Request for Proposals (RFP) for Affiliated Islet Isolation Centers (IICs)

Informational Webinar
January 24th, 2022
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NIDDK:
Kristin Abraham, Project Scientist
Sheryl Sato, Program Officer
HISTORY OF ISLET PROGRAM AT CITY OF HOPE

Islet Cell Resource

JDRF

CIT

Integrated Islet Distribution Program

IIDP Grant Renewal


Sponsors

National Center for Research Resource

Juvenile Diabetes Research Foundation

National Institute for Diabetes & Digestive Kidney Diseases

National Institute for Diabetes & Digestive Kidney Diseases
IIDP’s Research Impact

...By the Numbers

Since Program Inception:
- Averaged over 1,000 islet shipments per year
- Over 490 studies supported to date
- …across 16 countries
- …totaling over 271 million IEQ
- 78 pilot awardees (over 9.1 million IEQ)
- 814 publications using IIDP/ICR islets
- Over 1 million flash frozen IEQ shipped

Most Recent IIDP Statistics:
- Over $19.4 million reimbursed to IICs (2010-)
- Processed 1,942 subscription payments (2010-)
- Over $1.7 million Opportunity Pool funds issued (2011-)
- Over 10.5 million T2D IEQ distributed (2011-)
- 460 pancreas histology samples provided (2014-)
- 347 HIPP samples phenotyped (2017-)
- 72 NIPT shipments (2019-)
- Over 300 genetic risk scores analyzed (2020-)

IIIDP
Integrated Islet Distribution Program
Islets Isolated at 5 Current IICs

Distributed around the Globe

Data Collected from IICs & UNOS

IIDP Research Data Repository (RDR) Accessible

Genetic Risk Scores Analyzed

Islet Phenotyping Data Generated

Schematic of IIDP Islet & Data Flow
New U24 grant mechanism requires issuance of this Request for Proposals (RFP)

Identify and evaluate expert human IICs to continue to provide high quality human islets and related tissues in a dependable, consistent, cost-effective manner

- IIC application process: Jan 3 to March 31, 2022
- Awardees announced in June 2022
- Initial contracts issued for Aug 1, 2022 through July 31, 2023
  - Opportunity for annual renewals through July 31, 2026
Overall Objectives and Scope:

- Applicants should document experience/proficiency in procuring and processing human islets for research use
- Agree to utilize IIDP Policies & Procedures for Islet Isolation Centers

Award Information:

- Subcontract mechanism: new or renewal, anticipate 5-6 total IIC awards
- Reimbursement for shipped islets & associated tissue

**Key Dates**

- Posted Date: January 3, 2022
- Informational Webinar: January 24, 2022 at 11 am PST
- Letter of Intent Due Date: February 28, 2022
- Application Due Date: March 31, 2022
- Scientific Review: April 4-May 6, 2022
- Announcement of Awardees: June 2022
- Start Date: August 1, 2022
- End Date: July 31, 2023
- Potential renewals annually through July 31, 2026
**What Organizations Are Eligible?**

- Higher Education Institutions
  - Public or Private
- Non-Profits
  - With or without a 501c(3)
- For-Profit Organizations
  - Small or large businesses
- Institutions from North America

**Who Can Be a Program Director?**

- Any individual with requisite knowledge, skills, & track record of success in leading large multi-component resource intensive programs
  
  **AND**

- Experience providing islet resources to the diabetes research community

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**Apply online at:**

https://iidp.coh.org/IIC_RFP
**IIC Research Strategy:** (up to 10 pages, uploaded file)

- Overall Description
- Prior Experience (Table & Questions)
- Management Plan
- Personnel & Infrastructure
- Approach

**Approach:**

- Workflow
- Isolation Capacity
- Data Handling
- Shipping and Geographical Reach
- Estimated Cost per IEQ (Table)
- Innovation
APPLICATION PROCESS:
Reimbursement Schedule & Cost Estimates

<table>
<thead>
<tr>
<th>IIC Compensation Schedule as of September 24th, 2021:</th>
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<tbody>
<tr>
<td><strong>Human Islets</strong></td>
</tr>
<tr>
<td><strong>Non-Profit Recipients</strong></td>
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<tr>
<td>Non-diabetic donors $0.12 per IEQ</td>
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<tr>
<td>T2D donors $0.20 per IEQ</td>
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<tr>
<td><strong>For-Profit Recipients</strong></td>
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<tr>
<td>Non-diabetic donors $0.19 per IEQ</td>
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<tr>
<td>T2D donors $0.24 per IEQ</td>
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<td><strong>Flash Frozen Islets</strong></td>
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<tr>
<td>1,000-IEQ vial $120 per vial</td>
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<tr>
<td><strong>Pancreas Sample for Histology</strong></td>
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<tr>
<td>$250 per islet isolation</td>
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<tr>
<td><strong>Non-Islet Pancreatic Tissue (Acinar)</strong></td>
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<tr>
<td>Researchers and HIGI $200 per sample</td>
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To the best of your ability, please provide estimates for the following costs per isolation:

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Min</th>
<th>Max</th>
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<tbody>
<tr>
<td>Pancreas procurement</td>
<td></td>
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<tr>
<td>Staffing</td>
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<tr>
<td>Materials &amp; supplies</td>
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<tr>
<td>Other islet isolation costs</td>
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Number of years experience in isolating islets?

In the past 5 years, number of:
- Isolations performed
- IEQ isolated
- Islet shipments
- IEQ shipped
- Investigators receiving IEQ
- International shipments

Islet Quality Information

Provide the mean, min and max of the following parameters across all isolations for the past 5 years.

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<tr>
<th></th>
<th>Mean</th>
<th>Min</th>
<th>Max</th>
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<tbody>
<tr>
<td>IEQ</td>
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<tr>
<td>Islet Grade (0-10)</td>
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<tr>
<td>Purity %</td>
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<td>Viability (%)</td>
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<tr>
<td>Potency (Stimulation Index)</td>
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Contamination Problems?
APPLICATION PROCESS: OPOs & Director Experience

Relationships with OPOs
- List of OPOs with whom you work
- # of pancreata projected per year

Director Qualifications
- Background
- Expertise in islet biology
- Ability to provide high quality service
- Affiliation with diabetes community

Letters of Recommendation

Certification of IIDP SOP Adoption
Evaluation Method
- External Peer Review
- Technical & Scientific Merit
- NIH Scoring Convention (1-10)
- Overall Impact Score

Individual Review Criteria
- Overall strategy & prior experience
- Management plan, personnel & available infrastructure
- Approach
- Environment

Application Selection Process
- External Peer Review
- Recommended applications receive 2nd review from IIDP External Scientific Panel
- Final funding decision made by the IIDP
  - Scientific and technical merit
  - Relevance & benefit to program priorities

Final Decisions: June 2022
BENEFITS OF IIDP MEMBERSHIP

- Use of existing IIDP distribution infrastructure
- Fair & equitable islet placement via IIDP’s Matching Algorithm for Islet Distribution (MAID)
- Access to IIDP’s international, expanding researcher base
- Participate with IIDP & IICs on program advancements
BENEFITS OF IIDP MEMBERSHIP

- UNOS donor data download
- IIDP Human Islet Phenotyping Program (HIPP) data
- IIDP Human Islet Genotyping Initiative (HIGI) data
- Research Data Repository (RDR) integrated data & reports

Access to Expansive IIDP Data
BENEFITS OF IIDP MEMBERSHIP

- IIDP pays for:
  - Islet culture media
  - Packaging materials

- Bi-monthly reimbursement for:
  - Islet shipments
  - Freezing of islets
  - NIPT (acinar) shipments
  - Pancreas samples

- Opportunity Pool funds available for:
  - Bonus islets to researchers
  - Credits for shipping issues
  - T2D islet supplement
  - Future initiatives…
Expand the reach of your critical contribution to advancing science toward the prevention and cure of diabetes.
QUESTIONS?

IIDP.COH.ORG/IIC_RFP

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@IntegratedIsletDistributionProgram