<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
</tr>
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<tbody>
<tr>
<td>12/13/21</td>
<td>Added the enhanced Statistical Analysis Plan field (Refer 'HOW TO COMPLETE A STUDY APPLICATION')</td>
</tr>
<tr>
<td>01/05/22</td>
<td>Updated Support Contact Details(Refer System Support)</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

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**ROLE**

**ACTIONS**

**PROCESS**

**FLOW**

**YOUR**

**ROLE**

**ROLE**

**ACTIONS**

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**SUPPORT**
<table>
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<tr>
<th>Draft</th>
<th>Concept Submission</th>
<th>Concept Committee Review</th>
<th>Concept Committee Meeting</th>
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| 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.) | 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. | 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. | 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**
- **Once you submit your application, you will receive an email confirming that we have received it.**
- **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.**

**Your Actions**
- **Once you submit your application you will not be able to update it without contacting Abbvie first.**
- **Click on any of these Your Actions boxes to be navigated to the step-by-step training for these actions**
- **Click on this icon to be navigated back to the Process Flow at any time**

If **APPROVED:** you will receive a request to submit a protocol.  
If **DECLINED:** you will receive an email with our reasoning.
## Process Flow

<table>
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<th>Phase Overview</th>
<th>Your Actions</th>
<th>Protocol Submission</th>
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<th>Protocol Committee Meeting</th>
<th>Study Endorsed</th>
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<tbody>
<tr>
<td>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.</td>
<td>Please upload your final Protocol document within 6 months of Concept endorsed.</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 therapeutic areas of interest. Protocol has been endorsed and the support provided by AbbVie may be in the form of product and/or funding.</td>
<td></td>
</tr>
</tbody>
</table>

### Phase Overview

- **Protocol Submission:** 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.

- **Protocol Committee Review:** 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.

- **Protocol Committee Meeting:** 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.

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

### Your Actions

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

- **If there are any changes to the endorsed Protocol, you will need to upload a Protocol Amendment to the Protocol Documents Folder for review.**
What’s my responsibility?

• Create a study application

• Upload key documents

• Add new personnel

• Follow-up on questions / comments with AbbVie Representative
Contents

- Navigate Training
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**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 abbviegsd@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 Medical License Number, State, and Postal Code in addition to the marked fields.
HOW TO CREATE A SPIRIT ACCOUNT

6. You will receive an email with your SPIRIT username and a link to reset your password; select the link once you receive it.

7. 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
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

Be sure to scroll through to answer all applicable fields.

- 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 Design/Plan section each have a limit of 9000 characters.

Under List Agents and Sources add where you intend to source Combination Agents for Non-AbbVie Products.

After you select Save you will still be able to make edits before you submit.
HOW TO COMPLETE A STUDY APPLICATION

10 Once application is saved, you will be automatically redirected to the Study Application Draft.

11 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.

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

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

Once application is saved, you will be automatically redirected to the Study Application Draft.

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

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

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.

Select New

Complete the New Personnel form

Select Save to save personnel.
Once you add team members to the **Personnel** tab, you will need to assign them to the application.

Navigate back to the application and select **Study Team Assignment** on the right-hand side.
 Assigned contacts will have same access right as the application creator of the study application.

**How to add study team assignment (Cont.)**

7. Select **New**

8. Add the **New Study Team Assignment**

9. Select **Save** to add the new team member and select **Save & New** to save and add an additional team member.
When typing in the Personnel name under Contact Information, you may see a section appear: *Duplicates Found*.

1. If that happens, review the existing Personnel record/s.

2. To use an existing Personnel record, select *Cancel* and proceed to step 5 on slide 20.

3. If the existing record is not correct, continue completing the Personnel form (Step 3, slide 19).

**Pro Tip:** If you click on 100% under *Score* you may receive the error message above. This issue is being addressed with future SPIRIT release functionality, please close out the error message and disregard it.
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.
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.
To upload the Protocol, navigate to the right-hand side section labeled Files

Select Upload Files

Once file is uploaded, select Done

Select the Protocol Folder for the uploaded document and select Save

You will receive a Protocol Submission confirmation notification once submitted
During the Protocol Committee Review phase, the assigned AbbVie Representative may reach out via email with any comments / questions from the Review Committee.

You will be working 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.
HOW TO ADDRESS CONCEPT 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.
System Support

For questions around the **Submission Process**, please view additional resources and FAQ on the SPIRIT home page [here](#) or contact the MRS team at [medicalresearchsupport@abbvie.com](mailto:medicalresearchsupport@abbvie.com)

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

**Email:** abbvieg@abbvie.com

**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**

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<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>
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</table>

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