



External Quick Reference Guide

Date	Change Description
12/13/21	Revised to include the current screenshots, links, and references.
01/05/22	Revised Technical Support Contact Information(Refer How to Create an Account)
03/17/2022	Updated support contact details(Refer How to Create an Account)



External Quick Reference Guide

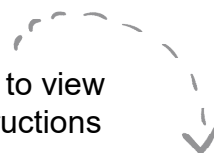
This External Quick Reference Guide is a high-level overview of the SPIRIT system and all its functionalities.

To use this document; [click on each of the highlighted boxes to be taken to that page and description.](#)

Step-by-step instructions on how to submit a study application can be found in the **External Submission Guide** by logging in to the SPIRIT portal [here](#) and viewing the home page.

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Click on the task to view
the detailed instructions



How to Create a
SPIRIT Account

How to Submit a
Study Application

SPIRIT System
Overview

How to Create an Account

Please follow the quick reference guide for how to create a SPIRIT account. For more detailed instructions please view the External Submission Guide

- 1 To create your SPIRIT account, navigate to the SPIRIT web portal by selecting;
www.abbviemedicalresearch.com/

- 2 Once on the SPIRIT web portal, select **Register New User** on the homepage

- 3 Fill out the **Email** field to set-up your account and select **Next**.

- 4 Once the **New User Registration** page opens, complete all required fields and select **Next**. *Please note: all fields marked in red and required to create an account*

- 5 You will receive an email your SPIRIT username and link to reset your password; select the link once you receive it. Fill out the Password fields and select **Reset Password**. Upon successful reset, you will be prompted to the SPIRIT homepage.

For technical support, please use the following contact information.

AbbVie Global service Desk Phone: 1-800-252-4415 (toll-free within the US)

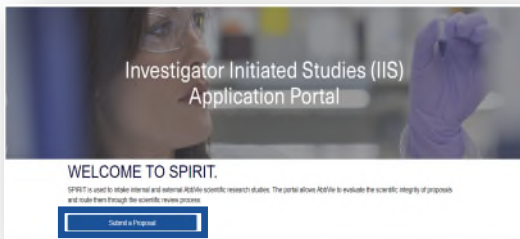
How to Submit an Application

Please follow this quick reference guide for instruction how to submit an AbbVie IIS application. For more detailed instruction, please view the External Submission Guide

- 1 To create your IIS submission, navigate to the SPIRIT web portal by selecting;

www.abbviemedicalresearch.com/

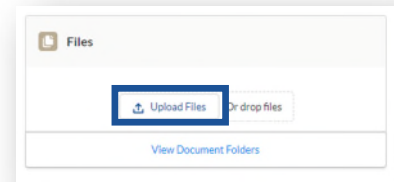
- 2 Once on the SPIRIT web portal, select **Submit a Proposal**.



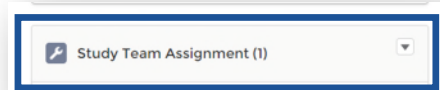
- 3 Select the appropriate **Record Type**. Then, select **Next**

- 4 Once the **New Study Proposal** application opens, complete all mandatory fields. Please use your discretion to fill out the non-mandatory fields as they apply to your application through pages 1-3. Select **Save**

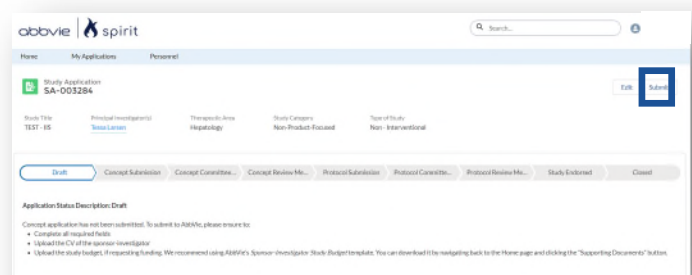
- 5 Next upload **Study Budget** and **CV** documents in the appropriate folders.



- 6 **Add study team and PI** who will be affiliated with the study. If they are not already in the system you will need to add them to **Personnel**



- 7 After all required files are uploaded and personnel are added, navigate back to the Study Application and select **Submit**



Home Page

Home Page

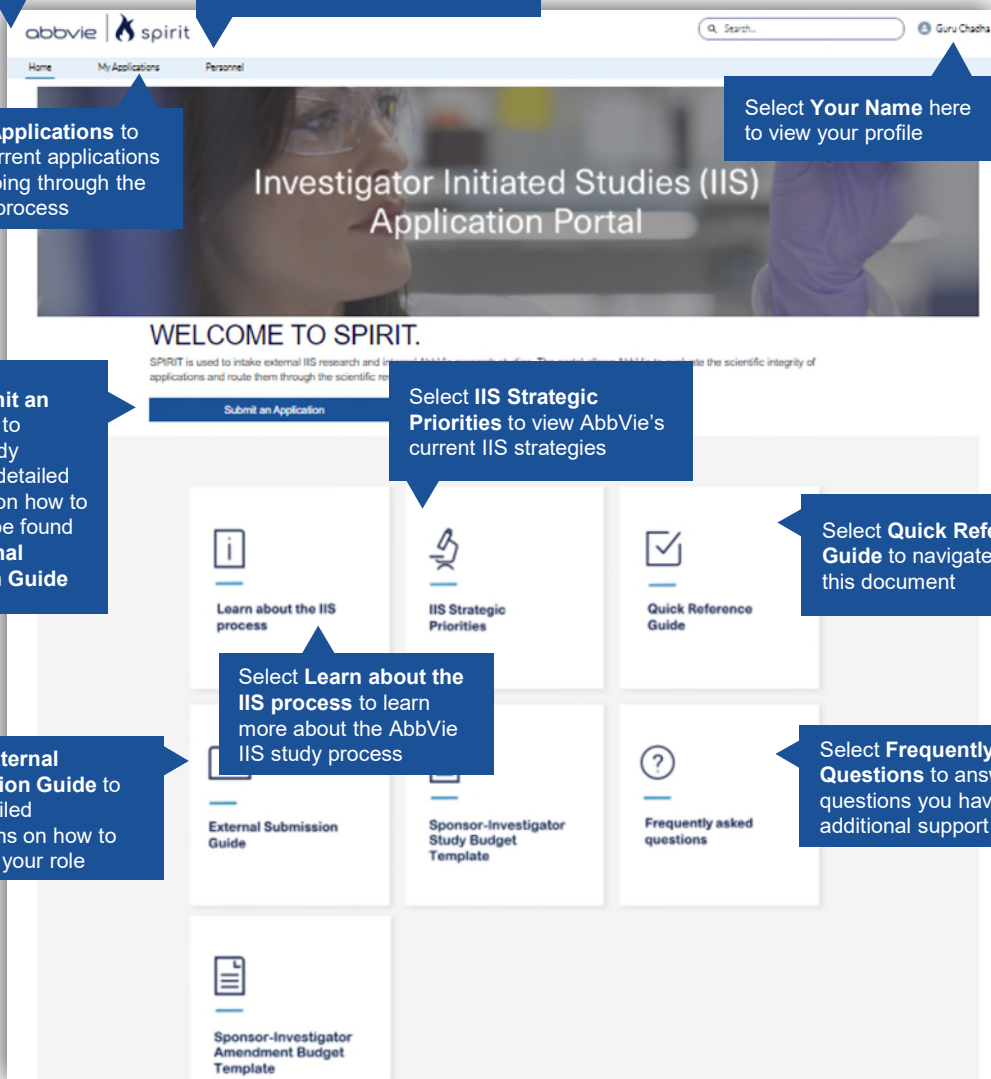
Select the **Home Page** box here to navigate back to this page at any time

Select **Home** to navigate back to this page at any point

Select **Personnel** to view and edit your study team members

Select **My Applications** to view any current applications you have going through the application process

Select **Your Name** here to view your profile



Select **Submit an Application** to submit a study application; detailed instructions on how to do this can be found in the **External Submission Guide**

Select **IIS Strategic Priorities** to view AbbVie's current IIS strategies

Select **Quick Reference Guide** to navigate back to this document

Select **Learn about the IIS process** to learn more about the AbbVie IIS study process

Select **External Submission Guide** to view detailed instructions on how to complete your role

Select **Frequently Asked Questions** to answer any questions you have or find additional support

Select **Sponsor-Investigator Amendment Budget Template** for requesting the needed budget

My Applications

Home Page

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Home My Applications Personnel

Study Applications All Study Applications [dropdown] [refresh]

1 item • Sorted by SPIRIT Number • Filtered by all study applications • Updated a minute ago

Search this list...

SPIRIT Nu...	Study Ac...	Principal Inve...	Therapeutic ...	Indication	Application ...	Product(...	Participating Country(s)	Date of S...	Applicati...
1 SA-003284			Hepatology	Cancer - Gastric (Stomach)	Clinical IIS		United States of America		Draft

New

View your Study Applications here

If you have another Study Application to submit you can either select **New** here or you can navigate back to **Home** and select the **New Application** button

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Home My Applications

Study Applications All Study Applications [dropdown] [refresh]

1 item • LIST VIEWS

- All Study Applications
- Recently Viewed (Pinned)

Search this list...

Application...	Product...	Participating Country(s)	Date of S...	Applicati...
(Stomach)	Clinical IIS	United States of America		Draft

New

The default **List View** is **All Study Application**, but you can also select the dropdown here and select **Recently Viewed** as a **List View** option

Personnel

The screenshot shows the 'Personnel' page in the Abbvie Spirit system. The page title is 'Personnel' and the sub-header is 'Recently Viewed Personnel'. There are callouts explaining various features: 'View your Personnel details here' points to the 'Personnel' breadcrumb; 'Use the filter here to filter your data on both the Personnel and Study Application lists' points to the search bar; 'View all Personnel associated with your study applications here' points to the 'Recently Viewed Personnel' dropdown; and 'Select New to add any additional personnel to your study application' points to the 'New' button.

View your **Personnel** details here

Use the filter here to filter your data on both the **Personnel** and **Study Application** lists

View all **Personnel** associated with your study applications here

Select **New** to add any additional personnel to your study application

This screenshot shows the 'Personnel' page with the 'List Views' dropdown menu open. The dropdown menu lists various list views, with 'Recently Viewed Personnel' selected. A callout points to the dropdown menu, stating 'Select the dropdown menu here to select alternative List Views available'.

Select the dropdown menu here to select alternative **List Views** available

My Profile

Home Page

View your personal profile details here

Select **Edit** to make any changes or updates to your personal profile

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Home My Applications Personnel

Customer Manager

Title Company Name

Email Phone

Address Mobile

About Me

Post Poll

Share an update... Share

Sort by: Most Recent Activity

Search this feed...

Edit User

*Name Manager

First Name

Middle Name

*Last Name

Suffix

Title Company Name

Email Phone

Address Mobile

Street

City State/Province

Zip/Postal Code Country

About Me

Cancel Save

Study Application

Home Page

View the assigned Study Application number for your study application here

If you need to make any edits to your application, select the Edit button here

Follow along with this chevron to know where your study application is in the review process

Find application status details and next steps highlighted here

Navigate to the Files section to upload any required files for your study application

All details completed in the study application can be found here under Concept Criteria

Any study team members assigned to this study application should be added here under Study Team Assignment

Follow along with the study application history by viewing the Study Application History for details on your study application progress

The screenshot shows a web interface for a study application. At the top, there are navigation tabs: Home, My Applications, and Personnel. The main header displays the application ID 'SA-003284' and 'Study Title: TEST - II'. Below this is a progress bar with stages: Draft (highlighted), Concept Submission, Concept Committee, Concept Review Meeting, Protocol Submission, Protocol Committee, Protocol Review Meeting, Study Endorsed, and Closed. A 'Draft' callout points to this stage. Below the progress bar is the 'Application Status Description: Draft' section, which includes instructions and a list of required uploads. A 'Files' section is visible with 'Upload Files' and 'Or drop files' buttons. Below that is 'Study Team Assignment (0)' and 'Study Application History (1)'. A 'Concept Criteria' section is partially visible on the left, containing fields for Principal Investigator (Tessa Larsen), Abbvie Contact (Tessa Larsen), and other study details. A 'Study Overview' section on the right lists therapeutic area (Hepatology), study type (Non-Interventional), and other metadata. Callout boxes provide instructions for each of these key areas.

Submit an Application

Home Page

Once you select **Submit an Application** you will be prompted to complete the **New Application**

New Application

Select a record type

Clinical IIS

Study where an Investigator independently generates a Scientific Research proposal for AbbVie review & for which AbbVie provides Scientific Research Support (study drug and/or funding and/or proprietary samples or assays) in the form of a research grant

Pre-Clinical IIS

Study conducted using in vitro or animal models by a scientific researcher which AbbVie may support with a drug and/or funding

Cancel

Next

For detailed instruction on how to submit a **New Study Proposal** view the **External Submission Guide** on the **Home Page**

Learn about the IIS process

Home Page

Once you select **Learn about the IIS process** you will be navigated to the AbbVie Investigator-Initiated Studies webpage where you will learn about the key details and process of IIS studies

The screenshot shows the AbbVie website's Investigator-Initiated Studies (IIS) page. At the top, there is a navigation bar with 'Global - EN', 'Investors', 'News Center', and 'Patient Assistance'. Below this is the main navigation menu with 'Our Company', 'Our Science', 'Societal Impact', 'Careers', and 'Partnerships'. A search icon is also present. The breadcrumb trail reads 'Additional Collaboration Opportunities / Investigator-Initiated Studies (IIS) / Select a Topic'. The main heading is 'Investigator-Initiated Studies', followed by a paragraph: 'We're committed to supporting investigator-initiated research that promotes the advancement of medical and scientific knowledge involving AbbVie's products and therapeutic areas of interest.' Below this is a section titled 'Advancing science through investigator-led research' with a paragraph explaining the program's goals. The 'How to apply' section states that investigators can submit a brief summary of proposed research through the 'IIS Study Submission Portal'. A final note mentions that IIS applications are accepted on a rolling submission basis.

Global - EN Investors News Center Patient Assistance

abbvie Our Company Our Science Societal Impact Careers Partnerships Q

Additional Collaboration Opportunities / Investigator-Initiated Studies (IIS) / Select a Topic

Investigator-Initiated Studies

We're committed to supporting investigator-initiated research that promotes the advancement of medical and scientific knowledge involving AbbVie's products and therapeutic areas of interest.

Advancing science through investigator-led research

The research from Investigator-Initiated Studies may expand our understanding of our products and their potential applications. Plus, it may improve patient care and spark new ideas for further disease-related research. The AbbVie IIS Program provides an opportunity to academic and community-based physicians and researchers worldwide interested in conducting their own research to apply for research support.

How to apply

If you're an investigator, you can initiate the application process by submitting a brief summary of the proposed research for AbbVie or legacy Allergan associated products through the: [IIS Study Submission Portal](#).

IIS applications are accepted on a rolling submission basis.

IIS Strategic Priorities

Once you select **IIS Strategic Priorities** you will be navigated to the **AbbVie IIS Strategic Priorities** where you will find all the details surrounding the IIS priorities

2022 IIS Strategic Priorities

Contents

Body Contouring: Coolsculpting, CoolTone	2
Facial Aesthetics: Botox/Vistabel, Fillers (Juvederm, Vycross, Hylacross, HAmonyCa), Kybella/Belkyra	3
Plastics and Regenerative Medicine: Breast Implants, ADMs, Fat Grafting	4
CNS – Migraine: OnabotulinumtoxinA/BoNTA from AbbVie (Botox), Ubrogapant (Ubrelyvy), Atogepant (Qulipta)	5
CNS – Neurotoxin Therapeutics – Botox (OnabotulinumtoxinA): Toxin Science, Spasticity and Movement Disorder, Urology	7
CNS – Psychiatry– Vraylar (Cariprazine): Bipolar Disorder I, Schizophrenia	9
Eye Care: Durysta, XEN 45/63, Ozurdex, AGN-190584 Pilocarpine 1.25% ophthalmic solution (Vuity) ..	11
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Immunology – Dermatology: Adalimumab (HUMIRA), Risankizumab (SKYRIZI), Upadacitinib (RINVOQ)	13
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Oncology: Epcoritamab (NHL)	18
Oncology: Telisotuzumab vedotin (Teliso-V), Non-small cell lung cancer (NSCLC)	19
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Specialty – COVID-19	21

External Submission Guide

Home Page

Once you select **External Submission Guide** you will be navigated to the **External Submitter Training** where you will find step-by-step instructions on how to submit a study



Supporting Documents

Home Page

Once you select **Supporting Documents**, you'll find the **AbbVie's Sponsor-Investigator Study Budget Template**. We recommend you use this when completing your study budget

The screenshot displays the 'Sponsor-Investigator Study Budget Request' template in Microsoft Excel. The spreadsheet is organized into several sections:

- Section I: Study Procedures** (Rows 11-23): A table with columns for Study Procedures, Description, CPT Code, Unit Cost, Number of Units, and Total (USD). It includes a Subtotal row.
- Section II: Administrative Services (if applicable)** (Rows 25-29): A table with columns for Name of Administrative Services, Unit Description, CPT Code, Unit Cost, Number of Units, and Total (USD). It includes a Subtotal row.
- Section III: Technical Services (if applicable)** (Rows 31-35): A table with columns for Name of Technical Services, Unit Description, CPT Code, Unit Cost, Number of Units, and Total (USD). It includes a Subtotal row.
- Section IV: Other Services/Data Analysis/Publication Costs (if applicable)** (Row 36): A table with columns for Other Services/Data Analysis/Publication, Unit Description, CPT Code, Rate per, Number of, and Total (USD).

The 'Name, Phone Number and Email Address of Contact(s) in Institution's Grants and Contracts' field is highlighted in green in the original image, and a blue callout box points to it with the text: 'Once you select **Supporting Documents**, you'll find the **AbbVie's Sponsor-Investigator Study Budget Template**. We recommend you use this when completing your study budget'.

Frequently Asked Questions

[Home Page](#)

Once you select **Frequently Asked Questions** you will be navigated to the **External Submission FAQ** document

