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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
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## Process Flow

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

### Your Actions
- **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.

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

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.
**Process Flow**

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<th>Phase Overview</th>
<th>Your Actions</th>
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<tbody>
<tr>
<td><strong>Protocol Submission</strong></td>
<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>
</tr>
<tr>
<td><strong>Protocol Committee Review</strong></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>
</tr>
<tr>
<td><strong>Protocol Committee Meeting</strong></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>
</tr>
<tr>
<td><strong>Study Endorsed</strong></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>

**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.
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**.

- **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

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 a Proposal
2. Select the appropriate Record Type
3. Select Next
HOW TO COMPLETE A STUDY APPLICATION

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.

5. Select Next to navigate to page 2.

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.

Pre-clinical IIS studies will not be Interventional.

Use the arrows for dropdown options to populate the fields.

Select all that apply.

Select the “i” next to each field for more details.

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

Note: fields with two asterisks are required to save as a draft and fields with one asterisk are required to submit a proposal.
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 3.
**How to Complete a Study Application**

1. Complete all mandatory fields.
2. Please use your discretion to fill out the non-mandatory fields as they apply to your application.
3. 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 Background and Rationale clinical**
- **Blinding Design**
- **Number of Subjects**
- **Number of Subjects (Lower limit)**
- **Number of Subjects (Upper limit)**
- **Study Design**
- **Study Design - Control Type**
- **Historical**
- **Proposed Study Arm 1**
- **Proposed Study Arm 2**
- **Proposed Study Arm 3**
- **Proposed Study Arm 4**
- **Proposed Study Arm 5**
- **Proposed Study Arm 6**
- **Description of Study Population**
- **Representative**
- **Subject Gender**
- **Both**
- **Subject Age (Lower limit)**
- **Subject Age (Upper limit)**
- **Program**
- **PID**

4. After you select **Save**, you will still be able to make edits before you submit.
5. Under **List Agents and Sources**, add where you intend to source **Combination Agents** for Non-AbbVie Products.

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*AbbVie*
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

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

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.

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 or select Save & New to save and add additional personnel.

Pro Tip: If duplicate names exist, refer to “How to Manage Duplicate Personnel Name” on slide 22.
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.
Remember you need to add them to Personnel before they are assigned here.

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

Personnel are limited to one PI assignment and can be assigned to multiple studies. If you need to assign personnel to more than one PI contact medicalresearchsupport@abbvie.com.

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. 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.

2. If that happens, review the existing Personnel record(s).

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

4. If the existing record is not correct, continue completing the Personnel form (Step 3).
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.
HOW TO ADDRESS CONCEPT REVIEW MEETING DECISION

1. During the Concept 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 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.
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 CONCEPT REVIEW MEETING DECISION

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

Application Status Description: Study Endorsed

AbbVie 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, pending contract execution.
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.
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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

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

Email: spirit@abbvie.com

Phone: +833-800-8338 (toll-free within the US)

International Toll Free with AT&T Direct Access Code:
  • Then dial 833-800-8338

Business Hours

English – 24x7
French – 09:00 – 22:00 (GMT+1)
Spanish – 09:00 – 22:00 (GMT+1)
German – 09:00 – 17:00 (GMT+1)
Chinese – 09:00 – 17:00 (GMT+8)
Japanese – 09:00 – 17:00 (GMT+9)
Russian – 09:00 – 17:00 (GMT+3)

If your request is outside of business hours, you will receive a response on the next business day.