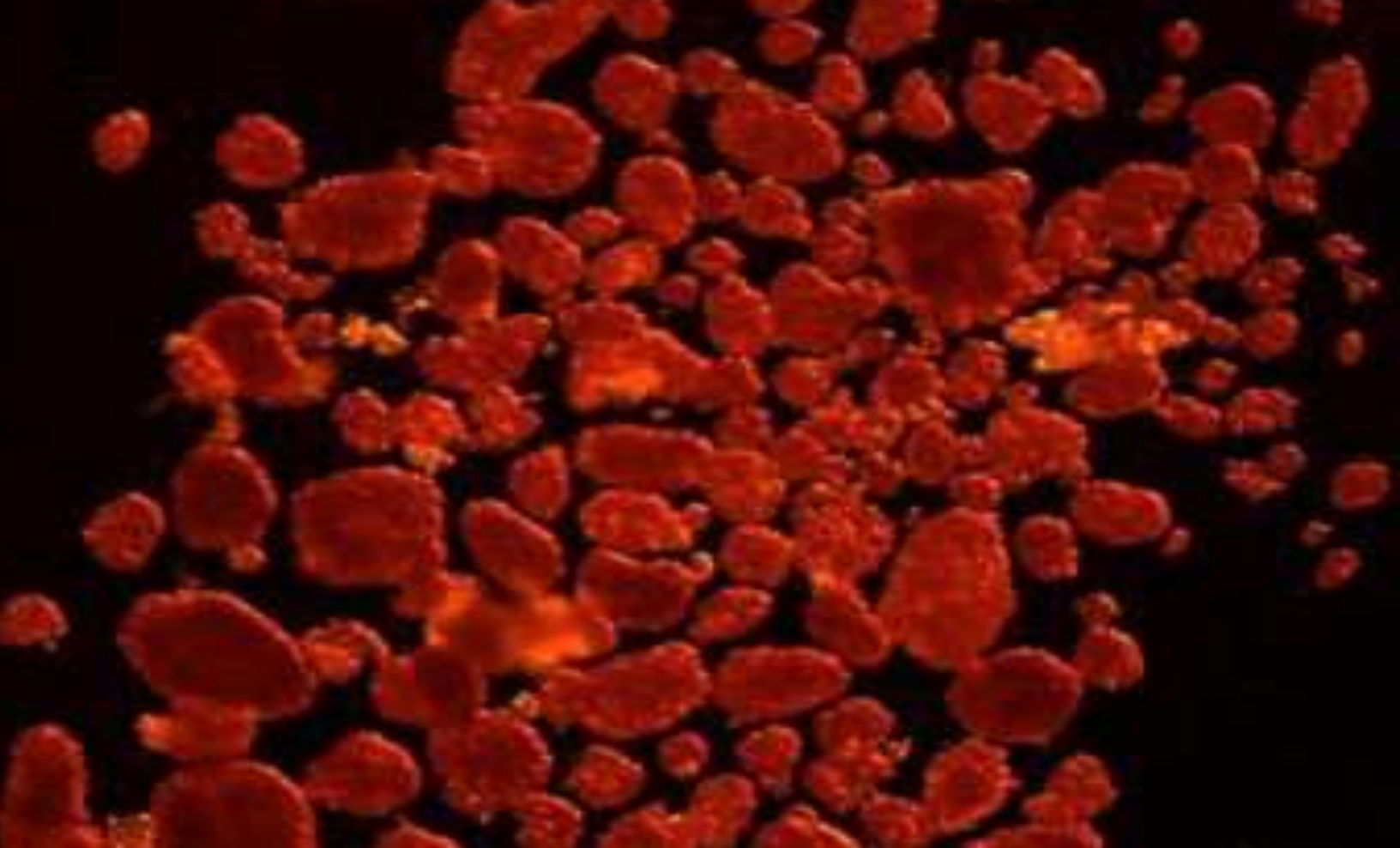




INVESTIGATOR BROCHURE

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PROGRAM OVERVIEW

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 biospecimens, and integrated data to advance diabetes research.

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.

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.

OUR TEAM

Joyce Niland, PhD
Co-Principal Investigator



Carmella Evans Molina PhD
Co-Principal Investigator



James Cravens
Program Manager



Jessica Girard
Project Manager



Heather Sibley
Software Developer



Jenny Chuang
Database Administrator



Julie Yousefi
Software Developer



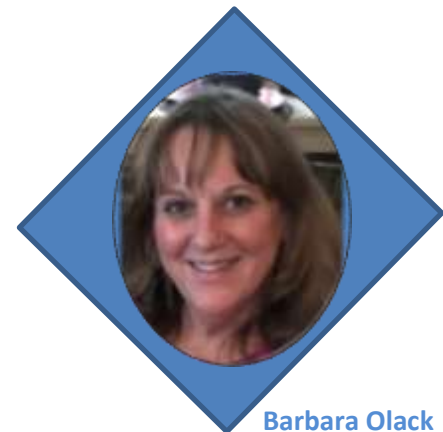
Julie Kilburn
Biostatistician



Shaunna Spears
Business Manager



Barbara Olack
Senior Research Coordinator



OUR SERVICES



Optimized 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)

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



Human Islet Genotyping Initiative (HIGI)

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

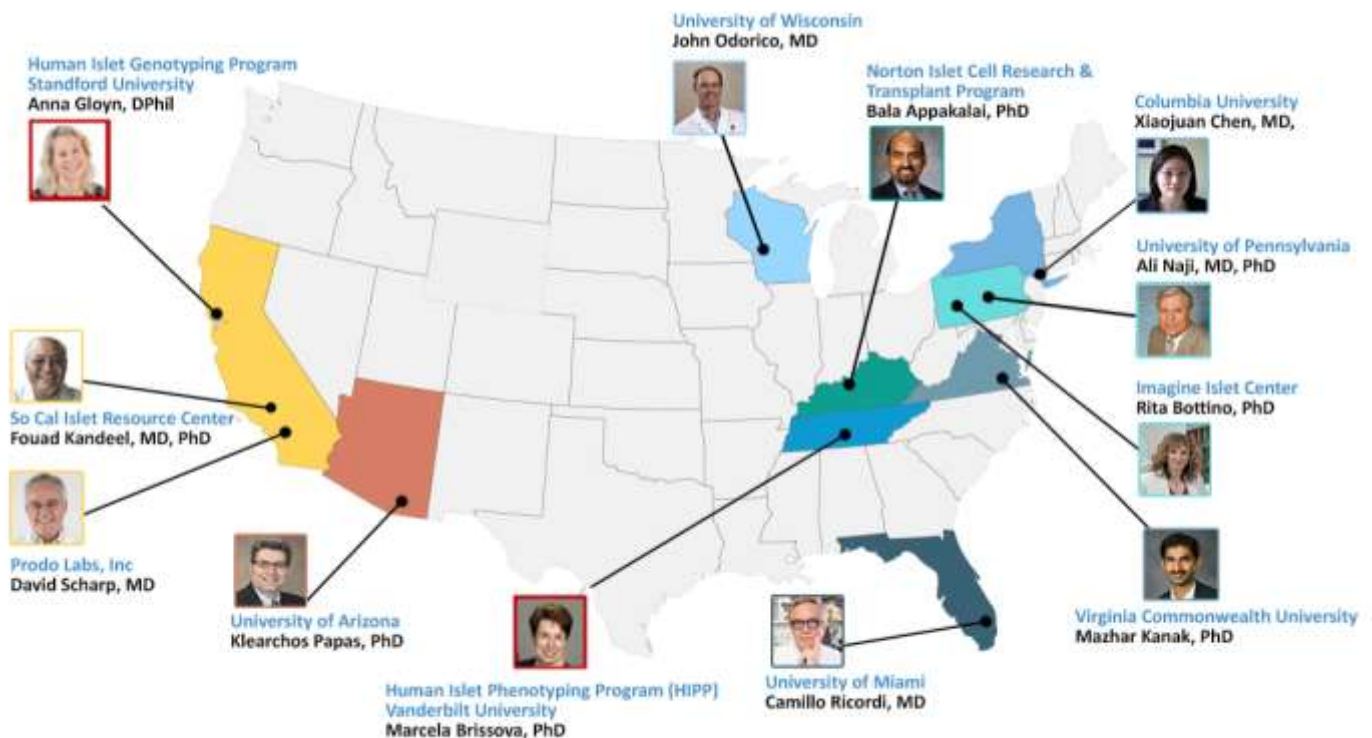
The IIDP distribution algorithm can group multiple studies from anywhere in the world to ensure that your collaborators receive the same islet offers as you.

OUR CENTERS

The IIDP coordinates the distribution of human islets and non-islet pancreatic tissue from the ten 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

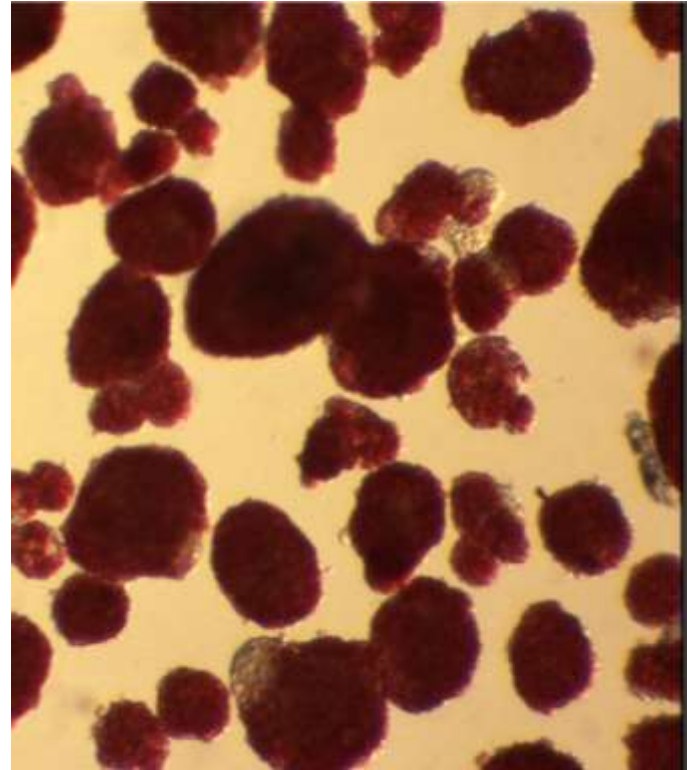


AVAILABLE RESOURCES

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 biospecimens (NIB) to active subscribers, that can be accepted with or without the islets from the same donor. Available NIBs include serum, plasma, spleen pieces, peripancreatic lymph nodes, duodenum samples, ductal tissue, frozen pancreas pieces, and non-islet pancreatic tissue (NIPT – acinar) as either fresh or frozen samples. Standardized processing, packaging, and shipping protocols for [fresh and frozen samples](#) are followed. Donors for IIDP NIB must meet the same minimal criteria as donors for IIDP islets. Formalin fixed native pancreas histology slides are available from islet/tissue donors.



PRICING

\$0.15/
IEQ

Viable Islets

\$0.15/
IEQ

T2D Viable Islets

\$150/1000
IEQ/VIAL

Frozen Islets

\$250/
SHIPMENT

Non-Islet Biospecimens

[Plasma, serum, ductal tissue,
peri-pancreatic lymph nodes, spleen, frozen
pancreas pieces, fresh & frozen acinar]

\$1000/
SHIPMENT

Duodenal Tissue

\$15/
SLIDE

Pancreas Histology Slides

*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

STUDY SUBSCRIPTIONS

SUBSCRIPTIONS

- Generally run from August 1st - July 31st
- No limit on the number of payments
- Subscription expires on July 31st
- 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

STUDY DEMAND

**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

TYPES OF ISLET OFFERS



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

- \$0.08 per IEQ for non-diabetic donors
- \$0.10 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

POST-SHIPMENT REQUIREMENTS



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](#)

FREQUENTLY ASKED QUESTIONS

Q1 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 has passed (30 days).

Q2 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.

Q3 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.

Q4 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.

Q5 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

CONTACT US



IIDP.CO.H.ORG

Investigator Website

IIDP.CO.H.ORG/SECURE/ISLETAVAIL



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IIDP...
providing high
quality
human islets,
associated tissue,
& integrated
data
to the
diabetes research
community
worldwide