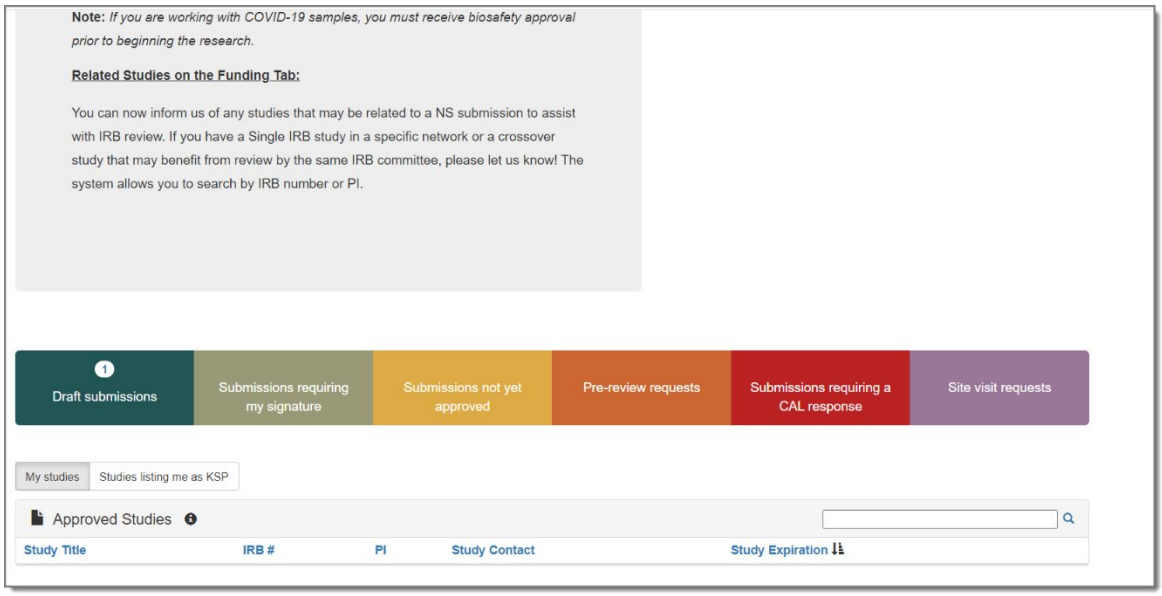
DISCOVR-e
USER MANUAL

Vanderbilt
Human Research Protection Program



Introduction

Welcome to the Vanderbilt University Institutional Review Board's new electronic submission system called DISCOVR-e (the **D**ata **I**ntegrated **S**tudy **C**onsole **o**f **V**anderbilt's **R**esearch **E**nterprise. Phase I allowed researchers to access basic study information, as well as their human subjects training/continuing education status. Phase II allowed researchers to complete an IRB submission online, including the ability to use electronic signatures. Every type of submission previously sent in by hard copy (e.g., new study, continuing review, adverse event, etc.) could be submitted with a few clicks of your mouse.

Another benefit of the DISCOVR-e portal allowed researchers to view their approved documents online, including Committee Action Letters (CALs), Final Approval Letters (FALs), and approved and date stamped consent forms.

Phase III of this project includes an intuitive investigator dashboard and the implementation of an IRB application wizard that incorporates supplemental form information like vulnerable populations in research, repositories, radiological procedures for research, and waiver into one cohesive document.

Future phases may include additional features and capabilities as the system grows and users provide the development team with feedback and suggestions. The IRB plans to continuously monitor the system to make enhancements and improvements where needed.

Overview

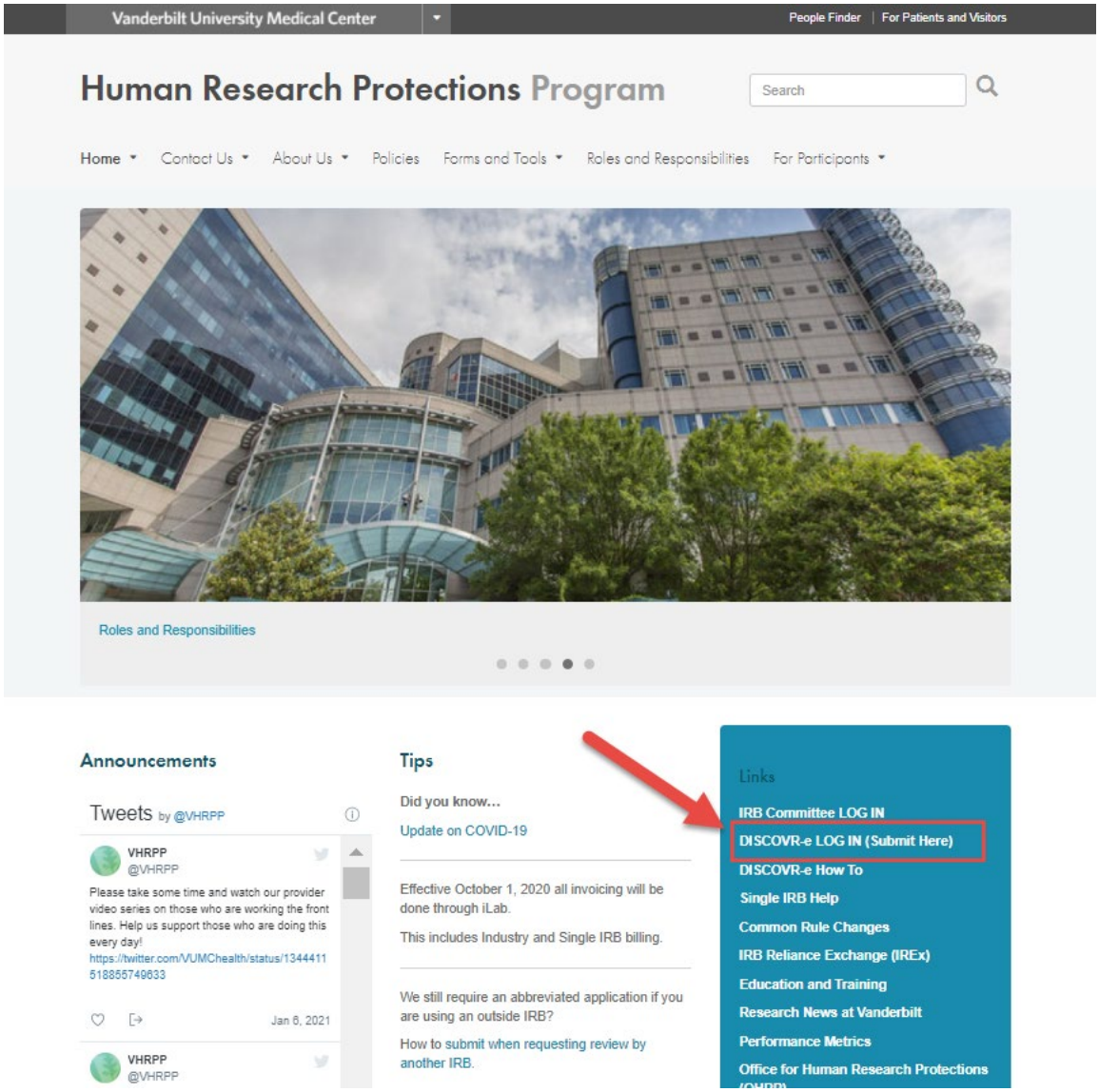
The DISCOVR-e portal is a web-based system. You can log in and submit documents or check the status of a previous submission anywhere in the world where you have a connection to the Internet. This section of the manual will give you an overview of the system and provide highlights of its capabilities.

To access the system, please visit the Vanderbilt IRB website at https://www.vumc.org/irb/ and click on the DISCOVR-e link on the right-hand section of the page. When prompted, enter your VUNetID and e-password. That's all it takes!!!

After logging in, you will see your Investigator Dashboard. This is your home page which shows all of your outstanding action items and approved studies. The following pages will provide step-by-step screenshots for creating and responding to outstanding submissions, as well as navigation tips for the site.

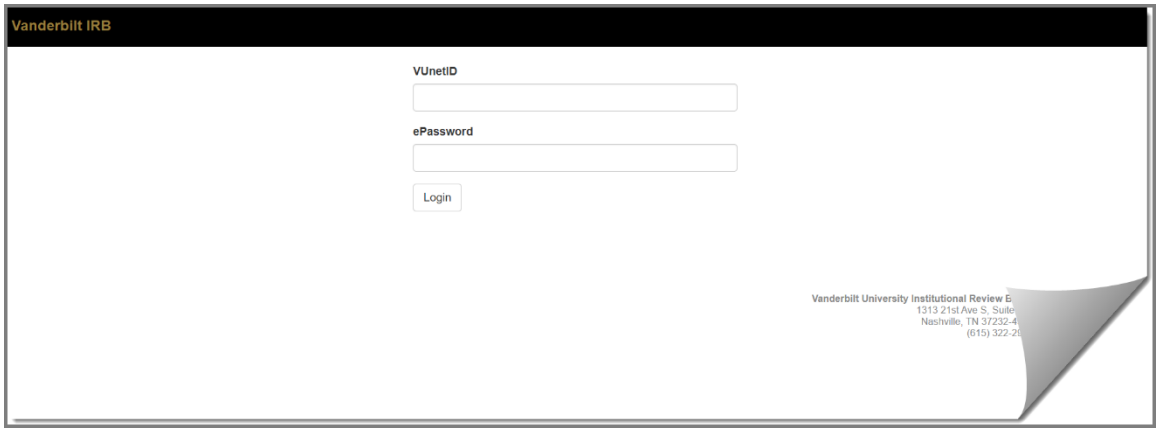
Log into the System

You can access the system by going to the IRB website, https://www.vumc.org/irb/ and clicking on the *DISCOVR-e link*.



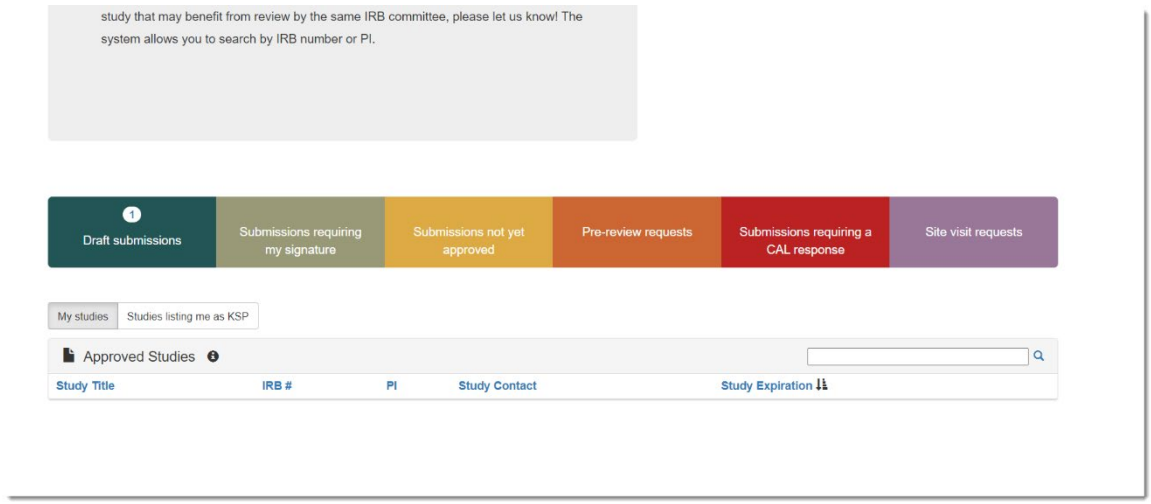
You can also access the system by typing the following internet address into your browser: https://irb.app.vumc.org/investigator

You may want to save this address in your list of favorites/bookmarks. This will bring you to the Login page. To enter DISCOVR-e, enter your VUNetID and password.

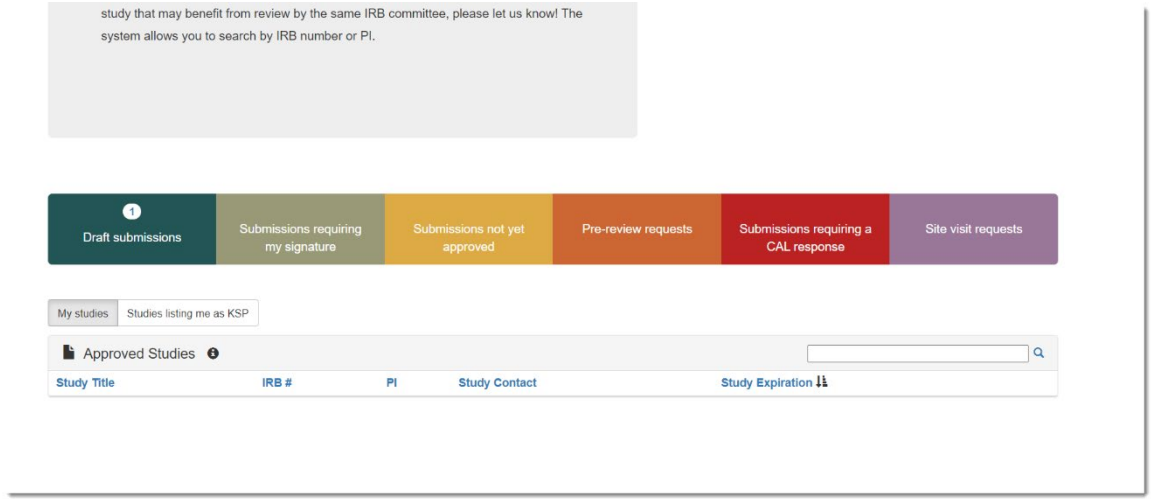


Investigator Dashboard Overview

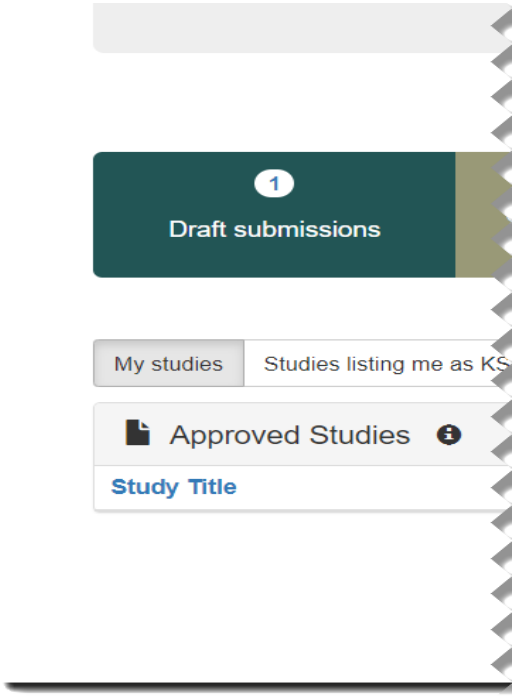
This is your Investigator Dashboard. When you log in, this is the first screen you will see. From here, you can access all your studies and view submissions that require action from you.



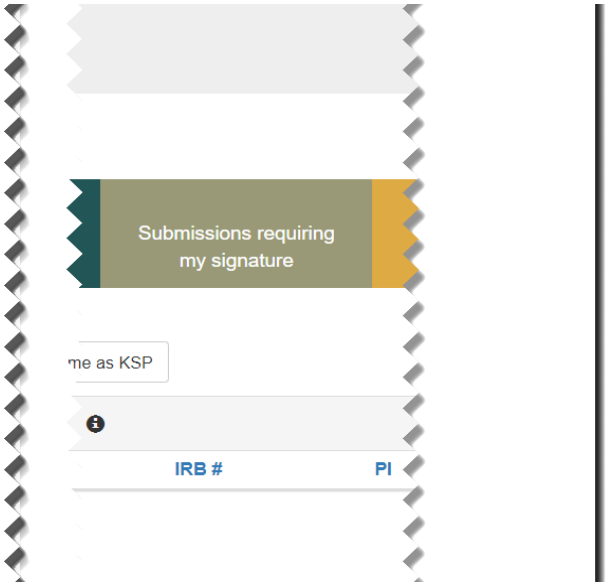
The colored squares on this page show items requiring action from you.



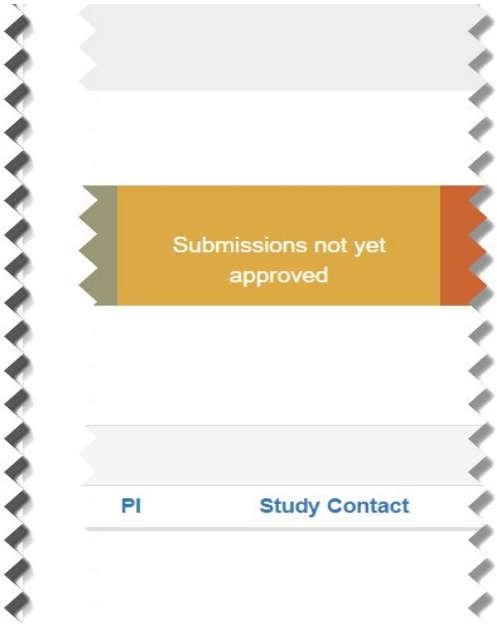
Notice the number in the middle of each button. This number indicates how many items are requiring that particular action. The first button is the *Draft Submissions* button. The number in the middle indicates how many draft submissions are awaiting to be finished and submitted for review.



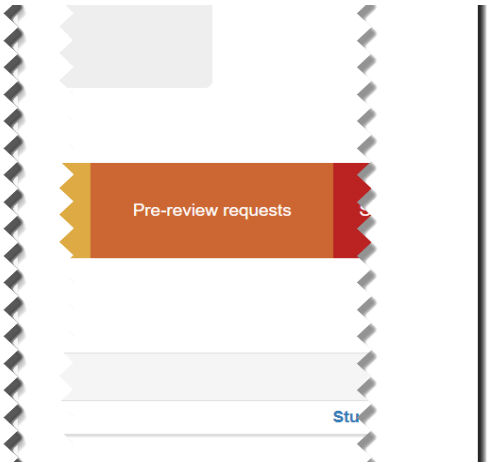
The second button is the *Submissions requiring my signature* button. If there is a number in the middle, this indicates how many submissions require a signature for submission. Clicking this button will allow you to access these studies and sign.



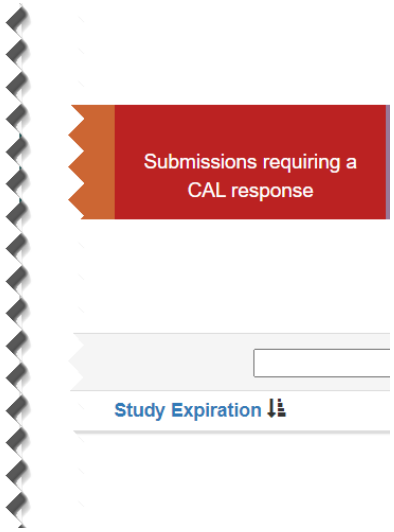
The next button is the *Submissions not yet approved* button. If there is a number in the middle, this indicates how many submissions have been submitted but not yet approved. Clicking this button will allow you to access these studies.



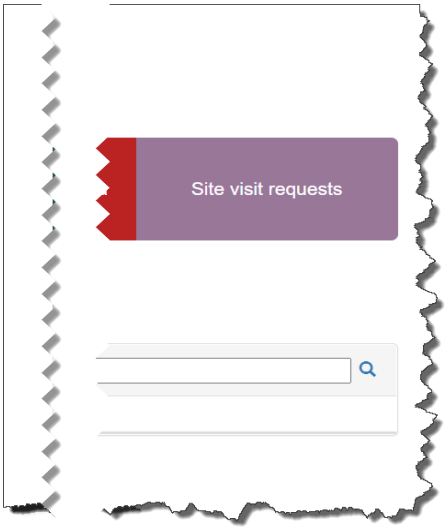
The next button is the *Pre-review requests* button. If there is a number in the middle, this indicates how many pre-review requests you have requiring a response. Clicking this button will allow you to access these studies.



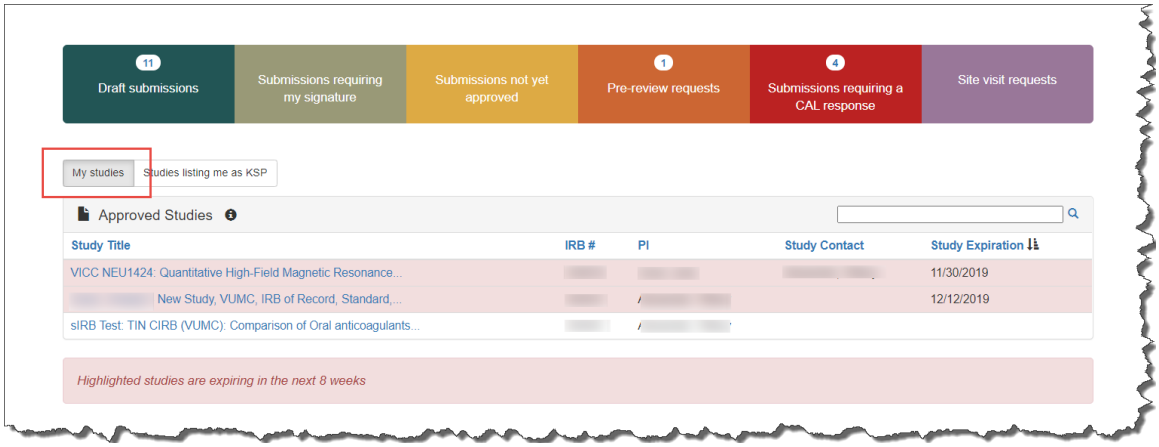
Next, is the *Submissions requiring a CAL Response* button. If there is a number in the middle, this indicates how many submissions have received a CAL but the IRB has not received a response or sent back for additional review. Clicking this button will allow you to access these studies.



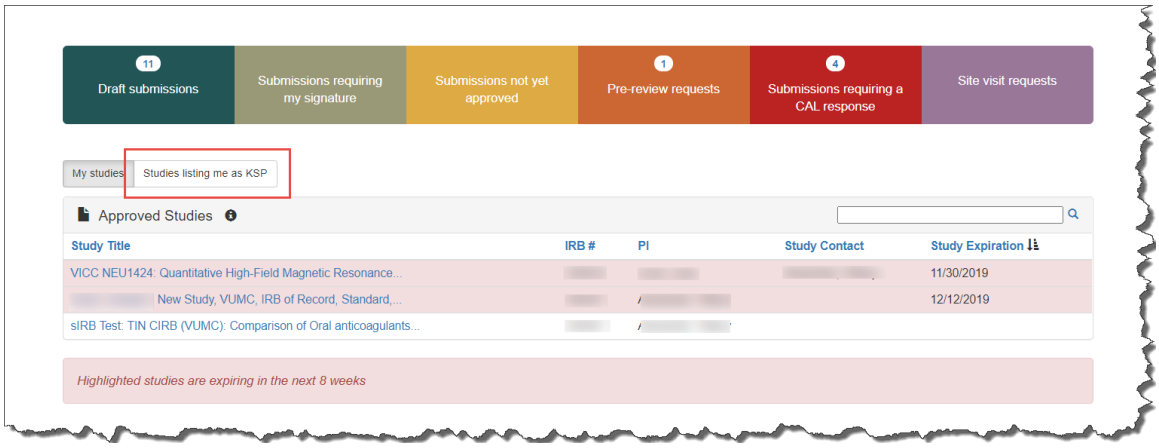
The last button is the *Site Visit requests* button. If there is a number in the middle, this indicates how many site visit requests from the HRPP. Site Visit requests may include: Post Approval Monitoring Visits, Directed Audits, or Directed Education sessions. Clicking this button will allow you to access these studies.



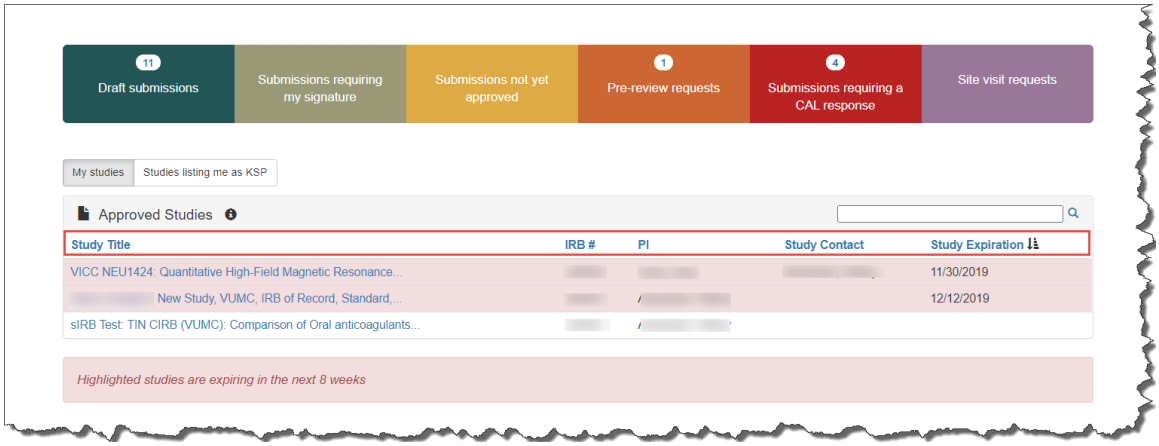
Lists of approved studies are located below the buttons for quick access. My studies is the default view on the dashboard. This view shows studies in which you are listed as PI, Study Contact, or Faculty Advisor.



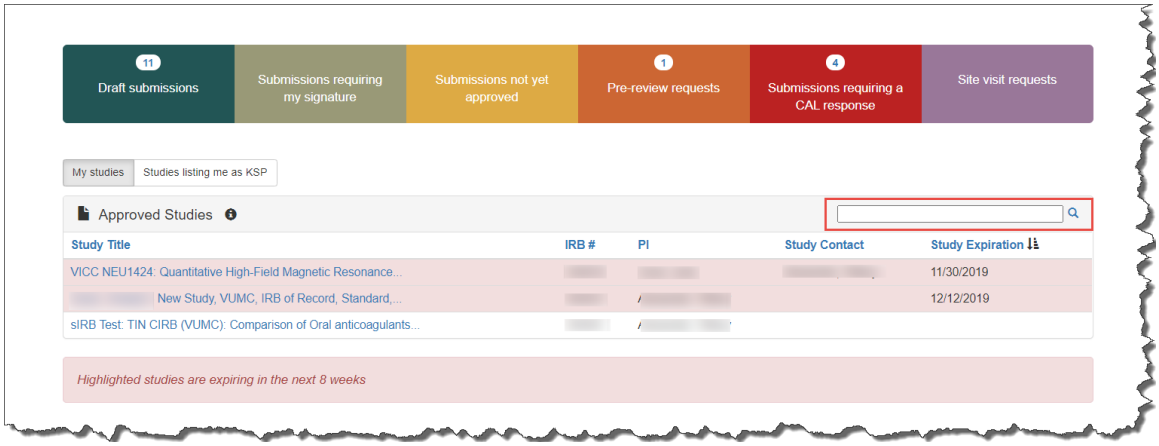
Studies listing me as KSP will display only studies in which you are listed as other KSP (not PI, Study Contact, or Faculty Advisor).



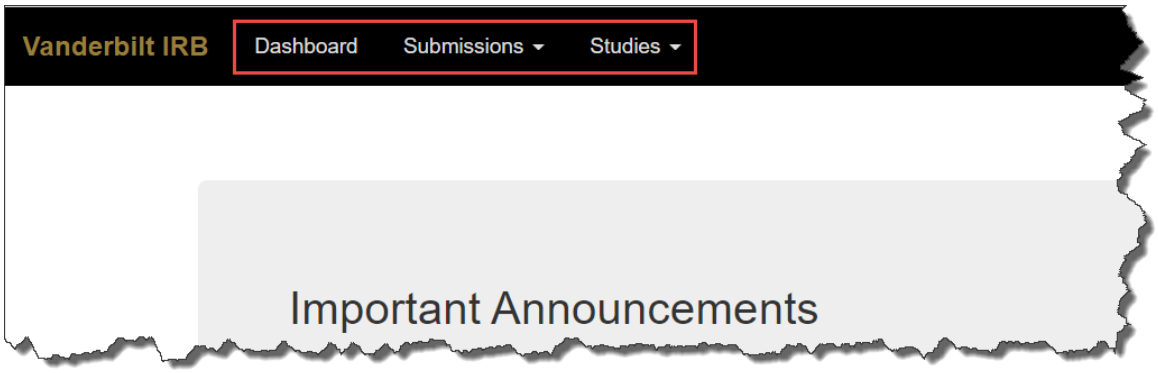
These lists are automatically sorted by *Study Expiration*. If a study is within 8 weeks of expiration, it will appear highlighted in red. Lists can be sorted by *Study Title, IRB Number, PI, and Study Contact* by clicking on the heading.



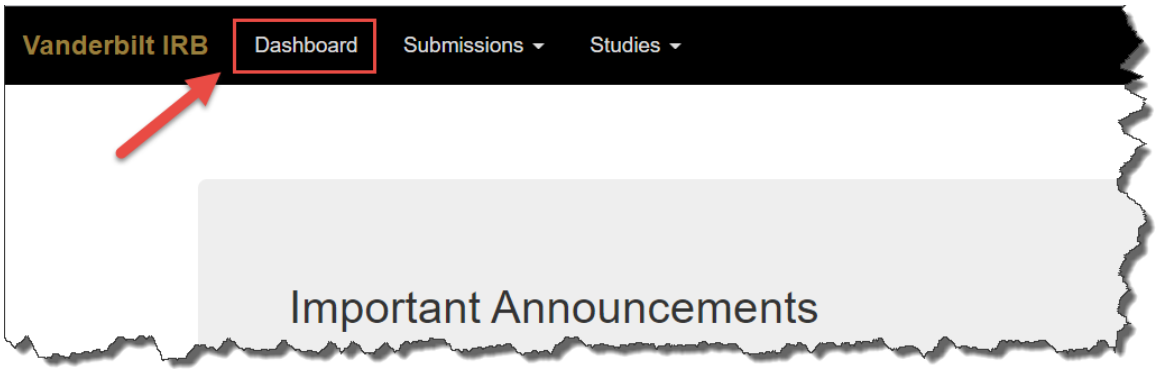
You can also search for studies in these lists by entering study identifiers such as *PI or Study Contact name, parts of the study title, or IRB number* into the search box.



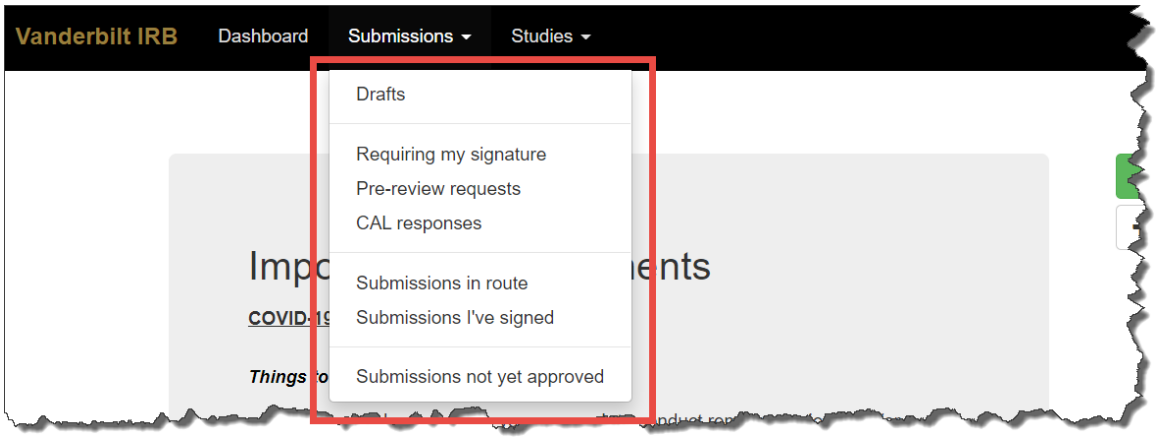
The views located on the Dashboard can also be accessed at any point via drop-down menus. These drop-down menus can be accessed on any screen, allowing you to access submissions without returning to your dashboard.



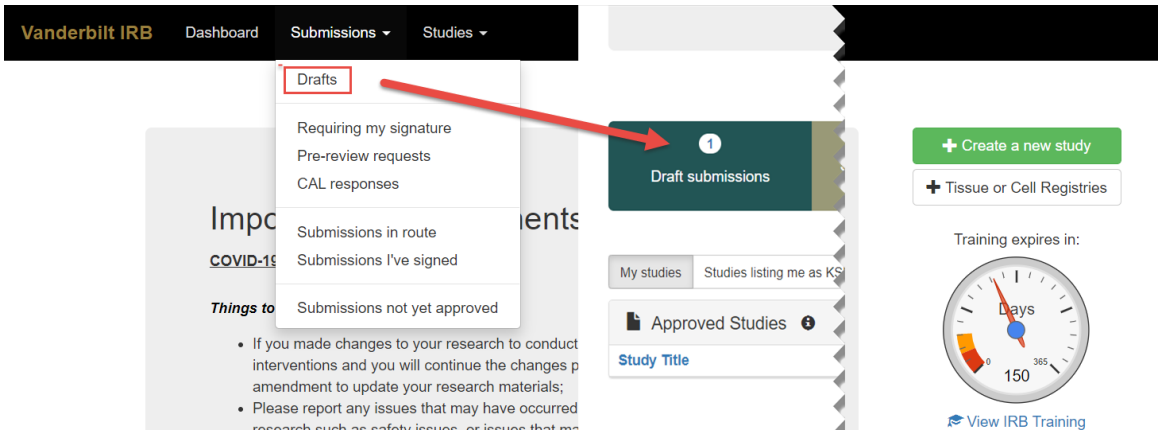
Clicking on *Dashboard* will return you to your Investigator Dashboard.



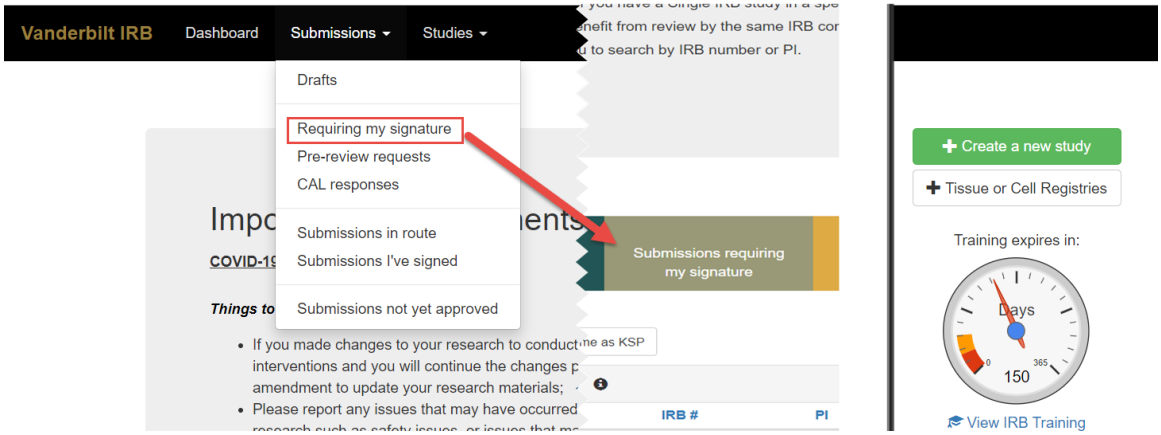
Clicking *Submissions* will display a drop-down menu. This menu holds items corresponding with the buttons on the dashboard, as well as other study views.



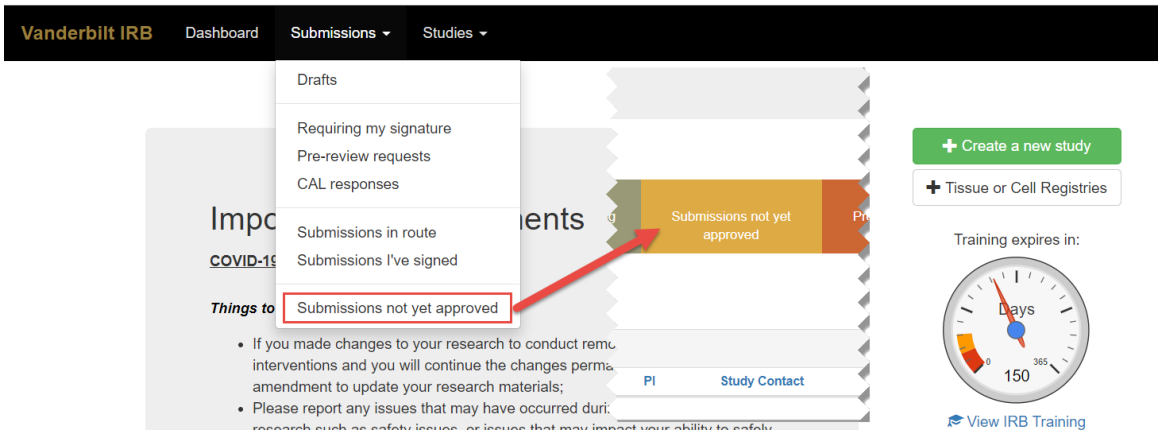
Drafts corresponds with the *Drafts* button.



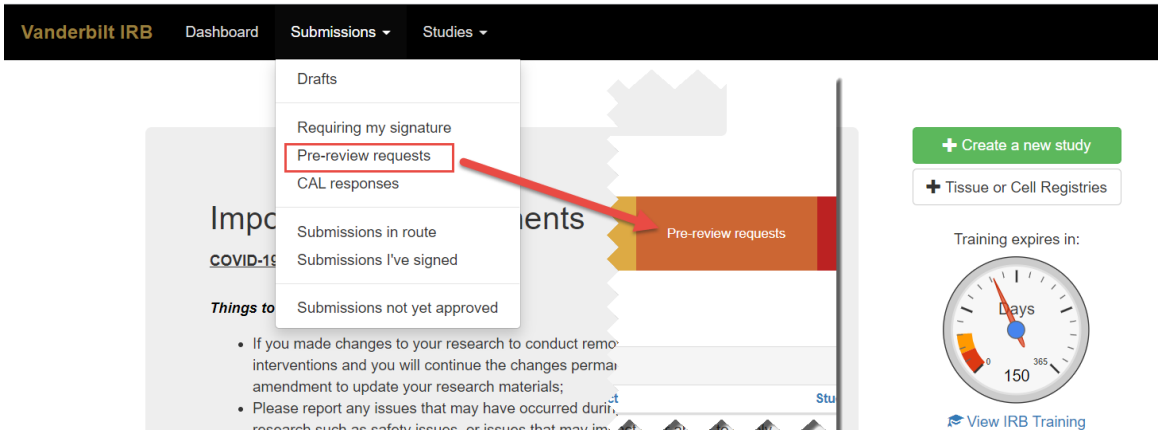
Requiring my signature corresponds with the *Submissions requiring my signature* button.



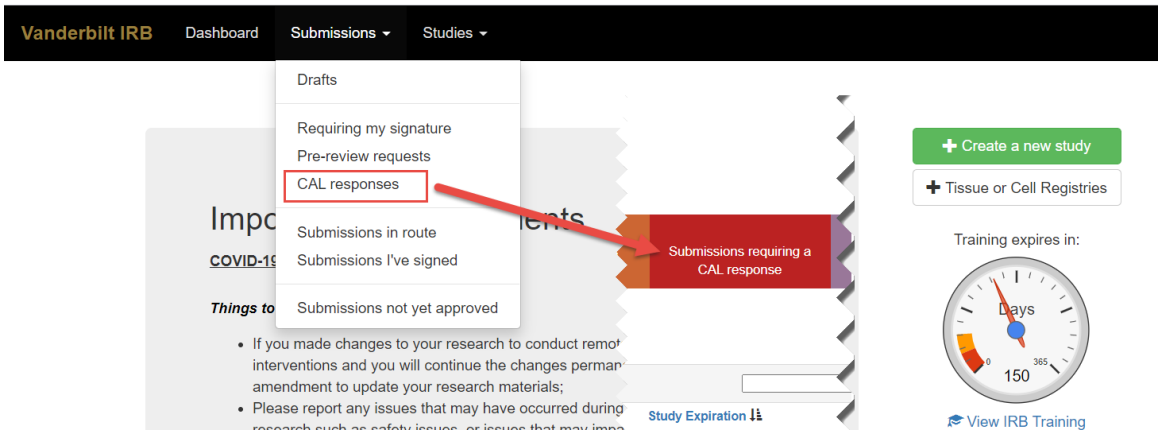
Submissions not yet approved corresponds with the *Submissions not yet approved* button. Clicking Submissions not yet approved will display a list of all submissions you have created and where you are listed as PI, study contact, or faculty advisor that have been submitted to the IRB and have been signed, but have not yet received approval.



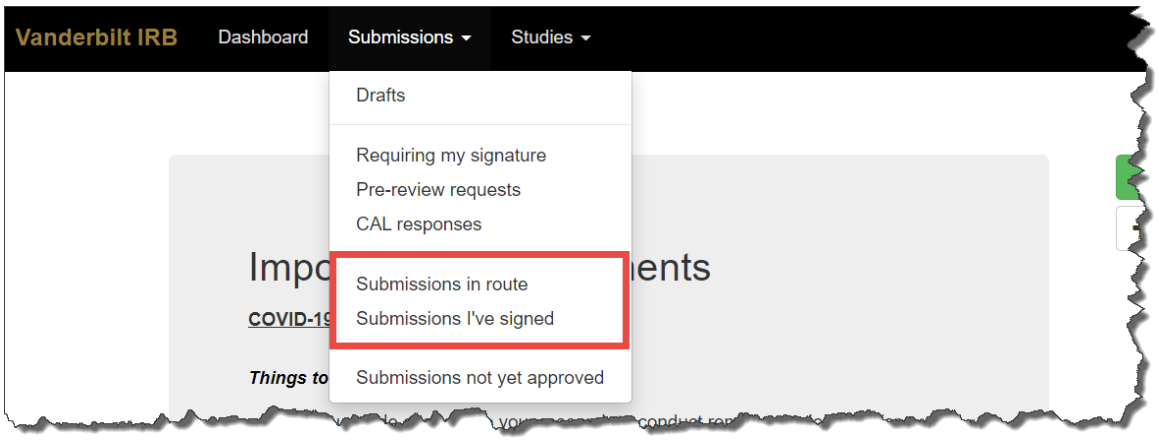
Pre-review requests corresponds with the *Pre-review requests* button.



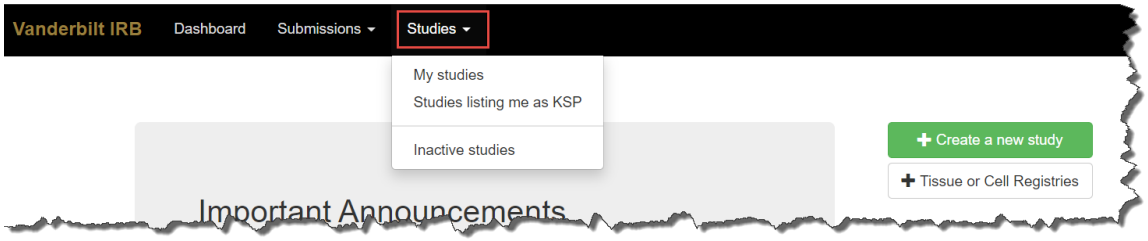
CAL responses correspond with the *Submissions requiring a CAL response* button.



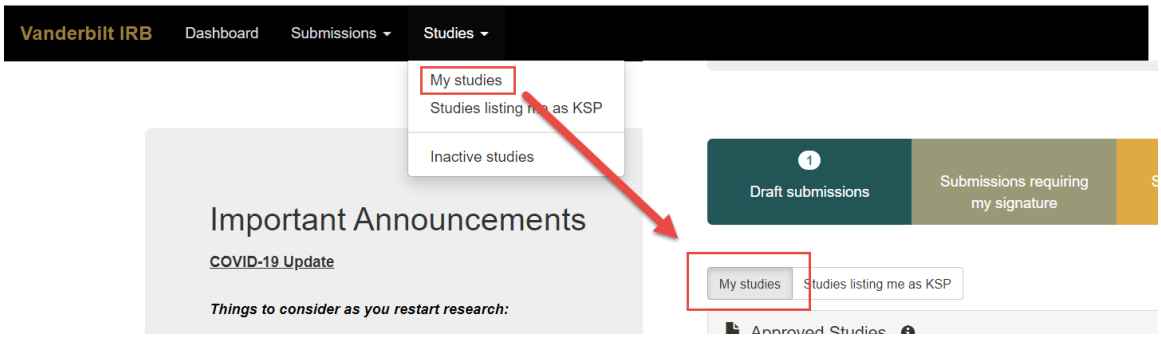
This drop-down also holds views for *Submissions in route* and *Submissions I've signed*. Clicking *Submissions in route* will display a list of submissions pending signature from another person. Clicking *Submissions I've signed* will display a list of all submissions signed by you.



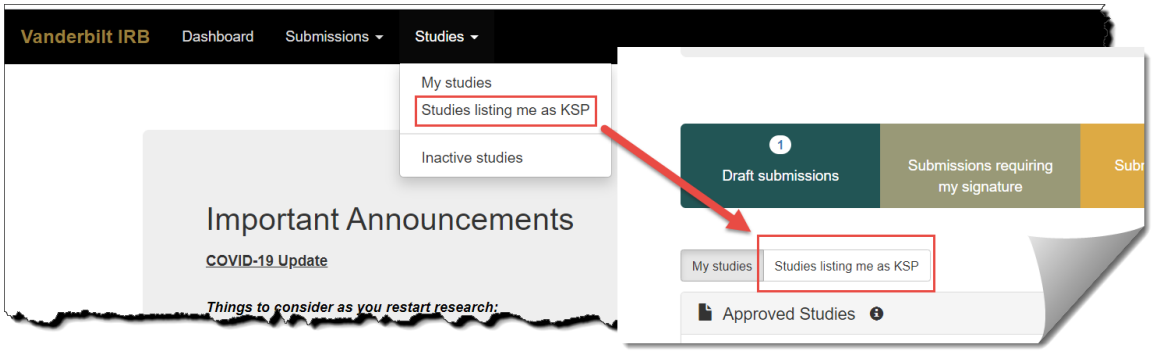
Clicking *Studies* will display another drop-down menu. This menu holds items corresponding with the studies lists on the Dashboard, as well as *Inactive studies*.



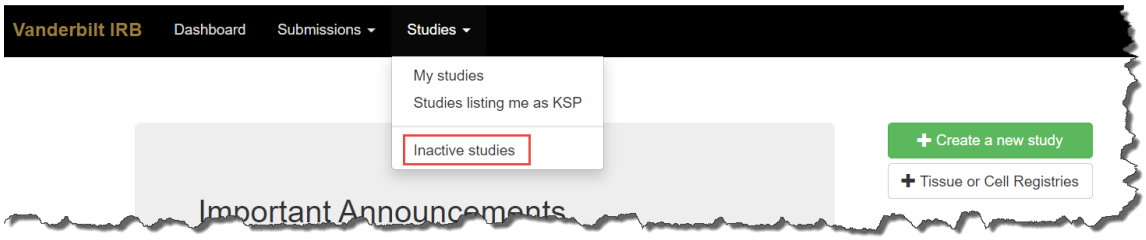
My Studies corresponds with the *My Studies* button.



Studies listing me as KSP corresponds with the *Studies listing me as KSP* button

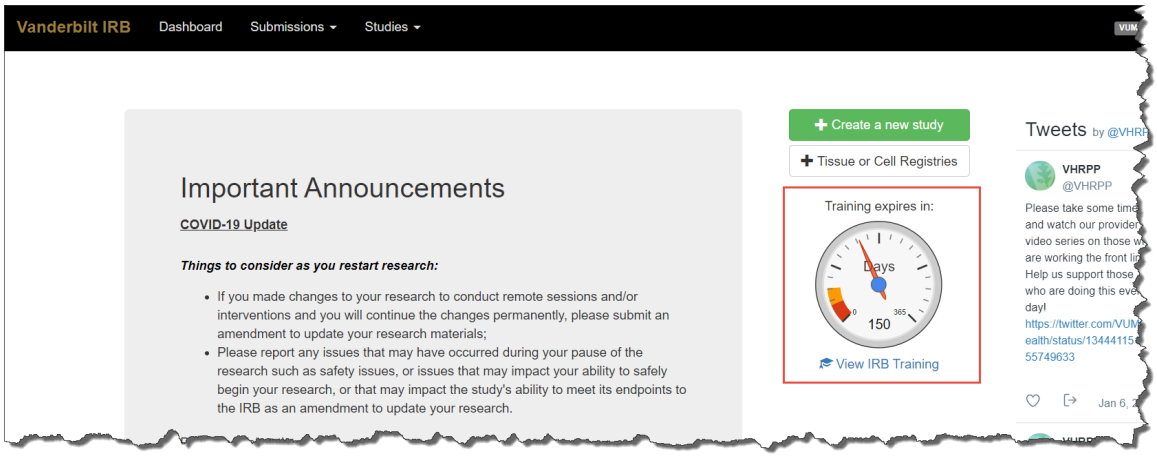


Clicking *Inactive* will display a list of your inactive studies.

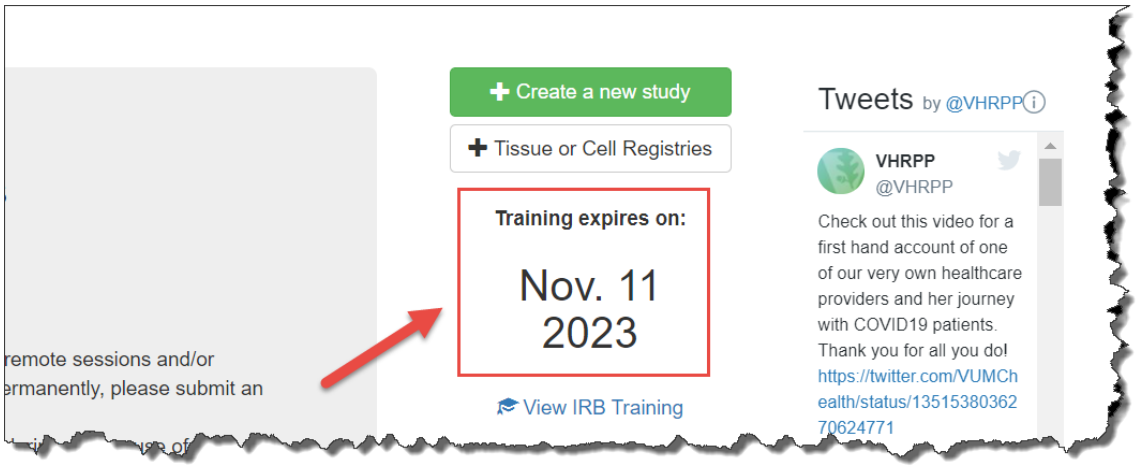


IRB Training Requirements

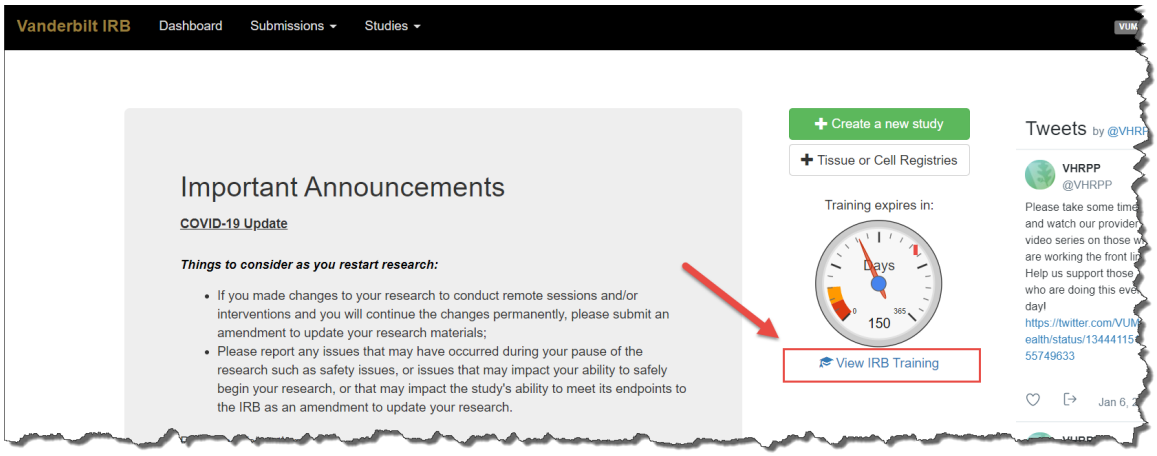
IRB Training expiration can be easily viewed on the Investigator Dashboard using the gauge displaying days until expiration.



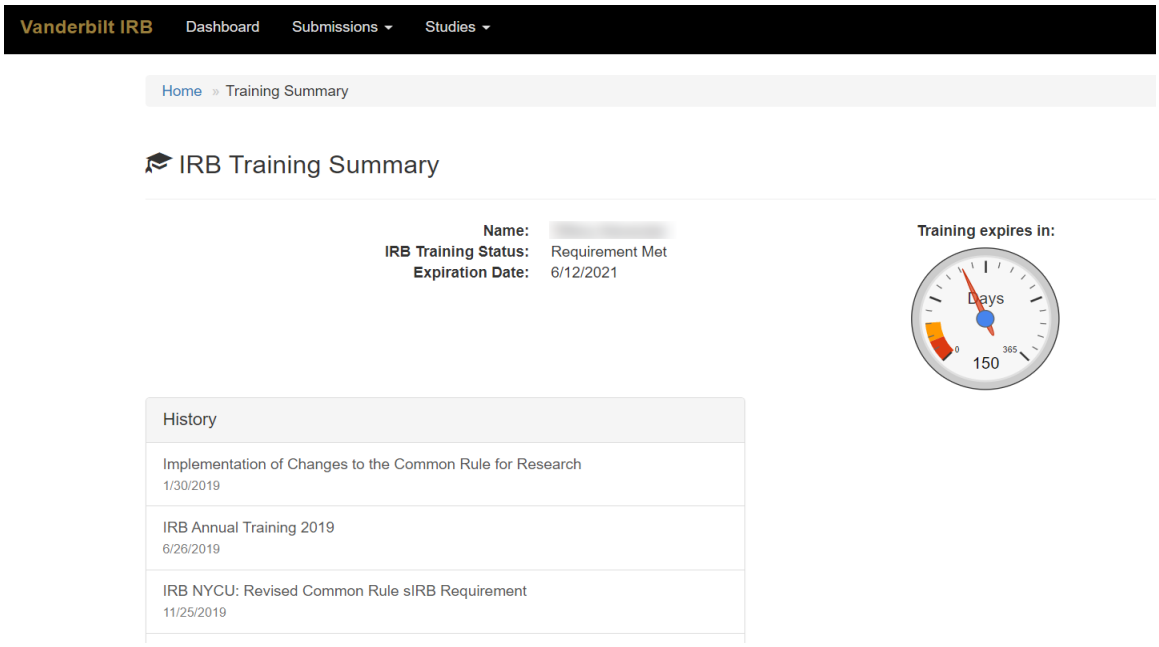
If the required training requirements were updated after 1/15/2021, the dashboard will have a date statement rather than a gauge notifying the date when training will expire.



Click on the link *under the gauge or date*, titled *View IRB Training* will open the view of your training status.

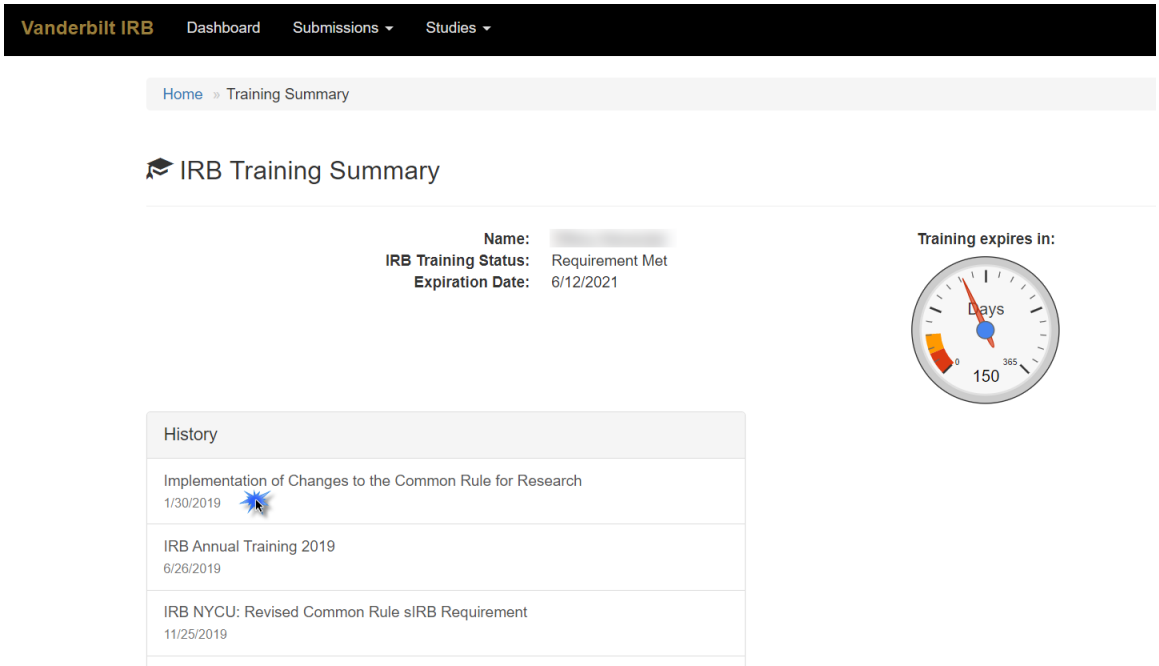


This view displays your *IRB Training status* and *expiration date*.



If you submitted a training certificate or completed training in the CITI program, your history will contain the certificate. Clicking on the document link will allow you to download the certificate.

Note: if you completed training through the Learning Exchange or Oracle, your certificates will be located in the Certificate or Transcript sections of these platforms.



To look up a training certificate for another member of KSP, enter the name or VUNet ID into the Look up another user textbox. Their IRB Training Summary will appear and will have the same features (expiration date, downloadable certificate, etc.).

Home » Training Summary

IRB Training Summary

Name: [redacted]
IRB Training Status: Requirement Met
Expiration Date: 6/12/2021

Training expires in:

History

Implementation of Changes to the Common Rule for Research
1/30/2019

IRB Annual Training 2019
6/26/2019

IRB NYCU: Revised Common Rule sIRB Requirement
11/25/2019

Group 1.Biomedical Research Investigators and Key Personnel
1/16/2020

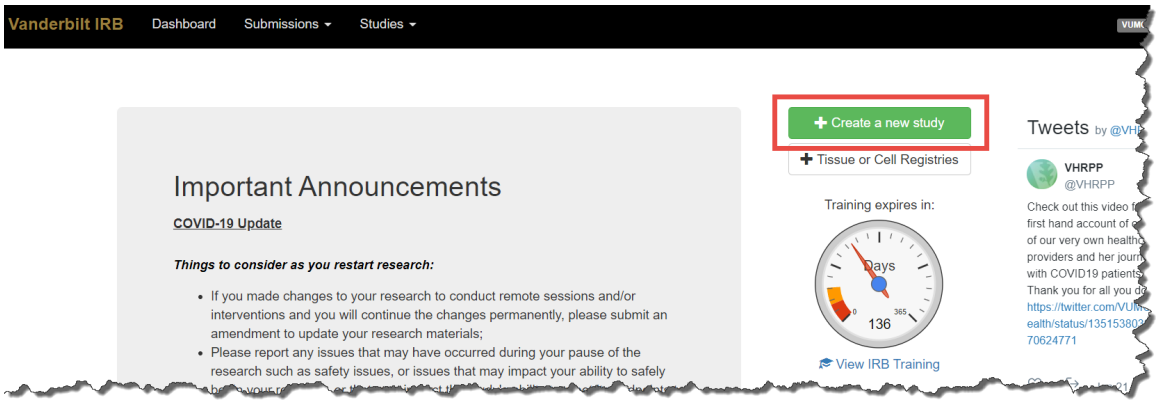
Group 2.Social Behavioral Investigators and Key Personnel
1/16/2020

VHRPP Annual Training - 2020
6/12/2020

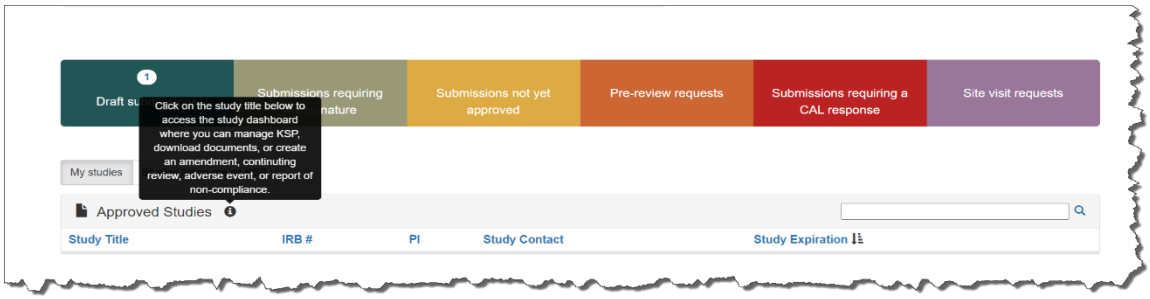
Look up another user:

Helpful Hints and Tips

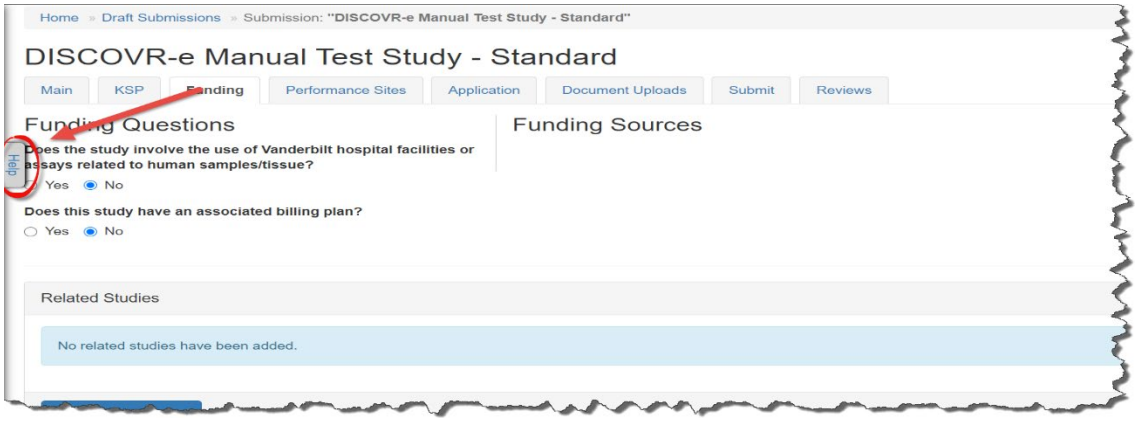
New study submissions are the only submissions created from the Investigator Dashboard. Clicking the *Create a new study* button will begin the process of creating that new study submission.



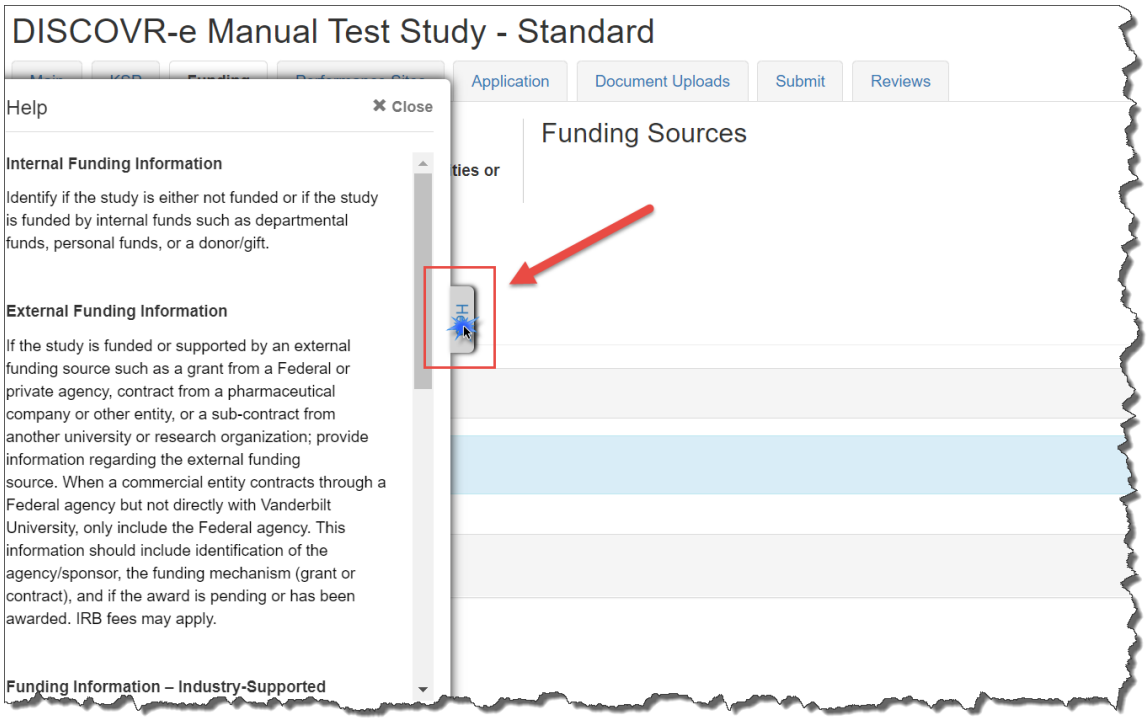
Throughout the website and application, you will find small black circle icons with an 'i' inside. These are information buttons. Hovering your mouse over these icons will display helpful information about that item. For example, hovering over this icon next to the Approved Studies heading displays information regarding the use of the Approved Studies view.



Another useful tool for moving through the submission process is the *Help resource tab*. The Help resource tab is present on the left side of the screen and can be expanded to review information on how to facilitate answering the questions on each page.



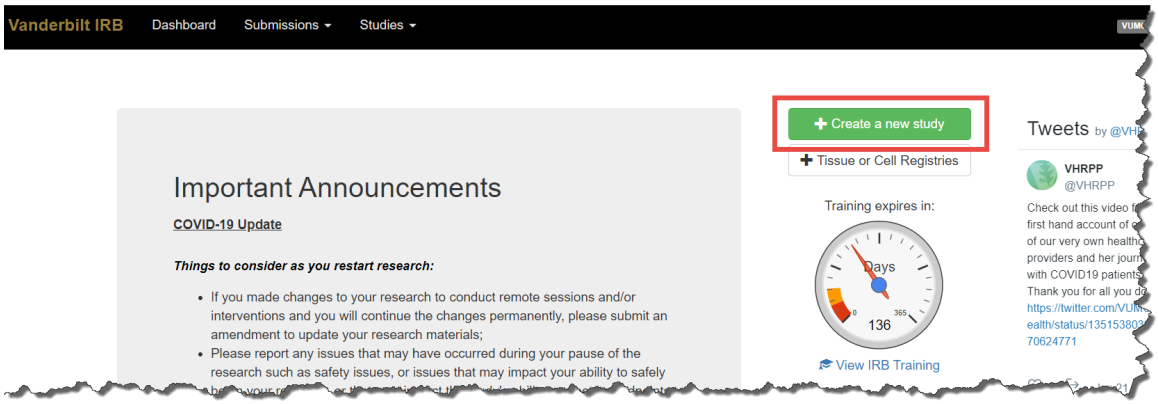
To expand the Help tab, click the *Help* tab which will slide out and provide information on how to complete the elements of each page from the KSP tab through Submit.



Submitting a New Study

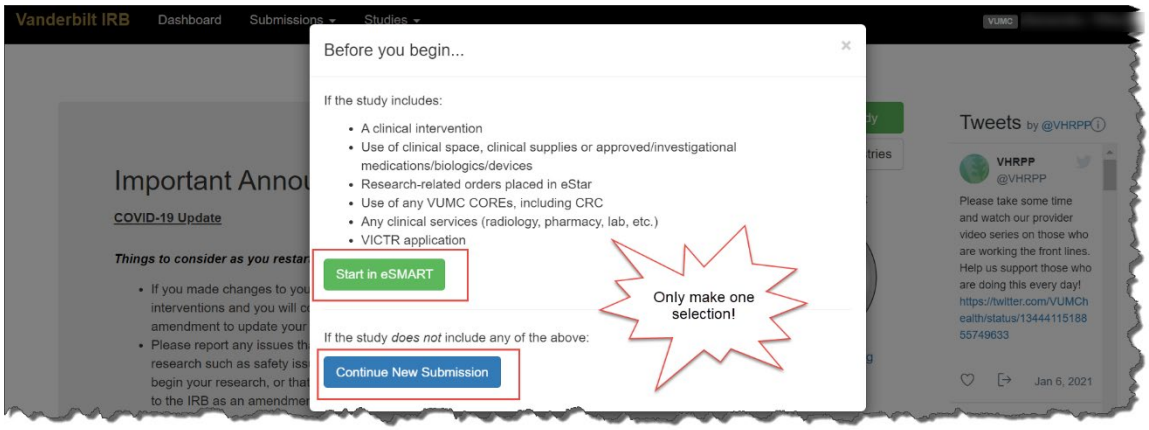
Submitting a new study through the DISCOVR-e portal does not require any special training. The following guide is a basic set of instructions and illustrations to help you in the submission process. If you have not logged into the system yet, please follow the instructions provided above.

Click on the *Create a New Study* button on the right side of the page to start the process.



After selecting the *Create a New Study* button, you will be prompted to begin your new study submission in *eSMART*. This feature provides a central location to view the status of your study's approval/regulatory requirements. To proceed in eSMART, click the *Start in eSMART* button. To bypass this feature, click the *Continue New Submission* button.

Note: only one selection is needed either eSmart or Continue New Submission.



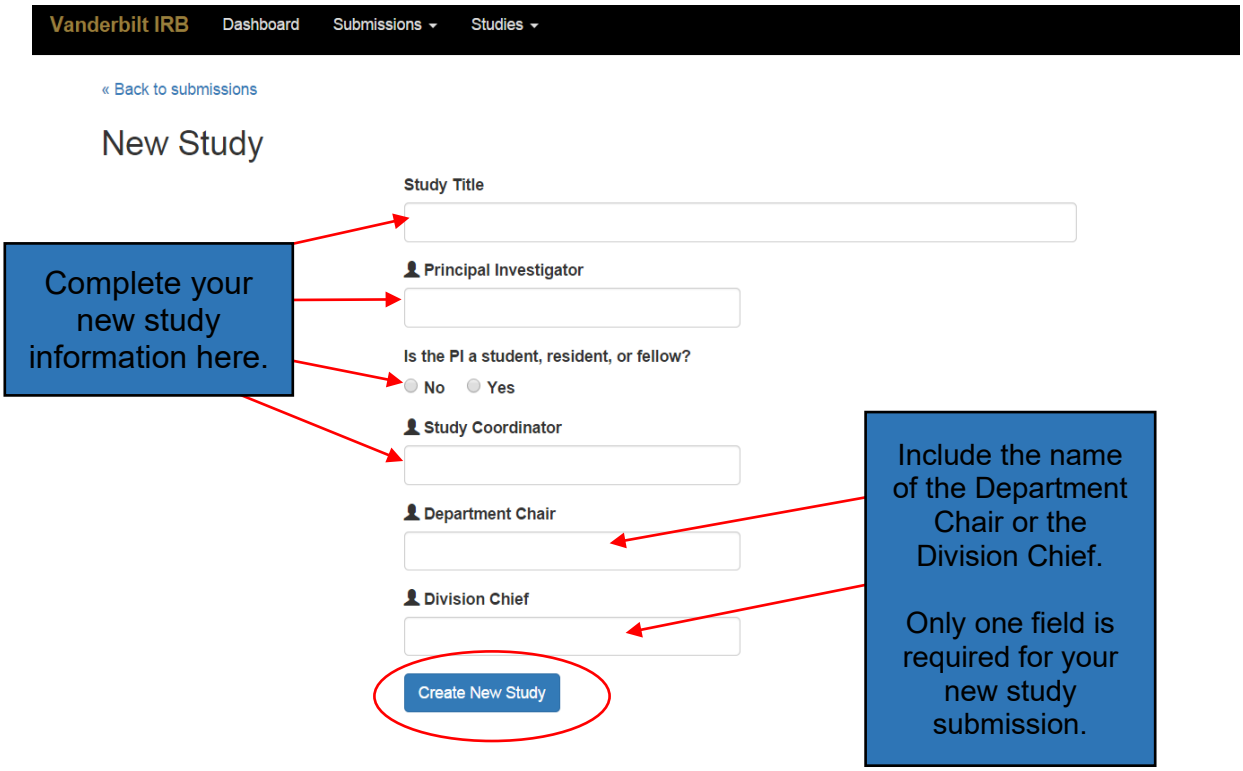
You will begin your new study submission by typing in a title for the study. Next, enter the Principal Investigator (PI) for the study. You can search for the Investigator by first and/or last name or even do a partial name search. Click the name of the PI you want to use. If you are not able to find the Investigator in the database, save your work and contact the IRB at 615-322-2918 for assistance.

Indicate whether or not the Principal Investigator is a student. If the answer is *yes*, you will be prompted to identify a *Faculty Advisor*. Selecting a Faculty Advisor follows the same process as choosing a Principal Investigator.

If applicable, select a Study Contact by choosing the appropriate contact person from the database. The process for indicating a study contact is the same as outlined previously for selecting a Principal Investigator or Faculty Advisor.

**All new study submissions require a department chair and/or a division chief signature.* The process for indicating this individual is the same as previously outlined. If you experience trouble identifying the department chair and/or a division chief for your research, save your work and contact the IRB at 615-322-2918 for assistance.

**Only ONE of these are required for submissions.*

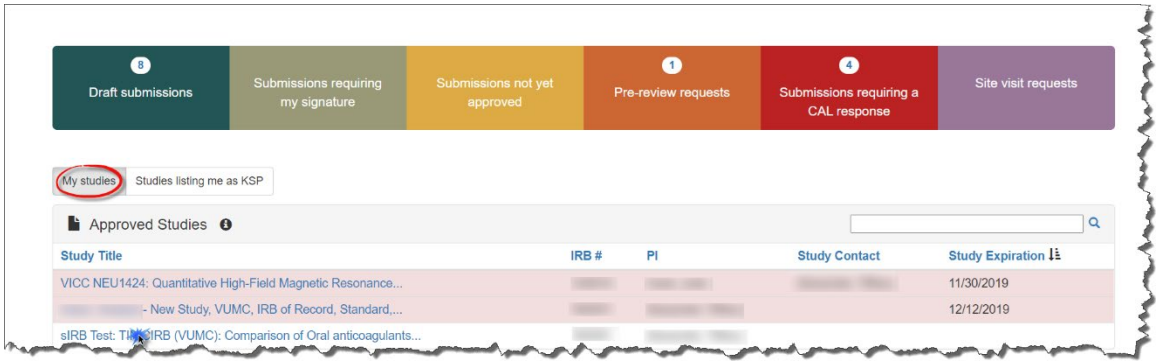


Click on the *Create New Study* button at the bottom of the page to advance in the new study creation process.

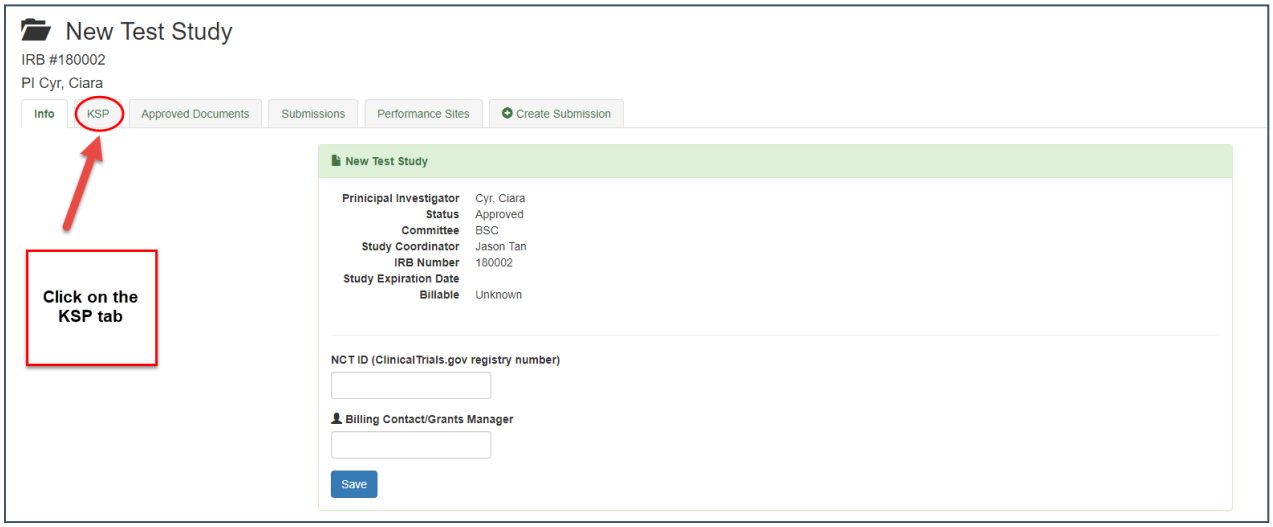
Selecting and Managing Key Study Personnel

Under *My studies*, Click on the title of study you wish to add KSP.

NOTE: If a KSP's requirement for annual VU IRB Human Subjects Training is not current, the individual may not be added to the KSP listing at this time. Those individuals may find information on how to update training at https://www.vumc.org/irb/education-and-training-0.

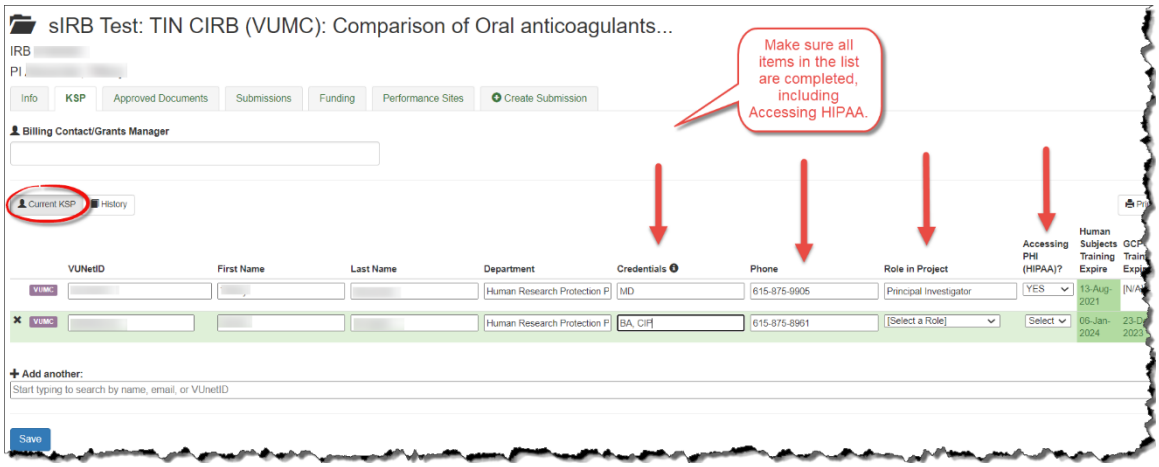


Click on the *KSP* tab



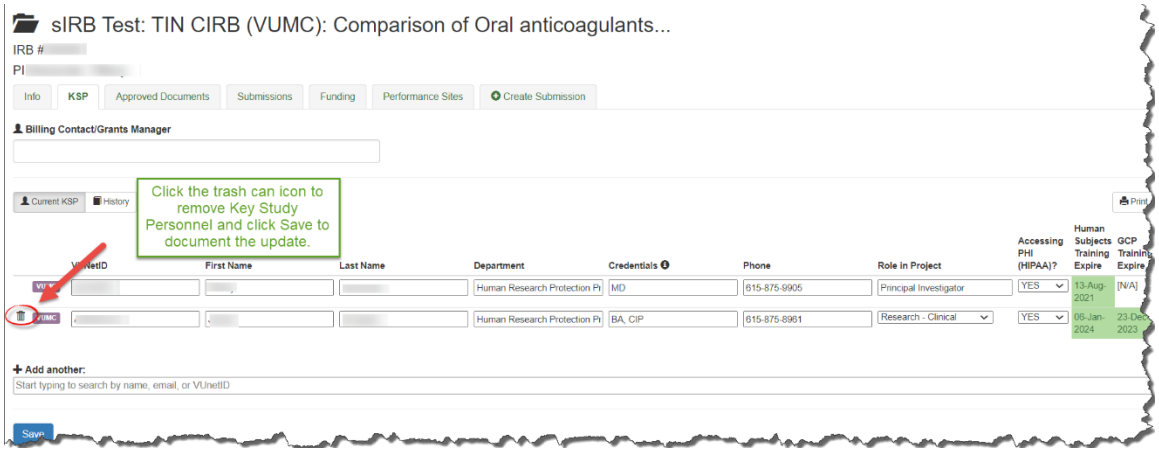
The PI, Study Coordinator, and Faculty Advisor, if applicable, identified in the *Info* tab will be the first to populate into the Key Study Personnel (KSP) tab.

Under the *Current KSP* tab, begin typing the name, email, or VUNetID in the *Add another* search field. You will be required to enter credentials, pager number, role in project and whether the KSP will be accessing Protected Health Information. These fields must be completed in order to advance to the subsequent sections of the Application Wizard. Repeat this process until you have identified all of the individuals that will help in the conduct of your research.

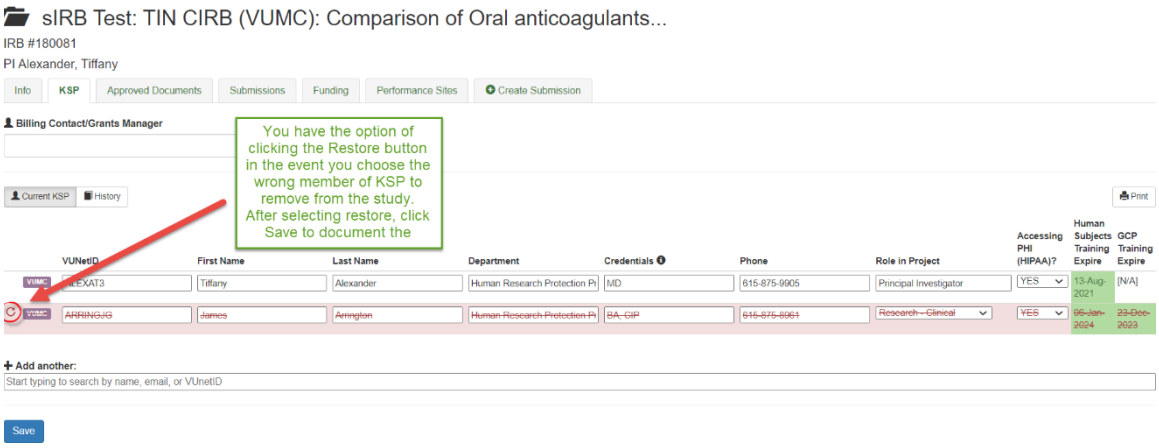


Hit the *Save* button to save your changes.

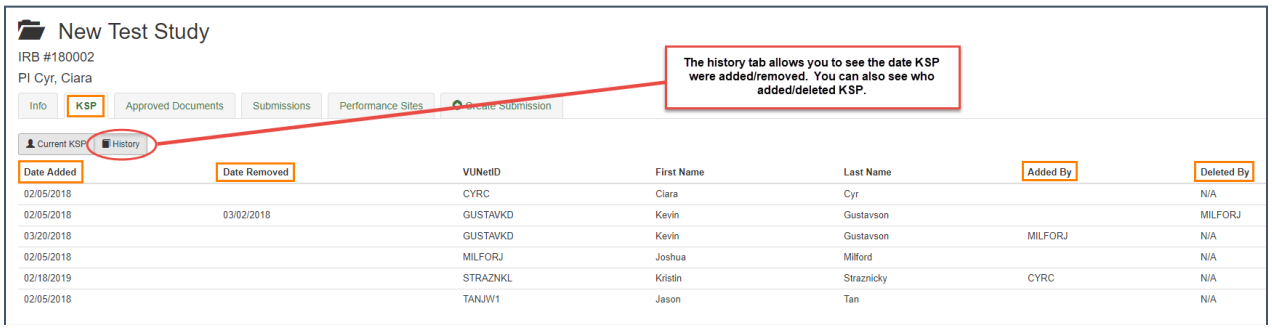
To remove a person from the list of KSP, click the *trash icon* next to the VUNetID of that person's name. The individual will be removed from your KSP listing.



Click the *restore icon* to restore a person's name. If you do not have any other KSP to add/delete, please click the *Save KSPs* button and proceed to the next section.

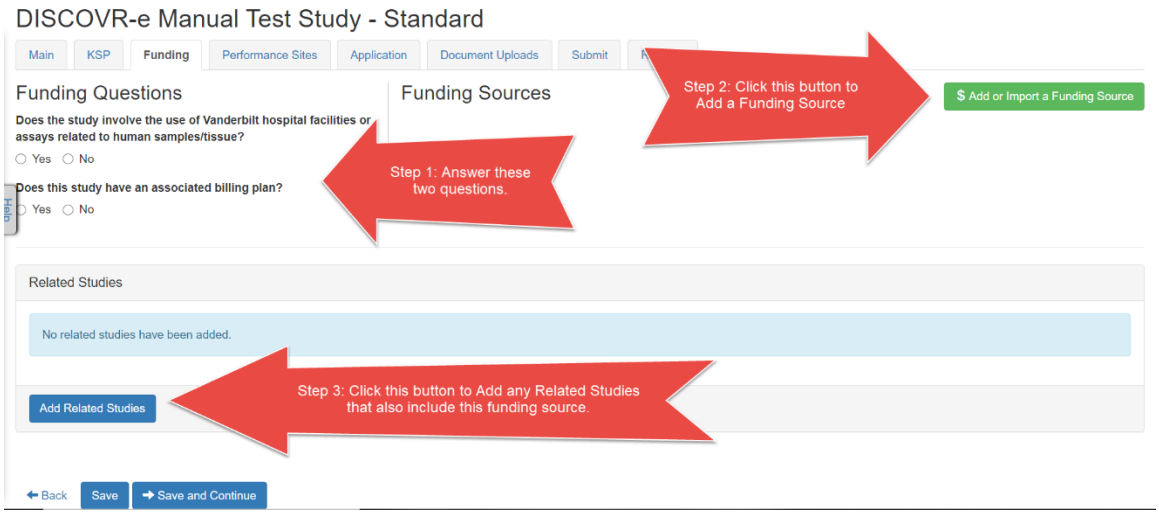


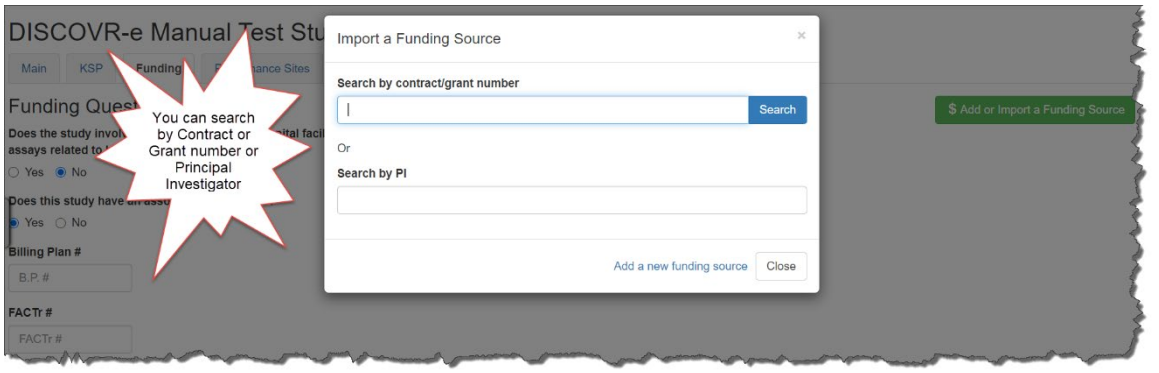
The history tab allows you to see the date KSP were added/removed. You can also see who added/deleted KSP.



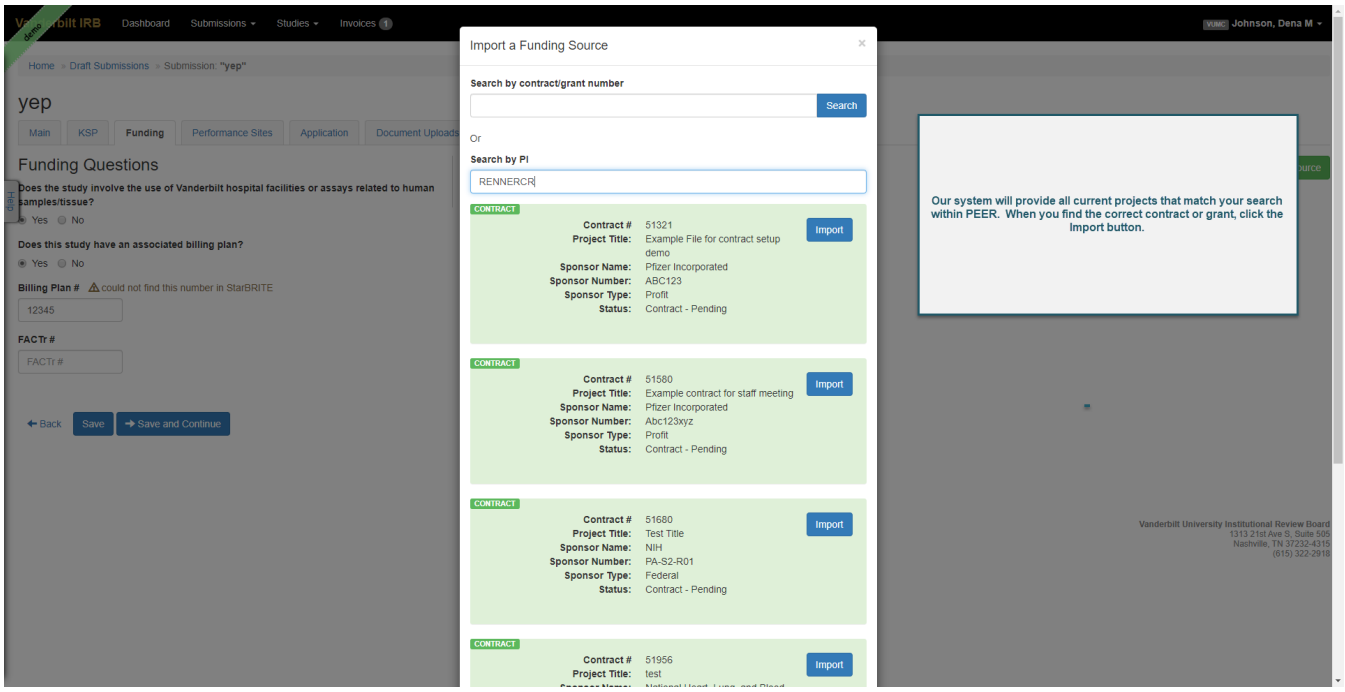
Completing the Funding Tab

You can add funding sources to your study by importing information from the Office of Contracts Management or the Office of Sponsored Programs or by keying the funding source. We suggest importing as it helps us ensure we have the right information for your IRB submission.

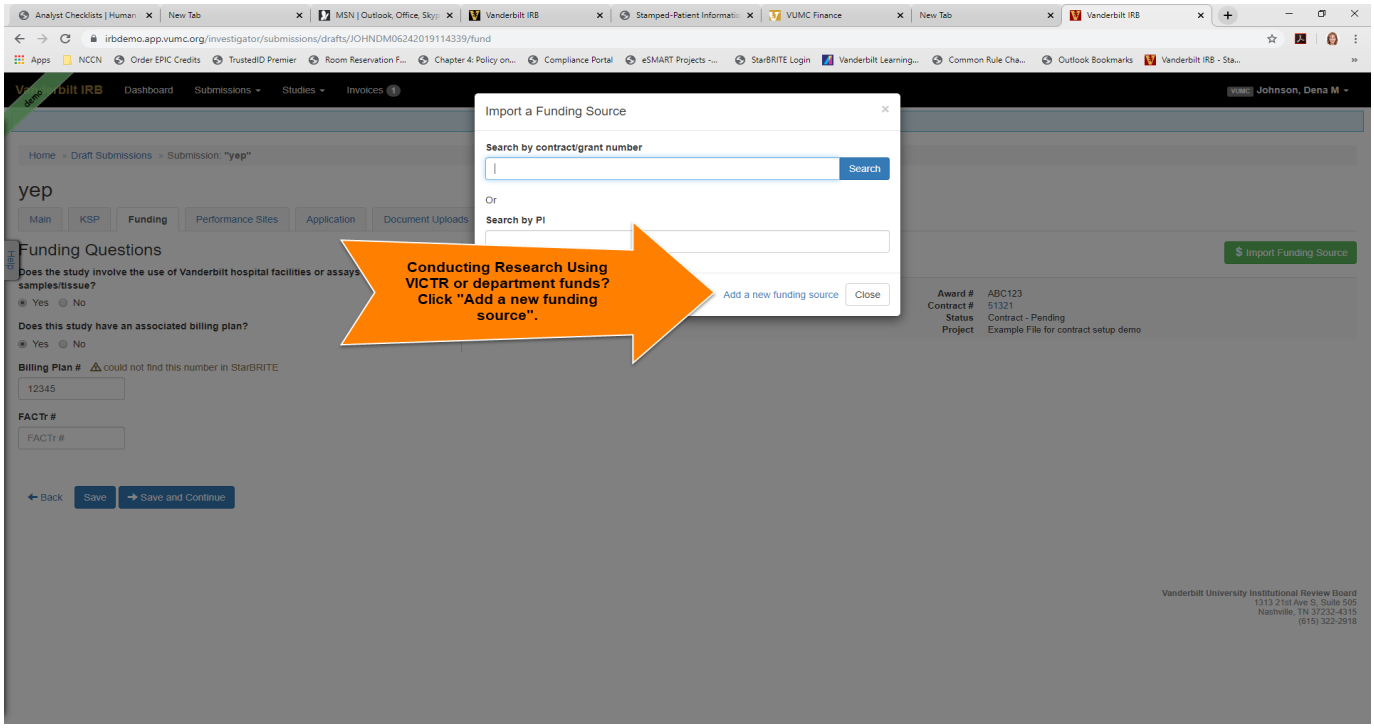


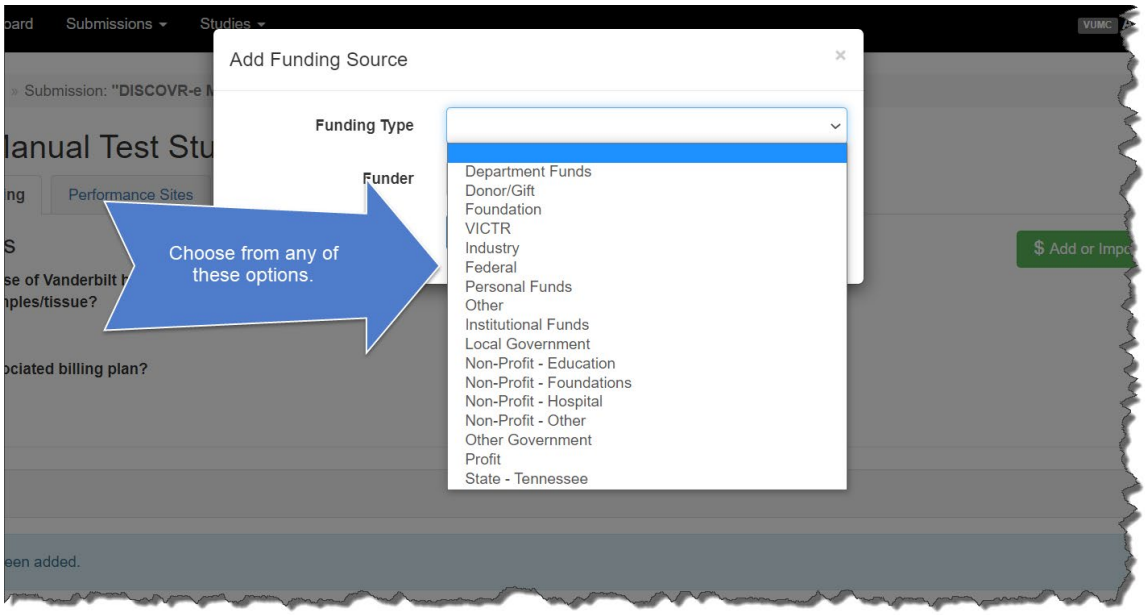


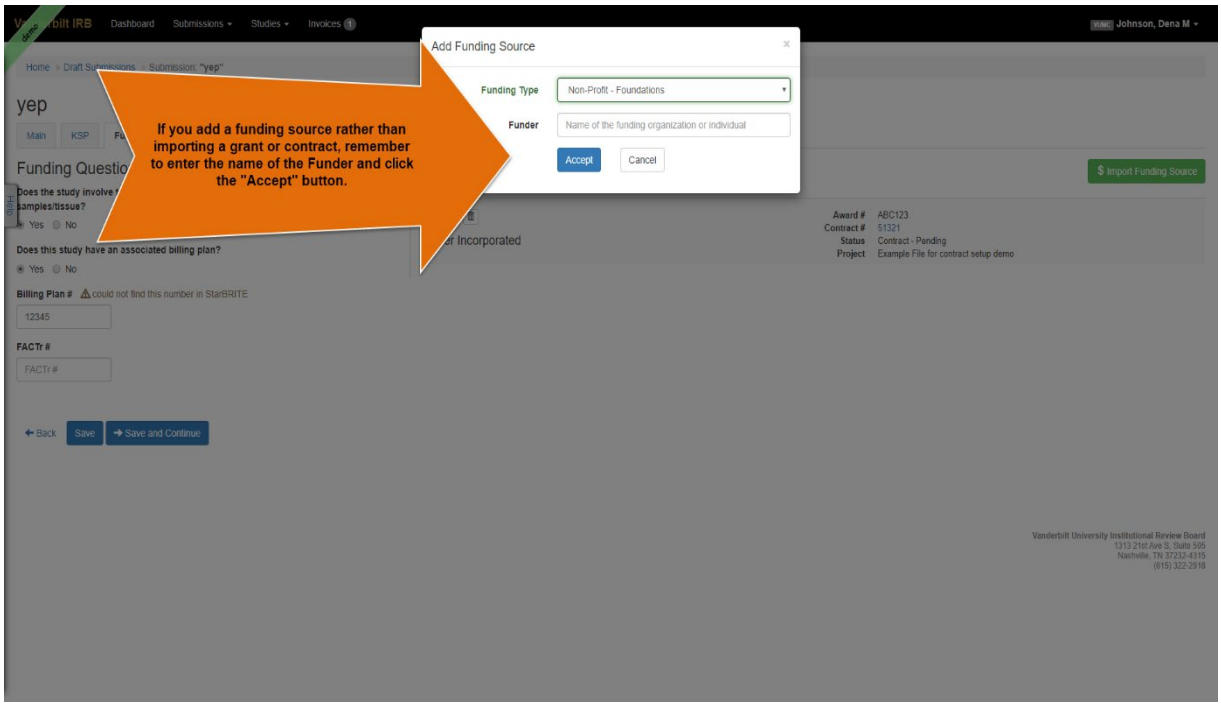
Contracts show up in green and Grants show up in blue to make it easier to find what you are looking for. You can search by any investigator to find what you need, but if you know the Contract or the PEER number, you can search by that as well.

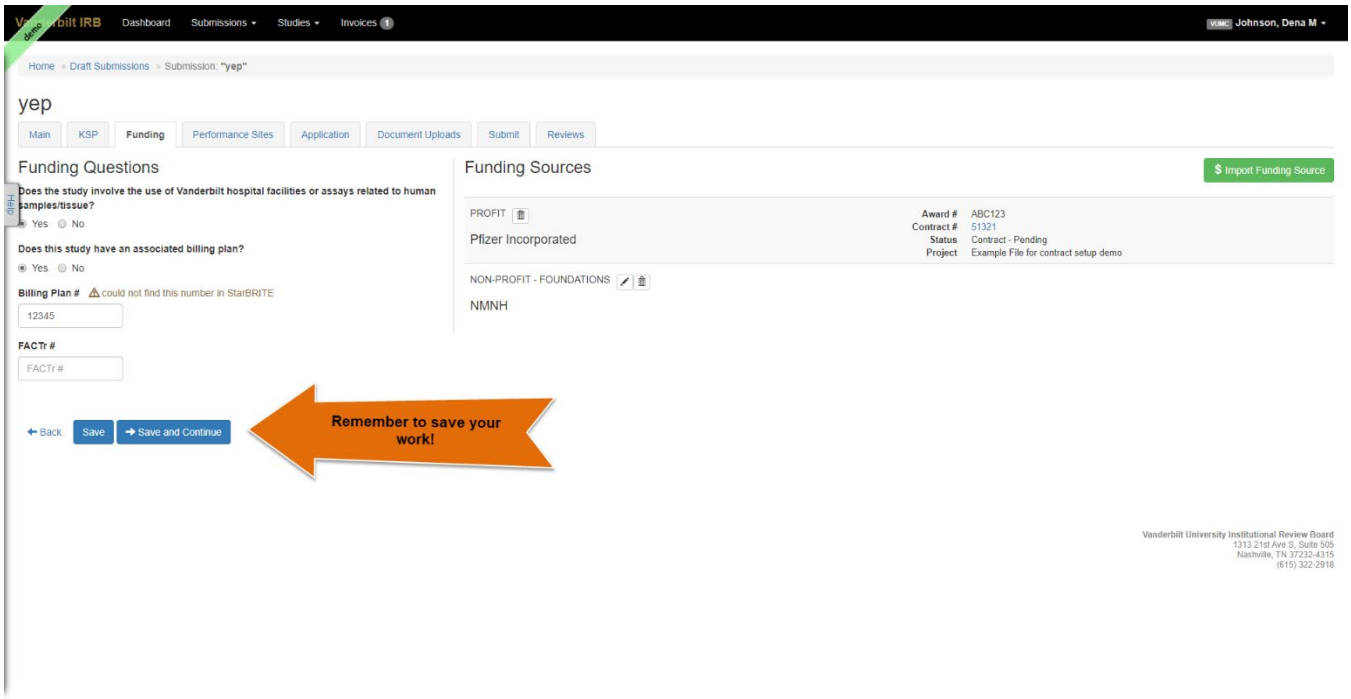


If your study does not include contract or grant, you can still tell us more about any additional funding you may have such as VICTR funds.




Add Funding Source
Funding Type
Funder
Department Funds
Donor/Gift
Foundation
VICTR
Industry
Federal
Personal Funds
Other
Institutional Funds
Local Government
Non-Profit - Education
Non-Profit - Foundations
Non-Profit - Hospital
Non-Profit - Other
Other Government
Profit
State - Tennessee
Choose from any of these options.

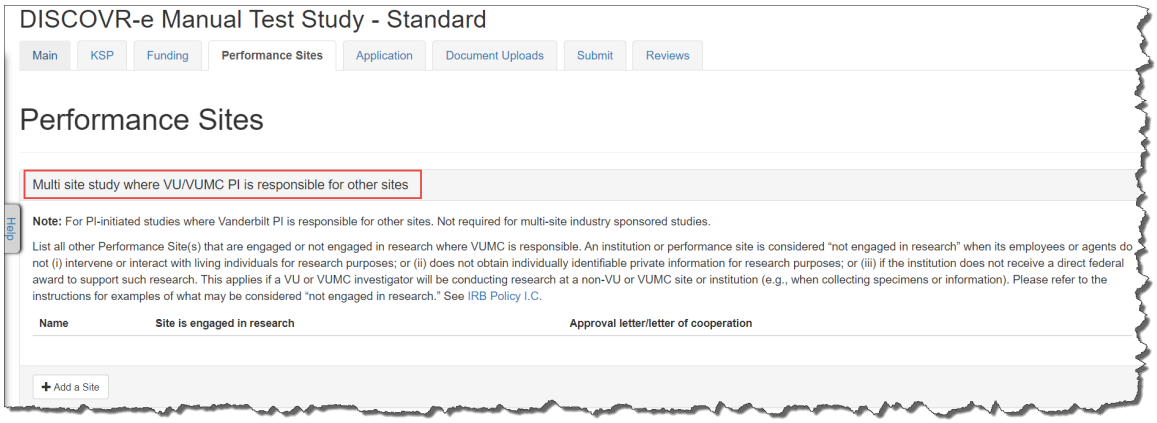

Add Funding Source
Funding Type
Non-Profit - Foundations
Funder
Name of the funding organization or individual
Accept
Cancel
If you add a funding source rather than importing a grant or contract, remember to enter the name of the Funder and click the "Accept" button.


Dashboard
Submissions
Studies
Invoices
Johnson, Dena M
Home » Draft Submissions » Submission: "yep"
yep
Main
KSP
Funding
Performance Sites
Application
Document Uploads
Submit
Reviews
Funding Questions
Does the study involve the use of Vanderbilt hospital facilities or assays related to human samples/tissue?
Yes
No
Does this study have an associated billing plan?
Yes
No
Billing Plan #
could not find this number in StarBRITE
12345
FACTr #
FACTr #
Back
Save
Save and Continue
Remember to save your work!
Funding Sources
$ Import Funding Source
PROFIT
Pfizer Incorporated
Award # ABC123
Contract # 51321
Status Contract - Pending
Project Example File for contract setup demo
NON-PROFIT - FOUNDATIONS
NMNH
Vanderbilt University Institutional Review Board
1313 21st Ave S, Suite 505
Nashville, TN 37232-4315
(615) 322-2918

Completing the Performance Sites Tab

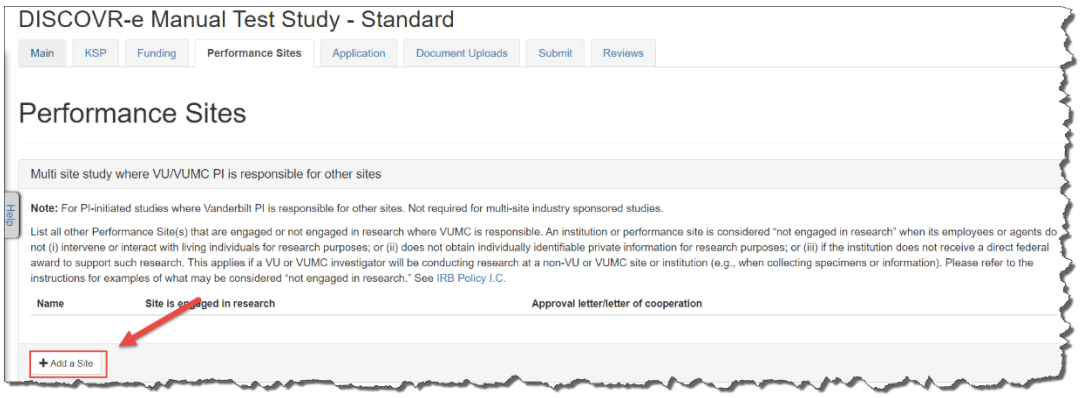
The Performance Sites tab will hold all the information about other sites involved in the study that are:

1) Performance sites for which the Vanderbilt PI is responsible that are either engaged or not engaged in research.
2) Participating sites in a Single IRB Study for which Vanderbilt is the reviewing IRB.

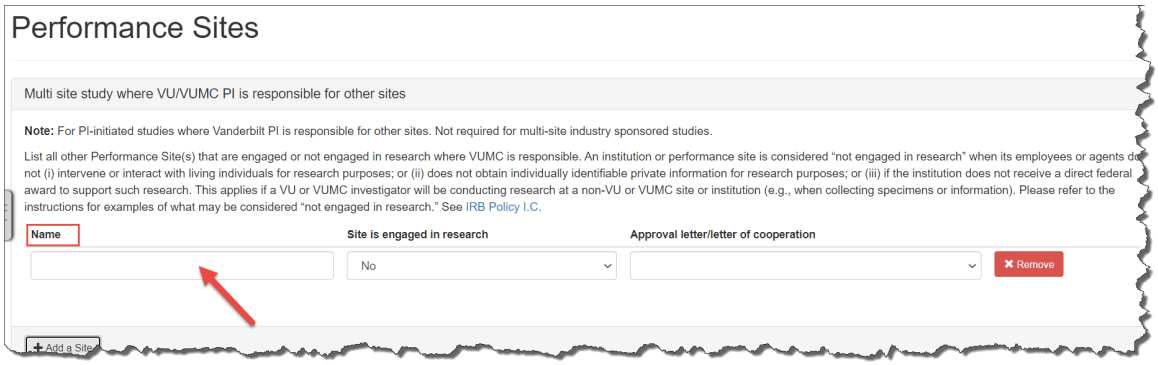


Note: Once a study is approved, this information is managed differently. Please see the Site Addition Submission for a Single IRB Studies section of this manual for further instructions on how to manage performance sites after initial study approval.

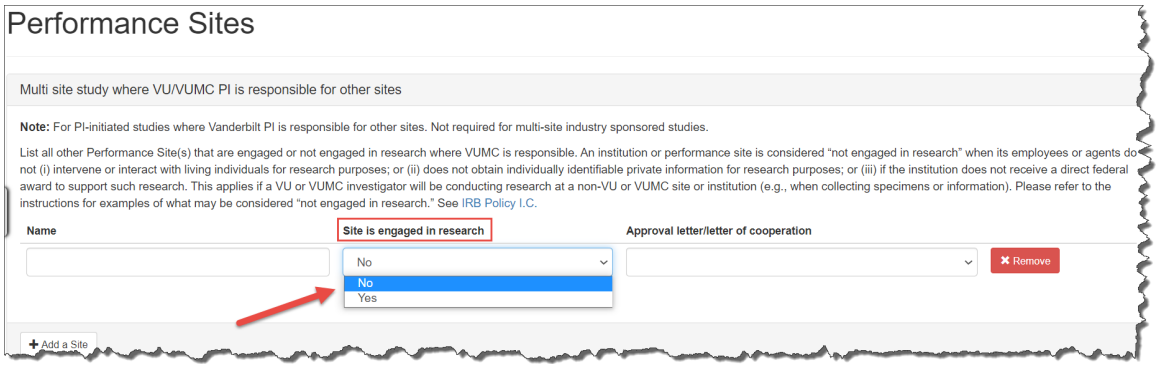
To add Performance Sites for which the Vanderbilt PI is responsible, click *Add a Site* under the Multi site study where VU/VIMC PI is responsible for other sites section.



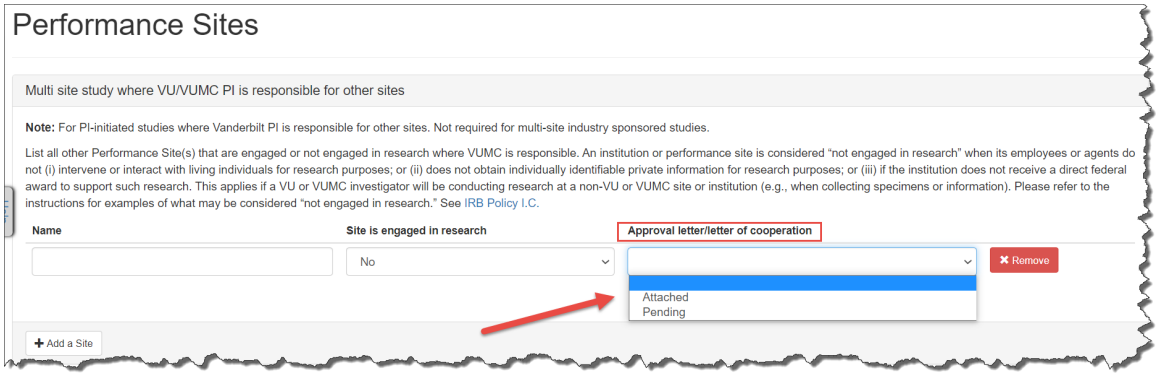
Enter the name of the site



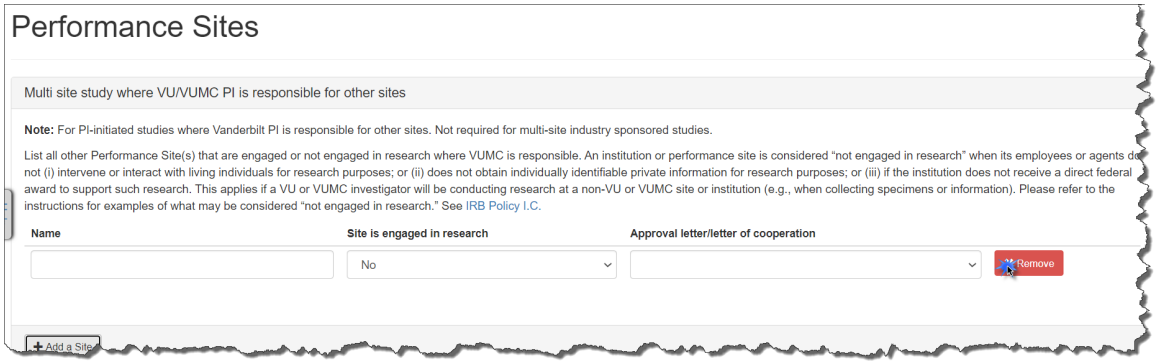
Indicate if the site is *engaged* or *not engaged* in research



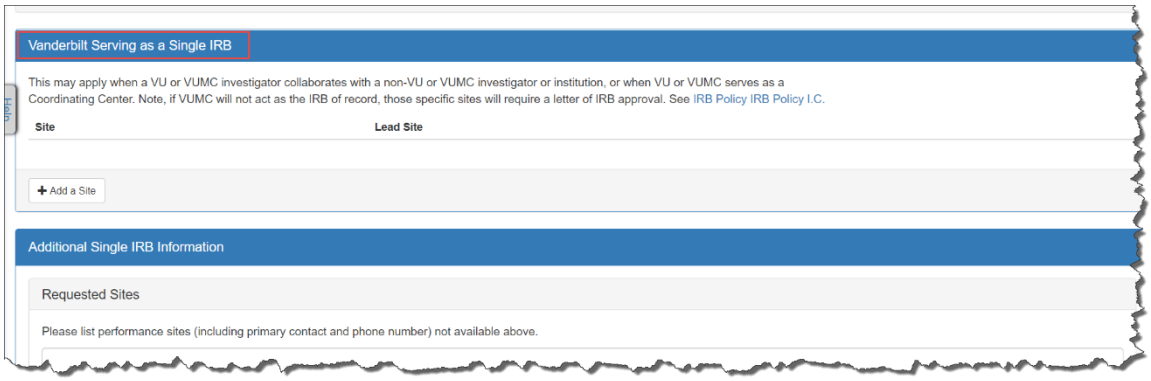
And indicate if the approval letter or letter of cooperation for that site is attached with this submission or if the letter is pending and will be submitted at a later date.



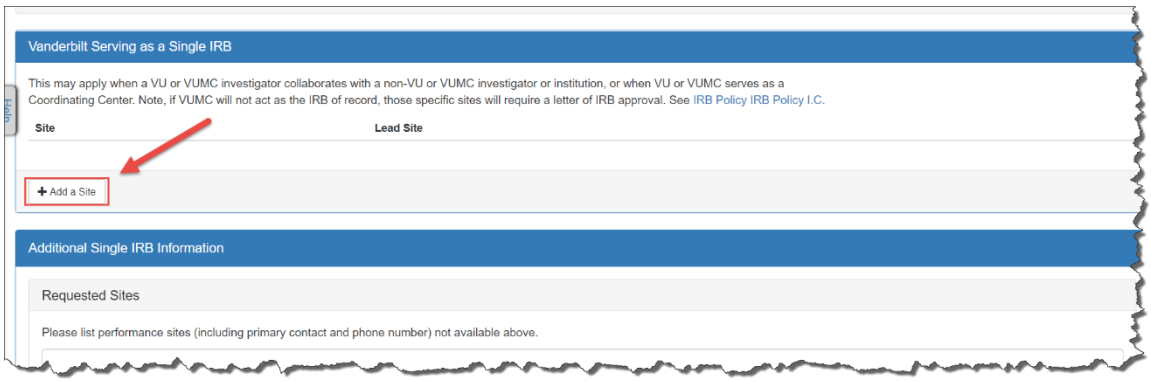
To remove a site once you have added it to the table, simply click the *Remove* button next to that site.



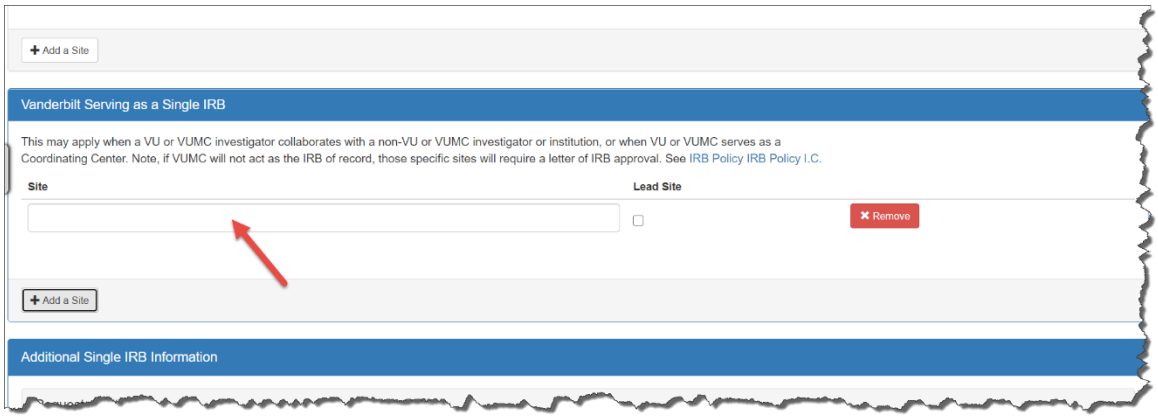
If the study is a Single IRB Study for which Vanderbilt is serving as the Single IRB, include the relying institutions in the *Vandebrilt Serving as the Single IRB* box.



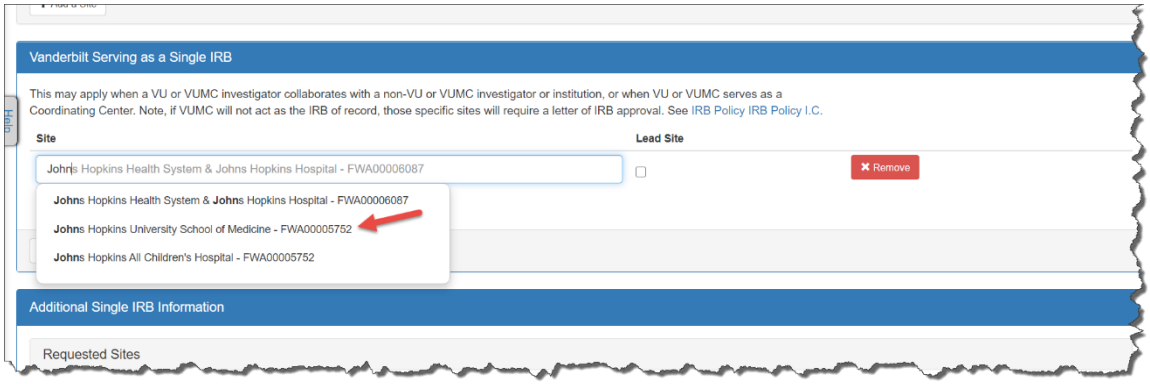
To add a Single IRB Performace Site, click *Add a Site*.



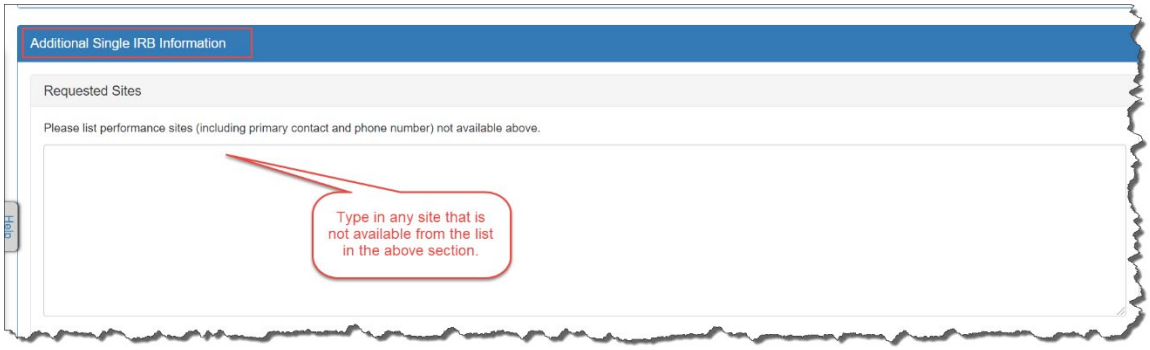
Begin typing the name of the site in the box labeled *Site*.



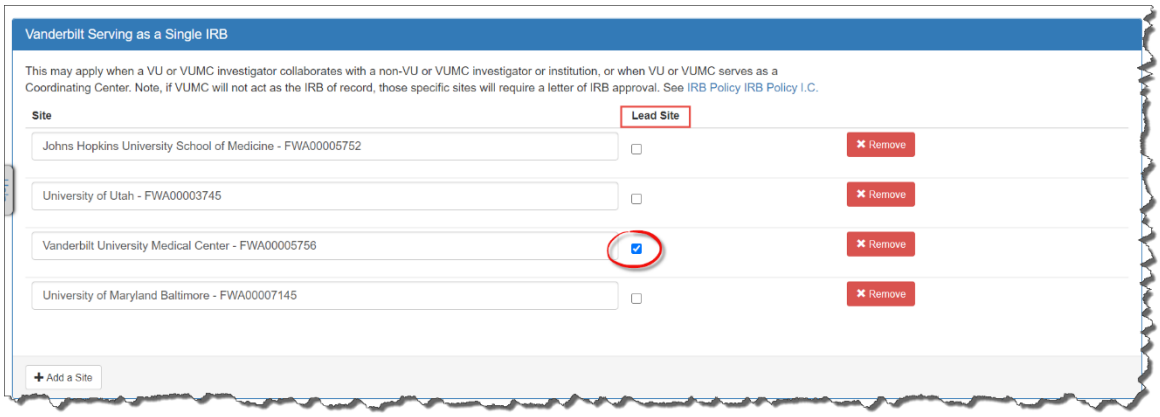
As you begin typing, options of sites that are already in the system will appear. Select the site from these options.



If the site you would like to add is not included in the drop down list, move to the section below Additional Single IRB Information labeled *Requested Sites*. In this text box, include the name of the site, the primary contact and phone number for that site.

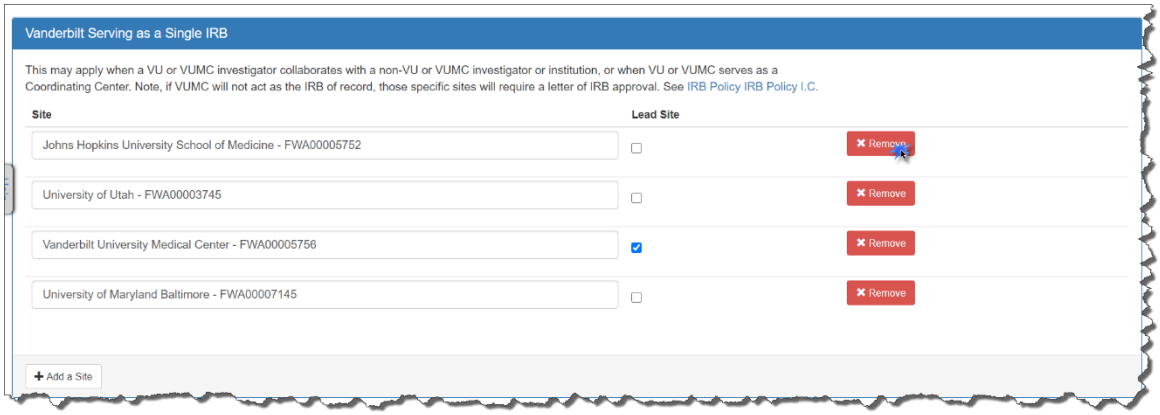


Indicate which site is the lead site for the study by clicking the check box next to that site on the *Vanderbilt Serving as a Single IRB* table.



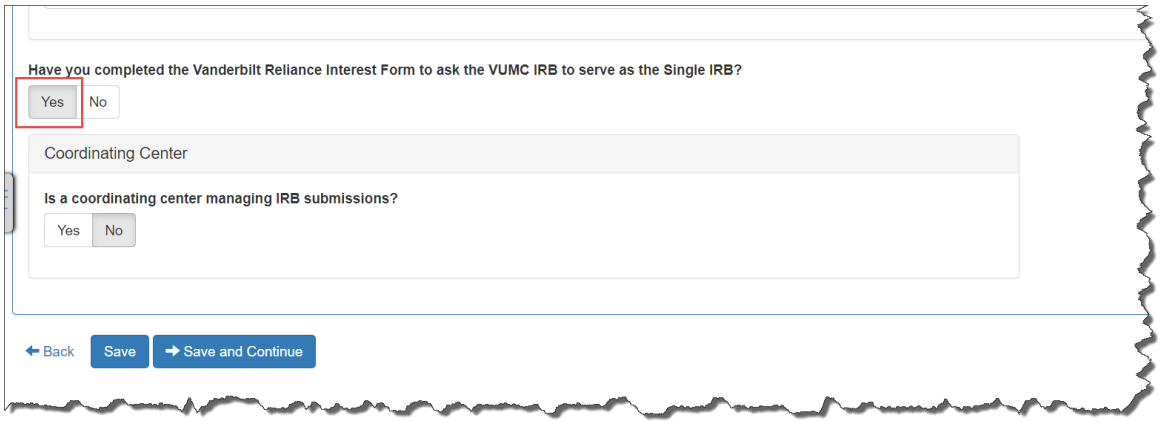
Note: If Vanderbilt University Medical Center or Vanderbilt University are participating in the study, they **WILL** need to be included in this performance sites table.

To remove a site from this table, click the *Remove button*.

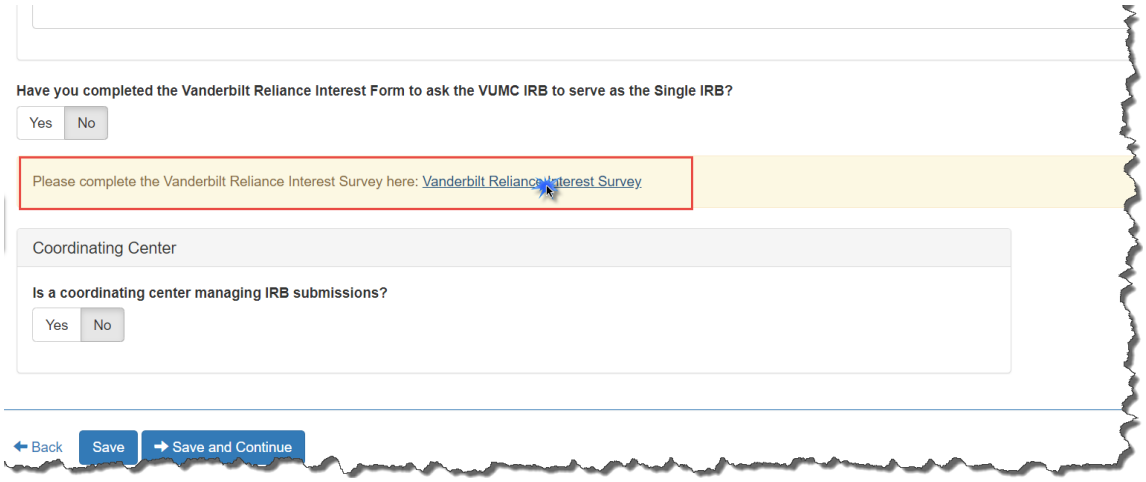


Next, answer either yes or no to the following question: *Have you completed the Vanderbilt Reliance Interest Form to ask the VUMC IRB to serve as the Single IRB?*

If yes was selected, move to the Coordinating Center question, *if applicable*. No other actions are needed at this time.

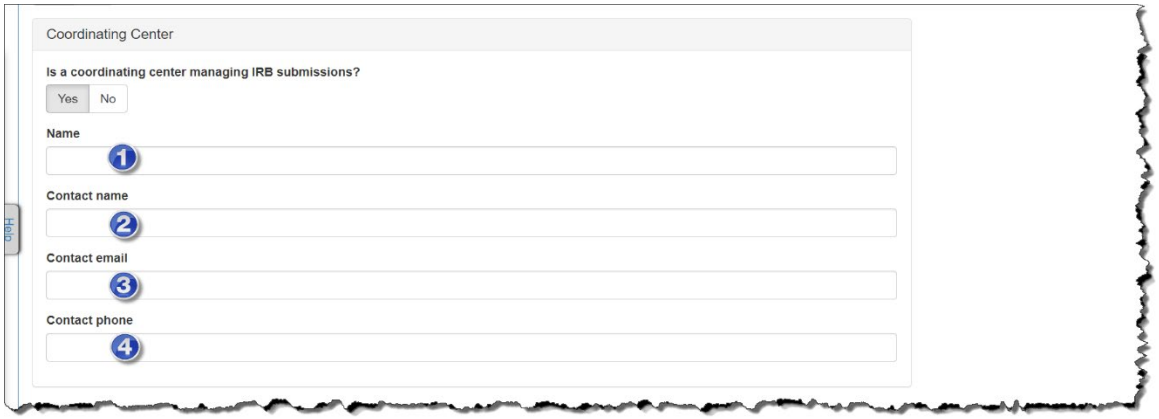


If no was selected, a notification will appear prompting completion of this form first before moving on in the Performance Site process. Click the link to access the Vanderbilt Reliance Interest Survey. Continue to the Coordinating Center question.

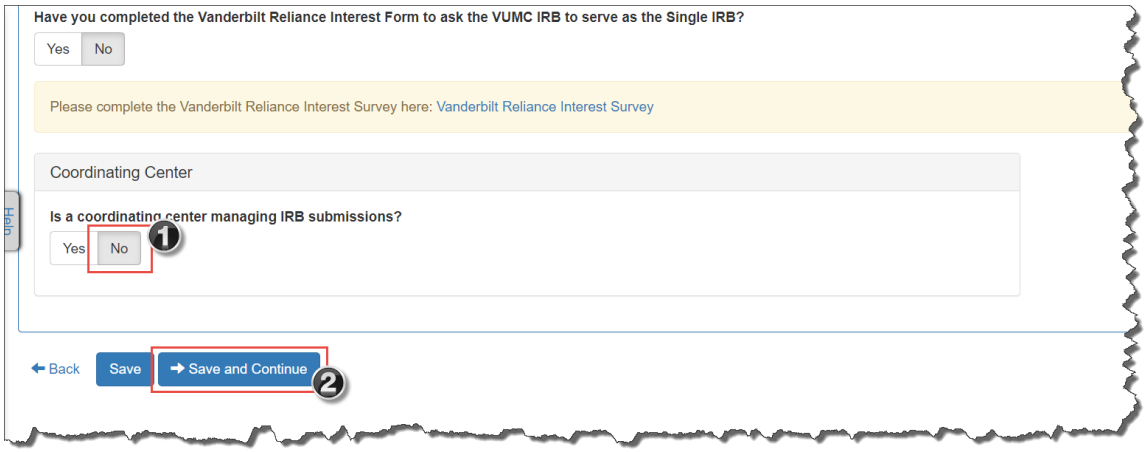


If the study involves a Coordinating Center, complete the following:

To add a *Coordinating Center*, change the response for the coordinating center question from No to Yes and enter the appropriate information in the boxes that appear.



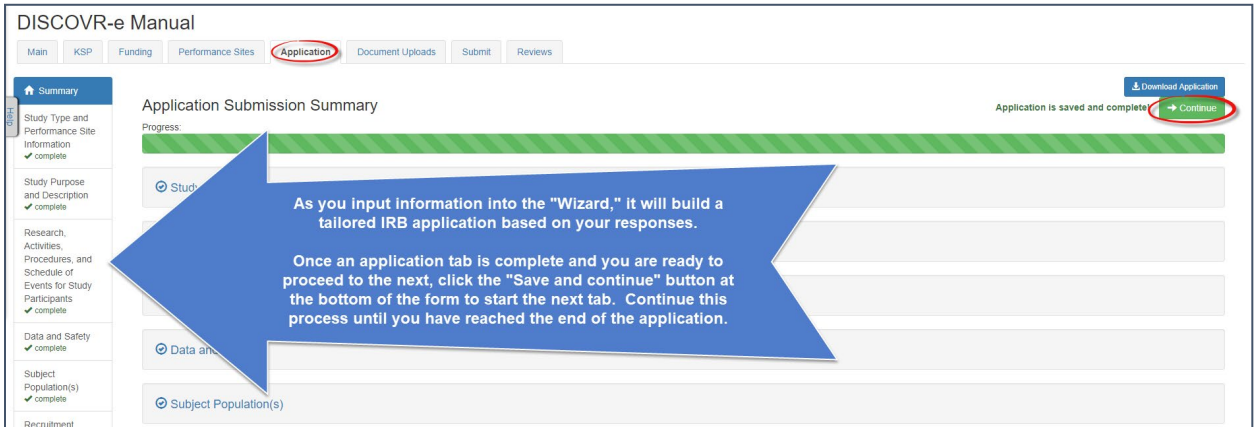
If the study will not involve a Coordinating Center, click no (Number 1), then Save and Continue (Number 2) to move to the next page.



Completing Your Wizard Application

You will begin your *Wizard application* by answering the questions found in each application tab. Your response(s) will prompt additional selections to populate regarding your submission. As you work through your submission, you will notice a progress bar building across the top of the page.

You can click any of application headings on the left side of your screen to go back and view or edit your submission.



Once all of the tabs appropriate for your research are complete, you have finished your *Wizard* application. Incomplete submissions can be saved and returned to later. These submissions can be accessed via the *Drafts submission* button on your Investigator Dashboard.

Note: The submission portal will not allow an incomplete submission to be submitted or routed for signature.

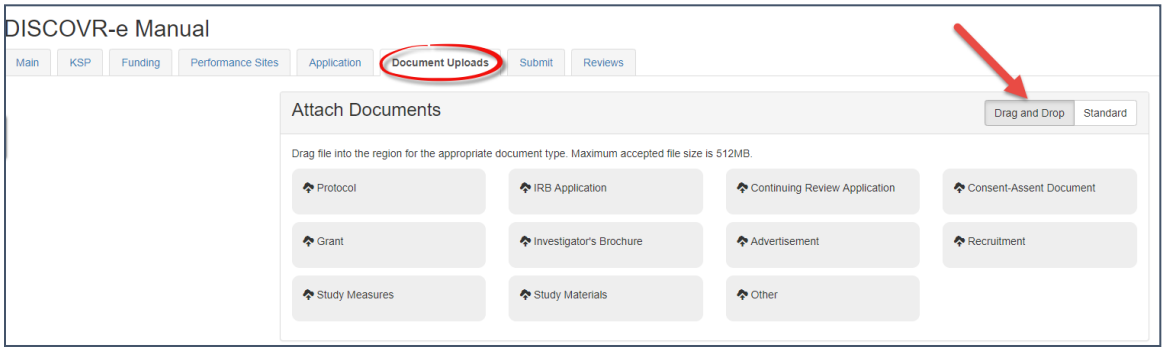
You may choose to download an electronic version of the IRB Application by clicking the *Download Application* button as shown in the example above.

To proceed to the next section of the submission process, click the *Continue* button.

Document Uploads

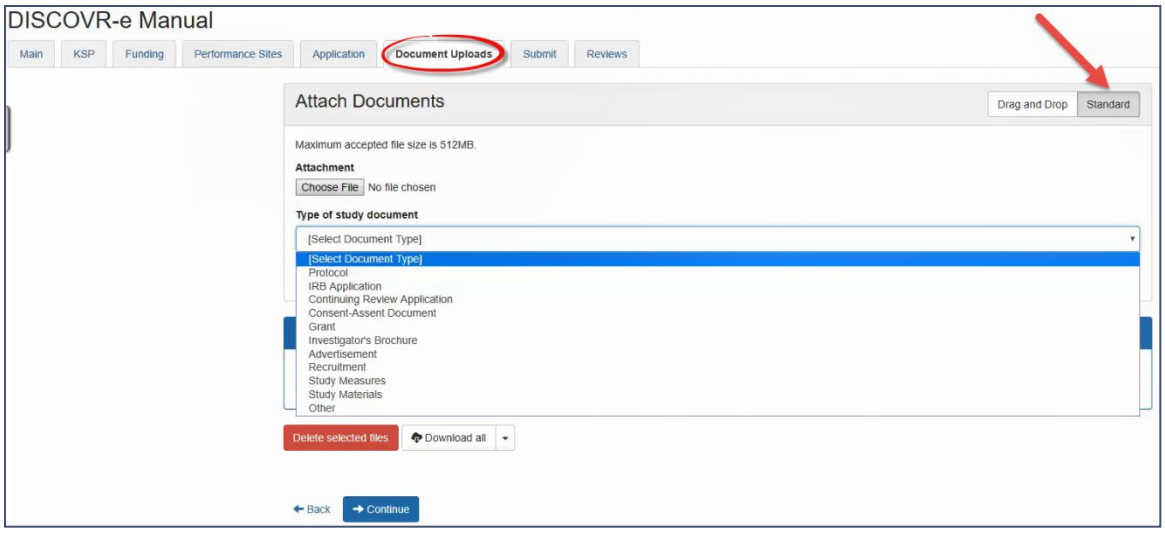
The Documents Uploads section is where you will attach/upload additional study documents such as consent forms, protocols, questionnaires, and any other study related documents or materials. Uploading documents is easy! You may upload/attach documents from locations saved on your computer by dragging and dropping the item(s) into the proper field or by browsing your computer for the appropriate file and attaching the document the standard way. To utilize the drag and drop feature, click the *Drag and Drop* button to activate it.

Next, select the document you wish to upload and drag it to the proper field and release the document. Multiple uploads may be dragged and dropped at a time if they will be uploaded to the same field. Otherwise, attachments must be uploaded one at a time. As you load additional items, a list will build showing what has been attached to your submission.

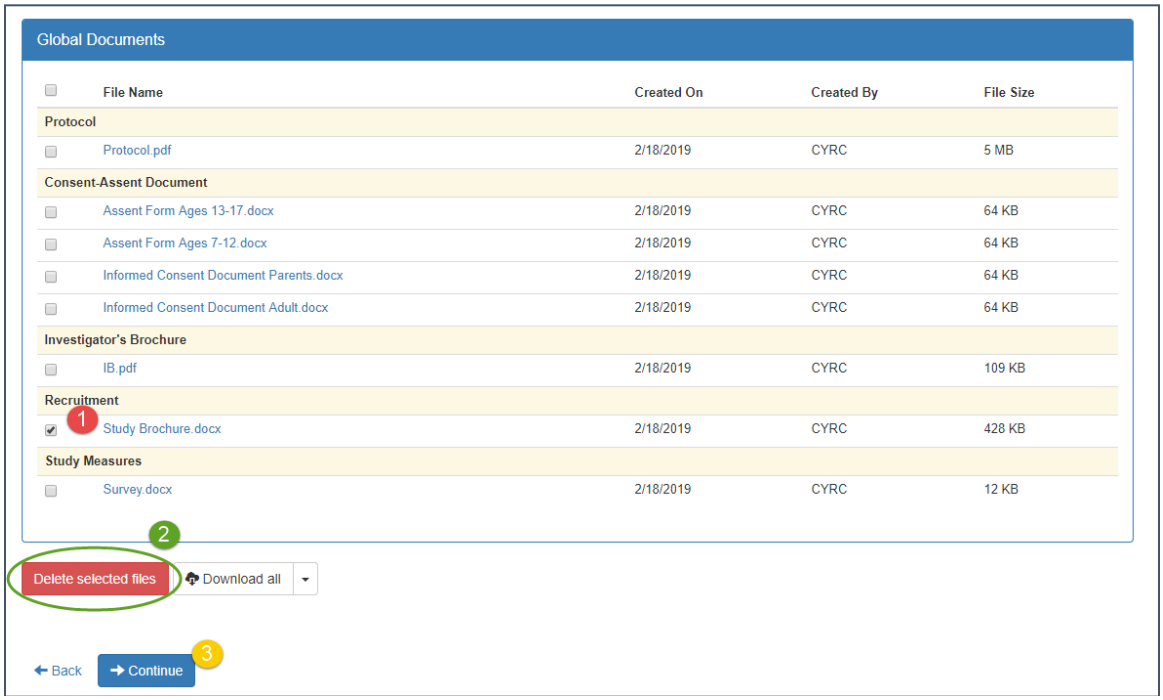


To upload/attach a document the standard way, click the *Standard* button to activate it. Click the *Choose File* button under the *Attachment* section to search your computer for the item you would like to attach. Select the item and then click the *Open* button. The item you selected will be automatically attached to your submission for review.

Next, indicate the type of study document by clicking the one of the choices from the dropdown menu. Once the type of study has been selected, click *Upload* to attach the document to your submission. Attachments should be uploaded one at a time. If you have a group of consent forms, you may zip them and attach the zip file as one attachment. However, we ask that you **do not** provide a zip file for **all** of your study documents.

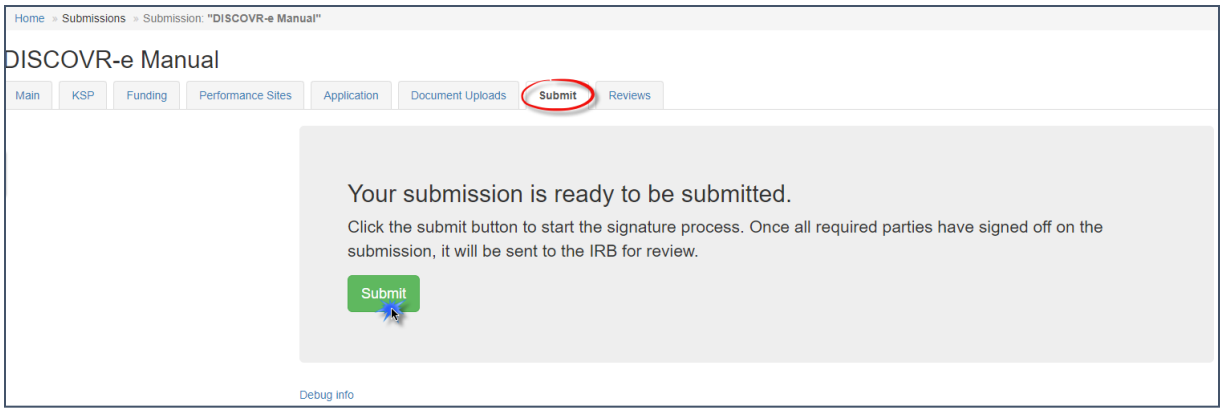


If you would like to delete an attachment, click the box next to item you wish to remove then click the *Delete Selected Files* button.



To continue with submission process, click the Continue button.

Your submission is now ready to be submitted. Click the *Submit* button to route your submission for the appropriate signatures.

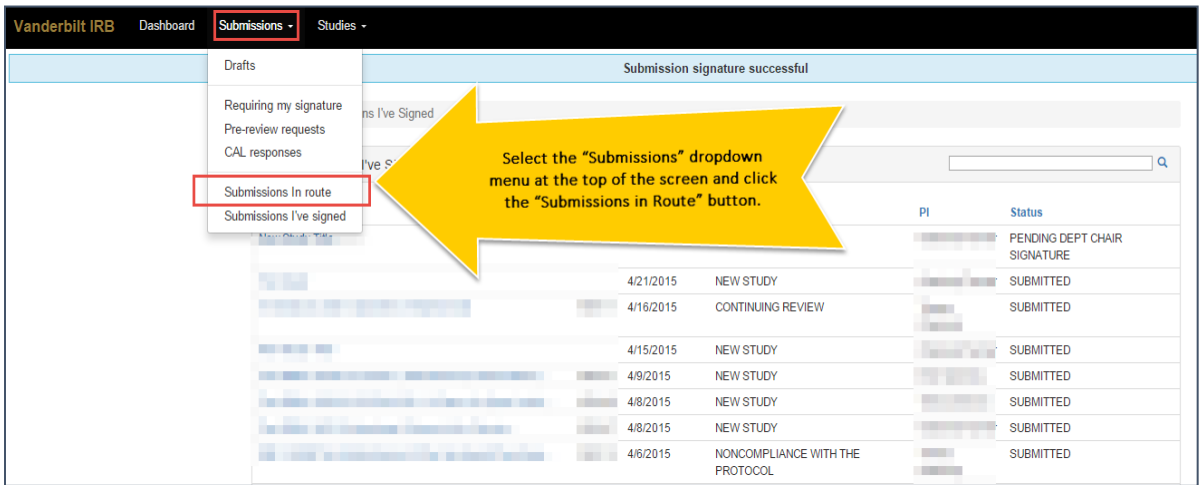


As other signatures are obtained, the submission is automatically routed through the submission portal and ultimately ends its journey at the IRB. Once it arrives at the IRB, the submission will be assigned an IRB number and routed to one of the teams for review.

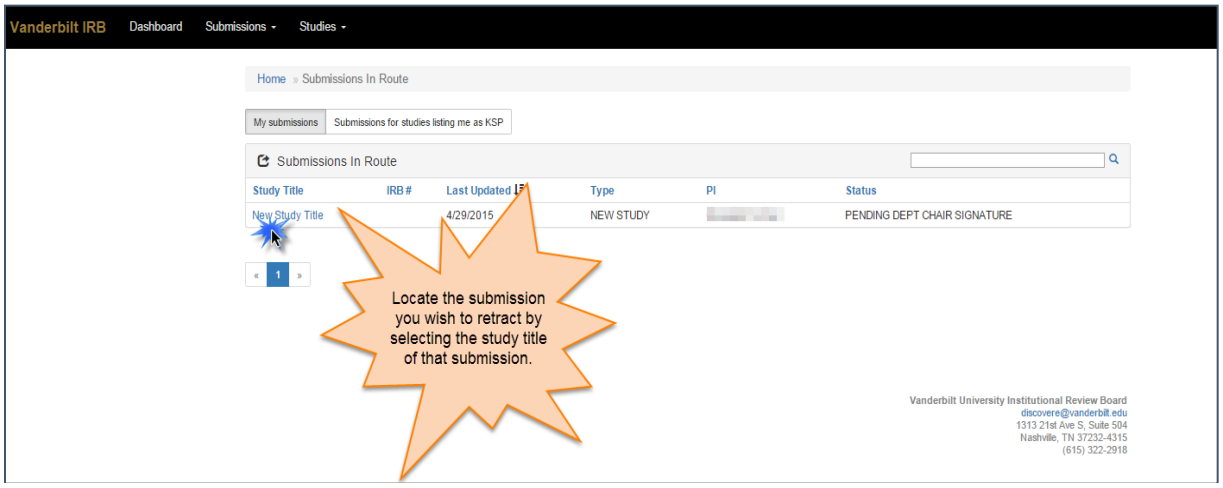
How to Retract a Submission

You may choose to retract a submission if you wish to make additional edits, or if you wish to delete the submission all together. *Please note, you can only retract submissions that have not been formally submitted to the IRB.*

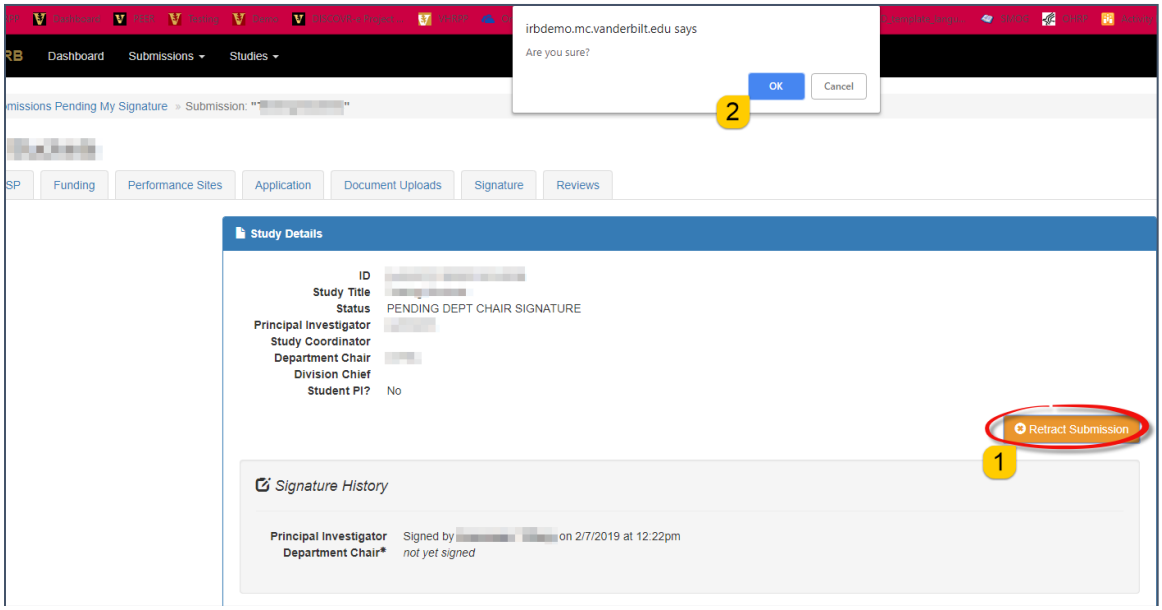
Only once a submission has been routed for additional signatures, such as those from a department chair and/or a division chief signature, shall it be retracted. To retract the submission after it has been signed off on by the PI, select the *Submissions* dropdown menu at the top of the screen and click the *Submissions in Route* button.



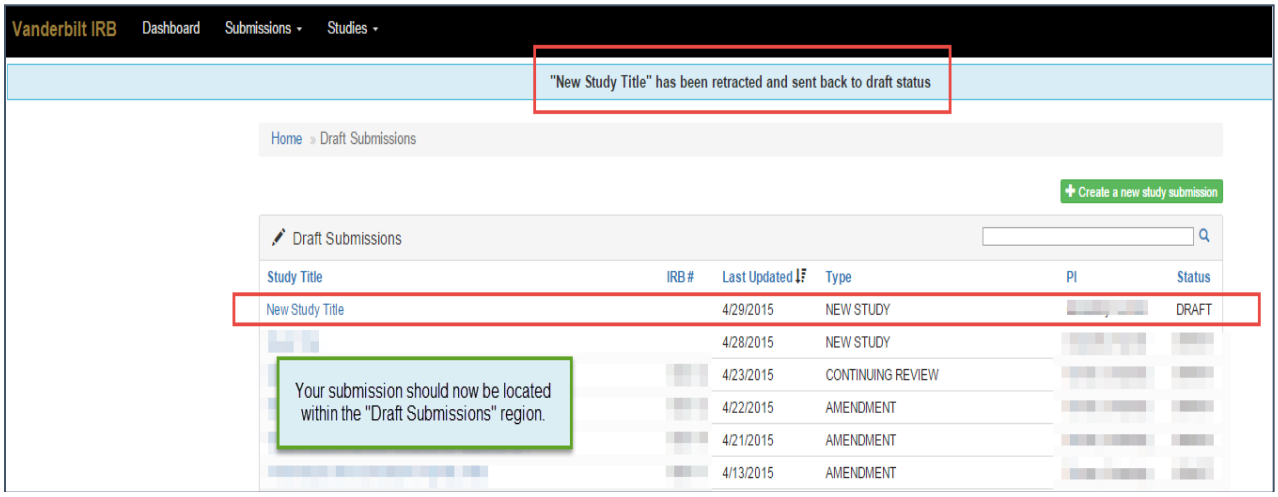
Locate the submission you wish to retract by selecting the study title of that submission.



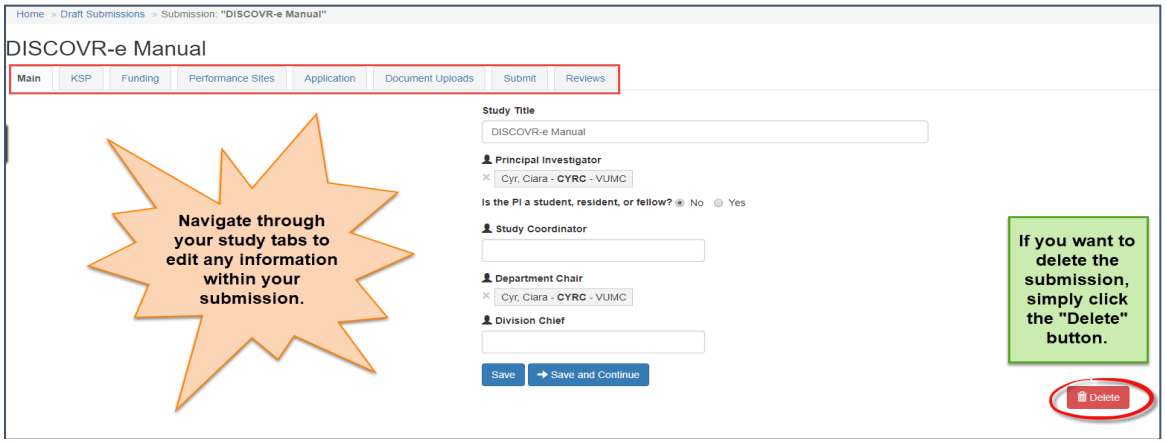
Click the *Retract Submission* button and then select *OK* on the confirmation prompt to continue with the submission retraction process.



Your submission should now be in your *Drafts Submissions* view within your Investigator's Dashboard.

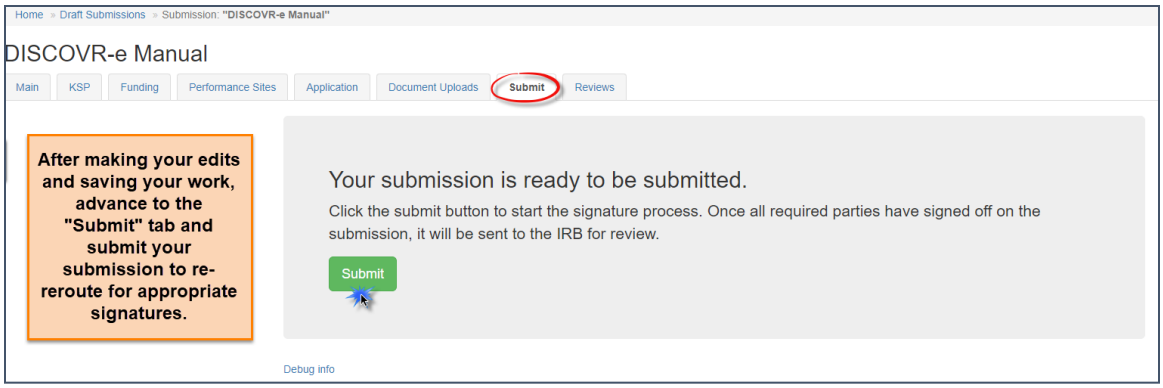


If you need to revise any information within your submission, navigate to the appropriate tab of your submission and update where necessary.



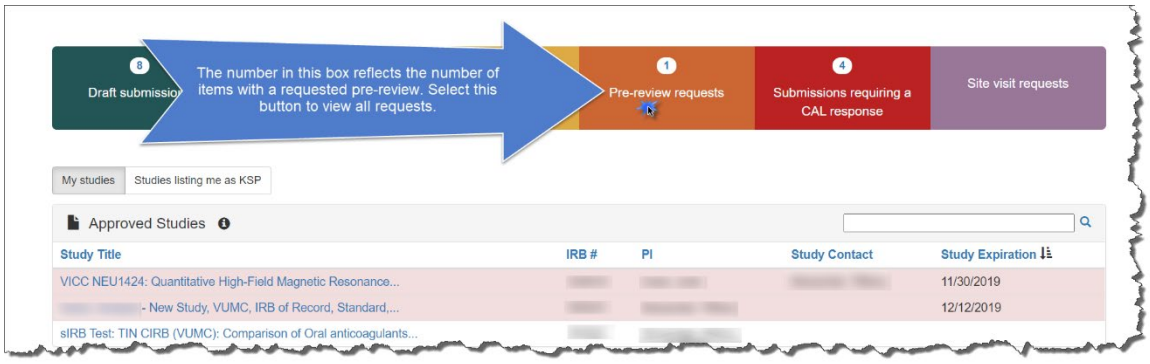
If you would like to delete your submission, simply click the *Delete* button.

After making your edits, select the *Save and Continue* button to save your changes and to advance you back to the *Submit* tab. Click the *Submit* button to re-route your submission for the appropriate signatures.

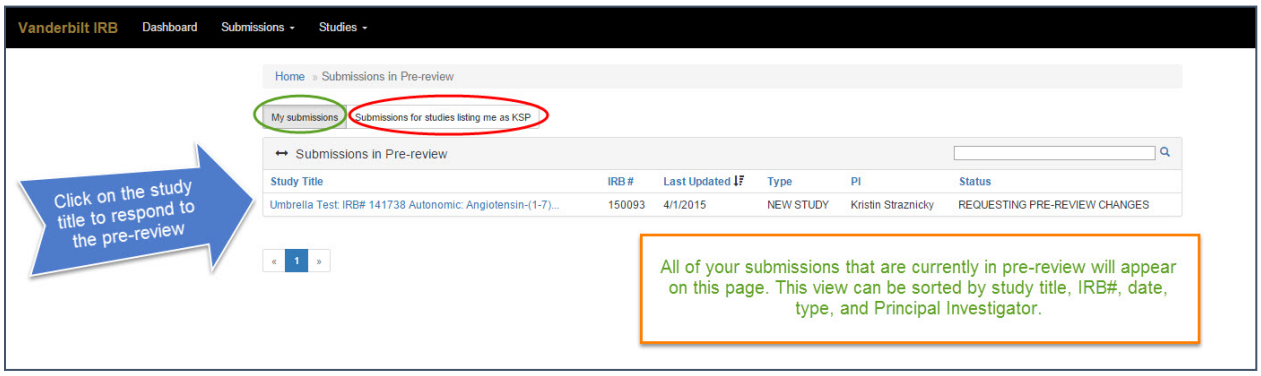


How to Respond to a Pre-Review

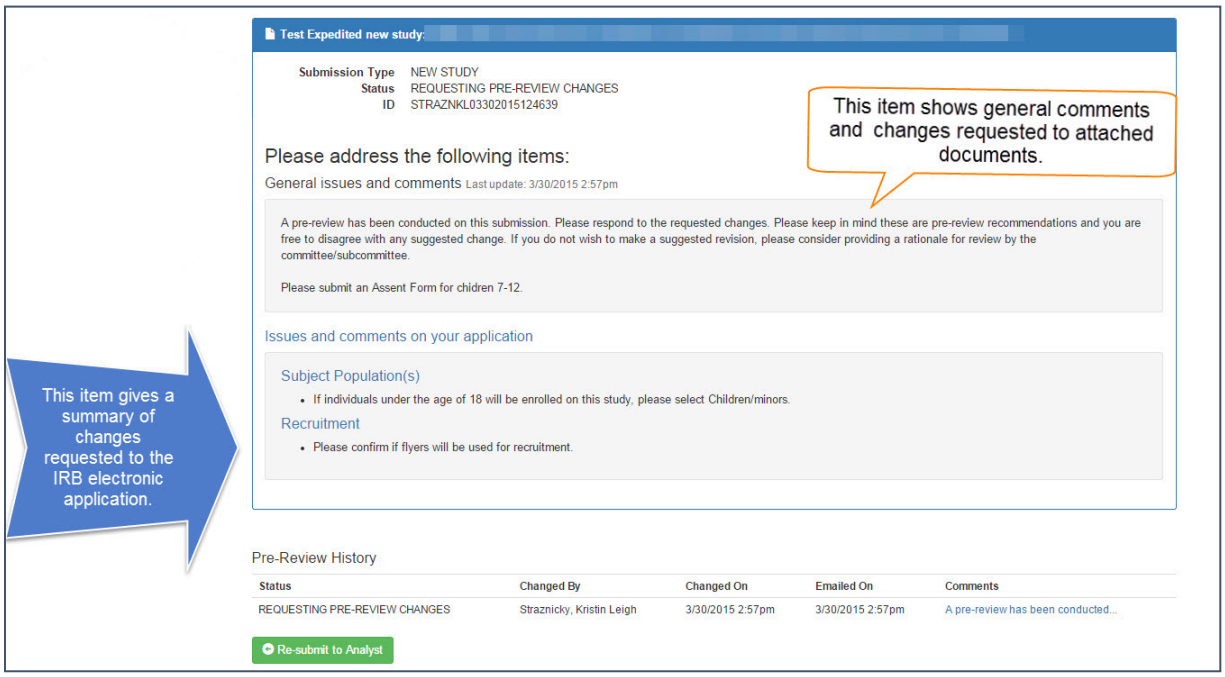
The Principal Investigator and Study Contact will receive an email when a pre-review request has been received. The link in this email will lead to the submission. These submissions can also be accessed on the dashboard. The pre-review requests button will contain a counter listing the number of items with pre-review requested changes.



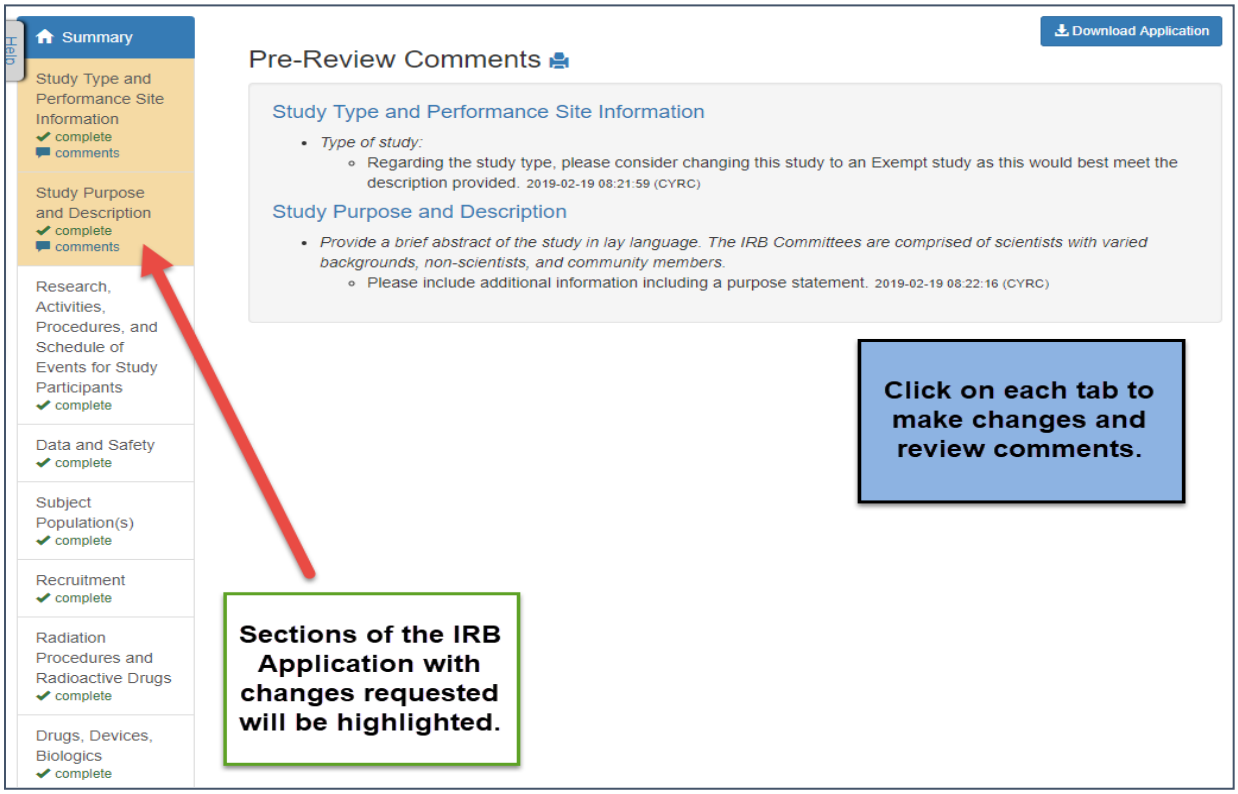
The pre-review requests are sorted by two categories: *My Submissions* (studies in which you are the PI or Study Contact) and *Submission for studies listing me as KSP.*



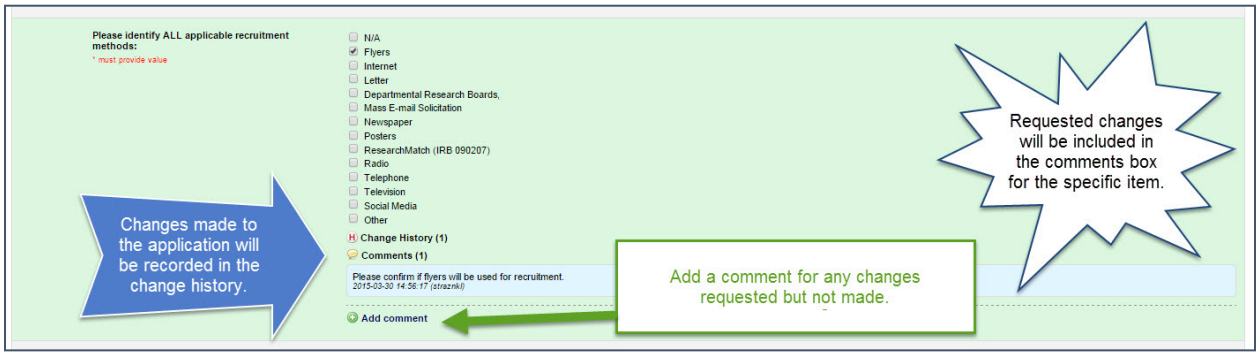
Select the study title for the submission you wish to respond to. The pre-review tab in the study submission will list general issues and comments. A summary of changes requested to the IRB application will also appear.



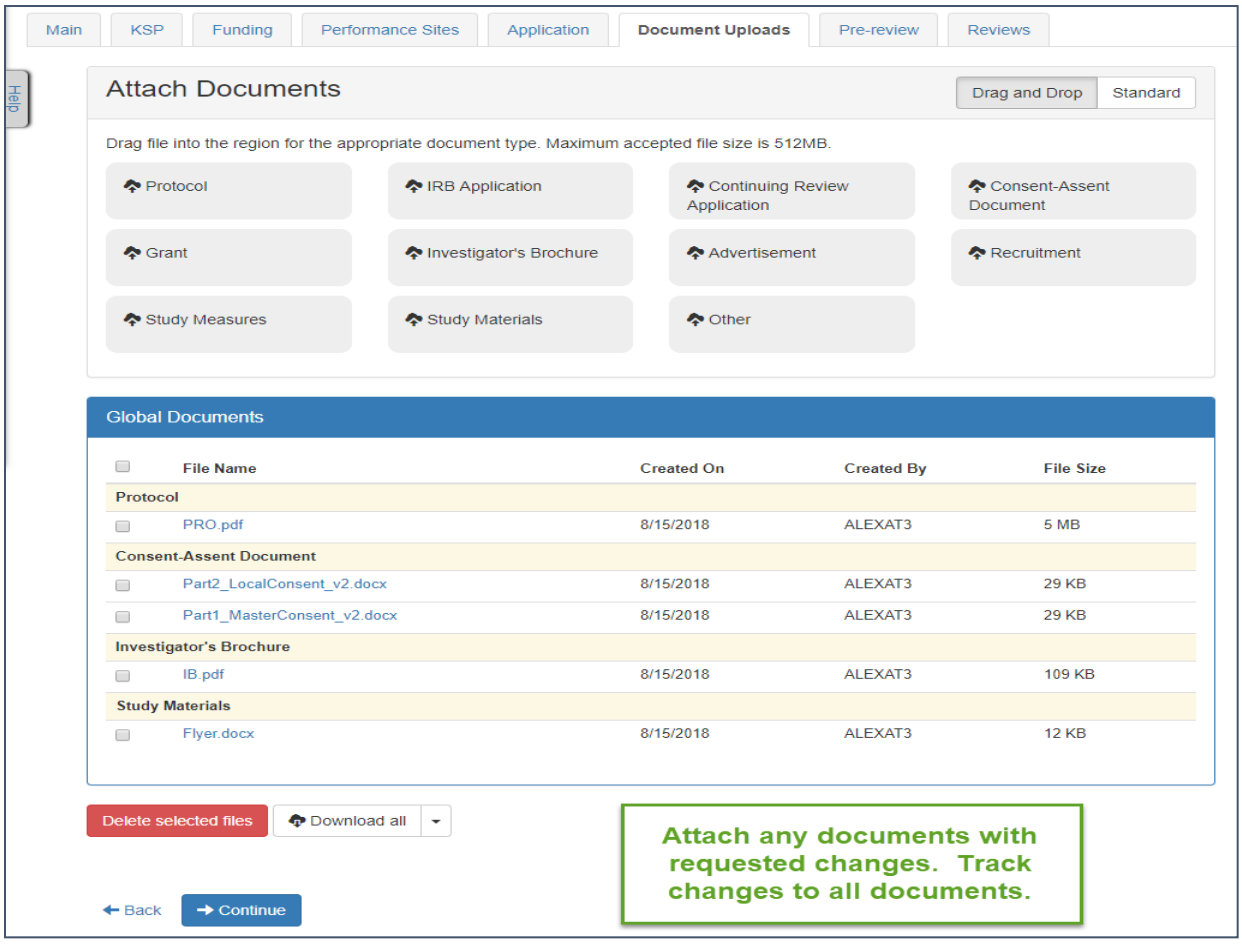
Select the application tab to respond to pre-review suggestions. All sections of the application with suggested changes will be highlighted. Select each section to view the specific items with change requests.



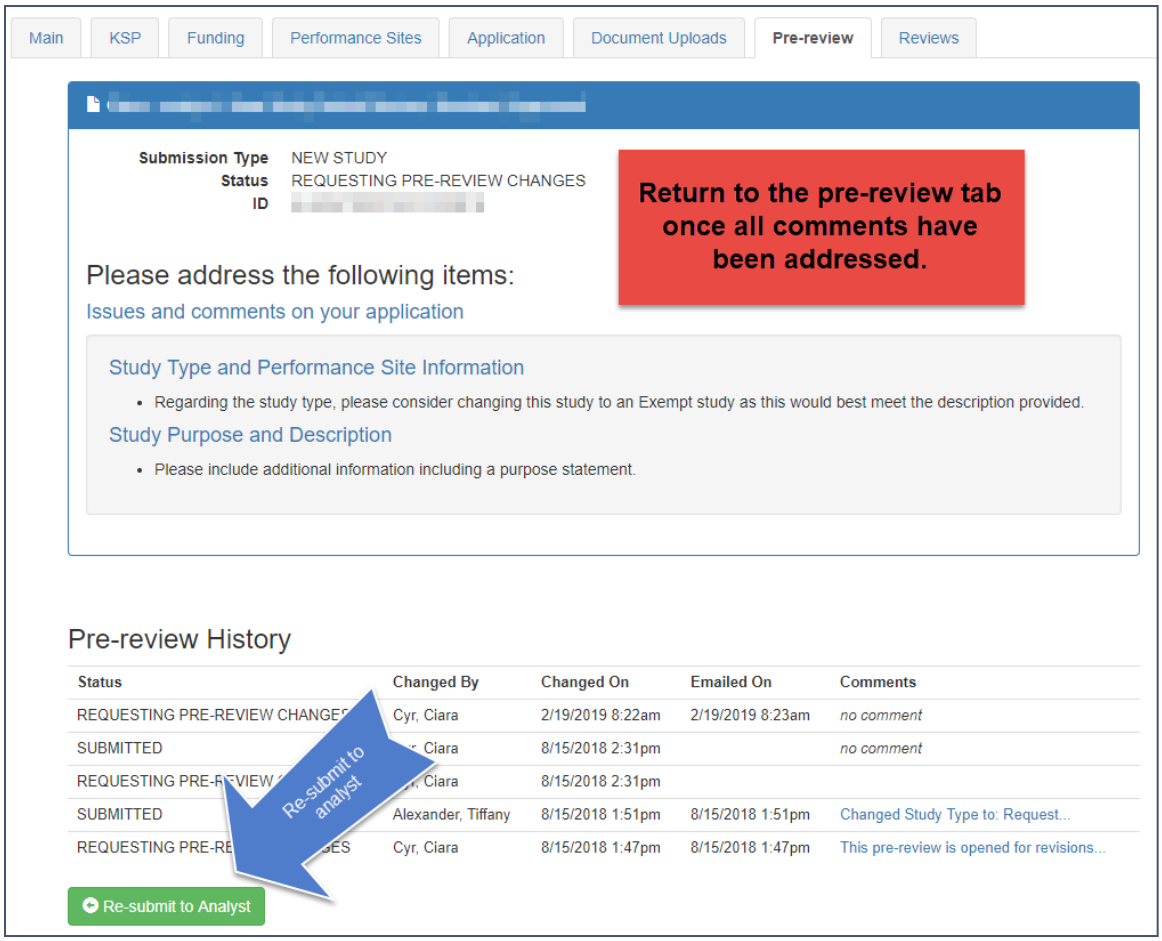
The pre-review comment will appear below the item. To revise an answer to align with the request, simply select the appropriate response or revise the text in the dialogue box as necessary. As all pre-review comments are suggestions, please add a comment providing a rationale for any requested changes not made.



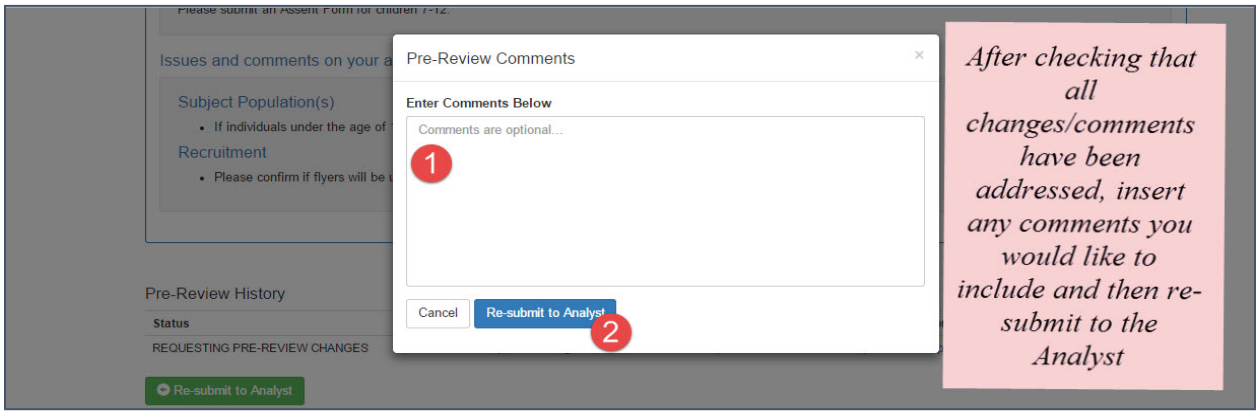
If revisions are necessary to study documents, attach any documents with pre-review requested changes in the document uploads tab. Please ensure that all changes are tracked. Documents can be uploaded by dragging and dropping the document into the corresponding box, or using the standard upload method to find the document on your computer.



Once all pre-review suggestions have been responded to, return to the pre-review tab. Review the requested changes and ensure that all necessary information has been included. Select the green button at the bottom of the tab to submit the pre-review response.



A dialogue box will appear giving you an opportunity to include comments to the analyst. Including comments is optional. To complete the pre-review response, select the blue button to re-submit to the analyst.



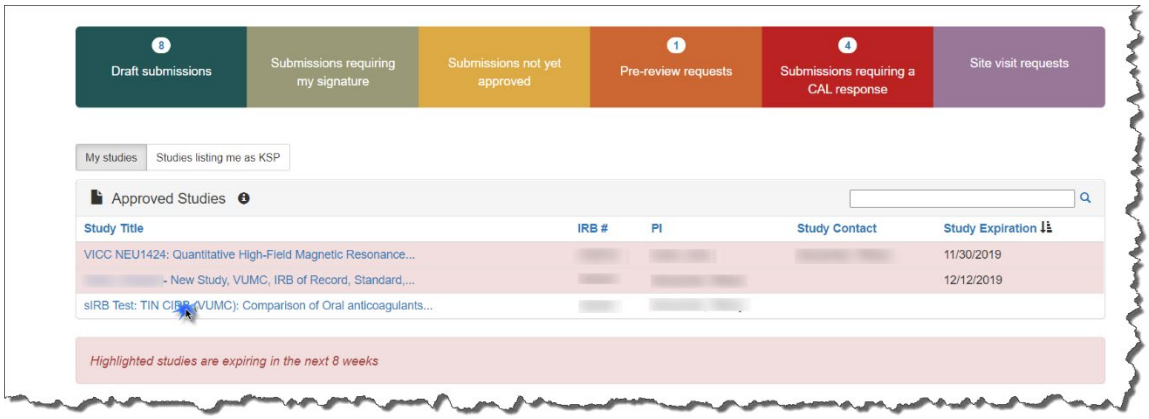
The pre-review response is now submitted. The submission will be processed and moved forward for review by the IRB.

Submitting an Amendment to an Approved Study

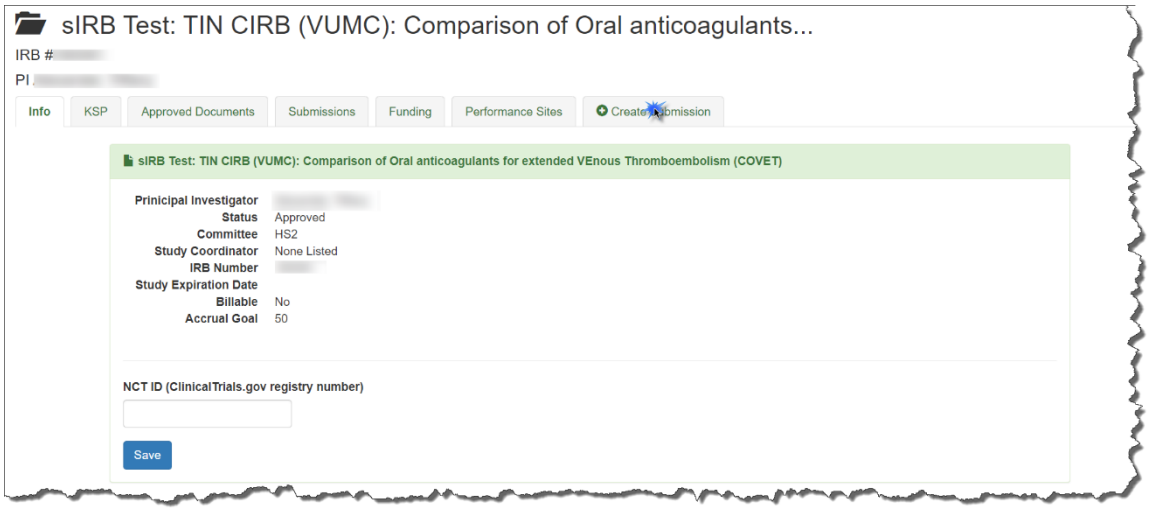
All amendments will be submitted using the same submission process.

Note: Changes to key study personnel no longer require the submission of an amendment.

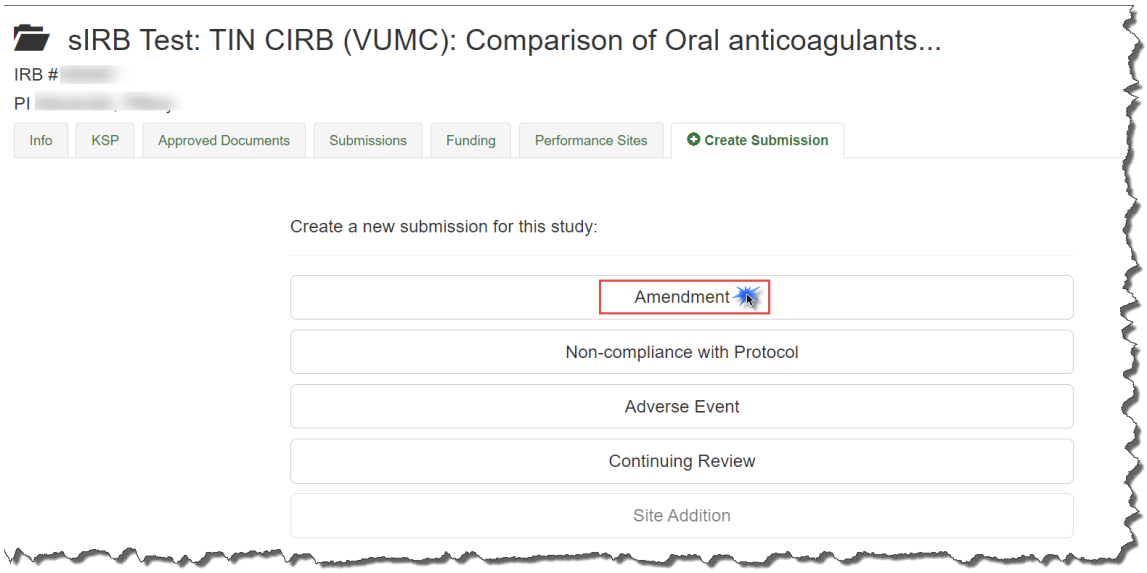
To initiate an amendment submission, select the study that requires an amendment.



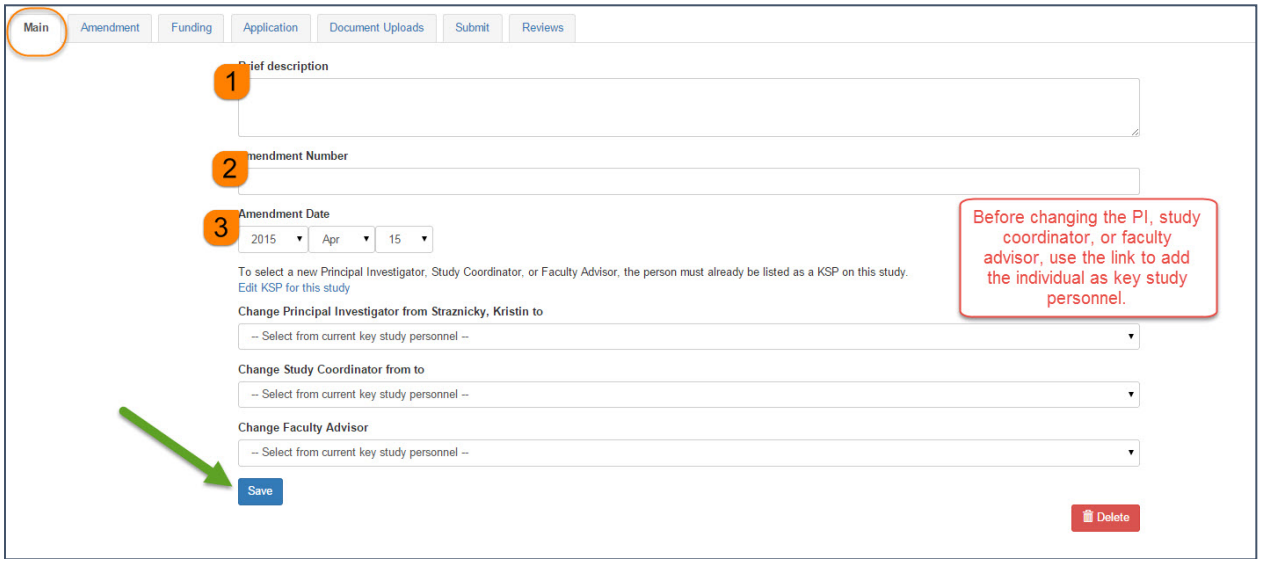
From the study page, click *Create Submission*.



This will open the study page. Using the *Create Submission* tab on the study page, select to create a new amendment submission.



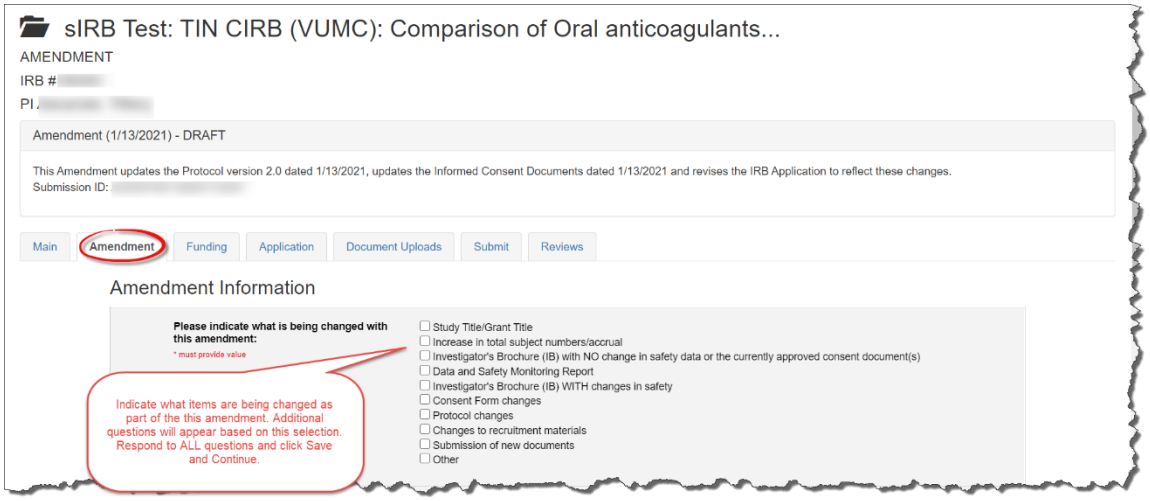
Begin by completing the *Main page* of the amendment. Save your changes at the bottom of the page before moving forward. Changes that are not saved before moving to a new tab may be lost.



Note: This tab is also used to change the Principal Investigator, Study Coordinator, or Faculty Advisor. This change must be made as an amendment after the individuals are added as Key Study Personnel.

Completing the Amendment Tab

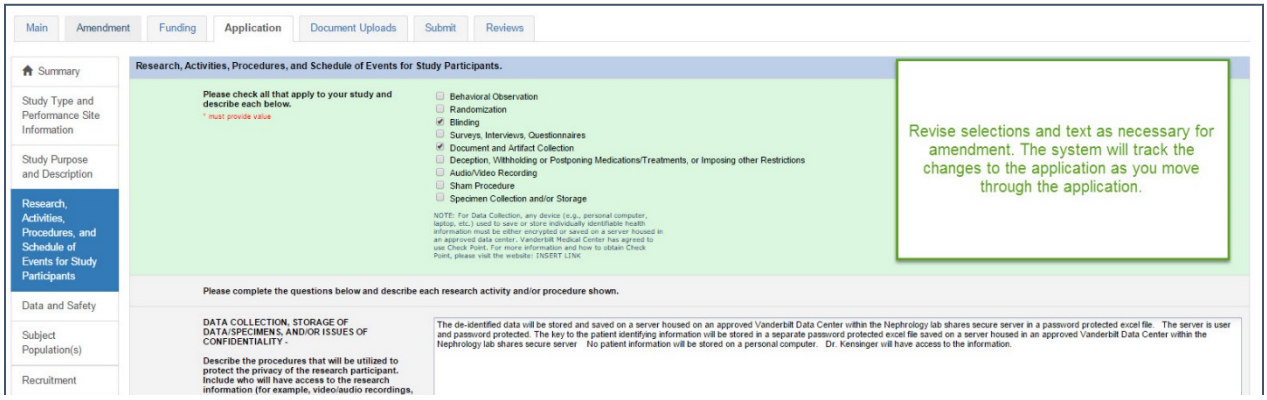
Check the boxes for each document being revised or change being made as a part of this amendment. Additional questions will appear based on these selections. Please answer each item and save to continue the submission.



Making Changes to the IRB Application

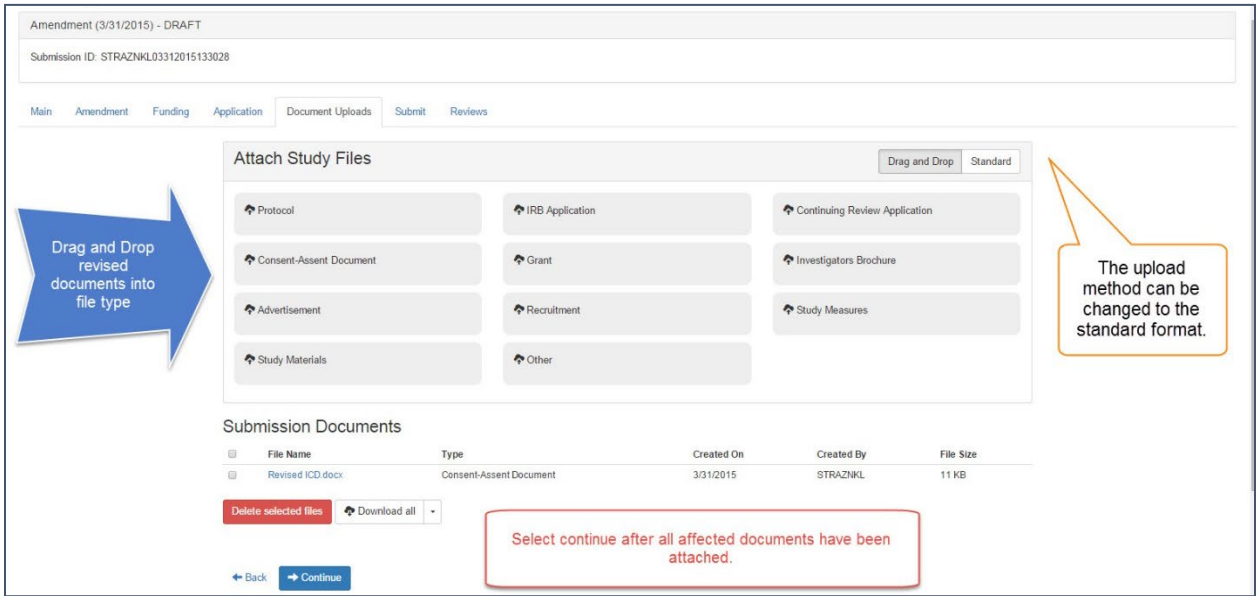
In the IRB application wizard, review each tab and make changes as necessary. The changes made will be tracked under each item.

Since the application builds based on the information input, some new questions may appear as you make revisions. Include answers to each new question that appears and save your changes before moving on to the next section of the application.

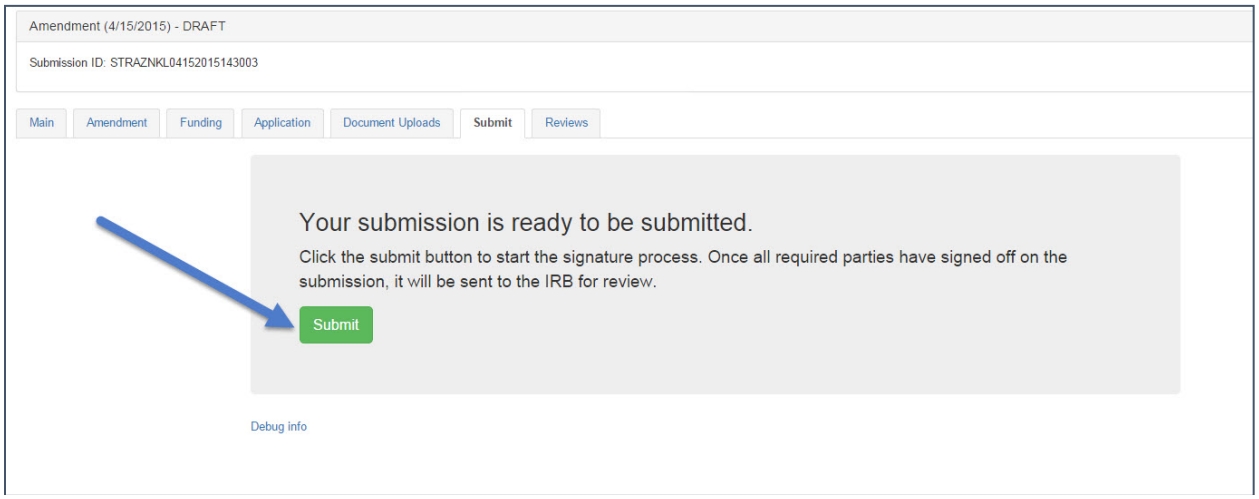


Attaching New or Revised Documents

Please track changes to all currently approved study documents that are affected by the amendment. This will aid the review process. In the *Document Uploads* tab, upload any new or revised study documents by dragging and dropping each document into the corresponding category. The *Other* category is available for any documents that do not fit a specific category. Alternatively, you can change the upload method to a standard selection method in the right corner of this tab.

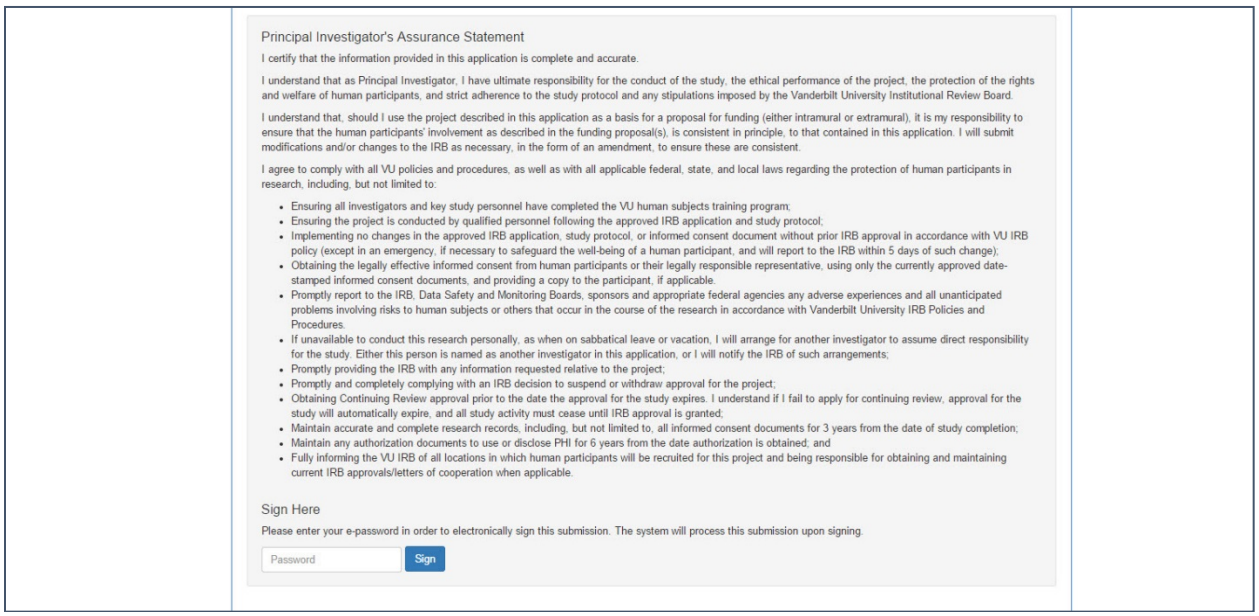


The Submit tab will notify you if any items are incomplete. This is a good time to review each section of the submission and ensure that all necessary changes have been made. When you are ready to move forward, select the submit button.

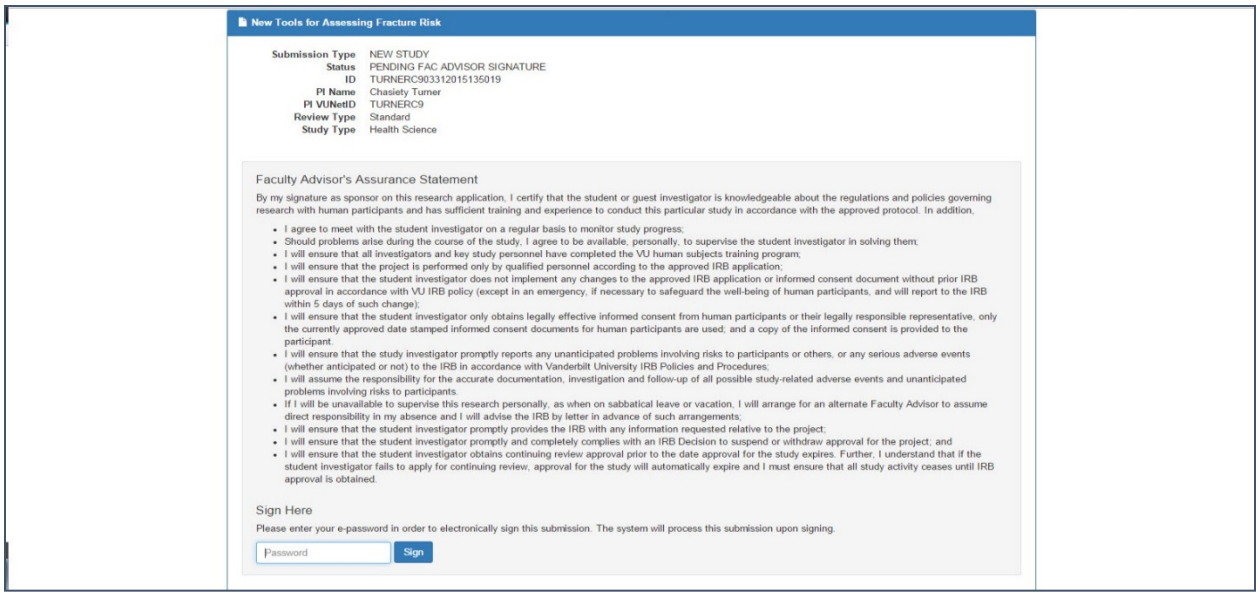


The amendment submission is now ready for the Principal Investigator's signature. If you are the Principal Investigator, a page will appear listing the responsibilities of the PI. Please review these responsibilities. At the bottom of the page, sign the document by inputting your Vanderbilt password.

If the submission is being made by key study personnel, the amendment will route for the PI's signature. The PI will receive an email notifying him or her that a submission is pending signature. The link in this email can be used to access the submission and signatory page. This submission can also be accessed for signature under the *Submissions Awaiting my Signature* item on the dashboard.

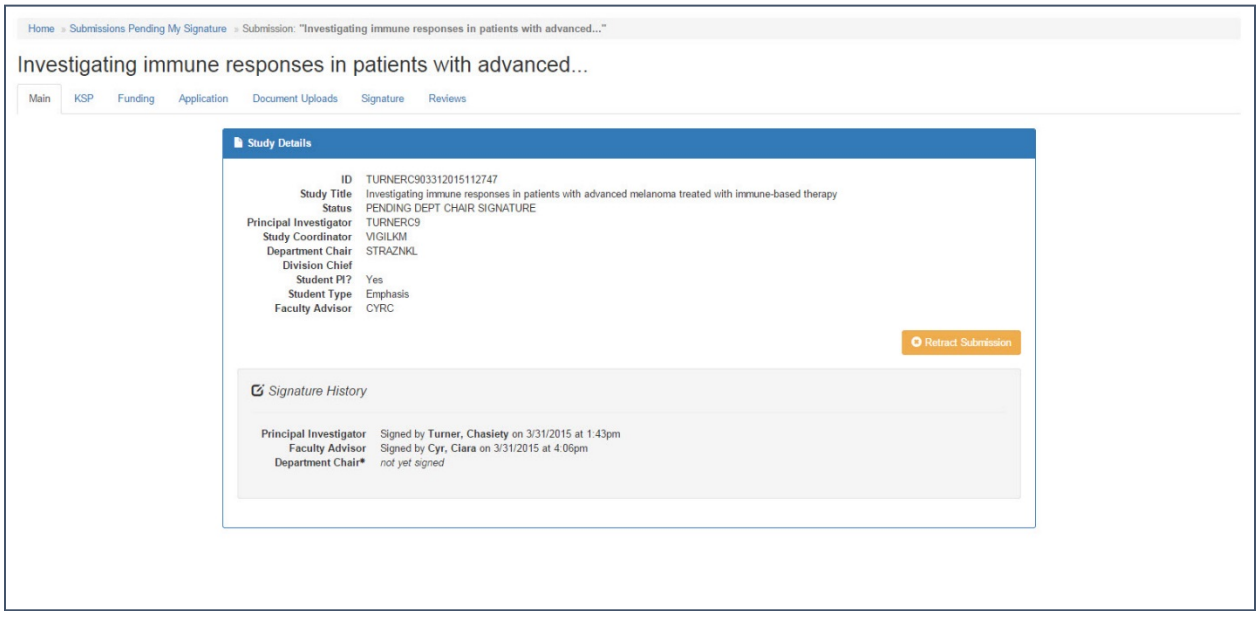


The amendment submission will now be routed for signature to the Faculty Advisor, *if applicable* for your study. Each of these individuals will have an alert on his or her dashboard to notify that a submission is pending signature, in addition to receiving an email notification. This item can be used to access the submission, review the amendment, and sign at the bottom of the page.



Retracting the Amendment Prior to Submission

If any signatories (PI, Faculty Advisor, Department Chair, or Division Chief) would like to make changes before the submission is sent to the IRB for review, the amendment can be placed in *draft* by retracting it on the main page of the amendment. After any changes are made, the amendment can be submitted by signing at the bottom of the signatory page.

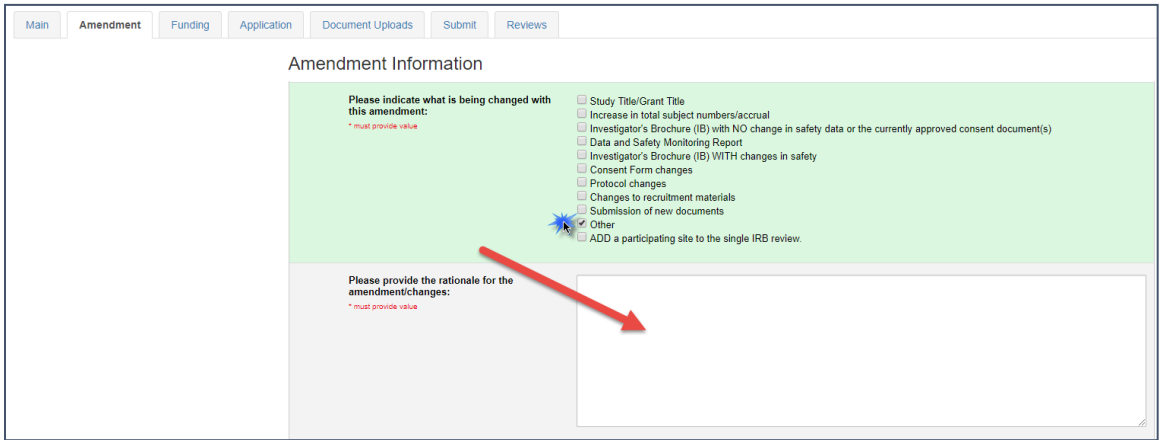


The Amendment is now submitted. You can track the progress of the amendment by accessing your submissions on your main Wizard page. You will receive a notification if a pre-review is necessary. Please see the *Respond to a Pre-Review* section of the manual for assistance in making your response.

Amendment to Add Non-Single IRB Performance Sites

This will function the same way the amendment usually does. On the Amendment Form click *Other*, and in the box to provide the rationale for the amendment, include the Site Name, if the site is engaged or not-engaged in research, and if the approval letter is attached with the amendment or if it is pending.

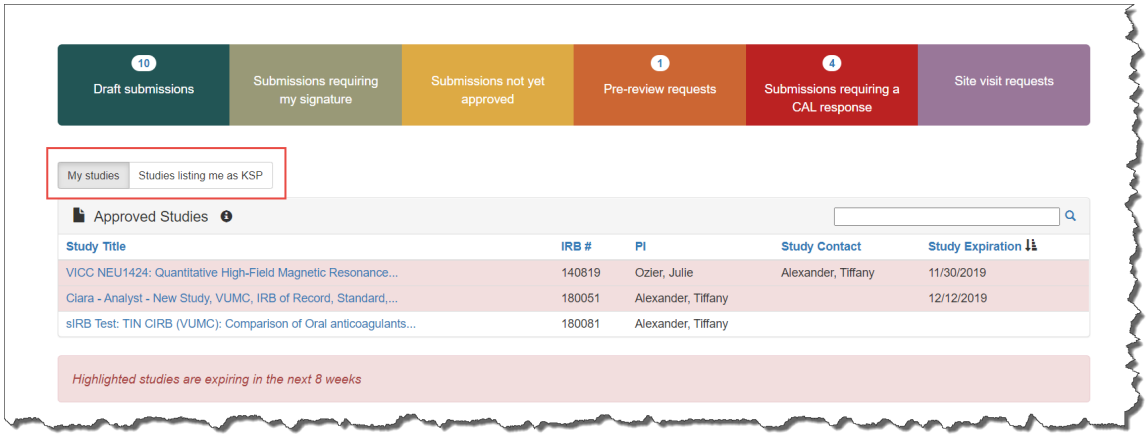
To remove a site, indicate the site in this box.



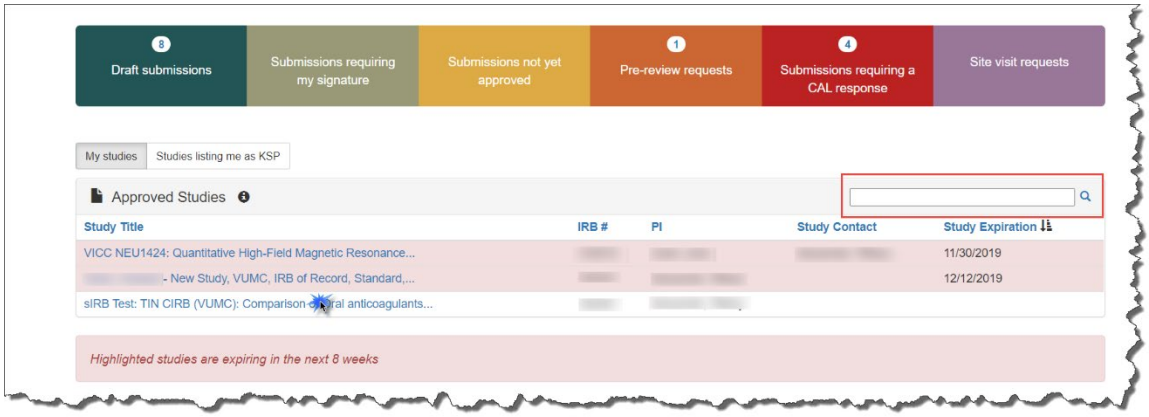
Managing Performance Sites on a Single IRB study where Vanderbilt is the IRB of Record

Once a new study is approved, the study team can manage performance sites from the study page.

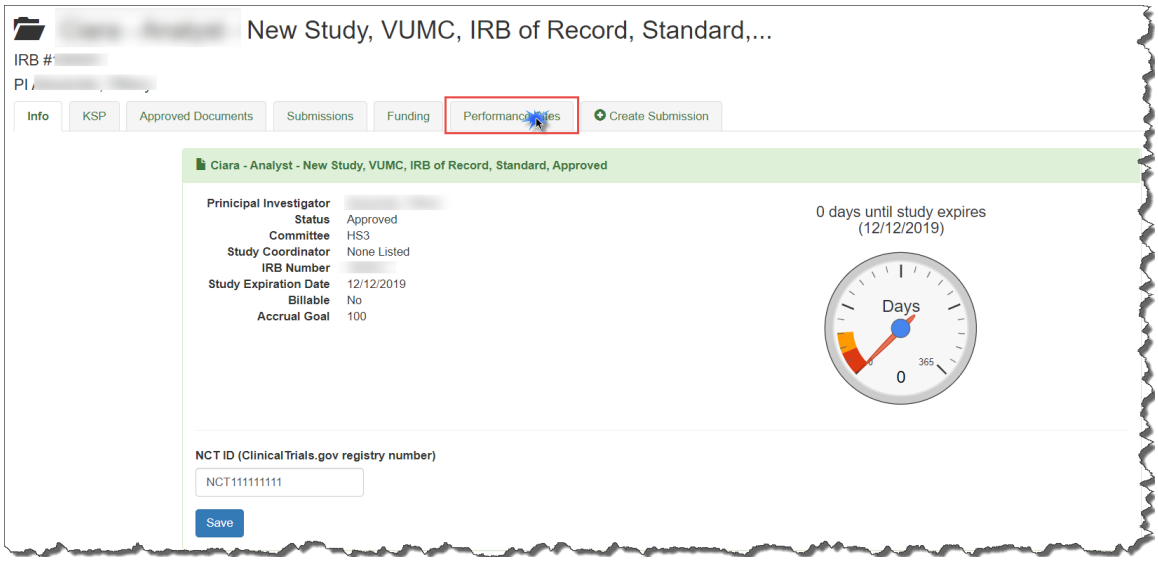
On the Dashboard, Approved Studies can be found in the list at the bottom of the screen. Approved studies for which you are the PI, Study Coordinator, or Faculty Advisor are found on the My Studies tab. This is the default view for the dashboard. Studies for which you are listed as KSP are found on the Studies listing me as KSP tab.



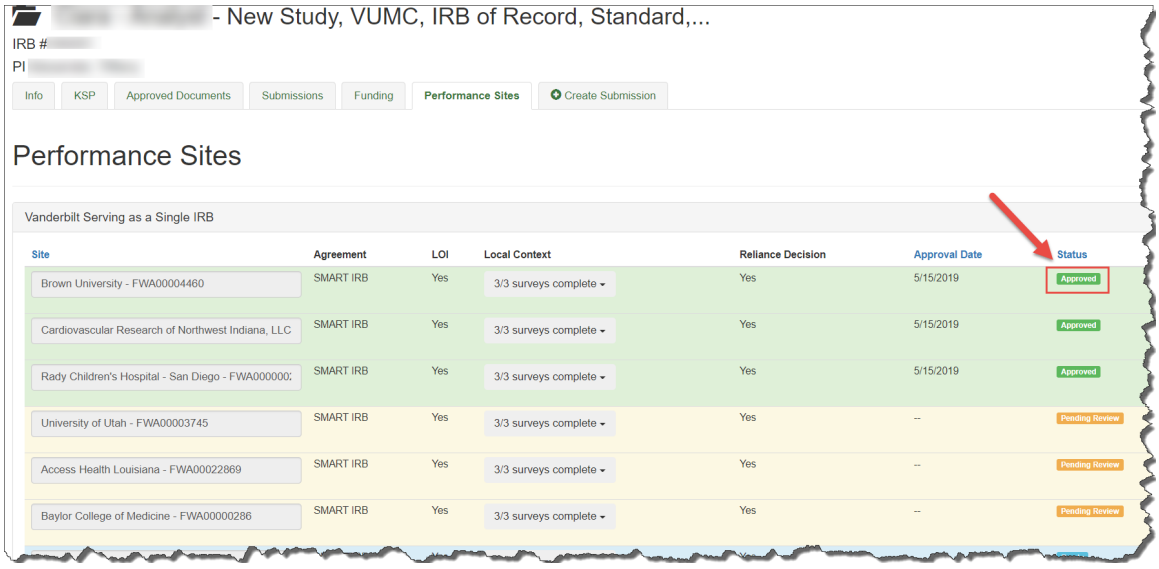
If you cannot find the appropriate study, you can use the “search” field by typing the IRB number, sponsor number, part of the title, or another relevant piece of study information. Once you have found the study, click the title to enter the study page.



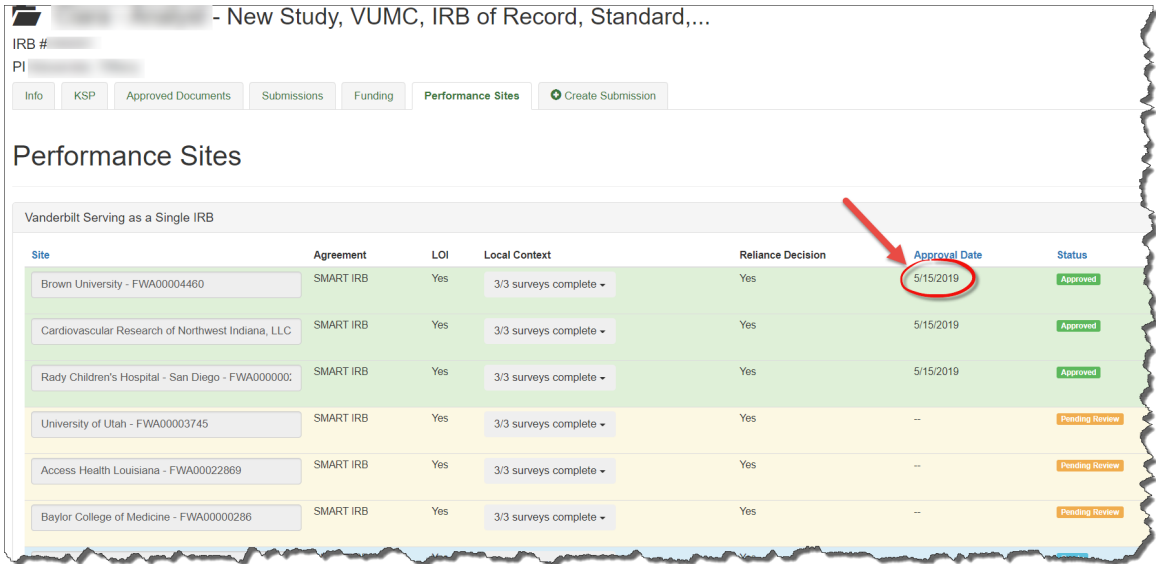
From the study page, click the *Performance Sites* tab.



On this tab, you can see the status of all sites that have been added to the study. You can also begin the process of adding sites and remove sites from this page. Studies that have been submitted with a Site Add submission and are approved will appear in and will have a status of *Approved*.

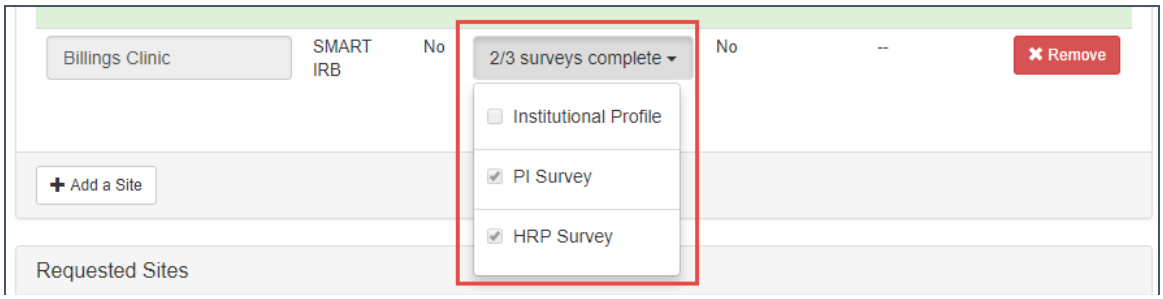

- New Study, VUMC, IRB of Record, Standard,...
IRB #
PI
Info
KSP
Approved Documents
Submissions
Funding
Performance Sites
Create Submission
Performance Sites
Vanderbilt Serving as a Single IRB
Site
Agreement
LOI
Local Context
Reliance Decision
Approval Date
Status
Brown University - FWA00004460
SMART IRB
Yes
3/3 surveys complete
Yes
5/15/2019
Approved
Cardiovascular Research of Northwest Indiana, LLC
SMART IRB
Yes
3/3 surveys complete
Yes
5/15/2019
Approved
Rady Children's Hospital - San Diego - FWA000000
SMART IRB
Yes
3/3 surveys complete
Yes
5/15/2019
Approved
University of Utah - FWA00003745
SMART IRB
Yes
3/3 surveys complete
Yes
--
Pending Review
Access Health Louisiana - FWA00022869
SMART IRB
Yes
3/3 surveys complete
Yes
--
Pending Review
Baylor College of Medicine - FWA00000286
SMART IRB
Yes
3/3 surveys complete
Yes
--
Pending Review

Approved sites will also have an approval date in the *Approval Date* column.

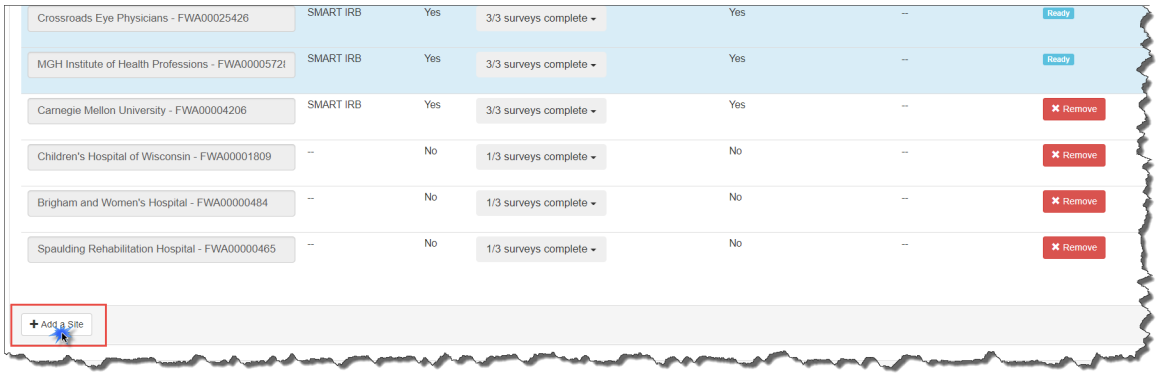


Sites that have been added to the table, and local surveys and questionnaires have not been completed in IREX, these sites can be removed by the study team by clicking the *Remove* button.

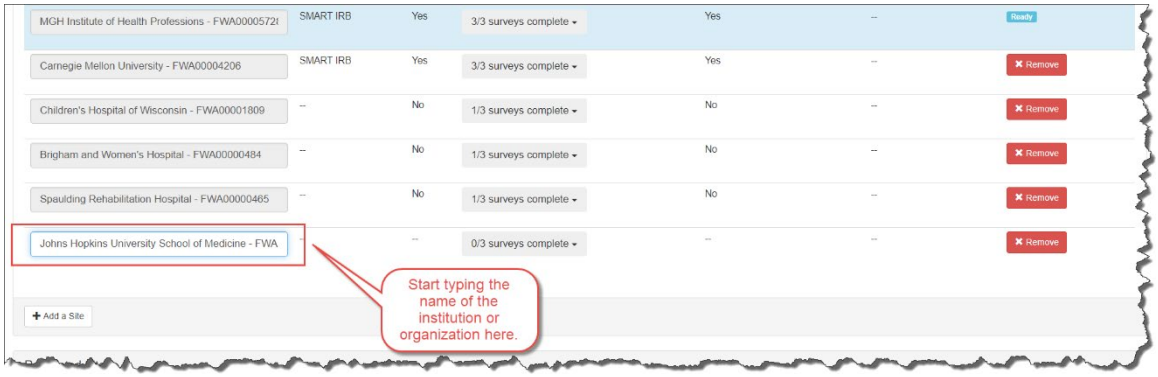
If there is an oustanding document preventing the site from being ready to be added, the *Local Context* column will indicate how many out of the 3 required surveys have been completed. Clicking on the arrow will display a drop down menu which will indicate which surveys have been completed and which have not. The surveys with a check mark next to them have been completed, and those with a blank box have not yet been completed.

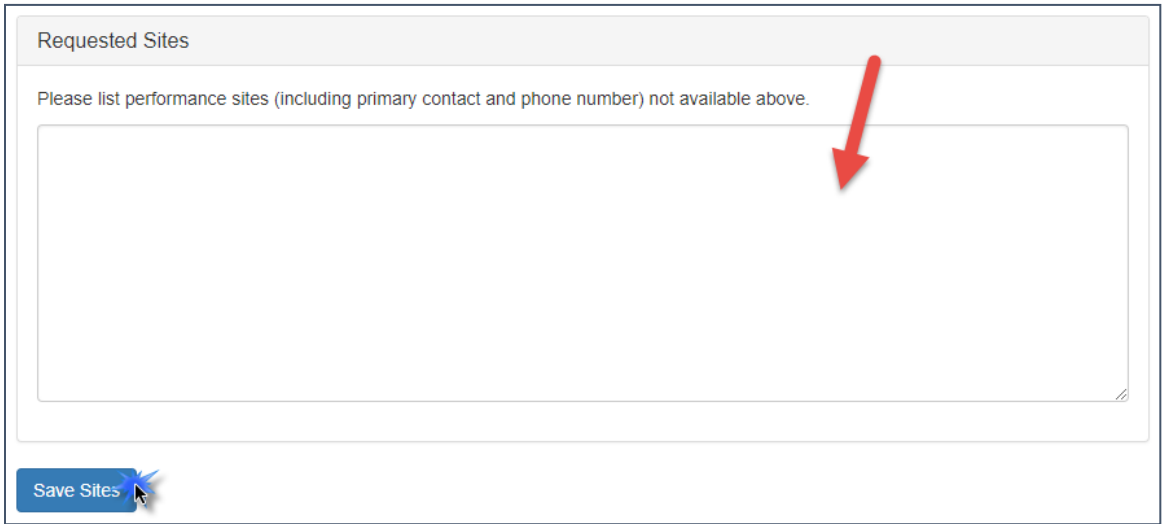


To add a new site to this table, click *Add a Site*.



You will be prompted to include the site name. If the site does not appear in the drop down list, add the site in the Requested Sites box. After entering the site name in either the Vanderbilt serving as the Single IRB table, or the Requested Sites box, click Save Sites. This will then appear for the IRB Analysts to begin gathering information for that site.

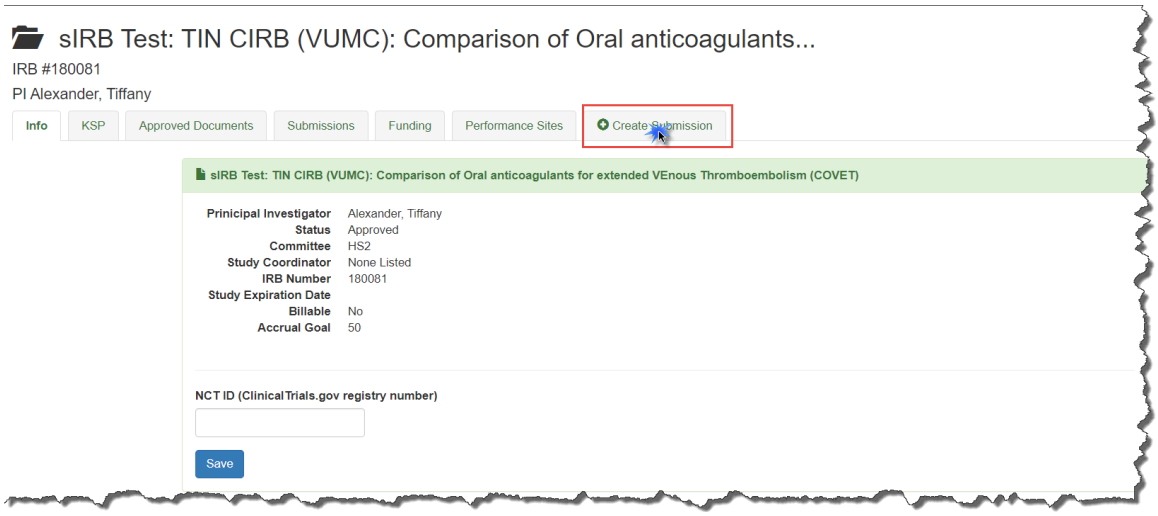




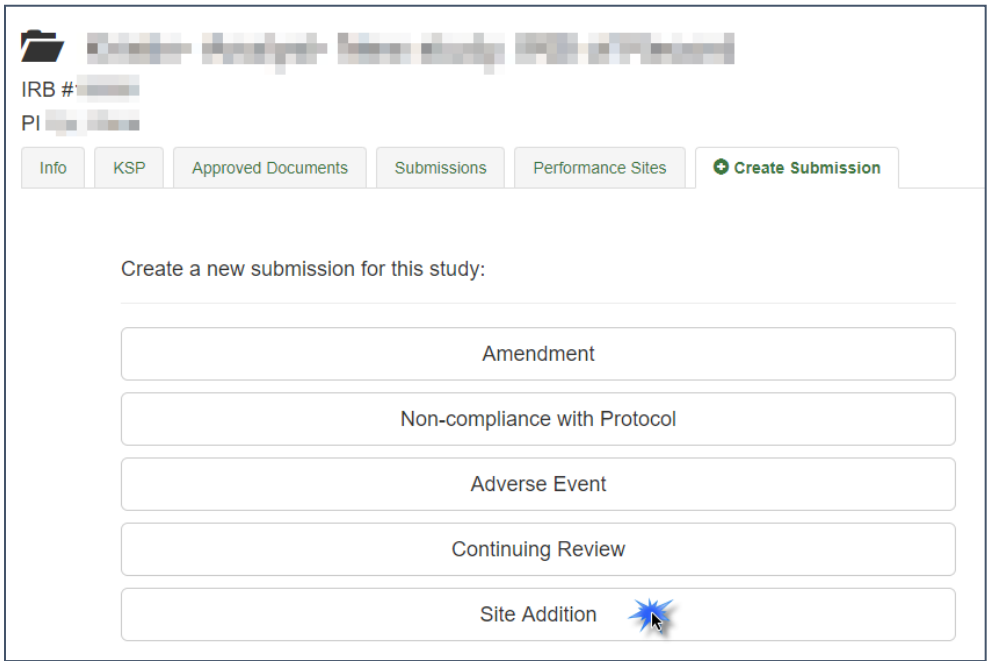
Once local surveys and questionnaires have been completed in IREX, it will appear with a status of *Ready*.

Submitting a Site Addition for Single IRB Studies

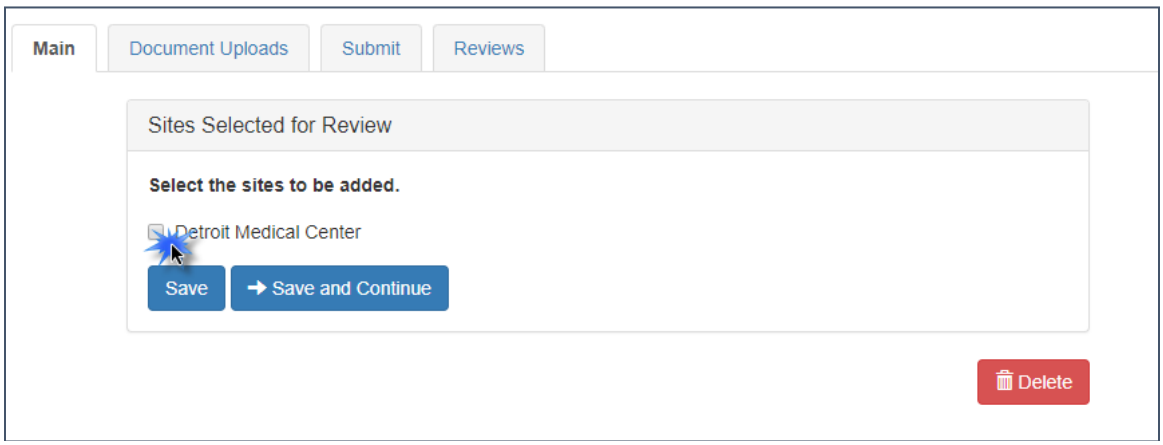
Once you have sites ready to be added as indicated on the Performance Sites table, click *Create Submission*.



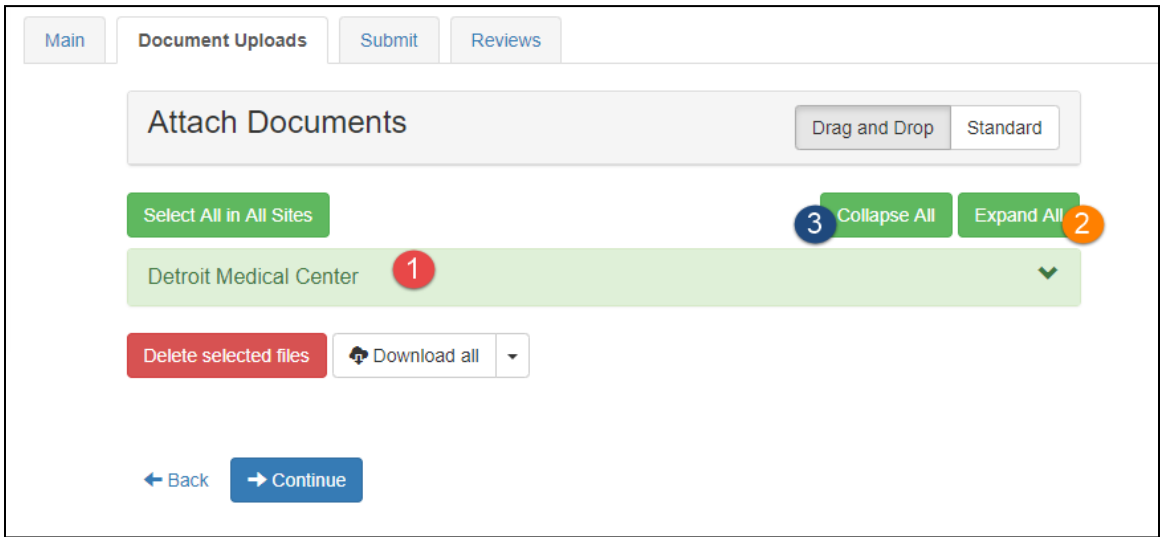
Select *Site Addition*.



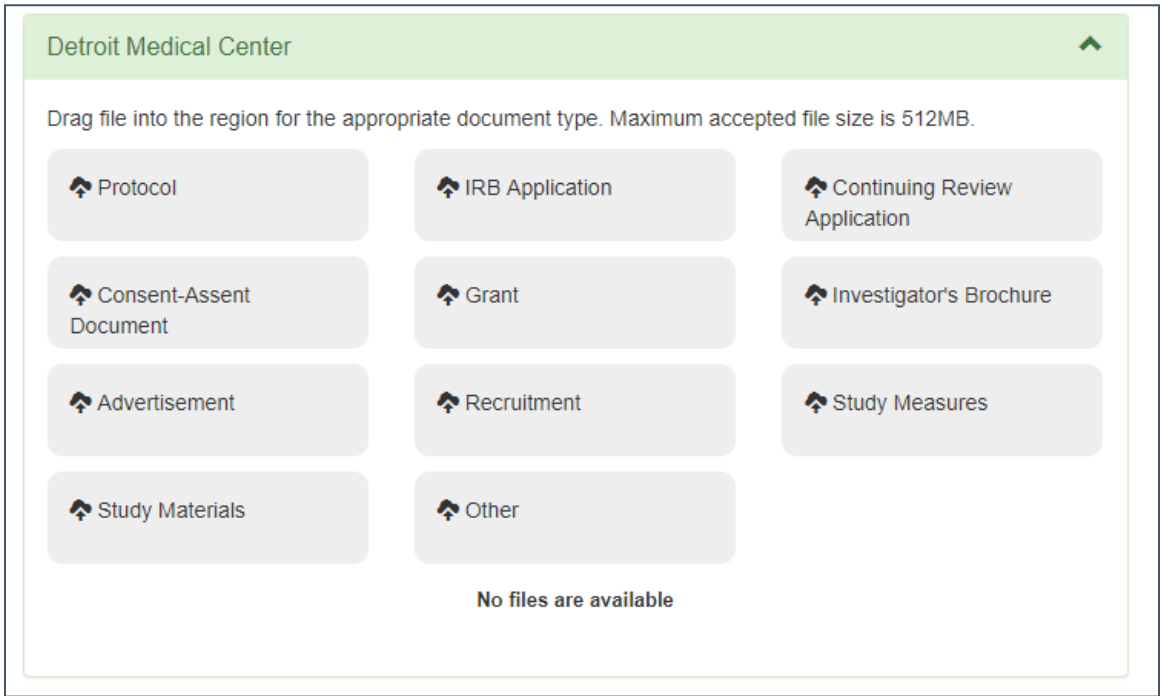
You will be prompted to select the sites to be added with this submission. Only the sites that have a status of Ready will appear in this section. Select the site(s) to be added by selecting the box next to the site name. Click save and continue when the sites have been selected to move forward to the Document Uploads tab.



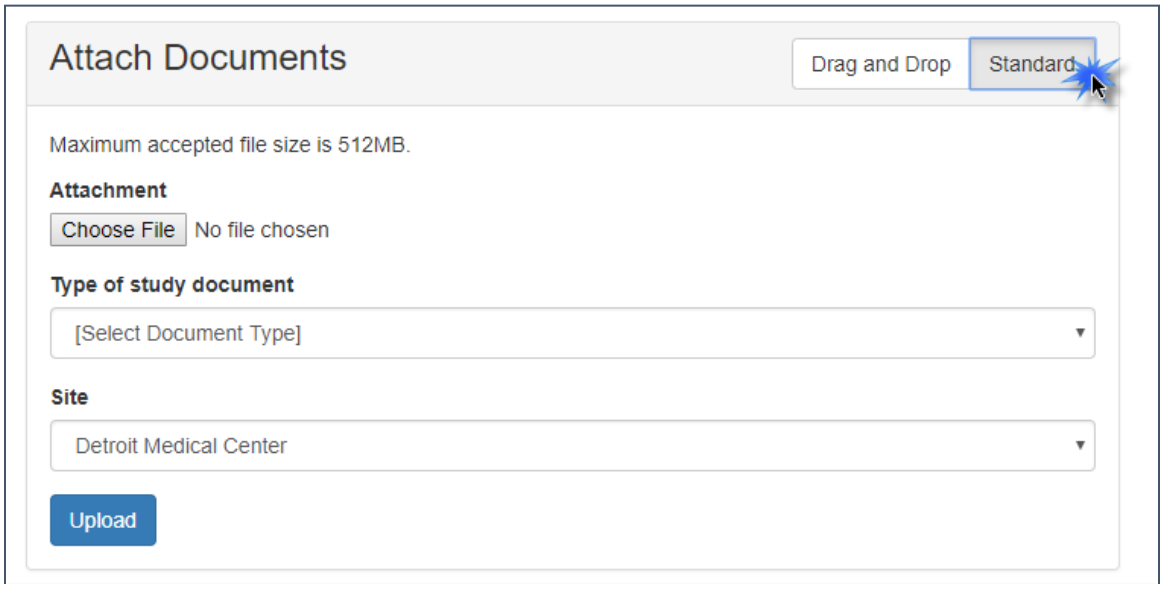
The system will create a section for documents to be uploaded for each site. In the Document Uploads tab you can *1) expand or collapse each site section individually by clicking on the bar with the site name in it, 2) expand all sections by clicking Expand All, and 3) collapse all sections by clicking Collapse all*.



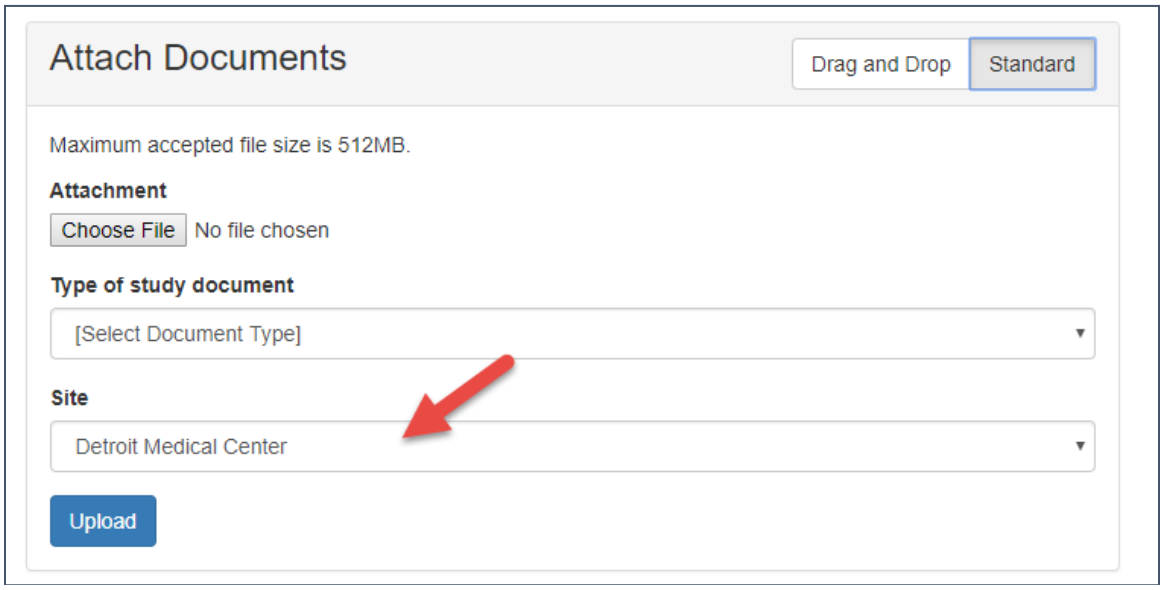
Once a site is expanded, it will have its own drag and drop section to attach documents.



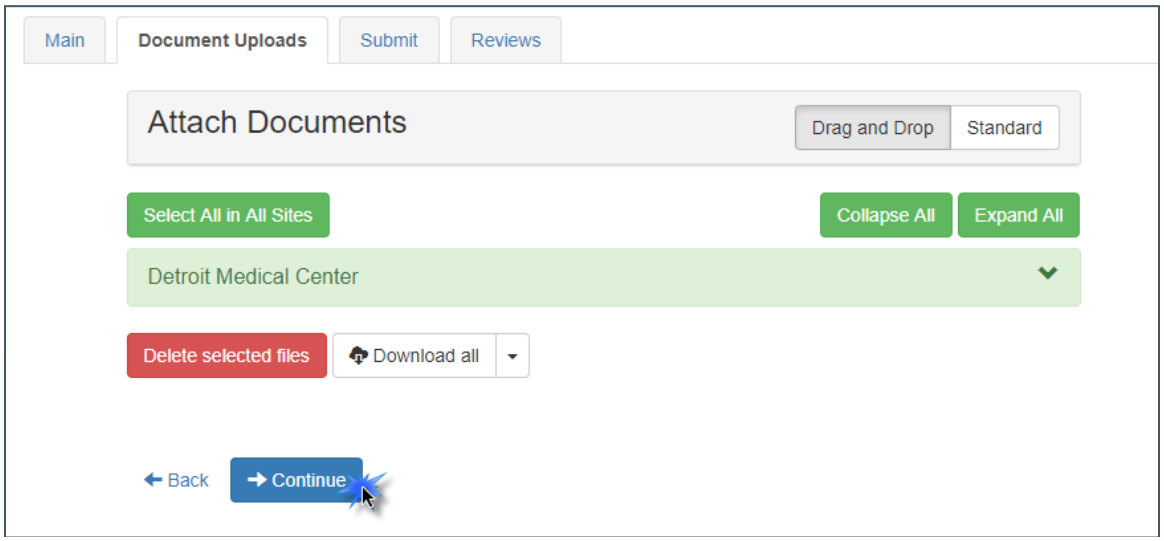
To use the standard document uploads feature, click *Standard*.



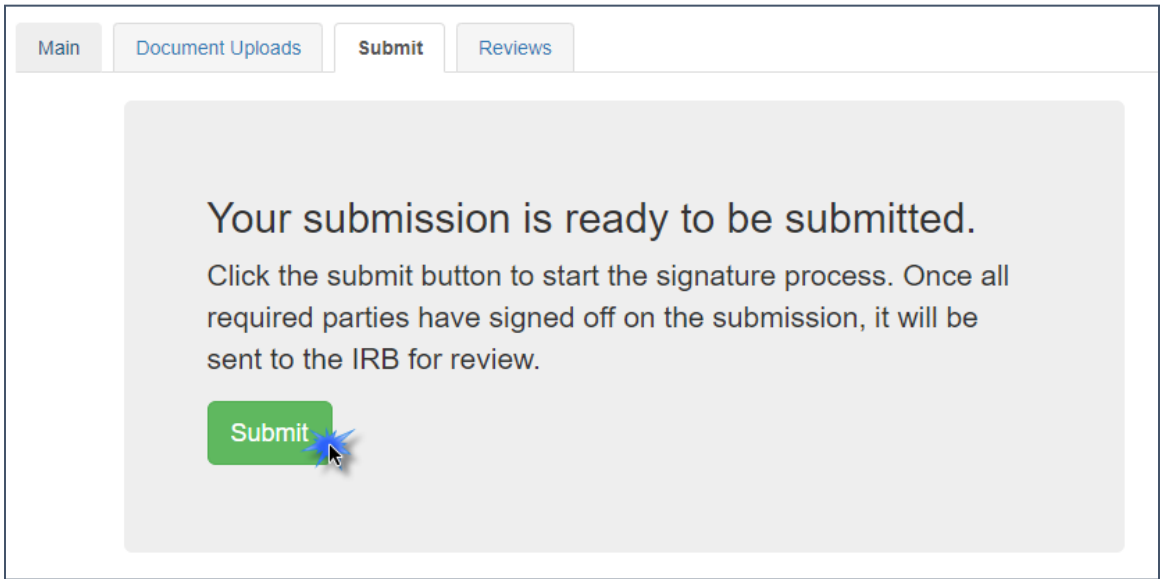
Each site will appear in the Site drop down menu. Select the appropriate site for the document you are uploading.



Once all documents are attached, click *Continue* to move forward to the Submit tab.

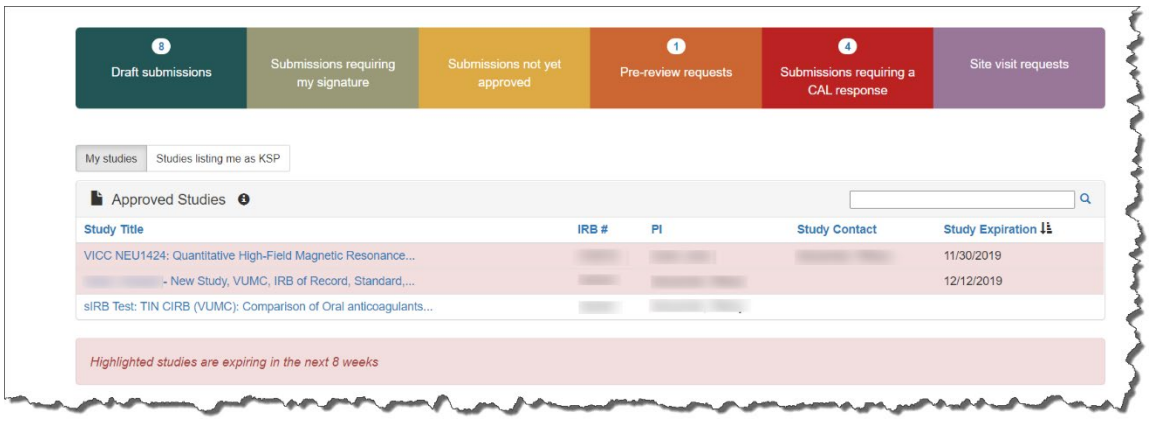


After clicking submit, the Site Addition submission will be ready for signature and routing to the IRB.

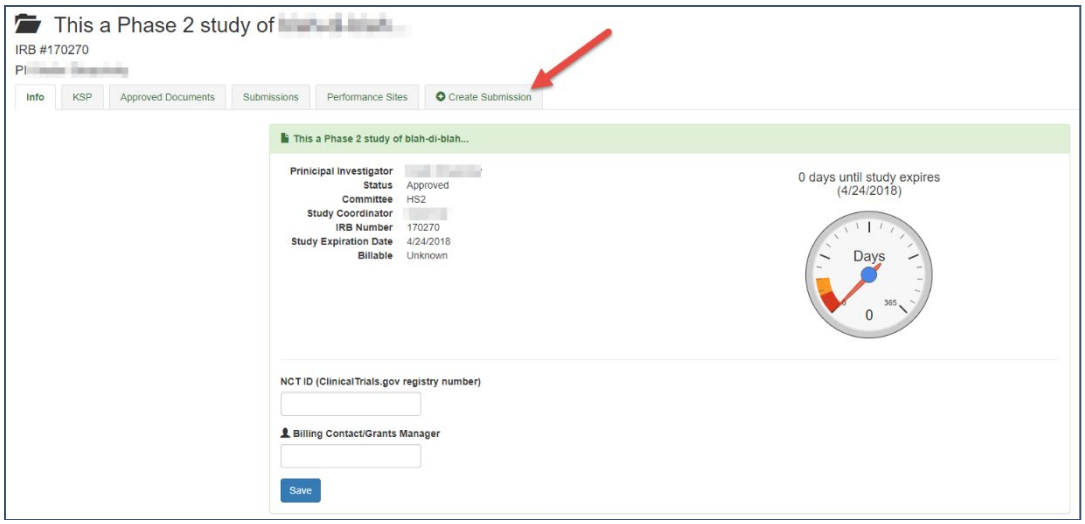


Submitting a Continuing Review

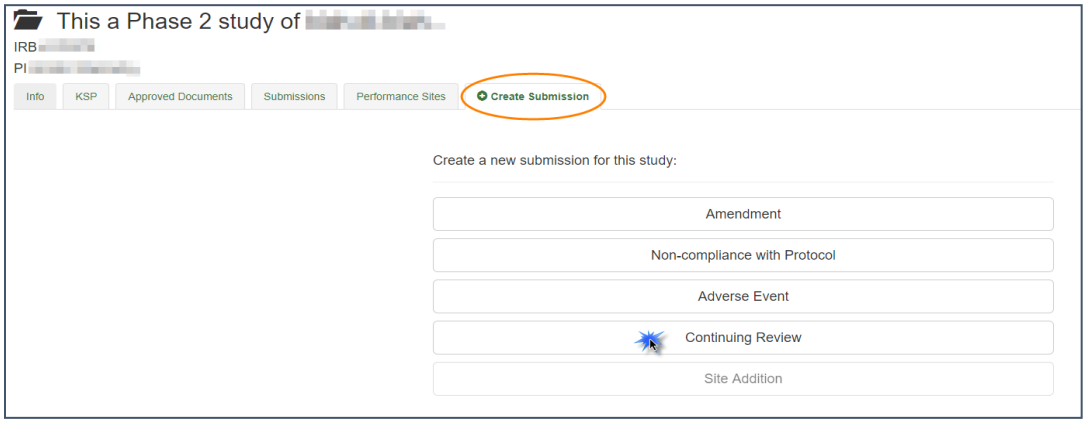
Submit a *Continuing Review* for continuing studies or to close a study with the IRB. To start a continuing review submission, access your approved studies and select the appropriate study. Note that any studies with approval expiring in the next 8 weeks will be highlighted red.



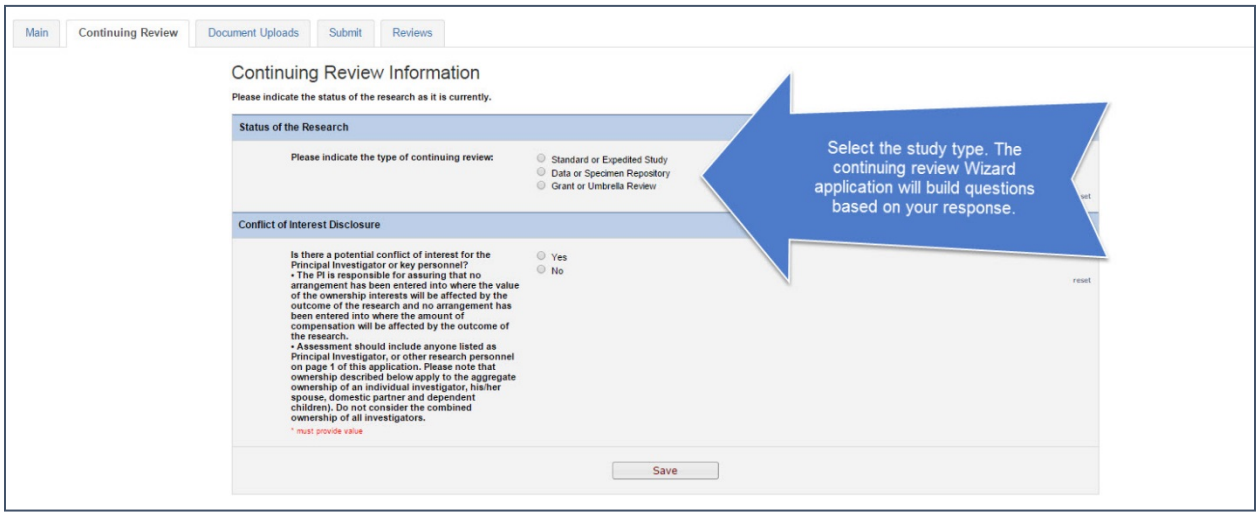
From the study page, click *Create Submission*.



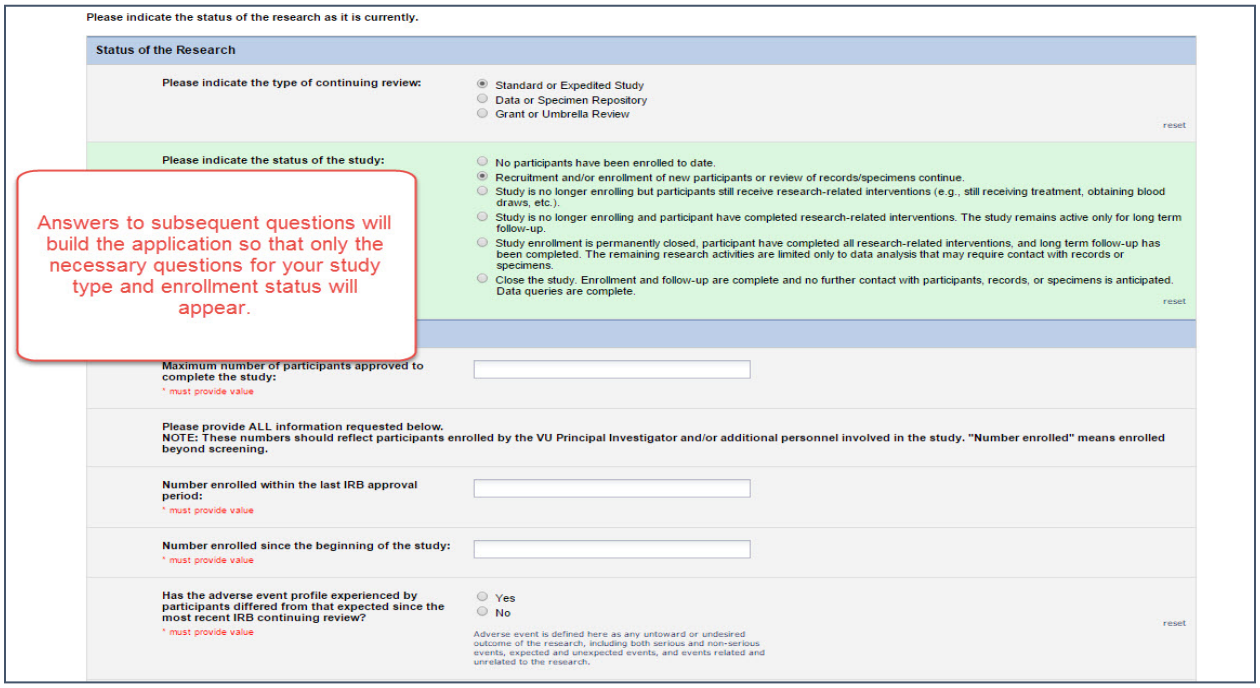
On the *Create Submission* tab, select to create a Continuing Review.



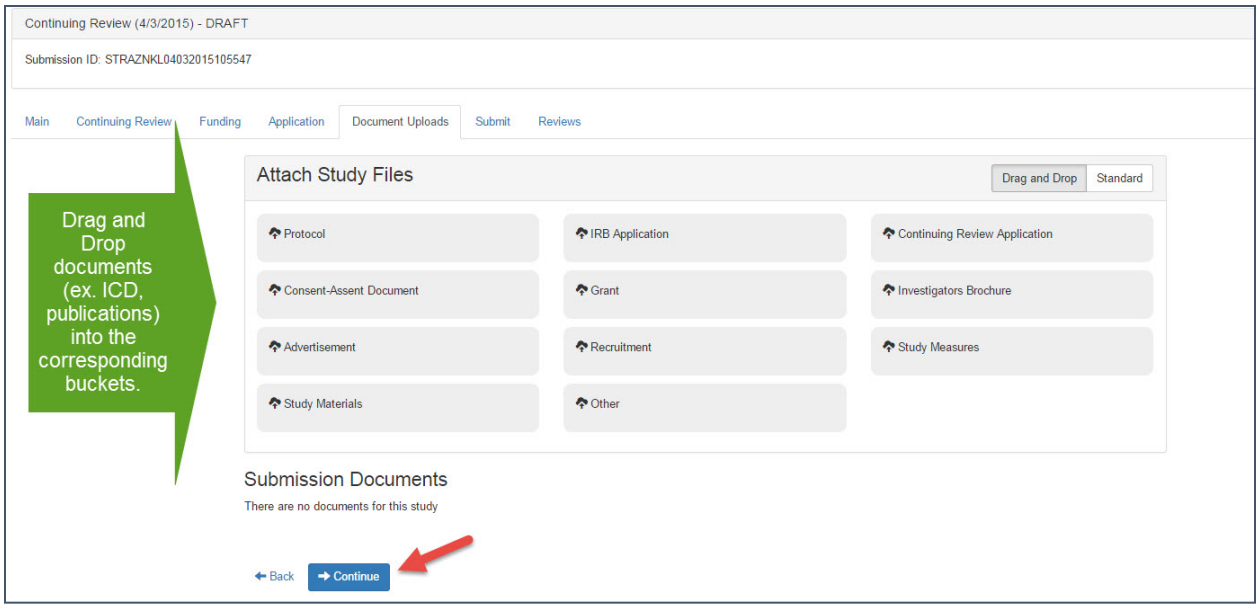
Select the *Continuing Review* tab to complete the Continuing Review wizard application. In the first item, select the study type. The corresponding continuing review application will begin to build based on this item.



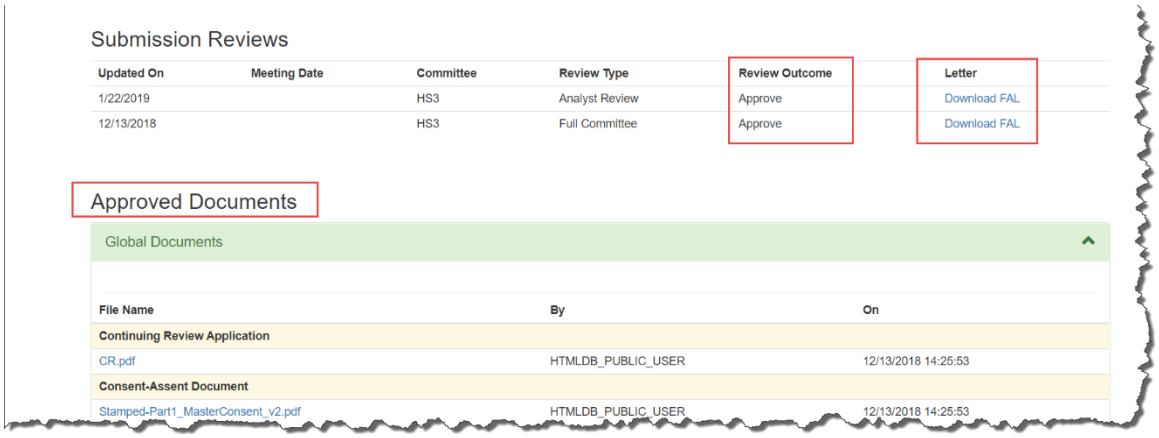
The Continuing Review application for Standard/Expedited studies and repositories will ask for the current status of the research. Additional questions will appear based on this information. Provide an answer to each question and save your answers. Incomplete submissions can be saved and returned to later. These submissions can be accessed via the Drafts Submission button on your dashboard. The system will not allow an incomplete submission to be submitted or routed for signature.



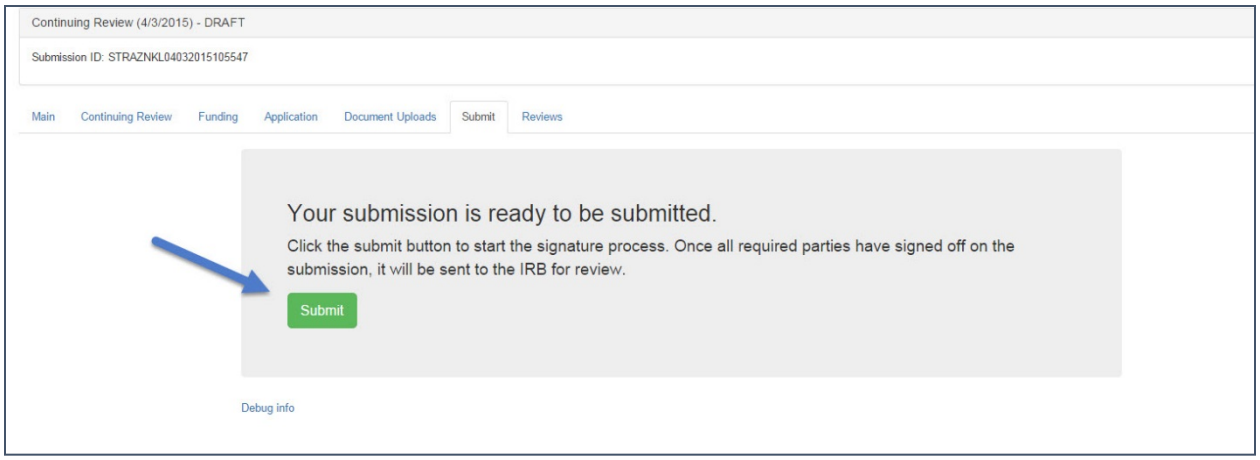
Attach any necessary documents (i.e. Consent forms, Progress reports) for the continuing review in the *Document Uploads* tab. Submit both a stamped and clean copy of all consent documents for review and approval.



The *Reviews* tab allow you to review the currently approved study information. This view will show currently approved documents as well as the Review Outcome and also has a letter download component for easy access to letters from the IRB. To make changes to this information, please see the Amendment submission section of this manual.



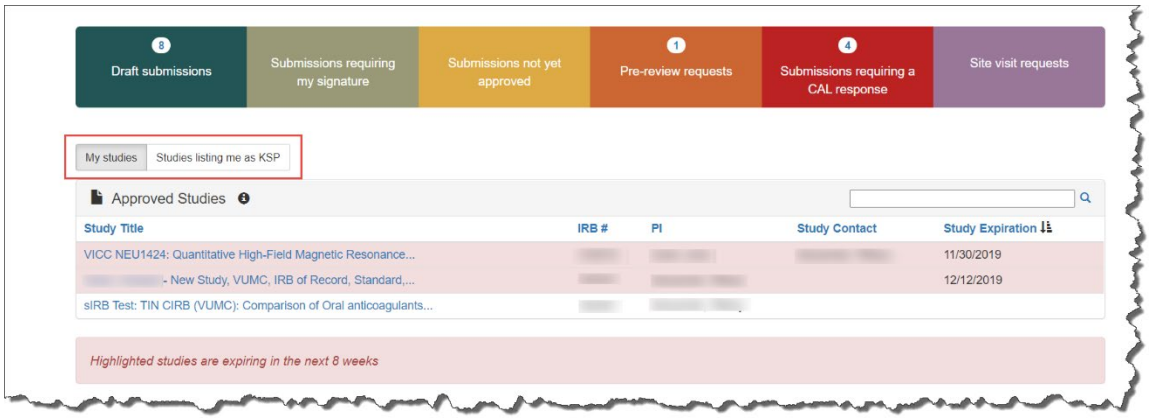
Review all tabs for completeness and submit the continuing review in the *Submit* tab. The submission will now route for signature before being sent to the IRB for review.



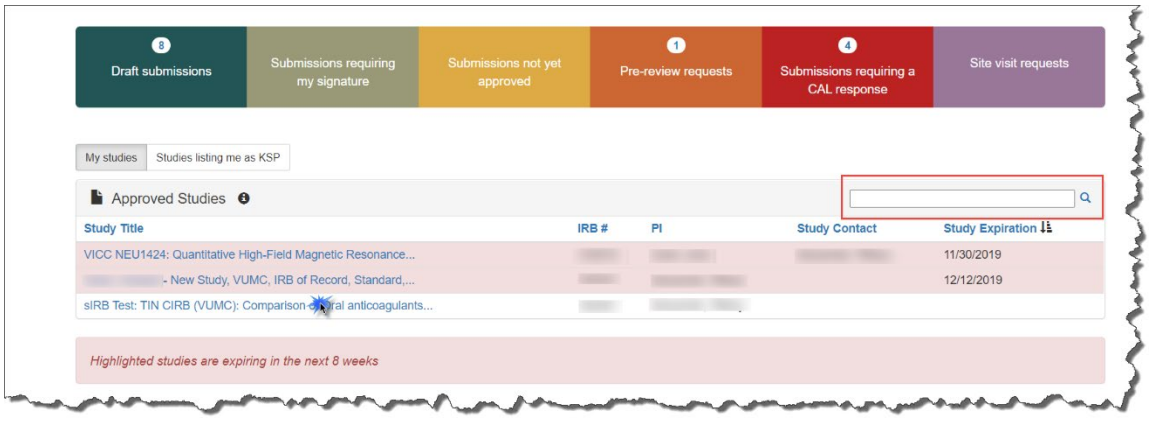
The Continuing review has now been routed for signature. The IRB will receive the submission after the Principal Investigator signs the submission. Submissions that are awaiting signature *Submissions in route* can be located in the submissions drop down menu at the top the screen.

Submitting an Adverse Event

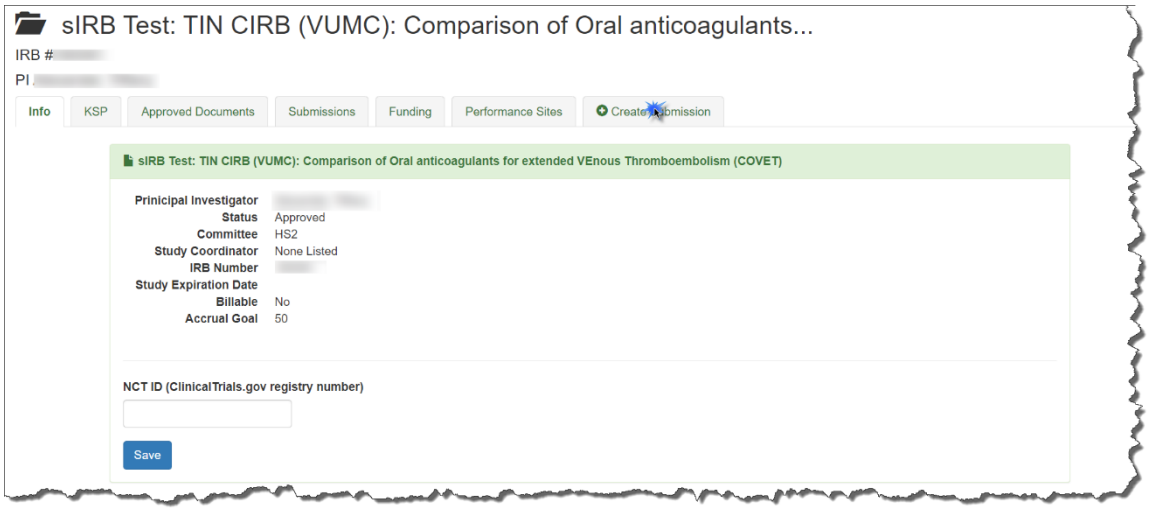
On the Dashboard, Approved Studies can be found in the list at the bottom of the screen. Approved studies for which you are the PI, Study Coordinator, or Faculty Advisor are found on the My Studies tab. This is the default view for the dashboard. Studies for which you are listed as KSP are found on the Studies listing me as KSP tab.



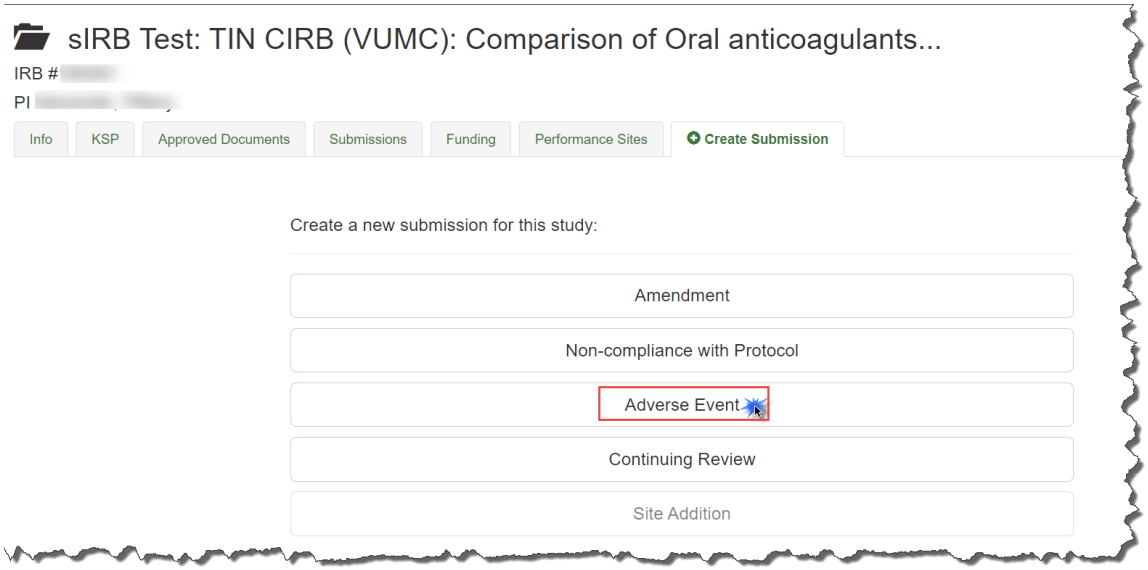
If you see the study that the adverse event is related to, click the study title to go to the study page. If you do not see the appropriate study, you can use the "search" field by typing the IRB number, sponsor number, part of the title, or another relevant piece of study information.



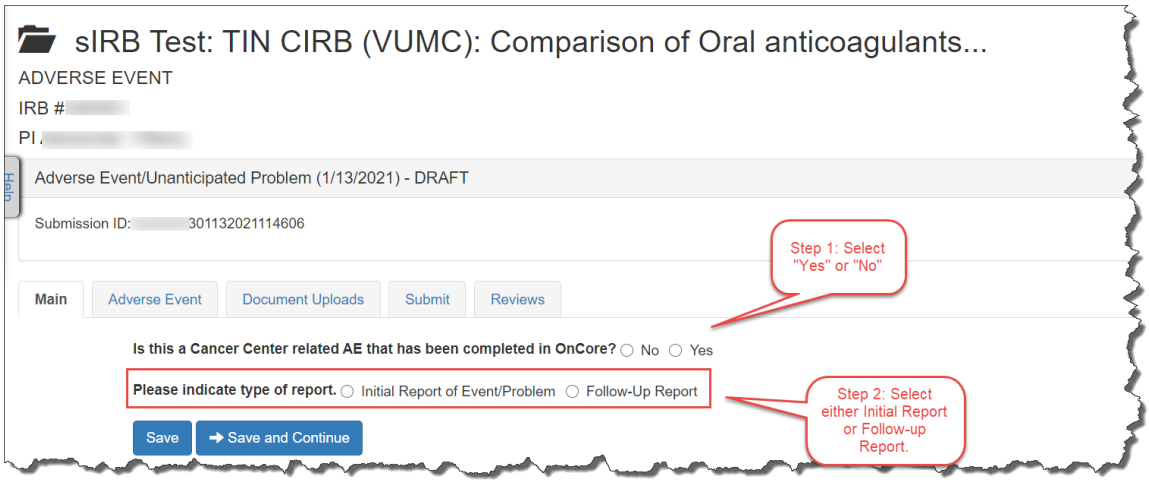
From the study page, click *Create Submission*.



Click *Adverse Event*. Clicking this button will create the Adverse Event submission.



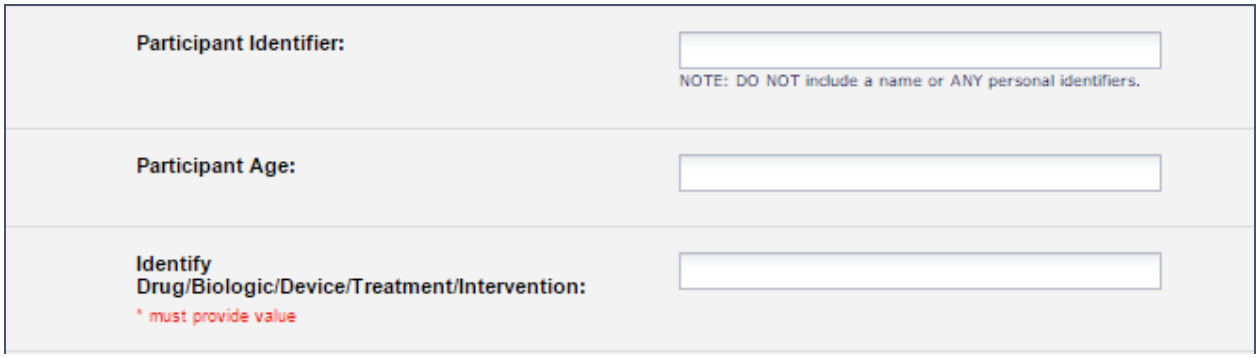
Complete the first form and click Save and Continue. This will move you to the Adverse Event tab. Click Save will save your information but will keep you on the Main tab.



On the Adverse Event tab, you will complete additional Adverse Event questions. Required items are marked with * must provide value. Please complete all of the requested items on the form. The Wizard system will not allow incomplete forms to be submitted.

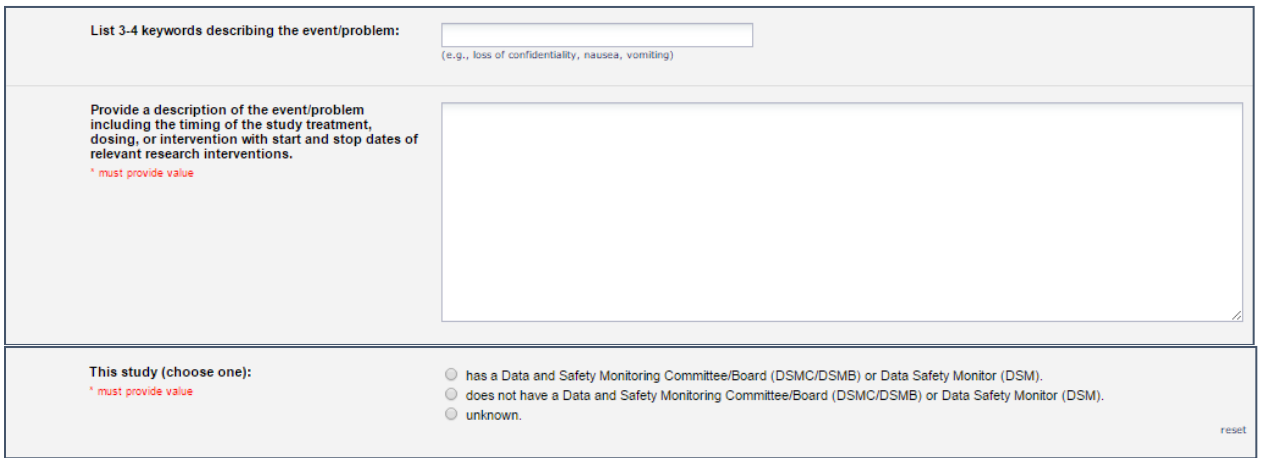
The following types of events are required to be reported to the IRB. If the event does not fit the categories shown, the event is not reportable to the IRB. However, the event may need to be reported to the sponsor. If you have any questions, please call the IRB (615-322-2918) of check with your sponsor.

In this section, please indicate the Participant ID# or initials. *Please do not include a name or any other personal identifiers.*

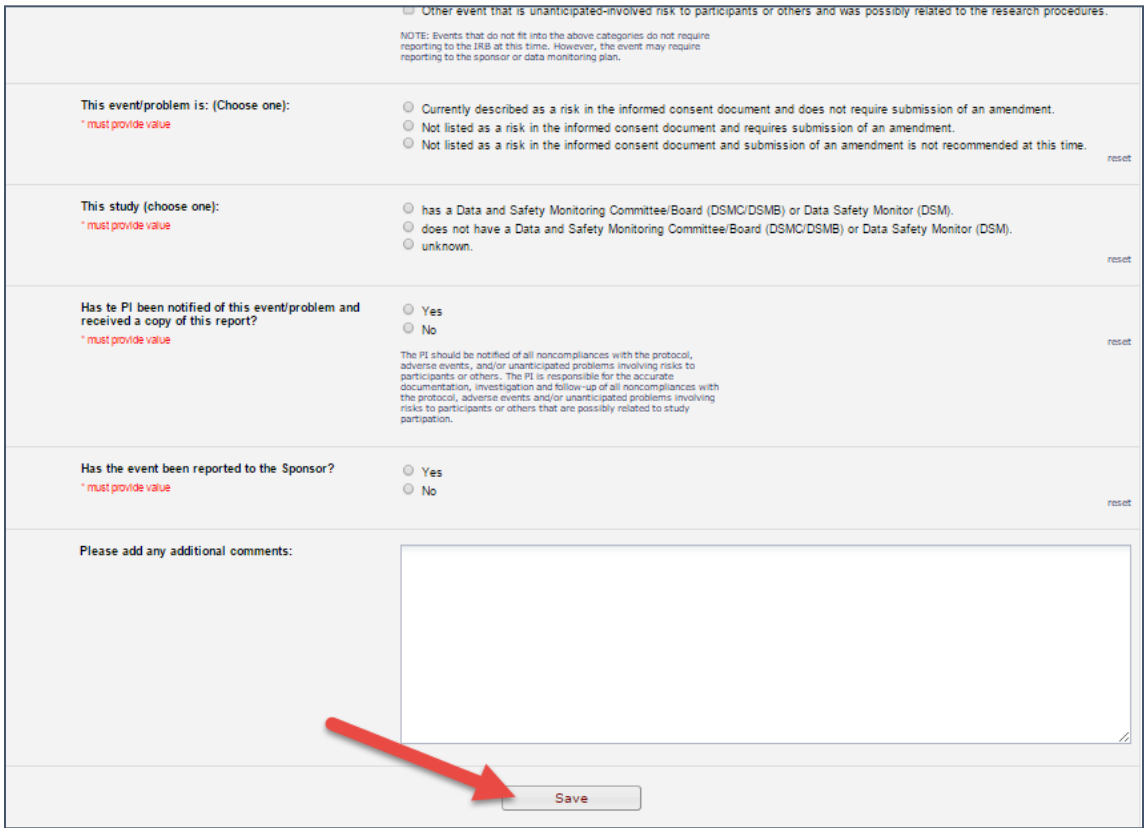


Provide a detailed description of the event/problem including the timing of study treatment, dosing, or intervention. Also remember to include start and stop dates of relevant research interventions.

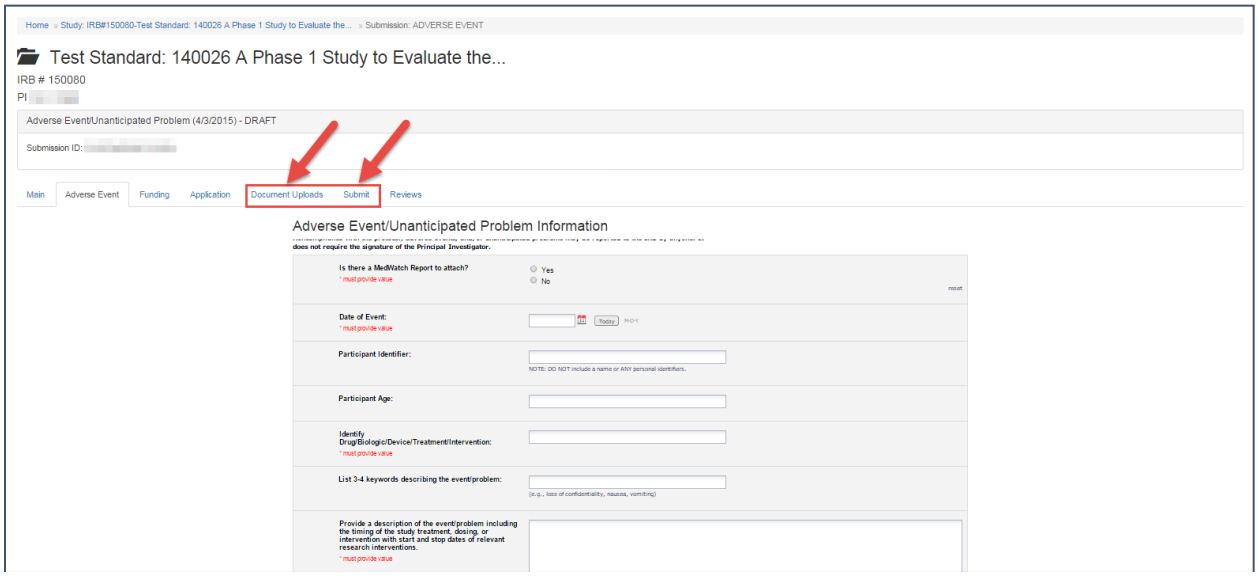
Indicate the timing of the event/problem in relation to the research intervention.
For example, 1) Research drug was started at 10:00; 2) Participant began wheezing at 10:15; 3) Drug stopped at 10:16; 4) Participant continued to have labored breathing and was treated with inhalers. 5) Respirations relaxed; 6) Breathing sounds clear by 11:00 and participant denied further complaints with breathing. 7) The sponsor was notified of the event/problem and the participant was withdrawn from further participation in the study.



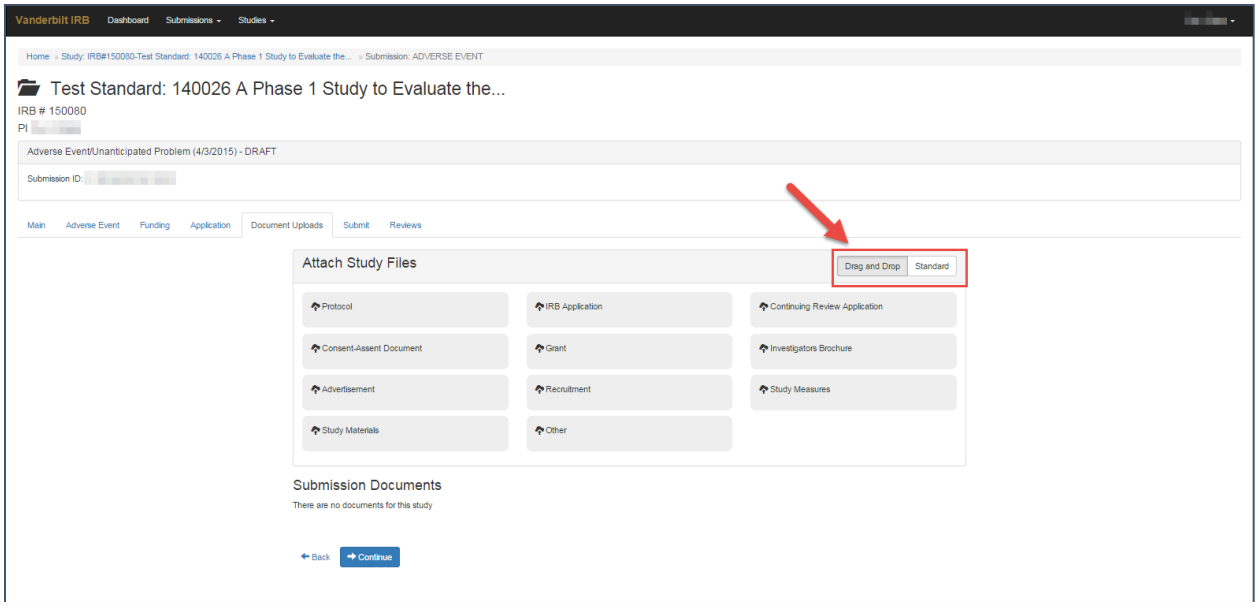
Once all required questions are complete, click the *Save* button at the bottom of the page.



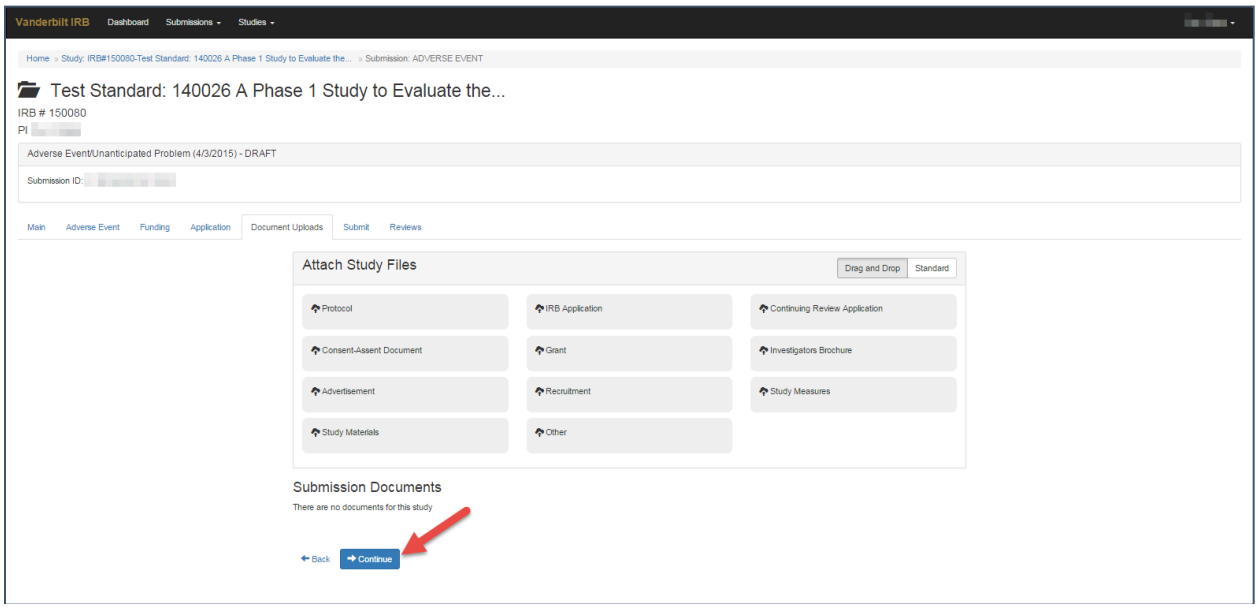
After saving, if you need to submit additional documents, click the *Document Uploads* tab at the top of the page. If no other documents need to be submitted, click the *Submit* tab.



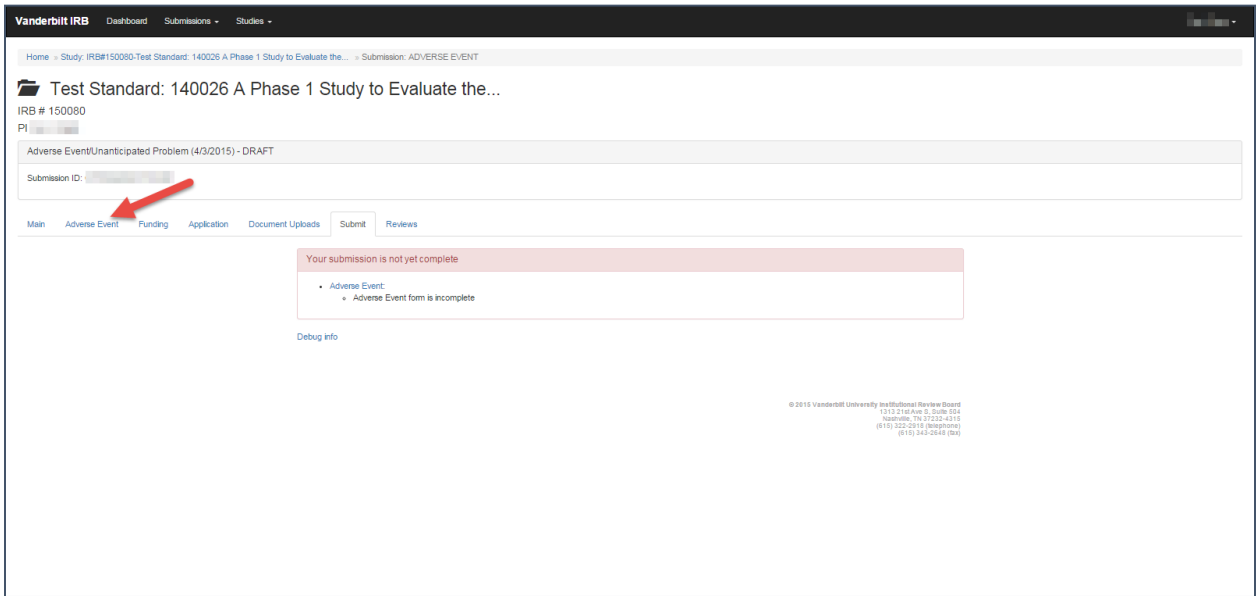
On the Document Uploads tab, documents can be submitted with either the Drag and Drop option, or the Standard option.



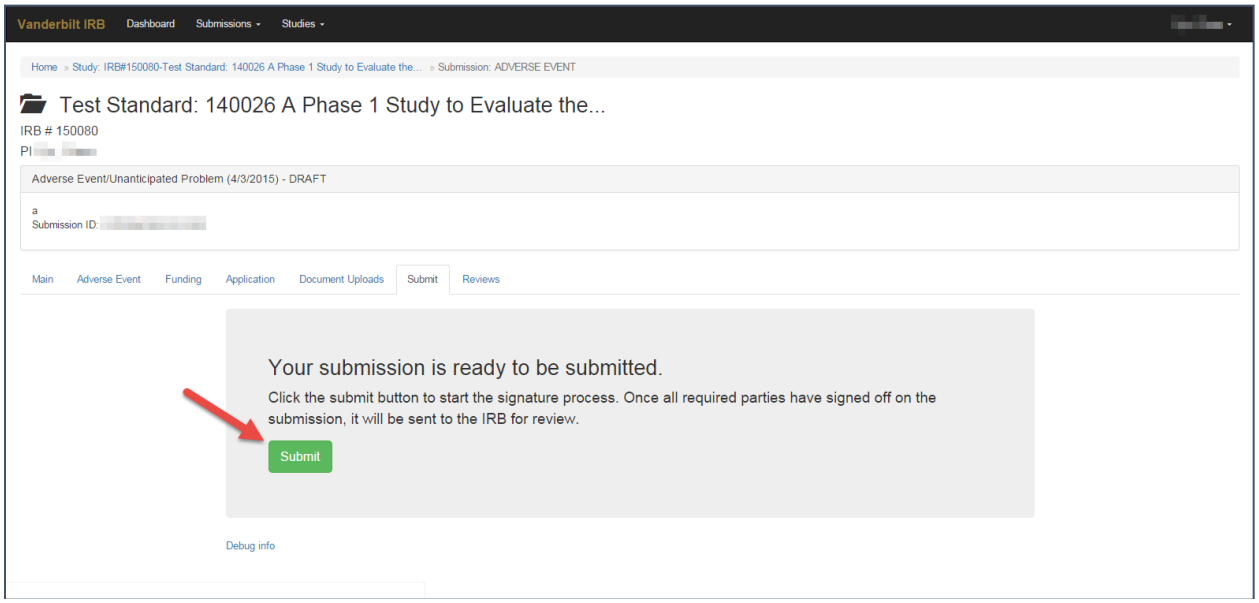
When all documents have been uploaded, click the *Continue* button at the bottom of the page. This button will bring you to the Submit tab.



If the Adverse Event form is not complete, you will see this error message on the Submit tab. Click the Adverse Event tab to complete the missing information, click save, and then click the Submit tab again.



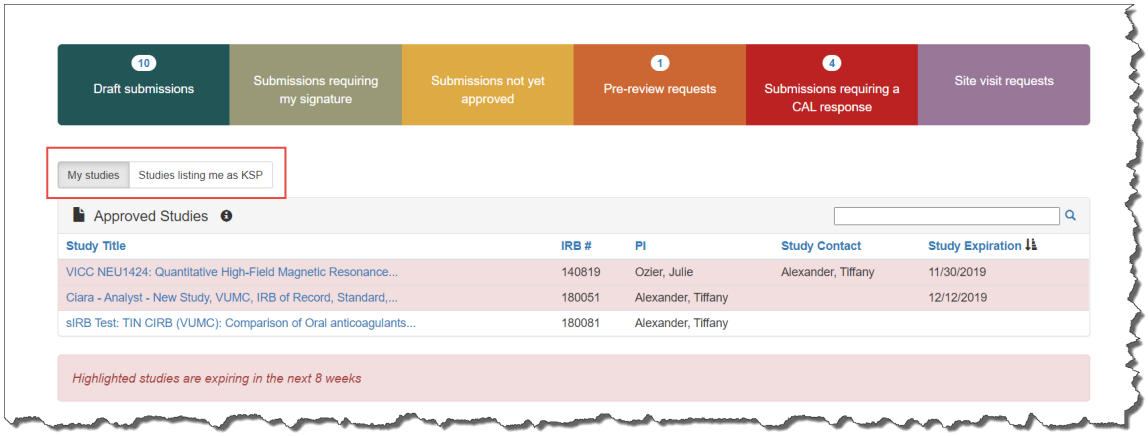
Once the required information is complete, you will be able to click the *Submit* button on the Submit tab.



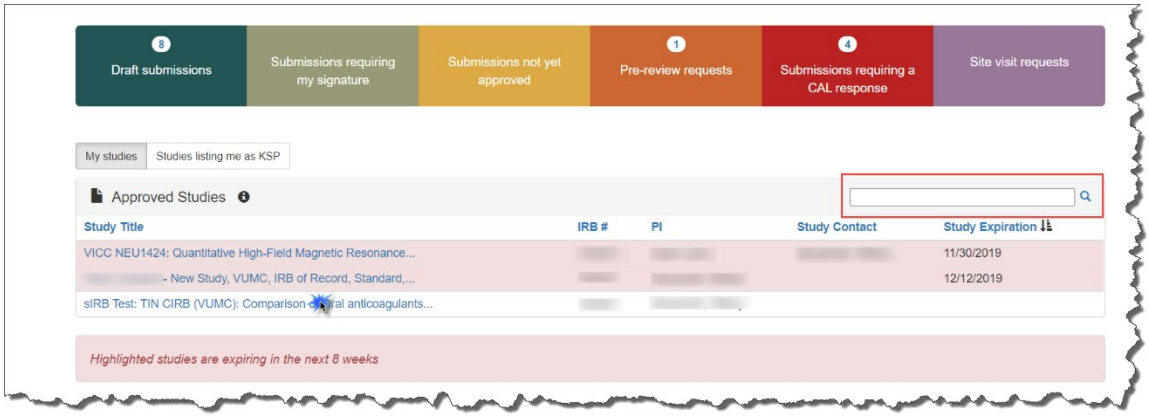
After a signature from the PI, the submission is automatically routed through the Wizard and ultimately ends its journey at the IRB where it will be sent to a team to start the review process.

Submitting a Non-Compliance with the Protocol

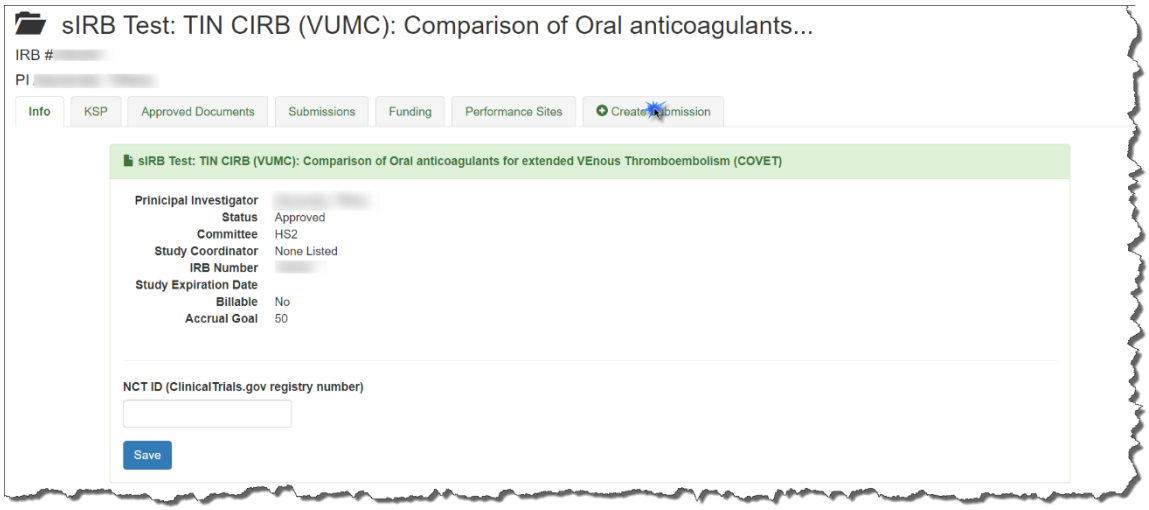
On the Dashboard, Approved Studies can be found in the list at the bottom of the screen. Approved studies for which you are the PI, Study Coordinator, or Faculty Advisor are found on the My Studies tab. This is the default view for the dashboard. Studies for which you are listed as KSP are found on the Studies listing me as KSP tab.



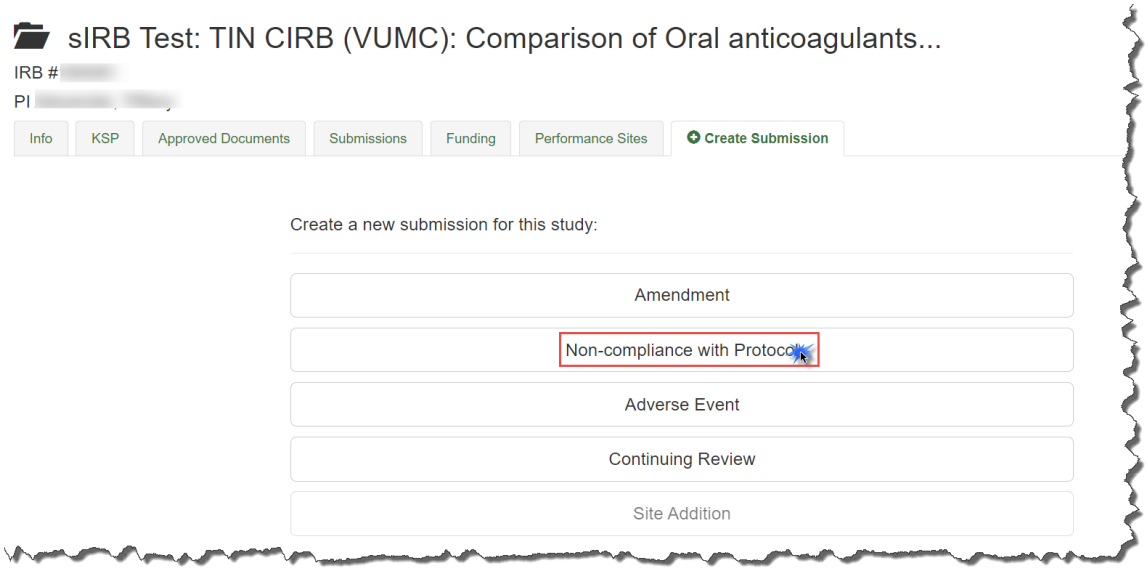
If you see the study that the non-compliance with the protocol is related to, click the study title to go to the study page. If you cannot find the appropriate study, you can use the *search* field by typing the IRB number, sponsor number, part of the title, or another relevant piece of study information.



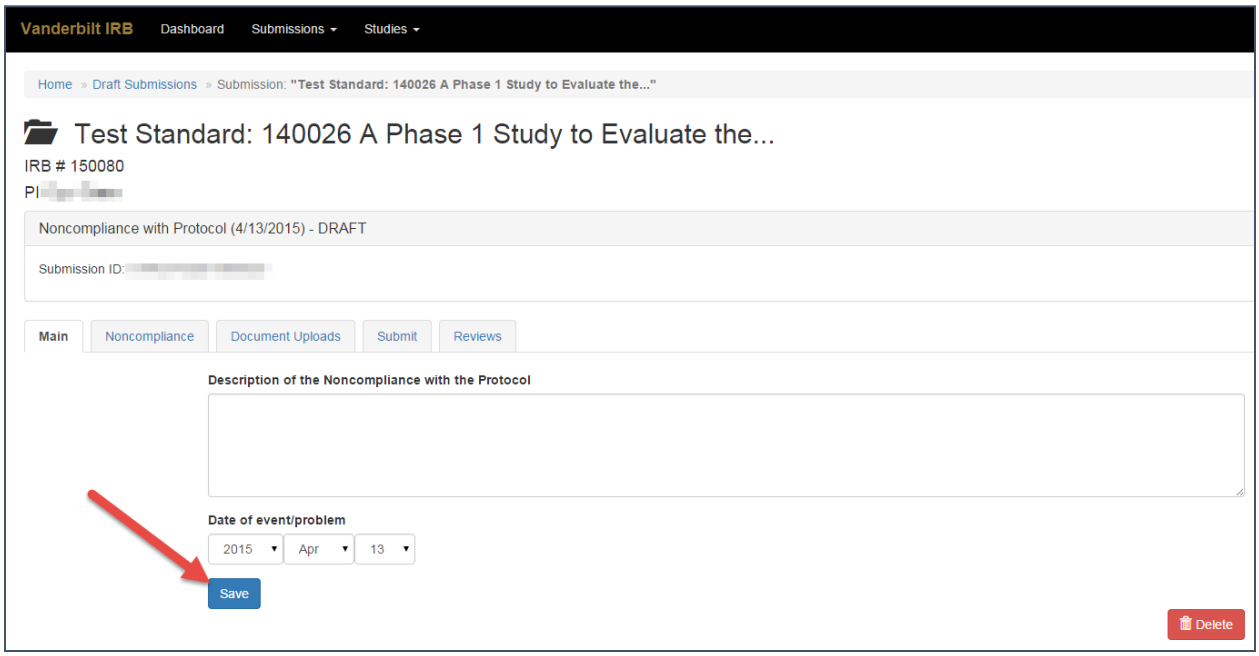
From the study page, click *Create Submission*.



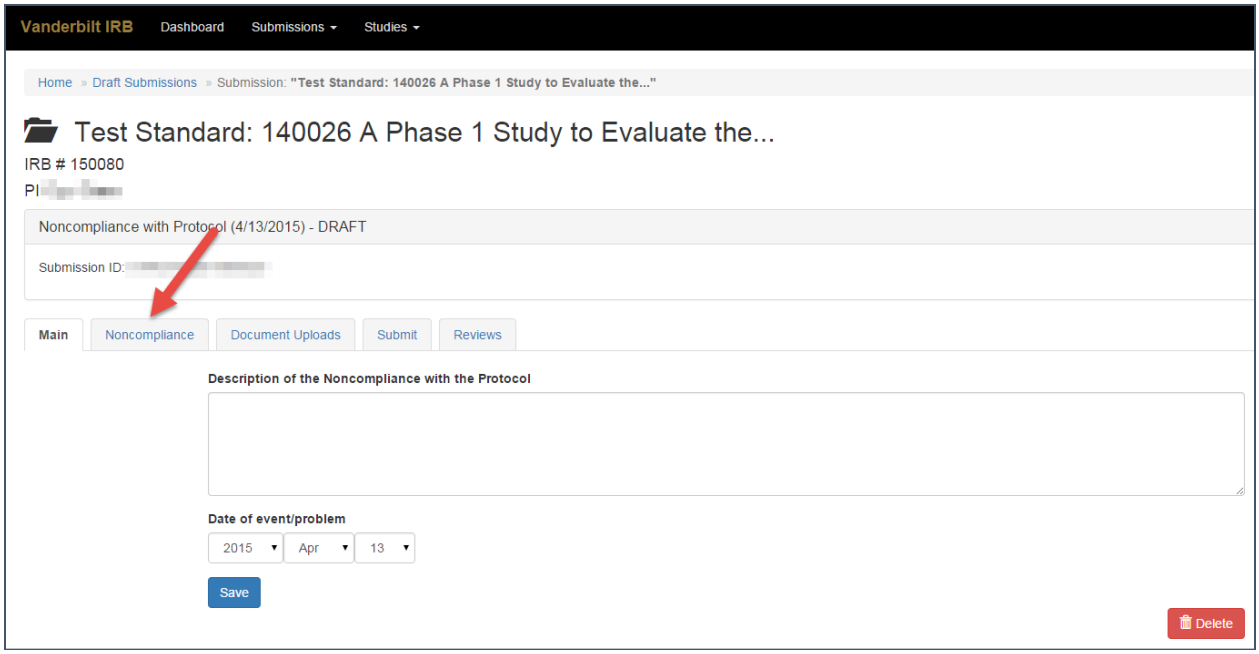
Click *Non-compliance with Protocol*. This will create the non-compliance with the protocol submission.



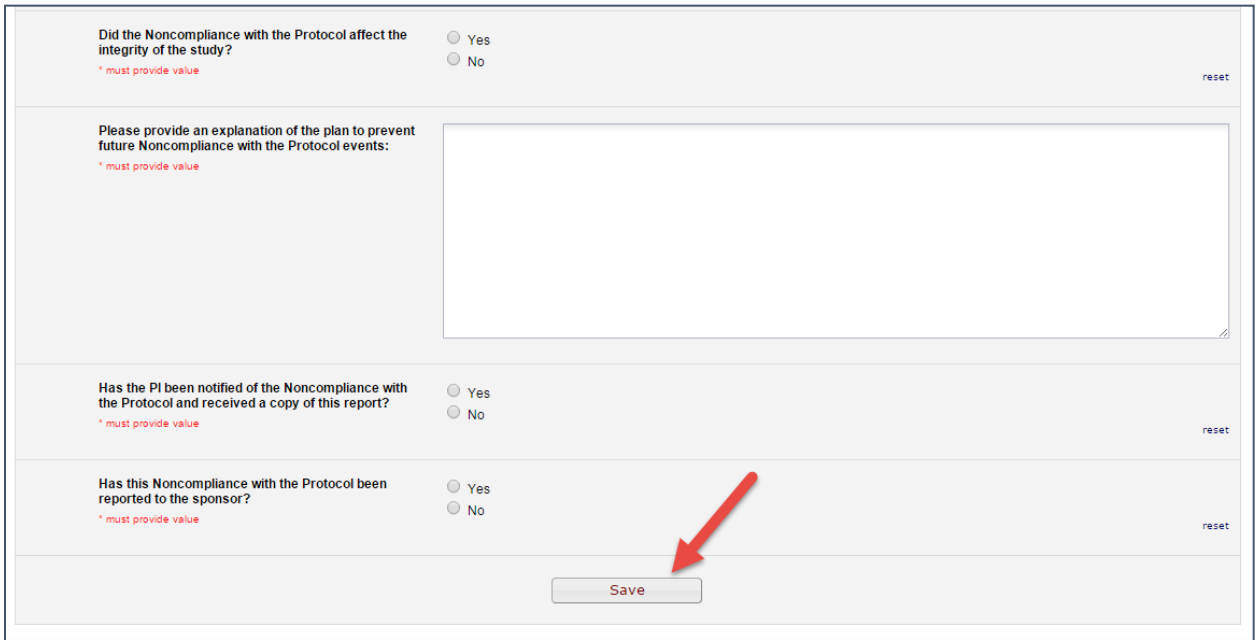
Enter the description of the Non-compliance and the date of the event or problem. Click *Save*.



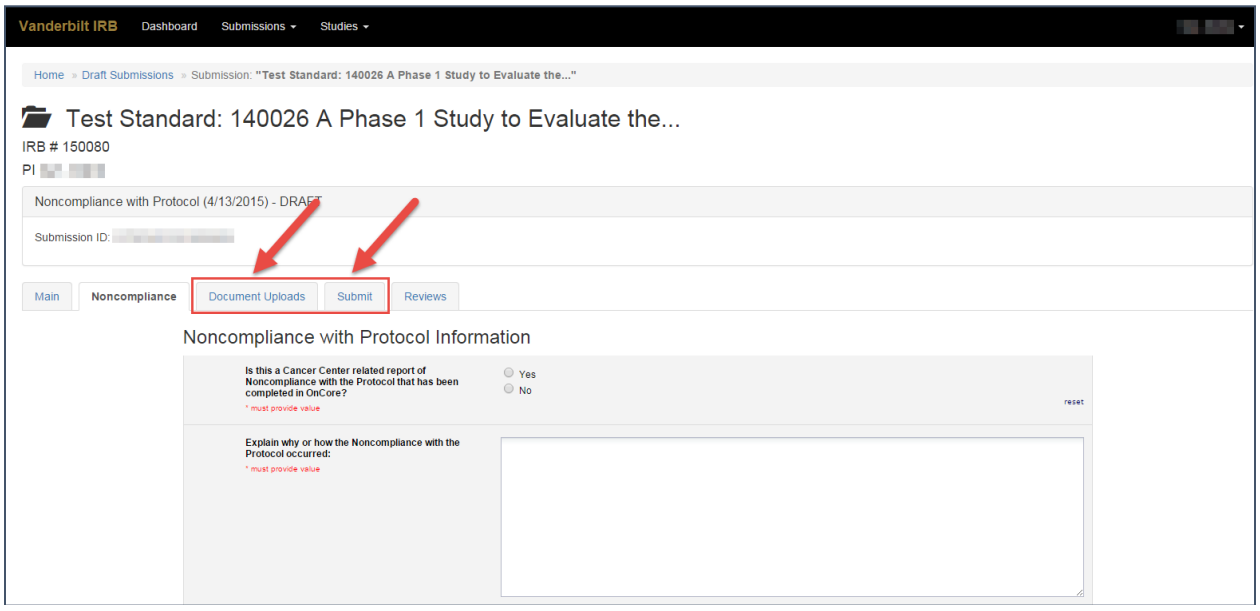
Once you have saved the Main tab, click the *Non-Compliance tab* to continue.



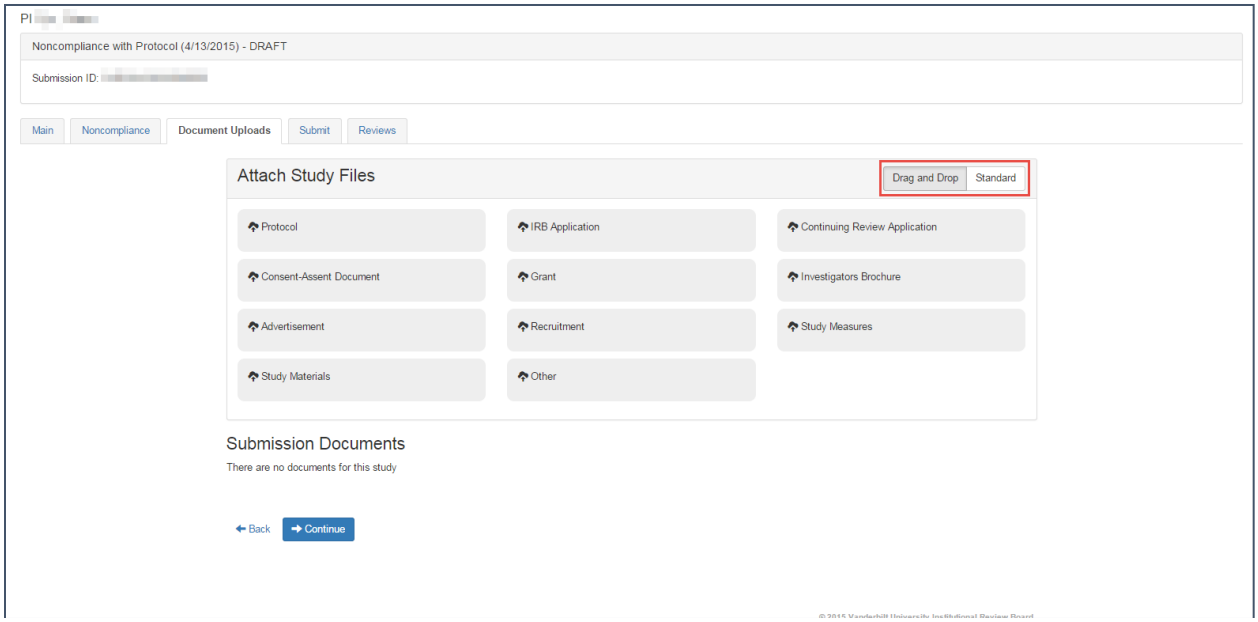
Complete all questions on the Non-Compliance form. The Wizard will not allow you to submit if a questions is not answered. Once all questions have been answered, Click *Save* at the bottom of the page.



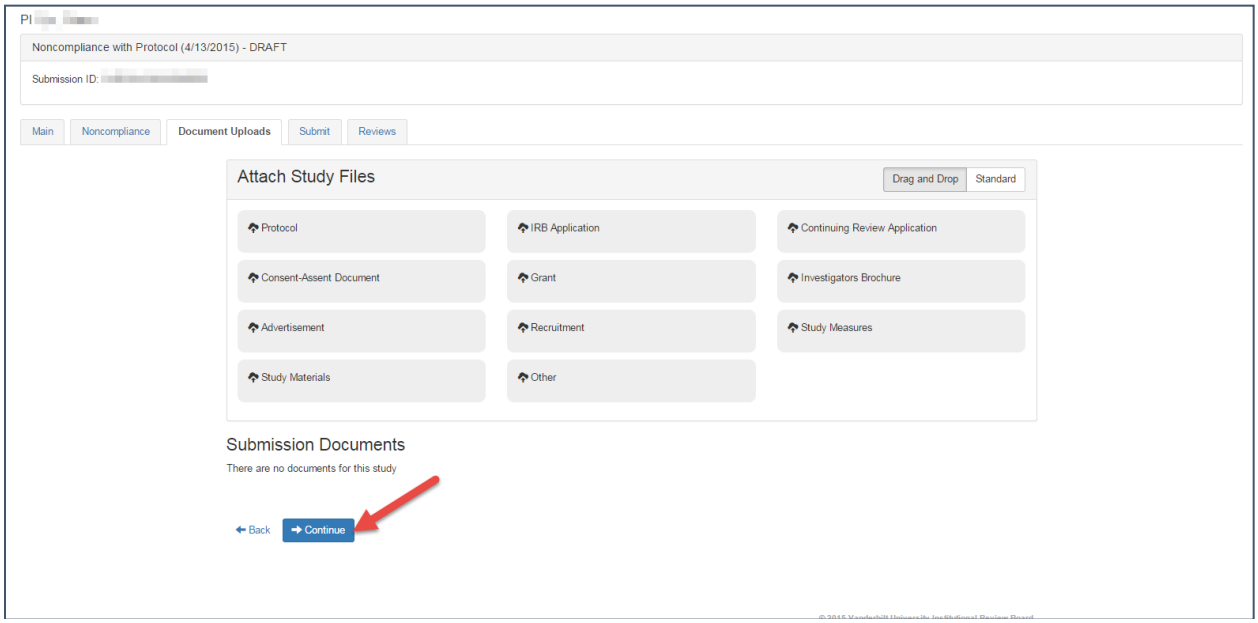
If you have additional documents to upload, click the *Document Uploads* tab. If you have no additional documents to upload, click the *Submit* tab.



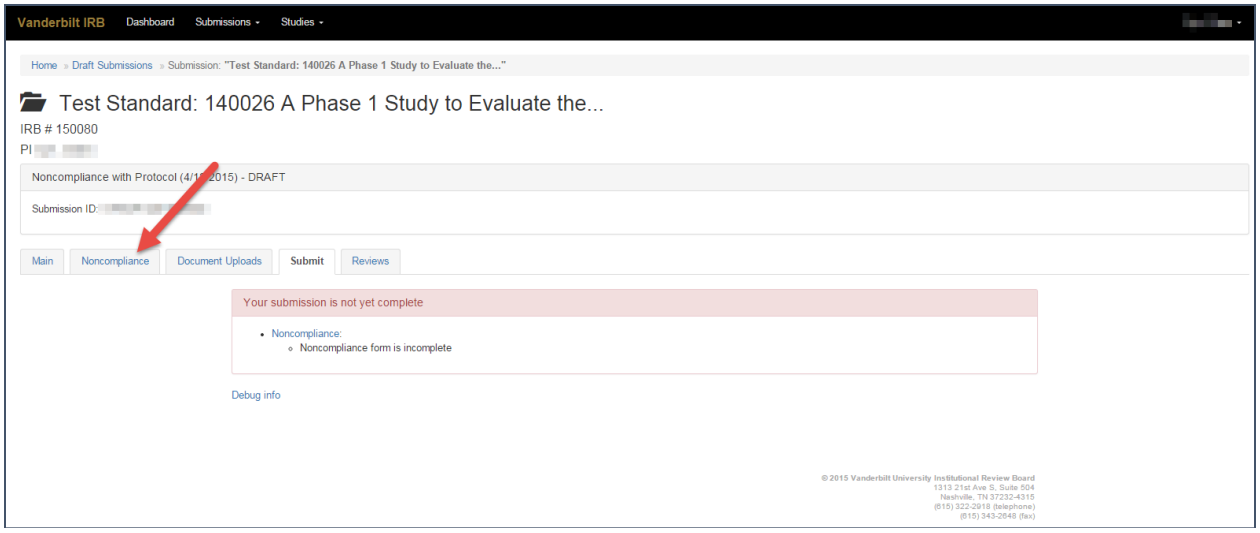
On the Document Uploads tab, upload additional documents using either the Drag and Drop or Standard method.



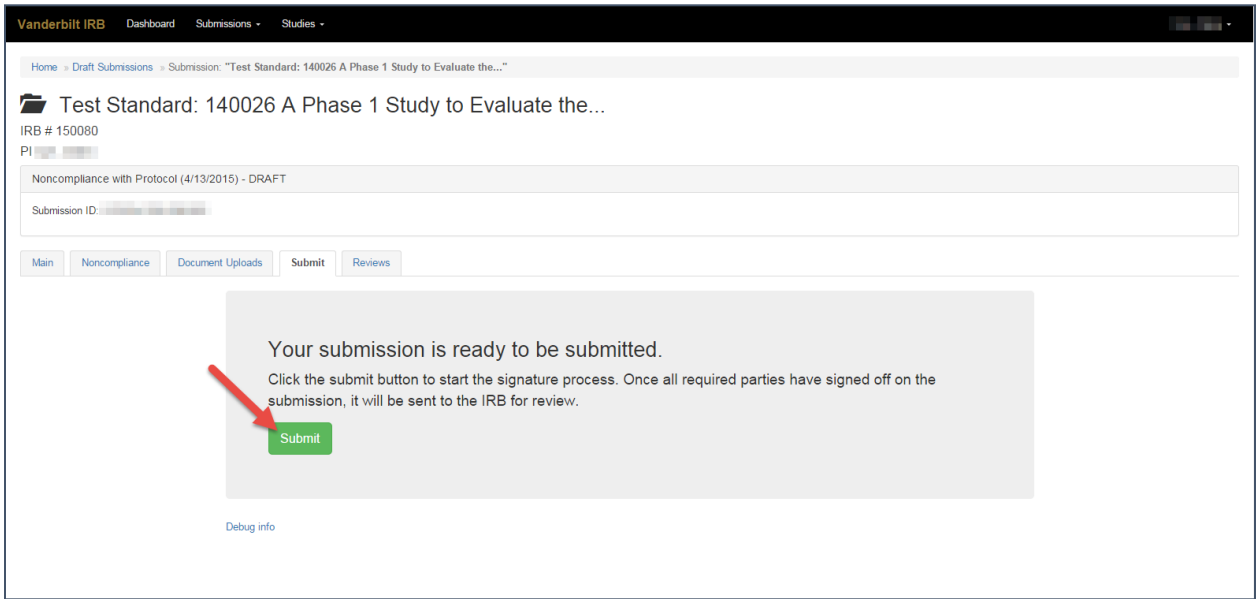
Once all documents are uploaded, Click *Continue*.



On the Submit tab, if the required information is not complete, you will get an error message. Click on the *Non-Compliance tab* to answer incomplete questions.



Once the form is complete, click the *Submit* button.

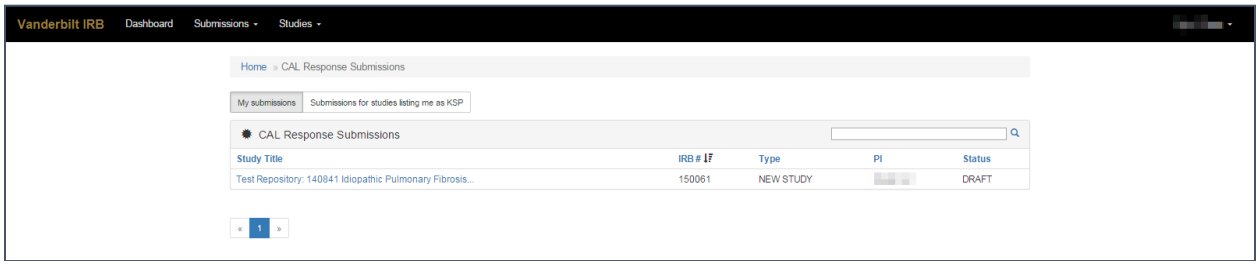


After a signature from the PI, the submission is automatically routed through the Wizard and ultimately ends its journey at the IRB where it will be sent to a team to start the review process.

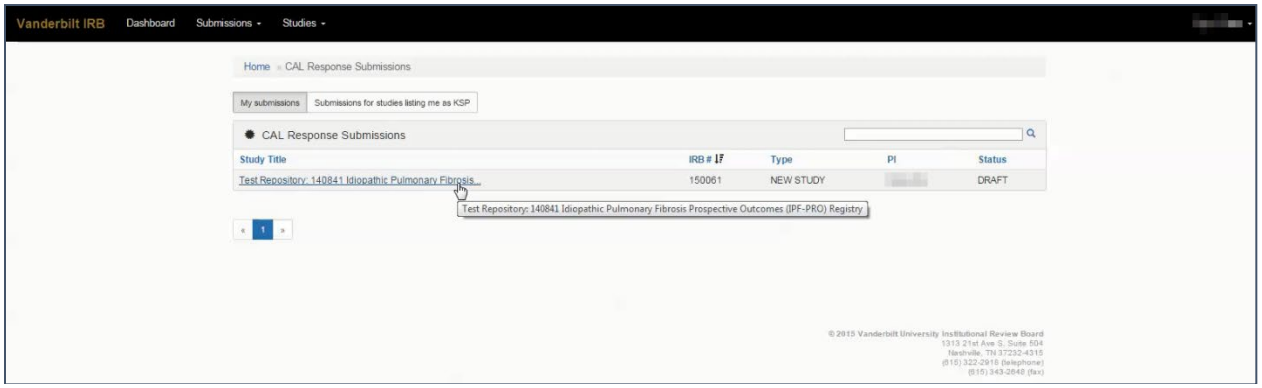
Submitting a Response to a Committee Action Letter (CAL)

On the dashboard, the Submissions Requiring a CAL Response button will display a number indicating the number of outstanding items awaiting a response from you.

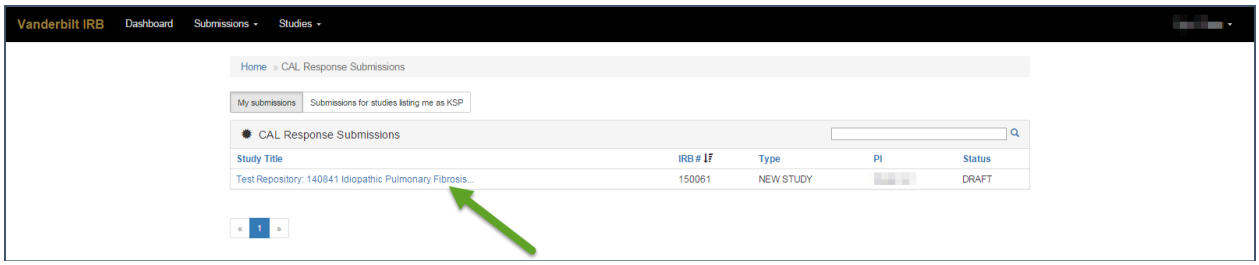
Clicking this button will show you a list of these outstanding items.



If the title is too long, the title will be truncated. Hover the cursor over the truncated title to display the entire title.

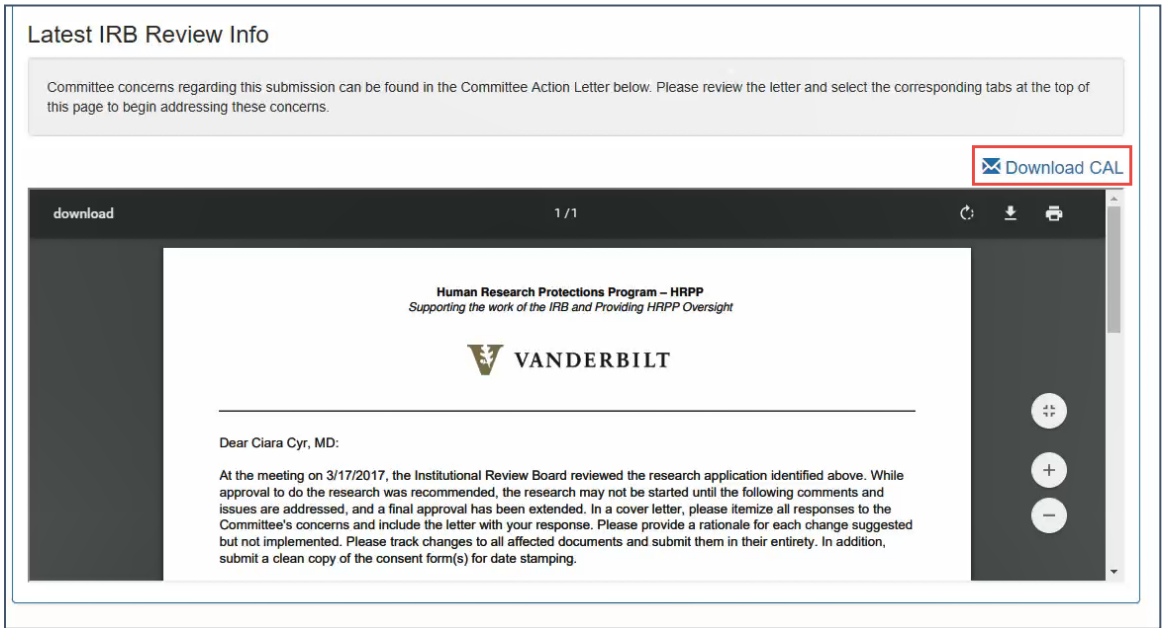


Select the appropriate response item.

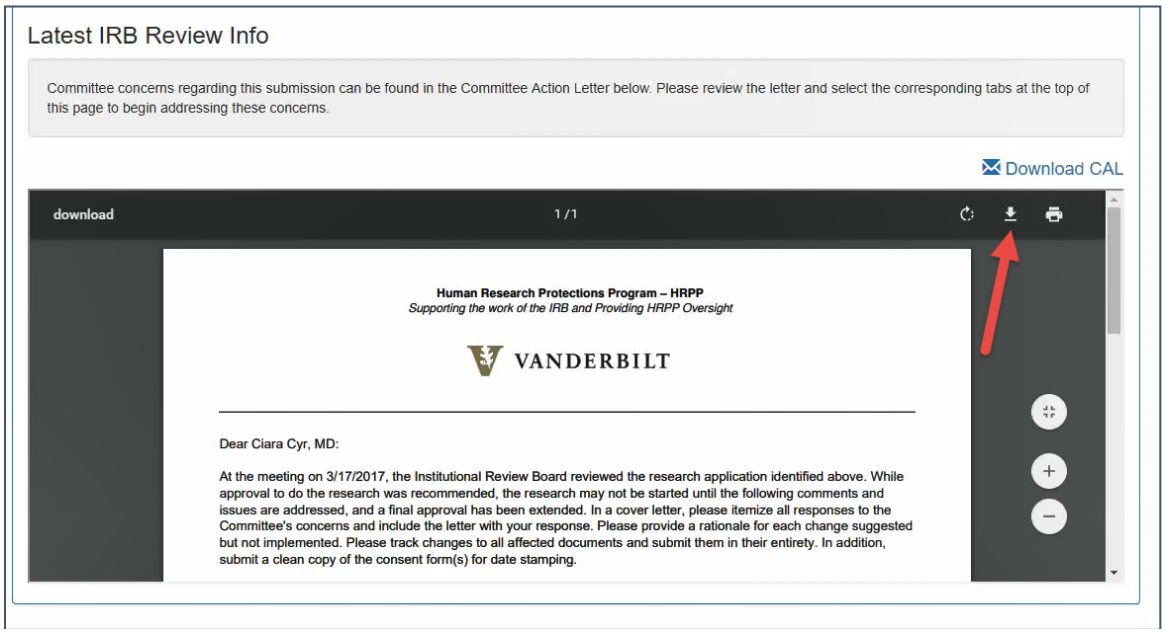


From the Review Screen there are three options to download the CAL:

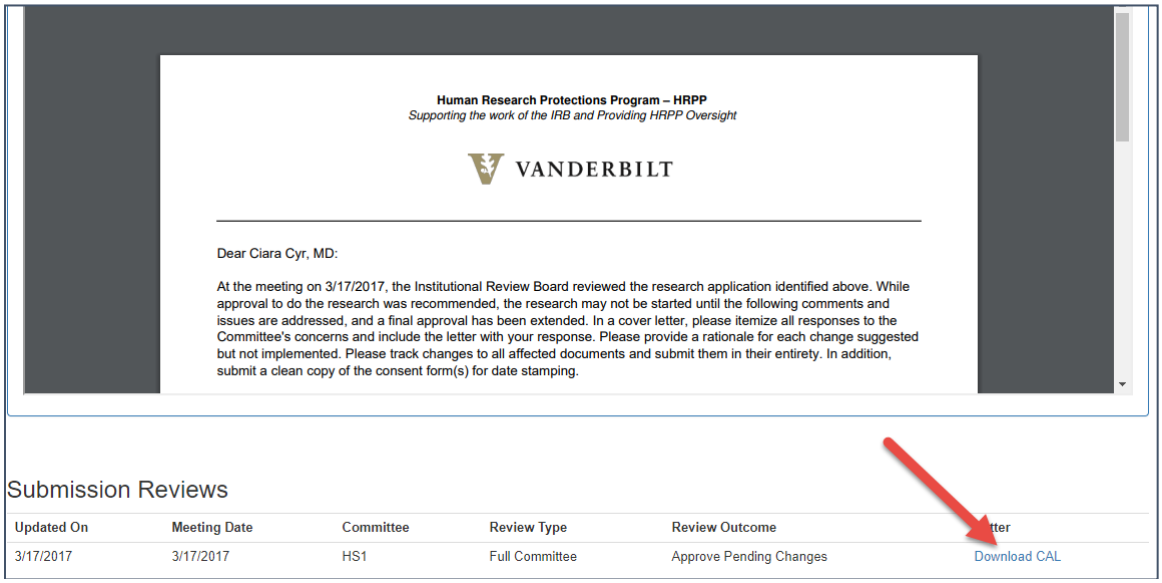
1. Click the *Download CAL* button above the letter



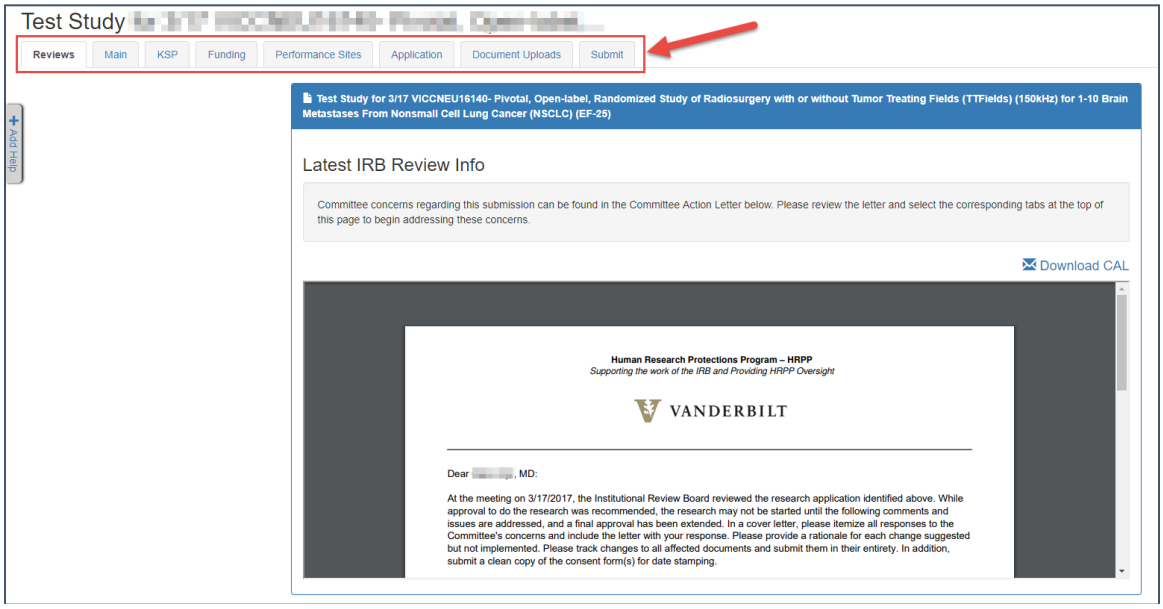
2. Click the *download* button in the PDF viewer



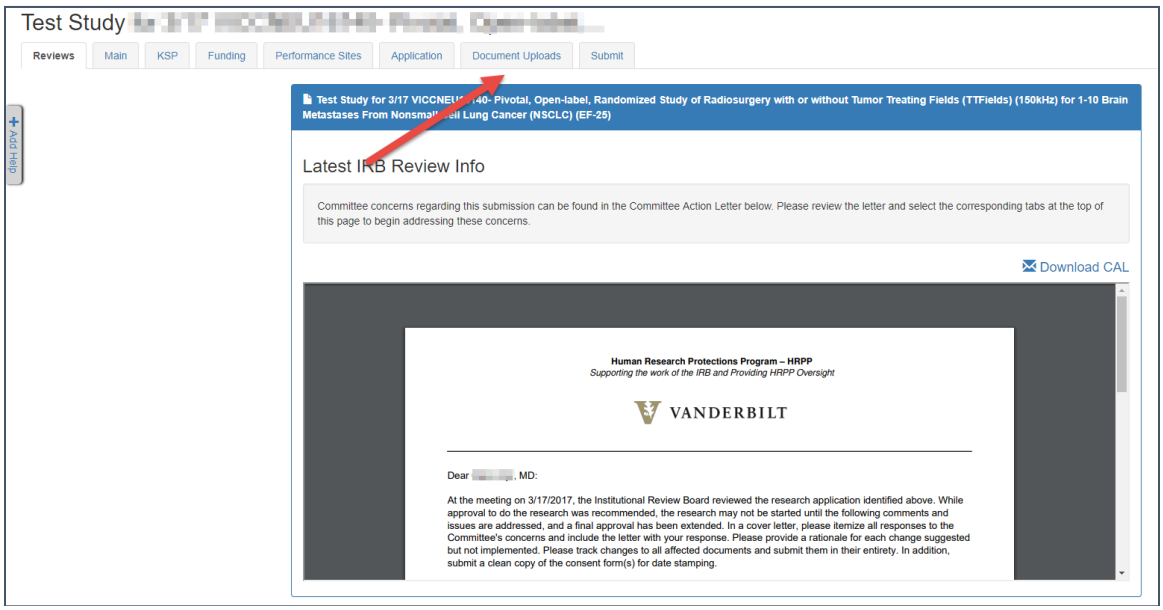
3. Click the *Download CAL* link at the bottom of the page under Submission Reviews



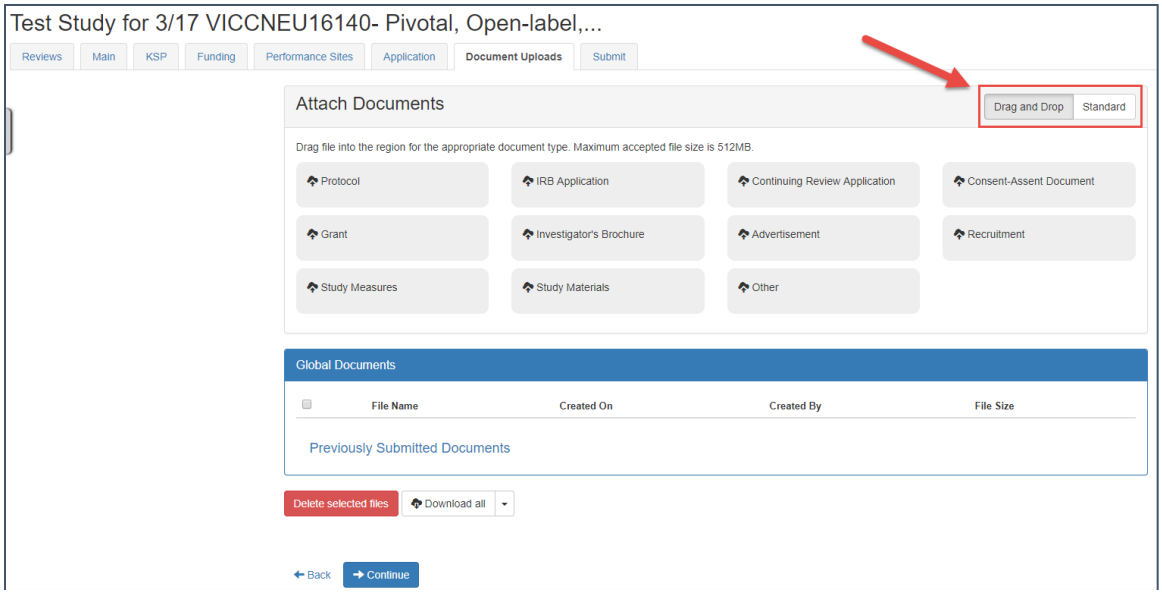
Once the CAL is downloaded, review the changes and concerns expressed by the Committee in the letter. Changes requested within the Wizard can be addressed by clicking the tab corresponding with the concern.



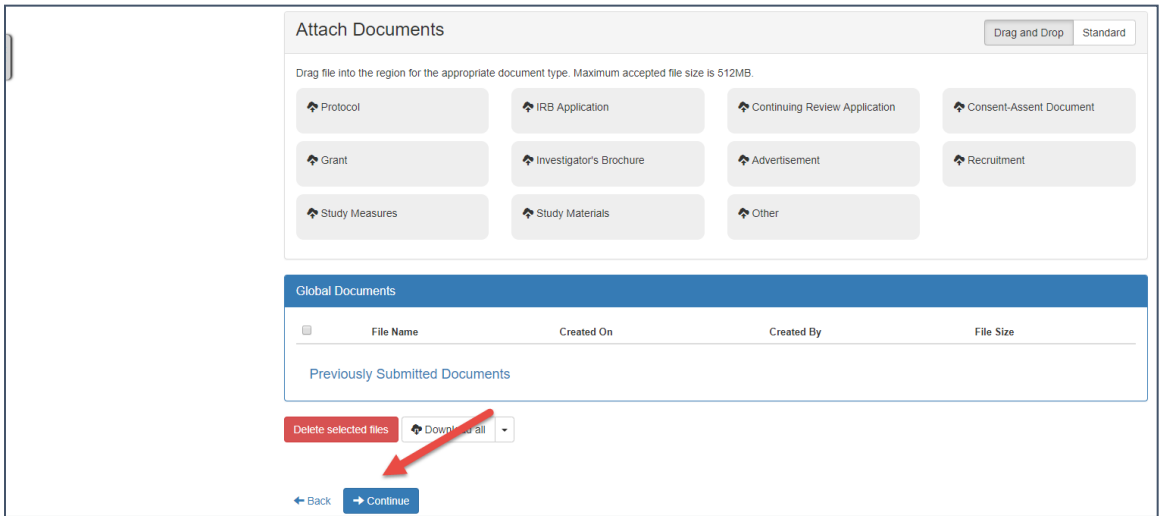
Please limit your changes to only those requested by the Committee. If the IRB has not requested any specific changes within the Wizard, simply click the Document Uploads tab, which is the tab where you can upload your cover letter to address each change requested by the Committee and any revised documents.



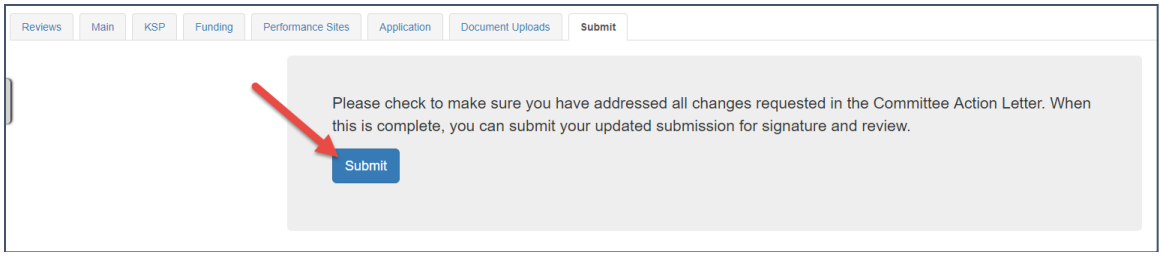
Please be sure to update the revision date and track all changes on any revised documents. Documents can be submitted with either the Drag and Drop option, or the Standard option.



When all documents have been uploaded, click the *Continue* button at the bottom of the page. This button will bring you to the Submit tab.



When you are sure every concern listed in the CAL has been addressed, click the *Submit* button.

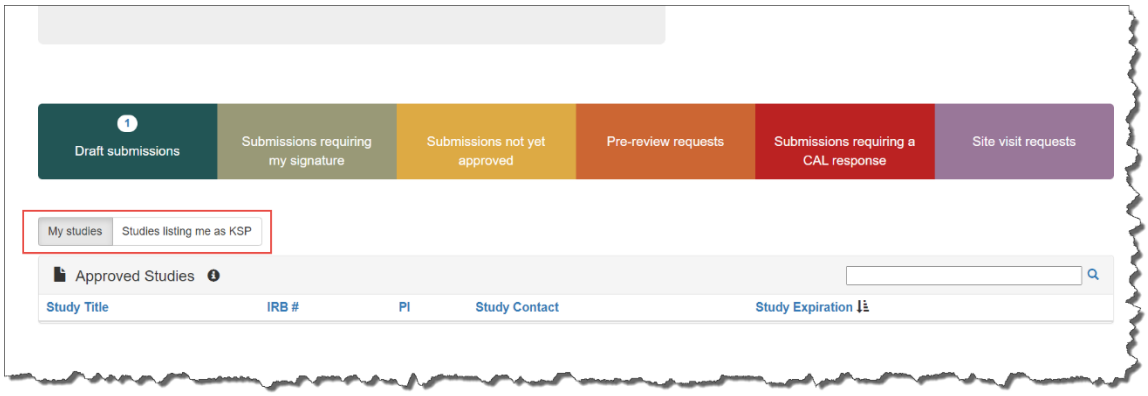


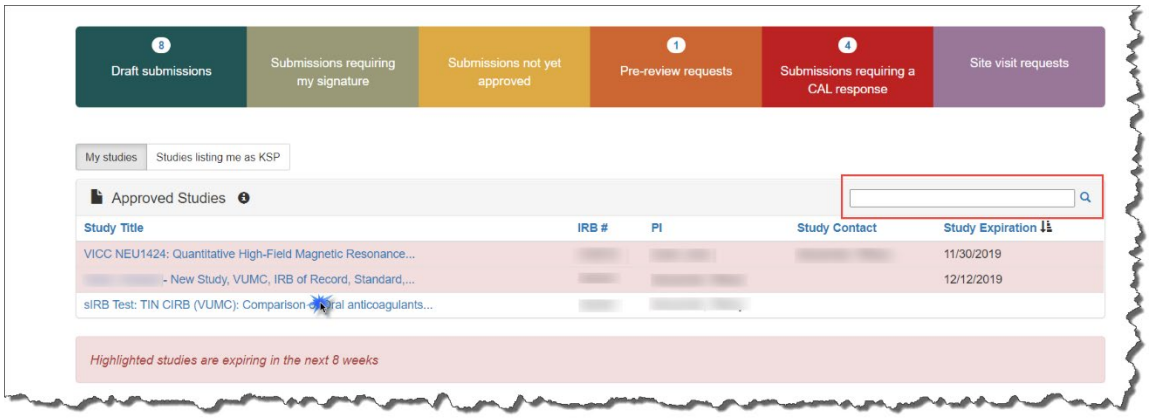
Once the CAL has been submitted, it will be routed for signature by the PI. If you need assistance, please do not hesitate to contact the IRB. Each team has a Regulatory Compliance Analyst that has been involved with the development of the Wizard system. These analysts are there to help you with any issues or difficulties you may encounter.

Assign an NCT number and/or Business Officer

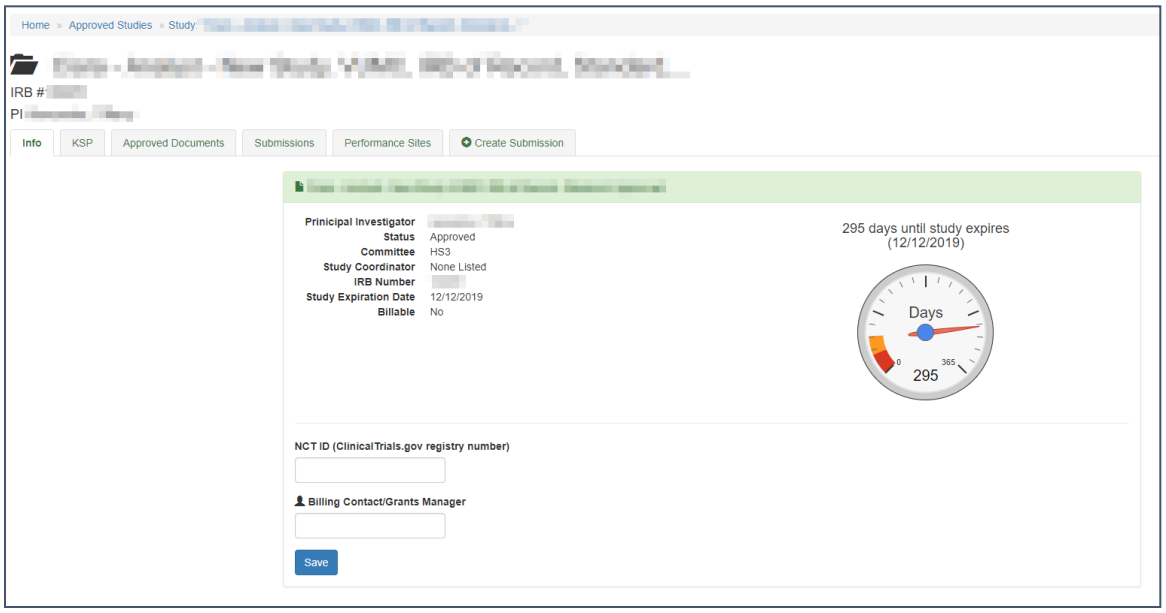
The *Info* tab within your approved study has been designed to allow you to enter information regarding your National Clinical Trial registry number (if you are required to register your study) or assign a Business Officer for your study. The Business Officer is responsible for the financial aspects of the study with regard to payment of IRB invoices. If you need to add/update either item, just follow the step-by-step instructions below:

On the Dashboard, Approved Studies can be found in the list at the bottom of the screen. Approved studies for which you are the PI, Study Coordinator, or Faculty Advisor are found on the My Studies tab. This is the default view for the dashboard. Studies for which you are listed as KSP are found on the Studies listing me as KSP tab.

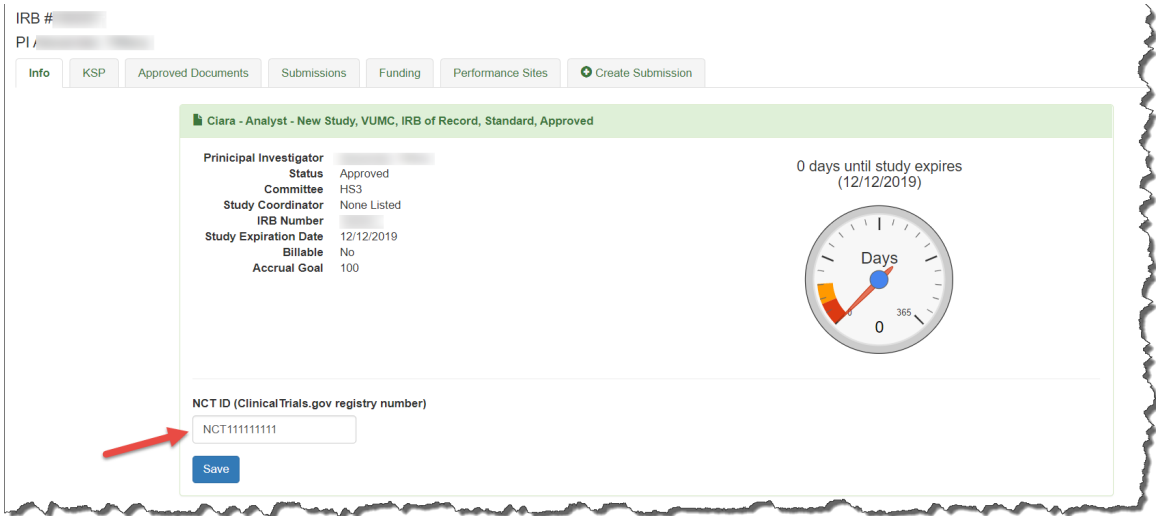




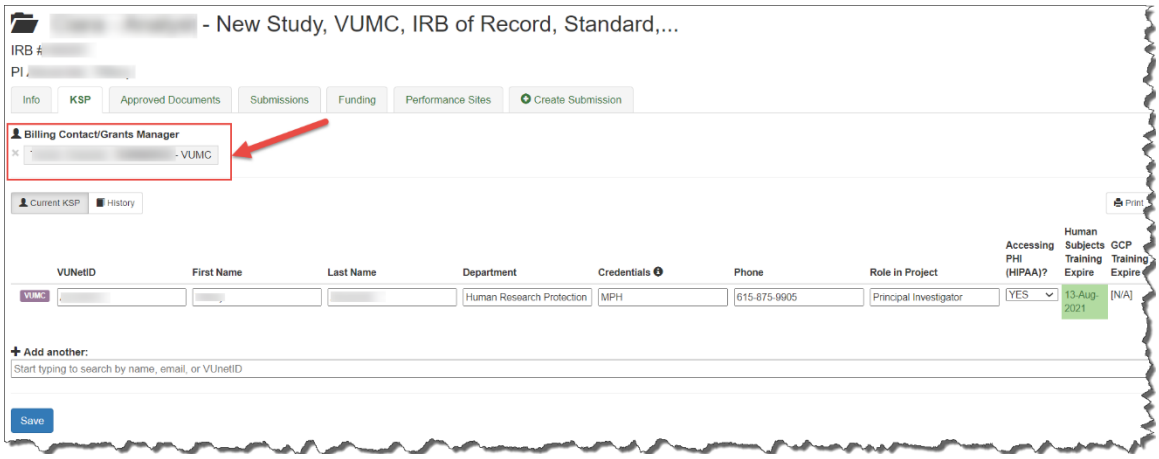
From the study page, be sure you are on the Main tab.



To include a ClinicalTrials.gov registry number, enter the *NCT ID* in the box provided and click save. When the page has saved, a message will appear on the top of the page indicating the save was successful.



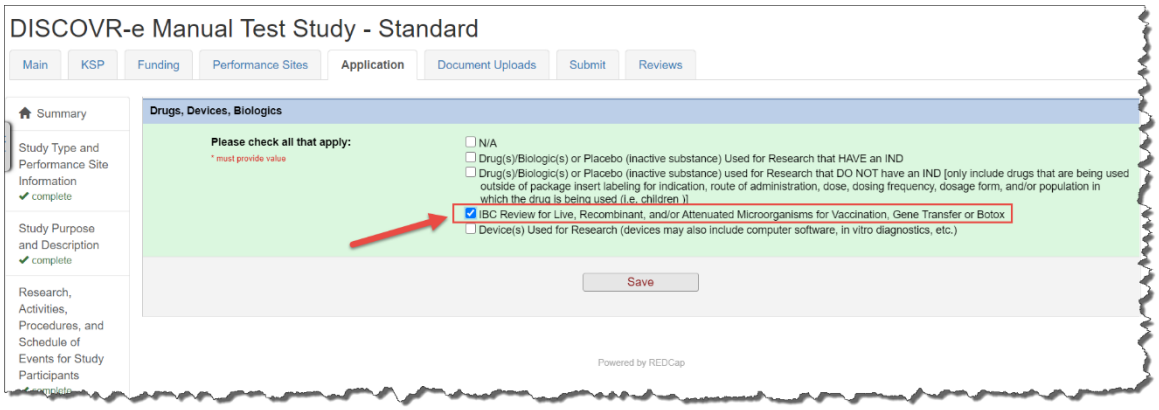
To add a *Billing Contracts/Grants Manager*, go to the KSP tab and enter the name in the box provided and click save. When the page has saved, a message will appear on the top of the page indicating the save was successful.



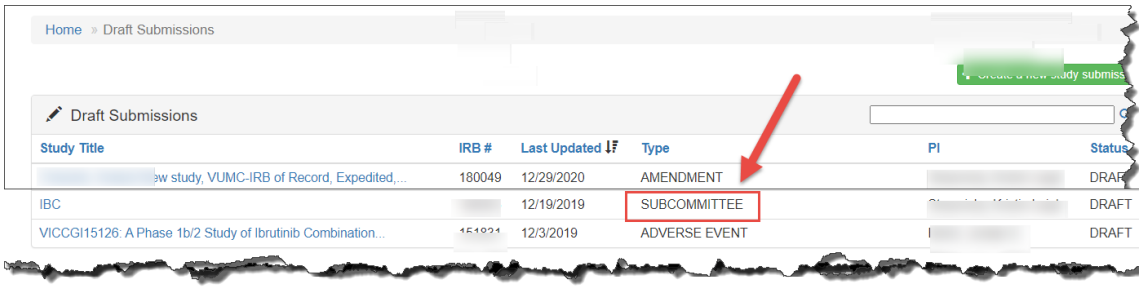
IBC Subcommittee Submission

Subcommittee submissons are ancillary reviews on studies that require both an IRB review and a review by another committee. Some possible subcommittee reviews may include Institutional Biosafety Committee (IBC) reviews.

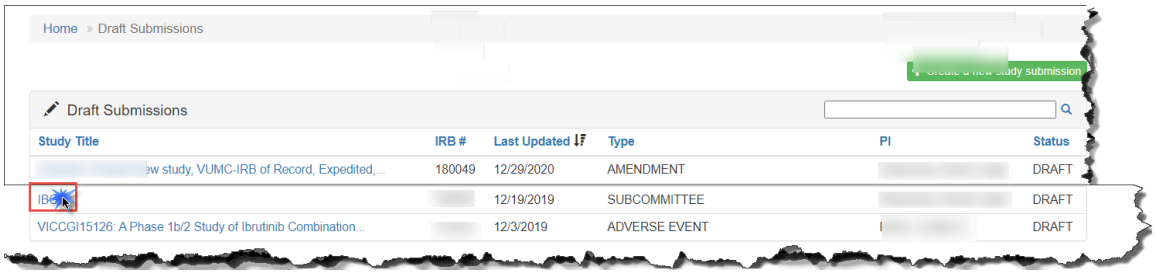
If the study requires Institutional Biosafety Committee (IBC) review, it will need to be indicated on the Drugs, Devices and Biologics section of the IRB Application.



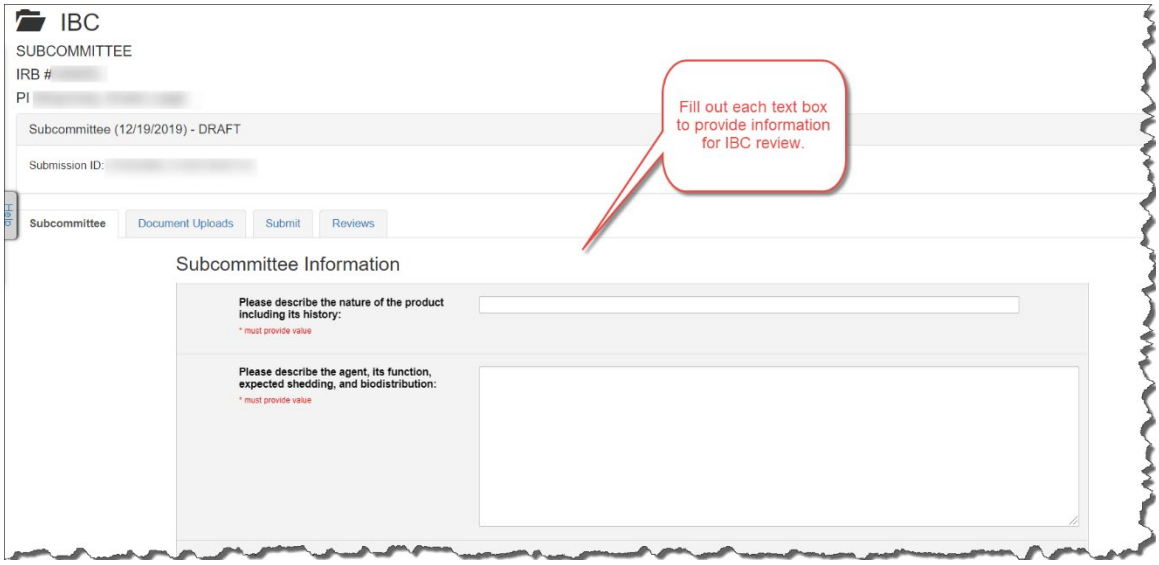
Once the selection is made, saved, and the rest of the application completed and submitted, a draft Subcommittee form will appear in the Investigator and KSP's Draft section of the DISCOVR-e dashboard.



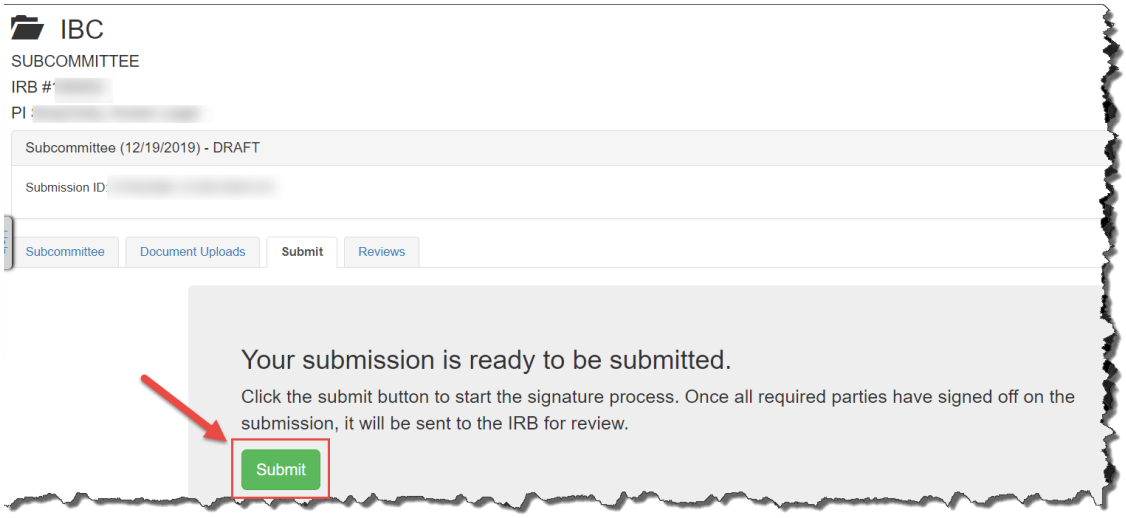
Click on the study to begin filling out the subcommittee form for IBC.



Fill out each text box in order to provide pertinent information to the IBC for review under the NIH Guidelines.



Once all information has been provided in the Subcommittee form, move to the Document Uploads tab to include copies of the Protocol, the Product or Pharmacy Manual, Investigator's Brochure and Informed Consent Document for review by the IBC. Once documents have been uploaded, move to the submit tab and select, *Submit* to be routed for review.



Glossary of Terms

Committee Action Letter (CAL) – A letter from the IRB that needs a response from the Principal Investigator

DISCOVR-e - Data Integrated Study Console of Vanderbilt's Research Enterprise

E-Submission – An electronic study submission sent to the IRB for review

Final Approval Letter (FAL) – A letter from the IRB stating that a submission has received approval.

KSP (Key Study Personnel) – People responsible for helping with the conduct of a study

Log-In – Use your VUNetID and password to enter the DISCOVR-e system

My Studies– The view within DISCOVR-e where you can view studies where you are listed as the PI, Faculty Advisor or Study Contact

Principal Investigator – The individual responsible for the conduct of a study

Portal – Another name for the DISCOVR-e system

Studies listing me as KSP – The tab within DISCOVR-e where you can view studies in which you are listed as KSP

View IRB Training– The dashboard in DISCOVR-e where you can view your current IRB Training Status and when that training will expire

Wizard – The computer programming that takes you step by step through DISCOVR-e