



# External Submission FAQ

# External Submission | FAQ

QUESTION	ANSWER
What is SPIRIT?	SPIRIT is an optimized scientific review process application for all study types that manages intaking, reviewing, and approving applications.
Is SPIRIT required for submitting study applications?	Yes, all study proposals must be submitted through SPIRIT, via the AbbVie IIS Study Submission Portal at <a href="http://www.abbviemedicalresearch.com/">www.abbviemedicalresearch.com/</a> This is necessary to ensure compliance with our standard operating procedures and optimize the scientific review process and study management for all of AbbVie and its Investigators.
How do I access SPIRIT?	You can access SPIRIT by creating and logging into the SPIRIT IIS Study Submission Portal at <a href="http://www.abbviemedicalresearch.com/">www.abbviemedicalresearch.com/</a>
How do I set-up a SPIRIT account?	Check out the <b>Quick Reference Guide</b> , on the AbbVie-Investigator-Initiated Study home page by clicking <a href="#">here</a> .
How do I submit an application?	You can find the entire study application process in the <b>External Submission Guide</b> or <b>Quick Reference Guide</b> by logging into the SPIRIT IIS Study Submission Portal <a href="#">here</a> .  It is highly recommended that you populate as many fields as applicable to the application. Fields with two asterisks are required to save an application as a draft and fields with one asterisk are required to submit a proposal.
What is required for a study application?	For Investigator Initiated Studies, you are also required to upload: <ul style="list-style-type: none"><li>• A current CV of sponsor-investigator (indicating it has been updated within the last 2 years)</li><li>• A budget (if requesting funding); we recommend using the AbbVie Sponsor-Investigator Study Budget Template on the <b>SPIRIT IIS Study Submission Portal</b> by logging in <a href="#">here</a>.</li><li>• A copy of the Investigator's medical license (for US and Puerto Rico investigators)</li></ul>
Can I save my application for later?	Yes, by clicking <b>Save</b> you will save your application as a draft. Fields with two asterisks are required to save an application as a draft.
What types of research may be of interest to AbbVie?	Please view AbbVie's Therapeutic areas of interest on the Investigator-Initiated Study home page <a href="#">here</a> .

# External Submission | FAQ

QUESTION	ANSWER
<b>When can I expect to hear back from AbbVie regarding my application?</b>	<p>The AbbVie IIS Review Committee meets monthly to review submissions. You can expect to hear back from AbbVie approximately 2 weeks following the review meeting.</p> <p>AbbVie works with alliance partners in the review of IIS applications for some compounds (e.g., Venetoclax (ABT-199)). In these cases, reviews may follow a different timeframe that has been agreed upon by AbbVie and the alliance partner. Expectations to hear back on the status of your application will be communicated to you by an AbbVie representative.</p>
<b>How can I follow the status of my application?</b>	<p>You can follow the status of your application by viewing the study application chevron (i.e. the process bar at the top of your application)</p>
<b>Do I need to submit an application if I am requesting study drug only?</b>	<p>Yes, submission is required for all application types.</p>
<b>What type of support can I request from AbbVie?</b>	<p>Applications may request product only, funding only, or both product and funding. The AbbVie IIS Review Committee applies the same review process for all applications.</p>
<b>Should I include a protocol along with my application?</b>	<p>AbbVie has a 2-step review and approval process for concept and then protocol. Once the concept is reviewed and endorsed by the Review Committee, a full protocol will be requested and then you may develop and submit your protocol on the SPIRIT IIS Study Submission portal.</p>
<b>Can my staff view the study?</b>	<p>Yes, your staff members can create user profiles that will allow you to link your staff to your application.</p>
<b>How do I add personnel to my application?</b>	<p>You can add personnel to your study by navigating to the <b>Personnel</b> tab on your SPIRIT homepage and adding your study team. However, there are some caveats when adding personnel to a study team.</p> <ol style="list-style-type: none"><li>1. If you've already self registered</li><li>2. If you are already associated with a different PI</li><li>3. If you migrated over from Insights 2</li></ol> <p>If you encounter one of the above situations, please contact the support team at <a href="mailto:spirit@abbvie.com">spirit@abbvie.com</a> for a manual adjustment.</p>

# External Submission | FAQ

---

## QUESTION

## ANSWER

**Can I change my submission after I've clicked "Submit"?**

Yes, please contact [medicalresearchsupport@abbvie.com](mailto:medicalresearchsupport@abbvie.com) in order to request the application to be sent back to you.

**How do I withdraw my application?**

Please contact [medicalresearchsupport@abbvie.com](mailto:medicalresearchsupport@abbvie.com) in order to withdraw an application after it has been submitted.

**How do I amend a study that has been endorsed?**

If your study has already been endorsed and requires an amendment, you will need to upload the protocol amendment and a summary of changes in SPIRIT.

**Who should I contact if I have any questions?**

Please send an email to [medicalresearchsupport@abbvie.com](mailto:medicalresearchsupport@abbvie.com) for additional support on the submission process. For technical support, email [spirit@abbvie.com](mailto:spirit@abbvie.com).

---