

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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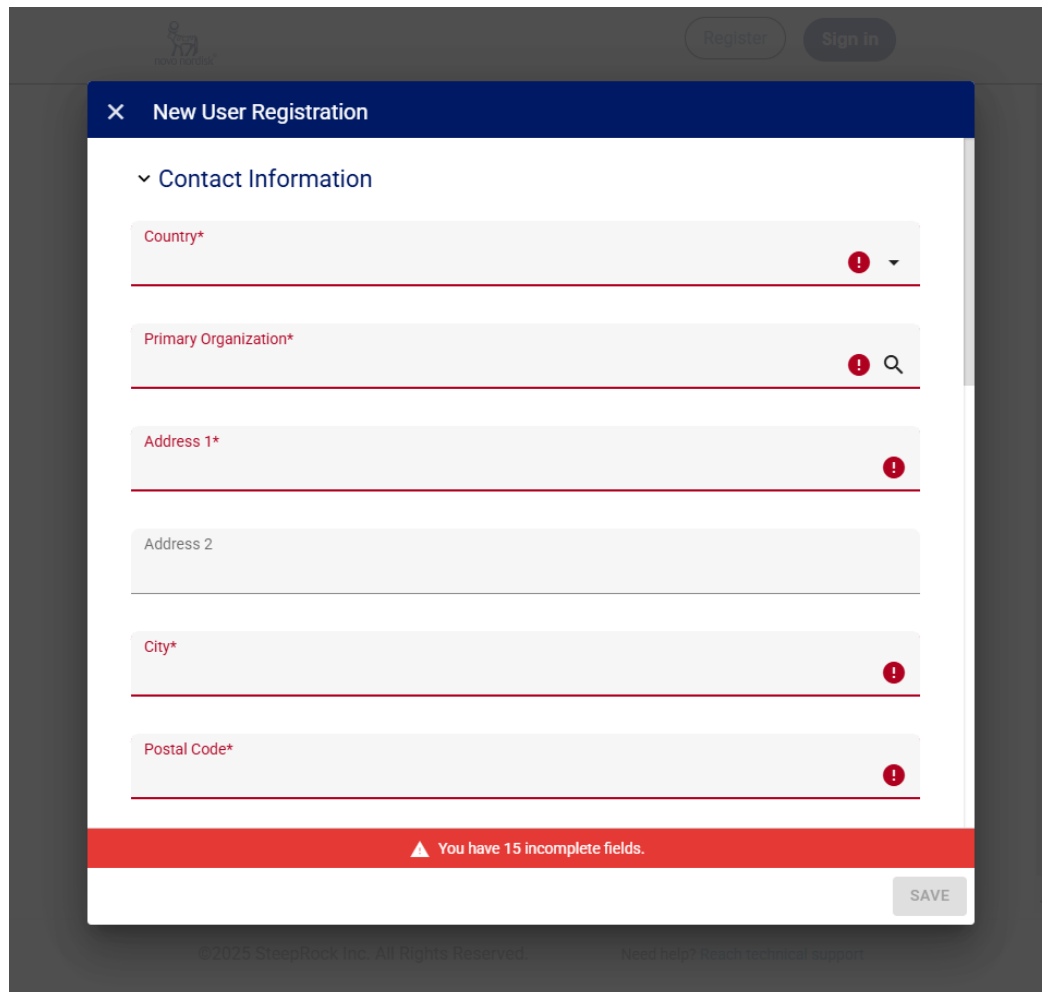
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Registering for Access

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



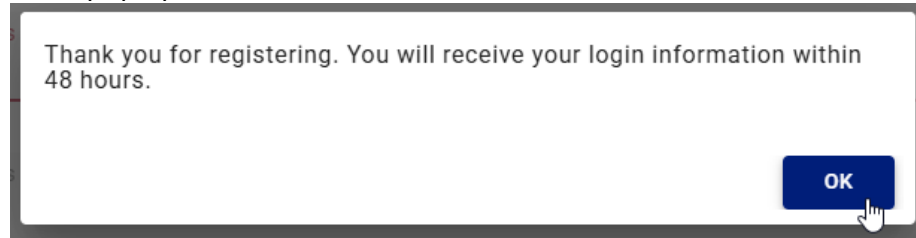
2. Complete the required fields (those *marked with red underline/asterisk/exclamation marks*) on the New User Registration form – the Save button at the bottom right will not be active until all required fields are completed.



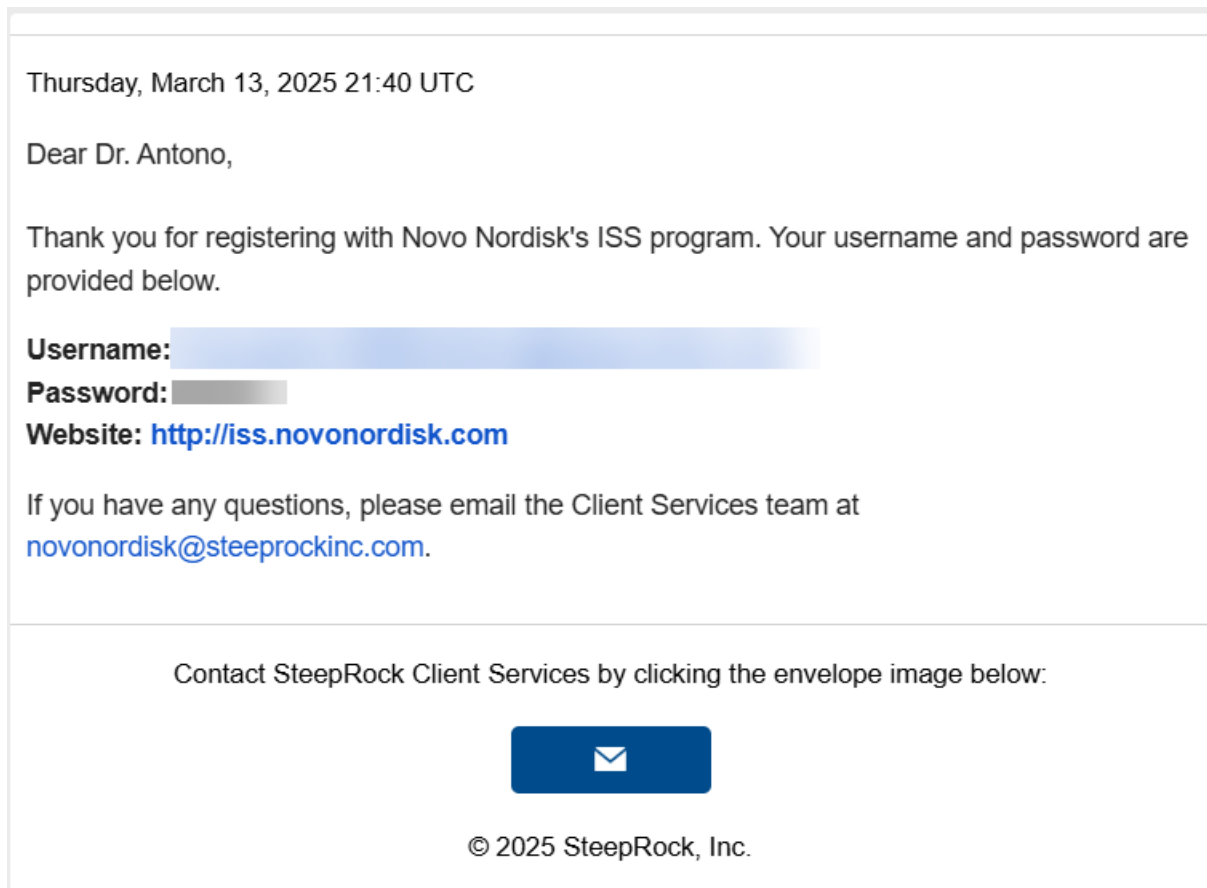
- a. When you click on **Primary Organization** you will receive a list of Organizations within the Country you selected. This list is not comprehensive and if you are unable to locate your Organization, click the **+ADD NEW** button at the bottom of the window and you can enter the details for your 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**.

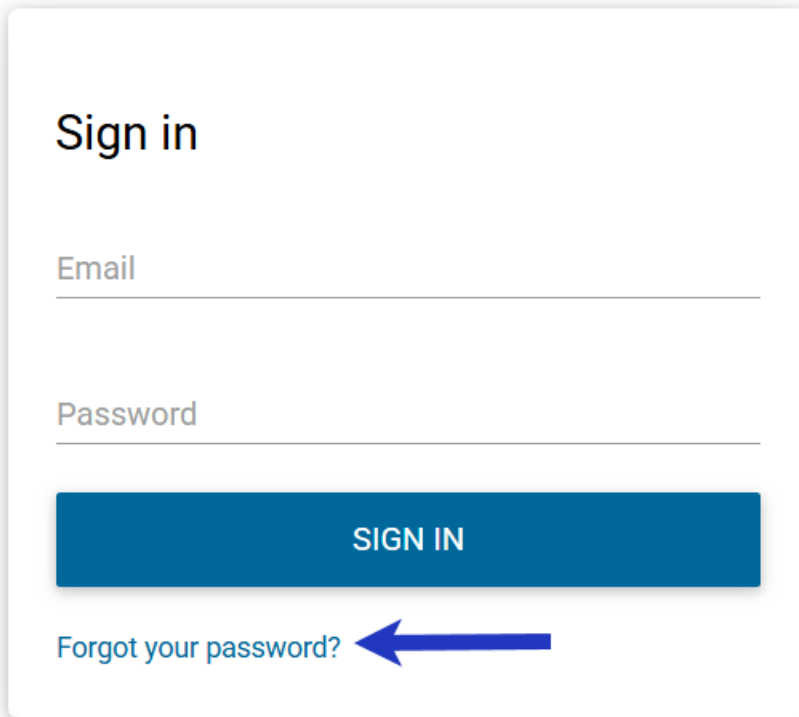


Logging In

1. Open a web browser, navigate to <https://iss-public.novonordisk.steeprocksinc.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.

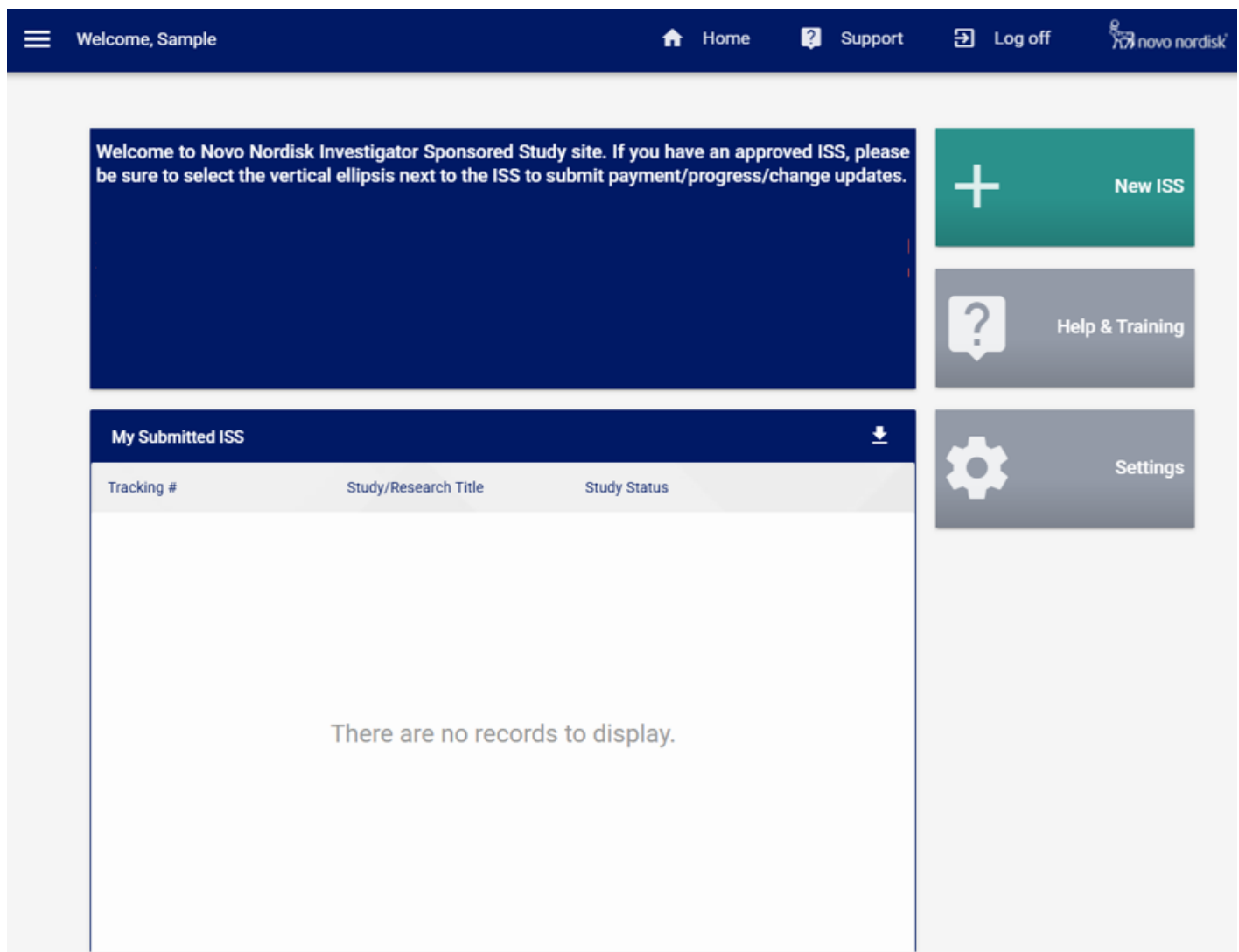
A screenshot of a 'Sign in' form. It has a title 'Sign in' at the top. Below it are two input fields: 'Email' and 'Password'. At the bottom is a large blue button labeled 'SIGN IN'. Below the button is a link 'Forgot your password?' with a blue arrow pointing to it from the right.

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

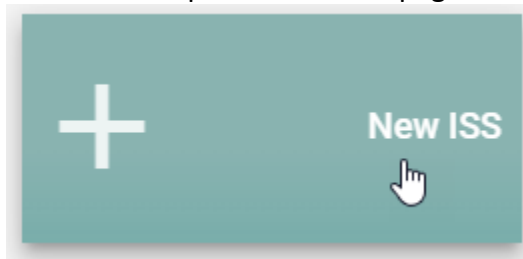
You can navigate throughout the platform by selecting the menu tiles. **Please Note:** The blue text box provides important updates related to the ISS program.



The screenshot shows the homepage of the Novo Nordisk Investigator Sponsored Study site. The top navigation bar is dark blue with a hamburger menu icon, the text "Welcome, Sample", and links for Home, Support, Log off, and the Novo Nordisk logo. The main content area is light gray. On the left, there is a large blue box with white text: "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." Below this is a section titled "My Submitted ISS" with a download icon. It contains a table with headers "Tracking #", "Study/Research Title", and "Study Status". The table is empty, and a message "There are no records to display." is shown. On the right, there are three menu tiles: "New ISS" (green with a plus icon), "Help & Training" (gray with a question mark icon), and "Settings" (gray with a gear icon).

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:

Primary Country where the program/study will be conducted?*

United States

Initial Submission Type*

Full Protocol

Utilize the protocol template to complete the full protocol submission.
 ~ Protocol

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

Full Protocol (in Word format)*

SELECT FILE...

This field is required.

- 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:

Primary Country where the program/study will be conducted?*

Austria

Initial Submission Type*

Proposal

- 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.

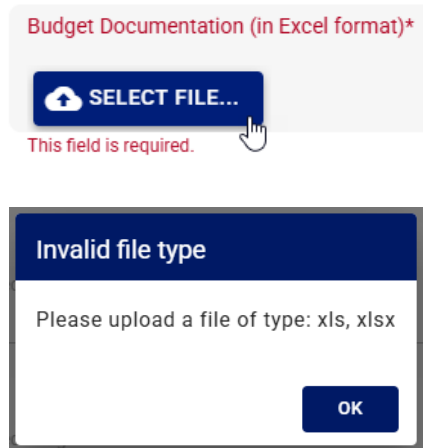
If you have specific questions about the detailed requirements of the application form you can contact, NNI_ISS@novonordisk.com for the United States, NNCI_ISS@novonordisk.com for Canada, or NN_ISS@novonordisk.com for the rest of the world, or for technical assistance you can contact SteepRock Client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

FOR ALL US-BASED STUDIES – please skip ahead to page 18

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*

USD
▼
!
?

Money
Currency

This field is required.

Estimated Budget Pass Thru Costs*

USD
▼
!

Money
Currency

This field is required.

Estimated Budget Other Costs*

USD
▼
!

Money
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*

!
📅

This field is required.

Last Patient First Visit*

!
📅

This field is required.

Study End/Last Patient Last Visit*

!
📅

- 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:

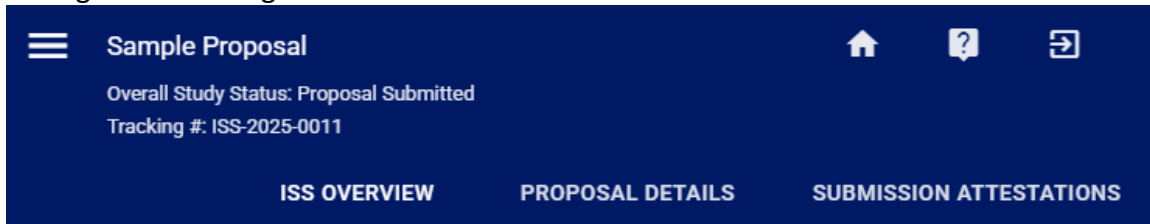
- Study name
- Patient identification (e.g. subject number, initials, sex, age)
- Event (preferably a diagnosis)
- Drug (e.g. Norditropin Simplex®)
- Reporter identification (e.g. name, or initials)
- Causality
- Outcome

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/Protocol Submitted”
- 3) A Tracking # will be assigned. You will receive a confirmation email.




Submitting Required Proposal Clarifications (Outside US Only)

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.




Sample Proposal

Overall Study Status: Proposal Clarifications Required

Tracking #: ISS-2025-0011


Update


 Overview

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

SAVE AS DRAFT

SUBMIT TO NOVO NORDISK

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



Sample Proposal

Overall Study Status: Proposal Resubmitted

Tracking #: ISS-2025-0011

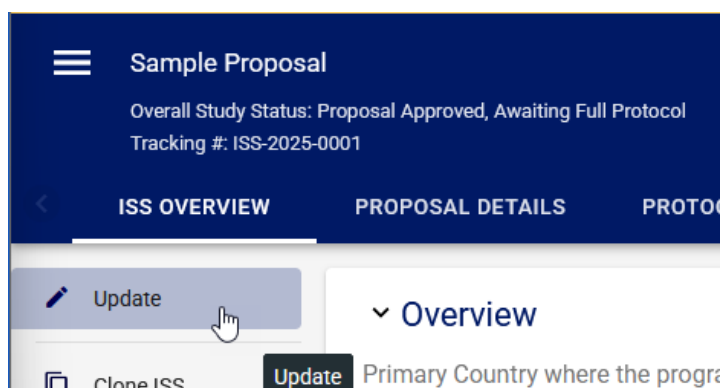
Submitting a Protocol for an Approved Proposal (Outside US Only)

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.

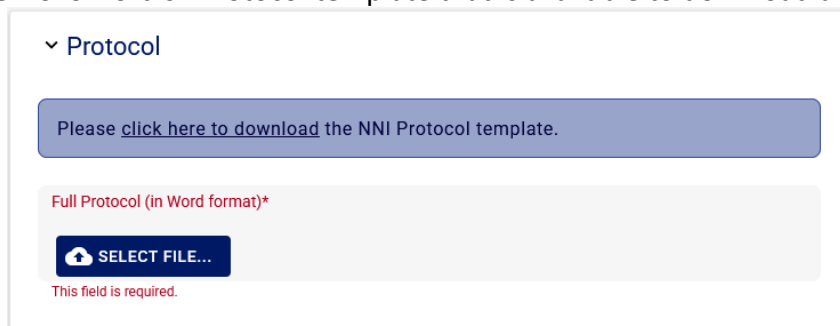
1. To submit the Full Protocol, once logged in to the ISS Portal, click the row that is **Proposal Approved, Awaiting Full Protocol**. This will open the record.

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.



- 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
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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

Documentation

References*

This field is required.

Supporting Documents 0

- Protocol Attestations

Protocol Attestation

Novo Nordisk Safety Reporting Requirements Policy

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

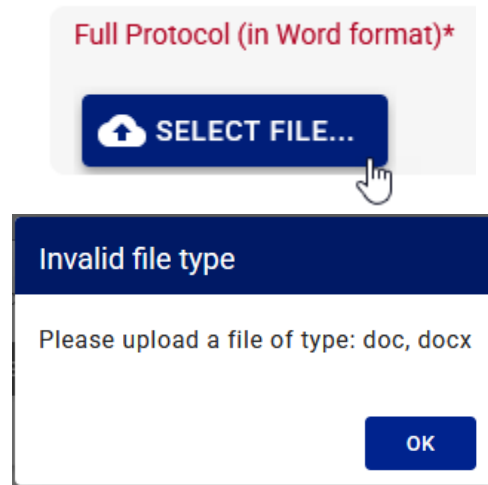
When reporting Adverse Events the following parameters must be recorded:

- 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

The Sponsor-Investigator shall be responsible for all required periodic updates to

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 a New (Initial) Protocol

**All US-based studies are required to submit a protocol only
(no proposal process for US studies)**

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.


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

- Protocol

▼ Protocol

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

Full Protocol (in Word format)*

 SELECT FILE...

This field is required.

- Abstract Details

▼ Abstract

Study Rationale / Goal*

This field is required.

Study Objectives*

This field is required.

Key Inclusion Criteria*

- Clinical Study Details
 - Screenshot below is an examples of Clinical Study Details. Observational Study Details will appear differently.

▼ Clinical Study Details

Projected Randomization Per Month*

!

 This field is required.

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.

- Proposed Timelines
 - Screenshot below shows example for Clinical Studies

▼ Proposed Timelines

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

Publication Plan* ⓘ

+

<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*

! ⓘ

 dd-Mmm-yyyy
 This field is required.

Last Patient First Visit*

! ⓘ

 dd-Mmm-yyyy
 This field is required.

Study End/Last Patient Last Visit*

! ⓘ

 dd-Mmm-yyyy
 This field is required.

Publication*

! ⓘ

 dd-Mmm-yyyy
 This field is required.

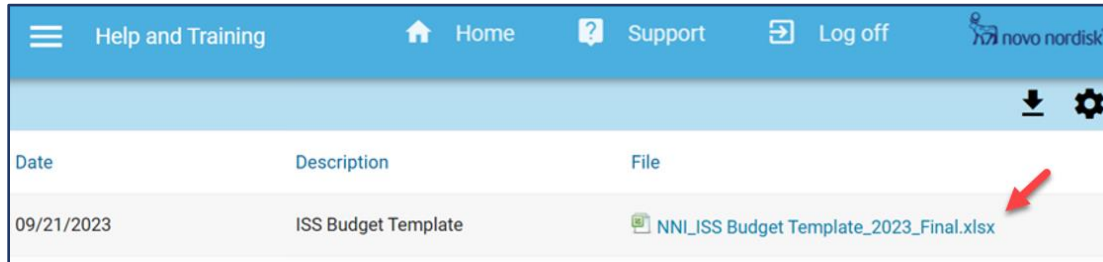
Final Report*


! ⓘ

 dd-Mmm-yyyy
 This field is required.

- Budget Template

- The NNI ISS Budget Template is required when submitting a budget for an ISS submission in the US.
- Please utilize the “Help & Training” tile to access the “ISS Budge Template” as shown below.



Date	Description	File
09/21/2023	ISS Budget Template	 NNI_ISS Budget Template_2023_Final.xlsx

- Budget Details

Budget Pass Through Costs

Please click [here](#) for an example of Clinical budget elements.

Ethics Approvals*

+

Budget Line Items

of Units

Unit

Rate per Unit

Total

This field is required.

Procedure / Tests

+

▼ Budget Staff Costs

Start-up*



Study Personnel	# of Hrs	Description	Rate per Hr	Total

This field is required.

Maintenance*



Study Personnel	# of Hrs	Description	Rate per Hr	Total

▼ Budget

Estimated Study Budget Requested from Novo Nordisk*

<input type="text"/>	<div>USD</div> <div>Currency</div>	
----------------------	------------------------------------	---

This field is required.

Institutional Overhead %

Overhead Cost

<input type="text"/>	<div>USD</div> <div>Currency</div>
----------------------	------------------------------------

Total Study Budget*

<input type="text"/>	<div>USD</div> <div>Currency</div>	
----------------------	------------------------------------	---

This field is required.


Budget Documentation (in Excel format)*

 SELECT FILE...

This field is required.

- Contract Contact Details

- Documentation – Conflict of Interest

- Novo Nordisk Contact
 - To add an NNI Contact to your study, click the  and select from the list of existing NNI Contacts.

▼ Novo Nordisk Contact



- Protocol Attestations
 - Complete the attestation to acknowledge safety reporting requirements of conducting an ISS

▼ Protocol Attestation

Novo Nordisk Safety Reporting Requirements Policy

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

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


a) Reporting to Health Authorities

The Sponsor-Investigator shall be responsible for all required periodic updates to

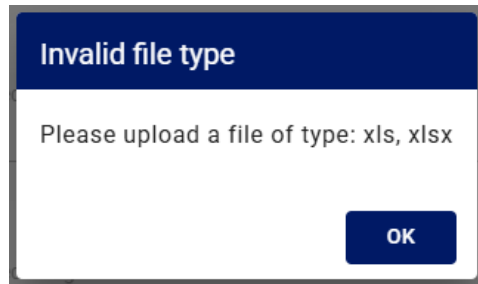
Uploading Documents

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:

Budget Documentation (in Excel format)*

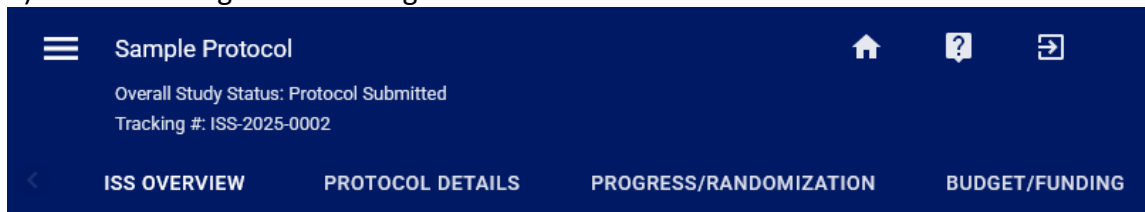
 **SELECT FILE...**

This field is required.



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/Protocol Submitted"
- 3) a Tracking # will be assigned. You will receive a confirmation email.



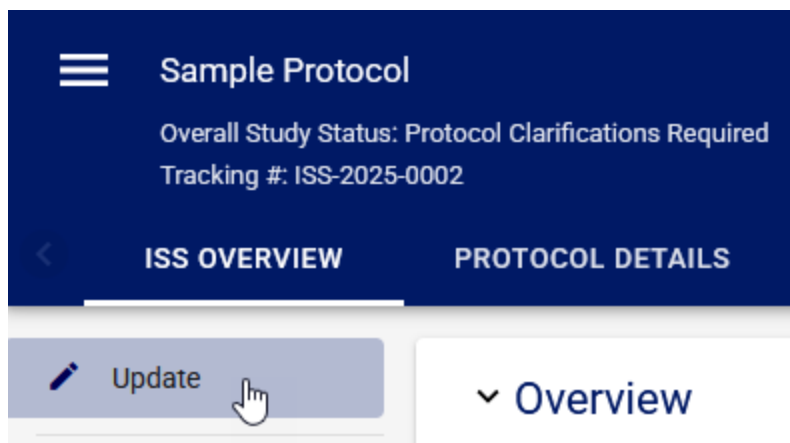
Submitting Required Protocol Clarifications

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.

