

NOVO NORDISK ISS INVESTIGATOR REFERENCE GUIDE

<https://iss-public.novonordisk.steeprockinc.com/>

Purpose

The following Reference Guide is intended to assist with basic navigation and frequently used features within the Novo Nordisk's ISS management system.

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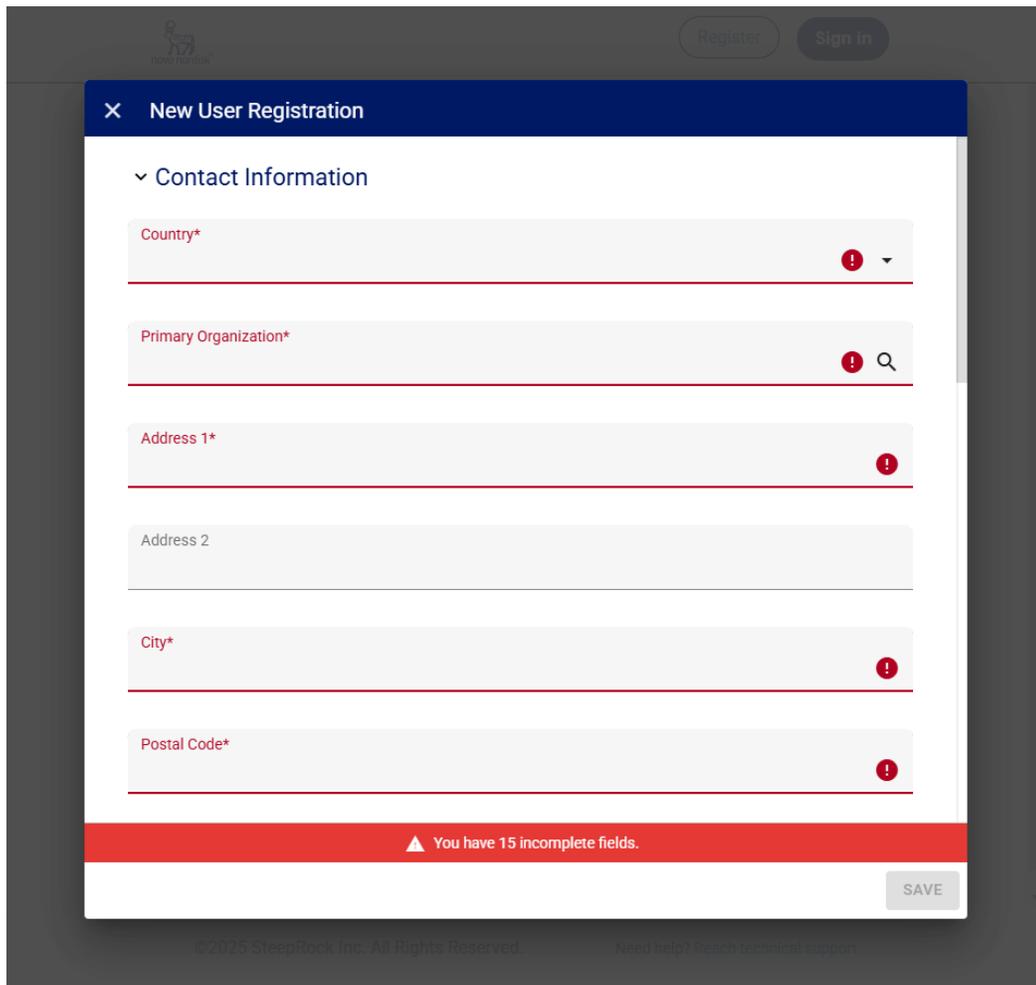
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Registering for Access

1. Open a web browser*, navigate to <https://iss-public.novonordisk.steeprokin.com/> and click **Register** to open the New User Registration window.

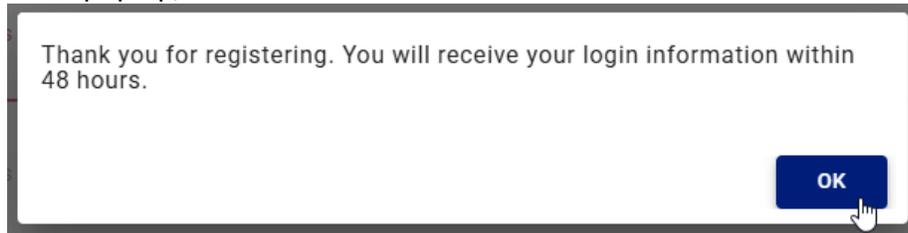


2. Complete the required fields (those *marked with red underline/asterisk/exclamation marks*) on the New User Registration form – the Save button at the bottom right will not be active until all required fields are completed.

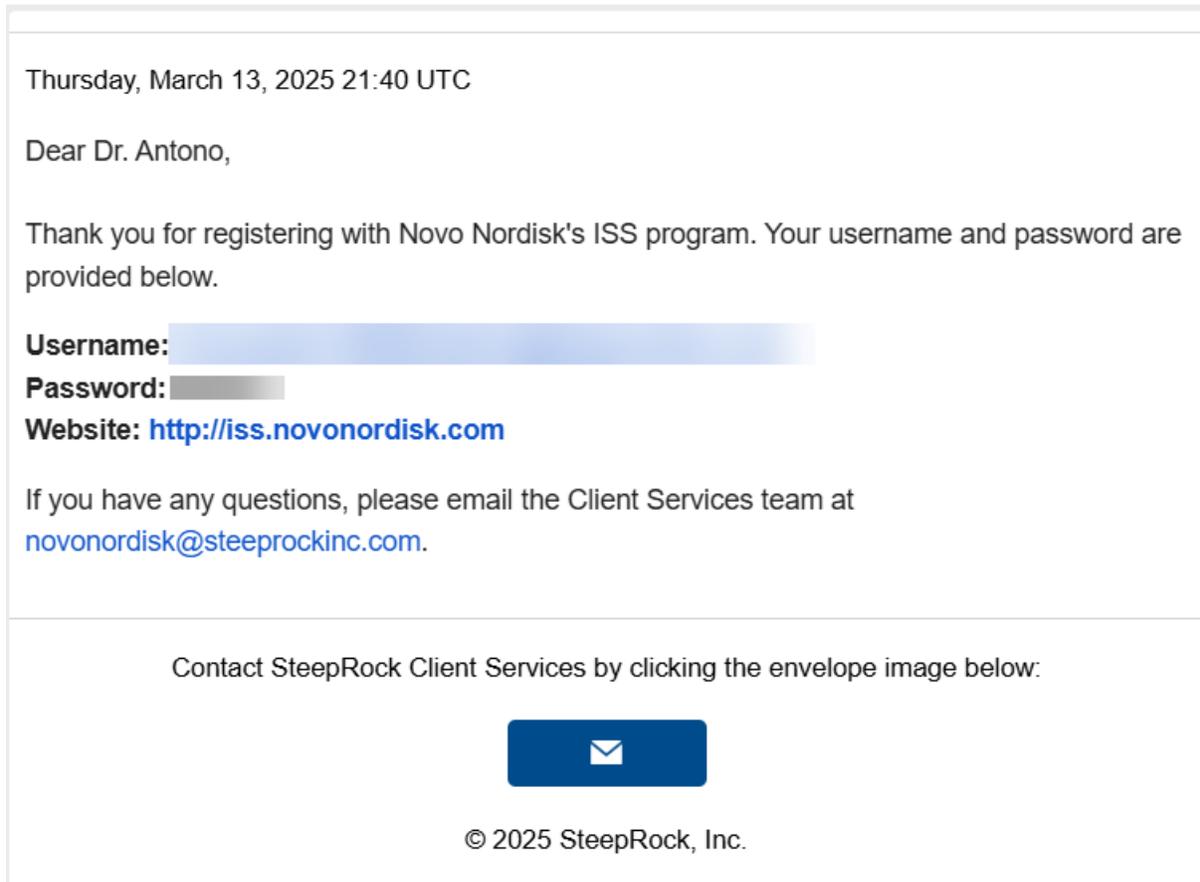
A screenshot of the 'New User Registration' form. The form has a blue header with a close button and the title 'New User Registration'. Below the header is a section titled 'Contact Information' with a dropdown arrow. The form contains several input fields: 'Country*' (with a red underline and exclamation mark), 'Primary Organization*' (with a red underline, exclamation mark, and search icon), 'Address 1*' (with a red underline and exclamation mark), 'Address 2' (no underline), 'City*' (with a red underline and exclamation mark), and 'Postal Code*' (with a red underline and exclamation mark). At the bottom of the form, there is a red banner with a warning icon and the text 'You have 15 incomplete fields.' and a grey 'SAVE' button.

- a. When you click on **Primary Organization** you will receive a list of Organizations within the Country you selected. This list is not comprehensive and if you are unable to locate your Organization, click the **+ADD NEW** button at the bottom of the window and you can enter the details for your Organization.
 - b. Note, the **Curriculum Vitae (CV)** must be in PDF or Word format and should not include a photo or personal information not relevant to your professional achievements or experience.
3. Once all required fields have been completed, click **SAVE** at the bottom right corner.

4. The message below will pop up, click **OK**.

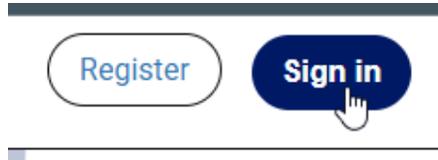


5. You will receive a welcome email (similar to the one below) from the Novo Nordisk ISS Portal with your **Username** and **Password**.

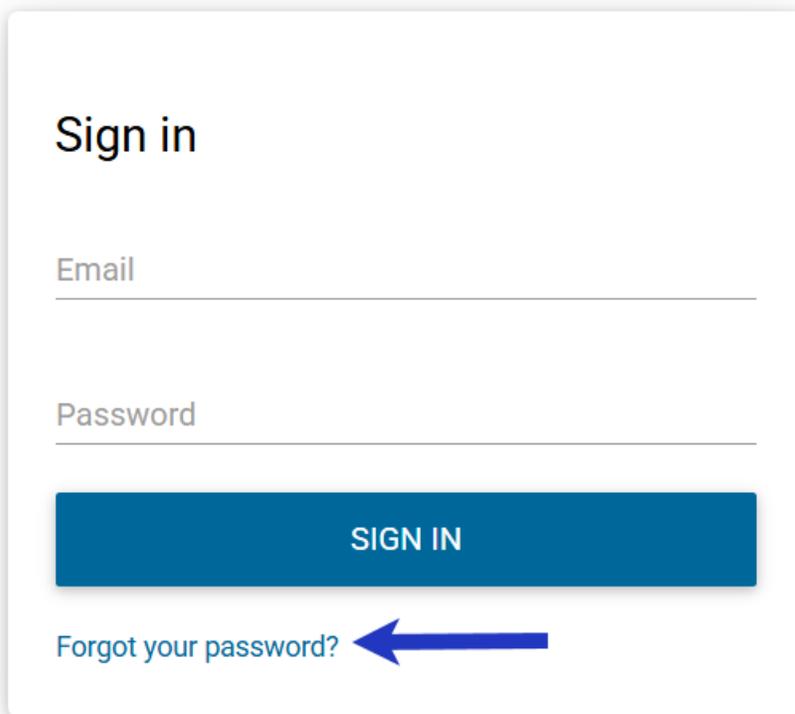


Logging In

1. Open a web browser, navigate to <https://iss-public.novonordisk.steeprockinc.com/> and click **Sign In**.



2. Enter your **Email** and **Password** and **SIGN IN**
 - a. Select **Forgot your password?** to Email a new temporary password, you will be prompted to change your password upon logging in.



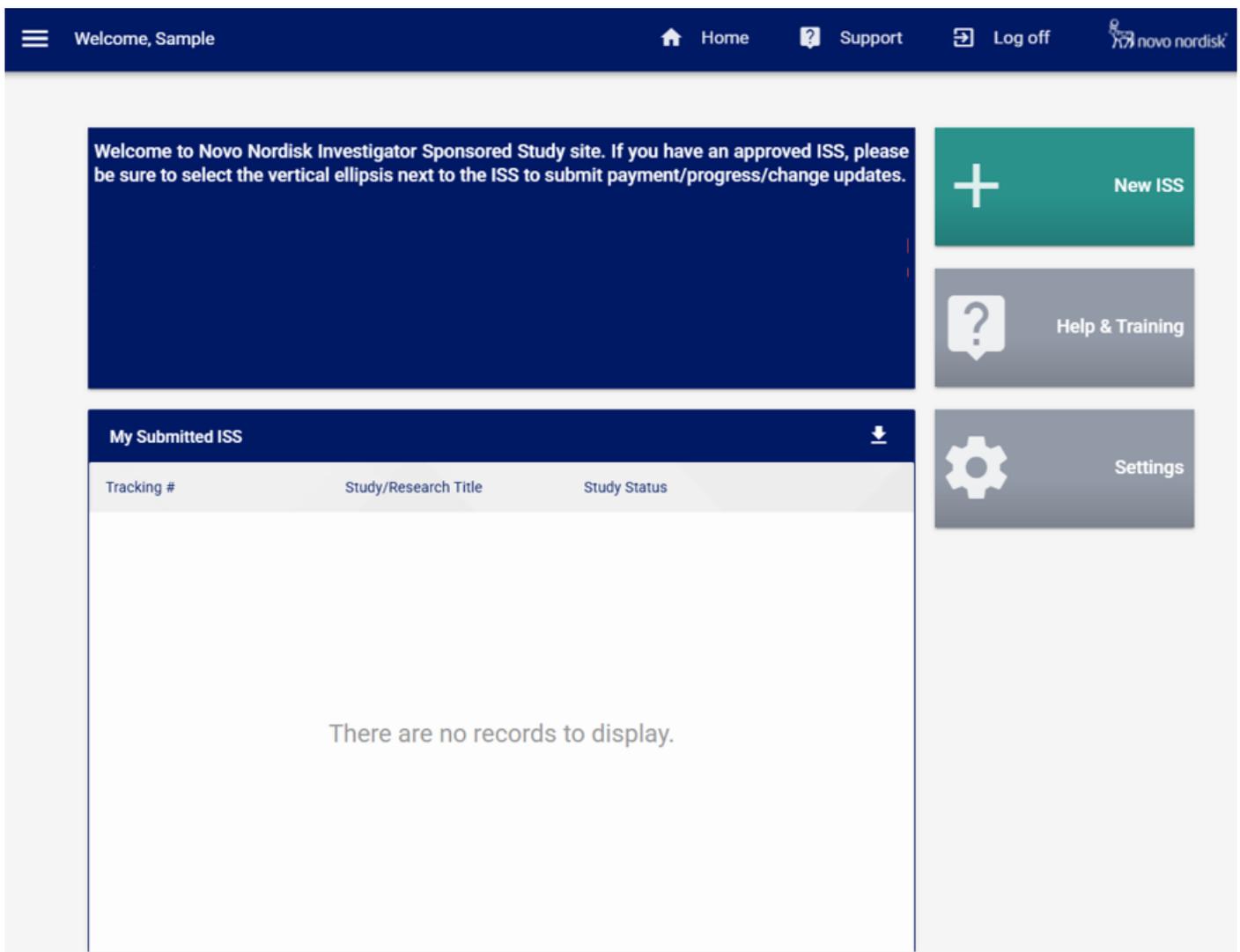
A screenshot of the 'Sign in' form. The form has a white background and a light gray border. At the top, the text 'Sign in' is displayed in a large, bold, black font. Below this, there are two input fields: 'Email' and 'Password', each with a horizontal line underneath. A large, dark blue button with the text 'SIGN IN' in white is positioned below the input fields. At the bottom of the form, the text 'Forgot your password?' is displayed in a blue font, with a blue arrow pointing to the left towards the text.

What is on My Home Page?

After logging in, you will see your Homepage, including the following menu tiles:

- Welcome message with instructions
- My Submitted ISS
- New ISS
- Help & Training
- Settings

You can navigate throughout the platform by selecting the menu tiles. **Please Note:** The blue text box provides important updates related to the ISS program.



The screenshot shows the user interface of the Novo Nordisk Investigator Sponsored Study site. At the top, a dark blue navigation bar contains a hamburger menu icon, the text "Welcome, Sample", and links for "Home", "Support", "Log off", and the Novo Nordisk logo. Below the navigation bar, the main content area is divided into three sections. On the left, a large blue box contains a welcome message: "Welcome to Novo Nordisk Investigator Sponsored Study site. If you have an approved ISS, please be sure to select the vertical ellipsis next to the ISS to submit payment/progress/change updates." To the right of this message are three menu tiles: a green "New ISS" tile with a plus sign icon, a grey "Help & Training" tile with a question mark icon, and a grey "Settings" tile with a gear icon. Below the welcome message is a section titled "My Submitted ISS" with a download icon. This section contains a table with three columns: "Tracking #", "Study/Research Title", and "Study Status". The table is currently empty, displaying the message "There are no records to display."

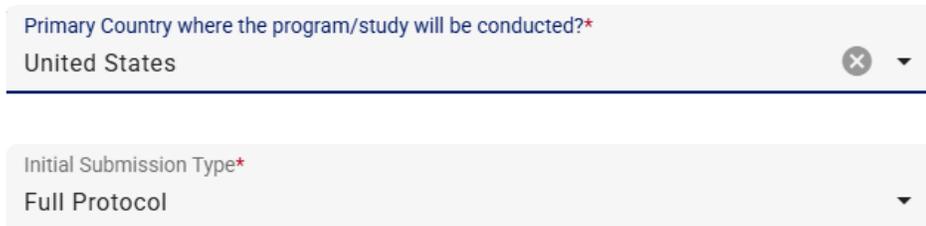
Submitting an ISS Application

From the homepage click on the New ISS tile to open the Add ISS page.



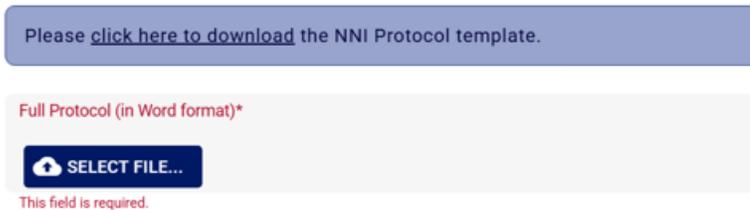
A few important quick tips:

- The **Primary Country where the program/study will be conducted?** will determine the application submission requirements
 - When **United States** or **Canada** is selected you will be required to submit a Full Protocol:

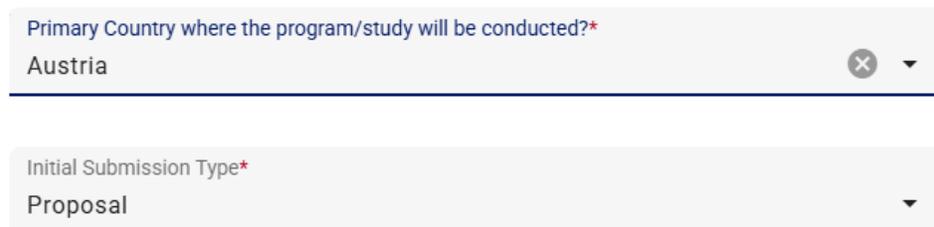


Utilize the protocol template to complete the full protocol submission.

▼ Protocol



- When **any other Country** is selected you will be required to submit a Proposal first, and if approved by Novo Nordisk, then you will be required to log back in and submit a Full Protocol:



- You may save a Draft of the application by clicking the **SAVE AS DRAFT** button on the bottom left. To save a Draft you do not need to have all required fields completed. The only field which must be populated is the **Study/Research Title**.



- The application will not auto-save as you progress, you should periodically click **SAVE AS DRAFT** manually to save your progress.

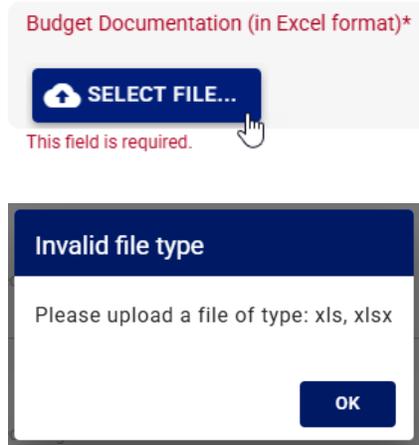
Note, due to the dynamic nature of the application forms, the screenshots included within this guide may not represent the exact fields/field values that you see when logged into the portal.

If you have specific questions about the detailed requirements of the application form you can contact, NNI_ISS@novonordisk.com for the United States, NNCI_ISS@novonordisk.com for Canada, or NN_ISS@novonordisk.com for the rest of the world, or for technical assistance you can contact SteepRock Client Services by calling +1 718-576-1406 or emailing support@steeprockinc.com.

Submitting a New (Initial) Proposal

Complete the required fields (those *marked with red underline/asterisk/exclamation marks*) on the ISS form – the **SUBMIT TO NOVO NORDISK** button at the bottom left will not be active until all required fields are completed.

Note if a file attachment requires a specific file type, e.g. PDF or Word, the field label will indicate that. You will receive a pop-up warning if you upload the incorrect file type:



The following are the sections required to be completed within the application:

- Abstract Details

▼ Abstract Details

Note: lack of clarity on the study rationale, objectives, and endpoints may potentially result in rejection.

Study Rationale / Goal*

This field is required.

Study Objectives*

This field is required.

Key Inclusion Criteria*

- Clinical Study Details

▼ Clinical Study Details

Number of Subjects*



This field is required.

Estimated Study Duration (in months)*



This field is required.

Duration of Subjects on Study Drug (in months)*



This field is required.

Study Population*



This field is required.

- Budget

▼ Budget

Estimated Study Budget Requested from Novo Nordisk*

Money

USD

Currency



This field is required.

Estimated Budget Pass Thru Costs*

Money

USD

Currency



This field is required.

Estimated Budget Other Costs*

Money

USD

Currency



This field is required.

Budget Documentation (in Excel format)*

 SELECT FILE...

This field is required.

- Proposed Timelines

Proposed Timelines

Please ensure your proposed timelines account for adequate lead time required for review, contracting and clinical supply processes.

Study Start/First Patient First Visit*
mm/dd/yyyy  
This field is required.

Last Patient First Visit*
mm/dd/yyyy  
This field is required.

Study End/Last Patient Last Visit*
mm/dd/yyyy  
This field is required.

- Documentation

Documentation

Please download, print, fill out, scan and upload this [Conflict of Interest form](#).

Completed Conflict of Interest Form*

 SELECT FILE...

This field is required.

References

- Novo Nordisk Contact

Novo Nordisk Contact

Novo Nordisk Contact Name & Email 

- Proposal Attestations

▼ Proposal Attestation

Novo Nordisk Safety Reporting Requirements Policy

Obligations and responsibilities of the Sponsor-Investigator related to safety reporting

When reporting Adverse Events the following parameters must be recorded:

- Study name
- Patient identification (e.g. subject number, initials, sex, age)
- Event (preferably a diagnosis)
- Drug (e.g. Norditropin Simplex®)
- Reporter identification (e.g. name, or initials)
- Causality
- Outcome

a) Reporting to Health Authorities

Once all fields have been completed, you may submit your application. When you click the **SUBMIT TO NOVO NORDISK** button at the bottom left, a few things will happen:

- 1) The ISS will be submitted,
- 2) The submission Status will update to “Proposal Submitted”
- 3) A Tracking # will be assigned. You will receive a confirmation email.



Sample Proposal

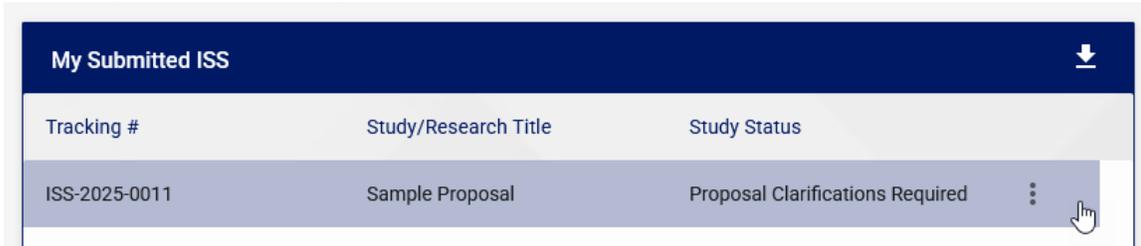
Overall Study Status: Proposal Submitted
Tracking #: ISS-2025-0011

ISS OVERVIEW PROPOSAL DETAILS SUBMISSION ATTESTATIONS

Submitting Required Proposal Clarifications

After your Proposal has been submitted, Novo Nordisk will start the review process. If clarifications are needed, your Novo Nordisk contact person will reach out to you directly outside of the portal.

1. To respond to a request for clarifications, once logged in to the ISS Portal, click the row that is **Proposal Clarifications Required**. This will open the record.



My Submitted ISS		
Tracking #	Study/Research Title	Study Status
ISS-2025-0011	Sample Proposal	Proposal Clarifications Required

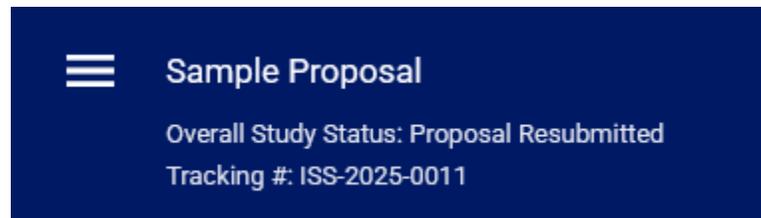
2. On the left menu pane, click **Update** to enter the edit screen.



3. Update the application as discussed with Novo Nordisk and click the **SUBMIT TO NOVO NORDISK** button at the bottom left.



4. The ISS will be resubmitted, the Status will update to Proposal Resubmitted. You will receive a confirmation email.



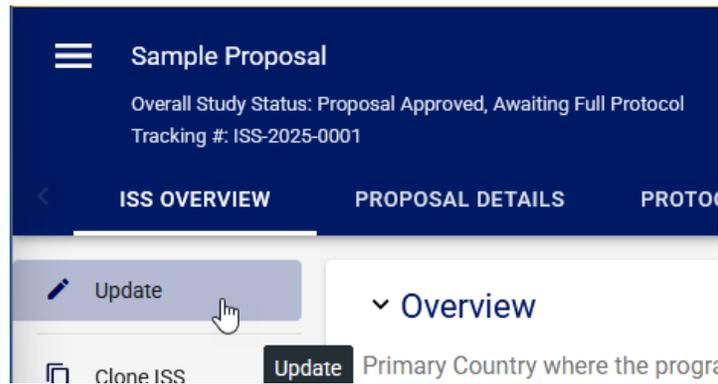
Submitting a Protocol for an Approved Proposal

When a Proposal is Approved you will receive an email notification, and you will be required to log back into the portal and complete the Full Protocol application.

1. To submit the Full Protocol, once logged in to the ISS Portal, click the row that is **Proposal Approved, Awaiting Full Protocol**. This will open the record.

My Submitted ISS ↓		
Tracking #	Study/Research Title	Study Status
ISS-2025-0001	Sample Proposal	Proposal Approved, Awaiting Full Protocol ⋮

2. On the left menu pane, click **Update** to enter the edit screen.



3. The following are the sections required to be completed within the Full Protocol application – note many of the sections/fields will be pre-populated with the values entered in the Proposal application.
 - Protocol – note the Novo Nordisk Protocol template that is available to download and populate.

Protocol

Please [click here to download](#) the NNI Protocol template.

Full Protocol (in Word format)*

This field is required.

- Abstract

▼ Abstract

Study Rationale / Goal*

X

Study Objectives*

X

Key Inclusion Criteria*

- Clinical Study Details

▼ Clinical Study Details

Projected Randomization Per Month*

|

This field is required.

Number of Subjects*

25

Estimated Study Duration (in months)*

12

Duration of Subjects on Study Drug (in months)*

- Proposed Timelines

▼ Proposed Timelines

Please ensure your proposed timelines account for adequate lead time required for review, contracting and clinical supply processes.

Publication Plan* 0 +

<input type="checkbox"/>	Type	Planned / Estimated Date of Submission	Journal	Meeting
There are no records to display.				

This field is required.

Study Start/First Patient First Visit*

03;Jan-2025 📅

Last Patient First Visit*

dd-Mmm-yyyy ! 📅

- Contract Details

▼ Contract Details

Legal Contact*

!

This field is required.

Institution Legal Name*

!

This field is required.

Mailing Address*

!

This field is required.

City*

!

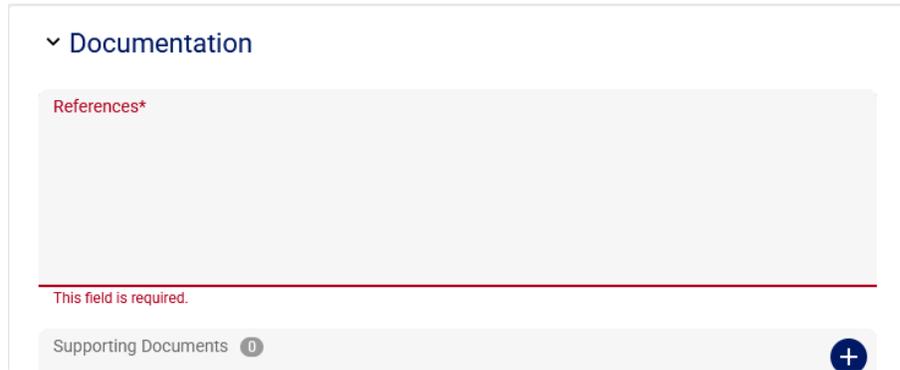
This field is required.

Country*

! ▼

This field is required.

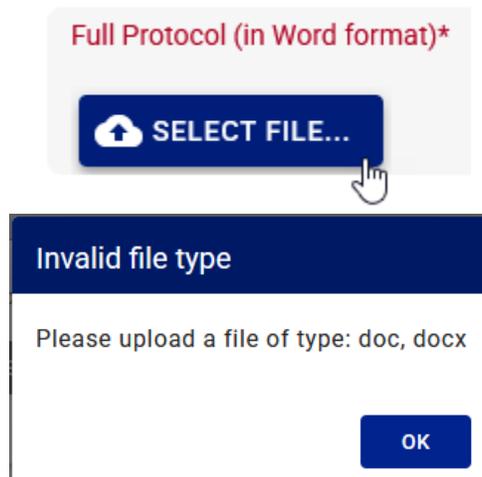
- Documentation



- Protocol Attestations



Note if a file attachment requires a specific file type, e.g. PDF or Word, the field label will indicate that. You will receive a pop-up warning if you upload the incorrect file type:



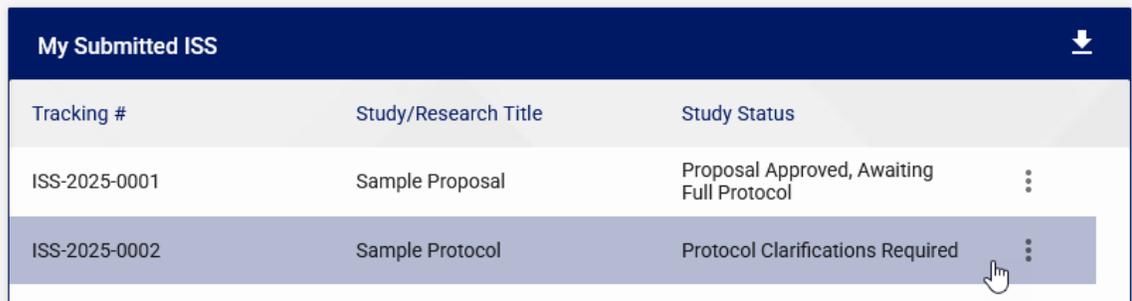


4. Once you click the **SUBMIT TO NOVO NORDISK** button at the bottom left, the ISS will be submitted, the Status will update to Protocol Submitted. You will receive a confirmation email.

Submitting Required Protocol Clarifications

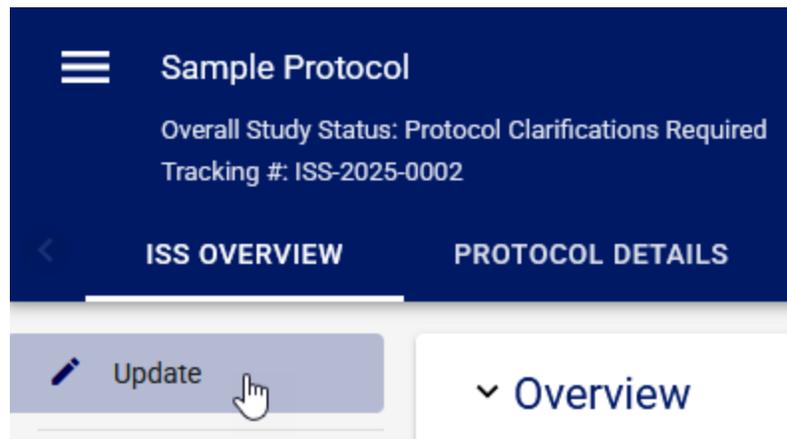
After your Protocol has been submitted, Novo Nordisk will start the review process. If clarifications are needed, a Novo Nordisk contact person will reach out to you directly outside of the portal.

1. To respond to a request for clarifications, once logged in to the ISS Portal, click the row that is **Protocol Clarifications Required**. This will open the record.



My Submitted ISS			↓
Tracking #	Study/Research Title	Study Status	
ISS-2025-0001	Sample Proposal	Proposal Approved, Awaiting Full Protocol	⋮
ISS-2025-0002	Sample Protocol	Protocol Clarifications Required	⋮

2. On the left menu pane, click **Update** to enter the edit screen.



3. Update the application as discussed with Novo Nordisk and click the **SUBMIT TO NOVO NORDISK** button at the bottom left.



4. The ISS will be resubmitted, the Status will update to Protocol Resubmitted. You will receive a confirmation email.

