# INVESTIGATOR SPONSORED REASEARCH (ISR)

# Step-by-Step System Process and System User Guide

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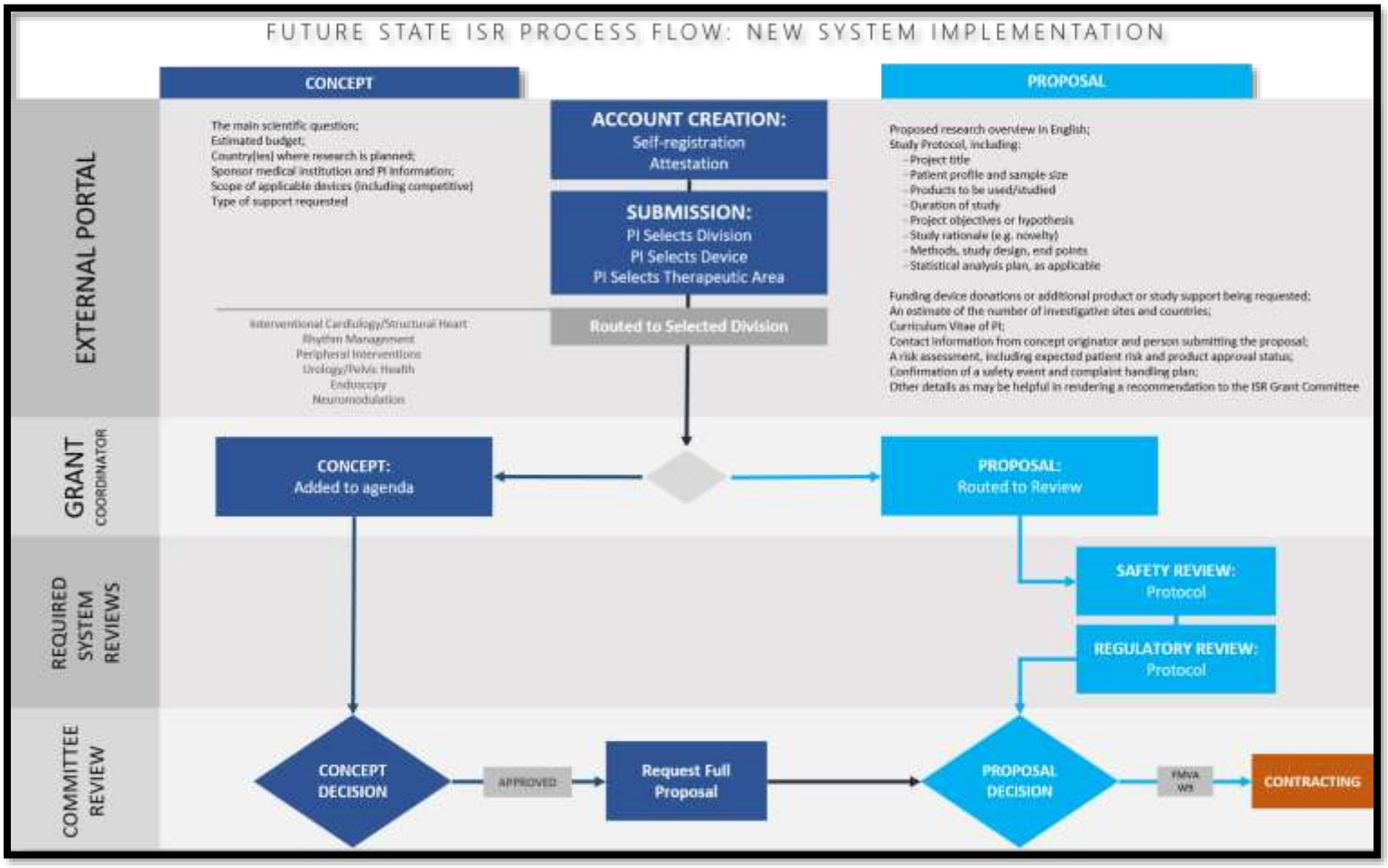
# 1. Submission process summary and flow




## Submission Process Summary:

1. Access the ISR portal https://qa-bsc-isr-portal.corp.idea-point.com/
2. Click "Log-In" on the right corner of the screen (see p. for further detail)
    a. Upon successful sign on, you will arrive at your ISR home page. From the home page you are able to:
        - Edit your profile
        - Create a new submission
        - View in progress submissions

3. Select Create Submission
    a. You have the option of submitting to the ISR committee as a concept first, or go directly to a full proposal:
        i. Concept - a high level summary of the research for which you would like support with a rough budget; submitted to get committee feedback prior to investing your time in a full proposal. (recommended for most submissions)
        ii. Proposal - a detailed description of the research for which you would like support including protocol and line-item budget.
    b. Attach required files
    c. Submit
4. The Investigator Sponsored Research Committee will review and a BSC representative will contact you following the next committee meeting with a decision and next steps.

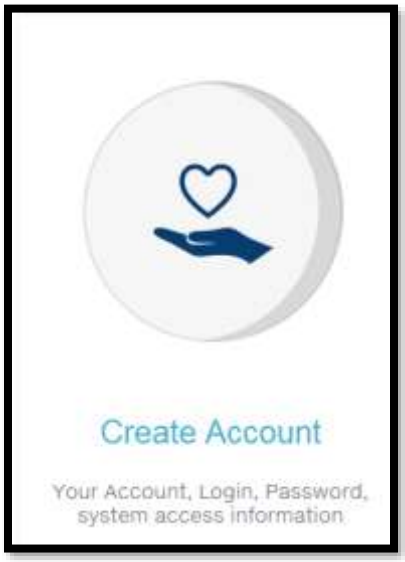
## 2. Home Page

The ISR website URL address is: https://qa-bsc-isr-portal.corp.idea-point.com/

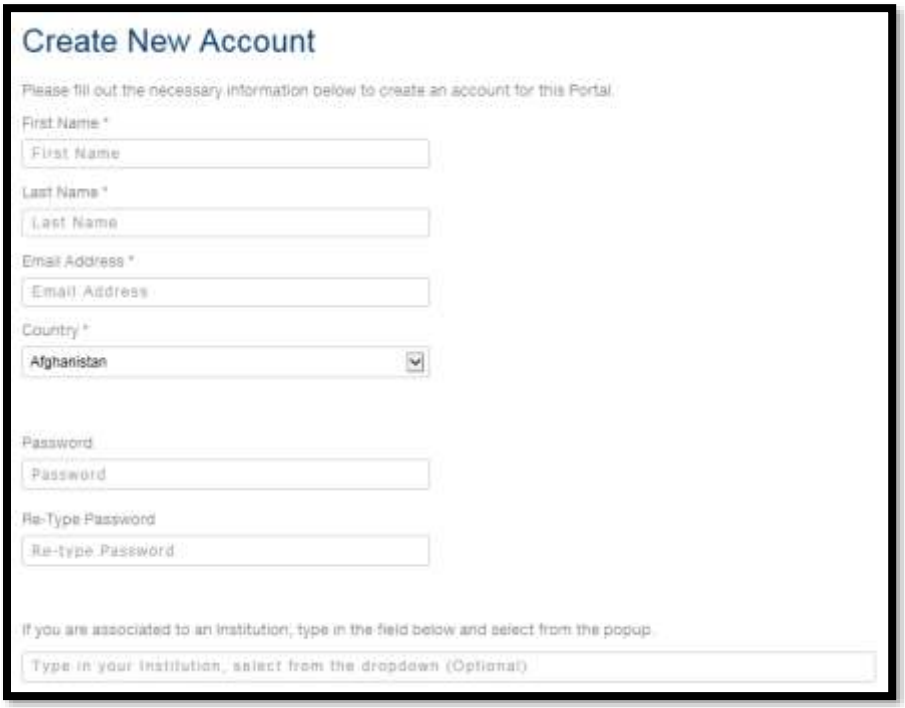
## 3. Registration

If you do not already have a user ID and password to the ISR website:

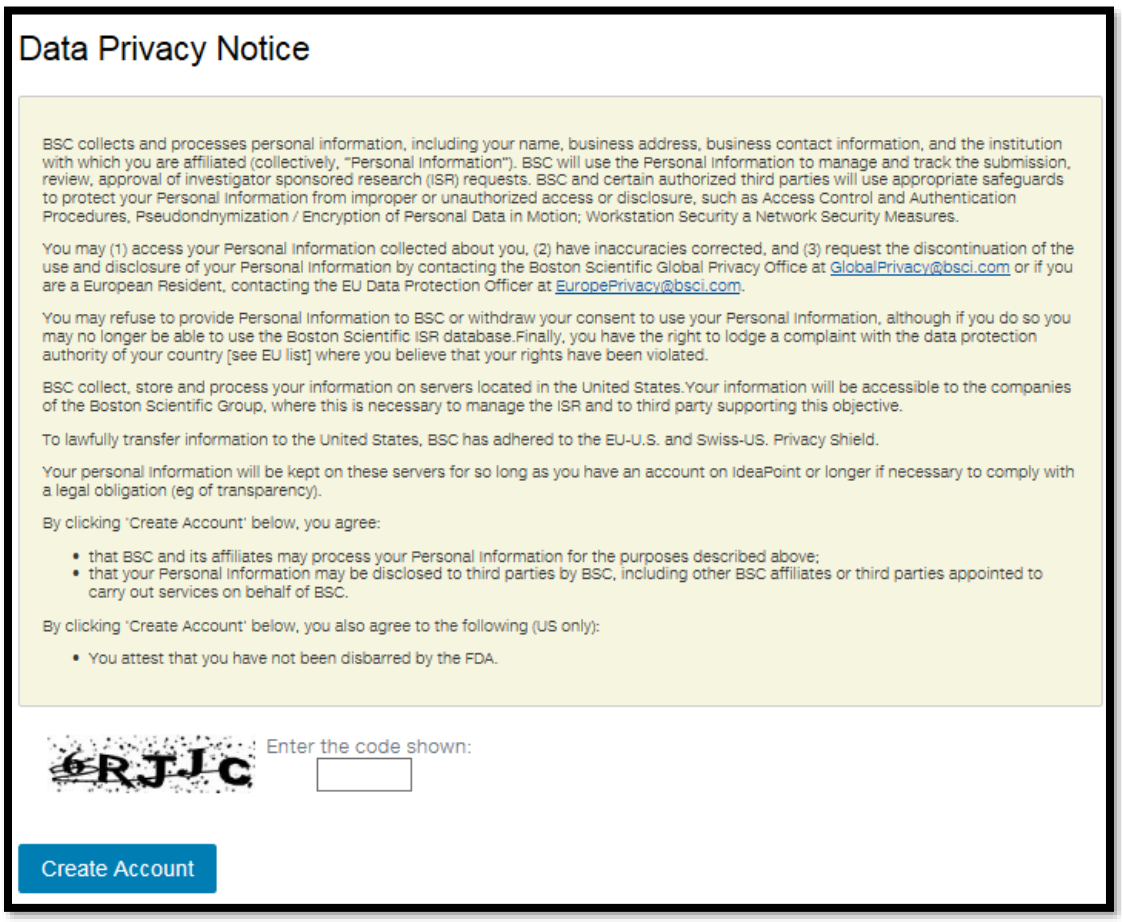
1. Click the "Create Account" link from the sign on page.



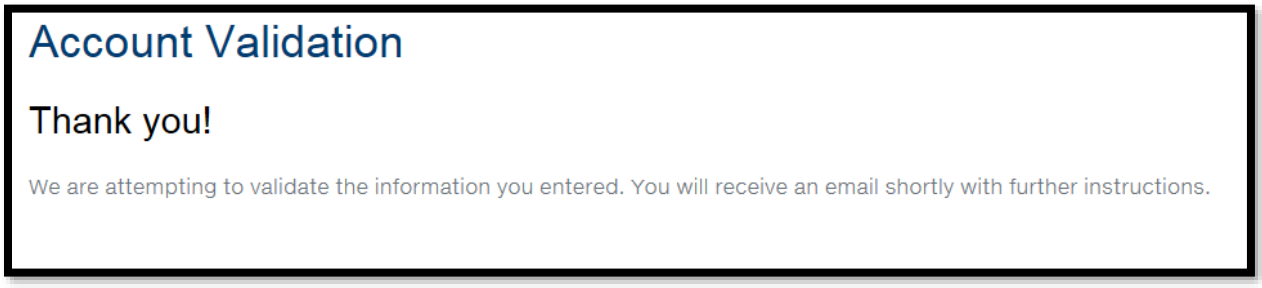

2. Fill in all the required fields.



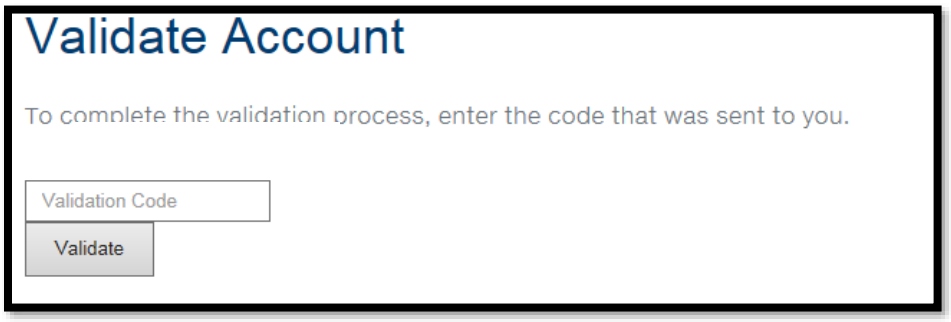
3. Enter Data Privacy Notice code shown on your screen and click on Create Account.



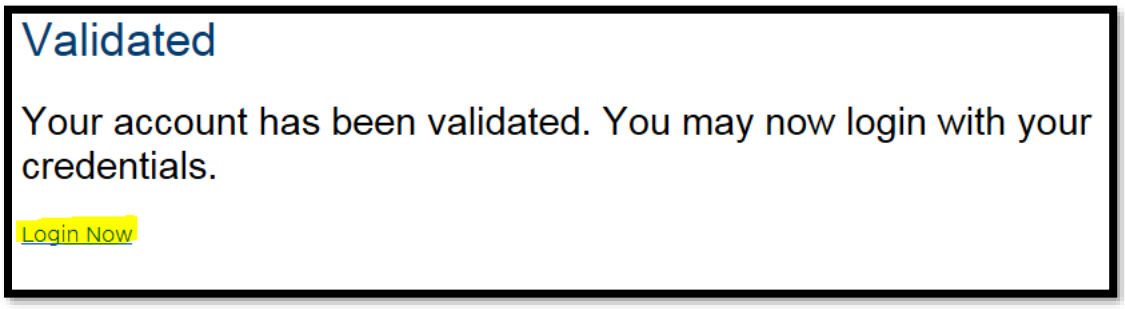

Once you have successfully created your account, the following message will appear:



4. You will receive an email notification from no-reply@idea-point.com to continue the process of your account.
    a. Click on the link and enter your validation code.

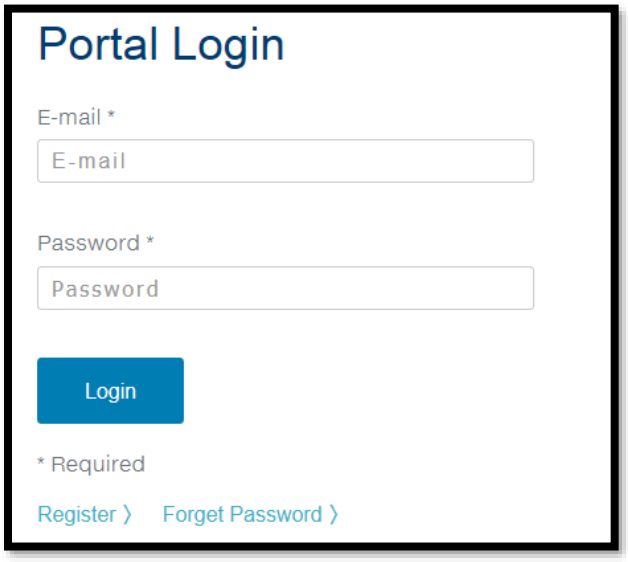



5. Once your account is validated you can Login to the system by simply clicking on **Login Now**



## 4. Sign on & Password Reset

Enter your email and password into the designated area fields of the sign on page.



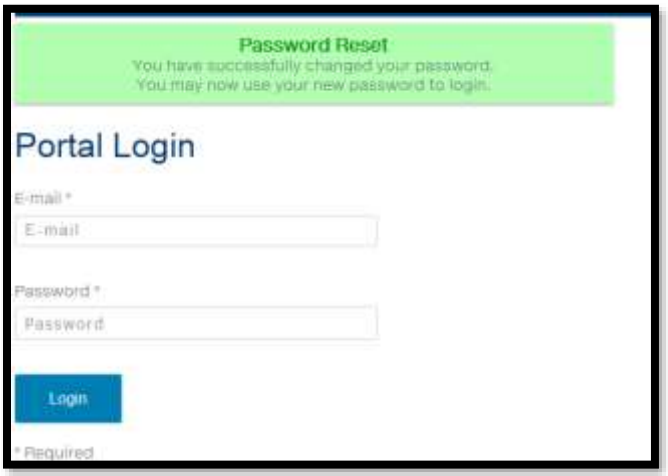

### Password Reset

1. To retrieve your password, click on "Forget Password"
2. Enter your Email address and the provided code shown and click Submit.

3. An email with your Reset code will arrive shortly, once received you need to enter the code that was sent to you and click on Validate

4. You can now enter a new password and click on Save Password.

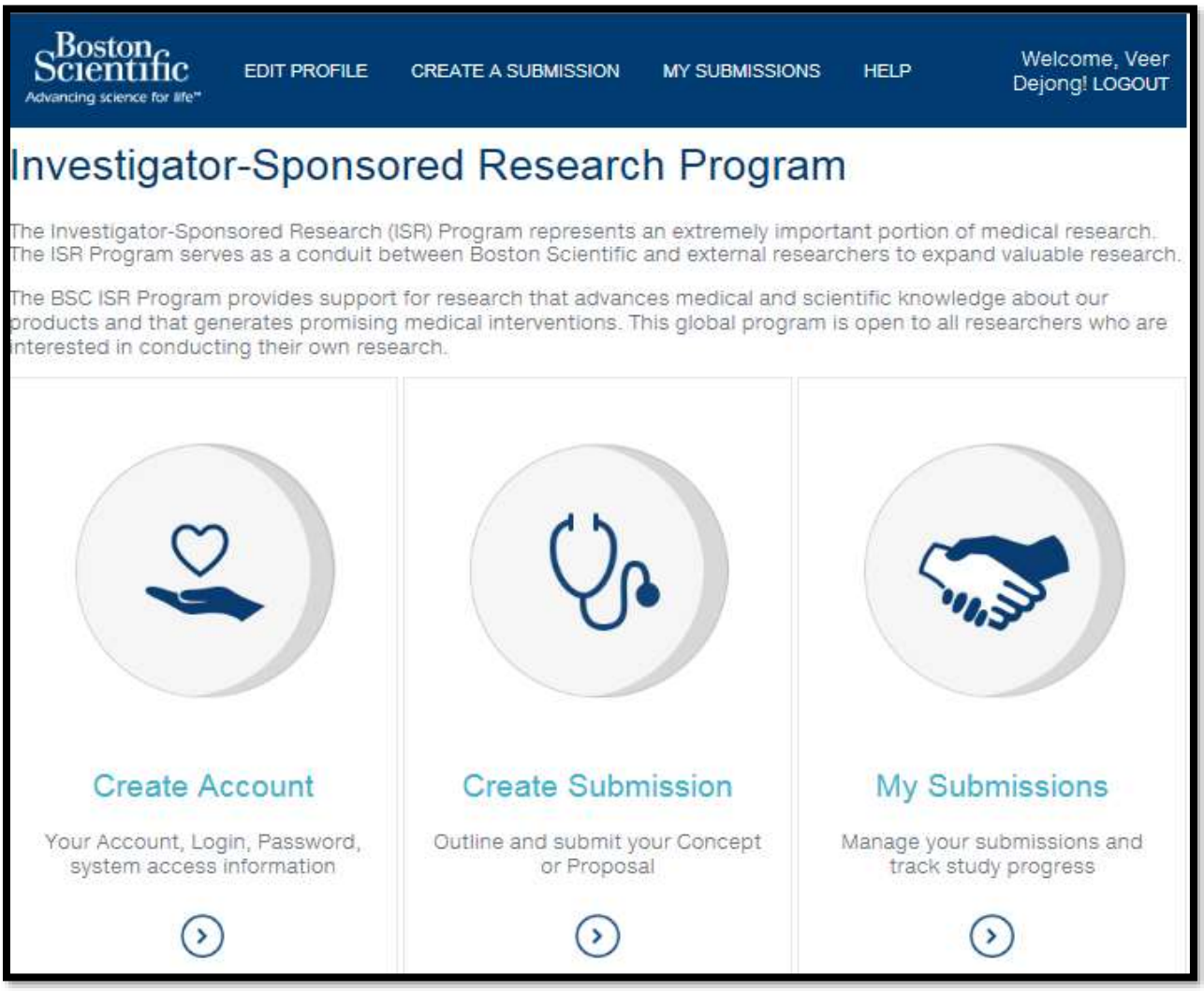
**5.** Once your password has been successfully saved you will be guided back to the login page.



## 5. Home Page Navigation

Upon successful sign on, you will arrive at your ISR home page. From the home page you can:

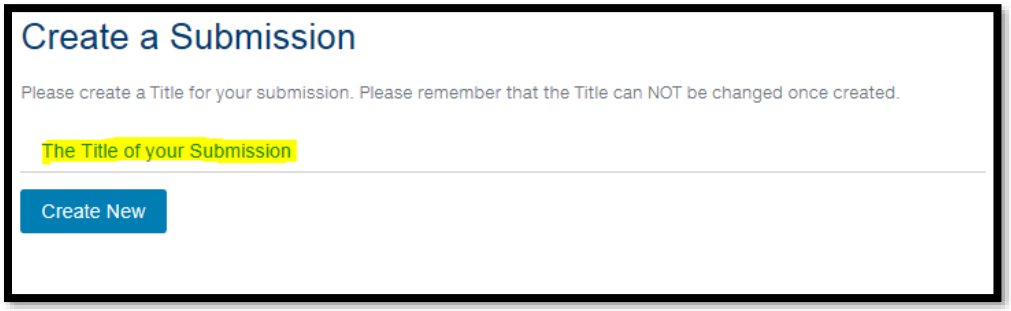
- Edit profile
- Create a submission
- View in progress submissions
- Request Help
- Log out



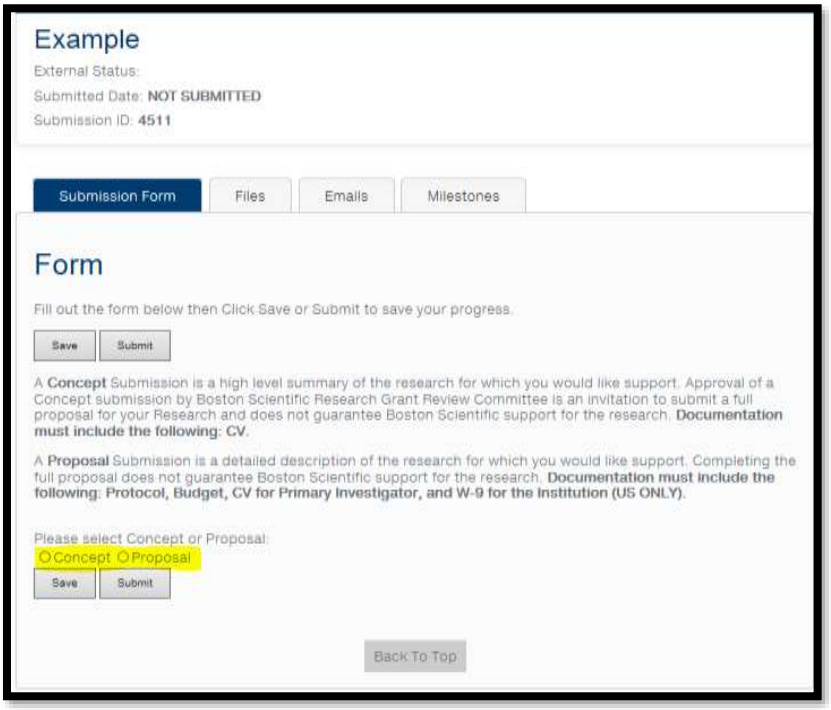
## 6. Submit New Study Request

To submit a new study

1. Select "Create Submission"
2. Enter The Title of your Submission and select "Create New"



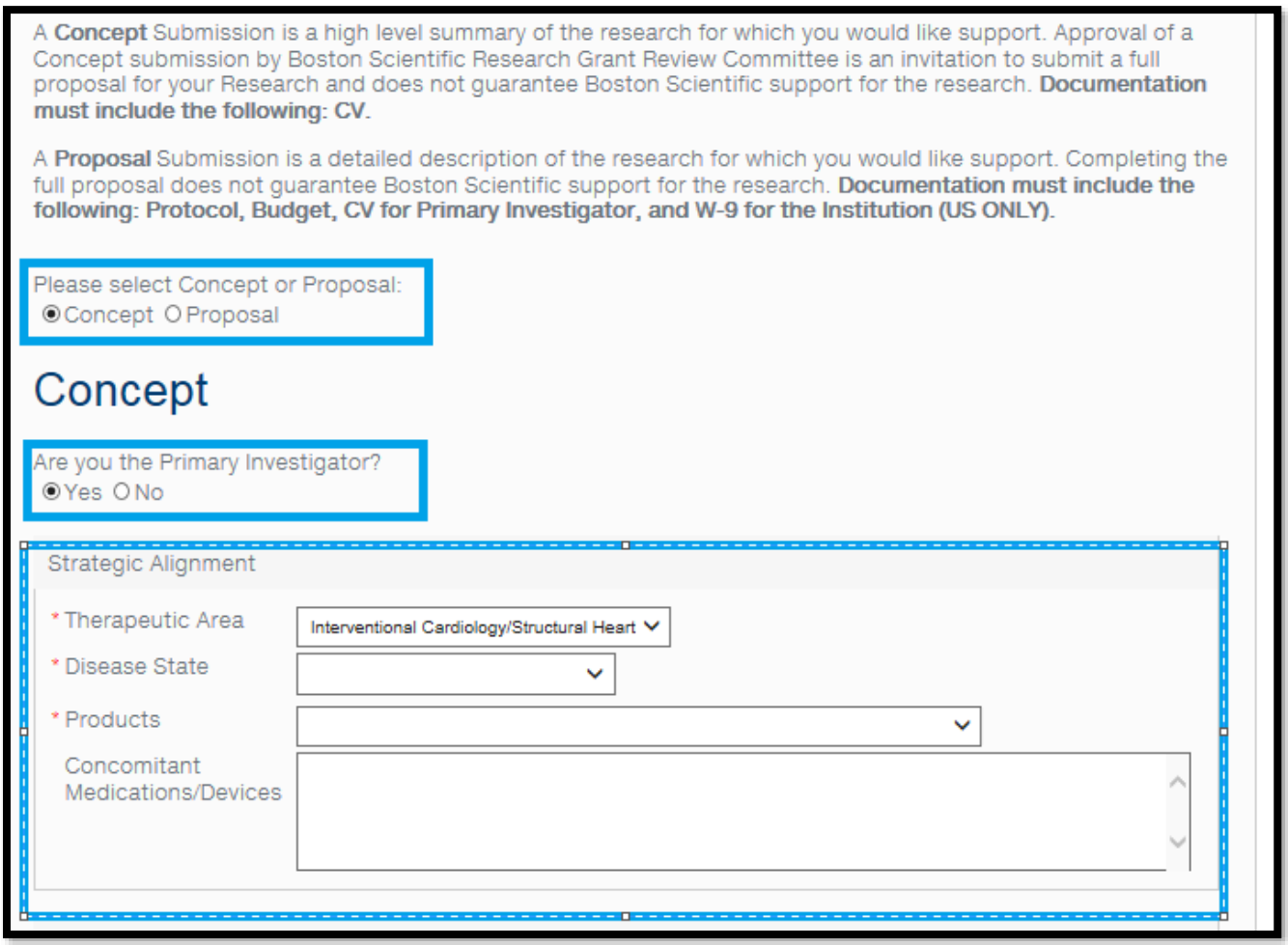

You will be taken to a page in which you can choose to submit a concept or a proposal. It is recommended to submit a concept prior to submitting a full proposal if possible. Submitting a concept will allow Boston Scientific to review your submission at a high level. If your study fits current Boston Scientific areas of interested and is strategically aligned, the committee would request a full proposal submission.



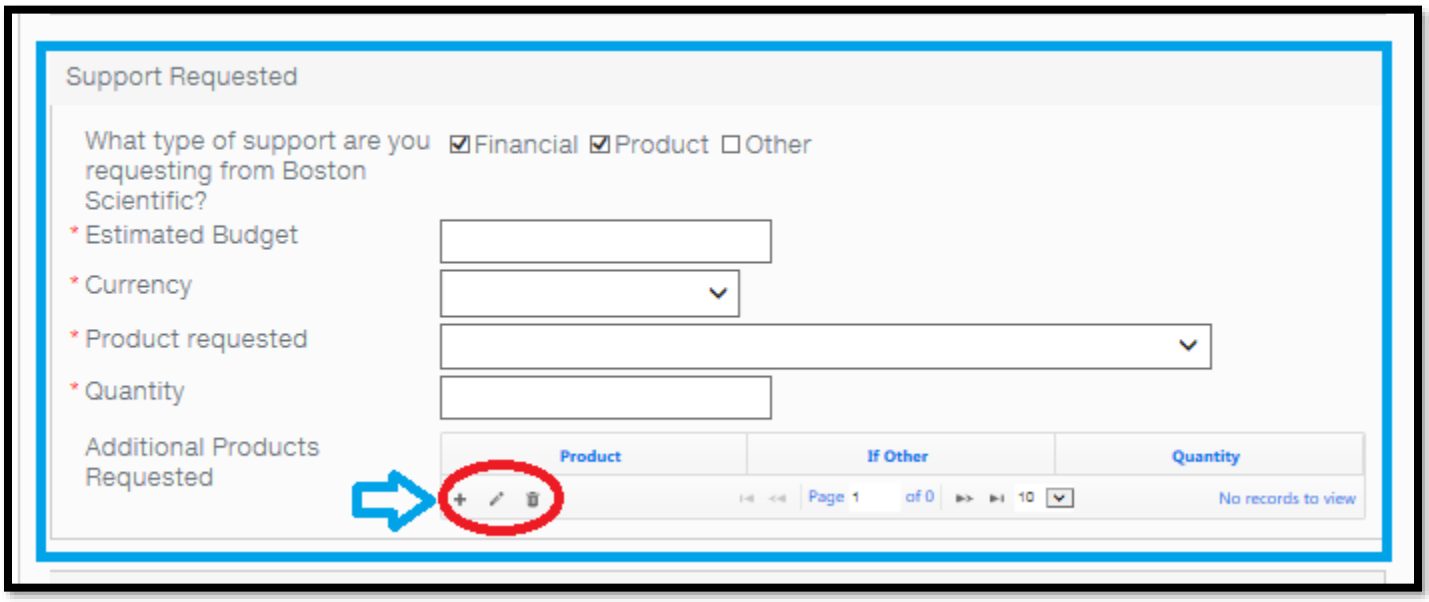
## 6a. Concept submission

To submit a concept:

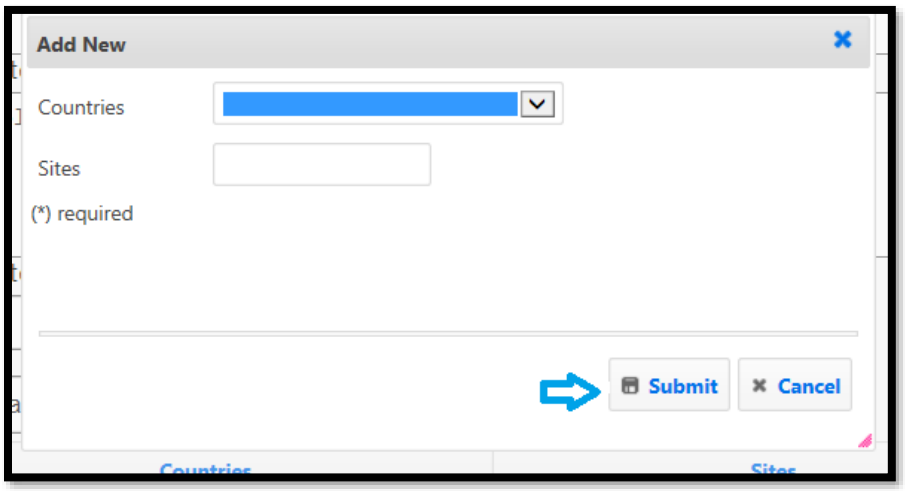
1. Select Concept
2. Indicate if you are the Primary Investigator by selecting Yes or No.
3. Select Therapeutic Area (Dropdown list)
4. Select Disease state
5. Select Products
6. Fill in Concomitant Medications/Devises as applicable.



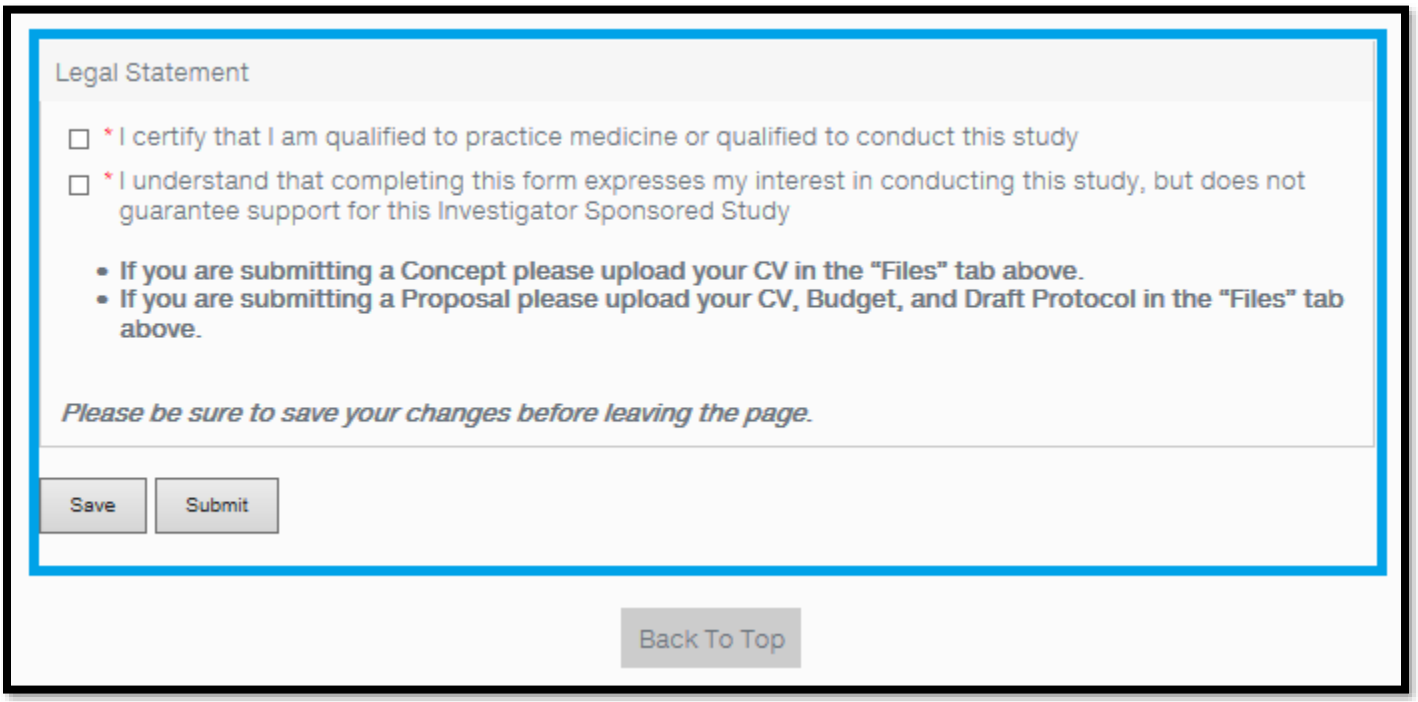
7. Check the box(s) for type of support you are requesting
    - To add additional products, click on the + button, another screen will appear where you can choose from a dropdown list.
    - Once the additional product is requested please add the quantity.
    - To enter more products, repeat this process.



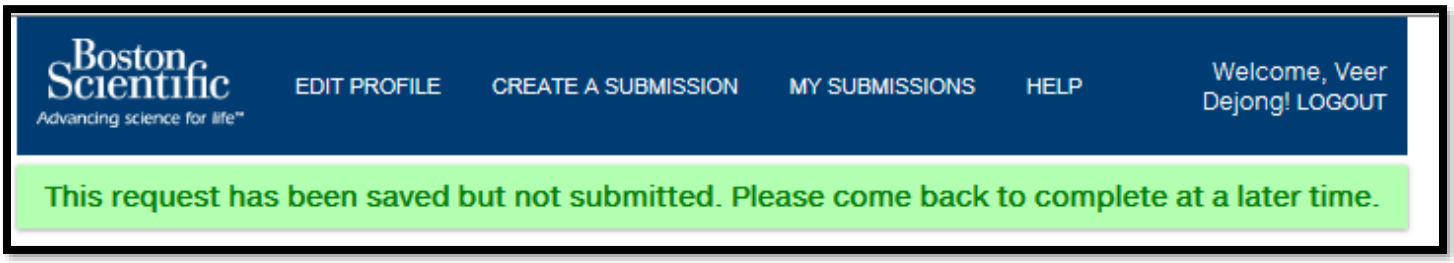
8. Fill in the Study Summary Section and provide:
    - Main Scientific Question.
    - Study Design
    - Projected number of subjects
    - Primary country. I
        - To add **other Sites and/or Countries**, click on the **+** button, another screen will appear where you can choose other countries from a dropdown list and enter the site name(s).
        - Once the country and site are selected you must select submit.
        - To enter more countries and sites, repeat this process.



9. Legal Statement:
    - Read legal statements
    - Acknowledge the statements by checking the box's
10. **Click the Save button**.

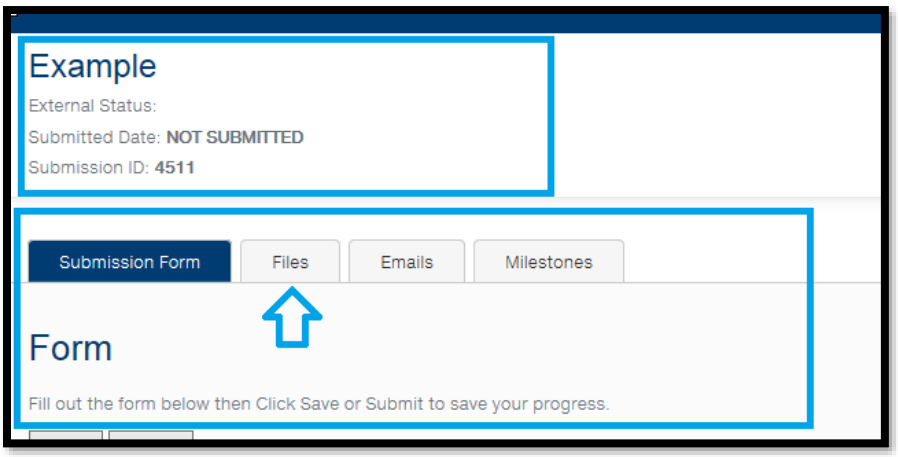



You will know your Concept has been successfully saved when the below message appears and your Concept receives a unique Submission ID number.

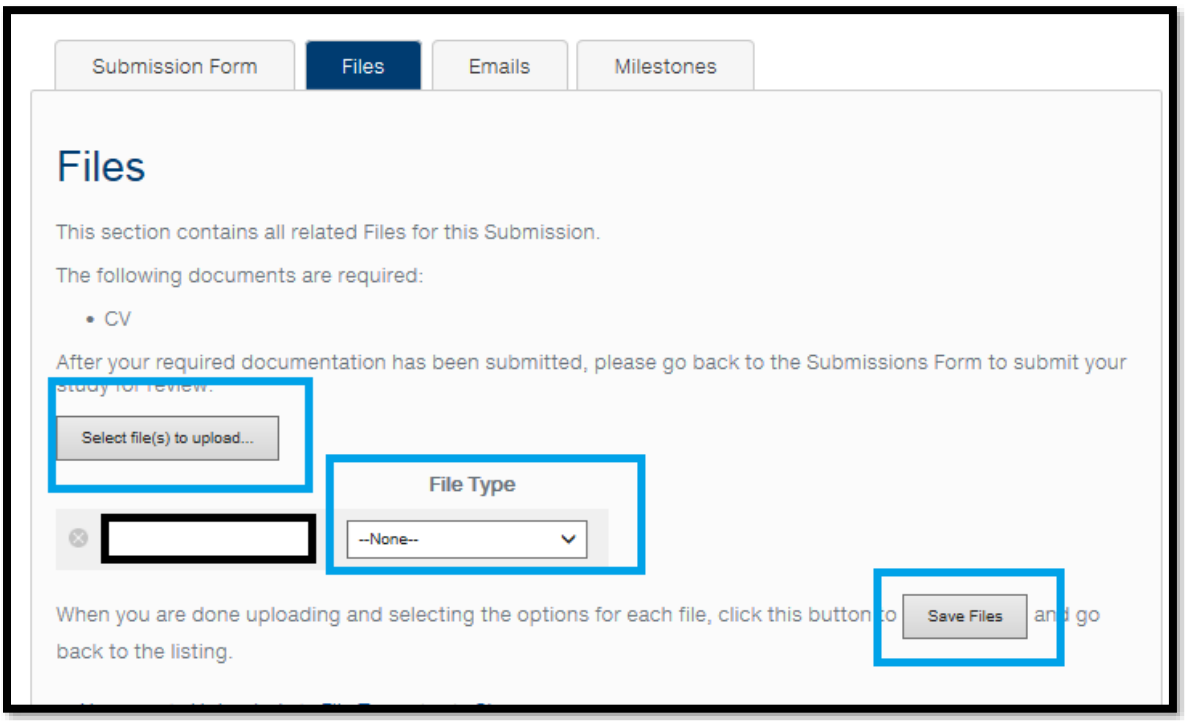


The final step required before submission is complete is to upload your CV.

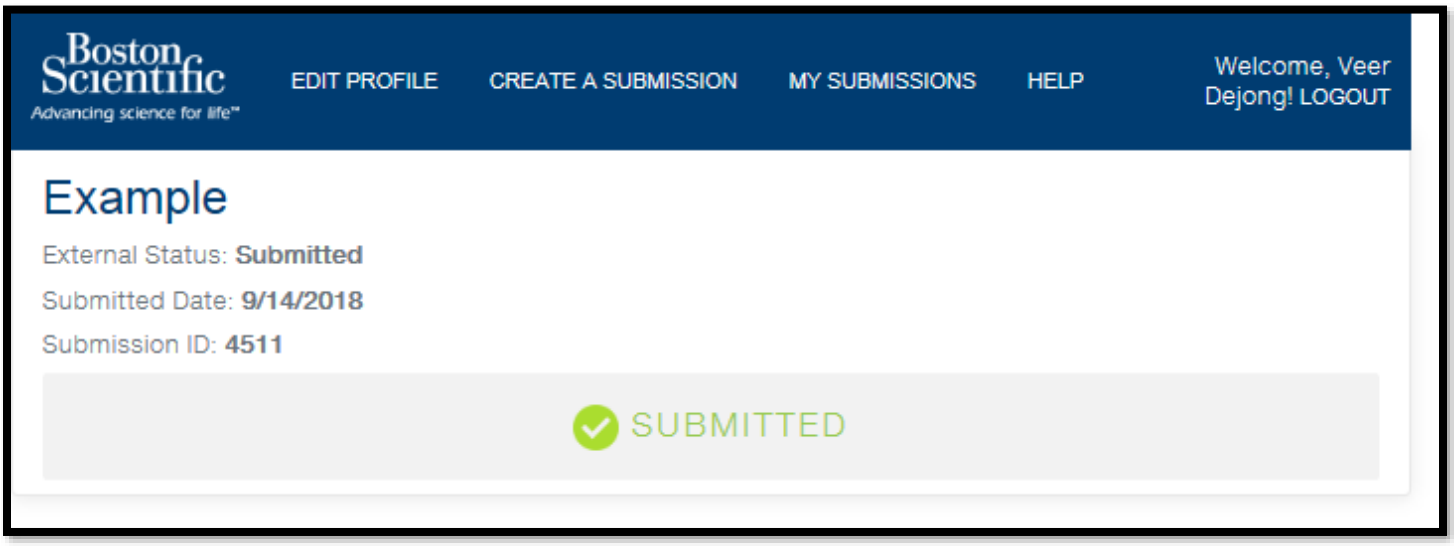
11. Select the Files Tab and click on Select file(s) to upload your CV




12. Click on "Select file(s) to upload – add your CV
13. Select the File Type from the dropdown list
14. Click on Save Files



15. Once your CV has been uploaded, go back to the Submission Form tab, scroll down and click on submit. You will see if your concept has been successfully submitted if you see below notification.

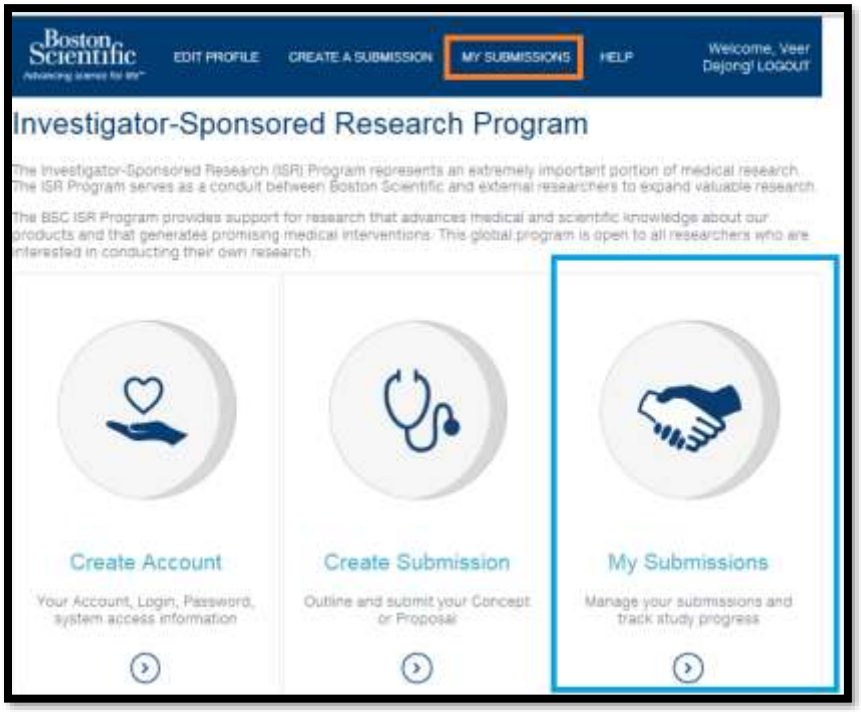



Note: You will be notified from a Boston Scientific representative once your study has been reviewed.

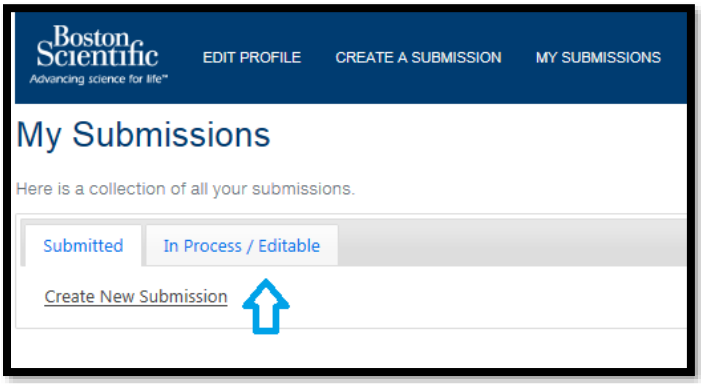
## 6b. Proposal submission (Approved Concept)

To access an approved concept:

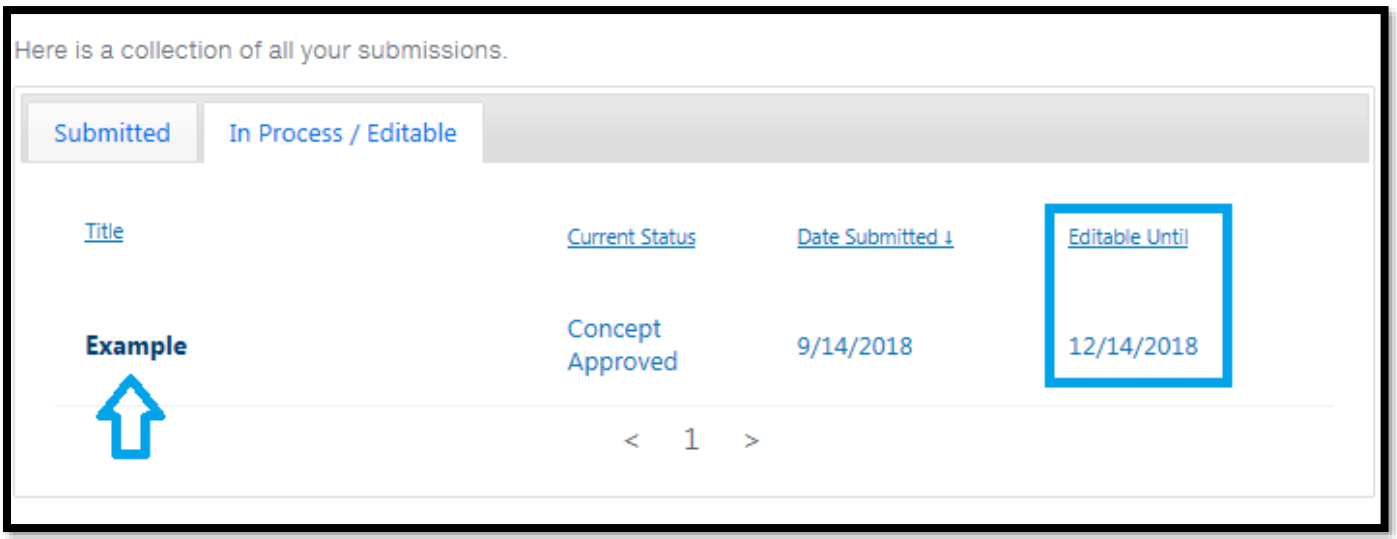
1. Login to your account and go to My Submissions




2. Click on the tab "In Process / Editable"

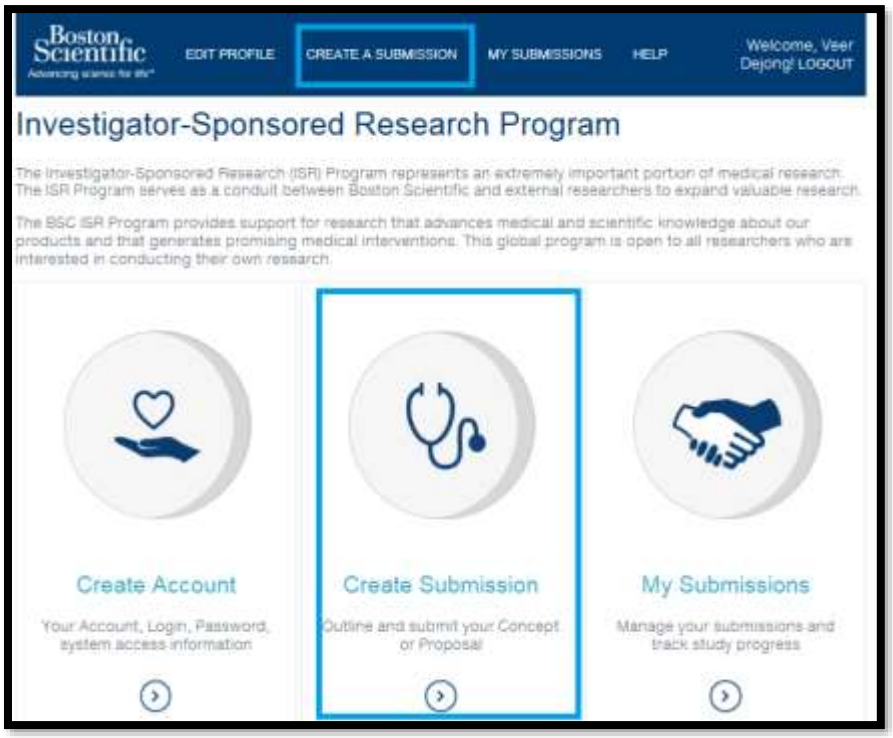


3. Click on the study Title
    a. The approved concept will indicate an "Editable Until" date. If you are unable submit your proposal before the date indicated, kindly reach out to your Grant Coordinator.

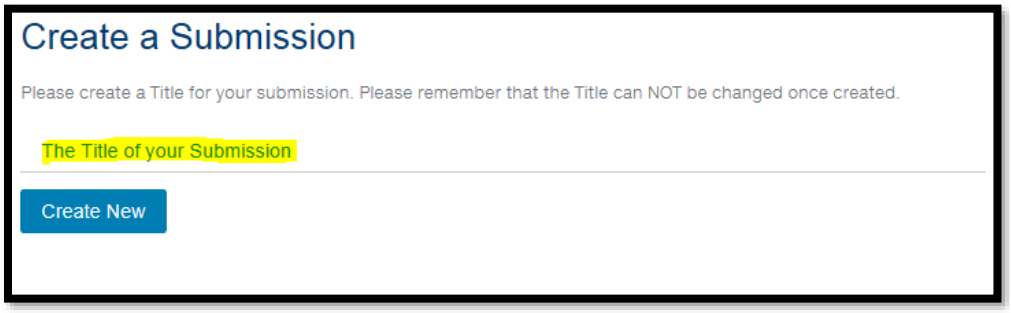


## 6c. New Proposal Submission

1. To submit a new study, select "Create Submission"

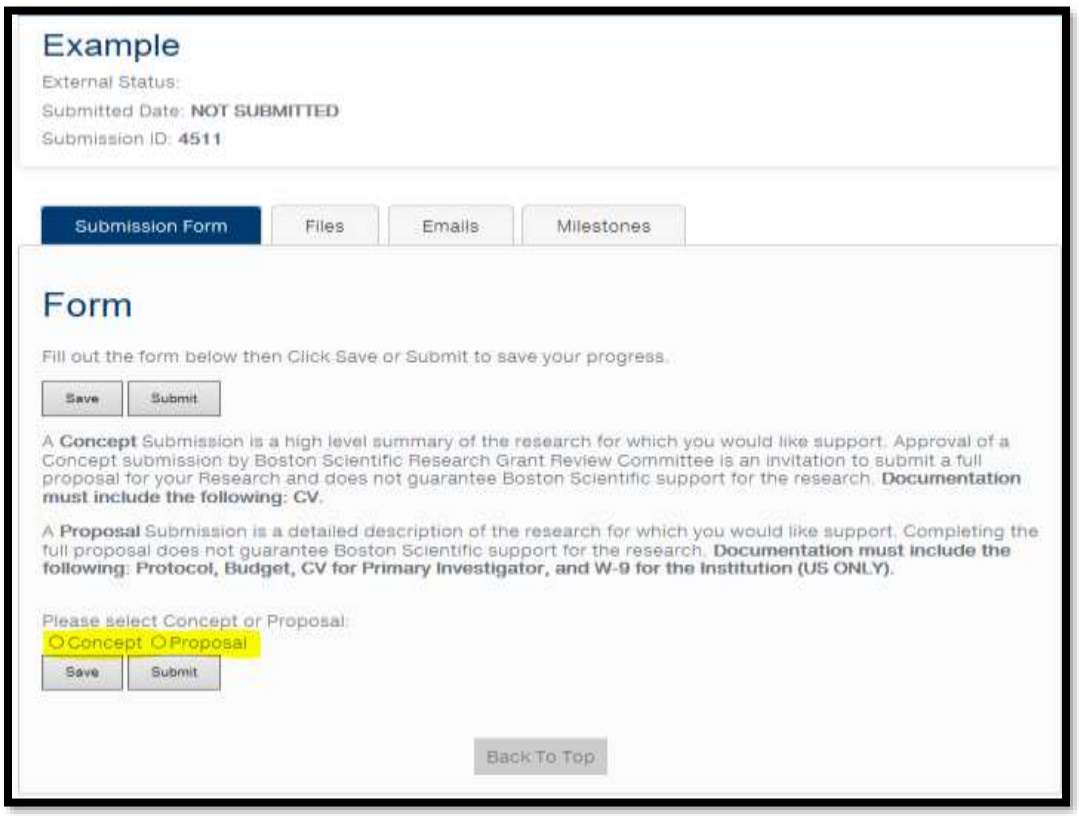



2. Enter The Title of your submission and select "Create New"

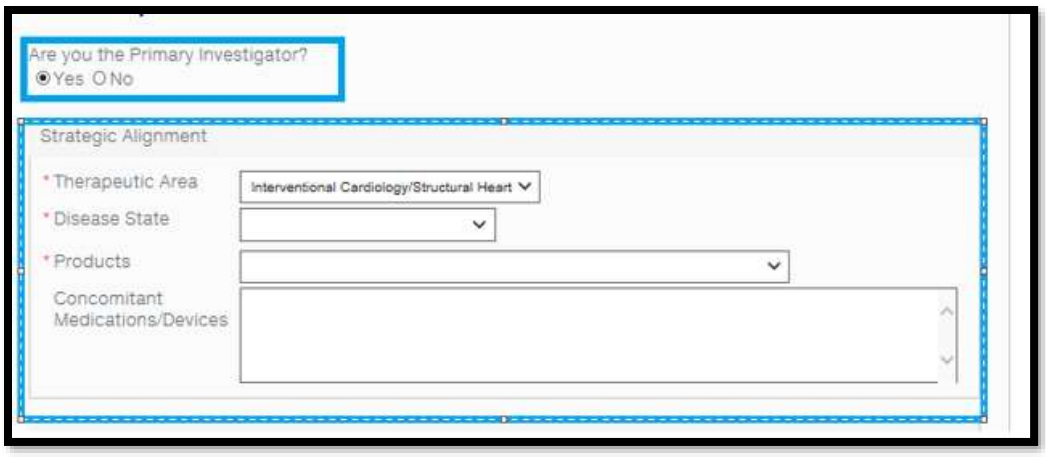



You will be taken to a page in which you can choose to submit a concept or a proposal,

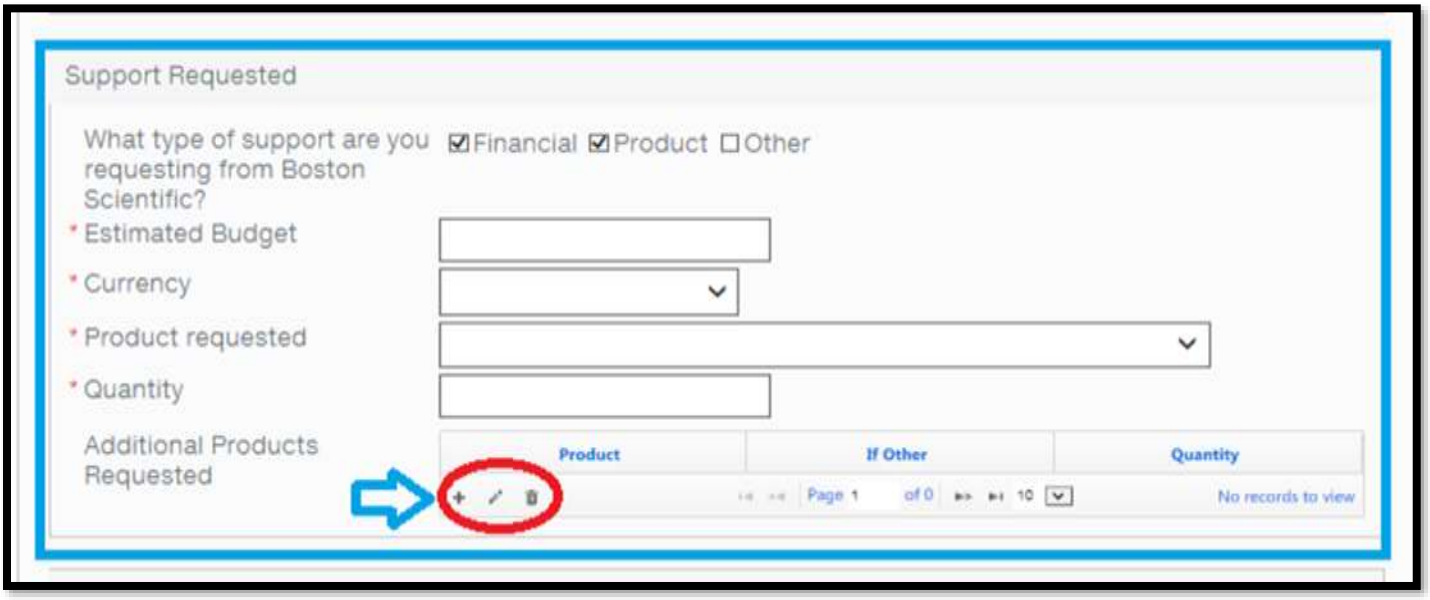
3. Select proposal and submit.



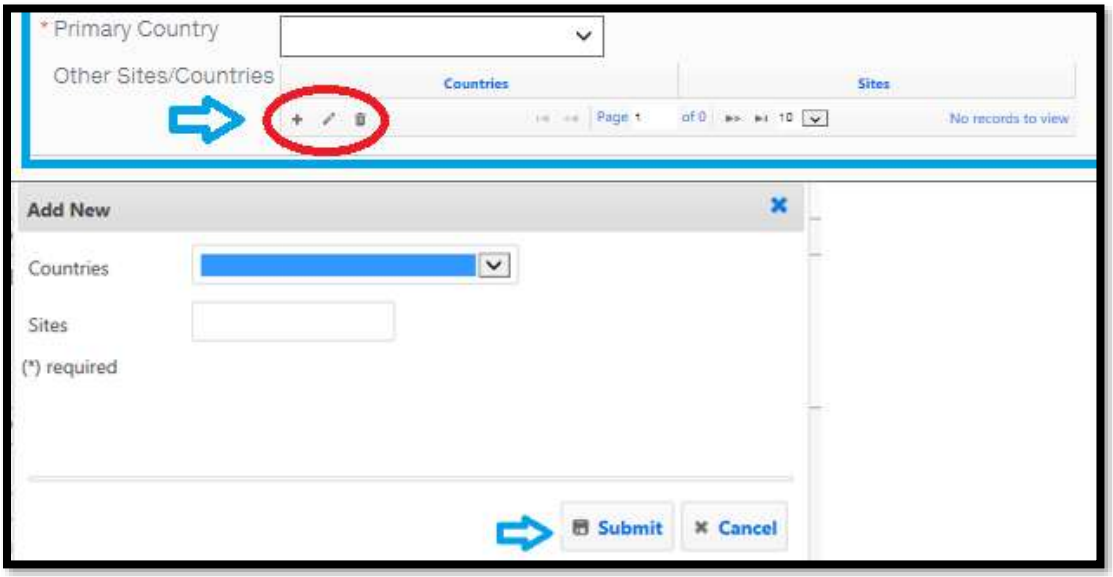

4. Indicate if you are the Primary Investigator by selecting Yes or No.
5. Select Therapeutic Area (Dropdown list)
6. Select Disease state
7. Select Products
8. Fill in Concomitant Medications/Devises as applicable.



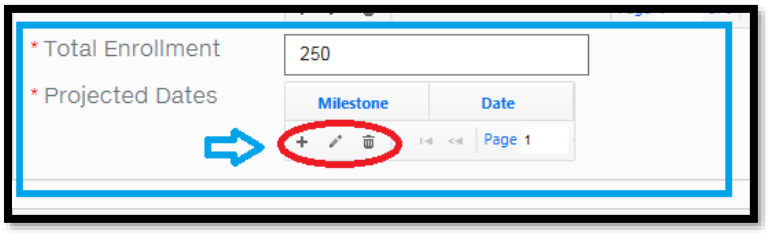

9. Check the box(s) for type of support you are requesting
    - To add additional products, click on the + button, another screen will appear where you can choose from a dropdown list.
    - Once the additional product is requested please add the quantity.
    - To enter more products, repeat this process.

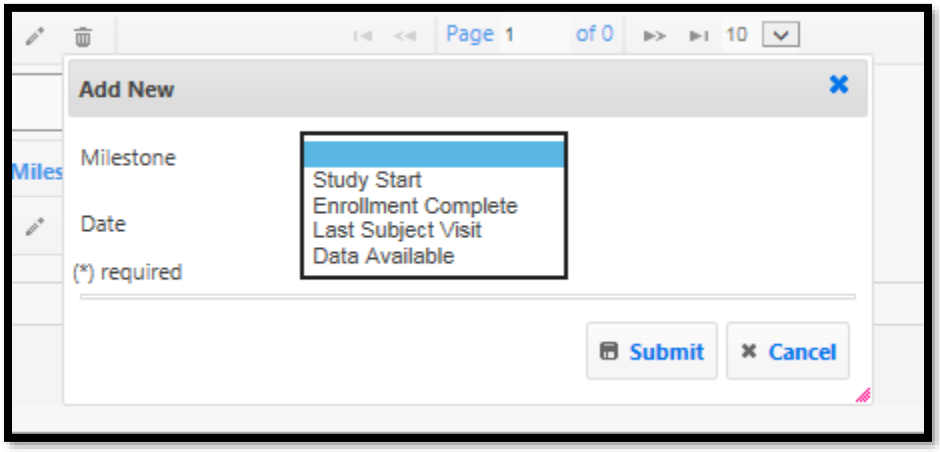


10. Fill in the Study Summary Section and provide:
    - Main Scientific Question.
    - Study Design
    - Research Design Setting
    - Statistical analysis
    - Main Efficacy Measurement
    - Regulatory Status
    - Primary country
        - To add **other Sites and/or Countries**, click on the + button, another screen will appear where you can choose other countries from a dropdown list and enter the site name(s).
        - Once the country and site are selected you must select submit.
        - To enter more countries and sites, repeat this process.



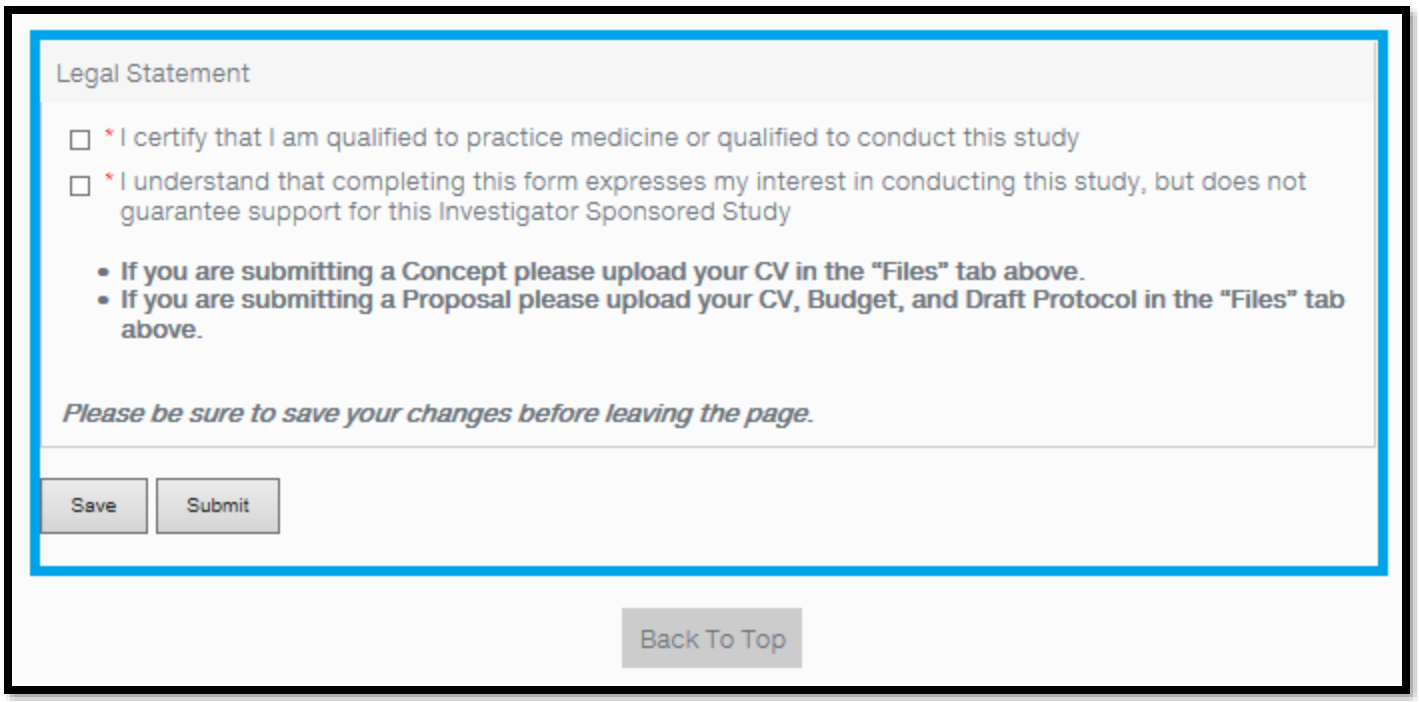
- Total enrollment (planned subjects to be enrolled)
  - Projected dates.
    - To enter your Projected dates, please click on the + button, another screen will appear where you must add your Expected milestone and estimated date. Once the required information has been entered you must select submit.
  - To enter all, please repeat this process.




- Publication strategy:
  - Manuscript submission
  - Conference Presentation
  - Proposed timelines
- Safety and complaint Reporting
- Organizational overview
- Legal Statement

11. Legal Statement:
    - Read legal statements
    - Acknowledge the statements by checking the box's
12. **Click the Save button**.




Your Proposal will receive a unique Submission ID – <u>if your concept was approved and you are submitting as a proposal, the Submission ID will remain the same</u>.

The final step required before submission is complete is to upload your CV, budget, study protocol and a W9 (US ONLY) for the institution.

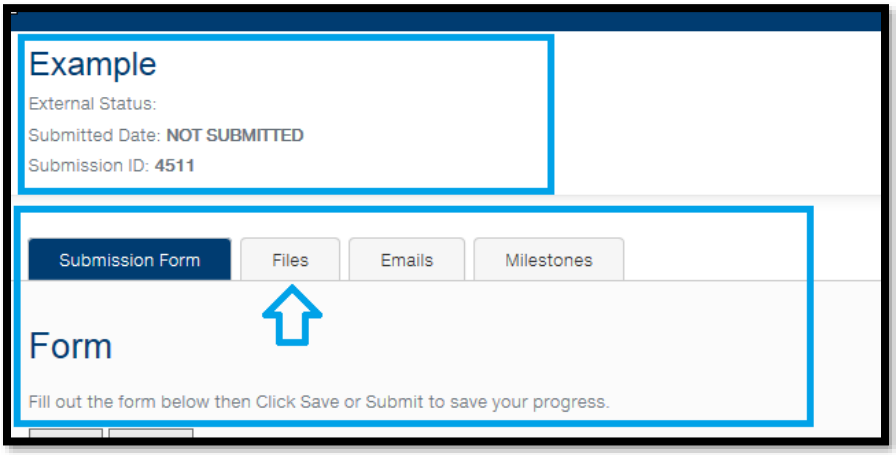
Note: When submitting your budget please keep in mind the list of <u>non-payable</u> items as per BSC's policy:

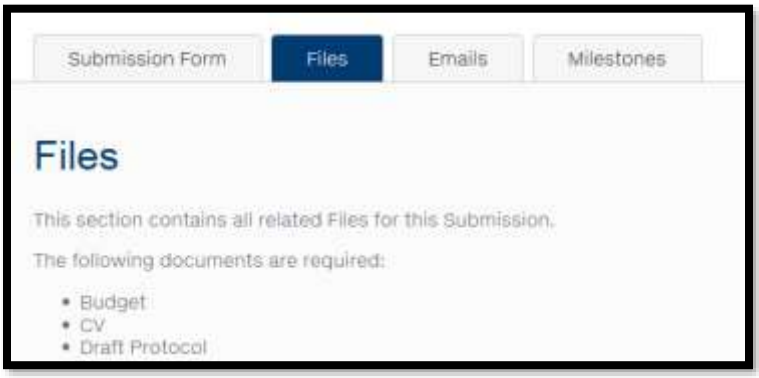
## <u>Non- Payable Items</u>:

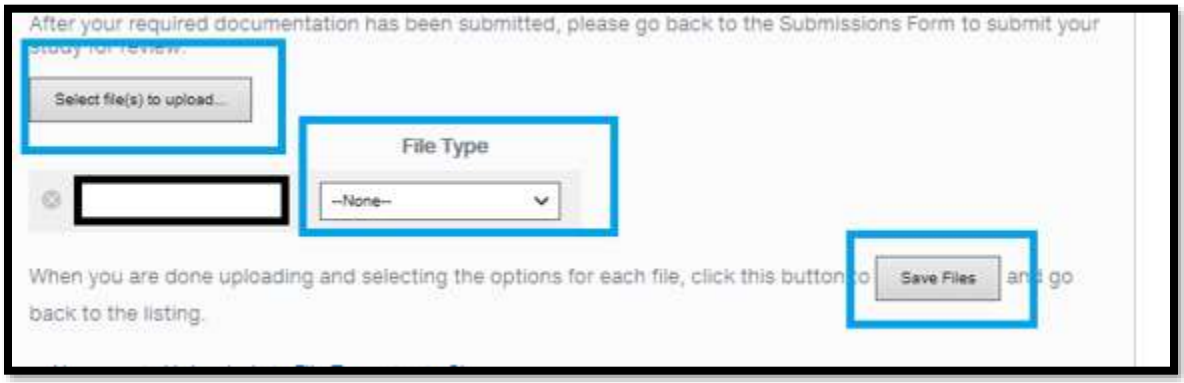
- Proposal design fees
- Protocol development fees
- Reporting AEs or SAEs to IRB and FDA, or other regulatory agencies
- Directly paying of salaries to investigators, study personnel or third-party vendors etc. This would not include Time and Effort that is included in the overall budget.
- Services rendered in the normal care of patients regardless of participation in the research
- Record storage/long term storage
- Archiving (beyond study closure)
- Time and effort for writing and publishing
- General education and training activities
- Fees or expenses related to routine operations
- Capital expenses; and
- Facilities Expenses.

To upload the required documents:

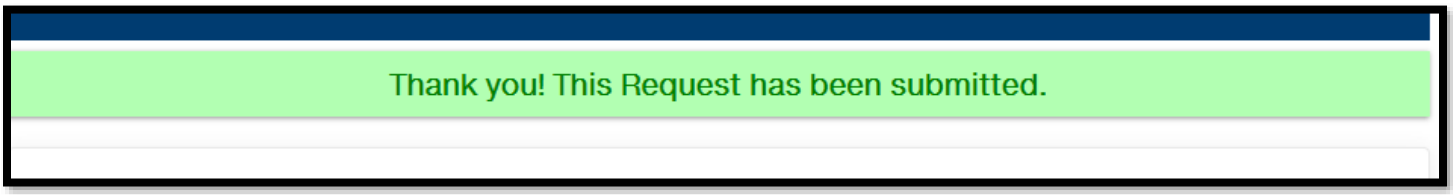
13. Select the Files Tab
14. click on Select file(s) to upload the required documents.
15. Select the File Type from the dropdown list
16. Click on Save Files



17. Once all required documents have been uploaded, go back to the Submission Form tab, and click on save/submit. You will see if your proposal has been successfully submitted if you see below notification.

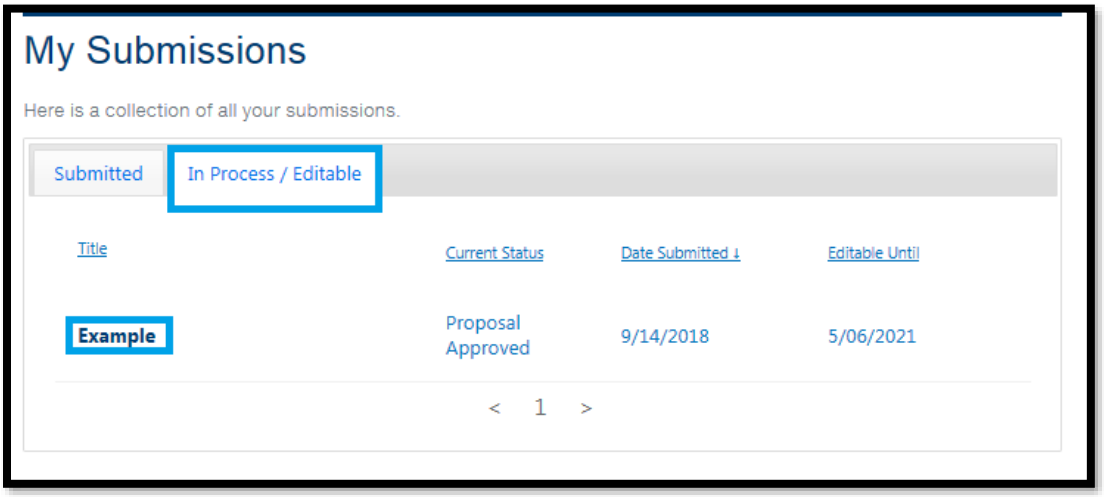



Note: You will be notified from a Boston Scientific representative once your study has been reviewed.

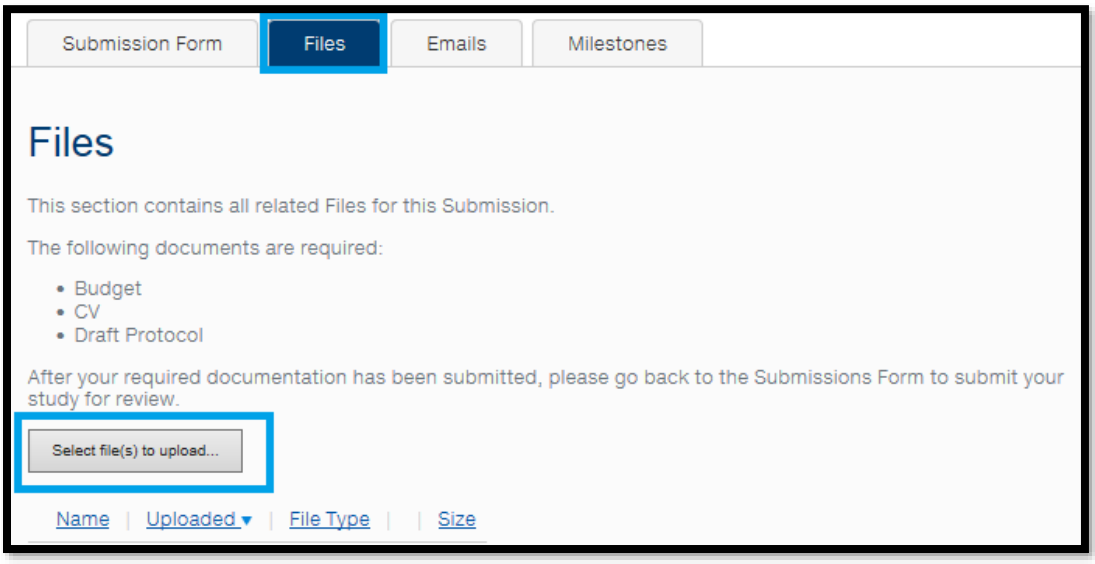
## 7. Approved Proposal

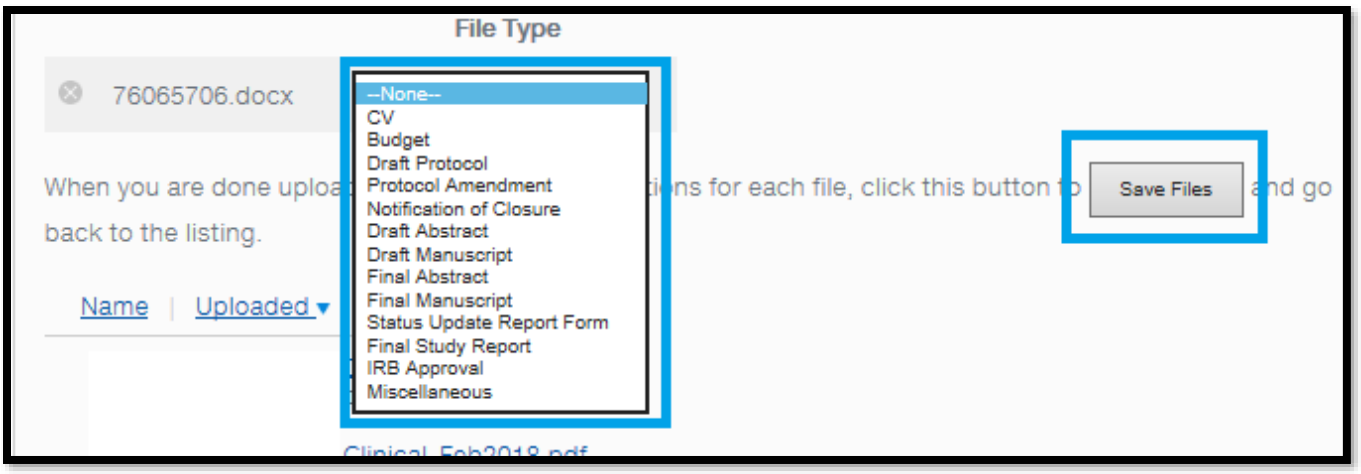
To follow-up on your submission, login in to the ISR portal and click on the In Process/Editable tab.

- Review your study by clicking on the study Title.




- Files can always be uploaded by clicking on the Files tab.
- Select your file which you would like to upload and indicate what you are uploading and click on save files.




File Type
76065706.docx
--None--
CV
Budget
Draft Protocol
Protocol Amendment
Notification of Closure
Draft Abstract
Draft Manuscript
Final Abstract
Final Manuscript
Status Update Report Form
Final Study Report
IRB Approval
Miscellaneous
When you are done uploa
ns for each file, click this button to
Save Files
nd go
back to the listing.
Name
Uploaded

## 8. Milestones

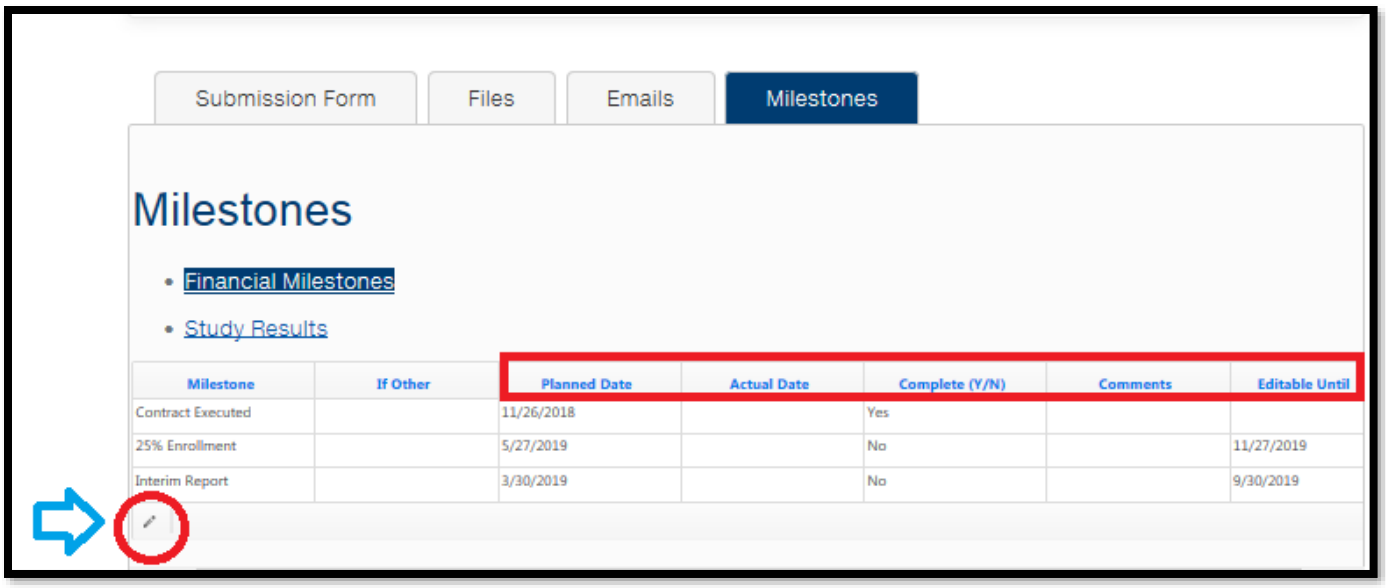
Upon completion of a Milestone or a Study Result you will be required to confirm they are complete.

To access Milestones or Study Results and Indication Completion:

1. Click on the Financial Milestones Link or Study Results.

Note: The Milestones or study results will be divided in separate columns which will indicate a Planned Date, an Actual Date, A complete (Y/N), a Comments and an Editable Until column.

2. Select the row you are planning to edit and click on the pencil.
    a. A New Window will appear where you can select if you completed the row you selected. You must select Yes to sign off for completion and add a comment with the completion date. Once this has been filled it, please click on Save.
    b. If you wish not to edit the selected row, simply click on cancel.
    c. If your milestone is delayed you will be required to notify your Grant Coordinator for BSC to understand the progress of the Study. "As Agreed in ARTICLE II – Institution's Responsibilities - Section 2.02 Reporting of The Agreement".


Submission Form
Files
Emails
Milestones
Milestones
Financial Milestones
Study Results
Milestone
If Other
Planned Date
Actual Date
Complete (Y/N)
Comments
Editable Until
Contract Executed
11/26/2018
Yes
25% Enrollment
5/27/2019
No
11/27/2019
Interim Report
3/30/2019
No
9/30/2019

Edit Current
Complete (Y/N)
Yes
No
Comments
(*) required
Save
Cancel

## 9. Help

For additional questions, please contact your research areas site coordinator.

| Research Areas | Suggested or actual address |
|---|---|
| Neuromodulation | BSN.ISR@bsci.com |
| Urology and Pelvic Health | UroPH.ISR@bsci.com |
| Peripheral Intervention | PI.ISR@bsci.com |
| Rhythm Management / Electrophysiology | RM.ISR@bsci.com |
| Interventional Cardiology | IC.ISR@bsci.com |
| Endoscopy | Endogrants@bsci.com |