Request for Proposals (RFP) Program Overview

The Novo Nordisk Inc. Investigator Sponsored Studies (ISS) program is dedicated to building on our 100-year heritage of putting patients first. That's why we support independent scientific investigations that improve patient outcomes and add knowledge to our therapeutic areas of interest. The Novo Nordisk Inc. ISS program includes Request for Proposals (RFP), which are publicly posted, specific to areas of interest, address unmet research needs/evidence gaps, and have set timelines for submission and review.

Note that this is a competitive process. Submission of an application in response to this RFP does not constitute agreement by Novo Nordisk to support your study. Submitted RFP applications will be reviewed by the Novo Nordisk teams on both the US (NNI) and Global level.

Program Eligibility

Geographic Region	Unites States
Applicant Eligibility	Eligibility includes: • Health Care Professional • An institution or organization • A company (which is not a pharmaceutical company)

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Program Overview

RFP Issue Date	**April 2024**
RFP Therapeutic Area	Cardiovascular Disease
RFP Study Focus	Observational Studies
Unmet Need/ Areas of Interest	This RFP will support observational research in the therapeutic area of Cardiovascular Disease. Specifically, Novo Nordisk has interest in supporting independent scientific investigations that focus on the role of systemic inflammation in patients living with Atherosclerotic Cardiovascular Disease (ASCVD), Heart Failure (HF), Acute Myocardial Infarction (AMI), chronic kidney disease (CKD), and other associated co-morbidities. **<u>Areas of Interest</u>** Systemic inflammation in patients with: • ASCVD + CKD • HF (primarily in HFmrEF and HFpEF) • AMI Systemic inflammation: • Functional outcomes in HF • Compared to other risk factors including but not limited to LDL, BP, Diabetes, Obesity • Other clinical biomarkers including but not limited to hsCRP, IL-6, NTproBNP • Predictors, progression over longitudinal timeframe • Anemia biomarkers • Imaging characteristics of heart musculature and vasculature Examination of hsCRP and clinical outcomes in: • ASCVD + CKD • CKD only • CKD and anemia • HFpEF/HFmrEF • Other cardiovascular complications Other: • Protocols not in conflict or redundant with Novo Nordisk's research/scientific commitment in the therapeutic area. **<u>Areas not in scope</u>** • Clinical studies and those that require drug supply. • Studies that overlap with completed, ongoing or planned research.
Award Funding Considerations	• Study duration in response to this RFP should be ≤ 12 months. • The allotted support for this RFP is $200,000 USD.

	• The final monetary value supported for this RFP, will be dependent on completion of a Fair Market Value (Analysis) on the budget.
Key Dates	• RFP issue date: April 2024 • Full application due date: May 20th, 2024 • Anticipated award notification date: July 2024

How to Apply & Submission Requirements

How to Apply	• Applications should be submitted through **www.novonordiskiss.com** • First time users will need to register for an account. • Refer to our Quick Reference Guide for instructions on how to navigate the portal and submit your application. • If you experience technical difficulties with the portal, please call + 1 718-576-1406 or email the system administrator at support@steeprock.com. **Submission Requirements include:** • A well-written protocol and detailed line-item budget utilizing the NNI protocol and line-item budget templates. All budgets will be subject to FMV analysis. **Please reference RFP 001 on the protocol title page.** • Investigator Curriculum Vitae • Conflict of interest form (signed and dated) For more information on how to access the protocol and line-item budget templates, refer to our Quick Reference Guide.
Review Process	• Submitted RFP applications will be reviewed by the Novo Nordisk teams on both the US (NNI) and Global level. The teams are comprised of representatives from Medical, Clinical & Regulatory Affairs, Clinical Data Science & Evidence, and other functions as appropriate. • Applicants will be notified of decisions via email.
Important Reminders	• This is a competitive process. Submission of a protocol and budget in response to this RFP does not constitute agreement by Novo Nordisk to support your study. Novo Nordisk may not have any influence over the content or development of your proposal or budget and is unable to provide input that may shape or influence the content of the RFP submission. All questions related to this RFP must be solely directed to the contact listed below.
Contact Information for Questions	• Please email NNI_ISS@novonordisk.com