

<b>Rationale</b>	<b>Request for Proposals</b>	<b>Application Process</b>	<b>Concept Note Instructions</b>	<b>Additional Details</b>
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# Understanding and Targeting Innate Immunity in Type 1 Diabetes Pathogenesis

## Rationale

The Leona M. and Harry B. Helmsley Charitable Trust's (Helmsley) Type 1 Diabetes (T1D) Program aims to support the discovery and development of new therapies to prevent or delay T1D and the identification and validation of biomarkers to predict disease initiation and progression.

T1D is a complex autoimmune disease where insulin-producing beta cells in the pancreas are targeted by immune cells. The predisposing factors, triggers, and other elements that affect disease pathogenesis in humans are not yet fully identified. Understanding these drivers of disease could lead to discoveries of new drug targets, guide intervention strategies to halt the disease, or improve prediction of disease development.

To date most T1D preclinical and clinical research has focused on the role T cells play in disease pathogenesis.

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pancreas during T1D, its significance, and what role these cells play in disease in humans is not yet fully understood.

## Request for Proposals

To address this gap, the Helmsley T1D Program seeks to support studies that aim to evaluate or modulate the function of innate immune cells and pathways in T1D, with an emphasis on human disease during relatively early stages of disease (i.e., autoantibody positivity through early onset of clinical disease).

Of specific interest are research plans that include:

Analyzing the type and function of innate cells (e.g. macrophages, dendritic cells, natural killer cells) present in the pancreas and their interactions with other cells, tissue-resident or otherwise;

Investigating mechanisms of T1D pathogenesis that involves innate immunity;

Identifying or validating biomarkers of disease progression or response to treatment based on innate immune cells;

Identifying or validating therapeutic innate immune cell targets; and

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Profiling or functional analysis of innate immune cells in pancreas samples and pancreas slices;

Analysis of preexisting relevant data sets, either publicly available or generated by the applicant; and

Preclinical or clinical activities that advance or build evidence for a specific therapeutic concept based on existing knowledge of the role of innate immunity in T1D.

Like other fields, scientific research in T1D has been challenged by limited access to human samples. To facilitate potentially impactful studies, Helmsley has partnered with two leading T1D networks, the Network for Pancreatic Organ donors with Diabetes ([nPOD](#)) and [INNODIA](#), to enable access to disease relevant samples and connected clinical and biological data in relation to this RFP.

Applicants who proceed to the full proposal stage with a project that includes access to nPOD or INNODIA samples will work with the relevant network team to hone final research plans and access to samples.

**Investigators with access to appropriate samples from sources outside of nPOD or INNODIA are also strongly encouraged to apply to the RFP.**

Investigators are welcome to reach out to Helmsley staff to discuss other potential sources of T1D samples and data.

Excluded from the scope of the announcement are studies that primarily focus on non-innate immune cells (e.g., T

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## Application Process

There are two phases: (1) submitting a Concept Note and, if invited by Helmsley, (2) submitting a Full Grant Proposal. Submitted materials may be reviewed by Helmsley staff, nPOD and INNODIA representatives to the extent applicable, and subject matter experts.

### **Phase 1:**

Applicants should register by filling out contact information, organization information, and the title of the proposed project at [helmsley.fluxx.io/apply/T1D\\_Innate\\_Immunity](https://helmsley.fluxx.io/apply/T1D_Innate_Immunity).

Following verification of organization information, Helmsley will provide the applicant access to Helmsley's application portal (Fluxx) to submit a Concept Note.

Applicants should allow 3-5 business days from registration to receive their login information for submitting their Concept Note.

If an applicant has two unique but high-impact ideas, they may register twice and submit two Concept Notes.

**Concept Notes must be submitted before 12:00pm PST on April 30, 2025.**

### **Phase 2:**

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outcomes;

Detailed budget (budget template will be provided); and

Biosketches of applicants and collaborators.

Applicants should be aware that if a proposal involving nPOD or INNODIA samples is successful, the applicant organization will be required to abide by that network's restrictions/requirements related to use of their samples and data management/sharing policies. This includes applying directly to the network to request samples.

## Concept Note Instructions

Applicants should complete the requested information in Fluxx **AND** upload a Word document or PDF (with figures) of no more than 1,200 words (figure legends do not count against the word limit) addressing the topics below.

**Background:** Identify existing evidence and data that justify the proposed studies.

**Activities:** Describe proposed research activities.

**Expected outcomes:** Describe what the research plan aims to produce by the end of the funded project and how this sets up the next phase of the study.

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direct costs can be requested to support institutional indirect costs. Detailed budgets are not needed at this stage.

## Additional Details

### Funding

The proposed funding term can be up to three years.  
Requested funding amounts can range based on activities:

Laboratory-based studies may be supported with a total budget of up to \$300,000 per year.

Clinic-based studies may be supported with a total budget of up to \$500,000 per year.

If the proposed research plan cannot be launched within the funding opportunity's boundaries, (e.g., an interventional trial requires a high number of subjects), applicants can reach out to Helmsley to discuss feasibility.

### Review Criteria

Proposed projects will be assessed based on:

Feasibility, novelty, and funding gap of the proposed activities;

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Any individual with a faculty-level (or equivalent) appointment at an institution performing medical research (including non-profit and for-profit corporations) with the skills, knowledge, and resources (individual and institutional) necessary to carry out the proposed research is invited to work with their organization to develop an application for support. Organizations who are invited to submit a Full Grant Proposal will be required to submit additional information regarding entity status at that stage. Grant awards will be subject to Helmsley's [grant agreement terms](#).

## **Timeline**

March 3, 2025: Concept Note submission period opens

**April 30, 2025: Concept Notes due**

June 4, 2025: Selected applicants invited to submit full grant proposals

**July 30, 2025: Full Grant Proposals due**

January 2026: Earliest notification of awards

February 2026: Earliest grant start date

**NOTE: Timing of the RFP process is subject to change.**

## **Questions**

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