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

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POLICIES AND PROCEDURES FOR THE
INTEGRATED ISLET DISTRIBUTION PROGRAM (IIDP)

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I. GENERAL POLICIES AND PROCEDURES

1.0 MISSION STATEMENT

The goal of the Integrated Islet Distribution Program (IIDP), funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), is to work with the leading human islet isolation centers and to distribute high quality human islets to the diabetes research community to advance scientific discoveries and translational medicine.

2.0 IIDP ORGANIZATION

The IIDP, funded by the NIDDK, consists of the NIDDK Project Scientist (PS), the NIDDK Program Official (PO), the External Evaluation Committee (EEC), the Coordinating Center (CC), specified human islet distribution centers, and approved investigators. 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 Information Sciences and is directed by Joyce C. Niland, Ph.D. The CC is contracted 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):

Kristin Abraham, Ph.D., as the NIDDK Project Scientist (PS), will act as the overseer of all policies and procedures initiated by the IIDP and scientific issues posed by the IIDP. She will act as the representative for NIH and NIDDK on the EEC.

2.3 IIDP NIDDK Program Official (PO)

Sheryl Sato, Ph.D., as the NIDDK Program Official (PO), will act as the overseer of all policies and procedures initiated by the IIDP and will have oversight on the IIDP budgetary issues. She will act as the representative for NIH and NIDDK on the EEC.

2.4 IIDP External Evaluation Committee (EEC):

2.4.1 Function

The IIDP is an interactive group of six IIDP academic laboratories whose primary purpose is to supply investigators with basic science islets for IIDP-approved studies. The EEC provides general guidance to the IIDP based on the present Policy and Procedures document.
2.4.2 Members

The IIDP EEC shall be composed of: 1) two representatives of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), 2) a representative from the Juvenile Diabetes Research Foundation International (JDRFI), 3) the IIDP CC Principal Investigator, 4) scientific experts and 5) if needed, a Committee chair. This committee will have a maximum of eight voting members. It is the prerogative of the PS to appoint a substitute for any member absent from an appropriately announced EEC meeting.

2.4.3 Experts

When additional expertise is deemed necessary to address specific items on the IIDP EEC agenda, ad hoc consultants may be invited by the Committee Chair or Project Scientist to participate in the meeting. Generally such appointments will be on an ad hoc or a per meeting basis.

2.4.4 Appointments

There are no term limits to serve on the EEC. However, NIH policy requires regular rotation of committee membership. Upon resignation of an EEC member, the PS may make a new appointment.

2.4.5 Meetings

The IIDP EEC will meet in person once a year. During these meetings, examples of topics that may be addressed include: (1) the production goals for each IIDP facility, (2) review of activities of the member facilities, including the number of pancreata obtained and islets generated for basic science studies, description of islet function and correlation with isolation parameters, identification of investigators and their institutions that received islets, and the laboratory protocols for which they were used, (3) discussion of quality control issues, (4) discussion of progress in all basic science, isolation, testing, shipping, and storage procedures, (5) review of applications submitted requesting islets for basic science use, (6) an update on basic science islet applications and distribution. The PS or the EEC Chairperson may call additional meetings, as needed.

The IIDP Director will be charged with generating and distributing an agenda prior to each meeting. The Committee members are encouraged to suggest topics requiring discussion to the Committee Chair or IIDP Director at least two weeks prior to each meeting. Any voting Committee member can suggest discussion topics. All motions must be seconded in order to be voted upon. Approval will require a simple majority, with the Chair casting the deciding vote in the case of a tie. Robert's Rules of Order will be followed for discussion of agenda topics, with the exception that the Chair may vote on issues proposed by the Committee. Each voting member, or their institutional designate, will be permitted to cast a single vote on proposals brought to the EEC.
A quorum for conducting an IIDP EEC meeting shall consist of a minimum of more than half the Committee membership. A member may be represented by an alternate of his/her choice who will, for that meeting, exercise full committee rights of the absent member. The IIDP CC will organize, record, and generate the complete written minutes of each EEC meeting.

2.5 IIDP Executive Committee:

The Executive Committee may be comprised of the chairperson, two NIDDK representatives, a JDRFI representative, the IIDP CC Director, and one rotating member of the EEC. The rotating member will be chosen by the Project Scientist and serve one year on the Executive Committee. The Executive Committee’s responsibilities will be administrative in nature, and decisions on major policy issues will not be made.

Meetings will be chaired and called by the chairperson of the EEC; meetings may be held by teleconference several times throughout each year. Each member will have one vote, and decisions will be based on a majority vote. The Chairperson will cast the deciding vote in case of a tie. An advance agenda of Executive Committee meetings will be sent to EEC members by e-mail. Deliberations of the Executive Committee will be open to EEC members.

2.6 IIDP Human Islet Distribution Centers:

The IIDP CC integrates an interactive group of academic laboratories including six subcontracted IIDP centers. All centers are bound by the language of the subcontract, its appendices and policies.

The following IIDP isolation centers will provide human islets for distribution through this program:

Subcontracted IIDP centers:

- Scharp/Lacy Institute: Director, Dr. David Scharp
- Southern California Islet Cell Resource Center: Director, Dr. Fouad Kandeel
- University of Illinois – Chicago: Director, Dr. Jose Oberholzer
- University of Miami: Director, Dr. Camillo Ricordi
- University of Pennsylvania: Director, Dr. Ali Naji
- University of Wisconsin: Director, Dr. Luis Fernandez

2.7 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 will need to be met to qualify for participation in the Program. Investigators that have been previously approved through the Islet Cell Resource Consortium (ICR) are considered grandfathered into the IIDP; however new subscription fees must be paid and updated islet needs must be submitted to the IIDP CC.
3.0 INFORMATION DISCLOSURE POLICY

Although centers are bound together in the IIDP through subcontracts issued by the CC, the IIDP envisions that this will be a truly collaborative project. The IIDP encourages the open sharing of information among centers so that there will be a continued optimization in the “harvest, purification, function, storage and shipment of islets”. Shared information among participating centers shall not preclude the protection of intellectual property or the filing of patent opportunities for members, with the exception of the islet distribution process which by contractual agreement will be assigned to City of Hope.

Appropriate confidentiality must be implemented for products that are not yet patented or for information that is not yet in the public domain. Participating centers shall not discourage the development of new inventions and/or the formation of business entities to commercialize components of cell processing technology.

4.0 RESPONSIBILITIES OF CENTERS PROVIDING IIDP ISLETS

Under the subcontracts signed by each of the participating centers, these centers shall have the following responsibilities:

1) To implement the IIDP Standard Operating Procedures (SOPs) for islet shipping, data entry, and quality assurance testing.
2) To maintain IEQ production levels as defined in the subcontracts.
3) To produce IEQs in accordance with the standards set for quality including quantification, purity, viability, potency, sterility, and to enter the test results into the database thus making these available in a time sensitive manner to approved users.
4) To use the supplies that are ordered by the IIDP and distributed to the centers. The centers will only use these supplies for islets shipped under this program.
5) To distribute islets from the IIDP using only the islet distribution algorithm, except in cases of pilot or special studies and agreed upon by both parties in advance.
6) To supply all IEQ processing and donor information data points that are required by the IIDP’s web-based Islet Allocation System at the time of broadcast in a time sensitive manner.

5.0 ADVERTISING OF IIDP RESOURCES

Advertisements will be included in NIH publications, on the internet, and at scientific meetings, when this can be done at low or no cost to the CC.

6.0 IIDP RESPONSIBILITIES

6.1 IIDP CC Responsibilities

The IIDP CC shall be responsible for organizing the IIDP EEC meeting. Dates will be set to maximize the attendance of committee members. The IIDP CC shall be responsible for arranging the meeting location and for distributing the agenda and review materials prior to the meeting. The CC shall prepare written minutes of the meeting and shall distribute to the EEC for modification or approval.
6.2 Solicit and Qualify Islet Isolation Centers for the IIDP

The IIDP CC has been given the charge to solicit and qualify islet isolation centers to be included by subcontract into 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.

6.3 Review of Requests for IIDP Access

The IIDP Director shall organize the review process. The “Application for IIDP Services” and assistance in application procedures shall be provided by the CC.

CC duties include receipt and logging in of applications and their administrative review of all applications. Investigators with peer-reviewed grant funding will be administratively reviewed only. For non-peer reviewed applicants, the grant application will be sent to one or more EEC members for review. Applications can be completed and submitted online. One copy of “Application for IIDP Services” and all related documents will be kept on file at the CC. A complete and continuously updated electronic roster of approved investigators and their projected needs will be maintained by the IIDP staff.

6.4 Creation and Maintenance of the IIDP Website

The CC shall develop and maintain an electronic communication system that will monitor and match islet availability from production sites with user requirements and shall notify production sites of need for islets and users availability. The user profile including approved islet limits, frequency of shipments, quantity of islets per shipment and the purity and viability of islets required will be maintained and used by the algorithm to prioritize user access.

The Website will include information for islet production centers such as SOPs. The collection of publications using IIDP islets will be posted on the website. There will be a public portion of the website that lists upcoming events, and relevant information on the project.

6.5 Maintenance of Databases

The CC shall maintain databases necessary to track the shipment and receipt of human islets. Data collected shall consist of basic donor information, islet processing facts, and islet quality assessments for the available islets offered through the IIDP Islet Allocation System (IAS); the recipients’ requested islet parameters, shipping information, and recipients’ islet assessments for quality control purposes. These data will be entered and subsequently accessible through the secured access IIDP website by both production centers and recipients. The CC shall facilitate contact between investigators and IIDP production facilities, acknowledging that information will remain confidential.

The CC shall maintain records of islet shipments from the production sites to islet recipients. The CC shall evaluate the quantity and quality of islets shipped as assessed by production sites and recipients and will analyze trends in demand for islets and project future requirements for islets.
The CC shall also establish and maintain financial tracking databases to record islet reimbursements to centers and receivables from islet users. The CC will be responsible for distributing subscription fee letters and collecting and tracking payments received.

The CC shall collect evidence of scientific progress attributable to human islet distribution through this program based on manuscripts published. The CC will ensure that the IIDP and participating islet isolation centers are cited in these publications.

7.0 CONFLICT OF INTEREST

Members of the EEC shall be required to sign a conflict of interest and financial disclosure statement yearly and at the time of each EEC in person meeting indicating any financial or fiduciary interest related to the applications under consideration. Investigators will also be required to disclose any such interests in the application being submitted. These documents will be provided and maintained by the CC.

8.0 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 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.

II. HUMAN ISLETS FOR RESEARCH

1.0 ELIGIBILITY REQUIREMENTS

ELIGIBILITY

Applicants 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.

Applicants for IIDP islets typically will be located at not-for-profit, institutions. However, for-profit companies may apply. For-profit companies may receive islets from the IIDP after all academic investigator requests have been filled. There is a differential pricing structure for for-profit companies. For-profits companies may be subject to restrictions of regional Organ Procurement Organizations (OPOs) that provide pancreata to the local islet distribution site.

2.0 APPLICATION AND REVIEW

All investigators requesting islets must complete the Application for IIDP Services: Human Islets for Research, and submit electronically to the CC.

All applicants will be notified of approval, disapproval, or requests for any supplemental information. Approved investigators will be required to submit partial or full payments for their islet subscription. Upon receipt of payment or guaranteed PO# the investigator will
then be eligible for islet shipments from all IIDP centers - If partial payments were made for the subscription, the investigator will be alerted prior to the reaching their paid limit of islets and residual payments will need to be made to the IIDP in order to maintain an uninterrupted flow of islets.

3.0 ISLET DISTRIBUTION

3.1 Selection of Preferred Centers and Charge Schedule

The applicant may choose to designate one or more IIDP centers as "blocked", and the IIDP Islet Allocation System (IAS) will consider this designation when determining islet offer recipients. Applicants may block an unlimited number of IIDP centers. Blocking a center removes the applicant’s eligibility from all islet offers originating at the blocked center.

The IIDP centers will ship islets using the standardized cold shipping protocol approved by the EEC. In order to access islets the subscription fee must be paid to the CC at any time during the year when the investigator wishes to access islets for which they have been approved.

If a user is dissatisfied with a shipment and can document via digital photograph or other functional assay that the quality is poor, the Compliance Administrator (CA) and the DCC Project Administrator will review the complaint and make a determination of credit. Under no circumstances will the subscription fee be refunded. Credits for unsatisfactory islets are limited to twice per year.

IIDP investigators may subscribe to any number of islets for which they have been approved. This subscription fee at $0.12/IEQ must be paid before any islets are distributed to the investigator.

The IIDP centers will also provide flash frozen islets. Excess islets (up to 50,000 IEQs per year/per center) that cannot be distributed can be flash frozen by the IIDP centers and stored in vials of 10,000 islets. All approved users can view the availability of these islets on the IIDP website. Should the investigator order these islets, they will be counted against their total approved subscription.

3.2 Material Transfer Agreements (MTAs)

In addition to completing the basic science application, investigators may be required 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.

3.3 Shipment Specifications

Prior to islet shipment, the recipient must complete the “Human Islet Request Form”; an example of this form, provided in the application, outlines shipment information such as recipient’s address, express shipping account number, desired tissue specifications and other relevant information. The recipient is expected to pay shipping costs. The IIDP will send shipments to the user in standardized IIDP packaging.
3.4 **Islet Characterization at IIDP Center**

Limited donor information, isolation data, islet specifications and release criteria will be provided on the IIDP “Tissue Shipment Form”; an example of this form is provided in the application. This form will accompany or closely follow the islet shipment. Additionally, the user will be able to obtain islet characterization data on-line at the time of broadcast and subsequently at ten days post (preliminary data) and thirty days post (final data).

3.5 **Islet Assessment by Recipients**

The recipient can access online a “User Feedback Form” on which they can 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 on line and submitted to the CC before the user is eligible to receive another islet shipment. The CC will track user satisfaction and provide regular summaries to the NIDDK. Quality feedback from the users will also be regularly shared with the IIDP production sites.

4.0 **TERMS OF ACCEPTANCE**

An approved investigator request will remain active during the life of the grant under which the request was submitted and as long as the above conditions are met. Competing renewals of the grant or new projects will require a re-application to the CC.

When islets are distributed, the receiving Investigator agrees that:

1) Human islets obtained through the IIDP will be used for approved human islet research purposes only. Human islets provided through this program may not be used for human transplantation.

2) The “User Feedback Form” (both Parts I and II) will be completed and submitted online after each shipment of islets is received. Failure to submit this information will disqualify the investigator from receiving any basic science islets until the form is completed.

3) Human islets and/or islet products obtained through the IIDP will not be transferred to a third party unless authorized through EEC review. All collaborators and their affiliations must be identified on the application.

4) 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 are being provided.

5) Approved users will pay shipping costs from the islet distribution site to his/her laboratory.


7) Approved users will cite the “IIDP” and may also cite the appropriate islet distribution site in any publications, press releases or abstracts resulting from the use of the human islets. A reprint of the document where the acknowledgement is made and/or the reference to the online publication must be submitted to the CC.

8) Users agree to pay the appropriate subscription fee before they may access IIDP islets.
5.0 TERMINATION OF AGREEMENT

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

6.0 CONFIDENTIALITY

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