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.

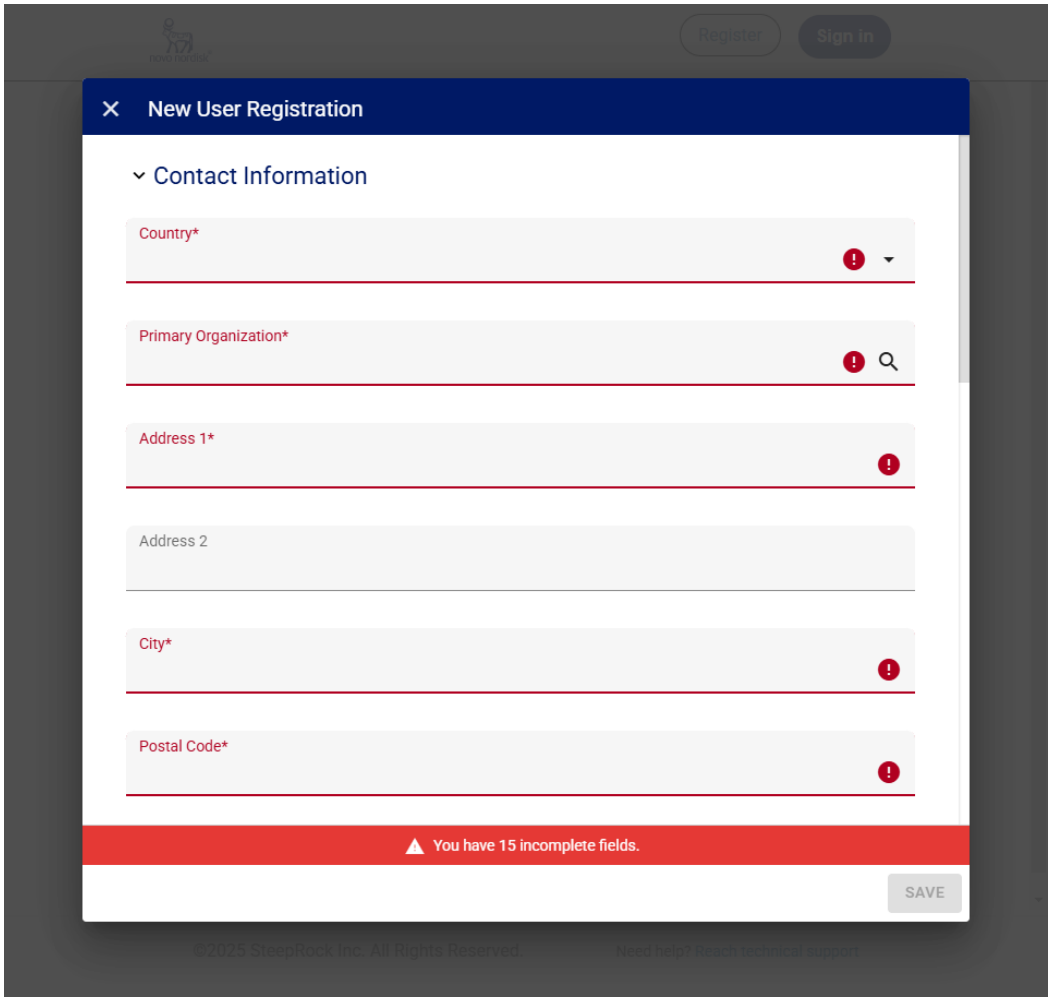
Last Updated: Mar-2025

Table of Contents

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.

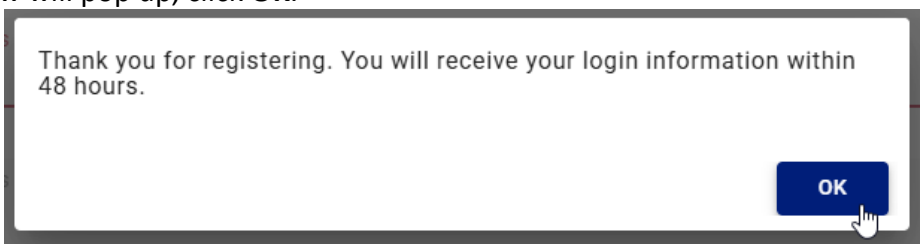


   a. When you click on **Primary Organization** you will receive a list of Organizations within the Country you selected. This list is not comprehensive and if you are unable to locate your Organization, click the **+ADD NEW** button at the bottom of the window and you can enter the details for your Organization.

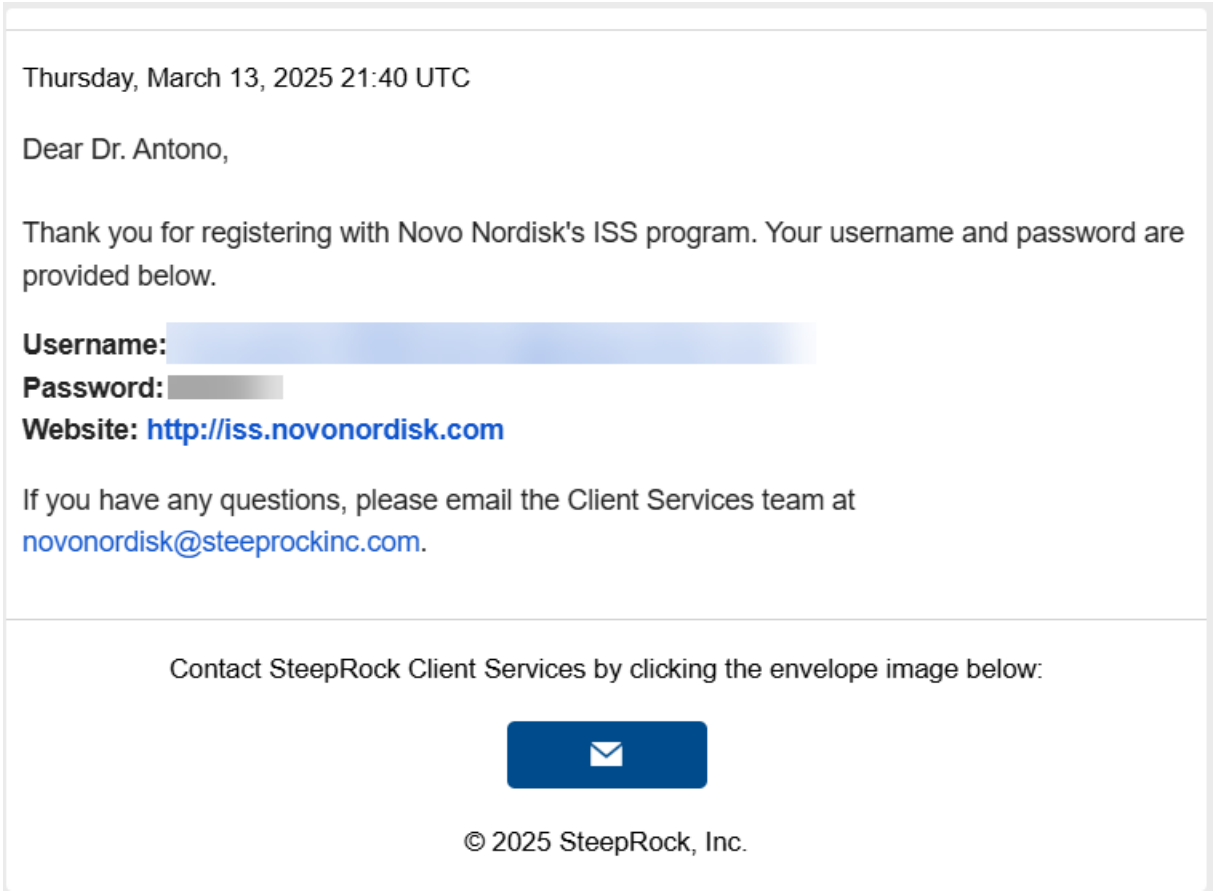
   b. Note, the **Curriculum Vitae (CV)** must be in PDF or Word format and should not include a photo or personal information not relevant to your professional achievements or experience.

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**.



Thursday, March 13, 2025 21:40 UTC

Dear Dr. Antono,

Thank you for registering with Novo Nordisk's ISS program. Your username and password are provided below.

Username:
Password:
Website: http://iss.novonordisk.com

If you have any questions, please email the Client Services team at novonordisk@steeprockinc.com.

Contact SteepRock Client Services by clicking the envelope image below:

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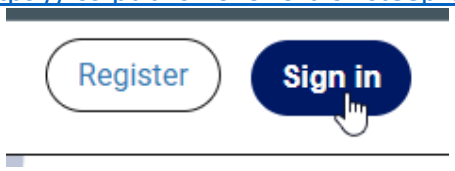
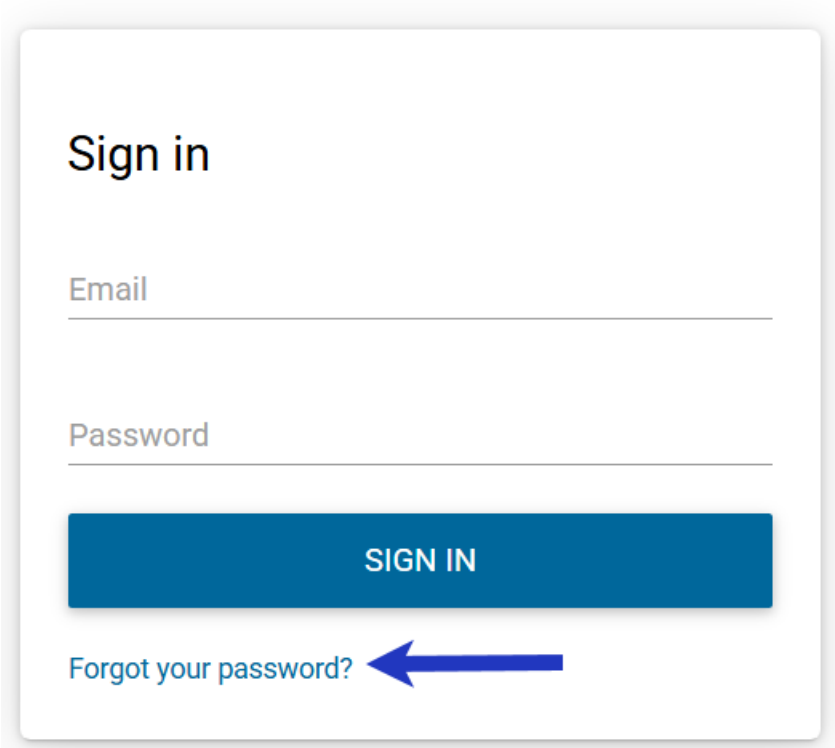
Logging In

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.

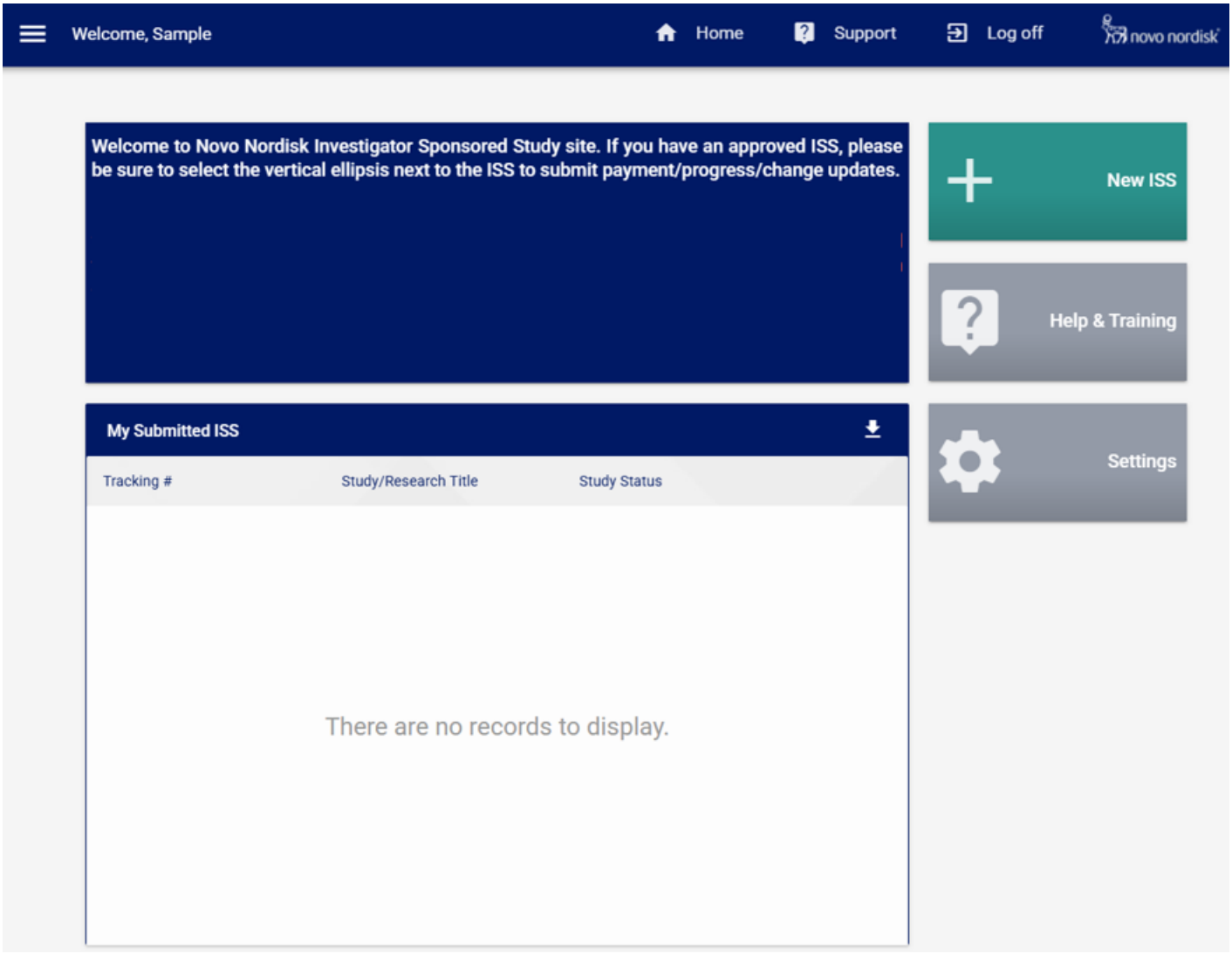


What is on My Home Page?

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

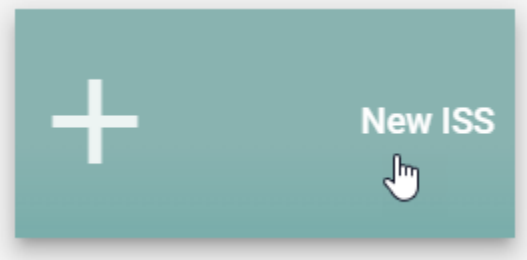
- Welcome message with instructions
- My Submitted ISS
- New ISS
- Help & Training
- Settings

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.



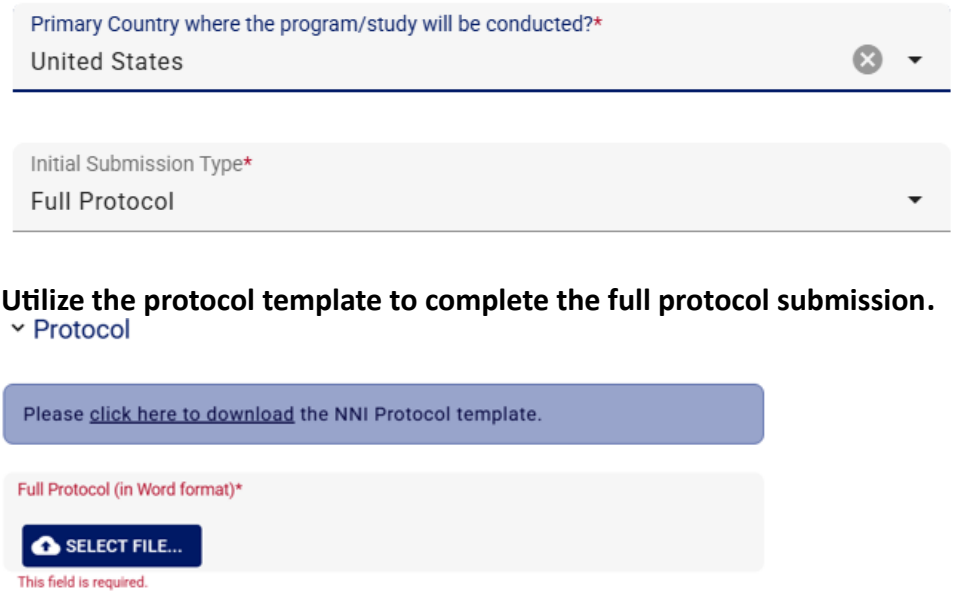
Submitting an ISS Application

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

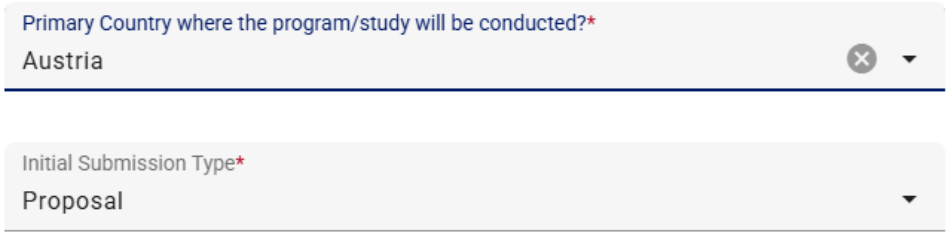


A few important quick tips:

- 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:



    - 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.

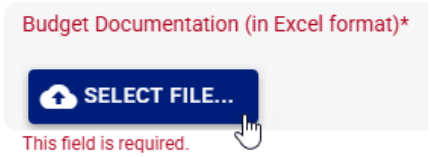
If you have specific questions about the detailed requirements of the application form you can contact, NNI_ISS@novonordisk.com for the United States, NNCI_ISS@novonordisk.com for Canada, or NN_ISS@novonordisk.com for the rest of the world, or for technical assistance you can contact SteepRock Client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

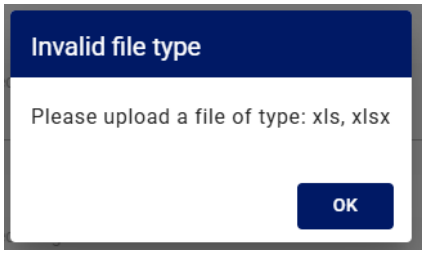
FOR ALL US-BASED STUDIES – please skip ahead to page 18

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.

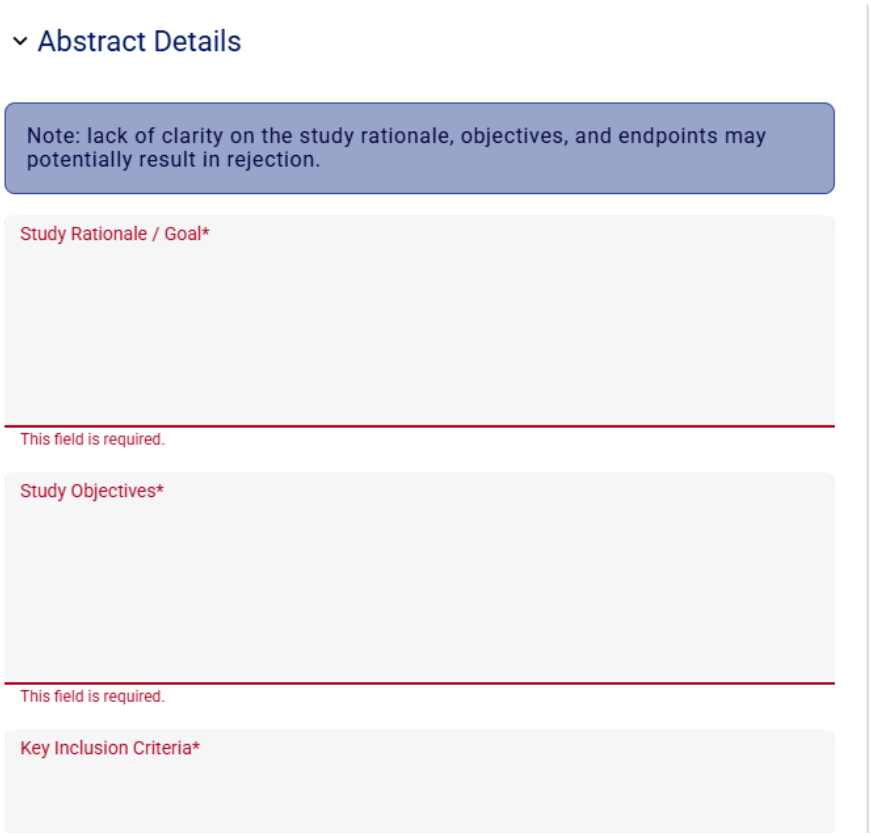
Note if a file attachment requires a specific file type, e.g. PDF or Word, the field label will indicate that. You will receive a pop-up warning if you upload the incorrect file type:



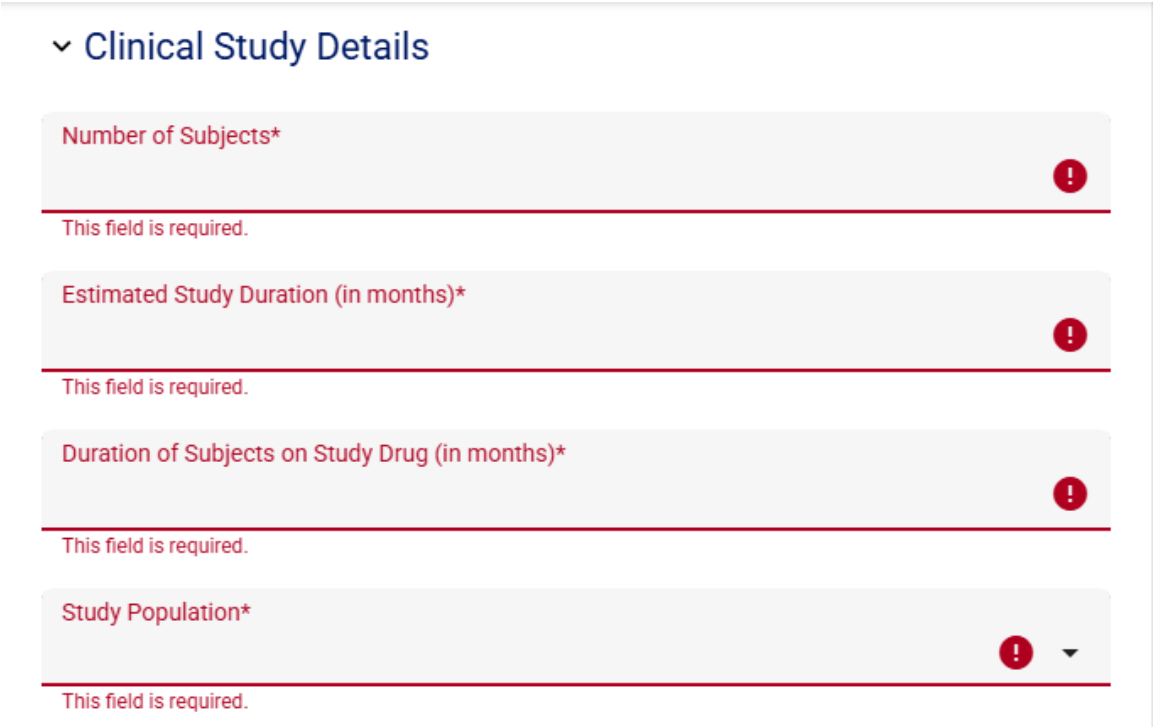


The following are the sections required to be completed within the application:

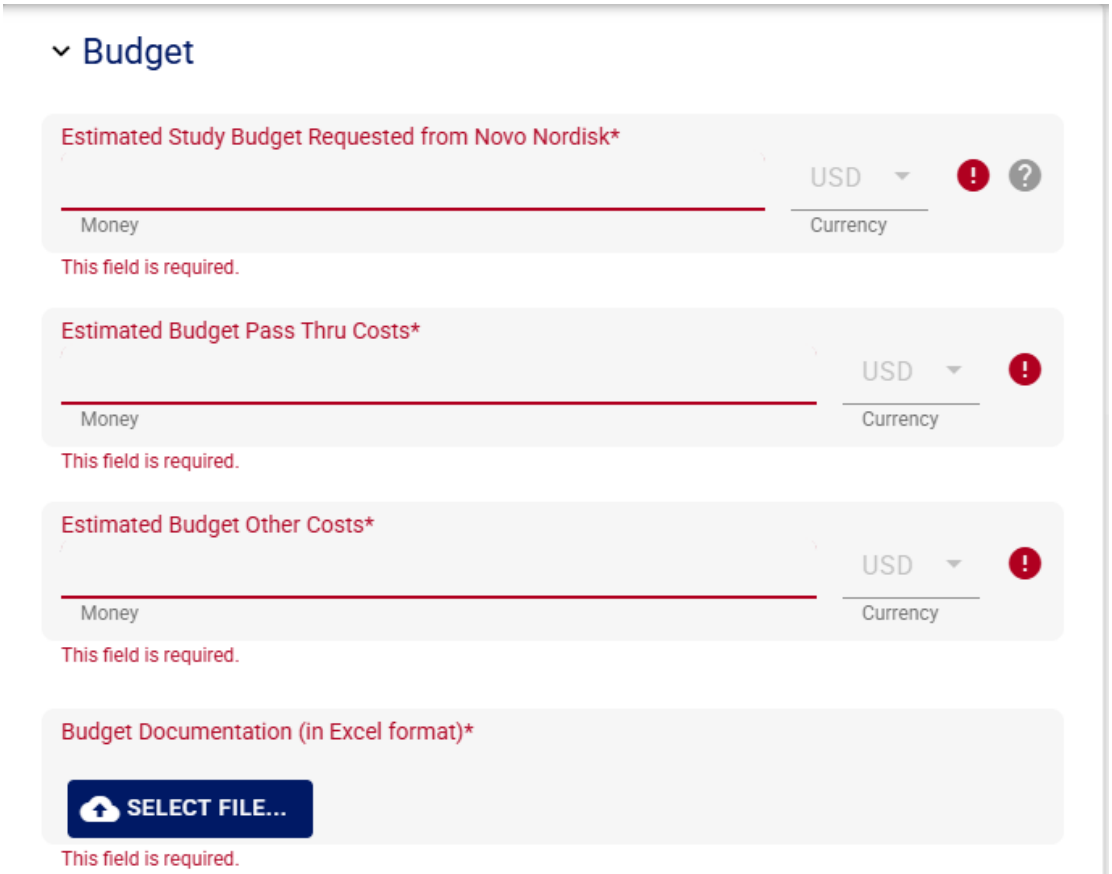
- Abstract Details



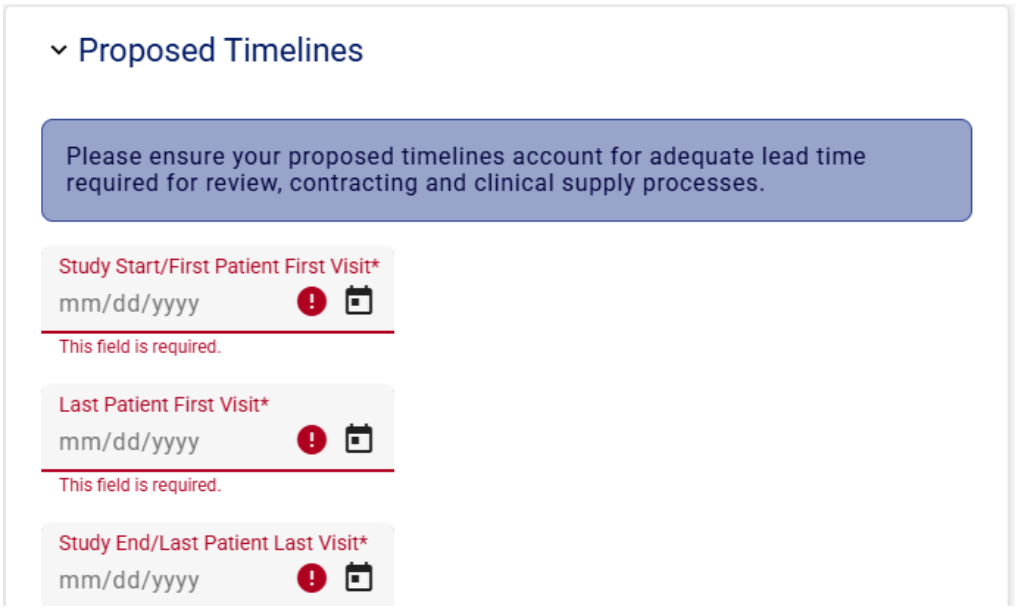
- Clinical Study Details



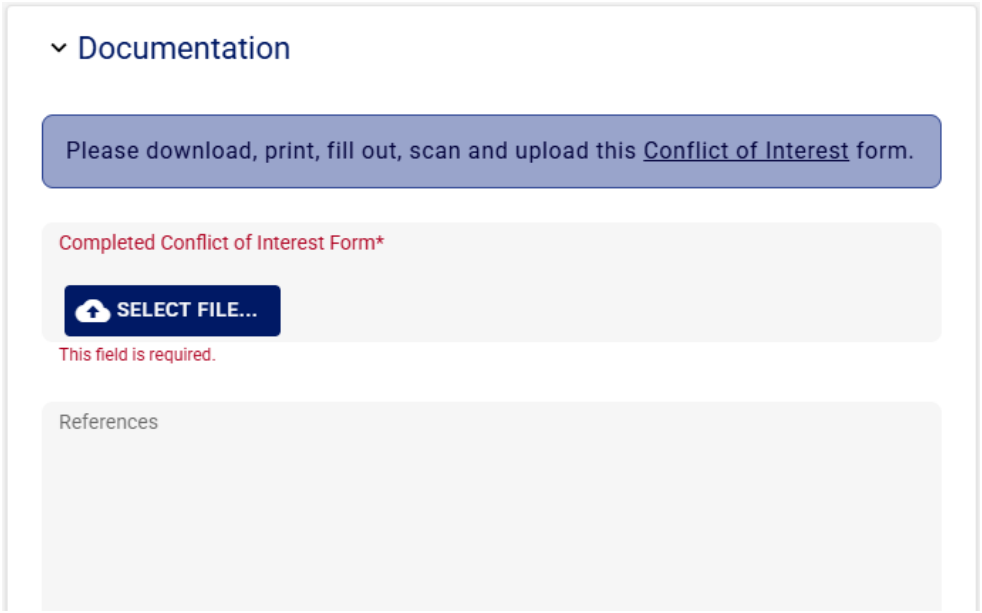
- Budget



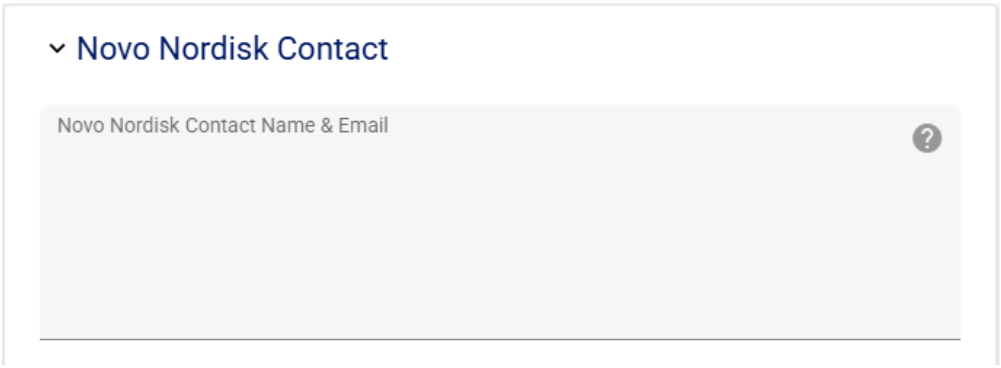
- Proposed Timelines



- Documentation



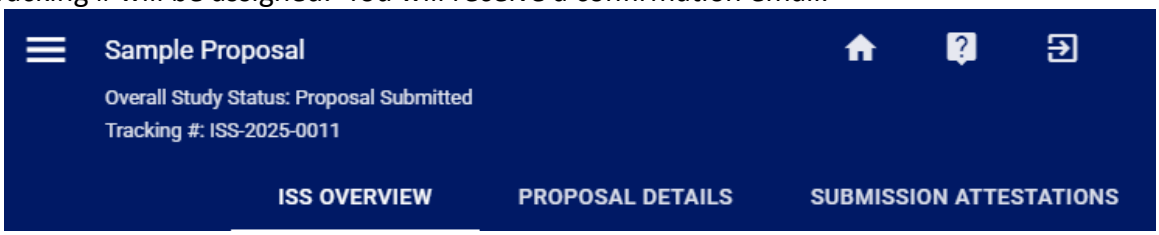
- Novo Nordisk Contact



- Proposal Attestations

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:

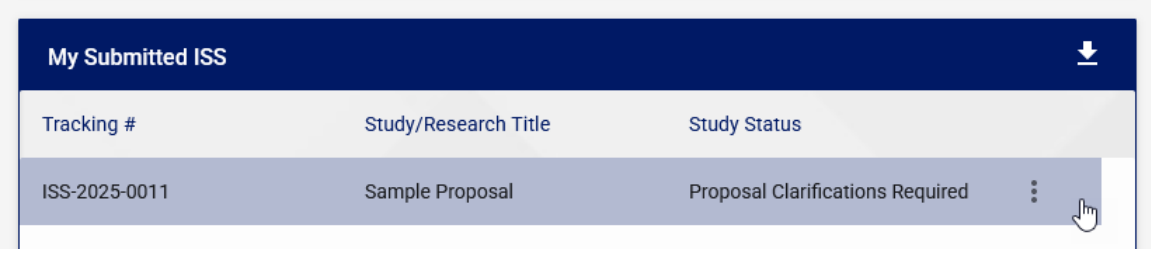
1) The ISS will be submitted,
2) The submission Status will update to “Proposal/Protocoll Submitted”
3) A Tracking # will be assigned. You will receive a confirmation email.



Submitting Required Proposal Clarifications (Outside US Only)

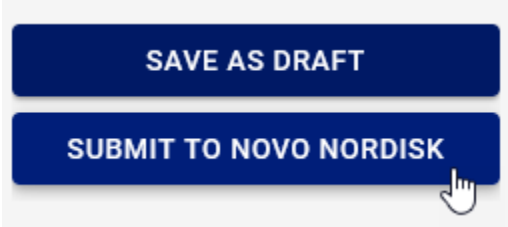
After your Proposal has been submitted, Novo Nordisk will start the review process. If clarifications are needed, your Novo Nordisk contact person will reach out to you directly outside of the portal.

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.

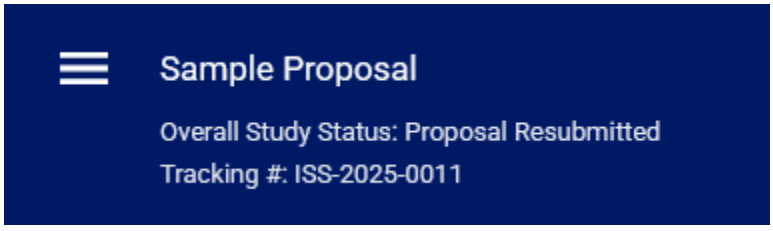


2. On the left menu pane, click **Update** to enter the edit screen.

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.

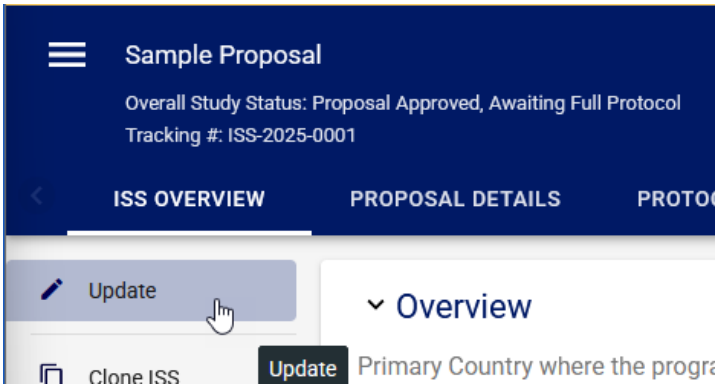


Submitting a Protocol for an Approved Proposal (Outside US Only)

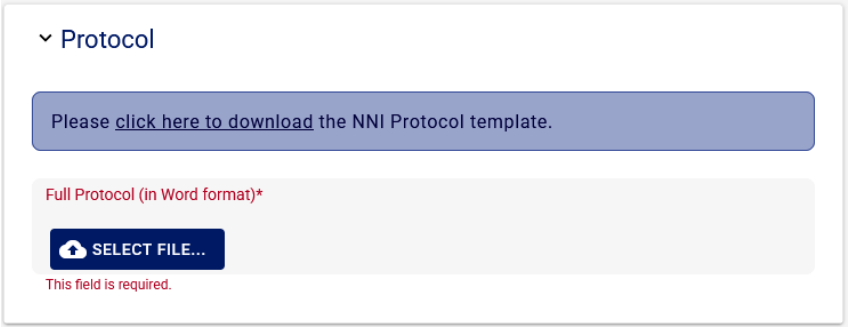
When a Proposal is Approved you will receive an email notification and you will be required to log back into the portal and complete the Full Protocol application.

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.

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

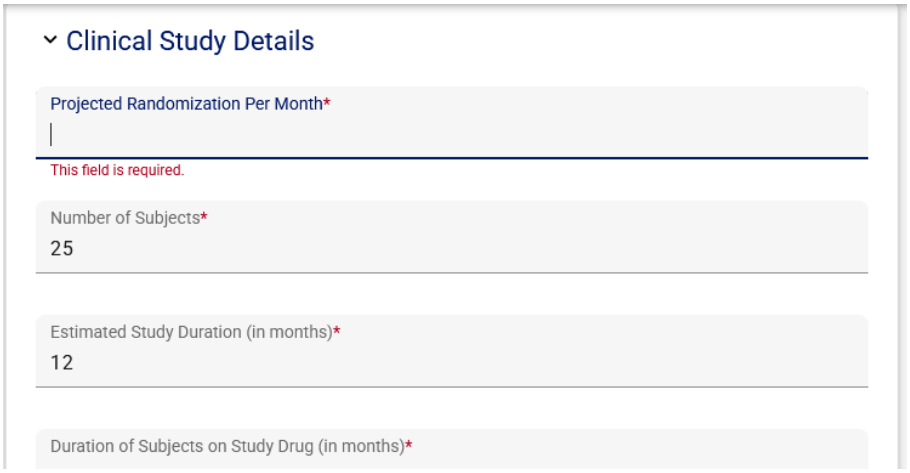


3. The following are the sections required to be completed within the Full Protocol application – note many of the sections/fields will be pre-populated with the values entered in the Proposal application.
   - Protocol – note the Novo Nordisk Protocol template that is available to download and populate.

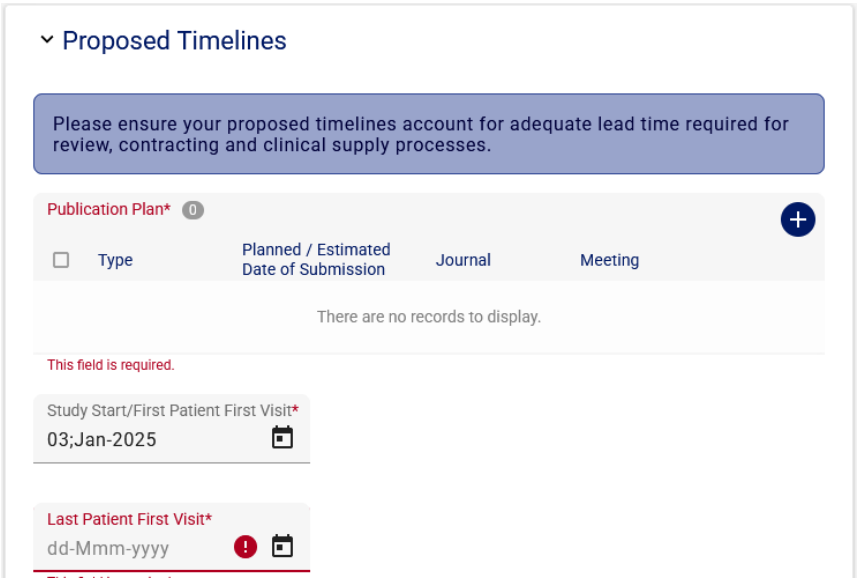


   - Abstract

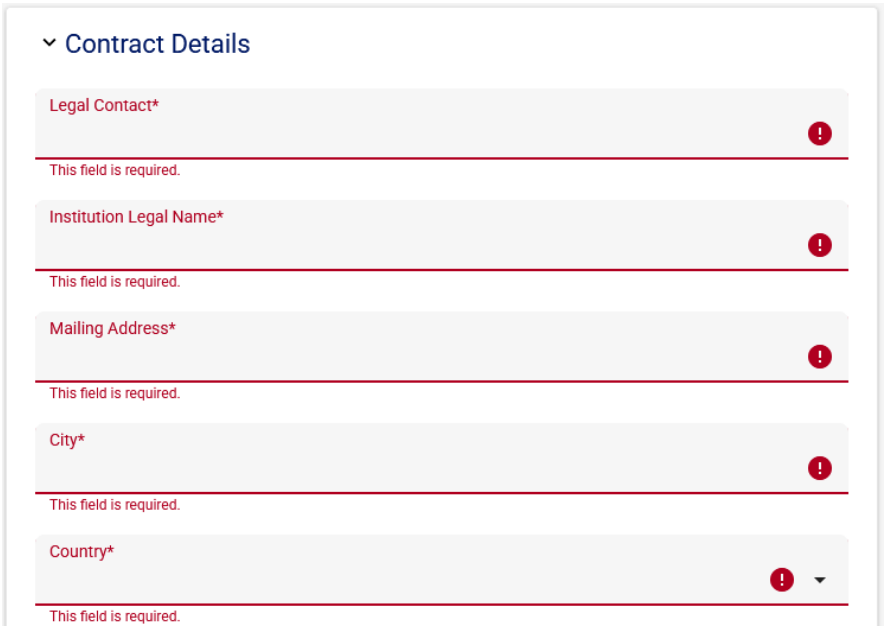
- Clinical Study Details



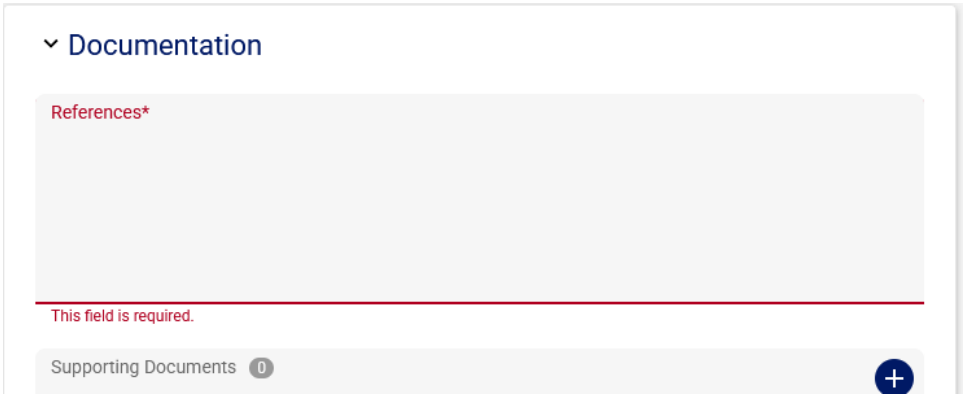
- Proposed Timelines



- Contract Details

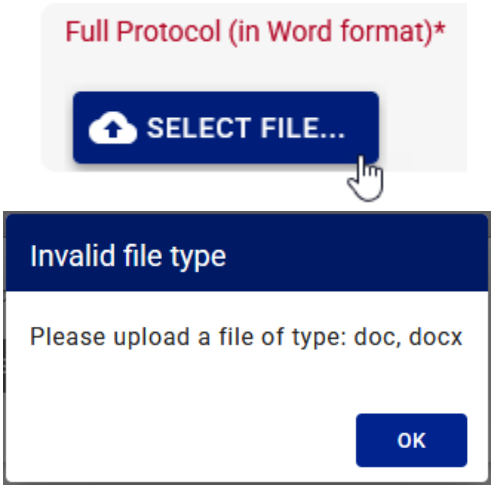


- Documentation



- 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.

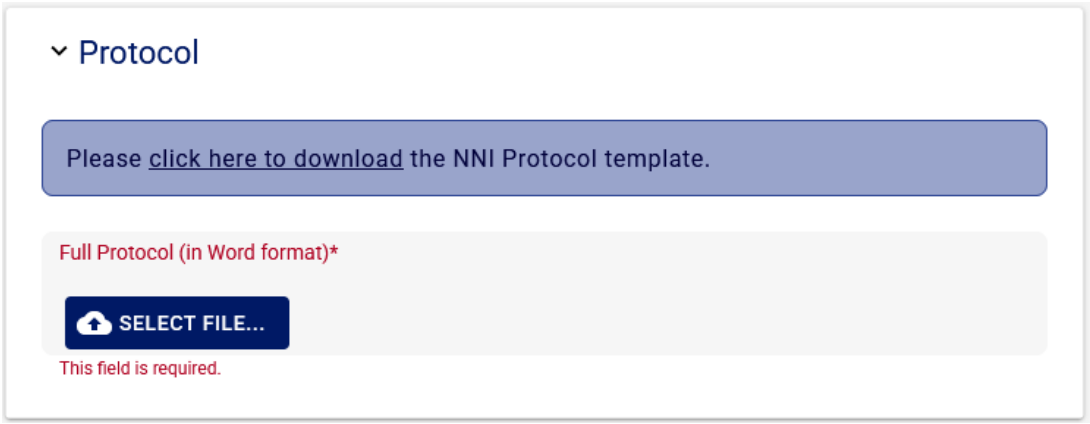
Submitting a New (Initial) Protocol

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

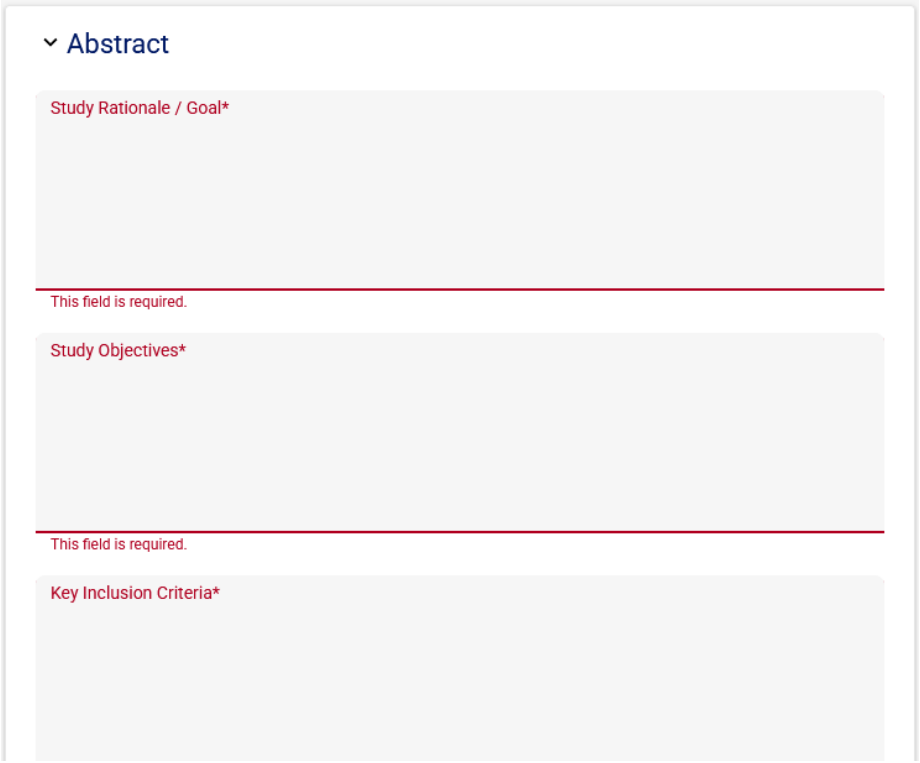
Complete the required fields (those *marked with **red underline/asterisk/exclamation marks***) on the ISS form – the **SUBMIT TO NOVO NORDISK** button at the bottom left will not be active until all required fields are completed.

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

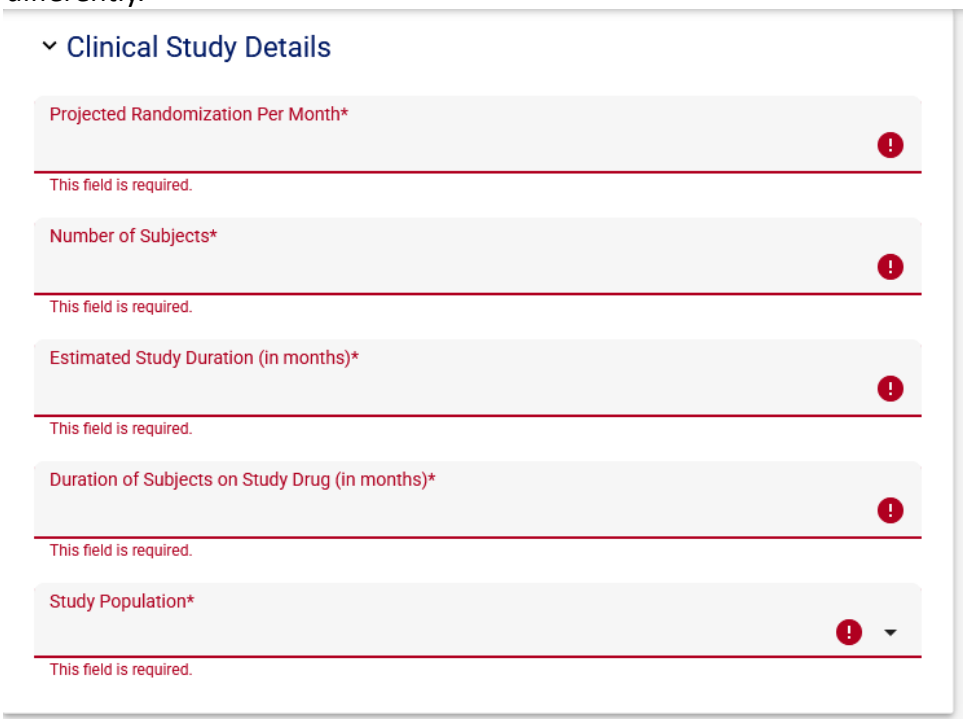
- Protocol



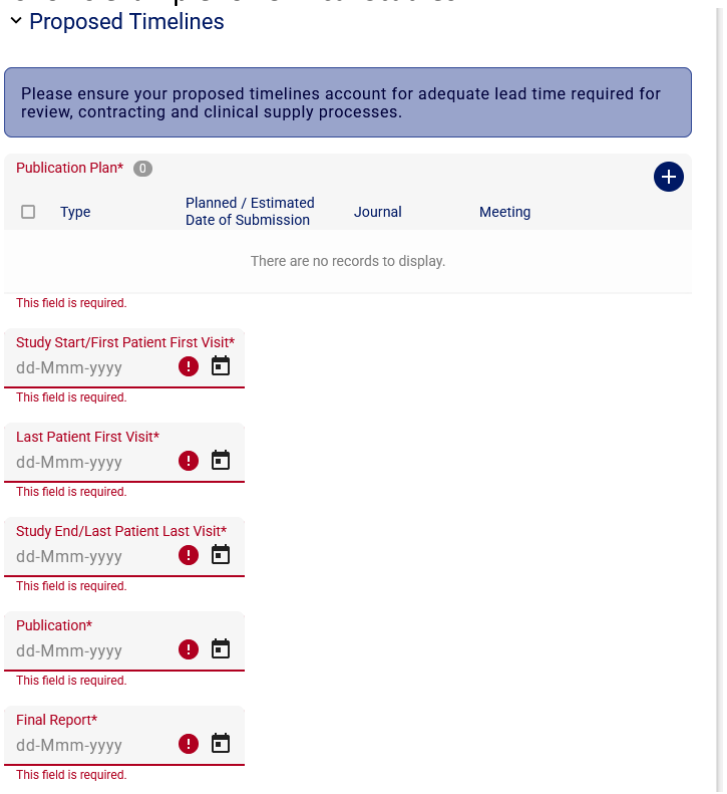
- Abstract Details



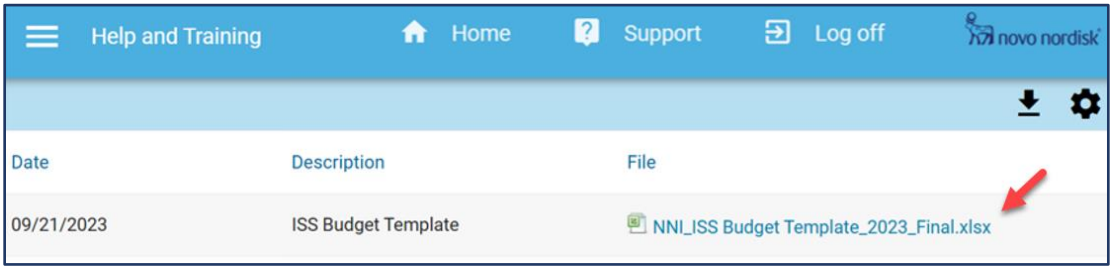
- Clinical Study Details
  - Screenshot below is an examples of Clinical Study Details. Observational Study Details will appear differently.



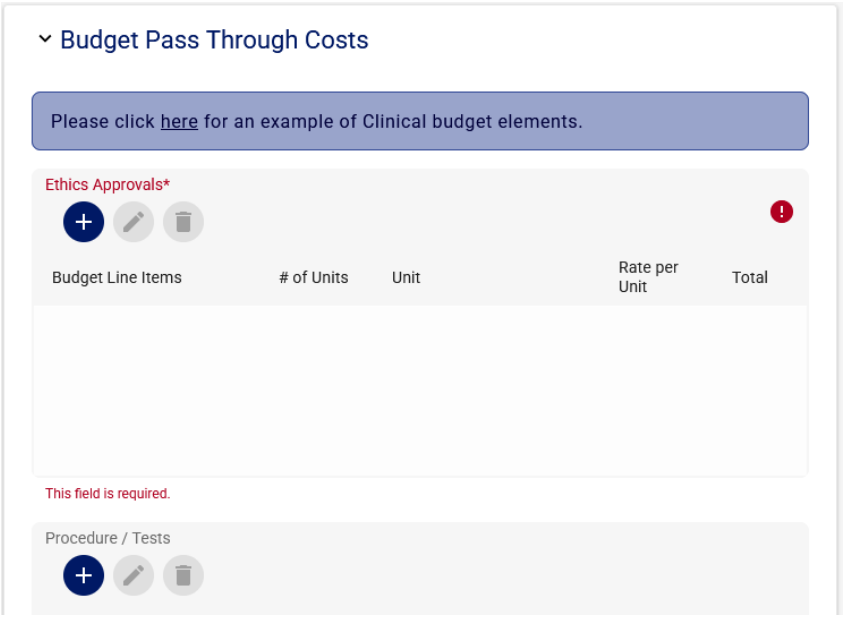
- Proposed Timelines
  - Screenshot below shows example for Clinical Studies

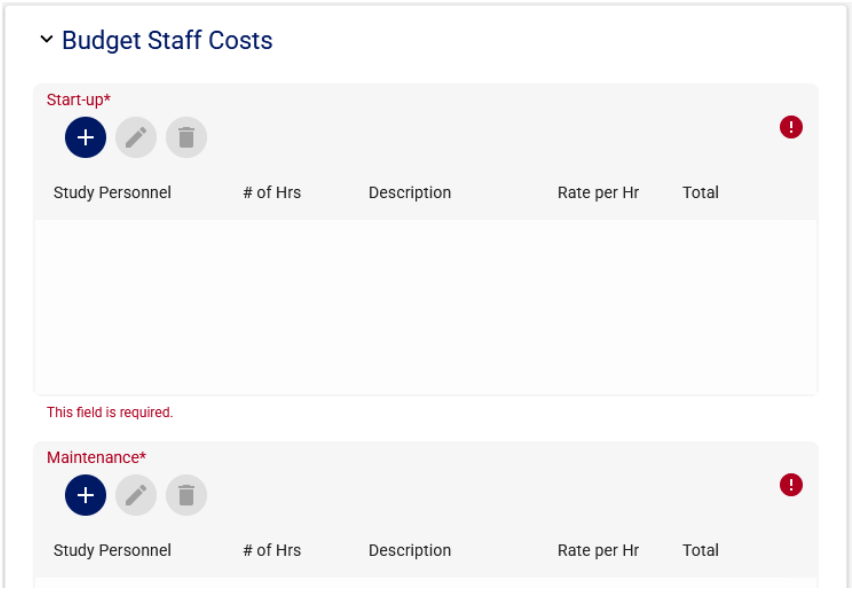


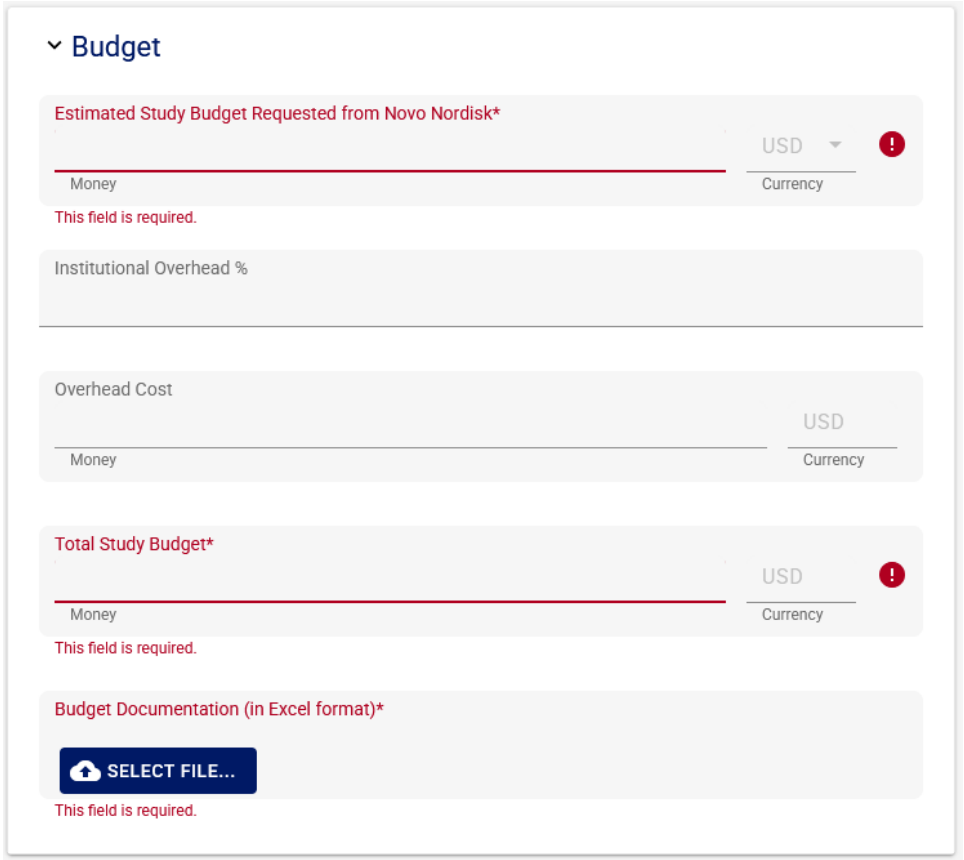
- Budget Template
  - The NNI ISS Budget Template is required when submitting a budget for an ISS submission in the US.
  - Please utilize the “Help & Training” tile to access the “ISS Budge Template” as shown below.



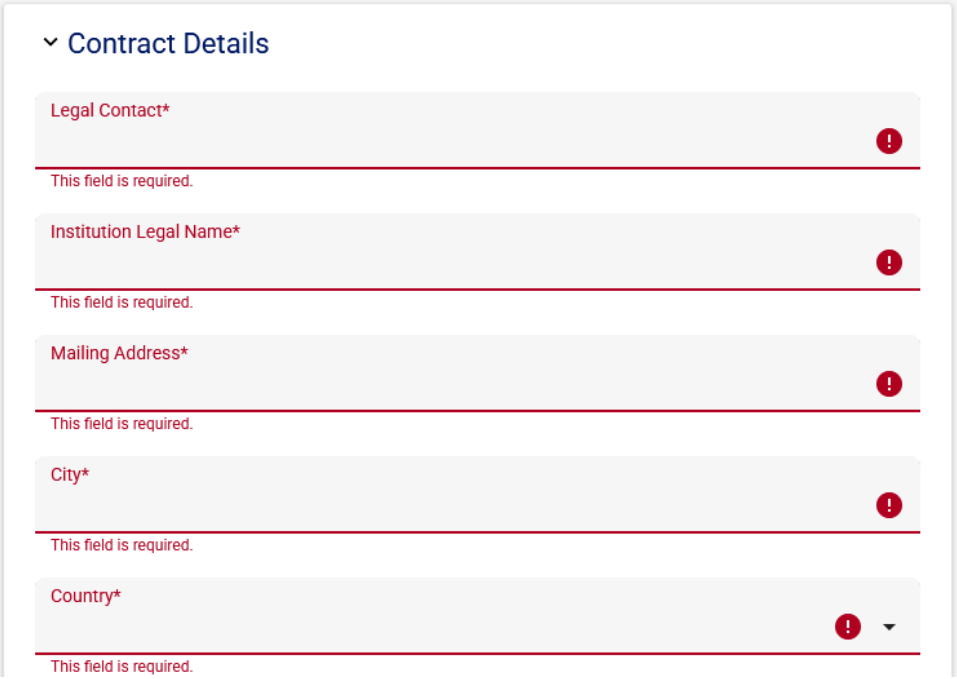
- Budget Details



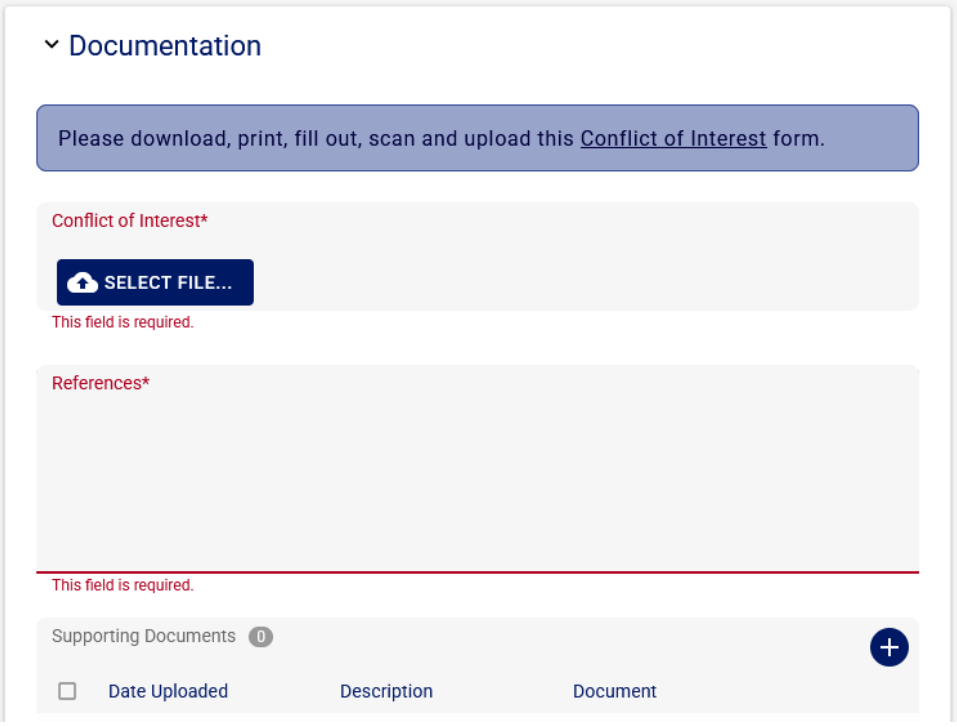




- Contract Contact Details



- Documentation – Conflict of Interest

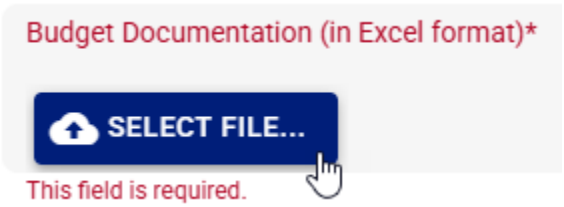


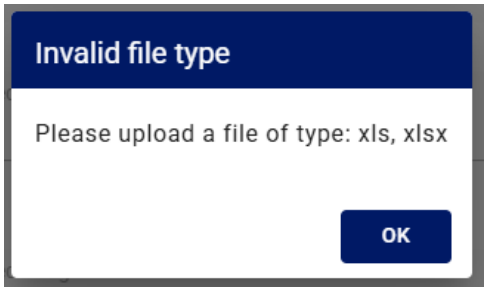
- Novo Nordisk Contact
  - To add an NNI Contact to your study, click the 🔍 and select from the list of existing NNI Contacts.

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

Uploading Documents

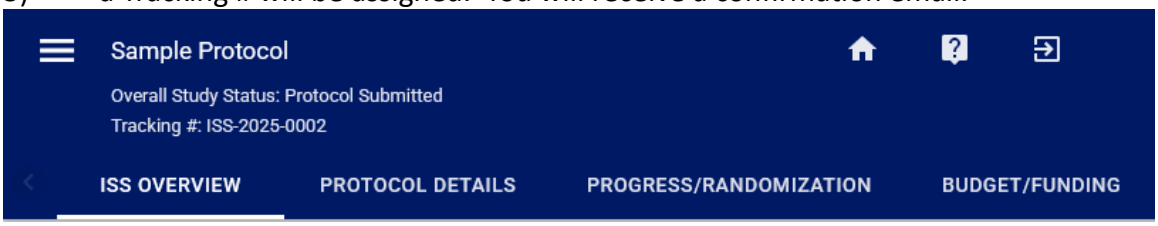
Note if a file attachment requires a specific file type, e.g. PDF or Word, the field label will indicate that. You will receive a pop-up warning if you upload the incorrect file type:





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:

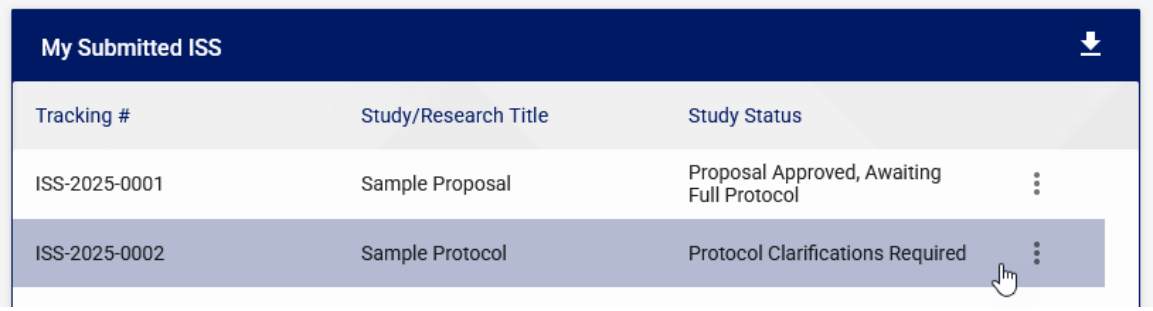
1) the ISS will be submitted,
2) the submission Status will update to “Proposal/Protocol Submitted”
3) a Tracking # will be assigned. You will receive a confirmation email.



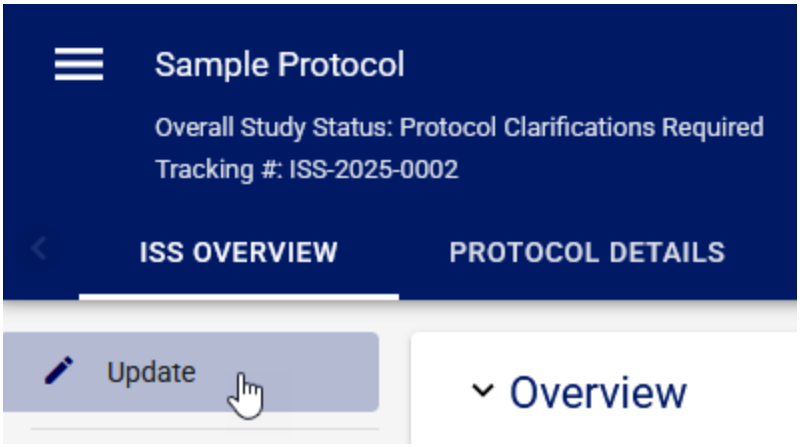
Submitting Required Protocol Clarifications

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.



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.