<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/13/2021</td>
<td>Added the enhanced Statistical Analysis Plan field (Refer ‘HOW TO COMPLETE A STUDY APPLICATION’)</td>
</tr>
<tr>
<td>01/05/2022</td>
<td>Updated Support Contact Details(Refer System Support)</td>
</tr>
<tr>
<td>03/17/2022</td>
<td>Revised Support Contact Details(Refer System Support)</td>
</tr>
<tr>
<td>07/07/2022</td>
<td>Added Instructions on a New Feature: How to Report System Issue</td>
</tr>
<tr>
<td></td>
<td>Added Instructions on ‘Email Reminder: Protocol Submission’</td>
</tr>
<tr>
<td>10/05/2022</td>
<td>Mandatory field ‘NPI id’ added on Registration page</td>
</tr>
<tr>
<td></td>
<td>Added Instructions on ‘How to withdraw a study application’</td>
</tr>
<tr>
<td>07/31/2023</td>
<td>Added feature Preventing Duplicate Personnel Entries for a Study Team</td>
</tr>
<tr>
<td></td>
<td>Added feature Removing a Team Member from an Assignment</td>
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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.

1. View process flow of entire Scientific Review Process and your specific highlight role

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
Contents

NAVIGATE TRAINING
PROCESS FLOW
YOUR ROLE
ROLE ACTIONS
SYSTEM SUPPORT
### Process Flow

<table>
<thead>
<tr>
<th>Protocol Submission</th>
<th>Protocol Committee Review</th>
<th>Protocol Committee Meeting</th>
<th>Study Endorsed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your Concept has been endorsed to move into the Protocol review process.</td>
<td>Your Protocol is being reviewed by our Scientific Review Committee in preparation for an upcoming Scientific Review Committee meeting. <strong>Please note:</strong> Review of an application does not imply or guarantee approval.</td>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>

#### Phase Overview

- **Protocol Submission**
- **Protocol Committee Review**
- **Protocol Committee Meeting**
- **Study Endorsed**

#### Your Actions

- **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
### Draft

If your application is in “draft,” it has not been submitted. In order to submit to AbbVie, please ensure to:

- Complete all required fields
- Upload the CV of the sponsor-investigator
- 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.)

### Concept Submission

During this phase, we are completing a preliminary review of your proposal to determine if it should move forward in our review process.

**Please note:** 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.

### Concept Committee Review

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.

During this phase, our Committee members review your application in preparation for an upcoming Review meeting.

**Please note:** Review of a proposal does not imply or guarantee approval.

### Concept Committee Meeting

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.

**Please note:** Concept endorsement does not imply or guarantee the Protocol will be approved by our Scientific Review Committee.

### Phase Overview

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft</td>
<td>If your application is in “draft,” it has not been submitted. In order to submit to AbbVie, please ensure to: Complete all required fields; Upload the CV of the sponsor-investigator; 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>Concept Submission</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. <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>
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</tr>
</tbody>
</table>

### Your Actions

**Once you submit your application, you will receive an email confirming that we have received it.**

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

**We will reach out to you, should we have any questions about your submission or if you are missing any important information needed to complete our review process.**

**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 APPROVED:** you will receive a request to submit a protocol.

**If DECLINED:** you will receive an email with our reasoning.

Click on this icon to be navigated back to the Process Flow at any time.

Click on any of these **Your Actions** boxes to be navigated to the step-by-step training for these actions.
Contents

NAVIGATE TRAINING  PROCESS FLOW  YOUR ROLE  ROLE ACTIONS  SYSTEM SUPPORT
External Submitter

What’s my responsibility?

• Create a study application

• Upload key documents

• Add new 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**

**SYSTEM SETUP**

US and Puerto Rico are required to complete the NPI ID, Medical License Number, State, and Postal Code in addition to the marked fields.

All fields marked in red are required fields.
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.
HOW TO COMPLETE A STUDY APPLICATION

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

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.

Select **Next** to navigate to page 2.
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.
**Applicable to Clinical IIS Applications only**

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.

Note: Maximum size of image/s you can add is 1MB.

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

Pro Tip: The maximum Size of image you can add is 1MB. If your image is greater than 1 MB, an error message indicating the size limitation will be displayed.
HOW TO COMPLETE A STUDY APPLICATION

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

9 Select Save

The Study Background and Rationale field has a limit of 32000 characters.

The Proposed Study Arm fields (1-6) each have a limit of 9000 characters.

The Blinding Design field has a limit of 9000 characters.

The Description of Study Population field has an increased limit of 32000 characters.

The Study Background and Rationale field has a limit of 32000 characters.

The Proposed Study Arm fields (1-6) each have a limit of 9000 characters.

The Blinding Design field has a limit of 9000 characters.

The Description of Study Population field has a limit of 32000 characters.

After you select Save you will still be able to make edits before you submit.

Under List Agents and Sources 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.

Follow the review process by viewing this chevron (i.e. study review process flow).

To find the Supporting Documents section, navigate to the SPIRIT homepage.

If you are requesting funding, we require you use the AbbVie’s Sponsor-Investigator Study Budget template.
HOW TO UPLOAD DOCUMENTS

1. Upload **Study Budget** and **CV** documents

2. To upload files, navigate to the right-hand side section labeled **Files**

3. Select **Upload Files**

4. Once the file is uploaded, select **Done**

5. Select the appropriate **Document Folder** for the uploaded document and select **Save**. Repeat steps 1–5 for all documents

For US and Puerto Rico you are required to attach a copy of your Medical License
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.

Please ensure correct PI is added to the study application prior to submission.

Ensure that ‘phone’ value is up to 20 characters. An error message will be displayed if more than 20 characters are added.

Pro Tip: If duplicate names exist, refer to “How to Manage Duplicate Personnel Name” on slide 24.

CONCEPT SUBMISSION

HOW TO ADD STUDY TEAM ASSIGNMENT

1. 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.

2. Select New.

3. Complete the New Personnel form.

4. Select Save to save personnel.
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.
Role Actions

Assigned contacts will have the same access right as the application creator of the study application.

Remember you need to add them to Personnel before they are assigned here.

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

Select New to add the New Study Team Assignment. Note: You must use the exact email address for the personnel to access their information and assign them to a team.

Select Save to add the new team member and select Save & New to save and add an additional team member.
PREVENTING DUPLICATE PERSONNEL ENTRIES FOR A STUDY TEAM

1. 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 Doe with john.doe@company.com is already added to the Study Team on SA-004699.
HOW TO SUBMIT A STUDY APPLICATION

1. After all required files are uploaded, navigate back to the Study Application and select Submit.

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

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

4. 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.

If you have any questions or do not know why you received this e-mail, please contact the AbbVie Medical Research Support Team at medicaresupport@abbvie.com.

Sincerely,
AbbVie Medical Research Support Team
HOW TO WITHDRAW A STUDY APPLICATION

1. In the event you need to withdraw your study application draft, click ‘Withdraw’ button on right corner of study application detail screen.

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

Application can only be withdrawn in ‘Draft’ status.
HOW TO ADDRESS PRE-REVIEW MEETING COMMENTS

1. During the Concept Committee Review phase, the assigned AbbVie Representative may reach out via email with any comments/questions from the Review Committee.

2. You will be working directly with the AbbVie Representative to address these offline.

3. Monitor Application History by navigating to your Study Application and viewing Study Application History on the right-hand side.
During the Concept Review Meeting phase, the assigned AbbVie Representative may reach out via email with any comments/questions from the Review Meeting.

You will be working directly with the AbbVie Representative to address these offline.

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.
HOW TO CREATE A FOLDER

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

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

3. Select View Documents Folder.

4. Select New.

5. Complete the New Document Folder details.

6. Select Save.
HOW TO UPLOAD PROTOCOL DOCUMENT

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.
5. You will receive a Protocol Submission confirmation notification once submitted.
In an event your study application is in ‘Protocol Submission’ phase for 90 days and no protocol document has been uploaded in SPIRIT, an automated email will be sent on your SPIRIT login email address.

Follow the instructions on previous slide (Click [here](#)) to upload your protocol. Once uploaded no further action is needed.

Reach out to your Abbvie contact or the associate copied in this email for any questions.

| To: <Submitter> |
| FROM: [medicalresearchsupport@abbvie.com](mailto: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
**HOW TO ADDRESS PRE-REVIEW MEETING COMMENTS**

1. During the Protocol Committee Review phase, the assigned AbbVie Representative may reach out via email with any comments/questions from the Review Committee.

2. You will be working directly with the AbbVie Representative to address these offline.

3. Monitor Application History by navigating to your Study Application and viewing Study Application History on the right-hand side.
HOW TO ADDRESS PROTOCOL REVIEW MEETING DECISION

1. During the Protocol Review Meeting phase, the assigned AbbVie Representative may reach out via email with any comments/questions from the Review Meeting.

2. You will be working directly with the AbbVie Representative to address these offline.

3. Once a decision is reached on the Protocol Submission, you will receive a notification with the decision and next steps.
If there are any changes to be made after your study has been endorsed, you will be required to upload a Protocol Amendment and a Summary of Changes document.

1. Navigate to the right-hand side section labeled Files and select Upload Files.
2. Once file is uploaded, select Done.
3. Select the Protocol Folder for the uploaded document and select Save.
4. Once uploaded, the AbbVie Representative will reach out with next steps.

Do not replace existing Protocol; upload new Protocol Amendment and Summary of Changes.
HOW TO REMOVE A TEAM MEMBER FROM AN ASSIGNMENT

1. Click the drop-down arrow on the far right of the personnel’s row. Select Edit.

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

3. 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.
HOW TO REPORT SYSTEM ISSUE

There are two ways to report a system issue from Spirit Login screen.

Option 1: Click on ‘Report an Issue’ at the bottom of the Spirit Login Page. This links to Issue creation screen (Refer 2 on next slide for more details).

Once you click ‘Save’ on Issue creation screen, a message prompt is displayed: this indicates that the issue has been created.

Option 2: If you are not yet registered, Click on ‘Register New User’ button on the Spirit Login screen.

At bottom, Click on ‘Report an Issue’. This links to Issue creation screen. (Refer step 2 on next slide for details). Once the issue is created, a success message is displayed. (Refer to Step 2)

A support Team member will reach out within 24-48 hours on the email address provided during issue creation.

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.

Click ‘Save’.

A ‘Success’ prompt indicates the successful creation of the issue.

A support Team member will reach out within 24-48 hours on the email address 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](mailto: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](#)

International Toll Free: [SPIRIT Global Service Toll-Free Listing Per Location](#)

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**Business Hours**

<table>
<thead>
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<th>Hours</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)