of the islets they receive. An example of this form is provided in the application. Both sections of this form must be completed online and submitted to the CC within the required timeframe before the user will be considered fully eligible to receive all islet offers. The CC will track user satisfaction and provide regular summaries to the NIDDK. Quality feedback from the users also will be shared regularly with the IICs.

IV. TERMS OF ACCEPTANCE

An approved investigator request will remain active during the life of the IIDP grant under which the request was submitted and as long as the above conditions are met. Should the investigator require IIDP services for projects unrelated to the specific, approved IIDP study, a new IIDP application will be required to address the needs of the new project. There are no limits to the number of IIDP studies that a single investigator can actively maintain simultaneously.

When islets are distributed, the receiving Investigator agrees that:

1) Users agree to pay the appropriate subscription fee before they may access IIDP islets or other tissues.
2) Human islets or other tissues obtained through the IIDP will be used for approved research purposes only. Human islets and other tissues provided through this program may not be used for human transplantation.

3) The User Feedback Form will be completed and submitted online after each IIDP shipment is received. Failure to submit this information within the designated timeframe will disqualify the investigator from receiving certain offers until the form has been completed.
4) Human islets and/or islet products obtained through the IIDP will not be transferred to a third party unless authorized through IIDP review. All collaborators and their affiliations must be identified on the application.
5) Users will disclose all forms of support for the project, private or academic collaborations, and fiduciary relationships relevant to the project for which the islets, other tissues, and/or associated data are being provided.
6) Approved users will pay shipping costs from the distribution site to his/her laboratory.
7) Approved users will abide by the IIDP Policies and Procedures. Any and all changes to the IIDP Policies and Procedures will be publicly posted, and all users are required to abide by the newly updated document posted therein.
8) Approved users will cite the IIDP and may also cite the appropriate distribution site in any publications, press releases or abstracts resulting from the use of the IIDP product(s). The IIDP CC must be notified of all publications referencing IIDP islets.

   The following type of acknowledgement, which includes the IIDP NIH grant #, should be documented in all publications where IIDP human islets and/or other resources were used:

   For Resources from Paid IIDP Subscriptions:
   Human pancreatic islets and/or other resources were provided by the NIDDK-funded Integrated Islet Distribution Program (IIDP) (RRID:SCR _014387) at City of Hope, NIH Grant # U24DK098085.

   For Islets and/or Resources received through the Islet Award Initiative (IAI):
   Human pancreatic islets and/or other resources were provided by the NIDDK-funded Integrated Islet Distribution Program (IIDP) (RRID:SCR _014387) at City of Hope, NIH Grant # U24DK098085 and the JDRF-funded IIDP Islet Award Initiative.
9) Investigators who have used UNOS data obtained via the IIDP Research Data Repository (RDR) for publication:
   I. The following citation is to be included in the methods section of the manuscript:
      - "This study used data from the Organ Procurement and Transplantation Network (OPTN). The OPTN data system includes data on all donor, wait-listed candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN contractor."

   II. The following disclaimer is to be stated:
      - "The data reported here have been supplied by UNOS as the contractor for the Organ Procurement and Transplantation Network (OPTN). The content, interpretation, and reporting of these data is solely the responsibility of the authors and does not necessarily represent the official views of the OPTN or the National

Institutes of Health."

III. Before submitting an abstract, manuscript, or other aggregation data using UNOS data to another party for presentation or publication, I agree to submit it to the OPTN Contracting Officer's Representative (COR) for review to ensure compliance with the terms of this agreement regarding confidentiality. The OPTN COR shall respond within 30 days. If the abstract, manuscript, or data aggregation does not reflect compliance with the terms of this agreement, I will revise and resubmit to the OPTN and COR. Upon publication, I will provide a copy of the final work and a complete citation to the OPTN and COR.

Contact iidp-email@coh.org to receive detailed instructions on submitting resources to the COR for pre-review.

V. CONFIDENTIALITY

All information submitted in conjunction with the application and subsequent correspondence will be held in confidence by the IIDP personnel and the EC.

VI. AUTHORSHIP ISSUES

The IIDP Centers are NIH-sponsored service facilities. Center staff and directors of the IIDP will not expect authorship on investigator publications if islet or tissue generation was the only contribution. Investigators will be required to acknowledge the IIDP in all publications, in the same manner that funding support is acknowledged.

VII. TERMINATION OF AGREEMENT

Failure to comply with the conditions stated above will result in cancellation of this agreement.