

NOVO NORDISK ISS INVESTIGATOR REFERENCE GUIDE

www.NovoNordiskISS.com

Purpose

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

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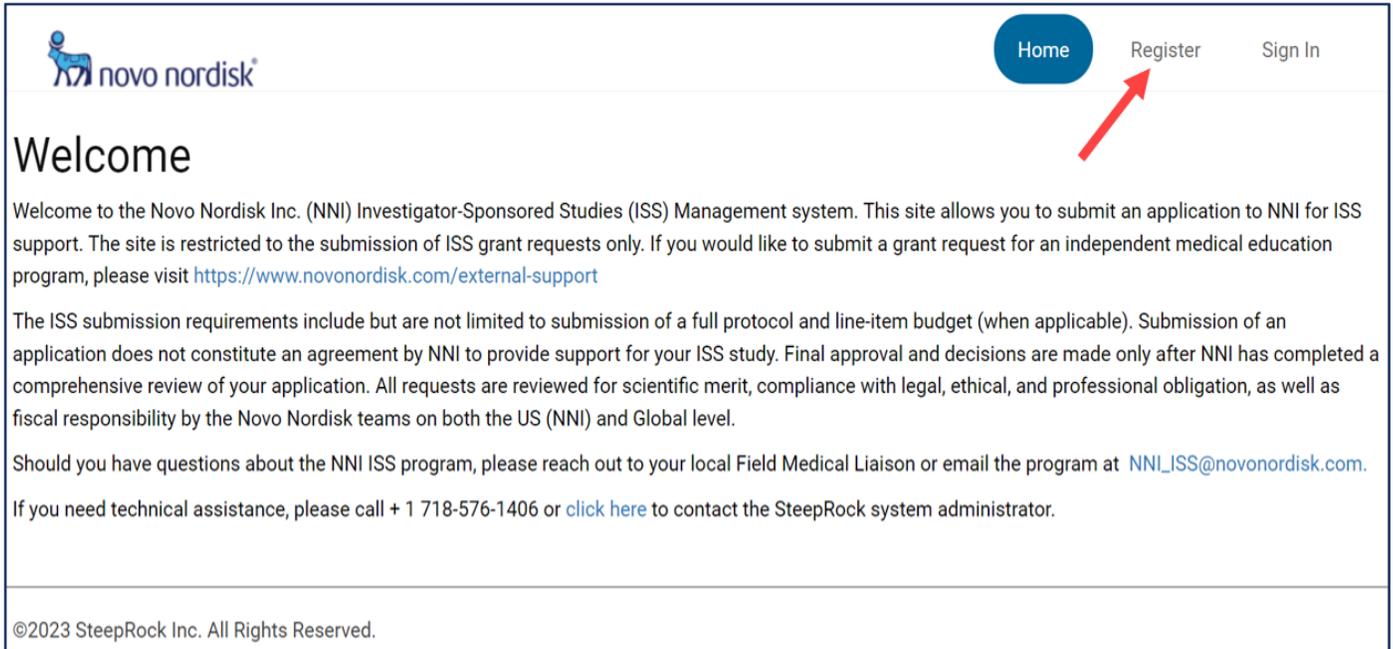
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Registering for Access

1. Open a web browser*, navigate to <http://www.novonordiskiss.com> and click **Register**.



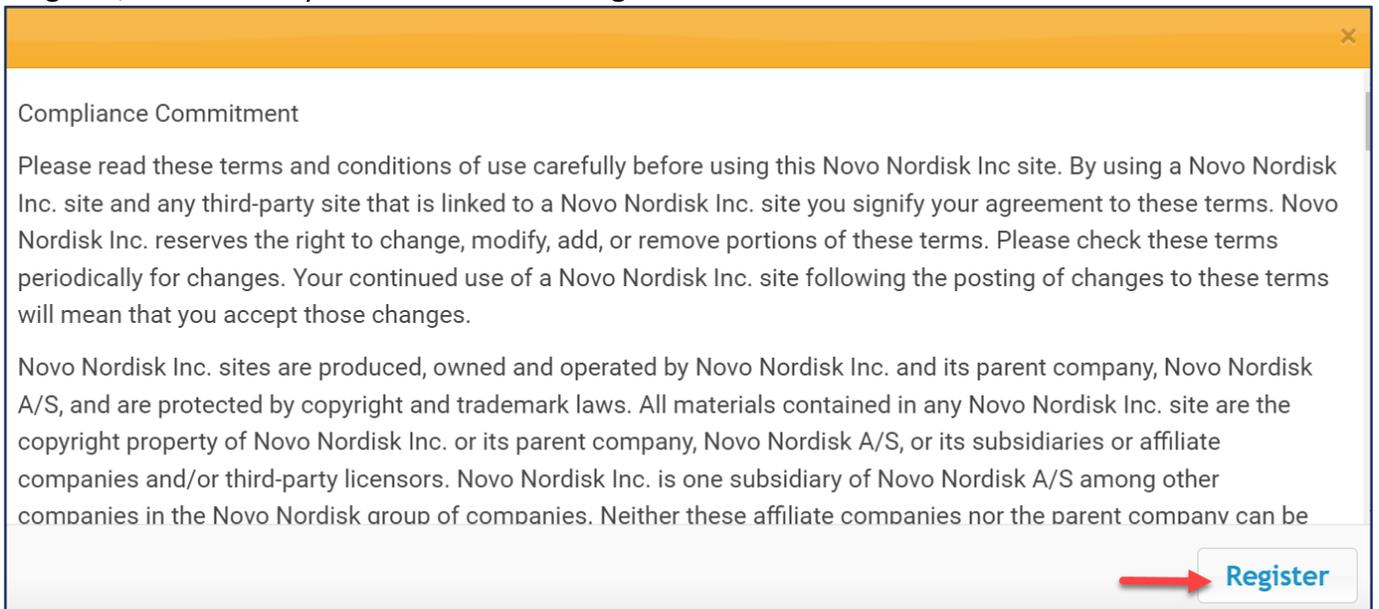
Welcome to the Novo Nordisk Inc. (NNI) Investigator-Sponsored Studies (ISS) Management system. This site allows you to submit an application to NNI for ISS support. The site is restricted to the submission of ISS grant requests only. If you would like to submit a grant request for an independent medical education program, please visit <https://www.novonordisk.com/external-support>

The ISS submission requirements include but are not limited to submission of a full protocol and line-item budget (when applicable). Submission of an application does not constitute an agreement by NNI to provide support for your ISS study. Final approval and decisions are made only after NNI has completed a comprehensive review of your application. All requests are reviewed for scientific merit, compliance with legal, ethical, and professional obligation, as well as fiscal responsibility by the Novo Nordisk teams on both the US (NNI) and Global level.

Should you have questions about the NNI ISS program, please reach out to your local Field Medical Liaison or email the program at NNI_ISS@novonordisk.com. If you need technical assistance, please call + 1 718-576-1406 or [click here](#) to contact the SteepRock system administrator.

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2. Once you read, understand, and agree to the Novo Nordisk Inc. site **Terms and Conditions of use**, click on **Register**, this will take you to the **New User Registration** form.



Compliance Commitment

Please read these terms and conditions of use carefully before using this Novo Nordisk Inc site. By using a Novo Nordisk Inc. site and any third-party site that is linked to a Novo Nordisk Inc. site you signify your agreement to these terms. Novo Nordisk Inc. reserves the right to change, modify, add, or remove portions of these terms. Please check these terms periodically for changes. Your continued use of a Novo Nordisk Inc. site following the posting of changes to these terms will mean that you accept those changes.

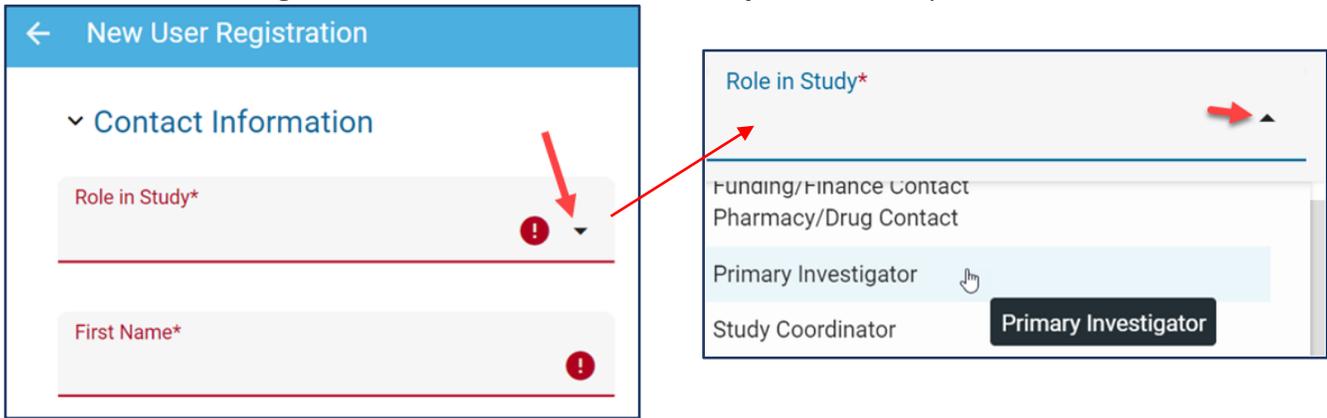
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[Register](#)

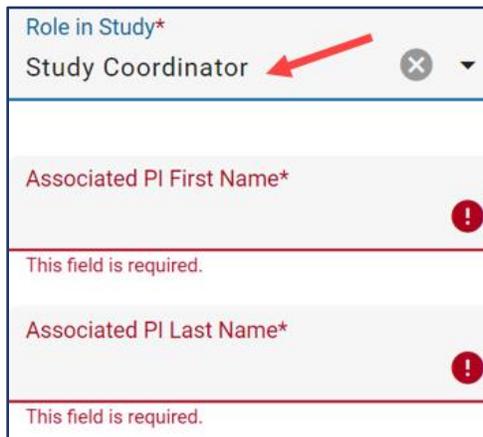
* Microsoft Edge, Chrome, Firefox, and Safari are the preferred browsers. Please reference **Helpful Settings** at the end of this guide for pop-up windows guidance.

Please Note: All fields marked with **red outlines/asterisk/exclamation marks** are required. You will not be able to save the record if one of the required fields is not completed.

3. On the **New User Registration** form select a **Role in Study** from the drop-down



- If you are not the **Primary Investigator** **Associated PI First Name** and **Associated PI Last Name** are required fields

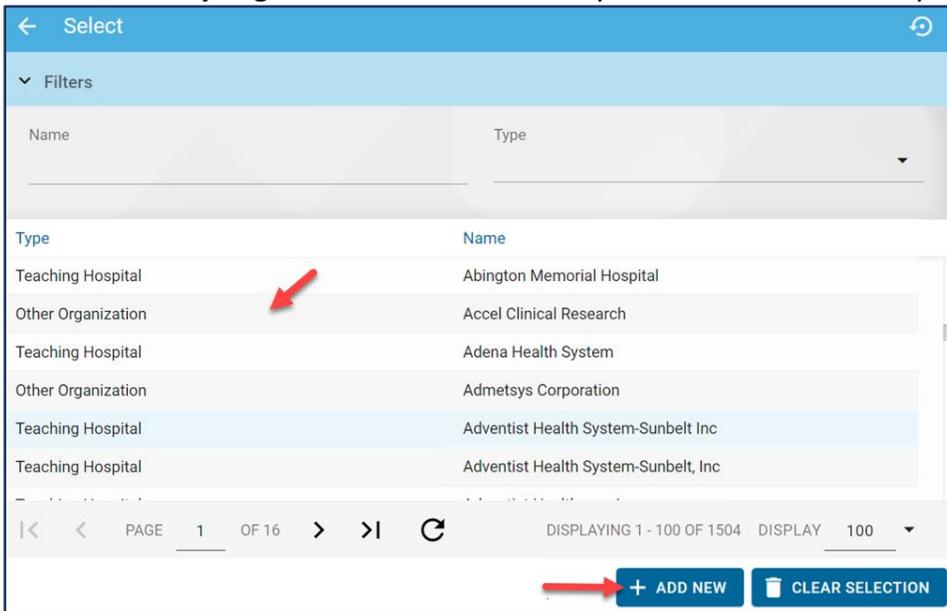


4. Enter your **First Name** and **Last Name**

5. Select the  to populate a list of existing **Primary Organizations**.



6. Select a **Primary Organization** from the list. If you are unable to locate your Organization click **+ADD NEW**.

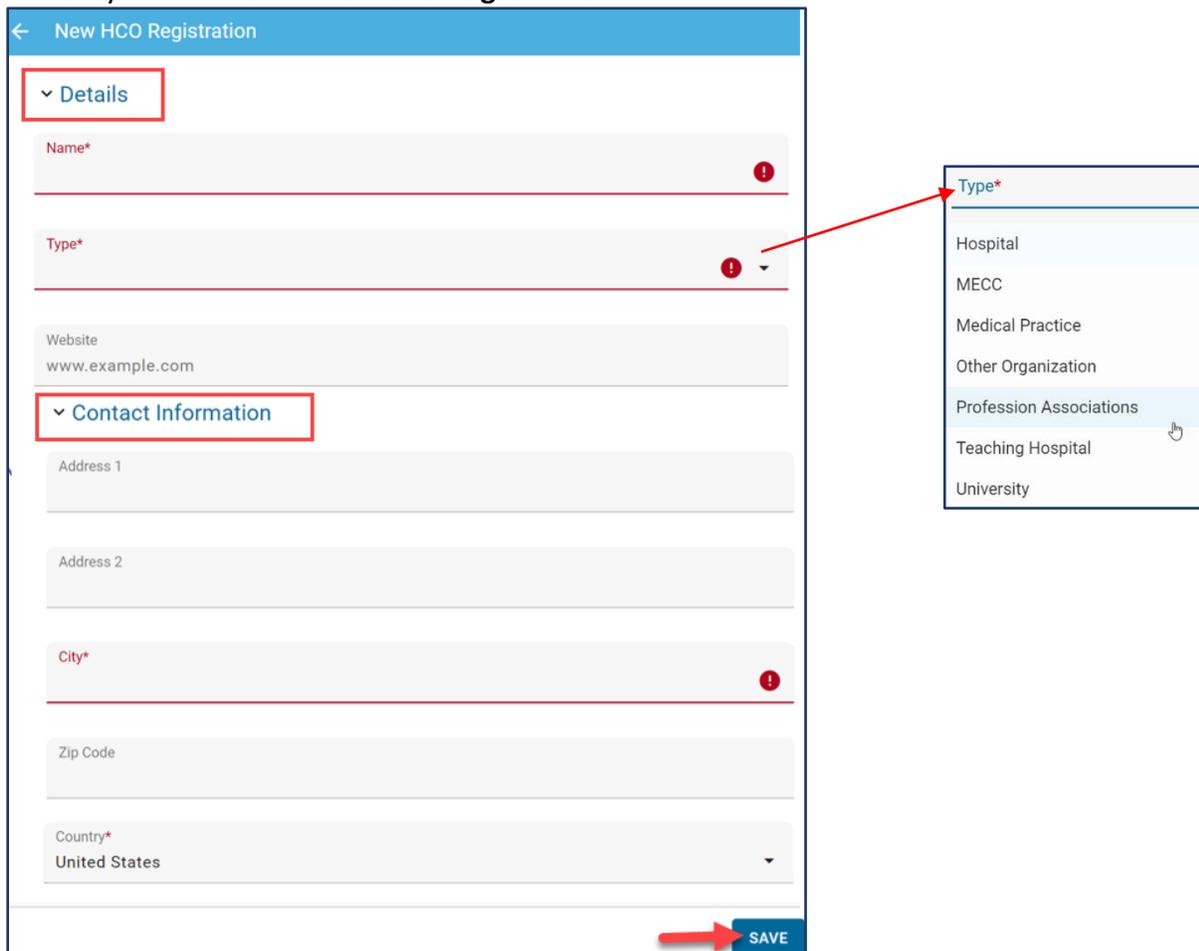


Type	Name
Teaching Hospital	Abington Memorial Hospital
Other Organization	Accel Clinical Research
Teaching Hospital	Adena Health System
Other Organization	Admetsys Corporation
Teaching Hospital	Adventist Health System-Sunbelt Inc
Teaching Hospital	Adventist Health System-Sunbelt, Inc

DISPLAYING 1 - 100 OF 1504 DISPLAY 100

+ ADD NEW CLEAR SELECTION

• To add a new Organization, enter the **Details** and **Contact Information**, then click **SAVE**. Once you **SAVE**, it takes you back to the **New User Registration** form.



New HCO Registration

Details

Name*

Type*

Website
www.example.com

Contact Information

Address 1

Address 2

City*

Zip Code

Country*
United States

SAVE

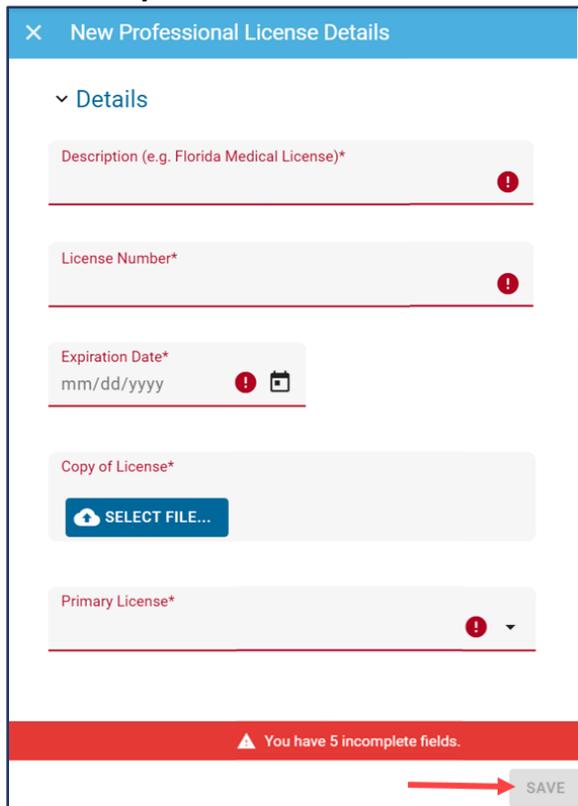
Type*

- Hospital
- MECC
- Medical Practice
- Other Organization
- Profession Associations
- Teaching Hospital
- University

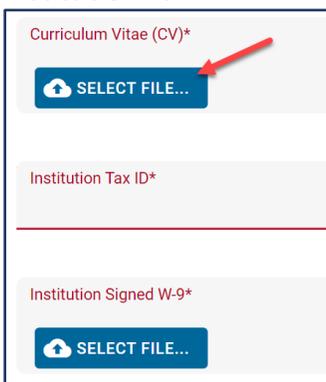
7. Enter your **Address, City, Country, State, Zip Code, Telephone** and **Email**
8. To add Credentials, click the + icon



- Enter a **Description, License Number, Expiration Date**, upload a **Copy of License**, and select **Yes** or **No** for **Primary License**.



9. Upload a **Curriculum Vitae (CV)** and **Institution Signed W-9** by clicking the **SELECT FILE...** button. Enter the **Institution Tax ID**.



10. Select **Yes** or **No** for **Do you have an NPI #?**

Do you have an NPI #?*

This field is required.



- If **Yes**, enter your **NPI #**.

NPI #*

This field is required.

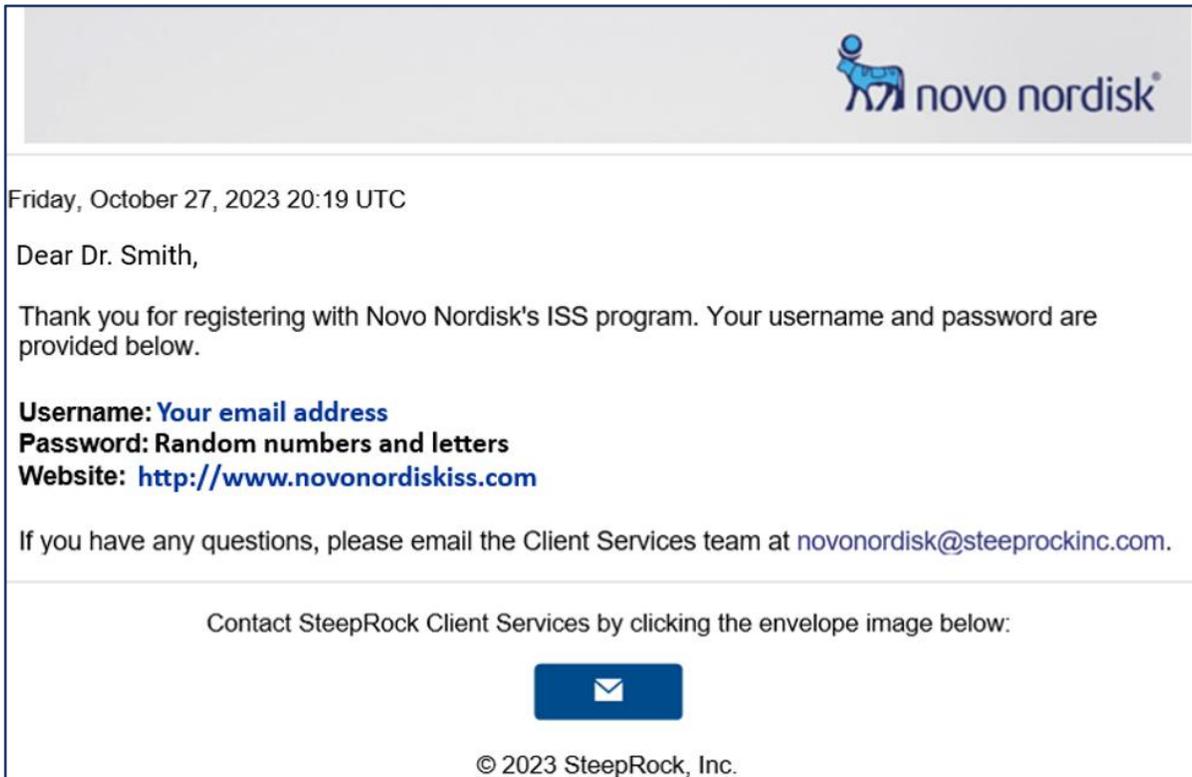
11. Once all required fields have been completed, click **SAVE** in the lower right hand corner.

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

Thank you for registering. You should receive your login information momentarily via email.

 **OK**

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



The screenshot shows a welcome email from Novo Nordisk. The header includes the Novo Nordisk logo. The email content is as follows:

Friday, October 27, 2023 20:19 UTC

Dear Dr. Smith,

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

Username: Your email address
Password: Random numbers and letters
Website: <http://www.novonordiskiss.com>

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

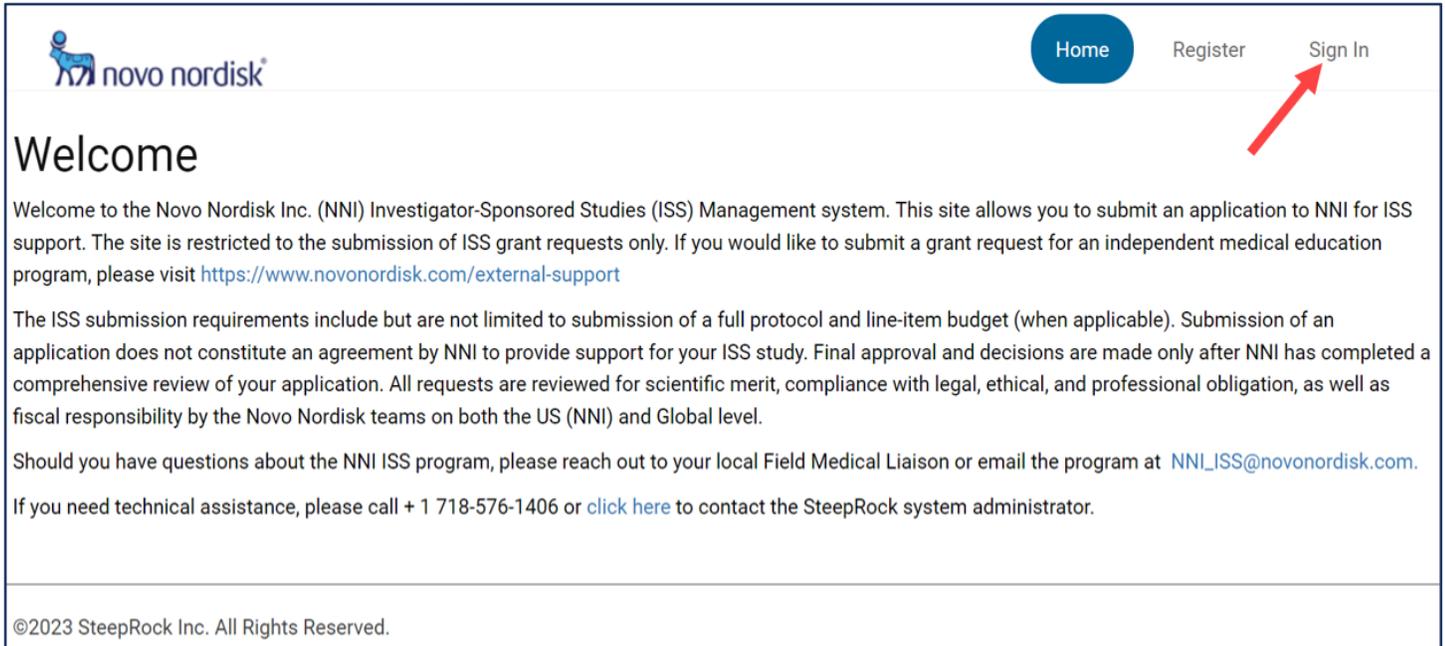
Contact SteepRock Client Services by clicking the envelope image below:



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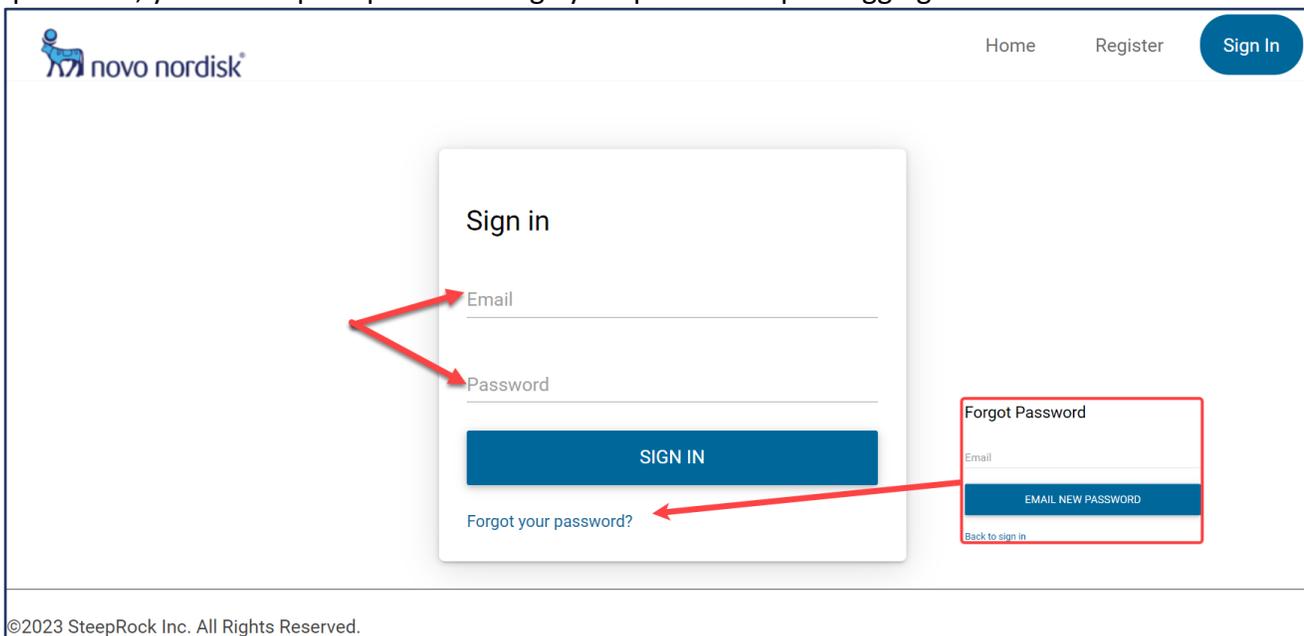
Logging In

1. Open a web browser*, navigate to <http://www.novonordiskiss.com>, and click **Sign In**.



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



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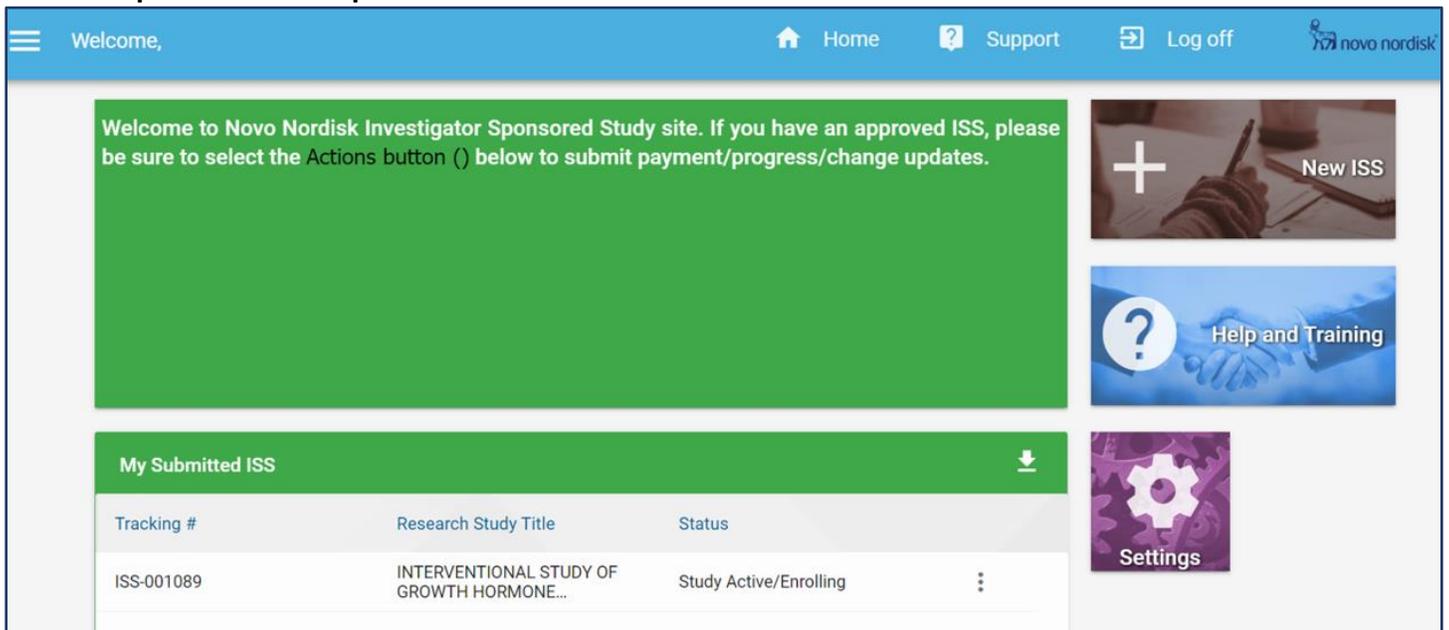
What is on My Home Page?

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

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

You can navigate throughout the platform by selecting the menu tiles.

Please Note: The top green box provides important updates related to the NNI ISS program. **Please recall that our NNI ISS program is currently on pause for accepting any new ISS applications requesting all formulations of semaglutide (e.g., injectables and oral). The pause will remain for 2023 with re-evaluation Q1 2024 as to when the process will re-open for submissions.**



The screenshot shows the user interface of the Novo Nordisk Investigator Sponsored Study site. At the top, there is a navigation bar with a hamburger menu, a 'Welcome,' message, and links for 'Home', 'Support', and 'Log off'. The main content area features a large green box with a welcome message and instructions. To the right of this box are three menu tiles: 'New ISS' (with a plus sign icon), 'Help and Training' (with a question mark icon), and 'Settings' (with a gear icon). Below the green box is a section titled 'My Submitted ISS' with a download icon. This section contains a table with the following data:

Tracking #	Research Study Title	Status	
ISS-001089	INTERVENTIONAL STUDY OF GROWTH HORMONE...	Study Active/Enrolling	⋮

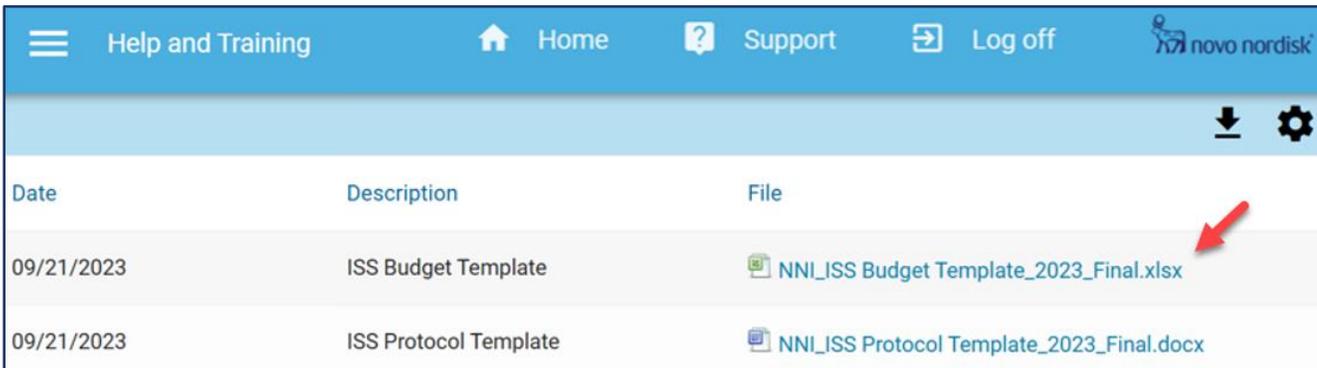
Submitting a New ISS Application

Submission of a full protocol with all supporting documents, including a detailed line-item budget (if requesting NNI funding support) is required for all new NNI ISS applications. The ISS application will be reviewed by the Novo Nordisk Research Committees on both the US (NNI) AND Global level. The committees will make a full evaluation of the application and determine whether support will be provided.

NNI strongly recommends utilizing NNI templates when submitting a protocol and line-item budget to the NNI ISS program. To access the NNI protocol and line-item budget templates: Select the **Help and Training** tile on your home page. *You can use the documents to copy/paste into the online form.*



This will bring you to the **Help and Training** page. Select the ISS Protocol Template titled, “NNI_ISS Protocol Template_2023_Final.docx” and the ISS Budget Template titled, “NNI_ISS Budget Template_2023_Final.docx” for download.

A screenshot of a web application interface. The top navigation bar is blue and contains a hamburger menu icon, the text "Help and Training", a home icon, "Home", a question mark icon, "Support", a log off icon, "Log off", and the Novo Nordisk logo. Below the navigation bar is a light blue header area with a download icon and a settings gear icon. The main content area is a table with three columns: "Date", "Description", and "File". The table contains two rows of data. A red arrow points to the "File" column of the first row.

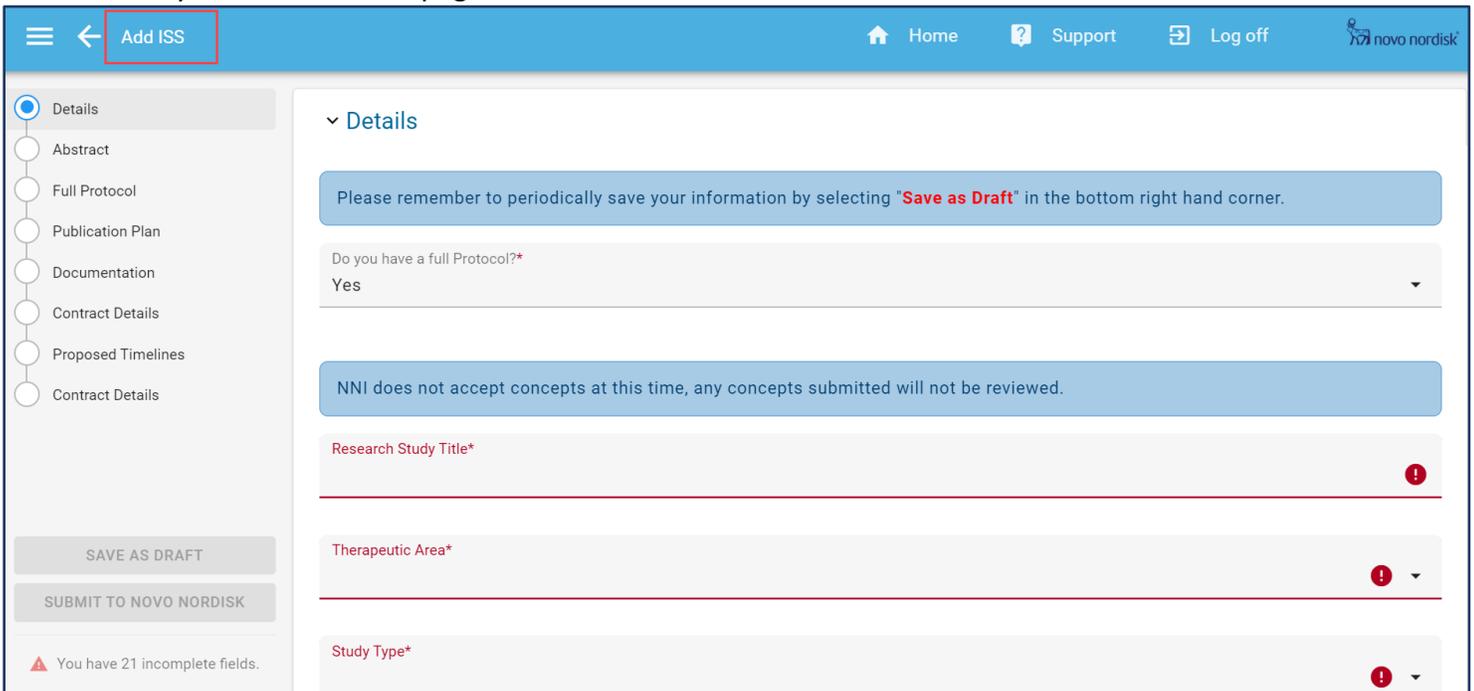
Date	Description	File
09/21/2023	ISS Budget Template	 NNI_ISS Budget Template_2023_Final.xlsx
09/21/2023	ISS Protocol Template	 NNI_ISS Protocol Template_2023_Final.docx

Submitting a New Protocol

Once you have downloaded the NNI protocol template and written your protocol, select the **+New ISS** tile on the home screen to start submission of a new protocol.



This will take you to the **Add ISS** page to enter information for the new **Protocol**.

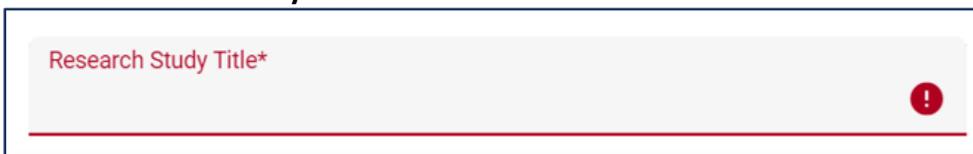


Details

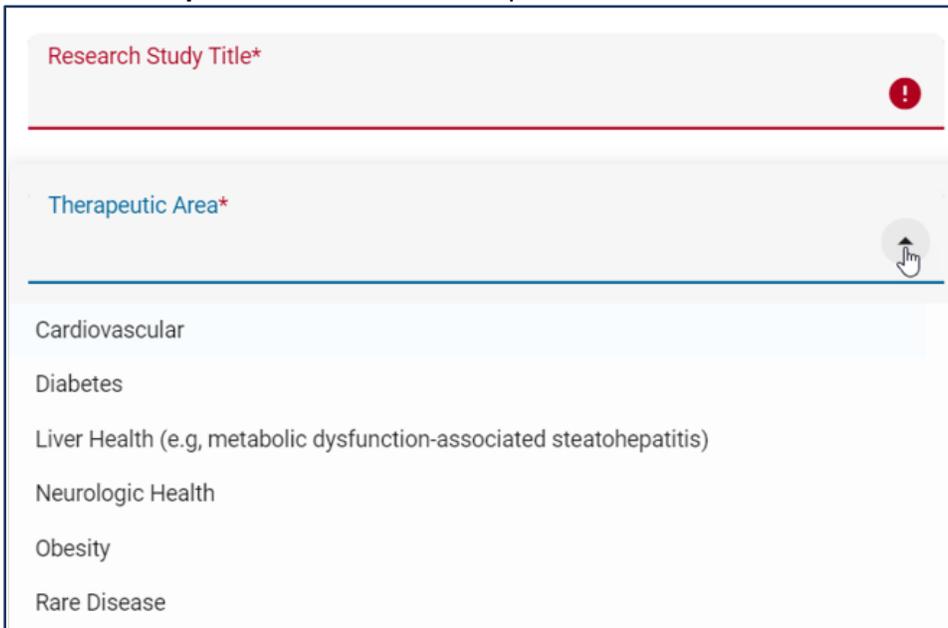
1. Select **Yes** for **Do you have a full Protocol?** Must be Yes, as NNI does not accept Concepts at this time. Any Concepts submitted will not be reviewed.



2. Enter a **Research Study Title**.



3. Select a **Therapeutic Area** from the drop-down

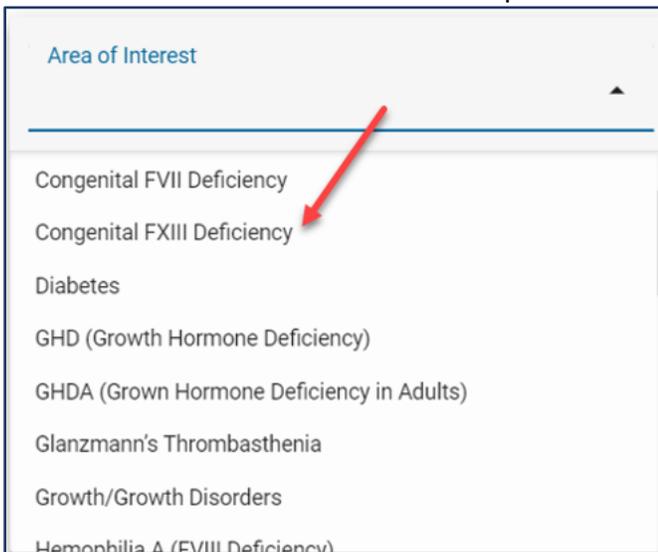


Research Study Title*

Therapeutic Area*

- Cardiovascular
- Diabetes
- Liver Health (e.g, metabolic dysfunction-associated steatohepatitis)
- Neurologic Health
- Obesity
- Rare Disease

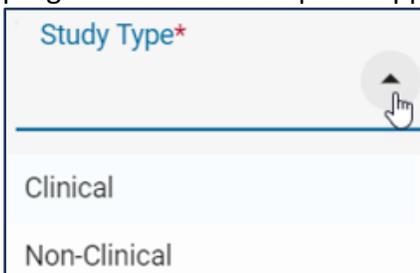
4. Select an **Area of Interest** from the drop-down.



Area of Interest

- Congenital FVII Deficiency
- Congenital FXIII Deficiency
- Diabetes
- GHD (Growth Hormone Deficiency)
- GHDA (Grown Hormone Deficiency in Adults)
- Glanzmann's Thrombasthenia
- Growth/Growth Disorders
- Hemophilia A (FVIII Deficiency)

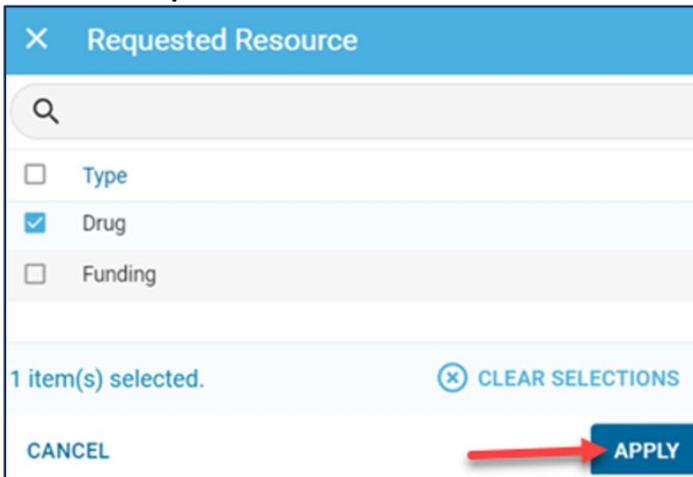
5. Select a **Study Type** of **Clinical** or **Non-Clinical (e.g., observational ISS)**. Please note that the NNI ISS program does not accept ISS applications for in-vitro or in-vivo studies.



Study Type*

- Clinical
- Non-Clinical

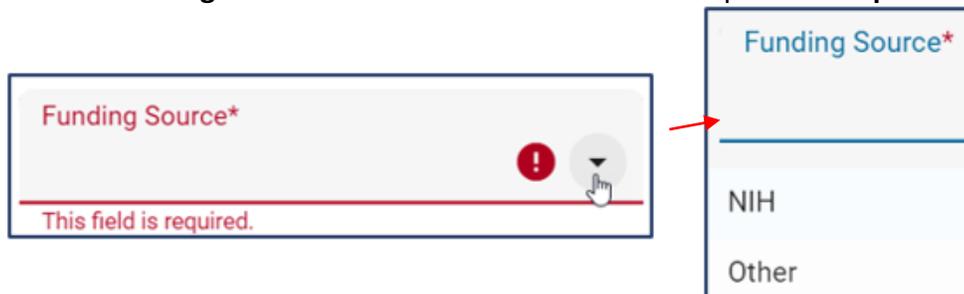
6. Choose a **Requested Resource** and click **APPLY**.



7. **Primary Product** is required if **Requested Resource** is **Drug**.



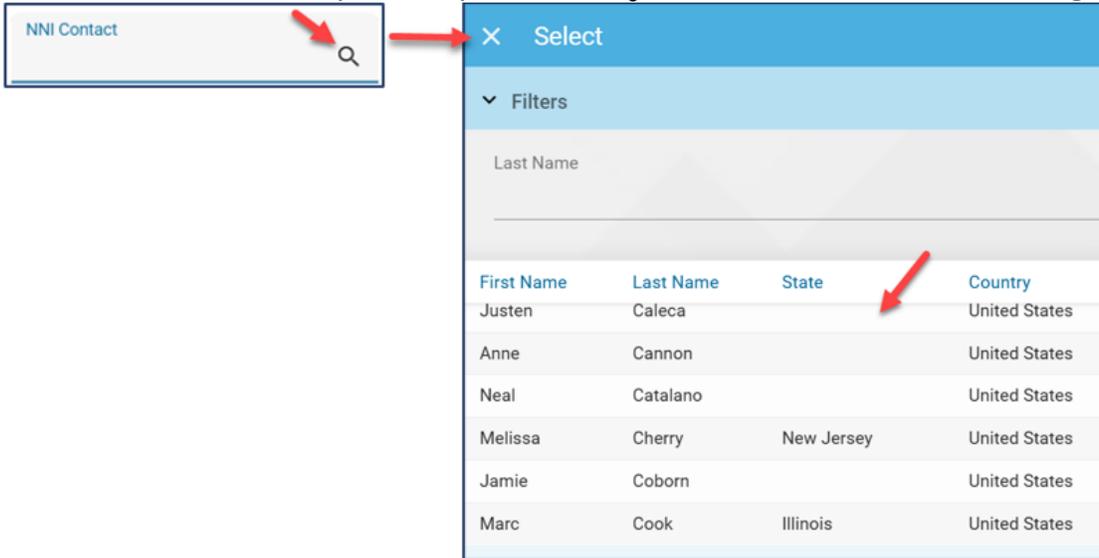
8. Select a **Funding Source** of **NIH** or **Other**. This field is required if **Requested Resource** is **Drug**.



9. **Please describe/identify funding source** field is required If **Funding Source** is **Other**.



10. To add an **NNI Contact** to your study, click the  and select from the list of existing NNI Contacts.

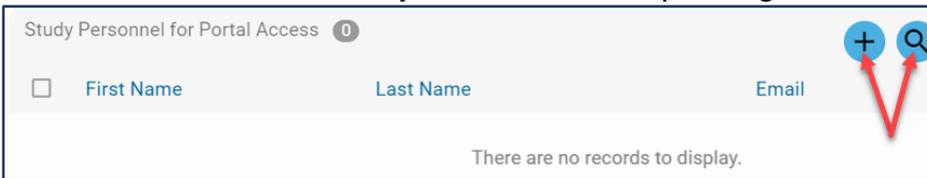


The screenshot shows a search box labeled "NNI Contact" with a magnifying glass icon. A red arrow points from the search box to a "Select" modal window. The modal window has a "Filters" section with a "Last Name" input field. Below the filters is a table of existing contacts:

First Name	Last Name	State	Country
Justen	Caleca		United States
Anne	Cannon		United States
Neal	Catalano		United States
Melissa	Cherry	New Jersey	United States
Jamie	Coborn		United States
Marc	Cook	Illinois	United States

A red arrow points to the "State" column header in the table.

11. Adding **Study Personnel for Portal Access**: Select  to Search/Select existing **Study Personnel** or select the **+** button to add **New Study Personnel** currently not registered as users in the NNI ISS portal.

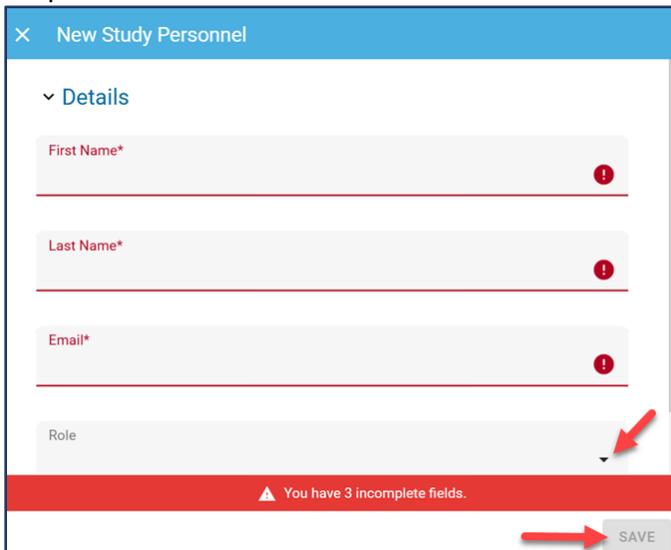


The screenshot shows a header "Study Personnel for Portal Access" with a notification icon. Below the header are three input fields: "First Name", "Last Name", and "Email". To the right of the "Email" field are two circular buttons: a "+" button and a magnifying glass icon. Red arrows point to both buttons. Below the input fields, the text "There are no records to display." is visible.

****Please Note**

The personnel you add will receive an email invitation to register for access to the NNI ISS portal. Once they have registered for access, they will have access to your study.

- Enter the Study Personnels **First Name**, **Last Name**, **Email**, and (if applicable) select their **Role** from the drop-down. Click **SAVE**.



The screenshot shows a "New Study Personnel" form with a "Details" section. It contains four input fields: "First Name*", "Last Name*", "Email*", and "Role". Each of the first three fields has a red exclamation mark icon to its right, indicating they are incomplete. The "Role" field is a dropdown menu with a red arrow pointing to the dropdown arrow. At the bottom of the form, a red banner displays the message "You have 3 incomplete fields." and a "SAVE" button with a red arrow pointing to it.

Budget

(Required if Requested Resource is Funding)

1. Enter an **Estimated Study Budget** amount. (no need to add the \$)

▼ Budget

Estimated Study Budget*

Money USD ▼ 

Currency

This field is required.

Abstract

1. **Background/Rationale, Objectives, Significance, Hypothesis, and Methods** are required free-text fields. You can copy and paste from the protocol template.

▼ Abstract

Background / Rationale*

This field is required.

Objectives*

This field is required.

Significance*

This field is required.

Hypothesis*

This field is required.

Methods*

This field is required.

Full Protocol

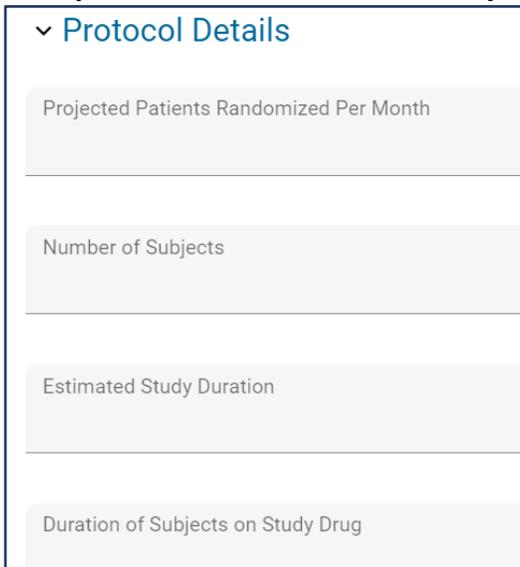
1. Click **SELECT FILE...** to upload the **Word** or **PDF** version of the full **Protocol** you wrote utilizing the NNI protocol template.



Protocol Details

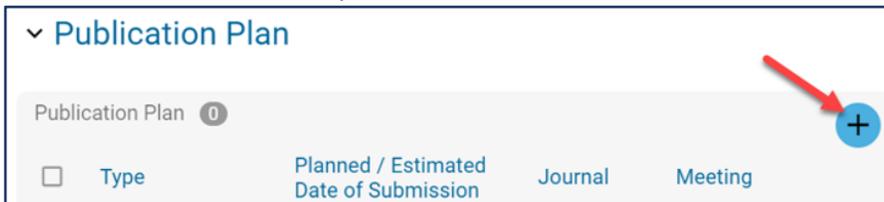
(Only if Study Type is Clinical)

1. Enter the Protocol Details, **Projected Patients Randomized Per Month**, **Number of Subjects**, **Estimated Study Duration**, and **Duration of Subjects on Study Drug** fields must be numerical values.

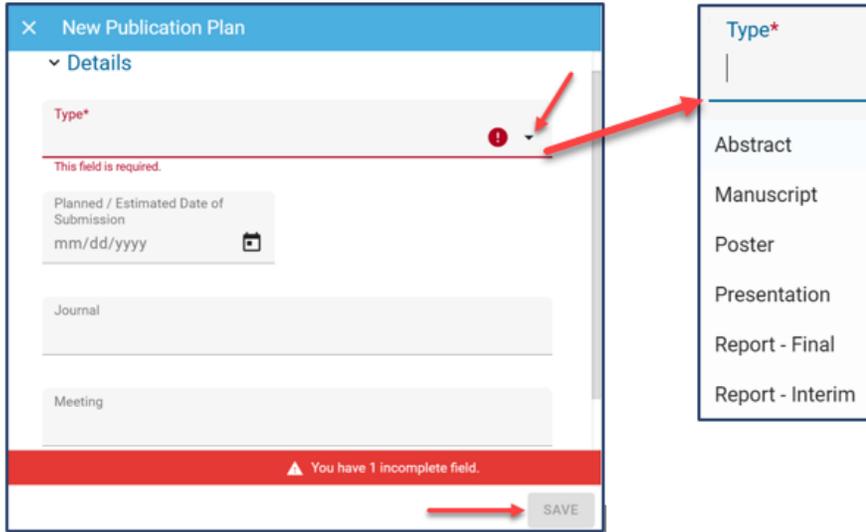


Publication Plan

1. To add a **Publication Plan**, click the + icon.



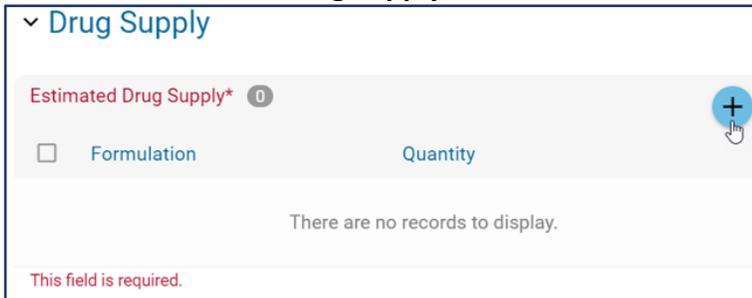
2. Select a **Type** from the drop-down, enter the **Planned/Estimated Date of Submission**, **Journal** or **Meeting** if known at the time of submission, click **SAVE**.



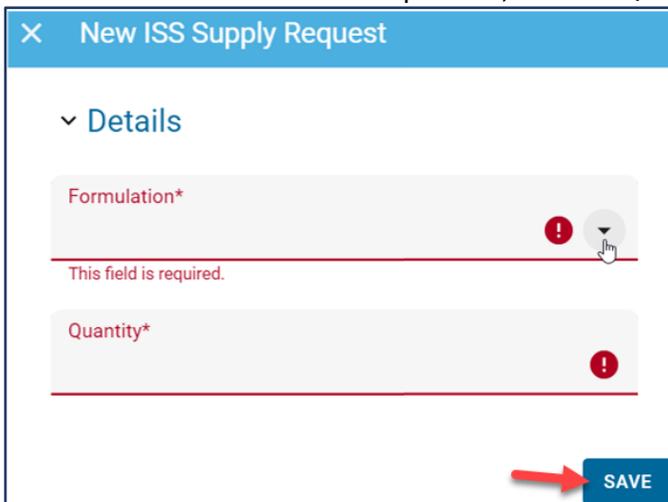
Drug Supply

(Required if Requested Resource is Drug)

1. To add an **Estimated Drug Supply**, click the + icon. This will bring you to the **New ISS Supply Request** form.



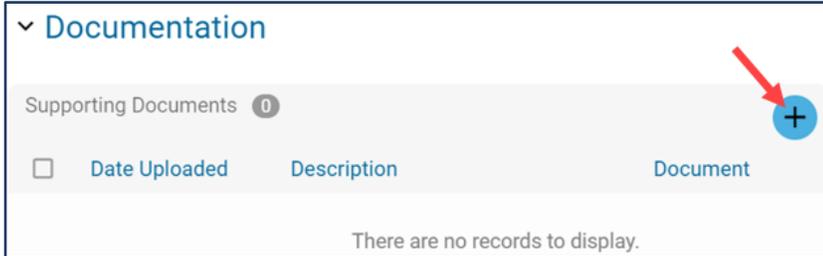
2. Select from a **Formulation** drop-down, enter a **Quantity** (e.g., #pens), and **SAVE**.



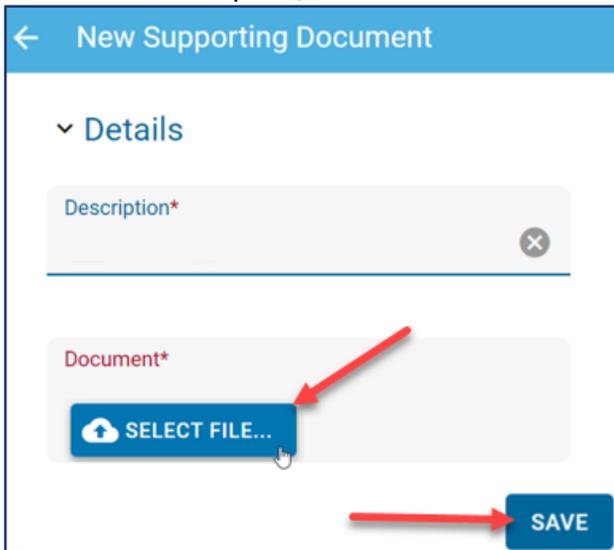
Documentation

The **Supporting Documents** field is used for any imperative source of information that needs to be submitted with the Protocol.

1. To upload documents, click the + icon.



2. In the **New Supporting Document** pop-up window enter a **Description** for the document and click **SELECT FILE...**. Once complete, click **SAVE**. Documents can be in any format (PDF, WORD, EXCEL, Email).



Contract Details

1. Complete all required fields.

Contract Details

Legal Contact*	Phone*
This field is required.	This field is required.
Institution Legal Name*	Fax
This field is required.	
Mailing Address*	Email*
This field is required.	This field is required.
City*	Tax ID Number*
This field is required.	This field is required.
Country*	UTN #*
This field is required.	This field is required.
Zip*	
This field is required.	

If you do not have a UTN (Universal Trial Number) please navigate to <http://apps.who.int/trialsearch/utn.asp> and complete the simple form.

Conflict of Interest Form

1. Click the **Conflict of Interest** link to download the form, print it, and fill it out.

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

2. Scan the completed **Conflict of Interest** form and click **SELECT FILE...** to upload.

Conflict of Interest*



This field is required.

Proposed Timelines

1. Enter the **Study Activation**, **Start of Study or FPFV**, **Last Patient First Visit (LPFV)**, **End of study or LPLV**, and **Final report** dates.

▼ Proposed Timelines

Study Activation*
mm/dd/yyyy  

This field is required.

Start of Study or FPFV*
mm/dd/yyyy  

This field is required.

Last Patient First Visit (LPFV)
mm/dd/yyyy 

End of study or LPLV*
mm/dd/yyyy  

This field is required.

Final Report*
mm/dd/yyyy  

This field is required.

Please remember to add at least one year to the **Start of Study or FPFV date to account for NNI review process, contracting, and the time it takes to receive study drug.

Compliance Commitment

1. Once you have read the Novo Nordisk Inc. site **Terms and Conditions of use**, check the box **Client Commitment** to confirm you have read, understand, and agree.

Compliance Commitment*

This field is required.

Ship To Details

(Required if the Requested Resource is Drug)

1. Enter the required information

▼ Ship To Details

Name*

!

This field is required.

Address*

!

This field is required.

City*

!

This field is required.

Country*

! ▼

This field is required.

Zip*

!

This field is required.

Budget Pass Through Costs

(Required if the Requested Resource is Funding)

This section includes:

- Ethics Approvals – Budget line items, # of Units, Unit and Rate per Unit
- Procedure/Tests – Budget line items, # of Units, Unit and Rate per Unit
- Lab Tests – Budget line items, # of Units, Unit and Rate per Unit
- Supplies – Budget line items, # of Units, Unit and Rate per Unit
- Other – Budget line items, # of Units, Unit and Rate per Unit

1. Click the “[here](#)” link to view an example of **Clinical budget elements**.

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

Ethics Approvals*

+
✎
✖

Budget Line Items	# of Units	Unit	Rate per Unit	Total
IRB Approval	100	Additional Institutions	10	1000

Ethics Approvals Subtotal

1000.00 USD

Money Currency

2. Add a **Budget Line Item**, click the + icon, enter the required information and click **UPDATE**.

▼ Budget Pass Through Costs

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

Ethics Approvals*

+ (highlighted)
✎
🗑️

Budget Line Items

*Not Applicable (enter 0 in # of Units and Rates per Unit)

IRB Approval

IRB Renewal

*Not Applicable

Additional Institutions

Primary Institution

# of Units	Unit	Rate per Unit	Total
!	!	!	!

UPDATE CANCEL

• **Subtotal** will automatically populate with running total for each line item entered.

Ethics Approvals Subtotal

1000.00	USD
Money	Currency

Budget Staff Costs

(Required if Requested Resource is Funding)

This section includes:

- Start-up – Study Personnel, # of Hrs, Description, Rate per HR
- Maintenance - Study Personnel, # of Hrs, Description, Rate per HR
- Completion - Study Personnel, # of Hrs, Description, Rate per HR

1. To add a **Budget Line Item**, click the + icon, enter the required information and click **UPDATE**.

Start-up*

+ (highlighted)

✎

🗑️

Study Personnel

of Hrs

Description

Rate per Hr

Total

!	!	!	!	!
---	---	---	---	---

UPDATE CANCEL

Budget Summary

(Required if Requested Resource is Funding)

1. Enter the **Institutional Overhead %** (Max of 25%), **Overhead Cost**, and **Total Study Budget**.

▼ Budget

Institutional Overhead %	
Overhead Cost	
0.00	USD
Money	Currency
Total Study Budget*	
2600.00	USD
Money	Currency

2. Click **SELECT FILE...** to upload the line-item **Budget Attachment** that was created utilizing the NNI budget template.

Budget Attachment*



This field is required.

Pay To Detail

(Required if Requested Resource is Funding)

1. Enter the required information.

▼ Pay To Detail

Pay To*

!

This field is required.

Pay To Attention*

!

This field is required.

Address*

!

This field is required.

City*

!

This field is required.

Country*

! ▼

This field is required.

Save Your Draft

1. If you need time to finish gathering the information required for your NNI ISS submission/Protocol, you can select **SAVE AS A DRAFT** on the bottom left corner during the editing. This saves the Protocol with the status **Protocol in Draft** without a Tracking # and allows you to come back to the Protocol later.

SAVE AS DRAFT

SUBMIT TO NOVO NORDISK

⚠ You have 20 incomplete fields.

Note:

- **SAVE AS A DRAFT** is only available after **Research Study Title** and **Do you have a full Protocol?** fields are completed.
- **SUBMIT TO NOVO NORDISK** is only available after all required fields are complete

- To work on your draft Protocol, go to the **My Submitted ISS** tile on the Homepage, click the vertical ellipsis on the right-hand side of the Protocol and select **Work On Protocol/Submit**.

My Submitted ISS			
Tracking #	Research Study Title	Status	
ISS-001089	INTERVENTIONAL STUDY OF GROWTH HORMONE...	Study Active/Enrolling	⋮
ISS-001509	Research	Protocol Clarifications Required	⋮
ISS-001510	Research	Protocol Resubmitted	⋮
ISS-001511	Research Study TEST1	Protocol Locally Approved	⋮
	Clinical Outcomes and Measurables	Protocol In Draft	⋮

-  Update
- Withdraw Study
- Work On Protocol/Submit 

Submit Your Protocol

- After completing all the required fields, click **SUBMIT TO NOVO NORDISK** to send your Protocol to Novo Nordisk for review.

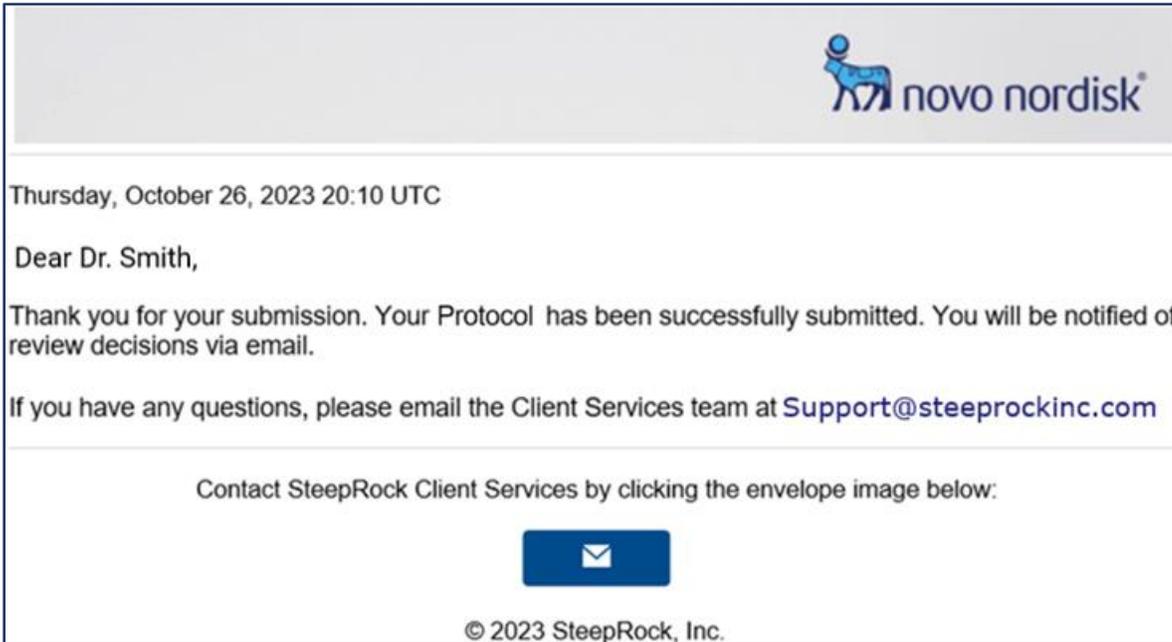
SAVE AS DRAFT

SUBMIT TO NOVO NORDISK

Once a Protocol has been submitted to Novo Nordisk you cannot edit the Protocol.

After Submitting a Protocol

Once you submit a Protocol, you will receive an email confirmation similar to the one below:



Locating My Submitted Protocols

1. The **My Submitted ISS** tile on your home page shows a list of Protocols you have submitted and/or saved as a draft. The list view shows the **Tracking #**, **Research Study Title**, and **Status**. Clicking the vertical ellipsis will show what actions are available.

My Submitted ISS			
Tracking #	Research Study Title	Status	
ISS-001089	INTERVENTIONAL STUDY OF GROWTH HORMONE...	Study Active/Enrolling	
ISS-001510	Test Study Title 1	Protocol Submitted	
	Test Study Title 2	Protocol In Dra	

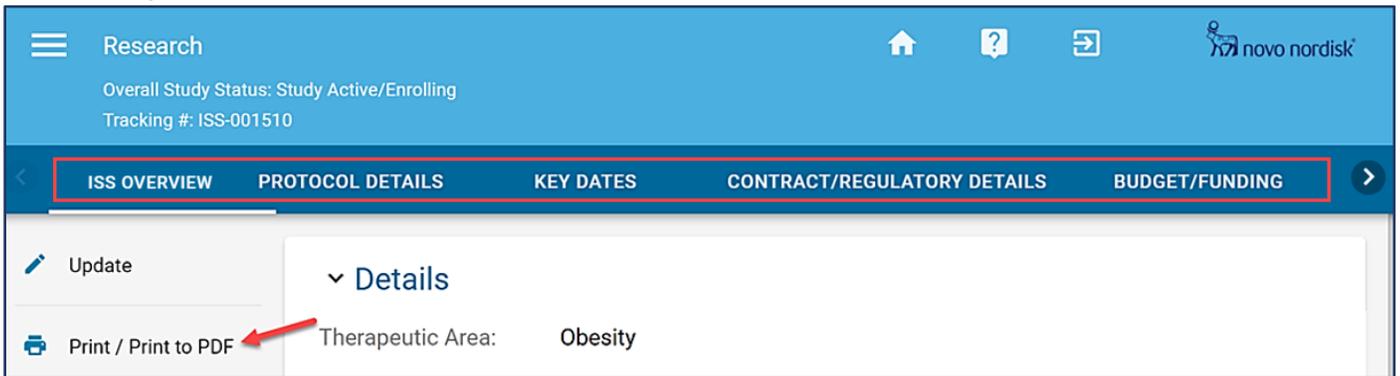
 Update

 Withdraw Study

2. To view more information for a specific study, click on the study title

ISS-001509	Research	Protocol Clarifications Required	⋮
ISS-001510	Research	Study Active/Enrolling	⋮
ISS-001511	Research	Study Active/Enrolling	⋮

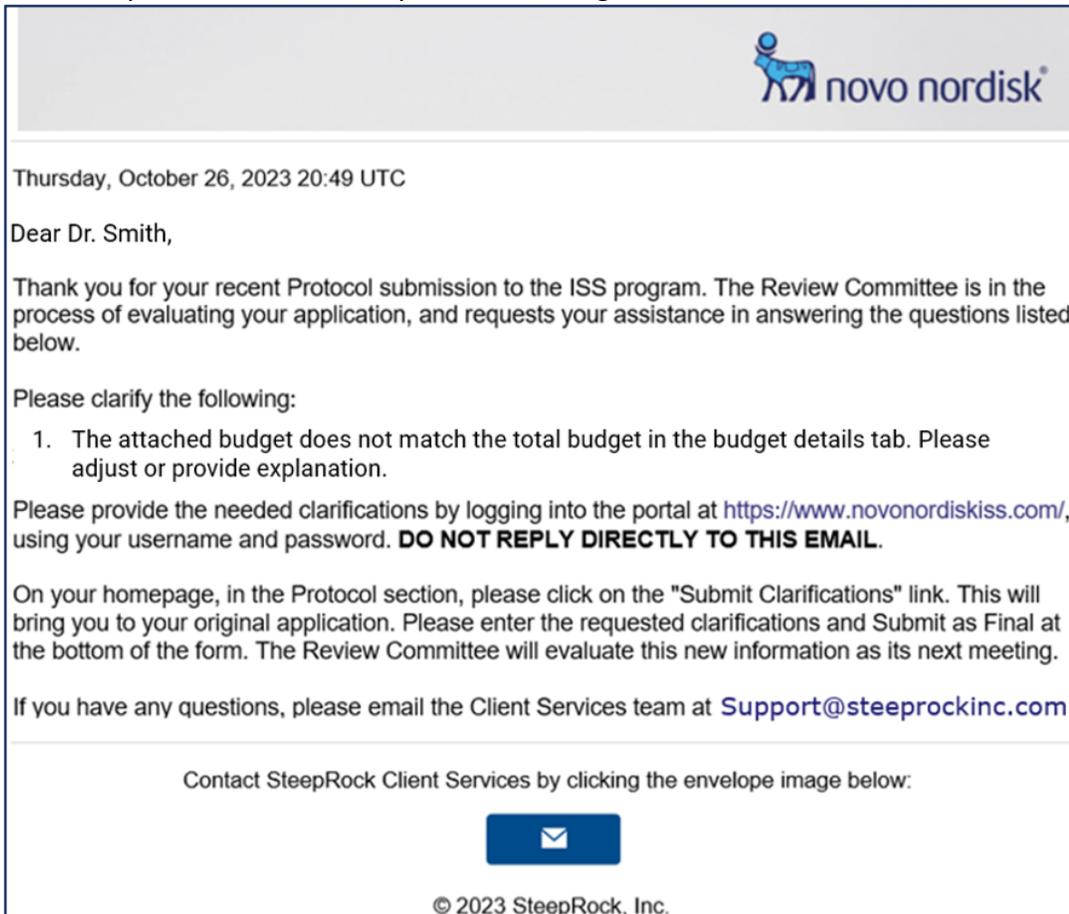
3. This takes you to the ISS record which is broken down into tabs. Not all tabs appear for all Protocols and will appear when data is populated in each tab. The contents in the tabs are relevant to the fields associated with the tab. Once the tab is selected the populated fields will appear. To print the details in full, select **Print/Print to PDF**.



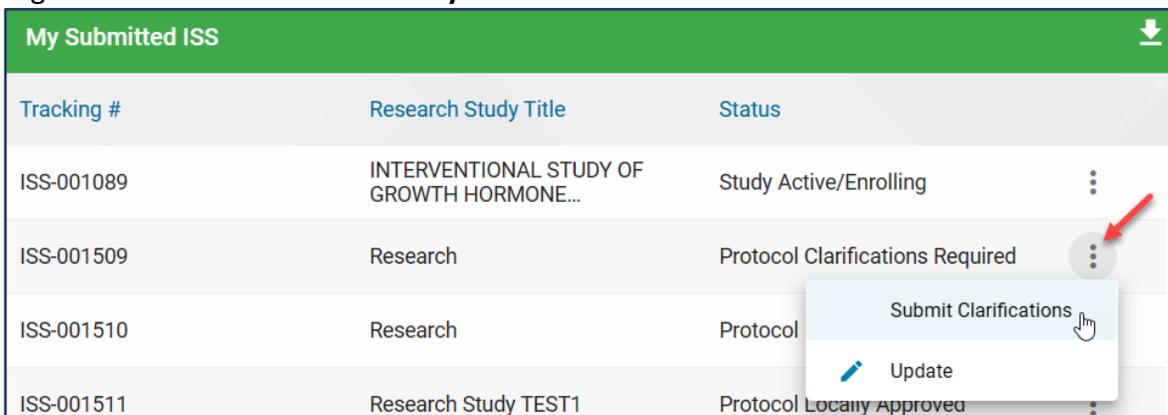
The screenshot shows the 'Research' interface for study ISS-001510. The overall study status is 'Study Active/Enrolling' with tracking number ISS-001510. A horizontal tab bar contains five tabs: 'ISS OVERVIEW', 'PROTOCOL DETAILS', 'KEY DATES', 'CONTRACT/REGULATORY DETAILS', and 'BUDGET/FUNDING'. The 'ISS OVERVIEW' tab is selected. On the left sidebar, there are 'Update' and 'Print / Print to PDF' buttons. The main content area shows a 'Details' section with 'Therapeutic Area: Obesity'. A red arrow points to the 'Print / Print to PDF' button.

Responding to a Request for Clarifications After Protocol Submission

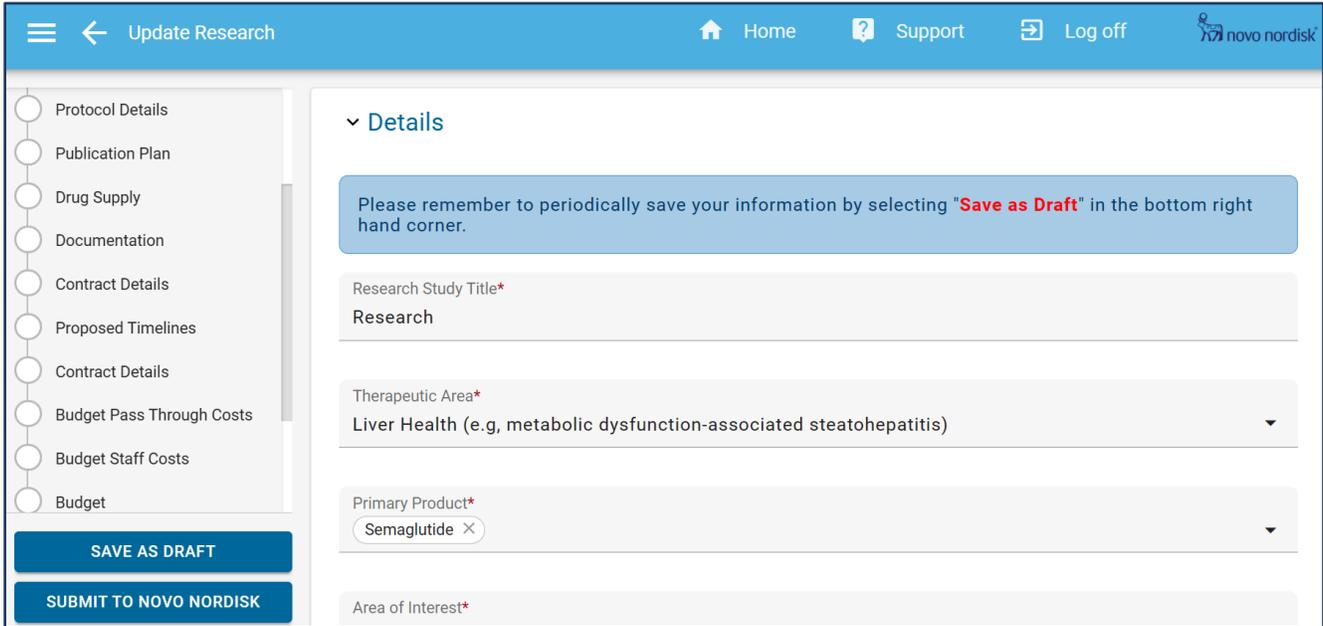
1. After your Protocol has been submitted, Novo Nordisk will start the review process. If clarifications are needed, you will be notified by email outlining the clarifications needed:



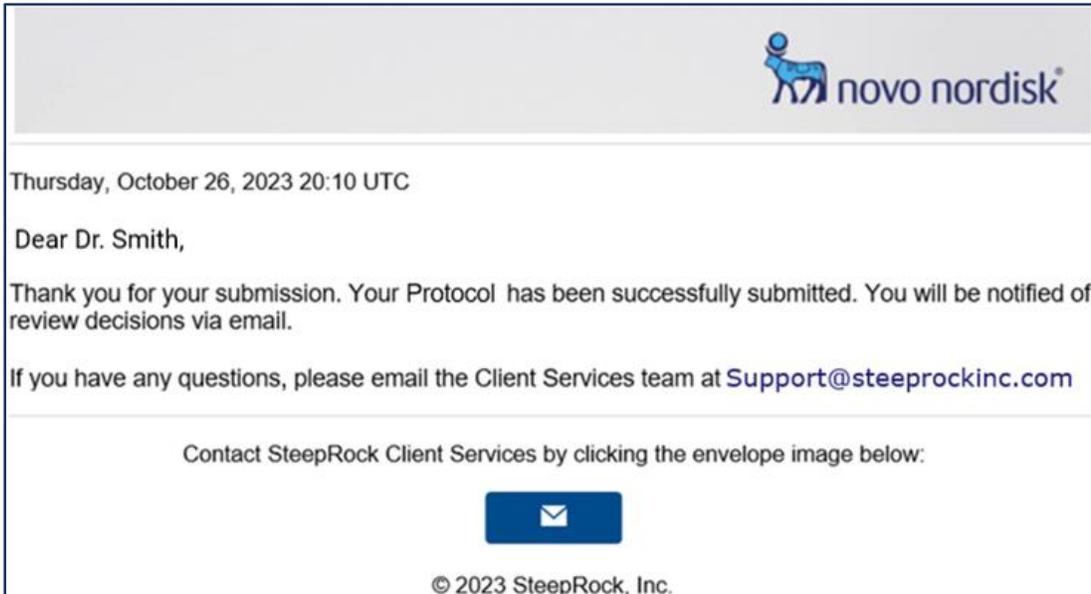
2. To respond to a request for clarifications, go to the ISS Portal Homepage, click the vertical ellipsis on the right-hand side of the IIS in the **My Submitted ISS** tile and select **Submit Clarifications**:



3. This will take you to the Edit ISS screen and allow you to update the information Novo Nordisk requested via email. Enter all the requested information and **SAVE AS DRAFT** or **SUBMIT TO NOVO NORDISK**.



4. Once you **SUBMIT TO NOVO NORDISK**, you will be notified by email:



5. The **Status** will now be **Protocol Resubmitted**.

My Submitted ISS		
Tracking #	Research Study Title	Status
ISS-001510	Research	Protocol Resubmitted

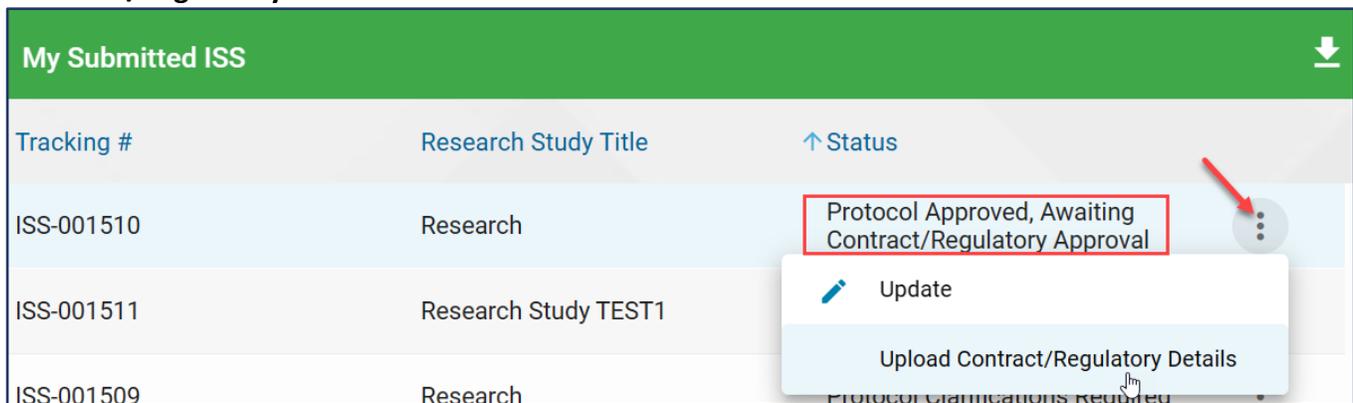
After Protocol Approval

Once your Protocol is approved, you will receive an email notification and you will be required to complete the **Contract/Regulatory Details**:



Contract/Regulatory Details

1. The **Status** will be **Protocol Approved, Awaiting Contract/Regulatory Approval**. You must click the vertical ellipsis on the right-hand side of the IIS in the **My Submitted ISS** tile and select **Upload Contract/Regulatory Details**.



2. The **Documentation** section is to enter the **Investigator IND #**, upload the **IND Letter/Waiver**, **IRB Letter**, and/or any other **Supporting Documents**.

Documentation

Investigator IND #

IND Letter / Waiver



IRB Letter*



An up to date IRB Letter is required prior to submitting a new payment request

This field is required.

Supporting Documents 0 +

<input type="checkbox"/>	Date Uploaded	Description	Document
There are no records to display.			

3. The **Contract Details** section is for uploading the **FDA IND Exemption Approval Ltr.**

Contract Details

FDA IND Exemption Approval Ltr



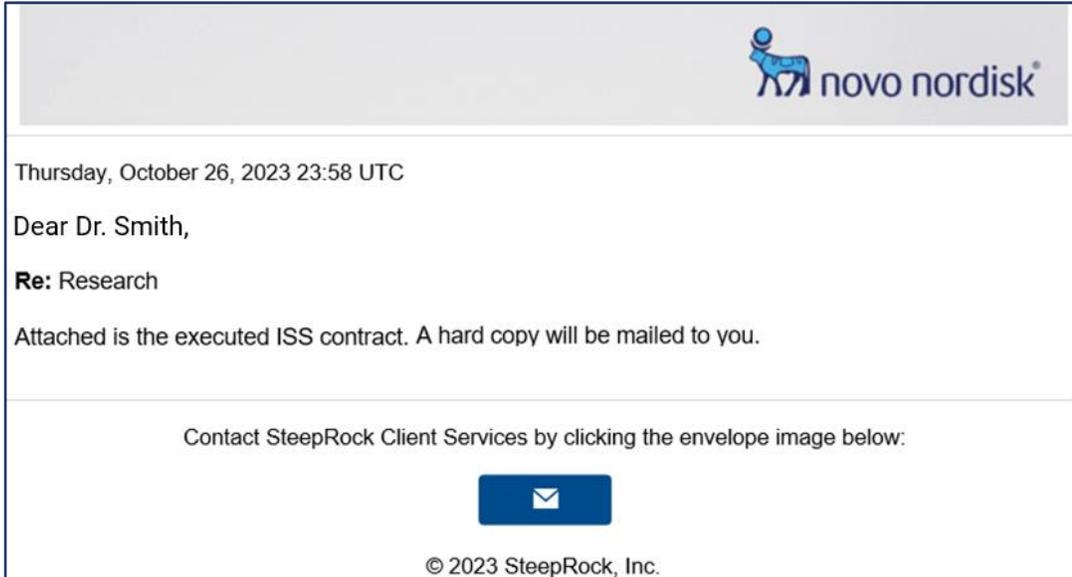
4. Once all applicable **Contract/Regulatory Details** have been uploaded the status will update to **ISS In Contracting**.

My Submitted ISS		
Tracking #	Research Study Title	↑ Status
ISS-001510	Research	ISS In Contracting

5. No actions will be available until you have the **ISS Draft Contract** completed/signed and returned to Novo Nordisk. Once the completed/signed version is received, the status will be **Contract Fully Executed**.

Contract Fully Executed:

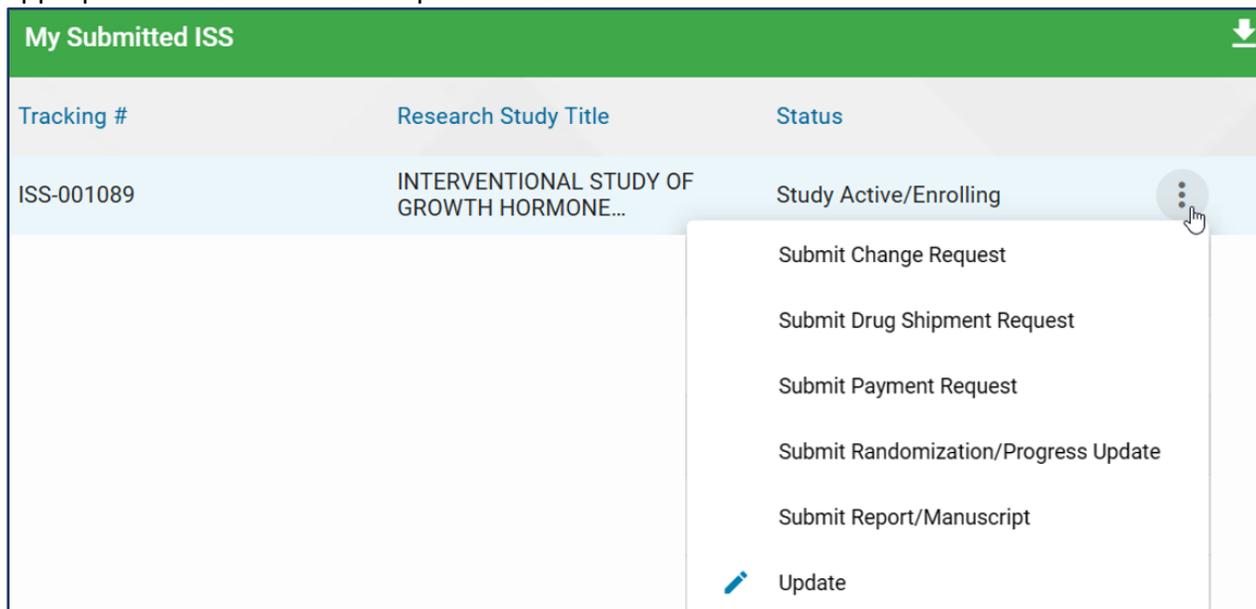
1. Once the contract is fully executed, you will receive an email notification.



Study Active/Enrolling

Once your contract has been fully executed, your study can start. Throughout the lifecycle of the ISS, you will be required to submit a **Protocol Change Request (e.g., for protocol amendments, budget amendments etc.)**, **Drug Shipment Requests**, **Payment/Milestone Requests**, **Randomization/Progress Updates**, or **Report/Manuscripts of Study Results** per the executed contract.

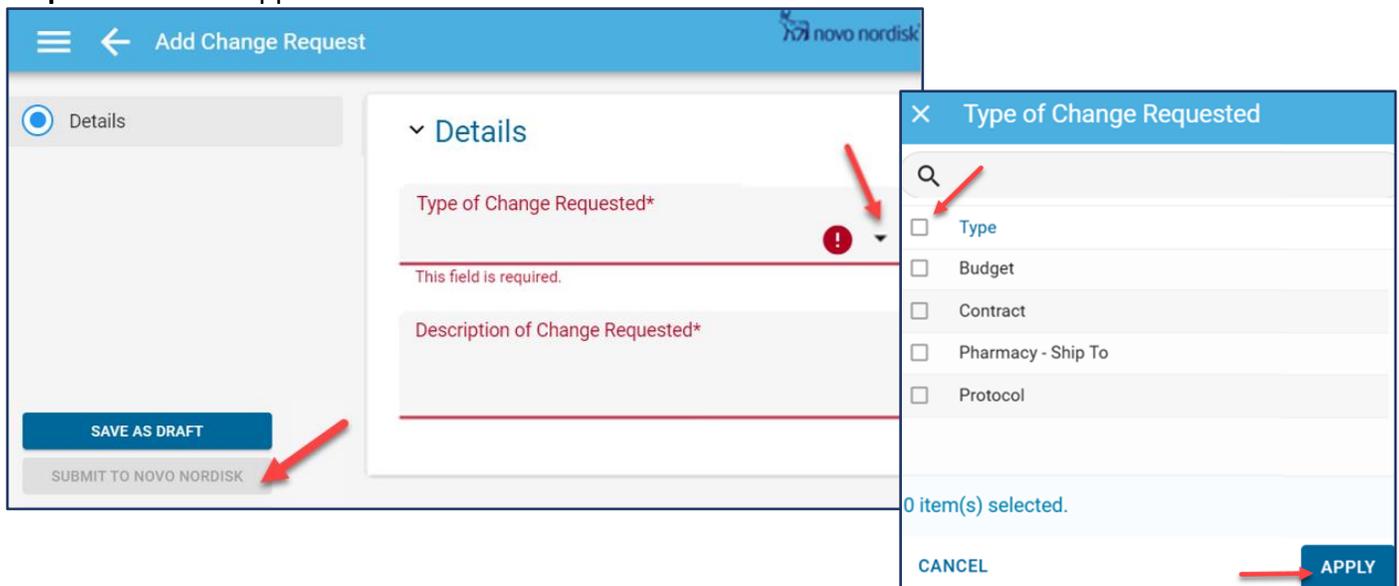
To complete any of these submissions, go to the **My Submitted ISS** tile on the homepage and choose the appropriate action from the dropdown menu.



Submitting a Change Request

1. Select **Submit Change Request** from the actions button of your ISS record.
2. You will be taken to the **Add Change Request** form. Enter a Description of Change Requested and select **Type of Change Requested**
 - **Budget Change Request:** Requires line item changes for your **Budget Pass Through Costs** or **Budget Summary**
 - **Contract Change Request:** Requires **Legal Contact** or **Institution** details information.
 - **Protocol Change Request:** Requires changes within the **Protocol Summary** information.

Once all required information for the **Change Request** has been entered, click **SUBMIT TO NOVO NORDISK** to submit the **Change Request** to the ISS Administrator. You will receive notification once the **Change Request** has been approved.



The screenshot shows the 'Add Change Request' form with a 'Details' section. The 'Type of Change Requested*' field is highlighted with a red exclamation mark and the text 'This field is required.' Below it is the 'Description of Change Requested*' field. At the bottom left are buttons for 'SAVE AS DRAFT' and 'SUBMIT TO NOVO NORDISK'. A dropdown menu is open for 'Type of Change Requested', showing options: Type, Budget, Contract, Pharmacy - Ship To, and Protocol. The 'APPLY' button is highlighted at the bottom right of the dropdown.

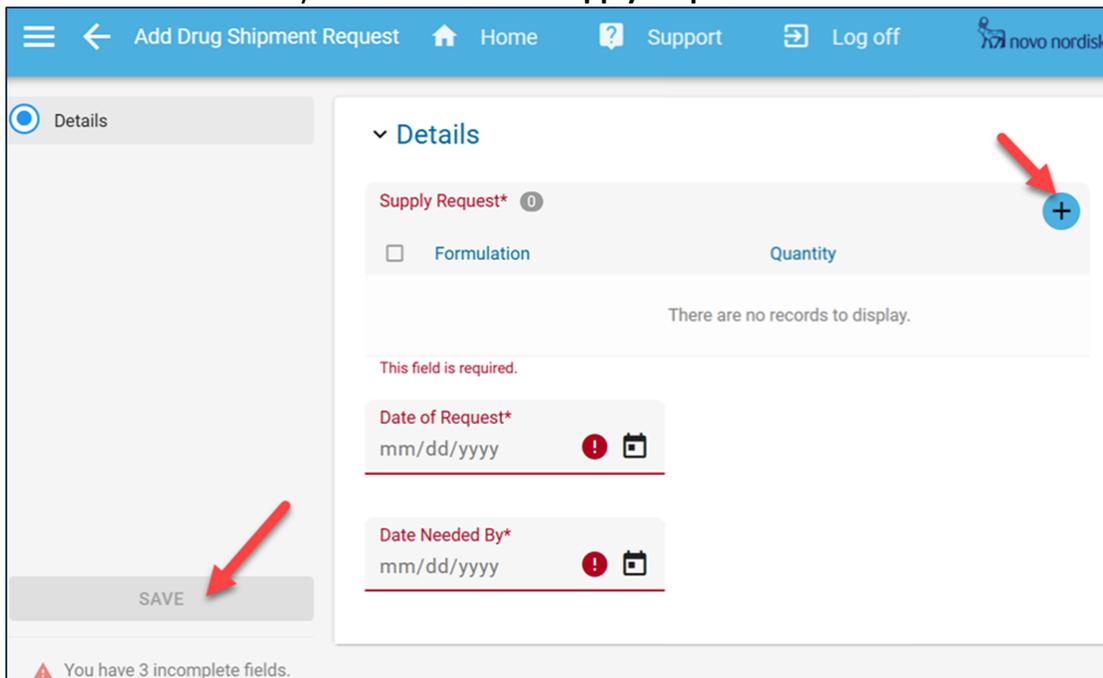
3. You will receive an email notification



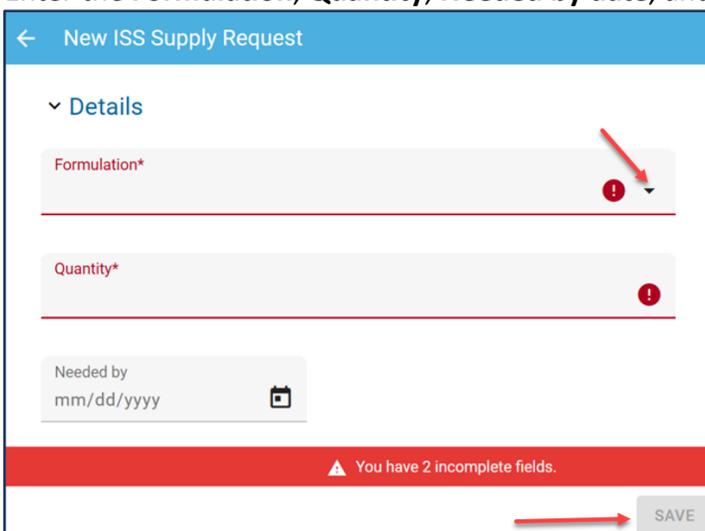
Submitting a Drug Shipment Request

Throughout the course of the study conduct, the Investigator may need to go into the ISS system and submit a drug shipment request for study drug, pen needles etc. Please submit request at least 4 weeks in advance of the **Date Needed By** to allow for processing and shipping time.

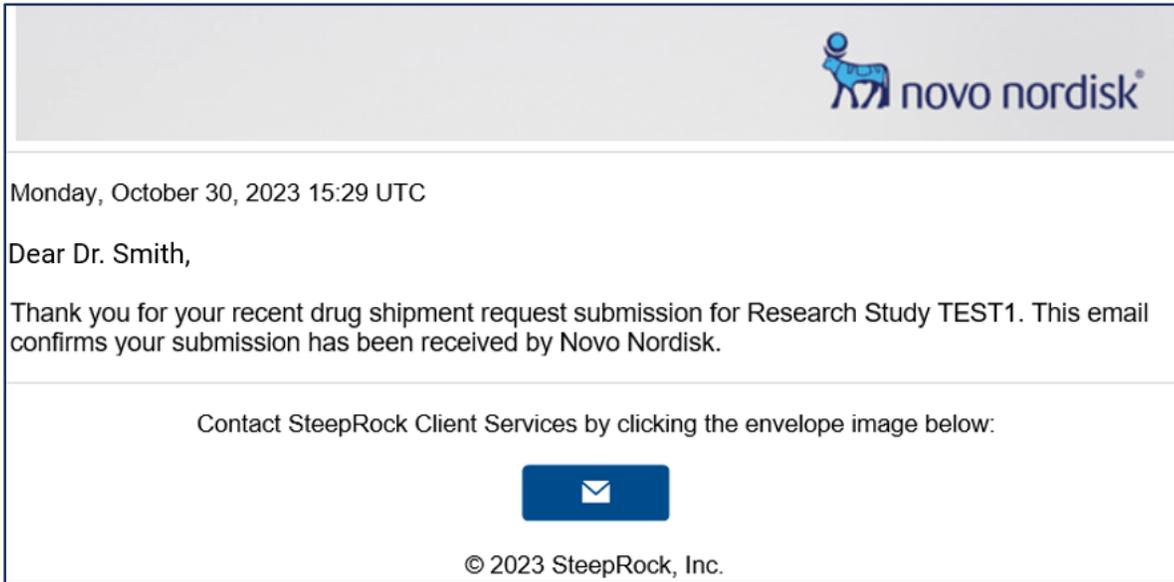
1. To submit a drug shipment request, select **Submit Drug Shipment Request** from the actions button of your ISS record.
2. This will bring you to the **Add Drug Shipment Request** tab. To add a new **Supply Request**, you must select the **+** icon which takes you to the **New ISS Supply Request** form.



3. Enter the **Formulation**, **Quantity**, **Needed by date**, and **SAVE**.

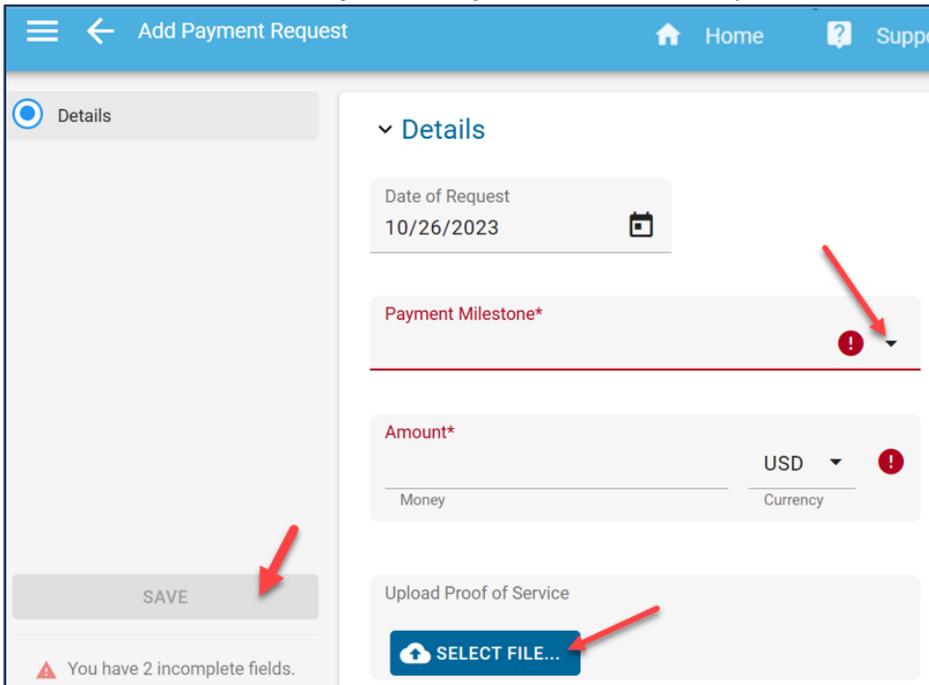


4. You will receive an email notification



Submitting a Payment Request

1. Select **Submit Payment Request** from your actions button of your ISS record.
2. Once selected you will be taken to the **Add Payment Request** form. Enter **Date of Request**, **Payment Milestone**, **Amount** requested and **Upload Proof of Service**. Once you have completed all required fields and selected **SAVE**, the **Payment Request** will be sent to your ISS Administrator.



3. If the IRB Letter on file was uploaded greater than 1 year ago, you will receive the below pop up message:

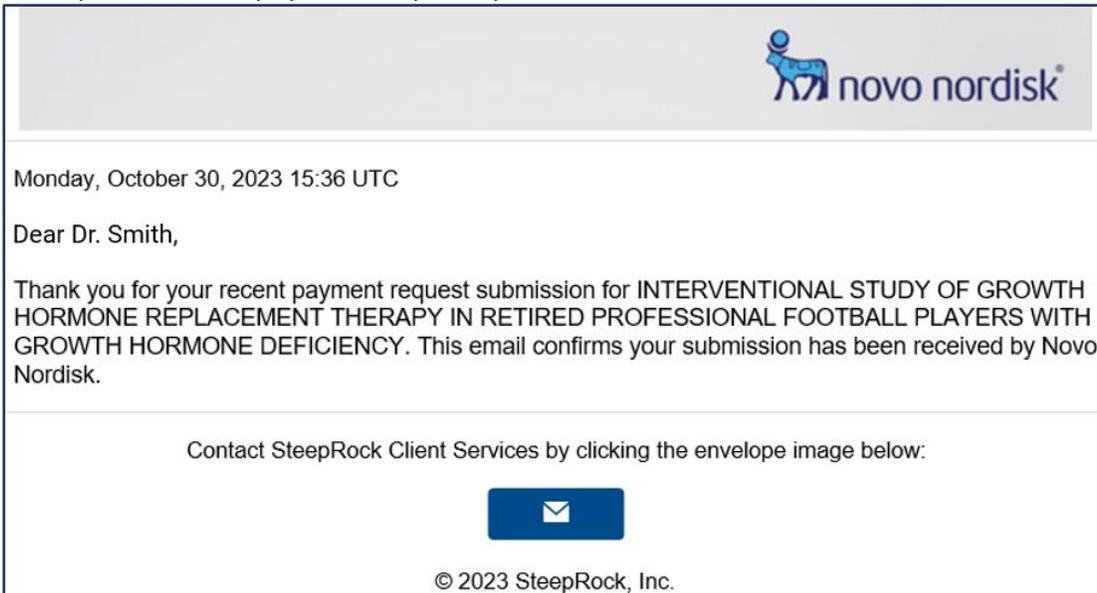
Your IRB letter is out of date. Please, update the study and upload a new IRB letter and IRB date. This must be completed prior to submitting a new payment request.

[CANCEL](#)

- To upload a new IRB Letter, **Update** the ISS, select **REPLACE**.

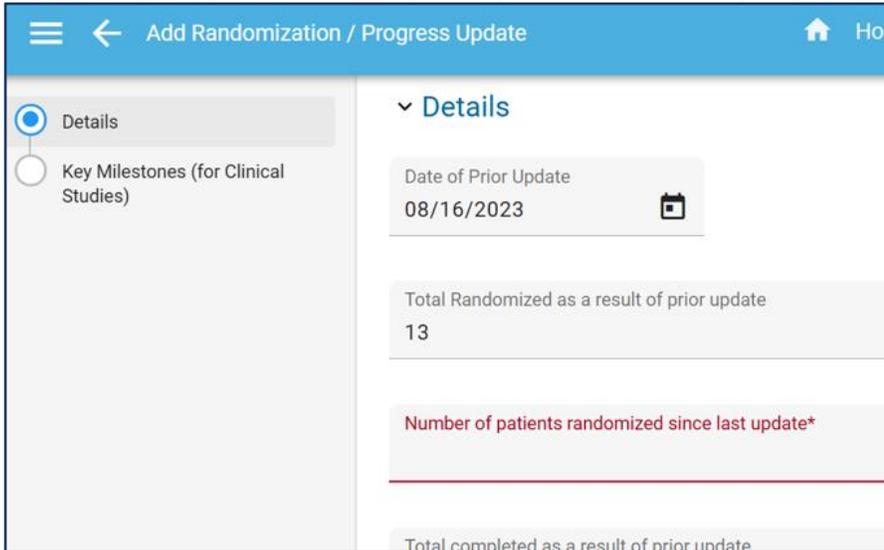


4. Once you **SAVE** the payment request, you will receive an email notification.



Submitting a Randomization/Progress Update

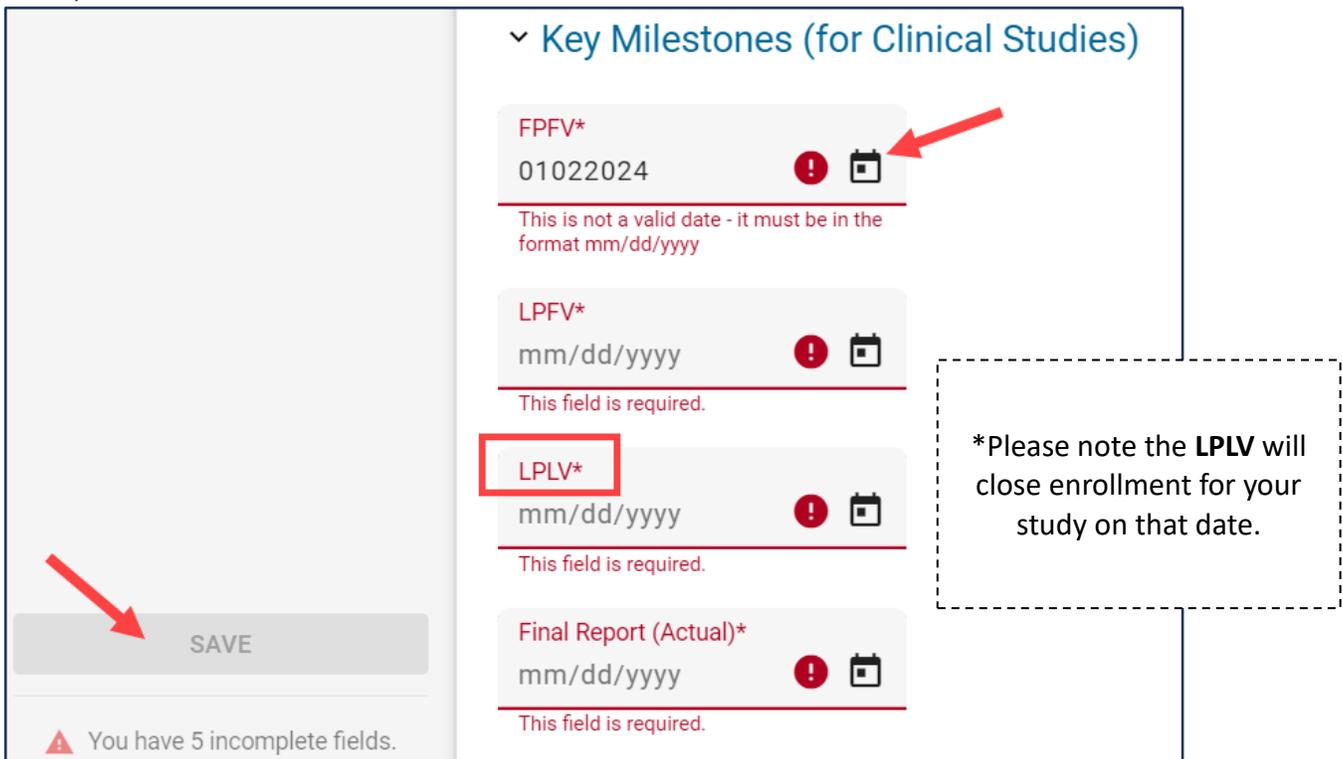
1. Select **Submit Randomization/Progress Update** from your actions button of your ISS record. Once selected you will be taken to the **Add Randomization/Progress Update** form. Under **Details**, enter **Date of Prior Update**, **Total Randomized as a result of prior update**, **Number of patients randomized since last update**, **Total completed as a result of prior update**, **Number of patients completed since last update**.



The screenshot shows the 'Add Randomization / Progress Update' form. The 'Details' section is expanded, showing the following fields:

- Date of Prior Update:** 08/16/2023
- Total Randomized as a result of prior update:** 13
- Number of patients randomized since last update*:** (field is empty)
- Total completed as a result of prior update:** (field is empty)

2. Under **Key Milestones (for Clinical Studies)**, enter **FPFV** (first-person-first-visit), **LPFV** (last-person-first-visit), **LPLV** (last-person-last-visit), and **Final Report (Actual)** dates. Once you have completed all required fields, select **SAVE**.



The screenshot shows the 'Key Milestones (for Clinical Studies)' section of the form. The following fields are visible:

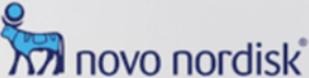
- FPFV*:** 01022024. A red arrow points to the date field, and a red error message below it states: "This is not a valid date - it must be in the format mm/dd/yyyy".
- LPFV*:** mm/dd/yyyy. A red error message below it states: "This field is required.".
- LPLV*:** mm/dd/yyyy. A red box highlights the field, and a red error message below it states: "This field is required.".
- Final Report (Actual)*:** mm/dd/yyyy. A red error message below it states: "This field is required.".

A red arrow points to the **SAVE** button at the bottom left. A dashed box on the right contains the text: "*Please note the **LPLV** will close enrollment for your study on that date." At the bottom left, a warning icon and text state: "You have 5 incomplete fields."

- The **Randomization/Progress Update** can be viewed on the **PROGRESS/RANDOMIZATION** tab.

REGULATORY DETAILS	BUDGET/FUNDING	DRUG SUPPLY	PROGRESS/RANDOMIZATION
Randomization / Study Updates			
Update Date	Number of patients randomized since last update	Number of patients completed since last update	
07/28/2023	1		
08/16/2023	1		
08/16/2023	0	1	
11/08/2023	20		

- You will receive an email notification.



Monday, October 30, 2023 15:30 UTC

Dear Dr. Smith,

Thank you for your recent study update submission for Research. This email confirms your submission has been received by Novo Nordisk.

Contact SteepRock Client Services by clicking the envelope image below:

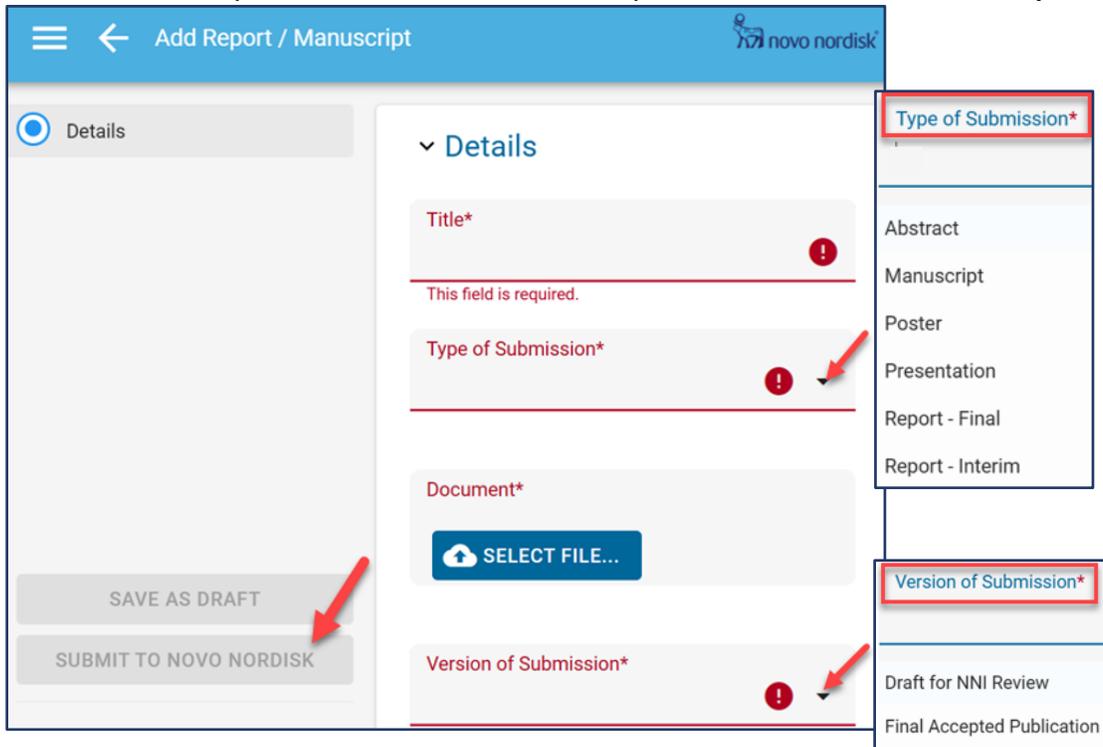


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Submitting a Report/Manuscript

Throughout the course of the study conduct, the Investigator will decide to communicate and/or present the results of the ISS study. Please note that Investigators are required per the ISS contract to submit any planned communication/presentation (e.g., abstract, poster manuscript, social media post, news article/interview etc.) to NNI for review 60 days ahead of the Investigator’s own deadline.

1. To submit an ISS communication/presentation for NNI review, select **Submit Report/Manuscript** from your actions button of your ISS record. Once selected you will be taken to the **Add Report/Manuscript** tab.



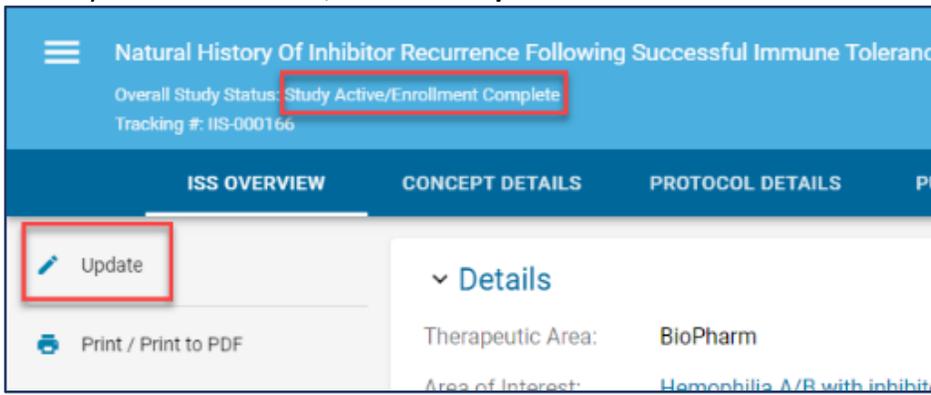
2. You will receive an email notification.



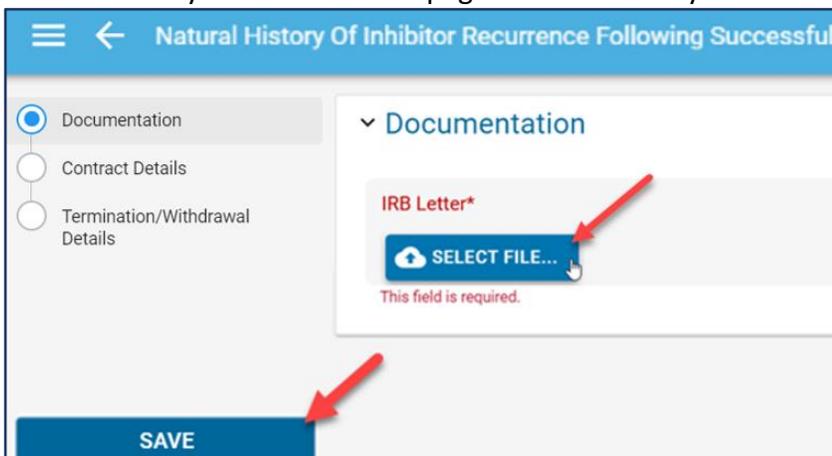
Replace IRB Approval Letter Prior to Study Close

The IRB can be updated once study is approved and prior to closed status.

1. From your **ISS Overview**, select the **Update** button.



2. This will take you to the Edit ISS page. Select the file you would like to upload and **SAVE**.



Study Close-out

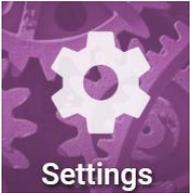
Your study will remain active until all Progress Payments have been requested for all milestones and paid, all enrollment/progress updates have been submitted, all drug supply requests have been approved and shipped. Your ISS Administrator will inform you that your Final Payment will be made once you have provided them with a Budget Reconciliation document.

1. Once all close-out documentation has been reviewed and approved your **Overall Study Status** will be changed to **Study Closed**.



Settings

This tile allows you to update your profile and change your password.

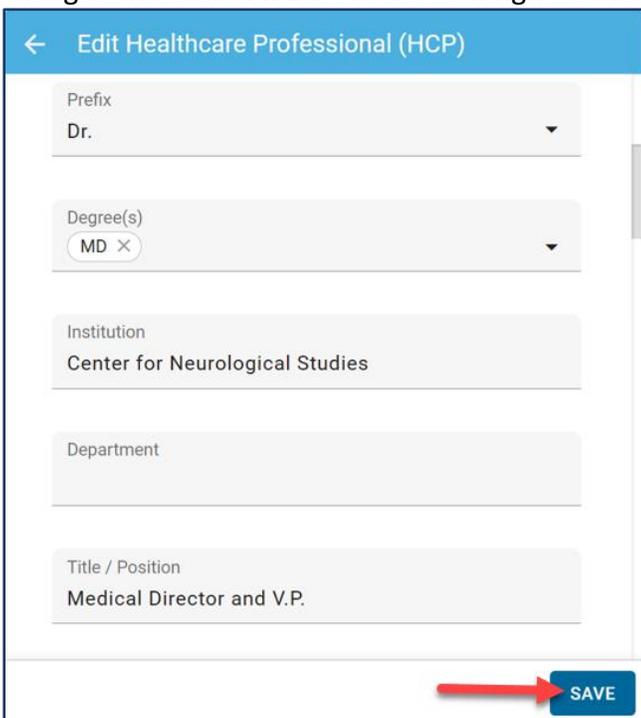


My Profile

This tile allows you to update your contact information and language preference



Clicking **My Profile** will display the information for the logged in user in edit mode. Make any necessary changes and click **SAVE** at the bottom right corner.

A screenshot of a mobile application form titled "Edit Healthcare Professional (HCP)". The form has a blue header with a back arrow on the left. Below the header, there are several input fields: "Prefix" with a dropdown menu showing "Dr."; "Degree(s)" with a dropdown menu showing "MD" and a close button; "Institution" with a text field containing "Center for Neurological Studies"; "Department" with an empty text field; and "Title / Position" with a text field containing "Medical Director and V.P.". At the bottom right of the form, there is a blue "SAVE" button with a red arrow pointing to it.

Change Password

This tile allows you to change your password.



Enter a Password, confirm the password by entering it again, then click **SAVE** in the bottom right corner.

Change Password

Your password must contain at least 6 characters and include at least one uppercase character, one lowercase character and one number. The new password may not be the same as the previous password.

This field is required.

CANCEL
SAVE

Help and Training

This tile contains this guide as well as any other helpful documentation.



Date	Description	File
12/01/2023	Investigator Guide	v9 NNI ISS Investigator User Guide.docx
09/21/2023	ISS Budget Template	NNI_ISS Budget Template_2023_Final.xlsx
09/21/2023	ISS Protocol Template	NNI_ISS Protocol Template_2023_Final.docx

Helpful Settings

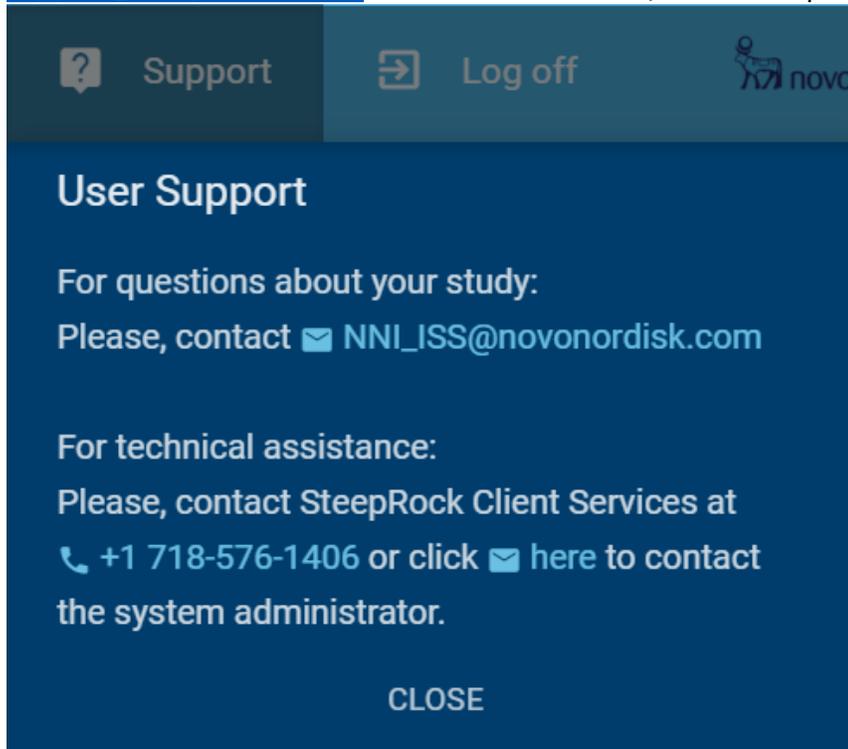
Pop-up windows must be allowed for certain features on the site to work.

- **MS Internet Explorer**
 1. Select the 'Tools' tab.
 2. Scroll down to 'Pop-up Blocker.'
 3. Select 'Pop-up Blocker settings.'
 4. Type '*.steeprokin.com' into the 'Address of website to allow:' field.
 5. Select 'Add' and 'Close.'
- **Firefox**
 1. Select the 'Tools' tab.
 2. Select the 'Content' tab.
 3. Select 'Pop-ups' 'Exceptions' button across from the 'Block pop-ups windows' check box.
 4. Type '*.steeprokin.com' into 'Address of website:' field.
 5. 'Save Changes.'
- **Chrome**
 1. Select the Chrome menu hamburger icon button on the top right-hand side.
 2. 'Settings.'
 3. 'Show Advanced Settings.'
 4. Under 'Privacy,' select 'Content Settings.'
 5. Under 'Pop-ups,' select 'Manage Exceptions.'
 6. Type '*.steeprokin.com' into the 'Hostname pattern' field.
 7. 'Done.'
- **Safari**
 1. Select the 'Safari' tab.
 2. Select 'Preferences' and 'Security.'

Support

For additional information about your study please speak with your Novo Nordisk Medical Liaison or email NNI_ISS@novonordisk.com.

For technical issues or training information please contact SteepRock Client Services at support@steeprocks.com or Call: 718-576-1406, M-F 9am-8pm EST.



The screenshot shows a dark blue modal window with a header bar. The header bar contains a question mark icon, the text "Support", a right-pointing arrow icon, the text "Log off", and the Novo Nordisk logo. The main content area of the modal is titled "User Support" and contains two sections of text. The first section is for study-related questions, directing users to email NNI_ISS@novonordisk.com. The second section is for technical assistance, directing users to call +1 718-576-1406 or click a link to contact the system administrator. A "CLOSE" button is located at the bottom right of the modal.