Spirit

External Quick Reference Guide
## Change Log

<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 Dec 2023</td>
<td>• Updated guide formatting and images</td>
</tr>
<tr>
<td>05 Oct 2022</td>
<td>• Added Instructions on ‘How to Withdraw an Application’</td>
</tr>
<tr>
<td>08 Jul 2022</td>
<td>• Added instructions on ‘How to Report an Issue’</td>
</tr>
<tr>
<td>17 Mar 2022</td>
<td>• Updated support contact details( Refer How to Create an Account)</td>
</tr>
<tr>
<td>05 Jan 2022</td>
<td>• Revised Technical Support Contact Information(Refer How to Create an Account)</td>
</tr>
<tr>
<td>13 Dec 2021</td>
<td>• Revised to include the current screenshots, links, and references.</td>
</tr>
</tbody>
</table>
External Quick Reference Guide

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

To use this document; click the tiles on table of content slide to navigate to the topic page and description.

Step-by-step instructions on how to submit a Study Application can be found in the External Submission Guide. Login to the SPIRIT portal here and access via the homepage.
Table of Contents

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 Withdraw a Study Application
- Report an Issue
How to Create an Account

Please follow the notes below to create a SPIRIT account. For more detailed instructions, please review the External Submission Guide.

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

2. When the SPIRIT homepage opens, select Register New User

3. Enter your email to setup an 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 are required to create an account

5. You will receive an email with 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 redirected 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 a Study Application

Use this quick reference guide to navigate 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:
   www.abbviemедicalresearch.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. 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 to the appropriate folders.

6. Add study team and the Principal Investigator (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 in the top right corner.

8. Use this quick reference guide to navigate how to submit an AbbVie IIS application. For more detailed instruction, please view the External Submission Guide.
Homepage

**My Applications** includes an overview of your applications currently in process.

**Personnel** allows users to view and edit study team members.

**External Submission Guide** provides detailed instructions on how to complete your role.

**Protocol Guideline** shares the AbbVie recommended template.

**Budget request templates** are categorized by Pre-Clinical and Clinical Study Application types.

**Detailed instructions on how to submit an application can be found in the External Submission Guide.**
My Application

To submit another Study Application, either select **New** in the top right corner of this page or navigate back to **Home** and click the **New Application** button.

View the details of a **Study Applications** by selecting the application number.
Personnel

Select New to add personnel to your Study Application.

Use the filter button to categorize data on both the Personnel and Study Application lists.

Select the dropdown menu to choose additional List Views.
My Profile

Select **Edit** to make changes to your personal profile.
Study Application

The chevrons show where the Study Application is in the review process.

Find application status details and next steps highlighted here.

All details completed in the Study Application can be found in the Concept Criteria section.

Navigate to the Files section to upload required files.

Assign study team members by clicking the drop-down arrow for Study Team Assignment.

Follow the Study Application progress by viewing the Study Application History.
Submit an Application

Clicking the ‘Submit an Application’ button initiates the application process—starting with choosing the record type.

For detailed instruction on how to submit a New Study Proposal, view the External Submission Guide on the Home Page.
How to Withdraw an Application

For more detailed instructions, please review the **External Submission Guide**.

1. In the event a Study Application draft needs to be withdrawn, click the ‘Withdraw’ button on the top right corner of Study Application detail screen.

2. The status of the Study Application will update to ‘Application Withdrawn’. No further action can be performed on this Study Application.
Learn About the IIS Process

Selecting ‘Learn about the IIS process’ opens the AbbVie Investigator-Initiated Studies webpage where information about the key details and process of IIS studies is available.

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 Allergen associated products through the IIS Study Submission Portal.

IIS applications are accepted on a rolling submission basis.
IIS Strategic Priorities

Selecting ‘IIS Strategic Priorities’ downloads the current AbbVie IIS Strategic Priorities document with details on the IIS priorities.

2022 IIS Strategic Priorities

Contents

Body Contouring: Coolsculpting, CoolTone ................................................................. 2
Facial Aesthetics: Botox/Vistabel, Fillers (Juvederm, Vycross, Hylacross, HArmonyCa), Kybella/Beikyra 3
Plastics and Regenerative Medicine: Breast Implants, ADMs, Fat Grafting ........................................... 4
CNS – Migraine: OnabotulinumtoxinA/BotoNTA from AbbVie (Botox), Ubrogepant (Ubrelvy), Atogepant (Gulipta) ........................................................................... 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-100584 Pilocarpine 1.25% ophthalmic solution (Vuity) ... 11
Immunology – Gastroenterology: Risaankizumab & Upadacitinib .................................................... 12
Immunology – Dermatology: Acalimunab (HUMIRA), Risaankizumab (SKYRIZI), Upadacitinib (RINVOQ) .......................................................... 13
Immunology – Rheumatology: Upadacitinib (RINVOQ) ................................................................. 15
Oncology: Venetoclax (ABT-199) ..................................................................................... 16
Oncology: Navibolax (ABT-263) ..................................................................................... 17
Oncology: Epcritamab (NHL) ............................................................................................ 18
Oncology: Telsotuzumab vedotin (Telo-Sy), Non-small cell lung cancer (NSCLC) ........................... 19
Specialty – Hepatology – Maviret/Mavyret: Hepatitis C Virus (HCV) .............................................. 20
Specialty – COVID-19 .......................................................................................................... 21
External Submission Guide

Supporting Documents

Selecting ‘Supporting Documents’ downloads the AbbVie’s Sponsor-Investigator Study Budget Template. We recommend using this template when completing your study budget.

![Budget template screenshot]

**Budget request templates** are categorized by Pre-Clinical and Clinical Study Application types.
Frequently Asked Questions

Selecting ‘Frequently Asked Questions’ downloads the **External Submission FAQ** document.
Protocol Guideline

Selecting ‘Protocol Guideline’ downloads the AbbVie recommended template.

<table>
<thead>
<tr>
<th>Section</th>
<th>Protocol Content Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>General Information</td>
</tr>
<tr>
<td>1.1</td>
<td>Study Title &amp; Study Phase:</td>
</tr>
<tr>
<td>1.1.1</td>
<td>Protocol title, study phase,</td>
</tr>
<tr>
<td>1.1.2</td>
<td>Protocol Version Number &amp; Date:</td>
</tr>
<tr>
<td>1.1.3</td>
<td>Protocol identifying version number(s) (if any), and date. Any amendments should also bear the amendment version number(s) and date.</td>
</tr>
<tr>
<td>1.2</td>
<td>Institution Name:</td>
</tr>
<tr>
<td>1.3</td>
<td>Investigator Contact Information:</td>
</tr>
<tr>
<td>1.3.1</td>
<td>Name and title of the investigator responsible for conducting the research, and the full address and telephone number(s) of the research site(s). Please include the name (if different from investigator) and e-mail address of a primary contact for the study.</td>
</tr>
<tr>
<td>2.0</td>
<td>Background Information</td>
</tr>
<tr>
<td>2.1</td>
<td>Rationale &amp; Background Information:</td>
</tr>
<tr>
<td>2.1.1</td>
<td>The rationale specifies the reasons for conducting the research. Include a well-documented statement of the need problem that is the basis of the project, the cause of the problem, and its possible solutions. Answer the question: why the research needs to be done and what will be its relevance and impact. Include selected literature references critical to the study design, medication or treatment or intervention selection, if appropriate dosage selection, or rationale for study with citations, if appropriate.</td>
</tr>
<tr>
<td>3.0</td>
<td>Core Protocol</td>
</tr>
<tr>
<td>3.1</td>
<td>Study Objectives and Purpose:</td>
</tr>
<tr>
<td>3.1.1</td>
<td>State primary objective of the study in a simple and specific manner. Include secondary, tertiary and/or exploratory objectives, as appropriate.</td>
</tr>
<tr>
<td>3.2</td>
<td>Study Design:</td>
</tr>
<tr>
<td>3.2.1</td>
<td>This section is a concise overview of the study design, including the following:</td>
</tr>
<tr>
<td>3.2.2</td>
<td>Type of experimental design (prospective or retrospective), observational or interventional, cross sectional or longitudinal, randomized blocks, crossover, etc.</td>
</tr>
<tr>
<td>3.2.3</td>
<td>Description of study controls, if applicable (treatments or interventions other than the test product and/or placebo).</td>
</tr>
<tr>
<td>3.2.4</td>
<td>Description of the type (e.g., open-label, single or double-blind, study phase).</td>
</tr>
<tr>
<td>3.2.5</td>
<td>A specific statement of the primary end points and the secondary end points, if any, to be measured during the study, and.</td>
</tr>
<tr>
<td>3.2.6</td>
<td>The number of the study centers (single or multi-center).</td>
</tr>
<tr>
<td>3.2.7</td>
<td>The number of study centers and country (single or multi-center/country) and the total number of subjects included in the study and how they will be assigned to treatment groups and countries must be indicated. When appropriate, state if and how the subjects will be stratified.</td>
</tr>
<tr>
<td>3.3</td>
<td>Inclusion Criteria</td>
</tr>
<tr>
<td>3.4</td>
<td>Exclusion Criteria</td>
</tr>
</tbody>
</table>
How to Report an Issue

1. Click on 'Report an Issue' on SPIRIT Home page

2. Issue creation screen prompt, Enter Details as requested. Click 'save'

3. A green 'Success' prompt indicates the successful creation of the issue

After an issue is submitted, a support Team member will reach out between 24-48 hours via email on the email address provided during issue creation.