# Table of Contents

- **Purpose** ............................................................................................................................................................. 2
- **How do I Register for Access?** ........................................................................................................................... 3
- **How do I Login?** ................................................................................................................................................ 8
- **What is on My Homepage?** .............................................................................................................................. 9
- **Submit a request for a New External Research** .............................................................................................. 10
  - Types of Testing........................................................................................................................................... 12
  - Concept Details........................................................................................................................................... 14
  - Projected dates........................................................................................................................................... 15
  - Budget Details............................................................................................................................................. 16
  - Drug Product details for Regimen/Duration/Dosing.................................................................................. 17
  - Translational Medicine Efforts................................................................................................................ 18
- **Supporting Documents** ................................................................................................................................... 20
  - Save your External Research in draft........................................................................................................ 20
  - Submit your Concept ................................................................................................................................... 21
  - Concept Submission....................................................................................................................................... 21
- **Respond to Request for Clarifications** ............................................................................................................ 22
- **Submit Protocol** ............................................................................................................................................... 23
  - Protocol section........................................................................................................................................... 23
  - Estimated Study Product Supply will be added with the selection of + Add New .................................. 23
  - Protocol documentation............................................................................................................................ 24
  - Publication Plan ....................................................................................................................................... 24
  - Contract Details ....................................................................................................................................... 25
  - Proposal Submission................................................................................................................................... 26
  - ICH GCP Guidelines Attestation.................................................................................................................. 26
  - Proposed Timelines................................................................................................................................... 27
  - Budget........................................................................................................................................................ 27
  - Submit Protocol ........................................................................................................................................... 27
- **Submit Amendment** ........................................................................................................................................ 31
- **Submit Drug Shipment Request** ....................................................................................................................... 32
- **Submit Enrollment/Progress Updates** ......................................................................................................... 34
- **Submit Manuscript** ......................................................................................................................................... 40
Purpose
This Investigator Guide will assist with basic navigation and frequently used features within the on-line Halozyme External Research Portal, including:

1. Submit a new External Research
2. Provide External Research progress updates
3. Respond to a Request for clarifications
4. Request payment
5. Request product
6. Submit a manuscript or report
7. Receive support from SteepRock Client Services
How do I Register for Access?
Open a web browser* and go to the Halozyme webpage [http://www.halozyme.com]. From the top menu bar, select Investigator this will display the available collaborations for your study. Within each collaboration study type, you will be able to read the mission and proposal requirements. When ready to submit, select the displayed Submission link.

You will be informed that you are being redirected from the Halozyme site to a vendor portal, https://halozyme-ist-public.steeprockinc.com/. Register for your access by clicking on Register for access at the left of screen.

* Internet Explorer 10+, Chrome, and Firefox are the preferred browsers. Please reference Helpful Settings at the end of this guide for pop-up windows guidance.
Selecting **Register for access** will take you to the **New User Registration** form. Follow the registration form instructions below to complete your registration.

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

For the **Primary Organization** click on the **Select** button and you will be brought to the select organization filter, enter your organization.
Use the filter options on the top of the window to search for your Organization.

If you do not see your Organization in the existing list, click on the **Add New** button at the lower right of the window.
Next, enter the information about your Organization and **Save**.

After you save and/or link the Organization, you will be returned to the **New User Registration** page. Select the **Country** from the dropdown.
To upload your Curriculum Vitae (CV), click on the Select file button and select the file from your computer. The Unique Identifier is used to identify one investigator from another in case there are multiple individuals with the same name. In the US, NPI numbers are used for this purpose, while there are other options for certain other countries.

Please remember the password you type in.

If your unique identifier type is not listed under the Unique Identifier Type dropdown list, select Other and specify the type in the If Other, please Specify field.
Once you have completed all red required fields, select **Save** on the registration form to complete your registration. You will receive a welcome email from the Halozyme External Research portal.

**How do I Login?**
To log in to your account, open the website [https://halozyme-ist-public.steeprockinc.com/](https://halozyme-ist-public.steeprockinc.com/) and enter your Email Address and Password you typed in upon registration. Click Login.
What is on My Homepage?
After logging in, you will see your Homepage, including the following menu tiles:

- My Submitted External Research – for easy access to your submitted study
- Settings – (my personal settings)
- Help
- New External Research – submit a proposal for a new External Research study

Homepage view:

You can navigate throughout the system by selecting the menu tiles.
Submit a request for a New External Research
Click on the +New External Research tile. You will be brought to the New External Research page to enter the details.

Enter the Research Study Title and then use the corresponding dropdown menu to choose the Therapeutic Area, Tumor Type, Study Type and Study Currency. You can select multiple options under the Requested Resource field by clicking on the check box(es).

For the field Requested Resource, click on the checkbox next to the desired resource(s).
Based on the selection of the Requested Resource, the required fields will expand and request information to match your requested resource.

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

Select the **Product** for the External Research by clicking on the **Select** button next to the **Product** field.

The available concepts are shown for the individual compounds. These concepts describe the formats in which investigational medicinal products can be delivered by Halozyme.

**Note:** If you are unable to complete your online application in one session, you may save it and come back to it later by clicking "Save Draft" at the bottom of the page. At any time before the submission, you will have the opportunity to come back and make changes to the application.
Types of Testing

If Testing is listed as a Requested Resource, the Types of Testing values will display for selection.

Select the Lead/Primary Site Country to indicate where the majority of research will be completed.

Use the Type of Site(s) dropdown menu for selection of site type.

When the Type of Site(s) selection is Cooperative Group, select the Lead Group and complete the dropdown Yes/No response for Is this an international study?
When the Type of Site(s) selection is **Multi-Center**, enter the **Proposed Sites and Investigators** and complete the dropdown Yes/No response for **Is this an international study?**

**Primary Investigator**
Identify the Primary Investigator. Select Yes/No from dropdown next to the question *are you, the person entering this request, the PI for the study?*

If the Response selected is *No*, complete the displayed **PI Details** field.

**Study Personnel for Portal Access**
You can identify any additional **Study Personnel for Portal Access** by clicking the **+Add New** button.
A **New Study Personnel** form will display where you can enter contact information. Once complete, click on **Save** at the bottom right corner of the screen and you will be returned to the **New External Research** page. The study personnel identified will receive separate login credentials via email.

![New Study Personnel Form](image)

**Concept Details**

The concept details are based on the Study Type selected. Biomarkers Precision Medicine, Clinical and Non Clinical will display the required Concept Details for completion prior to submission. If *Clinical* is selected as the Study Type, please enter all fields in the **Concept Details** section with text information on the study.

![Concept Details](image)
If **Pre-Clinical** is selected as the Study Type, please enter all fields in the **Concept Details** section with text information on the study.

**Projected dates**
Enter the Projected Start and End dates. If Study Type requires Data abstract, the projected Date fields will display.
**Budget Details**

If *Funding* is requested from your Requested Resources, complete the required fields:

- **Physician/Researcher Costs**
  - Total:
  - Per Patient:

- **Study Coordinator Costs**
  - Total:
  - Per Patient:

- **Regulatory Submission Costs**
  - Total:
  - Per Patient:

- **Data Costs**
  - Total:
  - Per Patient:

- **Reporting Writing Costs**
  - Total:
  - Per Patient:

- **Biopsy Costs**
  - Total:
  - Per Patient:

- **Procedure Costs**
  - Total:
  - Per Patient:

- **Blood Draw Costs**
  - Total:

- **Institutional Overhead (%)**:

- **IRB/EC Fees**:

- **Other Fees**:

- **Estimated Total Study Budget**:

- **Budget Attachment**: Select file...

- **Is funding being requested/provided by another source?**

- **Estimated Total Product Required**: This field is required.
Complete the Yes/No dropdown field next to **Is funding being provided by another source?**

**Drug Product details for Regimen/Duration/Dosing**

If **Requested Resource is Drug**, is requested on the New External Research Page, enter the **Estimated Study Drug**, **Regimen/Duration** and **Dosing**.
Translational Medicine Efforts
When the Study type is Biomarkers and Precision Medicine or Clinical IST, you will be required to complete the Translational Medicine Efforts specific to the Study Type. Below are the fields with the Study Type Biomarkers and Precision Medicine:

Below are the Translational Medicine Effort fields with the Study Type Clinical IST:
<table>
<thead>
<tr>
<th><strong>Translational Medicine Efforts</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prospective Patient Selection:</strong></td>
</tr>
<tr>
<td><em>This field is required.</em></td>
</tr>
<tr>
<td><strong>Other Biomarker(s) and Rationale:</strong></td>
</tr>
<tr>
<td><em>This field is required.</em></td>
</tr>
<tr>
<td><strong>Where will samples be analyzed?:</strong></td>
</tr>
<tr>
<td><em>This field is required.</em></td>
</tr>
<tr>
<td><strong>If an internal lab, please provide description of relevant equipment and storage:</strong></td>
</tr>
<tr>
<td><em>This field is required.</em></td>
</tr>
<tr>
<td><strong>Willing to share samples with Halozyme for research collaboration?:</strong></td>
</tr>
<tr>
<td><em>This field is required.</em></td>
</tr>
<tr>
<td><strong>Flexibility and interest in inclusion of additional time points and/or other sample types for research collaboration?:</strong></td>
</tr>
<tr>
<td><em>This field is required.</em></td>
</tr>
</tbody>
</table>
Supporting Documents

You have the option to attach additional documents by clicking on the Add New button next to the Supporting Documents field.

Enter the Description for your Supporting Document and click on the Select file button to upload the document, then select Save. Repeat the steps if you have multiple documents to upload.

Save your External Research in draft
On the New External Research Page, to save your submission as a draft, scroll to the bottom of the page and select Save Draft. Existing drafts can be modified until ready to submit as final.

Your saved Draft will be displayed on your Homepage under My Submitted External Research with the Overall Study Status of Concept In Draft.
Submit your Concept
From your Homepage, under **My Submitted External Research**, click on the **Actions** icon next to your External Research and select **Work On Draft** to update and complete the previous External Research saved as a draft.

You will be brought to the **Edit External Research** page where you can make updates. Once you have made the updates on your External Research draft, you will need to complete the Concept Submission to send to Halozyme.

**Concept Submission**
To submit the External Research study, the attestation to the legal agreement execution must be checked.
Respond to Request for Clarifications
After your External Research has been submitted, Halozyme will start the review process. If clarifications are requested for your External Research, you will be notified by Halozyme. Go to your Homepage, under the My Submitted External Research section, click on the Actions icon next to your External Research and click on Submit Clarifications.

This will bring you to the Edit External Research window, please enter the information requested on the Clarifications email into the External Research. You have the option to Save Draft or Submit.
Submit Protocol
If your Concept is approved, you will be invited to submit a Protocol. Go to the Homepage, under the My Submitted External Research section, click on the Actions icon next to your External Research and click on Submit Protocol.

Protocol section
Estimated Study Product Supply will be added with the selection of + Add New

A New External Research Supply Request window will display.

Select the Compound and Requested Quantity. Only the values from your initial Concept Submission will display.
When you entry is completed, select **SAVE**.

**Protocol documentation**
Upload the Full Protocol and attach. The Protocol needs to be submitted as a Word Document.

**Publication Plan**
For the **Publication Plan** field, click on the **Add New** button.

Next, you will be brought to the **New Publication Plan** form. Use the **Type** dropdown menu to select the type of publication. Type in a date or use the calendar icon to select a date for the **Planned/Estimated**
**Date of Submission.** Type in the Journal and **Conference** in the corresponding fields. Click on **Save** once complete.

**Contract Details**
Select **Use Investigator profile for Contract Details**: Yes/No.

If **No** is selected, please enter Legal Contact Information.

Upload the Collaborator Information Form that has been sent to you from Halozyrne. Upload the W-9 form from your computer.
Proposal Submission
ICH GCP Guidelines Attestation
Click on the link to read and review the ICH GCP Guidelines.

Then click the checkbox to attest you have read and understood that you hold all sponsor responsibilities for the External Research as described in the ICH GCP.
Proposed Timelines
Enter the Proposed Timelines by typing in the corresponding fields or clicking on the calendar icons to select the dates. If applicable, also enter the Projected Patients Enrolled per Month.

![Proposed Timelines](image)

Budget
The Budget section will gather Budget Estimation, Budget Requested and Budget Attachment.

![Budget](image)

For the budget-related fields, click on the Budget Attachment button and upload the required budget information.

Submit Protocol

Once you have entered the information about your Protocol, you have the option to Save Draft if you need to make updates or you can choose to Submit.
Once your External Research is approved you will receive an email notification to inform you that the External Research is now in contracting with the **Overall Study Status – Full Protocol Approved, Awaiting Contract/Regulatory Approval** with a draft contract for your review and completion.

To submit your reviewed and signed contract, log in and go to your Homepage, under the **My Submitted External Research** section, click the **Actions** icon in the **Actions** column, then select **Submit Contract/Regulatory Details**.

![Contract/Regulatory Details](image)

You will be brought to the **Edit External Research** page. For the fields accompanied by the **Select file** buttons, such as **IRB/Ethics Committee Approved Protocol** (approval letter), click on the buttons to upload the files. For the fields accompanied by the **+Add New** buttons, such as **Ship To Details** and upload your **IRB/Ethics Committee Approval Letter**, click on the buttons to open the corresponding pop-up window to input your information. When you have completed all required fields, click **Save**.
Addition of Pay to Details for Funding

From the Edit External Research page, the Pay To Details may be entered by selection of the +Add New button.
Upon selecting the +Add New button for the New Pay To Detail section, choose Yes or No from the dropdown menu for Use Investigator profile for Pay To Details? Enter the Attention field information, if applicable. Click on Save once complete. Then, you will be returned to the previous page where you can click Save on the Contract/Regulatory Details.

Addition of IRB/Ethics Committee Approval Letter

The Edit External Research page allows the attachment of the IRB/Ethics Committee Approved Protocol (approval letter) with the Select file button.
Submit Amendment
To Submit Change Request, click on the corresponding option under the Action icon from your Homepage in the My Submitted External Research section.

You will be brought to the New Change Request page. Select the Change Request Type by clicking on each applicable checkbox. Based on what you select, corresponding fields will display. The following is an example with Contract selected. You must complete all red required fields.
You will then have the option to **Save Draft** or **Submit**.

**Submit Drug Shipment Request**
To **Submit Drug Shipment Request**, click on the corresponding option under the **Actions** icon from your Homepage in the **My Submitted External Research** section.

Select **+Add New** to enter the new **Supply Request**.
Select the **Compound** from the drop down menu, enter **Requested Quantity**, then select **Save**. You can add as many Supply Requests as needed for each desired Compound.

Enter the **Needed by** date and select **Save** to Submit the Drug Shipment Request.
Submit Enrollment/Progress Updates
You will be asked to submit progress updates on your External Research. Through the Enrollment/Progress Update action, you will be able to:

- Submit a Monthly Progress Report
- Update Key Milestones
- Submit Enrollment updates
- Indicate if there are any amendments to protocol or study procedure
- Update Primary Contact information
- Update Pay To details
- Update Ship To details
- Share if there is an interim publication plan

To start the Enrollment/Progress Update, click on the corresponding option under the Actions icon from your Homepage in the My Submitted External Research section.
The **New Enrollment/Progress Update** will display.

Select monthly from the drop down in the **Type of Report** field. Enter the dates for the Month and the Year. This will attach to the Enrollment details.

From this action, you may also update the **Key Milestones-Please Update As Needed** dates.

The **Study Enrollment Update** section has 2 fields for the **Total number of new patients this month** and **Total number of patients receiving study drug**.
Enter the **Proposal Status** as appropriate for your Enrollment or Progress Report.

If the selection is **Yes**, answer the required report question.

Select the **Safety Information** as appropriate for your Enrollment or Progress Report.

If the selection is **Yes**, answer the required report question.

The **Contact Information** section will gather information on contact updates and **Pay to Details** and **Ship to Details**.

If the selection is **Yes**, the contact information on record will display and allow updating.
The **Contact Information** section will also allow the **Pay to Detail** to be entered.

If the selection is **No**, enter the required payee contact details.
The **Contact Information** section will also allow the **Ship to Details** to be entered.

If the selection is **No**, enter the required Shipping Name and Address.

Enter the details and select **Save**. The entered information will display.
**Project Milestones and Timelines** can be updated and reported.

**Publication Plans** can be updated and reported. Select **Yes** from the dropdown and then enter details in the **Please describe** text field.

The **Comments** section allows for any additional information to share with Halozyme regarding any of the items noted above. When completed, select **Save** to submit to Halozyme.
Submit Manuscript
To Submit Manuscript, click on the corresponding option under the Actions icon from your Homepage in the My Submitted External Research section.

Next, enter the required information and select Save Draft or Submit. Please note: the dropdown field options will be displayed when you click on the arrow and the Document can be uploaded by clicking on the Select file button.
My Profile

From the Homepage click **Settings** and then **My Profile** to display the **Edit HCP** page which includes information for the logged in user. The user can update their contact information by making the necessary changes and selecting **Save** at the bottom right hand corner.
Change Password

To change your password, select the Settings, Change Password tiles. The Change Password box will appear, fill in the Password and Password (Confirm). Click Save.

Please note: Your password must contain at least 6 characters and include at least one uppercase character, one lowercase character and one number.

Need Help?

To locate this Investigator Reference Guide click on the Help tile from your home page.

Helpful Settings

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

1. Open MS Internet Explorer.
2. Select the ‘Tools’ tab.
3. Scroll down to ‘Pop-up Blocker.’
4. Select ‘Pop-up Blocker settings.’
5. Type ‘*.steeprockinc.com’ into the ‘Address of website to allow:’ field.
1. Open **Firefox**.
2. Select the ‘Tools’ tab.
3. Select the ‘Content’ tab.
5. Type ‘*steeprockinc.com’ into ‘Address of website.’ field.
6. ‘Save Changes.’

1. Open **Chrome**.
2. Select the Chrome menu button on the top right hand side.
3. ‘Settings.’
4. ‘Show Advanced Settings.’
5. Under ‘Privacy,’ select ‘Content Settings.’
6. Under ‘Pop-ups,’ select ‘Manage Exceptions.’
7. Type ‘*steeprockinc.com’ into the ‘Hostname pattern’ field.
8. ‘Done.’

1. Open **Safari**.
2. Select the ‘Safari’ tab.
3. Select ‘Preferences’ and ‘Security.’
Support

For technical support a dedicated Client Services Team is available via email or phone for any questions or inquiries you may have regarding the site. There is an email link on the log in page and at the bottom of Homepage to send SteepRock questions, requests, or comments.

Email: support@steeprockinc.com
Phone: +1 718-576-1406

The User Support button is available at the top of the screen:

It may also be accessed from the bottom of the screen:

Upon selection of the User Support button, the following pop-up will display: