

Quick Reference Guide: Novo Nordisk Investigator Sponsored Studies www.NovoNordiskISS.com



How to Submit Your Investigator-Sponsored Study (ISS)

Research Concept*: An initial submission that contains a brief but adequate summary of the research idea. The Novo Nordisk Diabetes or Biopharm Research Grants Committees will determine initial level of interest and alignment with areas of potential support. If a concept is approved, a full protocol submission will be required.

Full protocol!: Submission of a full protocol with all required supporting documents including a detailed line item budget. The Novo Nordisk Research Committees will make a full evaluation and determine whether or not the proposal will be supported, subject to final approval by the global committee. A full protocol should contain a minimum of the following information:

- Name & contact information of investigator(s)
- Study title
- Background & Rationale
- Study objectives
- Research design & methods
- Statistical considerations
- Data analysis plan
- Study timelines
- Plan of handling adverse events
- Human subjects protection
- References
- Drug and Budget projections (as required)

*Research concept submission is not required if a full protocol will be submitted

**For additional information please speak with your
Novo Nordisk Medical Affairs Contact
or email**

**NNIDiabetesIIS@NovoNordisk.com
BiopharmIIS@NovoNordisk.com**

How to Apply Online

- **Step 1:** Register at www.novonordiskiss.com to create an account username and password (new users only)
- **Step 2:** Upload required documents (e.g., principle investigator's CV, medical license, w-9, research concept summary, full protocol, budget outline, etc)
- **Step 3:** login to your account using your e-mail address and password
- **Step 4:** Submit an investigator sponsored research application either as a research concept or as a full protocol

Review Process

- Novo Nordisk Diabetes or Biopharm Research Committees meet on a regular basis to review all applications for scientific merit
- Committee decision, determination of funding level, and provision of study product are made based upon merit, available funds, product availability, and global approval.
- Review process is confidential by design and any related documents received are solely used for the purpose of making a decision.

What Novo Nordisk Expects from Potential ISS Research Recipients

- A complete online application with sufficient detail
- A well written study protocol addressing all mandatory components
- Ability to conduct the proposed study and meet study timelines
- Submission of quarterly status reports or as required by the committee
- Submission of final study report and draft publications for review