stryker

Navigating Stryker Neurovascular's

Research Grant Portal

Medical Affairs



Research Grant Portal

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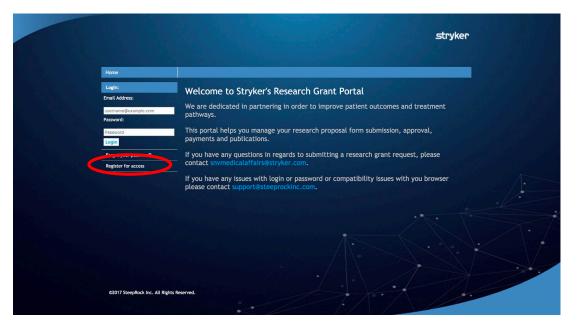


New User Registration

Getting started

Logging on for the first time: You must register for access.

www.researchgrants.stryker.com

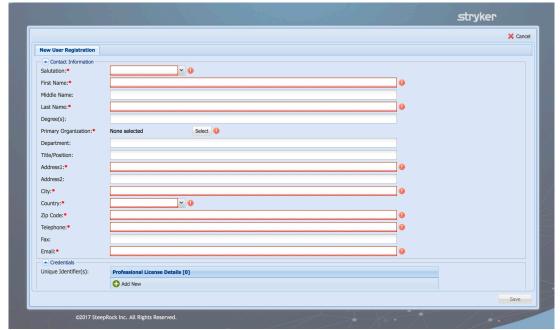




New User Registration Setting up your HCP profile

Note: red asterisks * indicates a field that must be completed in order to submit or

save.



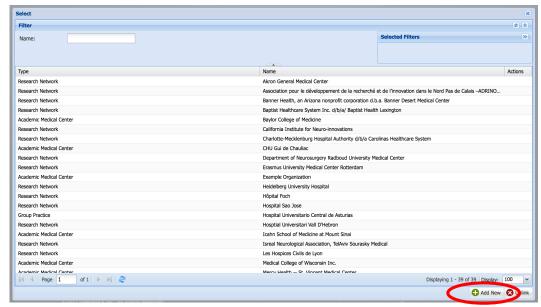


New User Registration

Adding your Primary Organization

If your institution is already listed, you may select it directly from the list.

If your organization is not listed, select "Add new" to add the details of your primary institution.

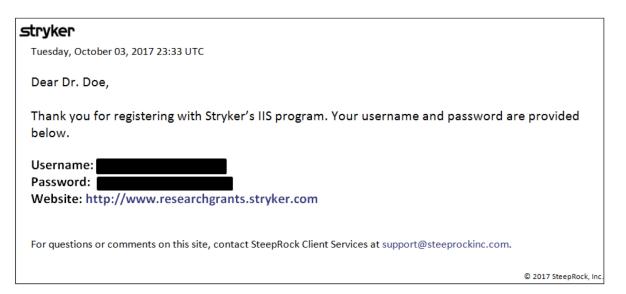




New User Registration Setting up your HCP profile

Next, you will receive an email with your temporary password.

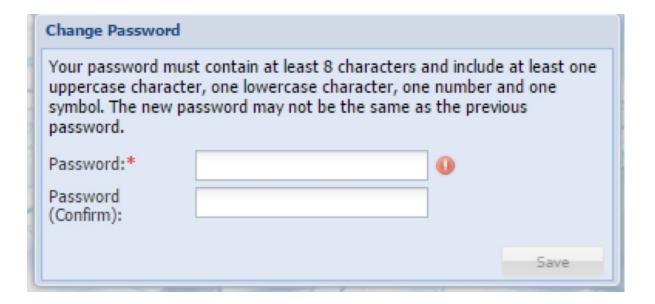
Subject: Confirmation of registration for IIS program





New User Registration Setting up your HCP profile

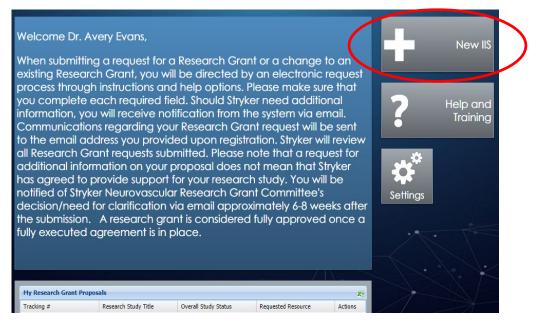
The first time you login, you will be required to change your password.





(Investigator Initiated Study)

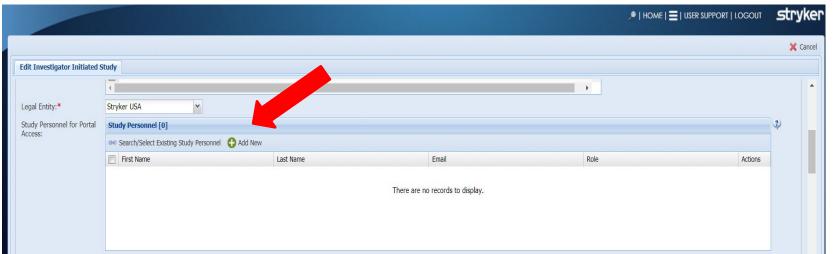
To submit a new Research Grant request:





(Investigator Initiated Study)

Identify any study personnel (e.g. Research Coordinator, Co-Investigator, etc.) that you will want to also have access to the Portal.

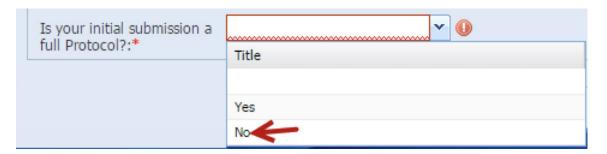


*The study personnel identified will receive an invitation email to make their own separate user account for the portal.



(Investigator Initiated Study)

You will be allowed to submit a Concept or a full Protocol. Mandatory fields are marked by a red asterisk (list of required fields for each option are on following slides).



Note: You always have the option to save your application as a Draft before submitting for consideration.





Concept Submission:

How much info is required?

You will see the following fields under the Concept Details section.

Required

- Study Rationale/Goal
- Primary Objective/Endpoints
- Study Design
- Follow-up Visit Schedule
- **Estimated Study Duration**
- Number of Sites
- Preliminary Publication Plan
- Planned Committees/Labs
- **Estimated Study Budget**

Optional

- Secondary Study Objectives/Endpoints
- **Key Inclusion Criteria**
- **Key Exclusion Criteria**
- Efficacy Variables/Measures
- Safety Variables/Measures
- Cohorts/Stratification
- Data Management Plan Summary
- Statistical & Analytical Plan
- Sample Size Justification
- Number of Subjects
- **Duration of Subject Participation**



Protocol Submission:

How much info is required?

You will see the following fields under the Protocol Details section.

Required

- Study Rationale/Goal
- Primary Objective/Endpoints
- Study Design
- Follow-up Visit Schedule
- **Estimated Study Duration**
- Number of Sites
- **Preliminary Publication Plan**
- Planned Committees/Labs
- **Estimated Study Budget**
- Full Protocol (Word or PDF)
- Indication if IRB approval is required
- **Budget Contact Information**

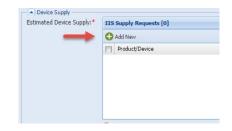
Optional

- Secondary Study Objectives/Endpoints
- **Key Inclusion Criteria**
- **Key Exclusion Criteria**
- Efficacy Variables/Measures
- Safety Variables/Measures
- Cohorts/Stratification
- Data Management Plan Summary
- Statistical & Analytical Plan
- Sample Size Justification
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- **Duration of Subject Participation**

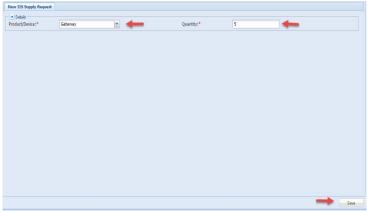


New Research Grant Submission If your IIS is a Device Supply Request

1. Select +Add New to enter the Estimated Device Supply



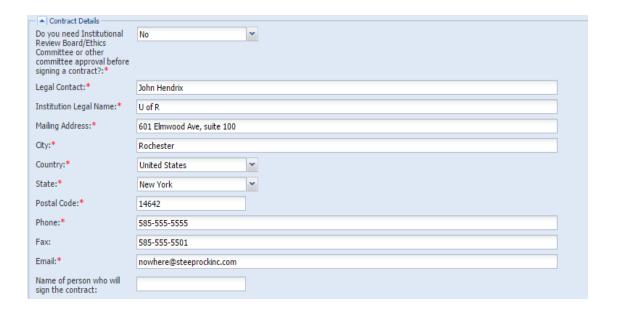
2. Select the **Product/Device** from the pre-populated options, then enter desired **Quantity, then select Save.**





Contract Details Section

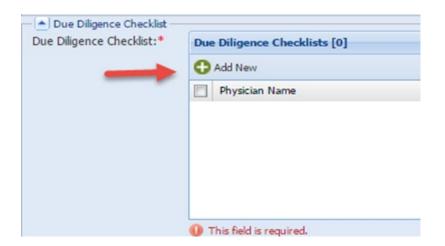
Enter the Legal Contact information where the contract should be sent.





Due Diligence Section

If your country is the United States, then a Due Diligence must be completed.

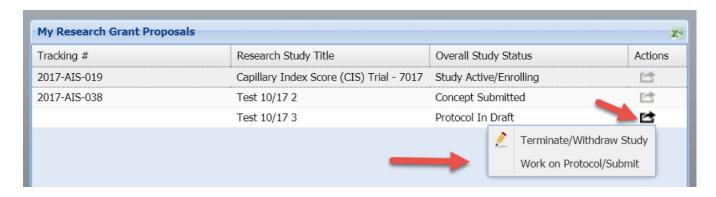


To complete the new Due Diligence Checklist, select +Add New Button.



(Investigator Initiated Study)

To edit a draft, you simply log back in and click under "Actions"



*If you are asked for any clarifications or additional information from Stryker, you will also log back into the portal and click under "Actions".



Review Process

What happens after you submit your IIS?

- 1. You will receive an email confirming your submission.
- Stryker will start the internal review process.
- If clarifications are requested, you will be notified by email.
- Approval/Rejections of requests will be sent via email.
- You will not be allowed to edit your submission while your request is under review.

*Please note that only the submitter and selected Stryker reviewers will have access to the submission. No information is available for other external users.

Subject: Request for Additional Information

strvker

Tuesday, October 03, 2017 23:06 UTC

Dear Dr. Doe,

This email is to alert you that the following clarifications are requested by the review committee for the IIS Research Study Title Here.

Here is where you would add the Additional Information Requested

Please provide the needed clarifications by logging into the portal at http://www.researchgrants.stryker.com, using your username and password.

DO NOT REPLY DIRECTLY TO THIS EMAIL.

On your homepage, in the Actions column, please click on the "Submit Clarifications" link. This will bring you to your original application. Please enter the requested clarifications and click "Resubmit to Stryker" at the bottom of the form

The Review Committee will evaluate this new information at its next meeting.

If you have any questions please contact Stryker via email by clicking HERE.

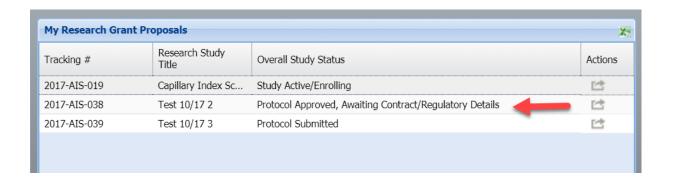
For questions or comments on this site, contact SteepRock Client Services at support@steeprockinc.com

@ 2017 SteepRock, In



After your request has been approved

- Stryker Neurovascular will contact you to begin contract negotiations.
- 2. To submit your reviewed and signed contract, click on the Actions button, then select Update.





After your request has been approved

Once your Contract/Regulatory Details have been reviewed/approved, you will receive an email notification with the Fully Executed Contract attached.

Subject: Contract Fully Executed

*s*tryker

Wednesday, October 04, 2017 00:16 UTC

Dear Dr. Doe.

Re: Research Study Title here

Attached is the executed IIS contract. A hard copy will be mailed to you. Please upload the Ethics Committee (IRB/IEC) approval letter, and the approved protocol/proposal by clicking here to log in.

If you have any questions please contact Stryker via email by clicking HERE.

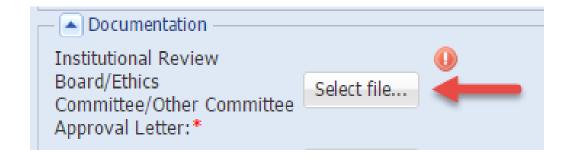
For questions or comments on this site, contact SteepRock Client Services at support@steeprockinc.com.

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After your request has been approved

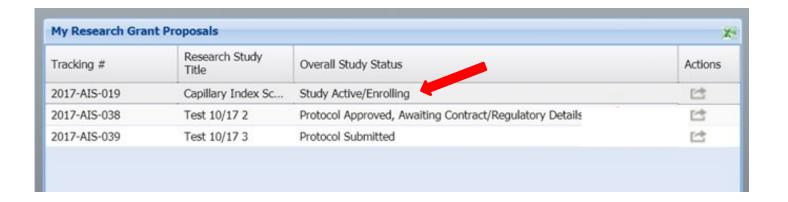
Next, you navigate to the Edit Investigator Initiated Study page where you will need to upload your IRB approval letter.





After your request has been approved

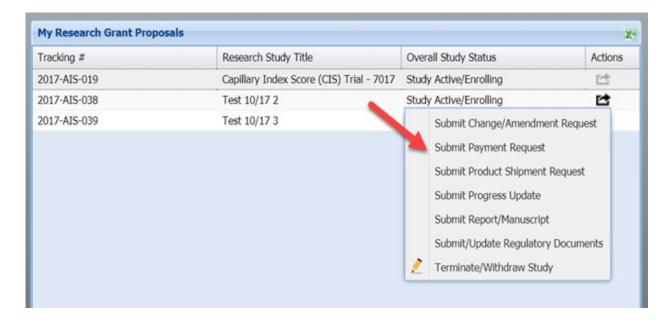
Once your study has a fully executed contract, your study will become Active.





After your request has been approved

Use the Actions icon to do the following for an 'Active' study:





After your request has been approved

To make updates to your profile:

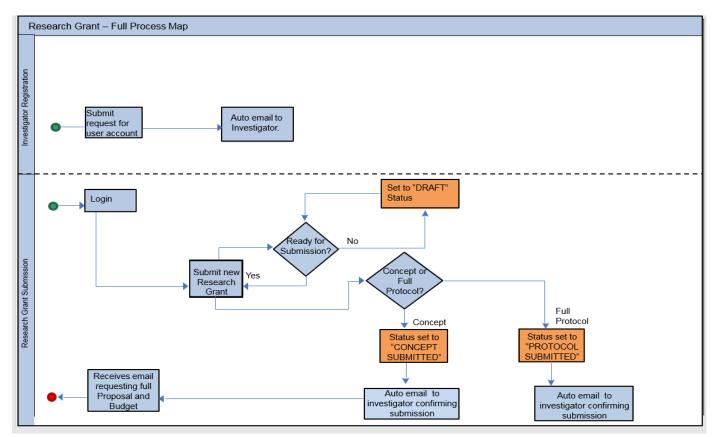






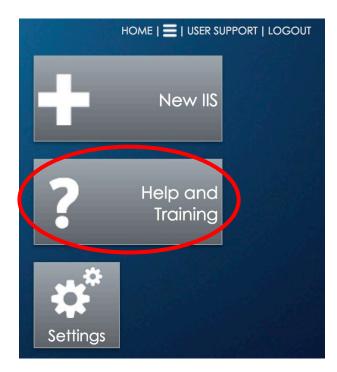
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Process Flow





Please view the Help and Training tile for a detailed Investigator user guide.





User Support

Technical:

Email: support@steeprockinc.com

Phone: +1 718-576-1406

Hours: Monday-Friday, 9am-8pm ET

Questions regarding your submission:

Email: snvmedicalaffairs@stryker.com