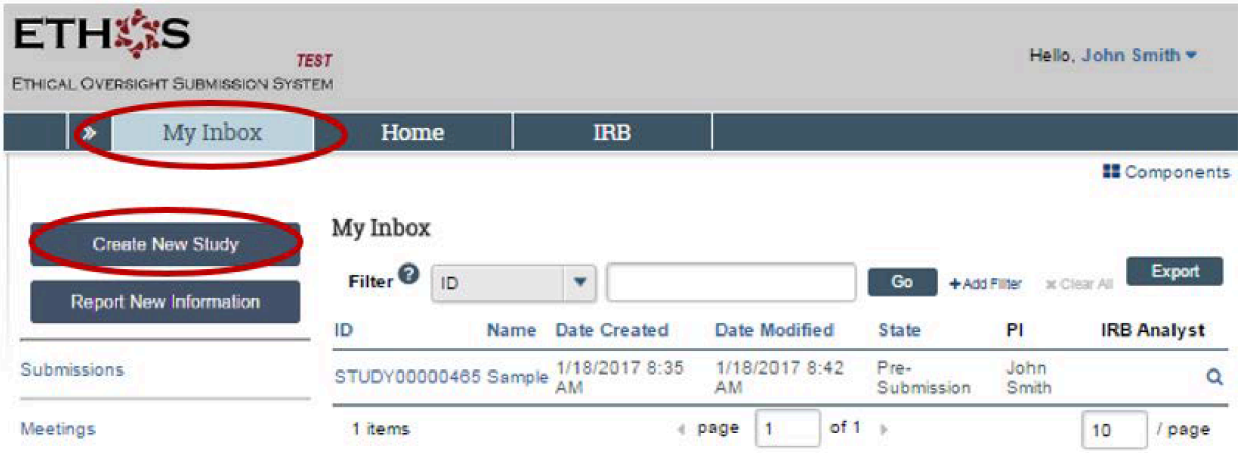
How to Request HRPP Scientific Assessment in ETHOS

Scientific assessment is required for medical research that is not exempt under CFR 45 §46.101(b) or does not qualify for expedited review under CFR 45 §46.110. Refer to the Investigator Manual for information on scientific assessment, including a list of acceptable methods for scientific assessment. Medical research that does not have the scientific assessment requirement met via other acceptable means requires HRPP Scientific Assessment.

If you know your study requires HRPP Scientific Assessment, you may request it after you submit your study in ETHOS, or before submitting if the study is not otherwise ready for review.

Requesting HRPP Scientific Assessment After Submitting in ETHOS



1. Log in to **ETHOS** using your UMN Internet ID and password.

> Need a UMN Internet ID? Forgot your password?

2. Click "My Inbox" on the left of the workspace.

3. Click "Create New Study" to create a new study smart form.

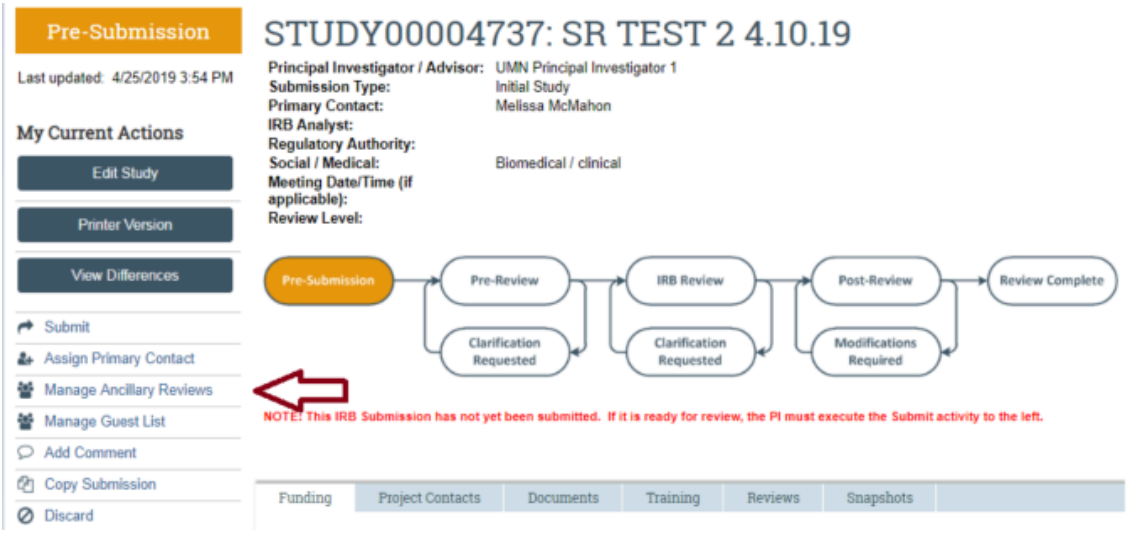
4. Complete the ETHOS smart form. See How to Submit on the IRB website for instructions on competing a submission in ETHOS.

> **TIP:** For reliance / sIRB submissions, refer to How to Submit a Reliance Request.
>
> **TIP:** If using a sponsor or other protocol created not using the IRB protocol template, include HRP-508 - Local Protocol Addendum.
>
> **TIP:** If the study involves FDA regulated drugs and/or devices, also upload the investigator brochure and/or package insert.
>
> **TIP:** For new studies, protocols and participant-facing materials should be uploaded as Word documents with no track changes.

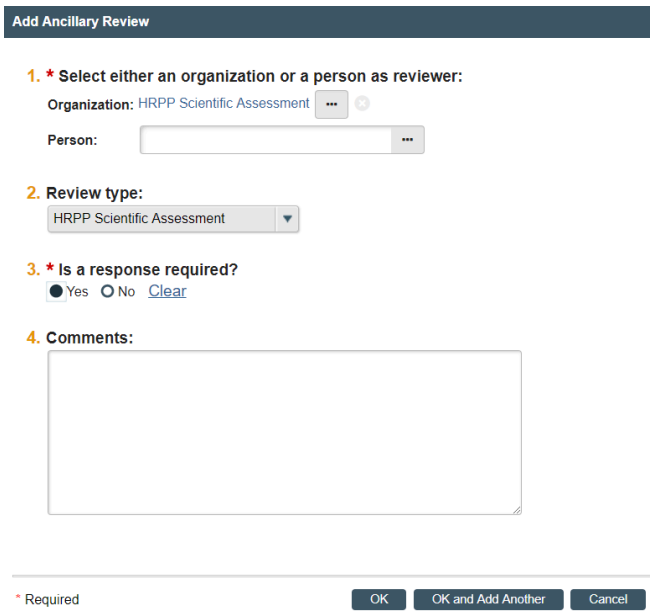
5. Upload HRP-538 - Scientific Review and the investigator's CV in the "Other Attachments" field of the "Supporting Documents" section of the smart form.

6. Submit the study for IRB review. Once you have completed all sections of the ETHOS smart form, click "Continue" to return the study workspace, and click "Submit."

7. Request HRPP Scientific Assessment using the "Manage Ancillary Reviews" action. This is found on the left side of the study workspace after the study is submitted.

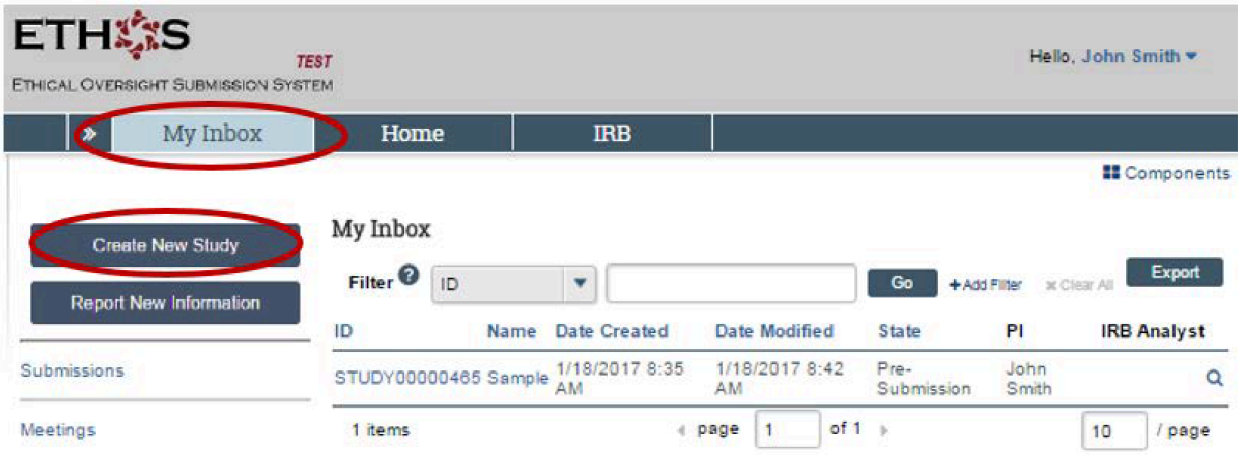


- Click "Manage Ancillary Reviews."
- Click "Add."
- Select "HRPP Scientific Assessment" in the list of organizations.
- Select "HRPP Scientific Assessment" as the review type.
- Select "Yes" as to whether a response is required.
- Click "OK."



If you are requesting scientific assessment after the study is submitted, no further action is required.

Requesting HRPP Scientific Assessment Before Submitting in ETHOS



1. Log in to **ETHOS** using your UMN Internet ID and password.

Need a UMN Internet ID? Forgot your password?

2. Click "My Inbox" on the left of the workspace.

3. Click "Create New Study" to display the IRB smart form.

4. Complete the ETHOS smart form. See How to Submit on the IRB website for instructions on competing a submission in ETHOS.

TIP: For reliance / sIRB submissions, refer to How to Submit a Reliance Request.

TIP: For new studies, protocols should be uploaded as Word documents with no track changes.

When requesting scientific assessment prior to submitting the study for review, the following documents are required:

In the "Basic Study Information" section, upload the study protocol. If using a sponsor or other protocol not created with an HRPP protocol template, HRP-508 - Local Protocol Addendum is required.

If the study involves FDA-regulated drugs and/or devices, upload the investigator brochure and/or package insert in the "Drugs" or "Devices" section, as appropriate.

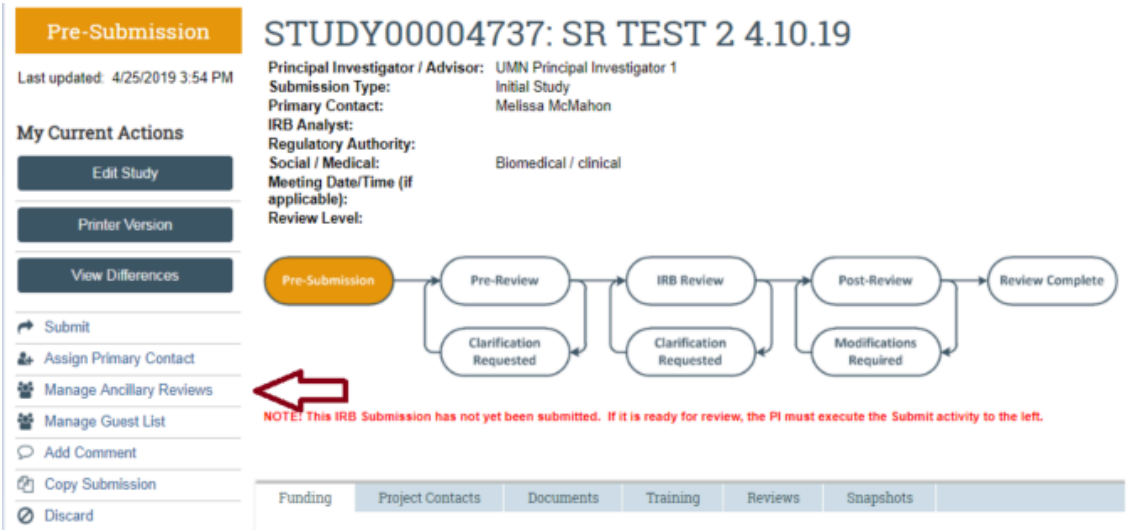
In the "Supporting Documents" section, under "Other Attachments," upload HRP-538 - Scientific Review and the investigator's CV.

Other study documents noted in the "How to Submit" guide do not need to be submitted for a pre-submission scientific assessment request, but can be added to the smart form when you ready to submit the study for review.

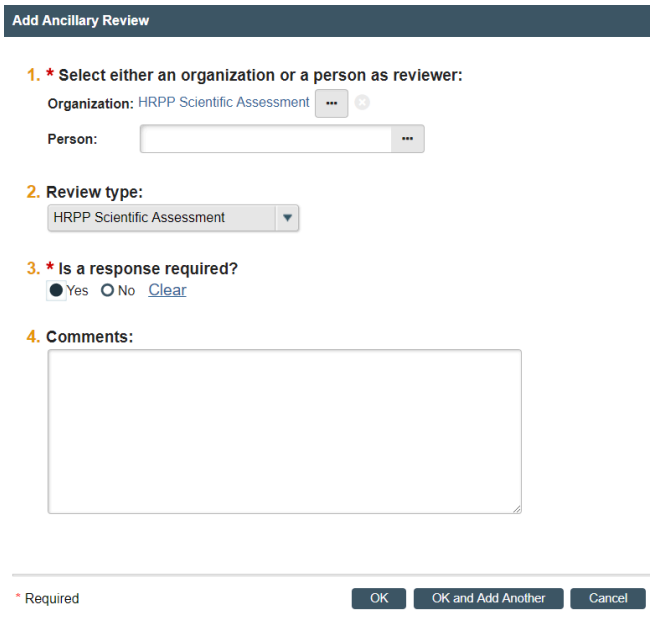
6. Save the study and click "Continue" to return the study workspace.

TIP: If you are requesting scientific assessment prior to submitting the study for review, do not click the "Submit" action.

7. Request HRPP Scientific Assessment using the "Manage Ancillary Reviews" action. This is found on the left side of the study workspace.



- Click "Manage Ancillary Reviews."
- Click "Add."
- Select "HRPP Scientific Assessment" in the list of organizations.
- Select "HRPP Scientific Assessment" as the review type.
- Select "Yes" as to whether a response is required.
- Click "OK."



8. Notify HRPP of your request.

- Email hrpp@umn.edu to request HRPP scientific assessment.
- Include the PI name, ETHOS study number, and title in your email.
- Indicate that you are requesting HRPP scientific assessment.

TIP: If you have questions or otherwise need to communicate with HRPP staff about your scientific assessment, email hrpp@umn.edu to do so. You may add a comment on your submission, but when a study is in a pre-submission state, ETHOS *will not* notify the staff handling your request that a comment was added. Emailing hrpp@umn.edu ensures communication happens in a timely manner.