<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
</tr>
</thead>
</table>
| 11 December 2023| • Edited field options for submitting a new Study Application (page 2 & 3)  
• Updated formatting and images                                                                                                                    |
| 31 July 2023    | • Added feature Preventing Duplicate Personnel Entries for a Study Team  
• Added feature Removing a Team Member from an Assignment                                                                                       |
| 05 October 2022 | • Mandatory field ‘NPI id’ added on Registration page  
• Added Instructions on ‘How to withdraw a study application’                                                                                     |
| 01 July 2022    | • Added Instructions on a New Feature: How to Report System Issue  
• Added Instructions on ‘Email Reminder: Protocol Submission’                                                                                     |
| 17 March 2022   | • Revised Support Contact Details(Refer System Support)                                                                                             |
| 05 January 2022 | • Updated Support Contact Details(Refer System Support)                                                                                              |
| 13 December 2021| • Added the enhanced Statistical Analysis Plan field (Refer 'HOW TO COMPLETE A STUDY APPLICATION')                                                 |
Contents

- Navigate Training
- Process Flow
- Your Role
- Role Actions
- System Support
Navigate Training

This training document is an interactive, clickable resource created to support you in your role in the SPIRIT study submission process.


2. Click each of your actions to be navigated to the step-by-step training for that specific action(s).

3. Access all training resources on the SPIRIT homepage at any time for on-the-job support.
Your Concept has been endorsed to move into the Protocol review process. You may be asked to submit a final study budget for further evaluation.

Your Protocol is being reviewed by our Scientific Review Committee in preparation for an upcoming Scientific Review Committee meeting. **Please note:** Review of an application does not imply or guarantee approval.

Your Protocol is scheduled to be reviewed at a Scientific Review Committee meeting. If approved, the support provided by AbbVie may be in the form of product and/or funding, dependent on the type of research and availability of funds.

AbbVie has concluded that this research promotes the advancement of medical and scientific knowledge involving AbbVie’s products and/or therapeutics areas of interest. Protocol has been endorsed and the support provided by AbbVie may be in the form of product and/or funding.

Please upload your final Protocol document within 6 months of Concept endorsed.

The meeting date will be listed below on your proposal record once it is ready to be placed on the agenda. We will contact you if we have any additional questions.

AbbVie will contact you to update you with the Review Committee outcome.

If there are any changes to the endorsed Protocol, you will need to upload a Protocol Amendment to the Protocol Documents Folder for review.

**If APPROVED:** you will receive a notification that it has been approved  
**If DECLINED:** you will receive an email with our reasoning
### Process Flow

<table>
<thead>
<tr>
<th>Phase Overview</th>
<th>Your Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Draft</strong></td>
<td>• If your application is in “draft,” it has not been submitted. In order to submit to AbbVie, please ensure to:</td>
</tr>
<tr>
<td></td>
<td>• Complete all required fields</td>
</tr>
<tr>
<td></td>
<td>• Upload the CV of the sponsor-investigator</td>
</tr>
<tr>
<td></td>
<td>• Upload the study budget, if requesting funding (We recommend you use AbbVie’s Sponsor-Investigator Study Budget template. You can download it by navigating back to the home page and clicking the “Supporting Documents” button.)</td>
</tr>
<tr>
<td><strong>Concept Submission</strong></td>
<td>• During this phase, we are completing a preliminary review of your proposal to determine if it should move forward in our review process.</td>
</tr>
<tr>
<td></td>
<td><strong>Please note:</strong> Submission of a Concept proposal does not imply or guarantee approval. A Review Committee evaluates proposals according to their scientific merit, alignment with our areas of research interest, and available funding. Financial and/or product support is contingent upon full execution of the research agreement by both parties.</td>
</tr>
<tr>
<td><strong>Concept Committee Review</strong></td>
<td>• If your application is approved to begin our review process, your Concept will be submitted to our Scientific Review Committee and placed on the agenda for an upcoming Scientific Review Committee meeting.</td>
</tr>
<tr>
<td></td>
<td>During this phase, our Committee members review your application in preparation for an upcoming Review meeting.</td>
</tr>
<tr>
<td></td>
<td><strong>Please note:</strong> Review of a proposal does not imply or guarantee approval.</td>
</tr>
<tr>
<td><strong>Concept Committee Meeting</strong></td>
<td>• Your Concept application is complete and ready to be reviewed at the Scientific Review Committee meeting. In this forum, AbbVie will evaluate the scientific merit of the application and alignment with our areas of research interest.</td>
</tr>
<tr>
<td></td>
<td><strong>Please note:</strong> Concept endorsement does not imply or guarantee the Protocol will be approved by our Scientific Review Committee.</td>
</tr>
</tbody>
</table>

**AbbVie will contact you to update you with the Review Committee outcome.**

**Click on any of these Your Actions boxes navigate to the step-by-step training for these actions**

**Once you submit your application you will not be able to update it without contacting AbbVie first**
External Submitter

What is my responsibility?

• Create a study application
• Upload key documents
• Add site personnel
• Follow-up on questions / comments with AbbVie Representative
HOW TO CREATE A SPIRIT ACCOUNT

1. To access the SPIRIT portal, select on link here.

2. When directed to the homepage, select on Register New User.

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

If you already have an account and any of your information needs to be updated, you can contact spirit@abbvie.com.

If you have changed affiliate institutions, please register as a new user with your new affiliate email address.
HOW TO CREATE A SPIRIT ACCOUNT

4 Once the **New User Registration** page opens, complete all required fields.

5 Once the fields are completed, select **Next**.

US and Puerto Rico are required to complete the NPI ID, Medical License Number, State, and Postal Code in addition to the marked fields.
HOW TO CREATE A SPIRIT ACCOUNT

You will receive an email with your SPIRIT username and a 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.
1. Navigate to the SPIRIT submission portal and select **Submit an Application**

2. Select the appropriate **Record Type** i.e. Clinical IIS or Pre-Clinical IIS

3. Select **Next**
HOW TO COMPLETE A STUDY APPLICATION

4 Once the New Study Application opens, complete all mandatory fields. Please use your discretion to fill out the non-mandatory fields as they apply to your application.

5 Select Next to navigate to page 2.

** Required to save as a draft
* Required to submit application

For Type of Study:
- **Interventional studies** are when participants receive intervention (i.e. medicine, product, etc.)
- **Non-interventional studies** are when participants do not receive any additional medicines, products, etc.

Note: Pre-Clinical IIS studies will be non-interventional.
HOW TO COMPLETE A STUDY APPLICATION

6 Complete all mandatory fields. Please use your discretion to fill out the non-mandatory fields as they apply to your application.

7 Select Next to navigate to page 3.
HOW TO COMPLETE A STUDY APPLICATION

The field ‘Statistical Analysis Plans’ field is a rich Text Field

This allows you to add graphs, charts, tables as images. To add your image, click on the image icon and upload the image from your computer

You can also add bulleted text and use the other formatting features available

**Applicable to Clinical IIS Applications only**
Complete all mandatory fields. Please use your discretion to fill out the non-mandatory fields as they apply to your application.

The fields highlighted in orange were updated with the December 2023 maintenance update to improve reporting.

Be sure to scroll through to answer all applicable fields.
HOW TO COMPLETE A STUDY APPLICATION

Once all fields are completed, select **Save**.

Even after saving, it is still possible to make edits to these fields before submitting.

The fields highlighted in orange were updated with the December 2023 maintenance update to improve reporting.

For Pre-Clinical IIS Only:
There is a field for List Agents and External Source. Add where you intend to source Combination Agents for Non-AbbVie Products.
Once application is saved, you will be automatically redirected to the **Study Application Draft**

Next, you will need to upload the **CV of the sponsor-investigator** and **Study Budget**

If you are requesting funding, we require you use the AbbVie’s **Sponsor-Investigator Study Budget template**

To find the Supporting Documents section, navigate to the SPIRIT homepage
HOW TO UPLOAD DOCUMENTS

1. To upload files, navigate to the right-hand side section labeled Files.
2. Select Upload Files.
3. Upload Study Budget and CV documents.
4. Once the file is uploaded, select Done.
5. Select the appropriate Document Folder for the file and Save. Repeat steps 1-5 for all documents.
The study team and PI who will be affiliated with the study should be included in the Personnel section of the application prior to submission. To add team, select Personnel on the toolbar.

1. **Select New**
2. **Complete the New Personnel form**
3. **Select Save to save personnel**

An error message will display if more than 20 characters are added to the phone number.

For US and Puerto Rico, Medical License Number, State, and Postal Code are required fields. If the person doesn’t have the Medical License, enter N/A.

Pro Tip: If duplicate names exist, refer to “How to Manage Duplicate Personnel Name” on slide 25.
HOW TO ADD STUDY TEAM ASSIGNMENT (CONT.)

5. Once you add team members to the **Personnel** tab you will need to assign them to the application.

6. Navigate back to the application and select **Study Team Assignment** on the right-hand side.
Select New

Add the New Study Team Assignment

Note: You must include the personnel's full email address to find their information.

Select Save to add the new team member and select Save & New to save and add an additional team member.

You must use the exact email address for the personnel to access their information and assign them to a team.

Remember to add the new team member to Personnel before they are assigned here.

Assigned contacts will have same access right as the application creator of the study application.
If a personnel has already been assigned to a Study Application, an error message will appear confirming they are already added to the Study Team and prevent you from adding them again.

John Smith with john.smith@company.com is already added to the Study Team on SA-004699.
After all required files are uploaded, navigate back to the Study Application and select Submit

Once Study Application is submitted, you will receive an email confirmation that Concept submission is complete

The AbbVie Representative will be in contact with you via email with any questions or next steps

You can monitor the status of your Study Application by viewing the chevron and below next steps

Once you select Submit, you will no longer be able to make changes to your application.

If your Study Application is missing required information, you will receive an error message explaining what is needed.
1. In the event you need to withdraw your study application draft, click the **Withdraw** button on the top right corner of the study application overview.

2. The status of study application will update to **Application Withdrawn**. No further action can be performed on this study application at this point.

An application can only be withdrawn in 'Draft' status.
During both the Concept and Protocol Committee Review phases, the assigned AbbVie Representative may reach out via email with comments or questions from the Review Committee. You will work directly with the AbbVie Representative to address these offline.

Monitor Application History by navigating to your Study Application and viewing Study Application History on the right-hand side.
Once your **Concept** is endorsed, you will receive an email from your SPIRIT representative and will have 6 months to submit the final **Protocol document**.

Once a decision is reached on the **Protocol Submission** you will receive a notification with the decision and next steps

**Application Status Description: Protocol Submission**

Concept has been endorsed to move into the Protocol review process. Submitter will upload the final Protocol document within 6 months of Concept endorsement.

You may be asked to submit a final study budget for further evaluation.

**Application Status Description: Study Endorsed**

AbbVie concluded that this research promotes the advancement of medical and scientific knowledge involving AbbVie’s products and/or therapeutics areas of interest.

Protocol has been endorsed and the support provided by AbbVie may be in the form of product and/or funding, pending contract execution.
HOW TO CREATE A FOLDER

Once Concept is endorsed, you will need to upload Protocol document, but first you will need to create a new Protocol Folder.

To create a new Protocol Folder, navigate to the right-hand side section labeled Files.

Select View Documents Folder.

Select New.

Complete the New Document Folder details.

Select Save.
HOW TO UPLOAD PROTOCOL DOCUMENT OR AMENDMENTS

1. To upload the Protocol, navigate to the right-hand side section labeled **Files**

2. Select **Upload Files**

3. Once file is uploaded, select **Done**

4. Select the Protocol Folder for the uploaded document and select **Save**

You will receive a **Protocol Submission** confirmation once submitted. If any changes are required after endorsement, you need to upload a **Protocol Amendment** and **Summary of Changes**

For US and Puerto Rico, you are required to attach a copy of your Medical License.
EMAIL REMINDER: APPLICATION IN ‘PROTOCOL SUBMISSION’ (>90 DAYS)

1. In the event your study application is in the Protocol Submission phase for 90 days and no protocol document is uploaded to SPIRIT, an automated email will be sent on your SPIRIT login email address.

2. Follow the instructions on previous slide to upload your protocol. Once uploaded, no further action is needed.

   Reach out to your AbbVie contact or associate copied in this email with questions.

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To: <Submitter>
FROM: medicalresearchsupport@abbvie.com
CC: <Medical Research Support email address>,<AbbVie Scientific Lead>

Subject: Protocol Submission Reminder: <Short Title><(SPIRIT Study application#)>

Your Concept was endorsed by the Scientific Review Committee and a protocol was requested approximately 90 days ago. Please accept this gentle reminder to submit your full protocol for review within the next 90 days. If your protocol is not received within the expected timeframe your concept approval will expire and will be subject to resubmission and reconsideration by the Scientific Committee Review. If you have any questions, please reach out to your AbbVie Contact or the Medical Research Support Associated cc’d here.

Kind Regards,
AbbVie Medical Research Support Team
Click the drop-down arrow on the far-right corner of the personnel's row. Select Edit

A new window will open, and End Date can be edited

Select Save

This change can be made by the PI and should be updated if a team member leaves in the middle of a Study Application.
Contents

NAVIGATE TRAINING  PROCESS FLOW  YOUR ROLE  ROLE ACTIONS  SYSTEM SUPPORT
There are 2 ways to report a system issue from the SPIRIT login page

1. **Option 1**: Click Report an Issue at the bottom of the page

2. **Option 2**: If you are not yet registered, Click Register New User on the SPIRIT login screen. At the bottom of the page, click Report an Issue.

For either option, clicking the Report an Issue will open the issue creation screen (shown on the next slide)

3. Once you click Save, a success message will appear

A support member will reach out within 24-48 hours to the email provided during issue creation
HOW TO REPORT A SYSTEM ISSUE (WITHIN SPIRIT)

1. From SPIRIT home, click Report an Issue

2. A New Issue screen prompt appears. Fill in the required details such as Name, Email, Contact, Summary and Description. Add supporting attachments using Upload Files button as applicable

3. Click Save. Once you click Save, a success message will appear

A support member will reach out within 24-48 hours to the email provided during issue creation
System Support

For questions around the **Submission Process**, please view additional resources and FAQs on the [Investigator-Initiated Study homepage](#) or contact the MRS team at medicalresearchsupport@abbvie.com.

For questions around the **Technical Support**, use the following contact information:

**Phone:** 1-800-252-4415  
(toll-free within the US)

For more information, please click:

- [Getting Support on Your Issue](#)
- [SPIRIT Global Service Toll-Free Listing Per Location](#)

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**Business Hours**

<table>
<thead>
<tr>
<th>Language</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>24x7</td>
</tr>
<tr>
<td>French</td>
<td>07:00-19:00 (Monday-Friday)</td>
</tr>
<tr>
<td>Spanish</td>
<td>06:00-00:00 (Monday-Friday)</td>
</tr>
<tr>
<td>German</td>
<td>24x7</td>
</tr>
<tr>
<td>Chinese</td>
<td>08:00-17:00 (Monday-Friday)</td>
</tr>
<tr>
<td>Japanese</td>
<td>08:00-20:00 (Monday-Friday)</td>
</tr>
<tr>
<td>Russian</td>
<td>07:00-19:00 (Monday-Friday)</td>
</tr>
</tbody>
</table>

If your request is outside of business hours, you will receive a response on the next business day.  
(***Note:** The above business hours are local Time zone Hours for the country listed)