



Funding Opportunity: HIRN Catalyst Award (2021)

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Key Dates

Posted Date:	December 1, 2021
Letter of Intent Due Date:	March 1, 2022
Application Due Date:	May 2, 2022
Scientific Review:	May – July, 2022
Start Date:	August 1, 2022
Expiration Date:	May 3, 2022

Section I. Funding Opportunity Purpose

The [Human Islet Research Network \(HIRN\)](#) announces a new funding initiative to support investigators developing bold, innovative, and challenging projects that will catalyze the field and provide important advances in topics of interest to the network. To be considered “catalyzing”, the proposed research must address significant and currently intractable problems by employing approaches or ideas that are currently outside the mainstream of contemporary research. The program is not intended to expand a current research program's funding in the area of the proposed project, but instead must reflect a fundamental new insight or understanding that will revolutionize the field. Catalyzing advances may emanate from the application of exceptionally innovative approaches and/or from testing radically unconventional hypotheses. Applicants must propose aims focused on an original scientific idea or question that is distinct from current HIRN funded research.

The scientific focus of application to the HIRN Catalyst program must fall within the purview of one (or more) of the current HIRN consortia (refer to Section II 2). In addition to receiving funds to support research activities, the award recipient will become an active member of the HIRN network. Awardees will be expected to participate in an array of HIRN collaborative activities and networking opportunities, including the HIRN annual investigator meeting and ongoing meetings of relevant HIRN consortia. Recipients of the HIRN Catalyst Award are expected to present findings supported by the award to the HIRN community at regular intervals.

Section II. Funding Opportunity Description

II-1. Background

Type 1 diabetes (T1D) is a disease caused by the autoimmune destruction of insulin-secreting beta cells in the pancreas. While the incidence of T1D is increasing worldwide, research

continues into mechanisms contributing to disease onset and severity, and into development of therapeutic strategies to effectively prevent or intervene in the disease process.

In 2014, NIDDK established the Human Islet Research Network (HIRN; www.hirnetwork.org) to support collaborative research in T1D. HIRN is jointly supported by NIDDK and the type 1 diabetes special funding program, and its overall mission is to better understand how human beta cells are lost in T1D and to find innovative strategies to protect or replace functional beta-cell mass in diabetic patients. The HIRN program is configured as a modular network of research consortia, each defined by a specific set of research priorities. All HIRN research consortia are focused on human disease biology, the use of human cells and tissues, and the development of tools and disease-modeling platforms that can help further our understanding of the human disease process. It is anticipated that HIRN efforts will ultimately lead to new and innovative treatment strategies for T1D patients.

II-2. Objectives and Scope

Research supported by these awards should be based on original questions and ideas that address significant barriers in T1D research. In addition, the scientific opportunities to be pursued should fit conceptually within the framework of goals of an existing consortium within the Human Islet Research Network.

The five current HIRN consortia include:

- (1) The Consortium on Beta Cell Death and Survival ([HIRN-CBDS](#)) is using human tissues to identify early disease mechanisms, discover highly specific biomarkers of beta-cell injury in asymptomatic T1D, and develop strategies to stop beta-cell destruction early in the disease process;
- (2) The Consortium on Human Islet Biomimetics ([HIRN-CHIB](#)) is combining advances in beta-cell and stem cell biology with tissue engineering technologies to develop microdevices that support functional human islets and immune cells;
- (3) The Consortium on Modeling Autoimmune Interactions ([HIRN-CMAI](#)) is developing innovative approaches to model basic aspects of human T1D immunobiology and pathobiology in vivo, and develop strategies to interrupt immune activation in T1D;
- (4) The Consortium on Targeting and Regeneration ([HIRN-CTAR](#)) is developing methods to increase or maintain functional beta cell mass in T1D through targeted manipulation of islet plasticity, or through engineering protection of islet beta cells from immune-mediated destruction; and
- (5) The Human Pancreas Analysis Consortium ([HIRN-HPAC](#)) is investigating the physical and functional organization of the human islet tissue environment, the cell-cell relationships within the pancreatic tissue ecosystem, and the contributions of non-endocrine components (acinar, ductal, vascular, perivascular, neuronal, lymphatic, immune) to islet cell function and dysfunction.

The following activities are non-responsive and should not be pursued under this award:

- Clinical Trials
- Research focused on non-human cells

Section III. Award Information

Funding Instrument:	Subcontract, awarded from the Human Islet Research Enhancement Center (HIREC) at City of Hope
Application Types Allowed:	New
Funds Available & Anticipated Number of Awards:	HIRN intends to commit funds in FY2022-2023 to support up to 4 awards.
Award Budget:	Applications may request budgets of up to \$125,000 in direct costs per year for up to two years.
Award Project Period:	The maximum project period is 2 years.

Section V. Eligibility Information

1. Eligible Applicants

Private Institutions of Higher Education

The following types of Higher Education Institutions are encouraged to apply for support as Public or Private Institutions of Higher Education:

- Hispanic -serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses/For-Profit Organizations (Other than Small Businesses)

Foreign Institutions

- Non-domestic (non-U. S.) Entities (Foreign Institutions) **are NOT** eligible to apply.
- Non-domestic (non-U. S.) components of U.S. Organizations **are NOT** eligible to apply.
- Foreign components, as [defined in the NIH Grants Policy Statement](#), **are NOT** allowed.

2. Required Registrations

Applicant / Applicant Organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible or receive an award:

- [DUN and Bradstreet Numbering System \(DUNS\)](#) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [eRA Commons](#) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

3. Additional Information on Eligibility

- Number of Applications: Applicant organizations may submit more than one application, provided that each application is scientifically distinct; however, the HIRN will only accept one application per individual PD/PI.

V-2. Eligible Individuals

APPLICANTS

Requirements for applicants applying to this FOA include:

- Candidates must hold a Ph.D., M.D., M.D./Ph.D, or equivalent degree signifying comparable research experience to the Ph.D, M.D., or MD/Ph.D.
- Candidates must have an eRA Commons ID and Open Research and Contributor ID (ORCID)
- Candidates must be able to propose an original scientific project to be pursued under this initiative. Proposed project should not be an aim or component of a currently funded project. There should be no overlap with any currently funded research.
- Only Single PD/PI applications will be allowed.
- Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply.

- There is no citizenship requirement for the applicant. Applicant may be a citizen or a non-citizen national of the United States, been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status).

Section VI. Application and Submission Information

VI-I. Requesting an Application Package

Applicants may access the application package associated with this funding opportunity on the HIRN website under “Funding”, specifically at: <https://hirnetwork.org/catalyst2021>

VI-2. Content and Form of Application Submission

Application Forms: It is critical that applicants follow the instructions in the HIRN Application Guide (see Appendix 1). Conformance to the requirements in the Application Guide is required and will be strictly enforced. Applications that are out of compliance with these instructions may be returned without review.

Letter of Intent: A letter of intent (LOI) is not required, it is not binding, and does not enter into the review of a subsequent application. However, the information provided in the LOI allows HIREC staff to estimate the potential review workload and plan the review. By the due date listed above, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name, address and telephone number of the applicant
- Participating institution
- Names of other key personnel
- Name of the one HIRN consortium most closely related to the project aims and goals

The letter of intent should be sent in electronic form to:

The Human Islet Research Enhancement Center (HIREC) City of Hope, Duarte, CA at:
hirnec@coh.org

VI-3. Instructions for Application Submission

Applications should be submitted directly to the Human Islet Research Enhancement Center (HIREC) **NOT** to the Division of Receipt and Referral at the NIH. The link to the online application will be posted at: <https://hirnetwork.org/catalyst2021>

VI-4. HIRN Research Plan

All instructions in the HIRN Application Guide must be followed, including provision of a face page, detailed budget, budget justification, NIH biosketch and research plan. The research plan should conform to the following instructions with careful attention to use of the headers and word limits outlined below:

Research alignment with HIRN goals (500 words max): Describe how your objectives and research design are related to, but distinct from, ongoing studies in HIRN.

Innovation (500 words max): Summarize clearly and concisely what makes your project innovative. If the approaches entail a high degree of risk, what will you do if these approaches are not successful? What concrete evidence can you provide for your claim of innovativeness? For example, qualities common to many highly innovative people include an interest in, and the ability to integrate, diverse sources of information; an inclination to challenge paradigms and take intellectual risks; persistence in the face of failure; an ability to attract the right collaborators; and the energy and concentration necessary to plan and execute effective strategies for accomplishing goals.

Applicant's Suitability for Catalyst Award (500 words max): Provide a brief narrative describing your current funded research activities. Include references to any publications, prior research interests, and experience that support your suitability for the HIRN Catalyst program. Explain why the proposed research is uniquely suited to stated goals of the HIRN Catalyst Award program.

Research Objectives (500 words max): How does the planned research differ from your past or current work? How does the proposed project represent a new and distinct direction for your research? While a new research direction may have as its foundation your prior work and expertise, it cannot be an obvious extension or scale-up of a current research project or concept. Rather, a new research direction must reflect a fundamental new insight into the potential solution of a problem, which may derive from the development of exceptionally innovative approaches and/or from the posing of radically unconventional hypotheses. Applications for projects that are extensions of ongoing research should not be submitted. If the proposed project represents an entirely new direction or shift into a new scientific field, explain how you will incorporate any field-specific expertise such as collaborators, consultants, or other approaches, to assist in addressing the problem or challenge.

Project Description (File upload, 5 pages max):

- **Vision:** Describe the scientific problem that you propose to address, its importance, and explain how solving this problem would have a major impact on T1D research. How does the research topic relate to HIRN goals, and why are the proposed studies uniquely suited to the “HIRN Catalyst” award program?
- **Approach:** What are the pioneering, and possibly high-risk, approaches that, if successful, might lead to groundbreaking or paradigm-shifting results? How will you ensure that the results will be robust and unbiased? Discuss potential problems, alternative strategies, and benchmarks for success in achieving your research goals. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.

Notes:

- *Figures and illustrations may be included but must also fit within the page limit.*
- *Bibliographic citations are not required but if included must fit within the page limit.*

Resource Sharing Plan: Individuals are required to comply with instructions for providing Resource Sharing Plans as provided in [NIH guidance](#). Post-award, grantees will be expected to comply with HIRN consortium-specific resource sharing and confidentiality agreements.

Supporting Documents

- **Collaborators:** Signed statements must be provided by all collaborators and/or consultants listed as “Key Personnel” confirming their participation in the project and describing their specific roles.
- **Letters of Support:** Support letters attesting to the applicant’s abilities or future potential are NOT allowed and will NOT be accepted. Any application containing letters of support will be returned without review for noncompliance.

VI-5. Planned Enrollment Report

DO NOT INCLUDE. Studies meeting the current NIH definitions of Clinical Research or Clinical Trials will **NOT** be eligible for support under this funding opportunity. For current definitions, please see guidance at: <https://grants.nih.gov/grants/glossary.htm#C>

Section VII. Application Review Information

VII-1. Criteria

Only the review criteria described below will be considered in the review process. Consistent with the HIRN program mission, all applications submitted will be evaluated for scientific and technical merit using external peer review.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

- **Significance:** Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project?
- **Innovation:** Does the application use novel theoretical concepts, approaches or methodologies? Alternatively, is a refinement, improvement, or new application of existing theoretical concepts, approaches or methodologies proposed?
- **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Has the applicant presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented?
- **Investigator:** Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- **Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigator adequate for the project proposed? Does the applicant have strong mentorship to support the proposed project?

Additional Review Criteria: As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects: DO NOT INCLUDE. Studies meeting the current NIH definitions of Clinical Research or Clinical Trials will **NOT** be eligible for support under this funding opportunity. For current definitions, please see guidance at:

<https://grants.nih.gov/grants/glossary.htm#C>

Inclusion of Women, Minorities, and Children: DO NOT INCLUDE. Studies meeting the current NIH definitions of Clinical Research or Clinical Trials will **NOT** be eligible for support under this funding opportunity. For current definitions, please see guidance at:

<https://grants.nih.gov/grants/glossary.htm#C>

Vertebrate Animals: While proposals including animals are not excluded from consideration, the core activities of the Human Islet Research Network revolve around human type 1 diabetes, and research plans should thus emphasize studies involving the human condition. When relevant, reviewers will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals.

Biohazards: Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

VII-2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by external peer reviewers convened by the HIREC using the stated review criteria.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.
- Appeals of the HIREC peer review **will NOT** be accepted for applications submitted in response to this funding opportunity.

Applications will compete for available funds with all other recommended applications submitted in response to this funding opportunity. Following initial peer review, recommended applications will receive a second level of review by an *ad hoc* group of HIRN External Scientific Panel members. NIH staff affiliated with HIRN will make final funding decisions, with consideration of the following:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

VII-3. Anticipated Announcement and Award Dates

After peer review and secondary review of the applications are complete, the recipient will be notified by the HIREC as to funding decisions by August 1, 2022.

Appendix I. Application Guide

The following items will be collected as part of the application:

- [Public Health Service Grant \(PHS\) 398: Face Page \(form page 1\)](#)
- [Public Health Service Grant \(PHS\) 398: Detailed Budget for Initial Budget Period \(form page 4\)](#)
- [Investigator Biographical Sketch \(Biosketch\) \(5 page max length\)](#)
- Application (General Applicant Information)
- Research Plan (as detailed in Section V-4)
- [NIH Checklist](#)

Supporting Documents:

- **Collaborators:** Signed statements must be provided by all collaborators and/or consultants listed as “Key Personnel” confirming their participation in the project and describing their specific roles.
- **Letters of Support:** Support letters attesting to the applicant’s abilities or future potential are NOT allowed and will NOT be accepted. Any application containing letters of support will be returned without review for noncompliance.