INVESTIGATOR BROCHURE
The Integrated Islet Distribution Program (IIDP) began at City of Hope (COH) as the Islet Cell Resource in 2002, and has been operating since 2009 as the IIDP, the largest organized effort in the world to provide human islet preparations for research. Because human islet research is critical to understanding pancreatic cellular biology and the pathophysiology of diabetes, and given the substantial differences from murine islets, access to human islets is essential to translate findings from cell lines and mouse models. Therefore, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), continues to fund the IIDP, which affords ongoing coordination, information technology, and financial infrastructure, while offering high quality human islets, innovative new biomaterials, and integrated data to advance diabetes research.

Joyce C. Niland, PhD, Chair of the Department of Diabetes & Cancer Discovery Science within the Arthur Riggs Diabetes and Metabolism Research Institute at COH serves as Principal Investigator (PI) for this program. Carmella Evans-Molina, MD, PhD, Director of the Indiana Diabetes Research Center at Indiana University (IU), its Islet and Physiology Core, and the IU Center for Diabetes and Metabolic Diseases, serves as co-PI. Each of these investigators brings her own critical expertise to this vital program: Dr. Niland with over 35 years of experience in study coordination, informatics, biostatistics, and overseeing national/international coordinating centers, and Dr. Evans-Molina as a physician scientist with expertise in human islet biology, specializing in clinical diabetes. The PIs are supported by a highly experienced staff with expertise in the relevant programming, islet biology, regulatory, biostatistical, and administrative areas to support the IIDP.
MEET THE TEAM

Joyce Niland, PhD
Co-Principal Investigator

Carmella Evans Molina PhD
Co-Principal Investigator

Julie Hom
Project Manager

Shaunna Spears
Business Manager

Heather Sibley
Software Developer

Julie Yousefi
Software Developer

Jenny Chuang
Database Administrator

James Cravens
Program Manager

Julie Kilburn
Biostatistician

Carol Swanson
Research Coordinator

Barbara Olack
Senior Research Coordinator
OUR SERVICES

**Fair and Equitable Islet Distribution**
IIDP uses a web-based optimization algorithm to match researchers with islets best suited for their studies. This system allows uninterrupted matching 24/7, 365 days per year to pair researchers with islets best suited for their studies whenever an isolation is offered by our Centers.

**Standardized Packaging and Shipping**
Islet isolations are shipped using a standardized packaging protocol, which has been scientifically tested and proven to maintain islet health and quality for > 5 days in transit. The IIDP provides islets to investigators in Europe, Australia, the Middle East as well as all sections of North America through commercial delivery systems.

**Customizable Data Reports**
Approved IIDP researchers have access to a wealth of donor and islet isolation data through the IIDP Research Data Repository (RDR). Records can be filtered, and individual data points can be selected to meet the unique needs of each researcher.

**Investigator Modifiable Islet Demand Levels**
The IIDP features a user-defined islet demand classification system which allows researchers to customize their study's relative priority for islets as: high demand, standard demand, low demand, and on-hold.

**Human Islet Phenotyping Program**
HIPP provides phenotypic data on islets post-shipment, received from the islet isolation centers following each isolation. These data include purity, viability, and potency assessments as well as hormone content and histological analysis of total preparation for endocrine vs exocrine cells and average composition of α, β, and δ cells through standardized assays.

**Human Islet Genotyping Initiative**
To provide a summary of the genetic characteristics of each donor, the HIGI will generate partitioned genetic risk (pGRS) scores for type 1 and type 2 diabetes. These pGRS will be visualized on the IIDP website, to provide an overview of the genetic contributions of a variety of physiological processes (e.g., islet cell, liver, adipose dysfunction) to each individual donor’s diabetes risk.

**User Satisfaction Analyses**
Quantitative and qualitative feedback are collected after every islet shipment and routinely analyzed to improve project satisfaction and success of the program.

**Multi-Study Collaboration**
The IIDP distribution algorithm can group multiple studies from anywhere in the world to ensure that your collaborators receive the same islet offers as you.
The IIDP coordinates the distribution of human islets and non-islet pancreatic tissue from the five exceptional islet isolation centers shown on the map below. These centers have extensive experience in isolating human islets from pancreata procured from deceased organ donors, with specific permission for research use of the organs, and delivering a high-quality product to the research community.

The isolation centers input into the IIDP website associated donor data, processing information, and quality assessments such as purity, viability, quantity, index, and ranking. These data are provided at the time of the tissue offer, allowing investigators to make an informed decision when accepting the shipment. Tissues are sent via overnight FedEx to your lab directly from the offering center. Following every shipment, the centers also provide islet potency and final sterility data for each isolation. Subsequently additional data also are integrated from UNOS, and our IIDP phenotyping and genotyping programs as listed previously under Our Services.

IIDP Islet Isolation, Phenotyping, and Genotyping Contracted Centers

IIDP Islet Isolation Center Managers Contact Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Tel</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brian Haight</td>
<td>949-727-1972</td>
<td><a href="mailto:bhaight@prodolabs.com">bhaight@prodolabs.com</a></td>
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<tr>
<td>Karol Ptasiewicz</td>
<td>773-733-3163</td>
<td><a href="mailto:kpalasiewicz@luc.edu">kpalasiewicz@luc.edu</a></td>
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<tr>
<td>Peter Chlebeck</td>
<td>608-262-8459</td>
<td><a href="mailto:chlebeck@surgery.wisc.edu">chlebeck@surgery.wisc.edu</a></td>
</tr>
<tr>
<td>Yesica Garciafigueroa</td>
<td>412-799-3403</td>
<td><a href="mailto:yesica@imaginepharma.com">yesica@imaginepharma.com</a></td>
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</tbody>
</table>
The IIDP offers islets from cadaveric organ donors meeting or exceeding the IIDP’s minimal donor criteria. Approved researchers are required to complete a study profile detailing the donor and islet quality parameters desired, to be utilized by the IIDP’s Matching Algorithm for Islet Distribution (MAID) when determining islet offer eligibility.

Both viable and flash frozen human islets are available to IIDP researchers with an active subscription to receive IIDP products. 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.

The IIDP also offers non-islet pancreatic tissue (NIPT - acinar) to active subscribers. Acinar tissue is made available as either fresh or frozen samples. Packing 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.

### AVAILABLE RESOURCES

<table>
<thead>
<tr>
<th>Resource</th>
<th>Price</th>
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<tbody>
<tr>
<td>Viable Islets</td>
<td>$0.12/IEQ</td>
</tr>
<tr>
<td>T2D Viable Islets</td>
<td>$0.12/IEQ</td>
</tr>
<tr>
<td>Frozen Islets</td>
<td>$120/1000 IEQ/VIAL</td>
</tr>
<tr>
<td>Acinar Tissue</td>
<td>$250/SHIPMENT</td>
</tr>
<tr>
<td>Pancreas Histology Slides</td>
<td>$15/SLIDE</td>
</tr>
</tbody>
</table>

For a list of prices applied to for-profit organizations please contact iidp-email@coh.org
GETTING STARTED

1. Apply to the IIDP
   - Submit your study application and letter of agreement
   - Studies with peer-review grant funding are automatically approved
   - Non-peer reviewed studies receive external review

2. Confirm Study Profile
   - Define your study’s criteria by completing donor and islet profiles
   - Donor gender, age, Body Mass Index, and diabetes history as well as islet type, purity, viability, and other factors can be indicated to ensure that your criteria are met

3. Fund Subscription
   - Create a subscription invoice to fund your study (credit card payments preferred)
   - Islet offers will begin

4. Accept Offers
   - Email and/or text messages will be sent to you when available islets are offered
   - When you accept an offer, islets are sent to your lab from the islet isolation center via FedEx
   - IIDP requests you to provide quantitative and qualitative feedback about the islets and packaging to continually monitor quality
SUBSCRIPTIONS

- Run from July 1\textsuperscript{st} - June 30\textsuperscript{th}
- No limit on the number of payments
- Subscription expires on June 30\textsuperscript{th}
- Unused subscription will be carried over into the next period
- Current pricing model guaranteed during the subscription period

INVOICE & ACCEPTED PAYMENT TYPES

Access our subscription module to create invoices, track invoices, payments, and islet subscription activities directly from our website

Payment Options

1. Checks
2. Credit Card
3. Automated Clearing House (ACH)

View the Creating Invoice and Credit Card Payment document for more information
A way to define your current islet need and tailor your offer frequency

- High Demand: immediate need for islets
- Standard Demand: default demand level
- Low Demand: eligibility for open offers only
- Unavailable: all offers paused by investigator

For IIDP production centers to assess program-wide islet demand

- All studies’ demand levels are summarized and displayed to the centers
- Allows the centers to make informed decisions when interacting with their OPOs

View the Islet Demand Presentation for more information
TARGETED OFFERS

• Non-competitive, i.e., islets set aside specifically for you, if response received before deadline for that round of offer
• Islets match all your pre-set study parameters
• Ineligible for new targeted offer for 30 days if 3+ consecutive targeted offers not accepted

IIDP advice:
Designate your study as “unavailable” or “low demand” when not in need of islets

OPEN OFFERS

• Competitive, i.e., multiple studies are offered the same islets if not placed via targeted offers
• Once offer deadline is reached, islets are distributed based on best matches to study parameters
• Islets may not always match 100% of your study’s parameters (no penalties for missed open offers)
REDUCED FEE ISLETS

PURPOSE
- To allow additional placement of remaining islets
- To provide lower cost islets to researchers

BENEFITS
- Foster scientific experimentation
- Utilize precious resource by placing maximum islets

CONDITIONS
- Only when leftover islets are available
- Islet isolation center agrees to reduced pricing
- Reduced pricing subtracted from user’s subscription

COST
- $0.06 per IEQ for non-diabetic donors
- $0.08 per IEQ for T2D donors
**BONUS ISLETS**

**PURPOSE**
- Provides 10-20% additional islets per shipment, free of charge to the investigator (if leftover islets are available)

**BENEFITS**
- Compensate for any loss of islets during transit
- Reduce waste of the precious resource of human islets
- Maximize reimbursement to centers for the isolation

**COST**
- Bonus islets paid by the IIDP, no impact on investigator’s subscription account
COMPLETE USER FEEDBACK FORMS

- Part 1 (questions about the integrity of packaging & initial impression of islets) to be completed when the islets arrive, due 10 days post receipt of islets

- Part 2 (quality of the islets) to be completed after use in experiments, due within 30 days of receipt of islets

PUBLICATION CITATIONS

- By accepting IIDP samples or data, investigators agree to abide by the IIDP Publications and Presentations SOP

- All publications and presentations shall cite: “Human pancreatic islets were provided by the NIDDK-funded Integrated Islet Distribution Program (IIDP) at City of Hope, NIH Grant # 2UC4DK098085

View more information on our Policies and Procedures webpage
Do I have to accept every islet offer that I receive?

No, you are free to accept, reject, or ignore any islet offer that you receive. However, if you reject or ignore several targeted offers consecutively, your study will be designated as temporarily ineligible for targeted offers until you demonstrate a need for islets by accepting an open offer (which you will continue to receive), or the end of the deprioritization period had passed (30 days).

What happens if I ignore or reject a targeted islet offer?

You will only receive a targeted offer if the available islets meet your desired islet parameters. There are no negative consequences for ignoring or rejecting 1 or 2 targeted offers. However, if you miss 3+ consecutive targeted offers, this is viewed as a lack of need for islets at that time, and you will be ineligible to receive additional targeted offers for 30 days, or until you accept an open offer (which you will still receive), whichever comes first. This ineligibility period is invoked to maintain efficiency of the IIDP Islet Allocation System (IAS), and to ensure that those studies with the highest current need for islets receive priority.

What do I need to do after I receive an islet shipment?

After you have received an islet shipment, you are required to complete Part I and Part II of the User Feedback Form online. Additionally, if the results of your IIDP-supported study are published, you are required to cite the Integrated Islet Distribution Program.

How can I receive more islets if I’ve reached my study limit?

If you’ve reached the overall islet limit on your IIDP study, but the experiments are ongoing, your islet limit can be expanded. Log onto the IIDP website and update the IEQ needed for your study.

What happens if I do not receive all islets for my study prior to the end of the subscription period?

All subscriptions will be valid from the date of payment through the end of the IIDP grant. Although the pricing rates may change from one subscription period to another, any unused subscription balance as of the end of one subscription period will carry over without loss into the next subscription period.

Check our FAQs webpage for more questions
IIDP... providing high quality human islets, associated tissue, & integrated data to the diabetes research community worldwide