Spirit

External
Submitter
Guide

Change Log

Date	Change Description
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')

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Contents

NAVIGATE TRAINING	PROCESS FLOW	YOUR ROLE	ROLE ACTIONS	SYSTEM SUPPORT

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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)
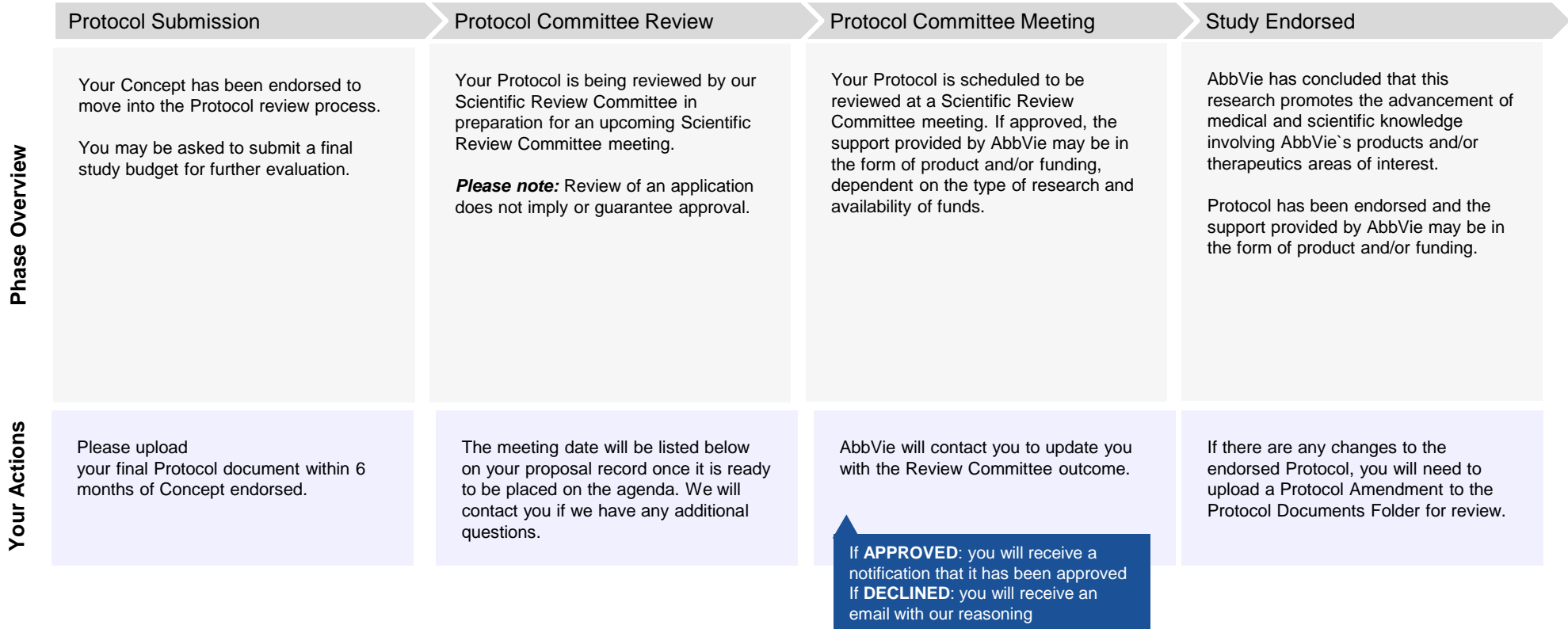
3 Access all training resources on the SPIRIT homepage at any time for on-the-job support

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Process Flow

Protocol Submission	Protocol Committee Review	Protocol Committee Meeting	Study Endorsed

Phase Overview

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.

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 **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.

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Process Flow

	Draft	Concept Submission	Concept Committee Review	Concept Committee Meeting
Phase Overview	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.
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 any of these **Your Actions** boxes navigate to the step-by-step training for these actions

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External Submitter

What is my responsibility?

- Create a study application

- Upload key documents

- Add site personnel

- Follow-up on questions / comments with AbbVie Representative

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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**

Log In

Email

Password

Forgot Username/Password?

☐ Remember user

2

Log In   Register New User

Note: user accounts will be locked after 5 unsuccessful login attempts

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

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NEW USER REGISTRATION

EMAIL

3   Next   Cancel

Privacy Policy | Terms of Use | Contact Us

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

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

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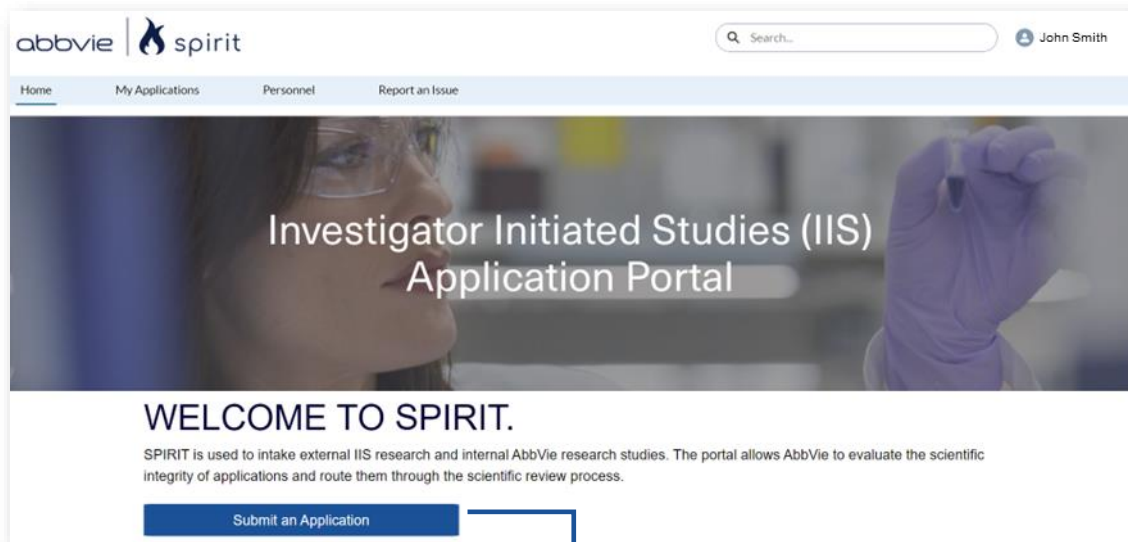
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4 Once the **New Study** Application opens, complete all mandatory fields. Please use your discretion to fill out the non-mandatory fields as they apply to your application

5 Select **Next** to navigate to page 2

4

New Study Application: Clinical IIS (Page 1)

Therapeutic Area ** ⓘ
--None--

Study Category ** ⓘ
--None--

> Hover over the "i" next to each field for more details

Type of Study **
--None--

Type of Support ** ⓘ
Select an option

Single or Multi Country ** ⓘ
--None--

Database Type * ⓘ
--None--

Study Descriptor * ⓘ
Select an option

Research Type *
Select an option

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

Cancel Next

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

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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

6 New Study Application: Clinical IIS (Page 2)

Study Title *

Principal Investigator(s) *

Search Personnel

If you selected the **Pre-Clinical IIS** Record Type, this will say **Other Product(s) Studied**

AbbVie Product(s) Studied * ⓘ

If Product-Focused Study, select all products that apply. If **Non-Product-Focused,** leave field blank. _All AbbVie Products must be included here._

Search Compounds

Non-AbbVie Product(s) Studied * ⓘ

List all Non-AbbVie Products that apply. If no Non-AbbVie drugs apply type N/A

Leading Product ⓘ

--None--

Indication * ⓘ

Search Indication

Select all Indications that apply

Phase *

--None--

Additional Non-AbbVie Funding Secured? ⓘ

--None--

Treatment Line ⓘ

If yes, more information

Requested Funding ($USD) * ⓘ

Participating Country(s) *

Search Country

Planned # of Sites * ⓘ

Who is your AbbVie Contact? * ⓘ

7

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

Cancel   Previous   **Next**

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

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

New Study Application: Clinical IIS (Page 3)

Sample Size Justification *

References

Formatting features

Statistical Analysis Plans *

Salesforce Sans   12

Image icon

Header1	Data 1	Data 2	Data 3
Text 1	+-10%	+-10%	+-1.90%
Text 2	+-1.345%	+-1.340%	+-1.40%

Pro Tip: The maximum image size is **1MB**.

Product Information

Example image

Product Requested

Formulation

Search Compounds

Units

Quantity

Dosing Regimen

Dosing Regimen Units

--None--

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

8 New Study Application: Clinical IIS (Page 3)

Be sure to scroll through to answer all appliable fields

Study Details

Study Research Question *

Study Objective(s) and Endpoints *

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

Rationale

Study Design/Investigational Plan *

Study Design - Control Type *
--None--

Proposed Study Arm 2

Proposed Study Arm 1

Proposed Study Arm 4

Proposed Study Arm 3

Proposed Study Arm 6

Proposed Study Arm 5

Number of Subjects *

Blinding Design
--None--

Subject Gender
--None--

Description of Study Population

Subject Age (lower limit) *

9 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

Frequency
--None--

Additional Products? ⓘ
--None--

Combination Agents ⓘ
--None--

If yes, which ones ⓘ

List Agents and External Source ⓘ

Regulatory Information

Regulatory Submission Required?
--None--

Additional information ⓘ

Planned Study Milestone Dates

First Subject In * ⓘ

Last Subject In * ⓘ

Last Subject Out * ⓘ

Key Study Results Available * ⓘ

Target Journal ⓘ

Additional Planned Publications
Select an option

Target Congress/Year ⓘ

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

Cancel   Previous   Save

9

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**
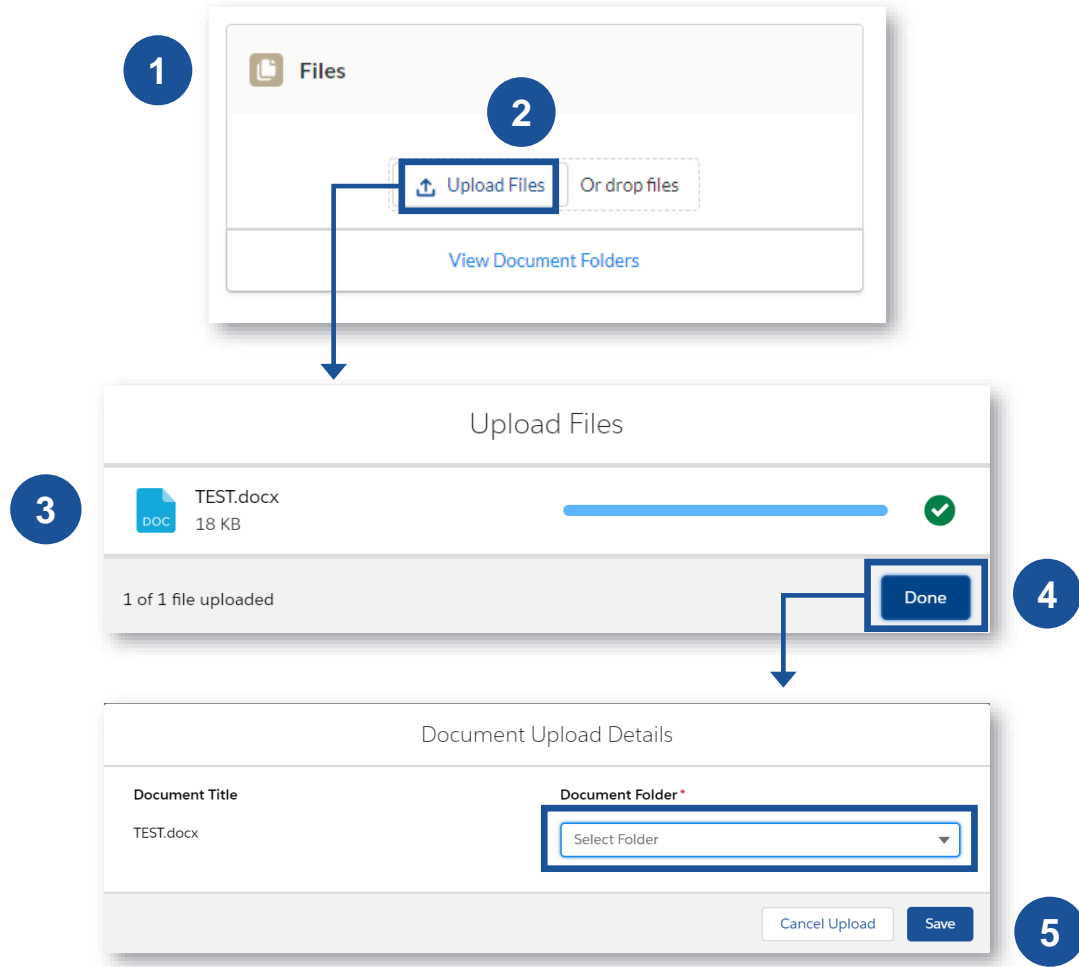

The chevrons show where the study application is in the review process

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

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

1

Files

2

⬆ Upload Files   Or drop files

View Document Folders

3

Upload Files

DOC   TEST.docx
18 KB   ✓

1 of 1 file uploaded   Done   **4**

Document Upload Details

Document Title

TEST.docx

Document Folder *

Select Folder ▼

Cancel Upload   Save   **5**

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

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
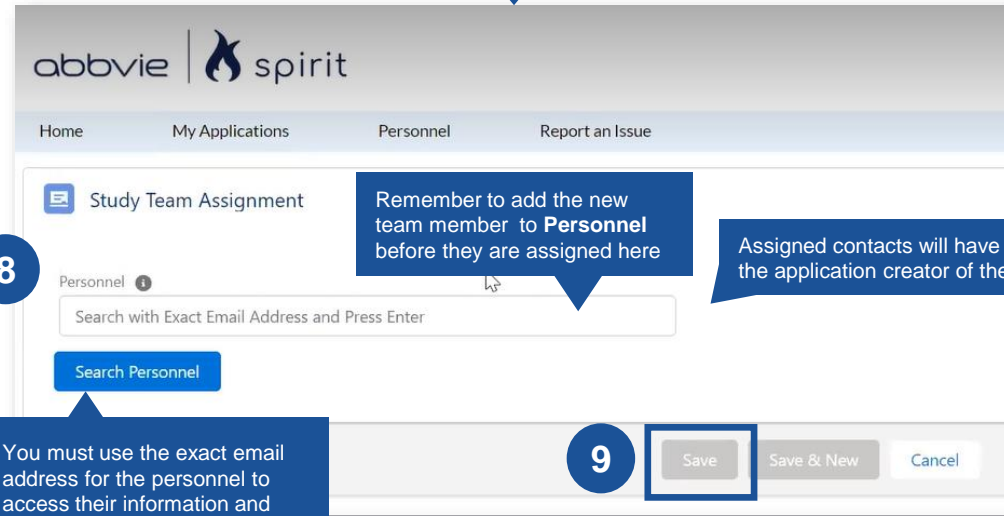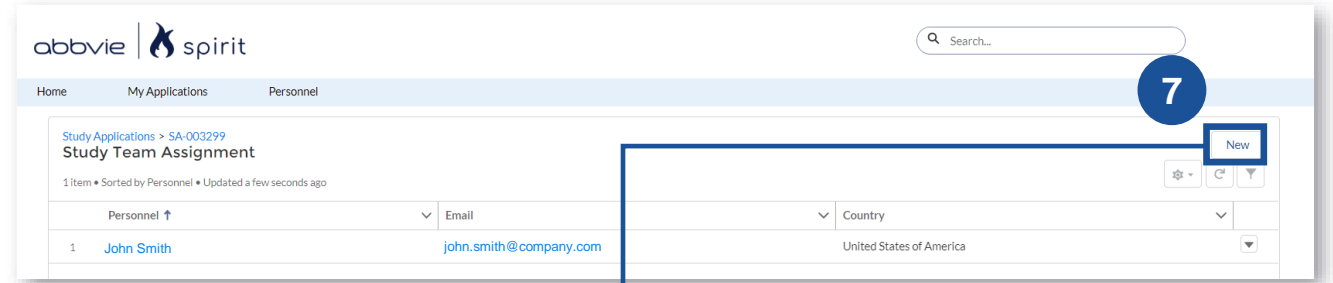
7 Select **New**

8 Add the **New Study Team Assignment**

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

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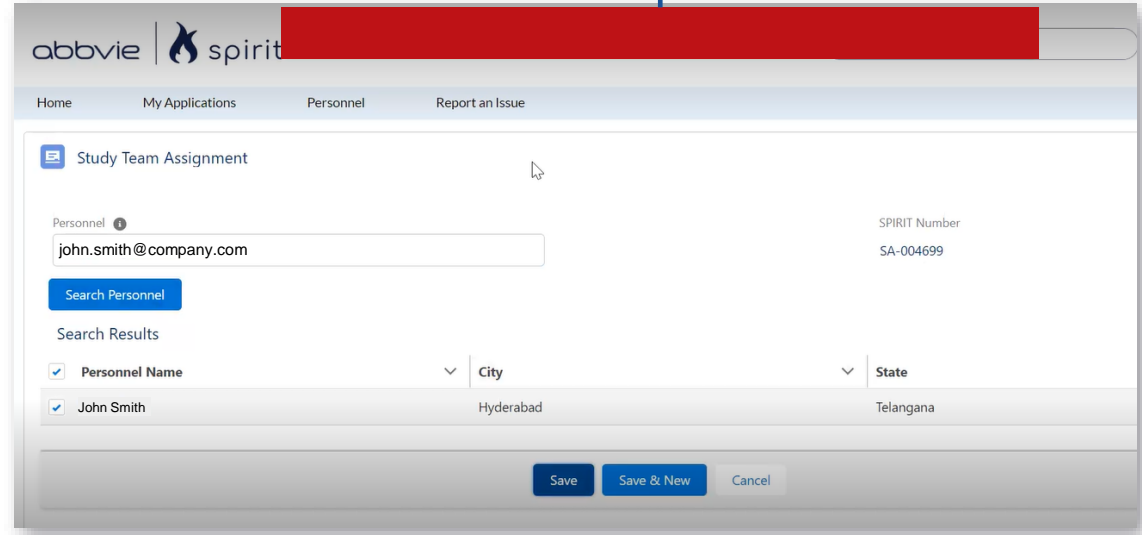

Remember to add the new team member to **Personnel** before they are assigned here

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

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

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

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

1 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

4

2

Study Title:
Spirit #: SA-003284
Principal Investigator:

We have received your Investigator-Initiated Study (IIS) submission in the AbbVie medical research submission portal, referred to as SPIRIT. You may continue to review the status of your submission in the SPIRIT system. We are completing an initial review of your application and will reach out should we have any questions or require additional information.

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

Sincerely,
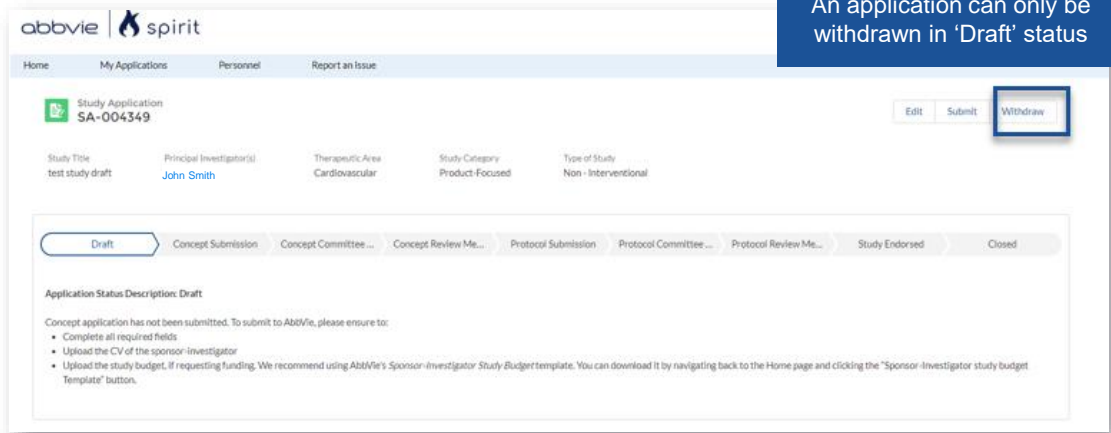AbbVie Medical Research Support Team

HOW TO WITHDRAW A STUDY APPLICATION

1 In the event you need to withdraw your study application draft, click 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
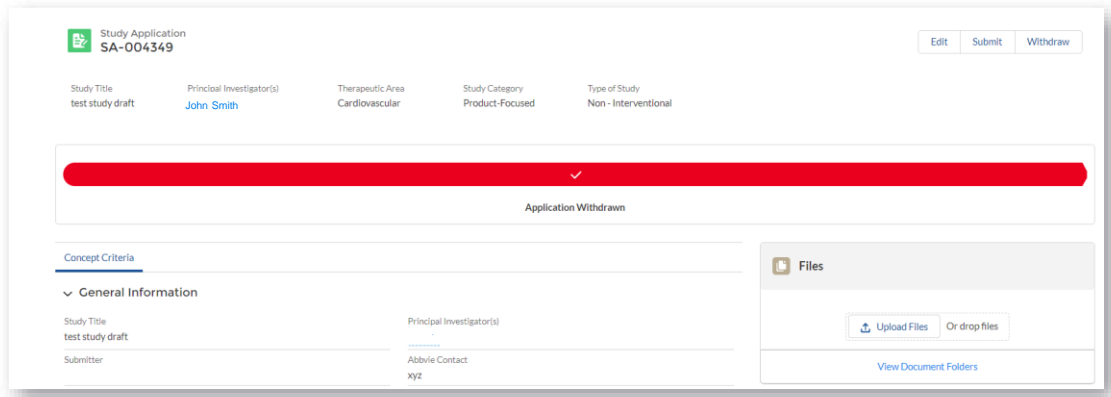
1 During both the **Concept and Protocol Committee Review** phases, the assigned AbbVie Representative may reach out via email with comments or questions from the Review Committee. You will work directly with the AbbVie Representative to address these offline

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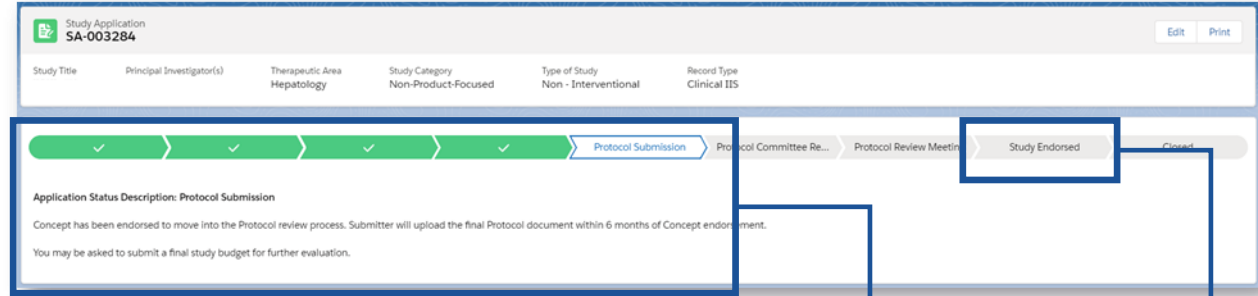
3 Once your **Concept** is endorsed, you will receive an email from your SPIRIT representative and will have 6 months to submit the final **Protocol document**

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

---

Study Application
SA-003284

Edit | Print

Study Title	Principal Investigator(s)	Therapeutic Area	Study Category	Type of Study	Record Type
		Hepatology	Non-Product-Focused	Non - Interventional	Clinical IIS

✓　✓　✓　✓　Protocol Submission　Protocol Committee Re...　Protocol Review Meeting　Study Endorsed　Closed

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.

---

3 **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.

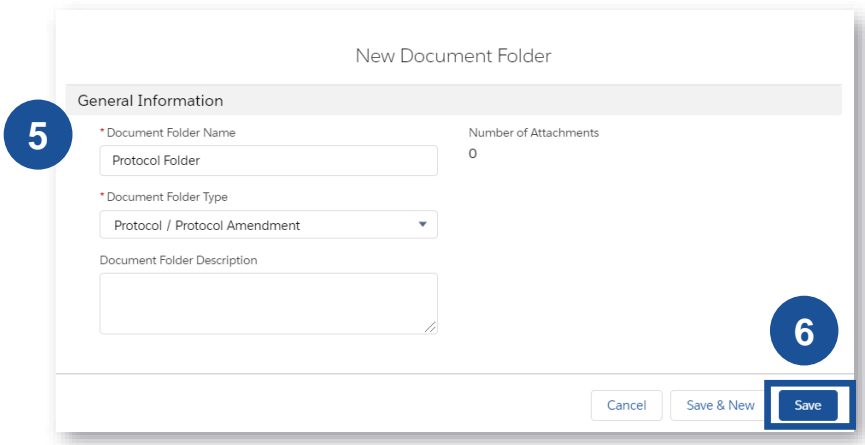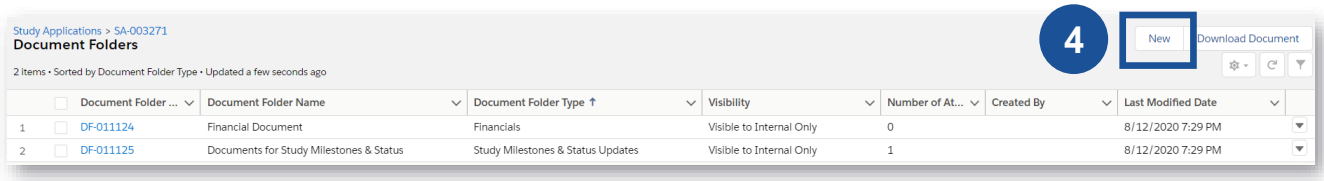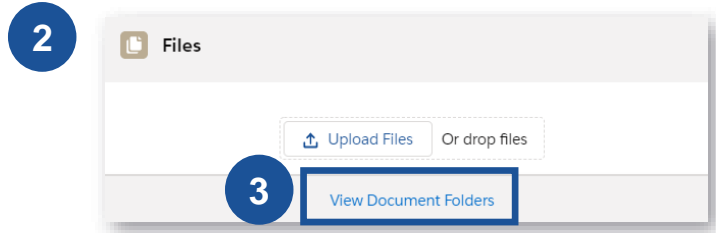**4** **Application Status Description: Study Endorsed**

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

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**

2
Files

Upload Files   Or drop files

3 View Document Folders

Study Applications > SA-003271
Document Folders
2 items • Sorted by Document Folder Type • Updated a few seconds ago

4 New   Download Document

		Document Folder ...	Document Folder Name	Document Folder Type ↑	Visibility	Number of At...	Created By	Last Modified Date	
1		DF-011124	Financial Document	Financials	Visible to Internal Only	0		8/12/2020 7:29 PM	
2		DF-011125	Documents for Study Milestones & Status	Study Milestones & Status Updates	Visible to Internal Only	1		8/12/2020 7:29 PM	

New Document Folder

General Information

5

* Document Folder Name
Protocol Folder

Number of Attachments
0

* Document Folder Type
Protocol / Protocol Amendment ▼

Document Folder Description

6

Cancel   Save & New   Save

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HOW TO UPLOAD PROTOCOL DOCUMENT OR AMENDEMENTS

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**

1 Files

2 ⬆ Upload Files   Or drop files

View Document Folders

Upload Files

📄 TEST.docx
18 KB   ✅

1 of 1 file uploaded   Done   **3**

Document Upload Details

Document Title   Document Folder *

TEST.docx   Select Folder   ▼

⚠ If an amendment is required, do not replace the **existing** Protocol. Upload a **new** Protocol Amendment and Summary of Changes

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

Cancel Upload   Save   **4**

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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

1

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

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HOW TO REMOVE A TEAM MEMBER FROM AN ASSIGNMENT

1 Click the **drop-down arrow** on the far-right corner 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

Status and Start Date are automatically populated fields that cannot be edited.

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HOW TO REPORT A SYSTEM ISSUE (LOGIN)

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
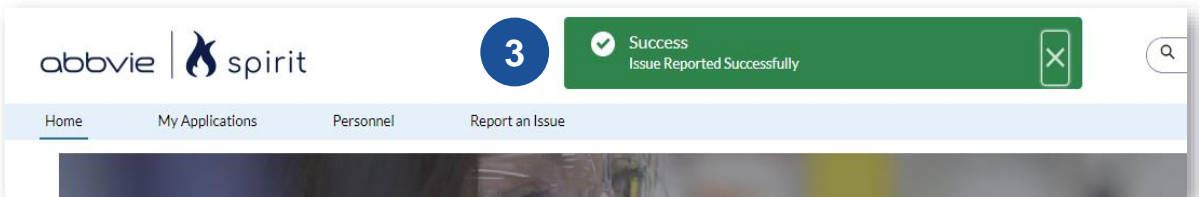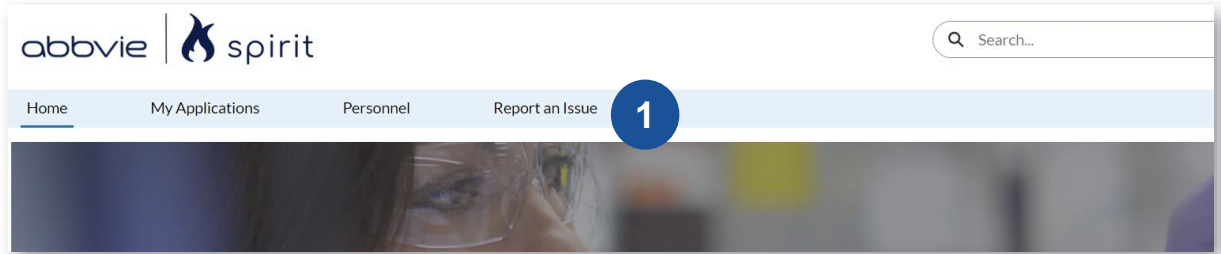
System Support

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

International Toll Free:
SPIRIT Global Service Toll-Free Listing Per Location

Business Hours

English – 24x7
French –07:00-19:00 (Monday-Friday)
Spanish – 06:00-00:00 (Monday-Friday)
German – 24x7
Chinese – 08:00-17:00 (Monday-Friday)
Japanese – 08:00-20:00 (Monday-Friday)
Russian 07:00-19:00 (Monday-Friday)

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)