

DISCOVER-e USER MANUAL

Vanderbilt Human Research Protection Program

Note: *If you are working with COVID-19 samples, you must receive biosafety approval prior to beginning the research.*

Related Studies on the Funding Tab:

You can now inform us of any studies that may be related to a NS submission to assist with IRB review. If you have a Single IRB study in a specific network or a crossover study that may benefit from review by the same IRB committee, please let us know! The system allows you to search by IRB number or PI.

1 Draft submissions	Submissions requiring my signature	Submissions not yet approved	Pre-review requests	Submissions requiring a CAL response	Site visit requests
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My studies Studies listing me as KSP

Approved Studies ⓘ 🔍

Study Title	IRB #	PI	Study Contact	Study Expiration ⏴
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Introduction

Welcome to the Vanderbilt University Institutional Review Board's new electronic submission system called DISCOVER-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 DISCOVER-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

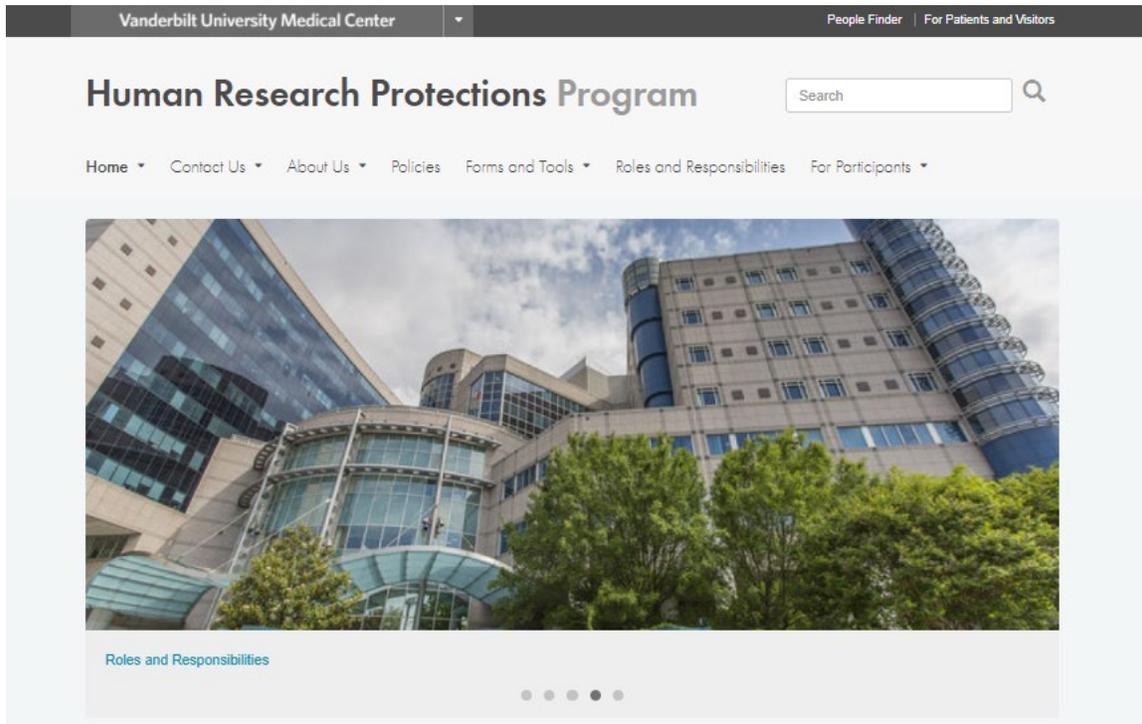
The DISCOVER-e portal is a web-based system. You can log in and submit documents or check the status of a previous submission anywhere in the world where you have a connection to the Internet. This section of the manual will give you an overview of the system and provide highlights of its capabilities.

To access the system, please visit the Vanderbilt IRB website at <https://www.vumc.org/irb/> and click on the DISCOVER-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 *DISCOVER-e link*.



Announcements

Tweets by @VHRPP

A screenshot of a tweet from the account @VHRPP. The tweet text reads: 'Please take some time and watch our provider video series on those who are working the front lines. Help us support those who are doing this every day!' followed by a URL and a timestamp of 'Jan 6, 2021'.

Tips

Did you know...

Update on COVID-19

Effective October 1, 2020 all invoicing will be done through iLab. This includes Industry and Single IRB billing.

We still require an abbreviated application if you are using an outside IRB?

How to submit when requesting review by another IRB.

Links

- [IRB Committee LOG IN](#)
- [DISCOVER-e LOG IN \(Submit Here\)](#)
- [DISCOVER-e How To](#)
- [Single IRB Help](#)
- [Common Rule Changes](#)
- [IRB Reliance Exchange \(IREx\)](#)
- [Education and Training](#)
- [Research News at Vanderbilt](#)
- [Performance Metrics](#)
- [Office for Human Research Protections \(OHRP\)](#)

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 DISCOVER-e, enter your VUNetID and password.

Vanderbilt IRB

VUNetID

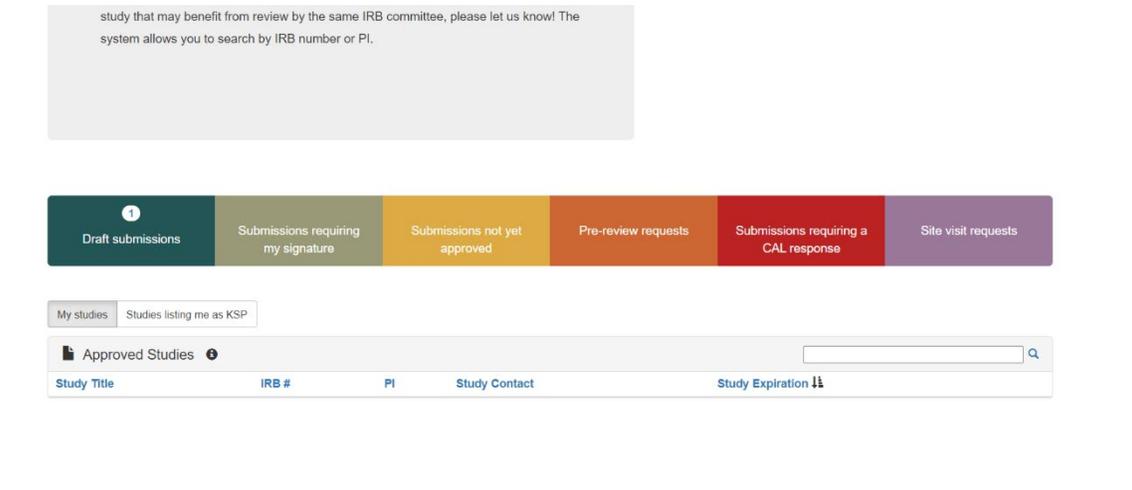
ePassword

Login

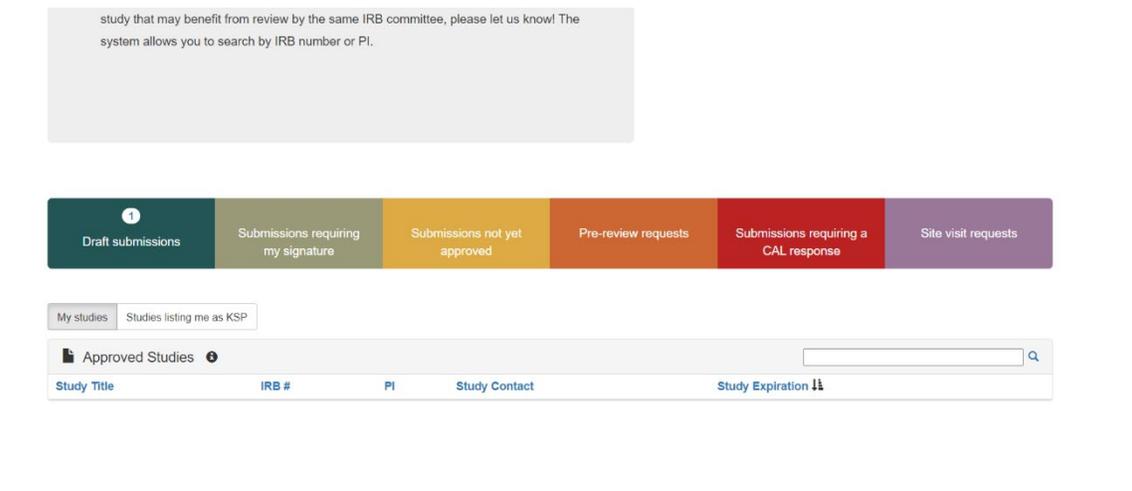
Vanderbilt University Institutional Review Board
1313 21st Ave S, Suite
Nashville, TN 37232-4
(615) 322-21

Investigator Dashboard Overview

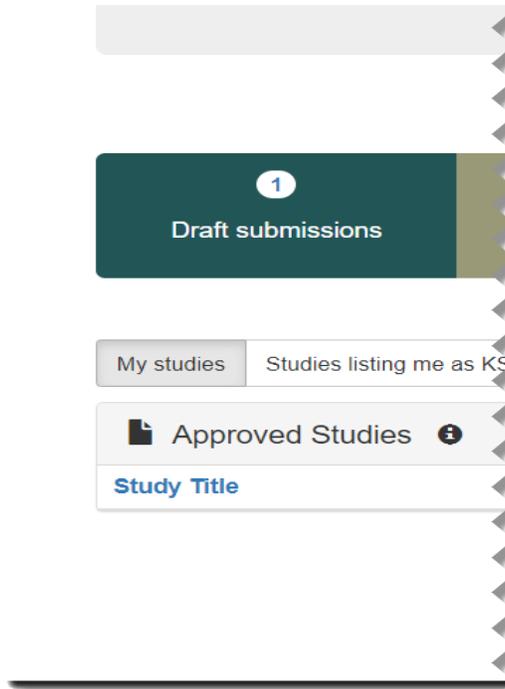
This is your Investigator Dashboard. When you log in, this is the first screen you will see. From here, you can access all your studies and view submissions that require action from you.



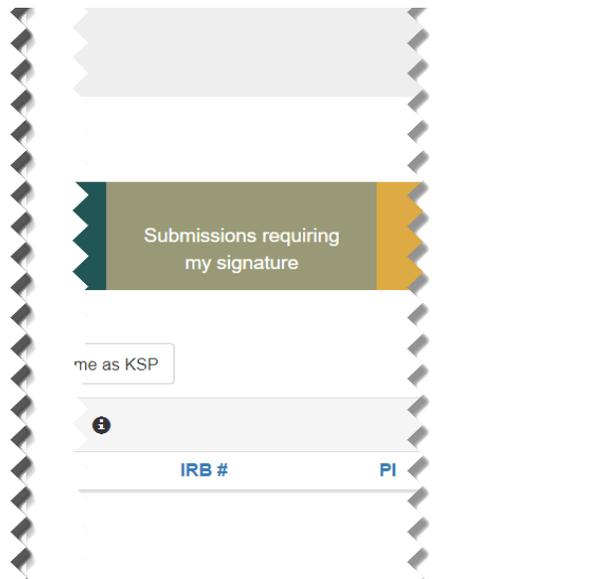
The colored squares on this page show items requiring action from you.



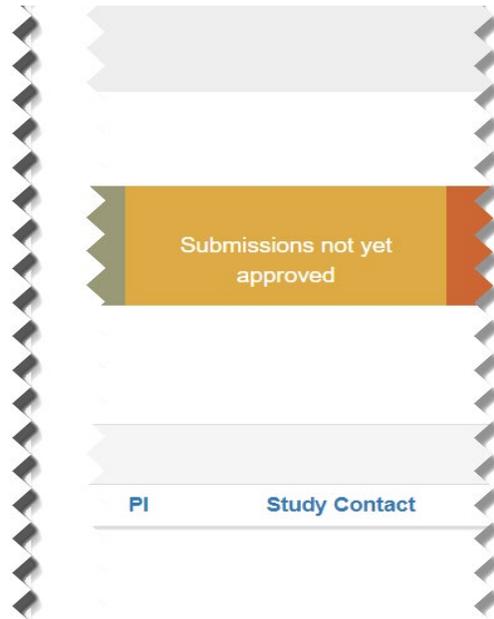
Notice the number in the middle of each button. This number indicates how many items are requiring that particular action. The first button is the [Draft Submissions](#) button. The number in the middle indicates how many draft submissions are awaiting to be finished and submitted for review.



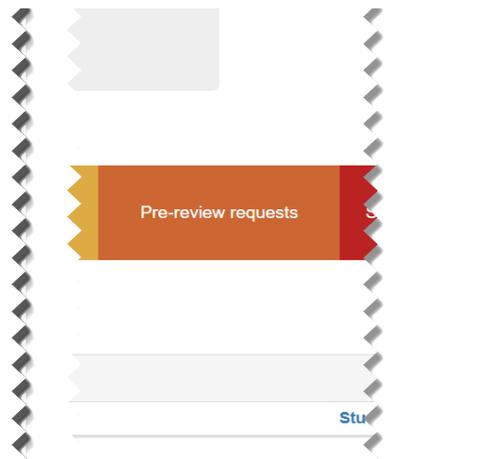
The second button is the [Submissions requiring my signature](#) button. If there is a number in the middle, this indicates how many submissions require a signature for submission. Clicking this button will allow you to access these studies and sign.



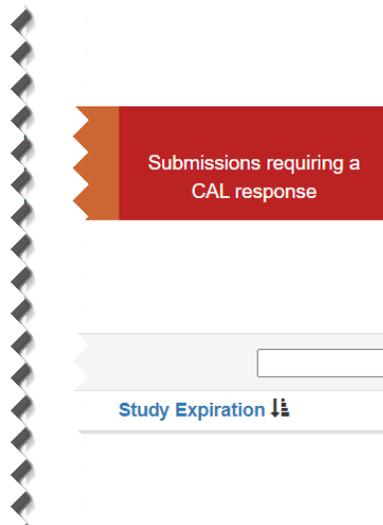
The next button is the *Submissions not yet approved* button. If there is a number in the middle, this indicates how many submissions have been submitted but not yet approved. Clicking this button will allow you to access these studies.



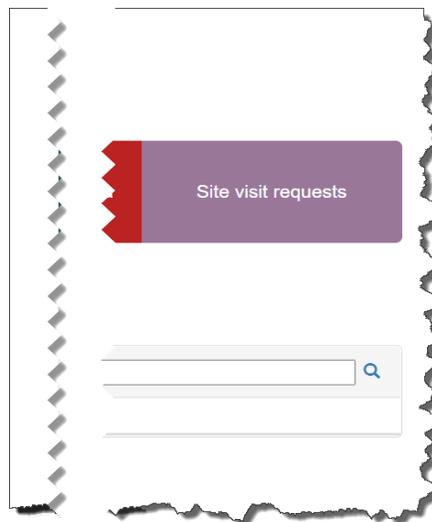
The next button is the *Pre-review requests* button. If there is a number in the middle, this indicates how many pre-review requests you have requiring a response. Clicking this button will allow you to access these studies.



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.

11 Draft submissions Submissions requiring my signature Submissions not yet approved 1 Pre-review requests 4 Submissions requiring a CAL response Site visit requests

My studies **Studies listing me as KSP**

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
VICC NEU1424: Quantitative High-Field Magnetic Resonance...				11/30/2019
New Study, VUMC, IRB of Record, Standard,...				12/12/2019
sIRB Test. TIN CIRB (VUMC): Comparison of Oral anticoagulants...				

Highlighted studies are expiring in the next 8 weeks

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

11 Draft submissions Submissions requiring my signature Submissions not yet approved 1 Pre-review requests 4 Submissions requiring a CAL response Site visit requests

My studies Studies listing me as KSP

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
VICC NEU1424: Quantitative High-Field Magnetic Resonance...				11/30/2019
New Study, VUMC, IRB of Record, Standard,...				12/12/2019
sIRB Test. TIN CIRB (VUMC): Comparison of Oral anticoagulants...				

Highlighted studies are expiring in the next 8 weeks

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.

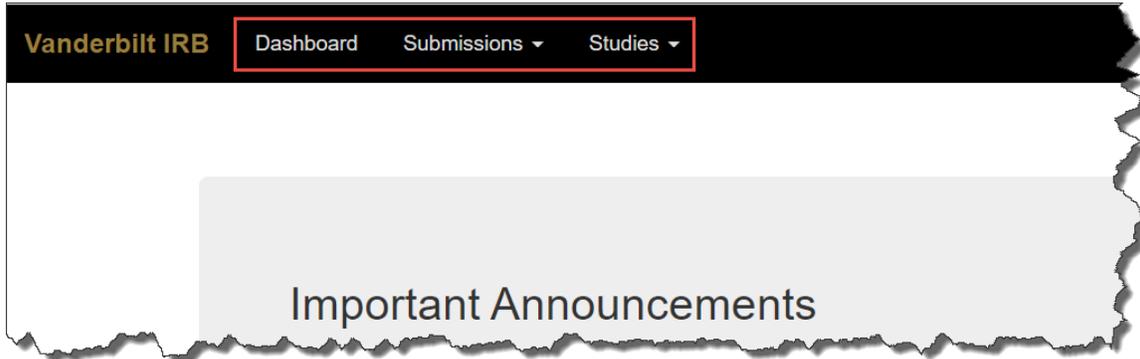
The screenshot shows a navigation bar with six categories: Draft submissions (11), Submissions requiring my signature, Submissions not yet approved, Pre-review requests (1), Submissions requiring a CAL response (4), and Site visit requests. Below the navigation bar, there are tabs for 'My studies' and 'Studies listing me as KSP'. A search bar is present with a magnifying glass icon. The main content area is titled 'Approved Studies' and contains a table with the following columns: Study Title, IRB #, PI, Study Contact, and Study Expiration. The table lists three studies, with the first two highlighted in red. A red banner at the bottom of the table states 'Highlighted studies are expiring in the next 8 weeks'.

Study Title	IRB #	PI	Study Contact	Study Expiration
VICC NEU1424: Quantitative High-Field Magnetic Resonance...				11/30/2019
New Study, VUMC, IRB of Record, Standard,...				12/12/2019
sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...				

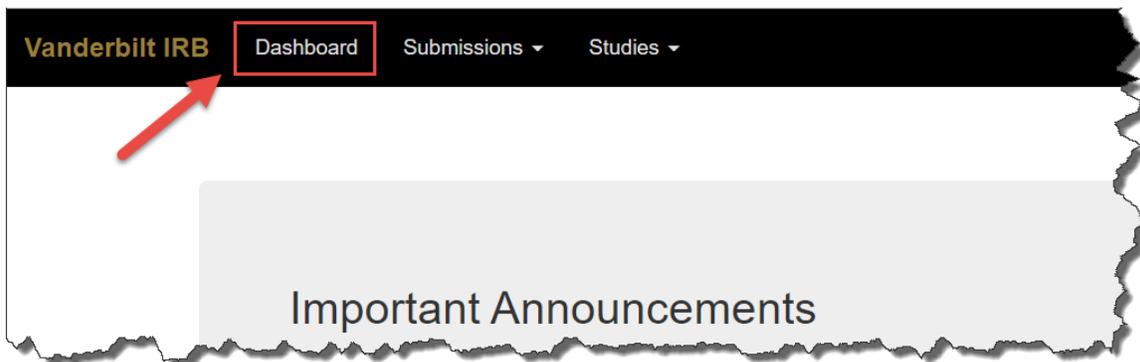
You can also search for studies in these lists by entering study identifiers such as *PI or Study Contact name, parts of the study title, or IRB number* into the search box.

This screenshot is identical to the one above, but the search bar is highlighted with a red rectangular box to indicate where users can enter search criteria.

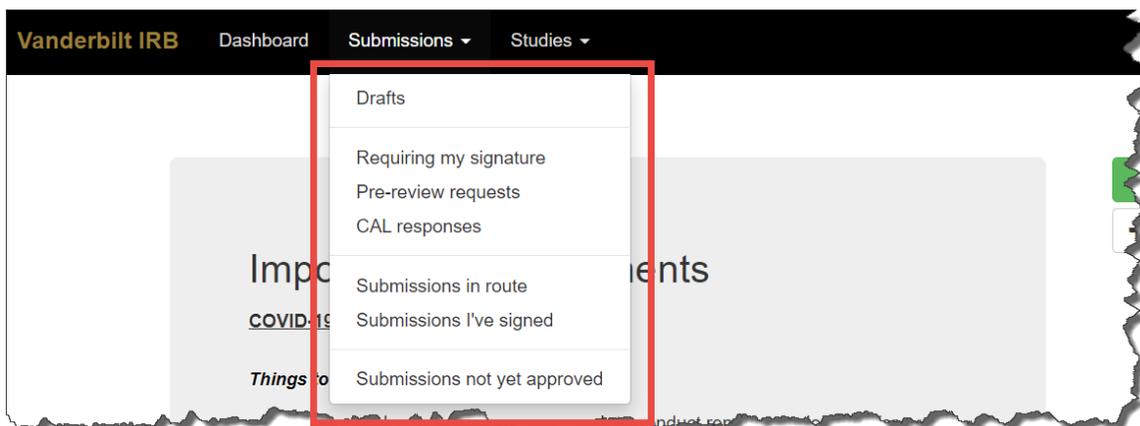
The views located on the Dashboard can also be accessed at any point via drop-down menus. These drop-down menus can be accessed on any screen, allowing you to access submissions without returning to your dashboard.



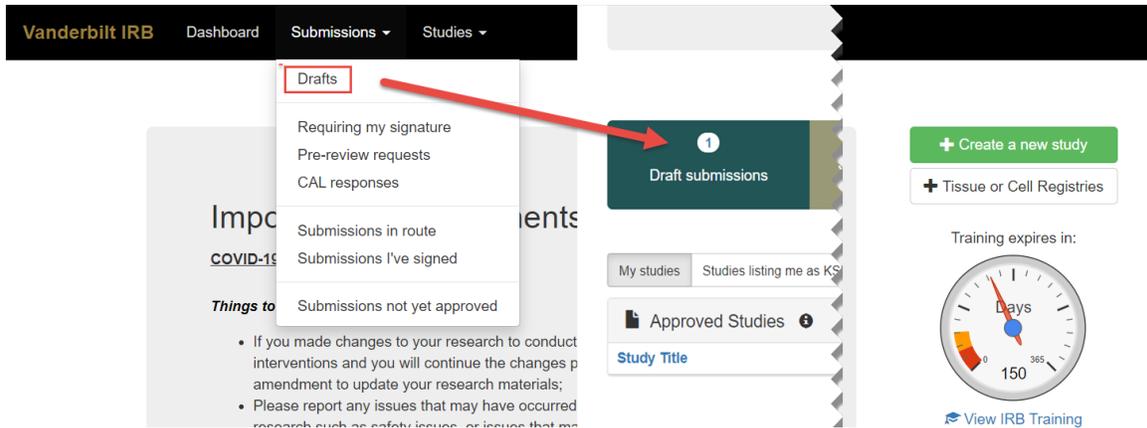
Clicking on [Dashboard](#) will return you to your Investigator Dashboard.



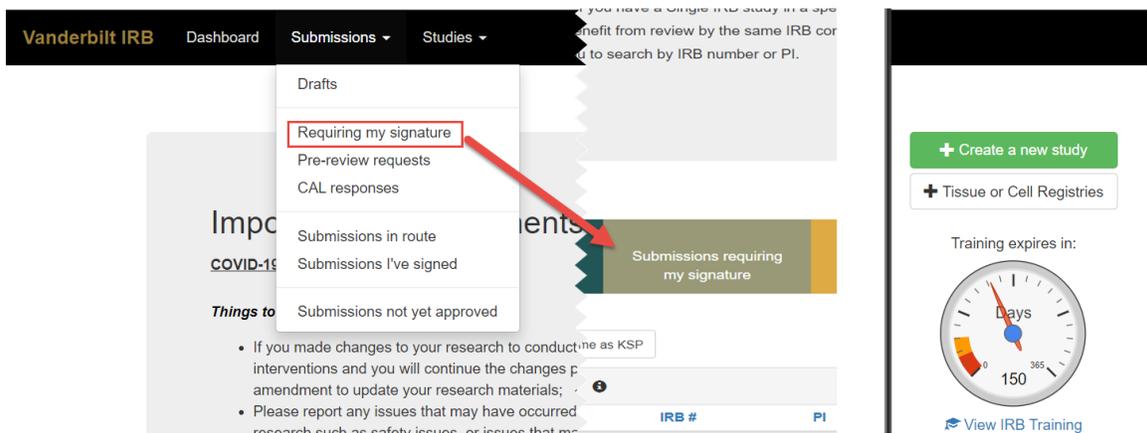
Clicking [Submissions](#) will display a drop-down menu. This menu holds items corresponding with the buttons on the dashboard, as well as other study views.



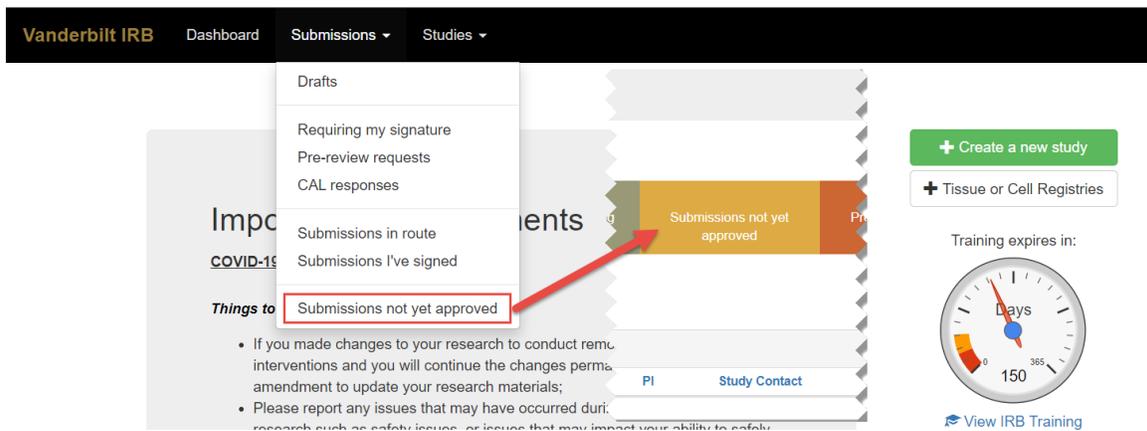
Drafts corresponds with the *Drafts* button.



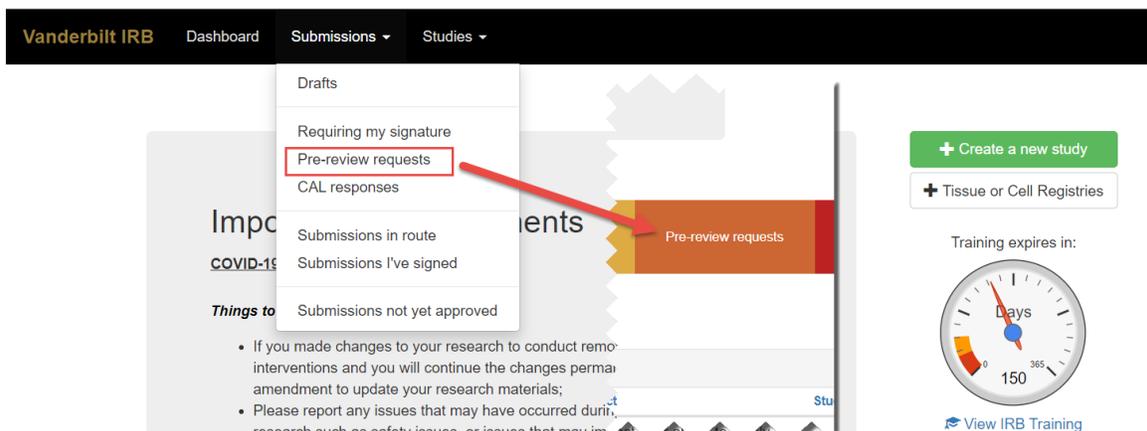
Requiring my signature corresponds with the *Submissions requiring my signature* button.



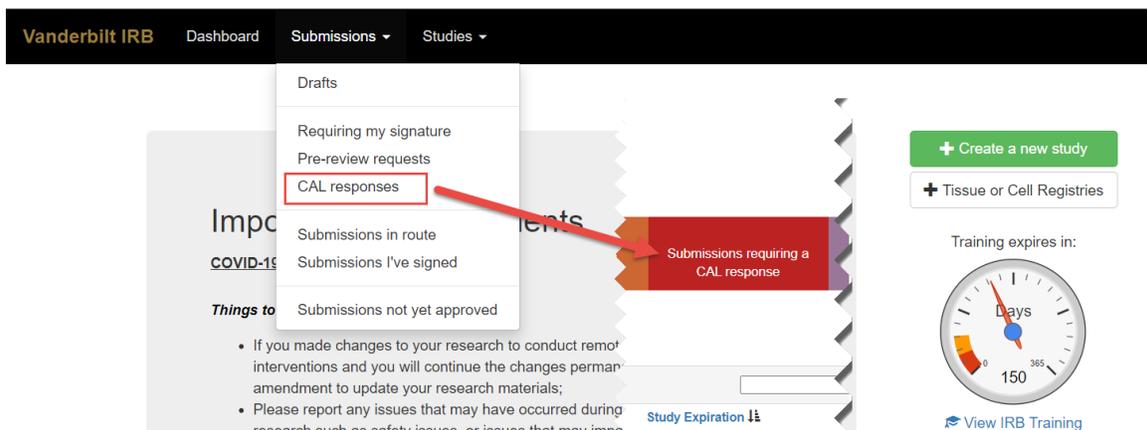
Submissions not yet approved corresponds with the *Submissions not yet approved* button. Clicking Submissions not yet approved will display a list of all submissions you have created and where you are listed as PI, study contact, or faculty advisor that have been submitted to the IRB and have been signed,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



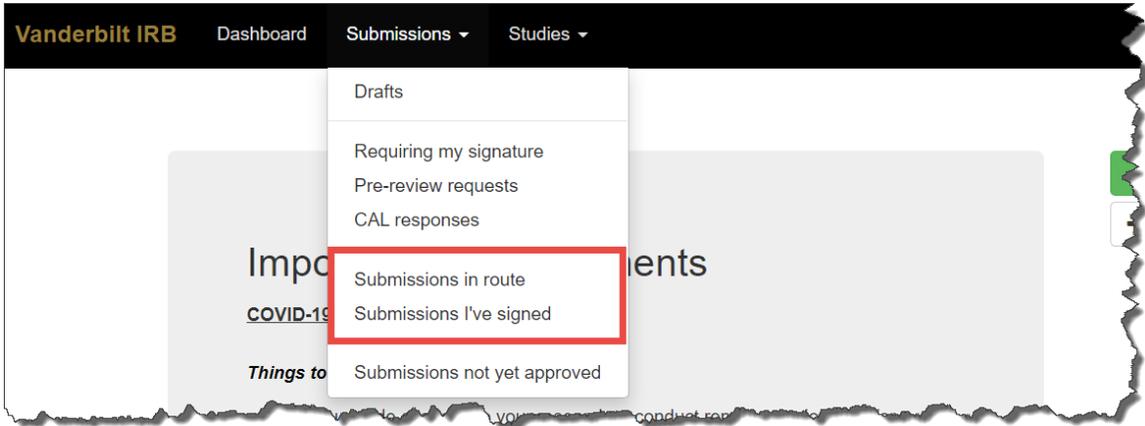
Pre-review requests corresponds with the *Pre-review requests* button.



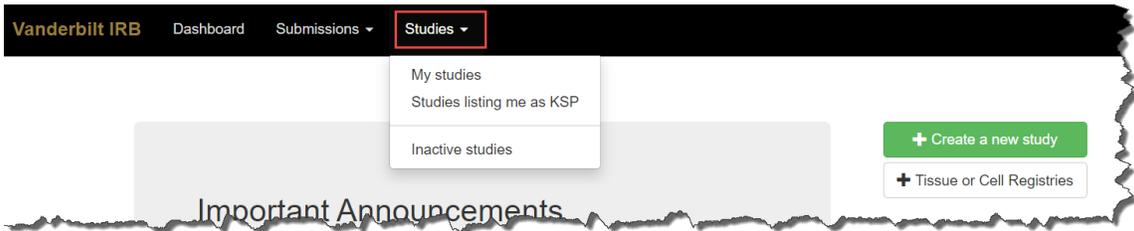
CAL responses correspond with the *Submissions requiring a CAL response* button.



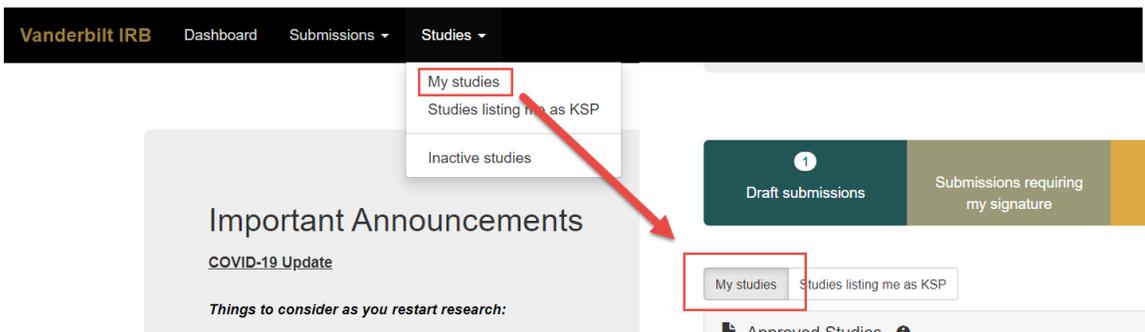
This drop-down also holds views for *Submissions in route* and *Submissions I've signed*. Clicking *Submissions in route* will display a list of submissions pending signature from another person. Clicking *Submissions I've signed* will display a list of all submissions signed by you.



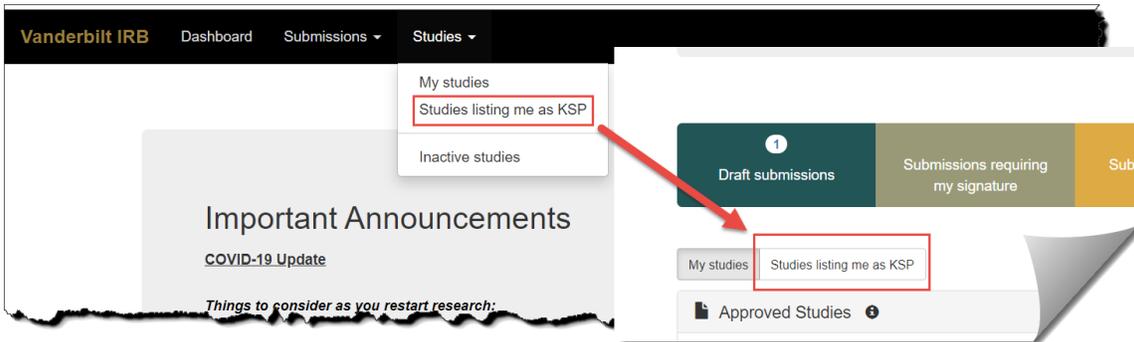
Clicking [Studies](#) will display another drop-down menu. This menu holds items corresponding with the studies lists on the Dashboard, as well as [Inactive studies](#).



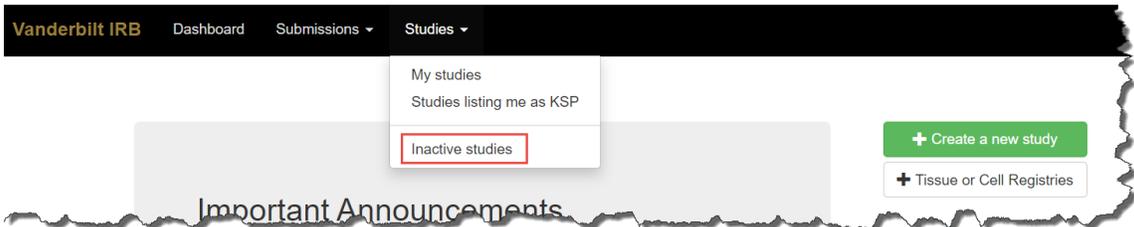
My Studies corresponds with the [My Studies](#) button.



Studies listing me as KSP corresponds with the [Studies listing me as KSP](#) button

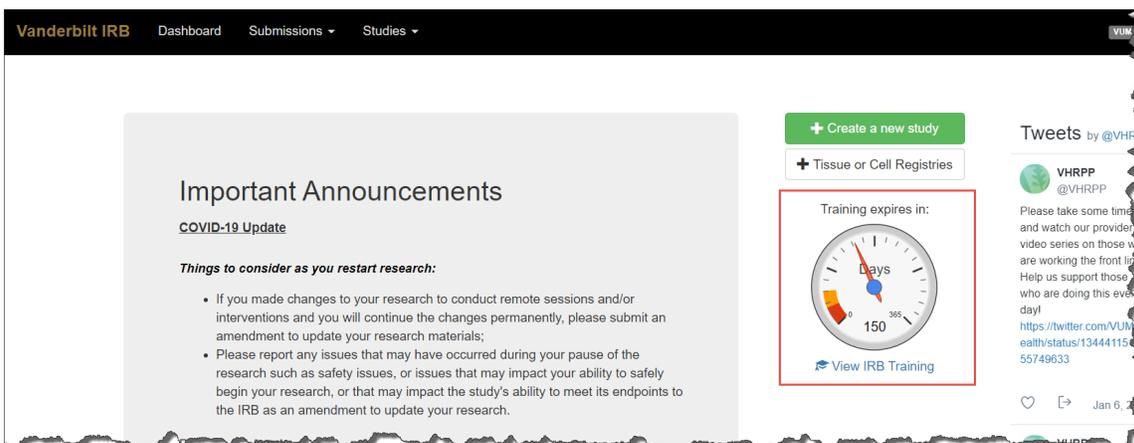


Clicking *Inactive* will display a list of your inactive studies.

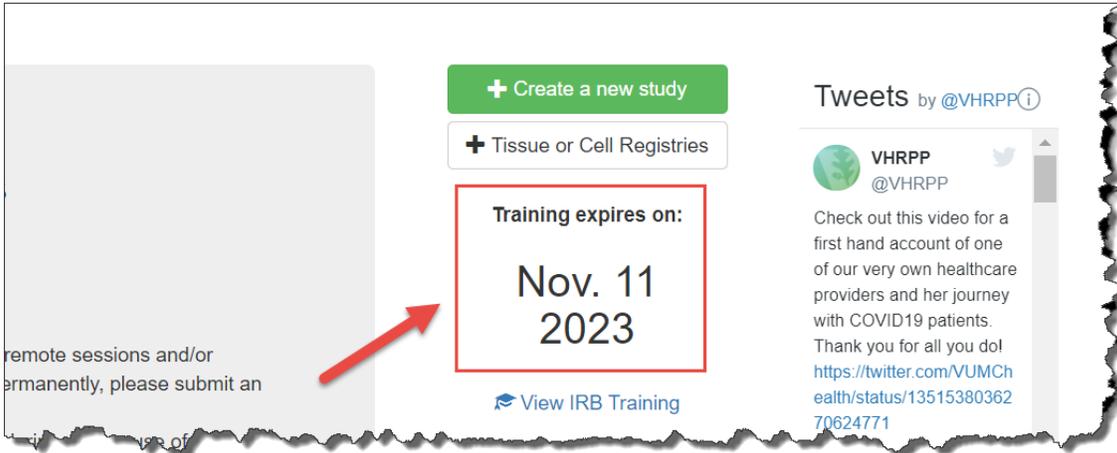


IRB Training Requirements

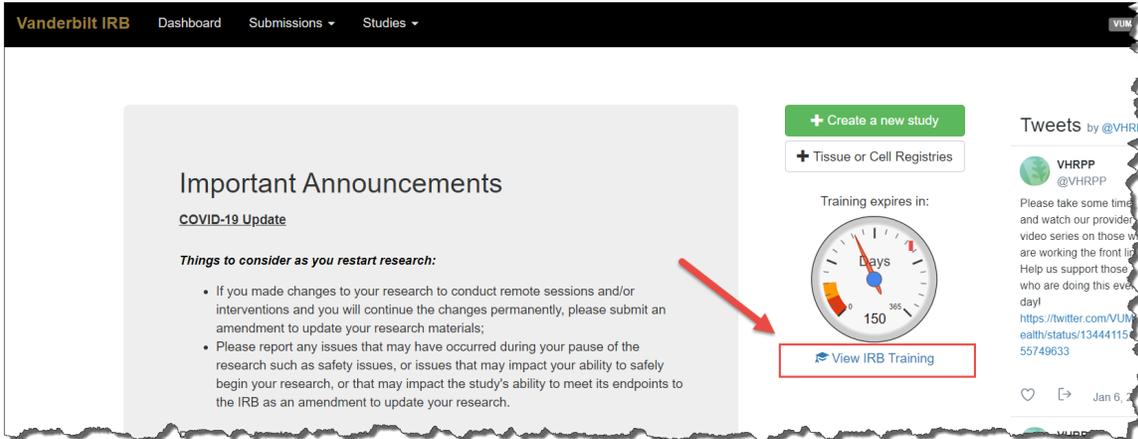
IRB Training expiration can be easily viewed on the Investigator Dashboard using the gauge displaying days until expiration.



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](#).

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

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.

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 [Download]
IRB Annual Training 2019 6/26/2019
IRB NYCU: Revised Common Rule sIRB Requirement 11/25/2019

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.).

IRB Training Summary

Name: ██████████
IRB Training Status: Requirement Met
Expiration Date: 6/12/2021

Training expires in:

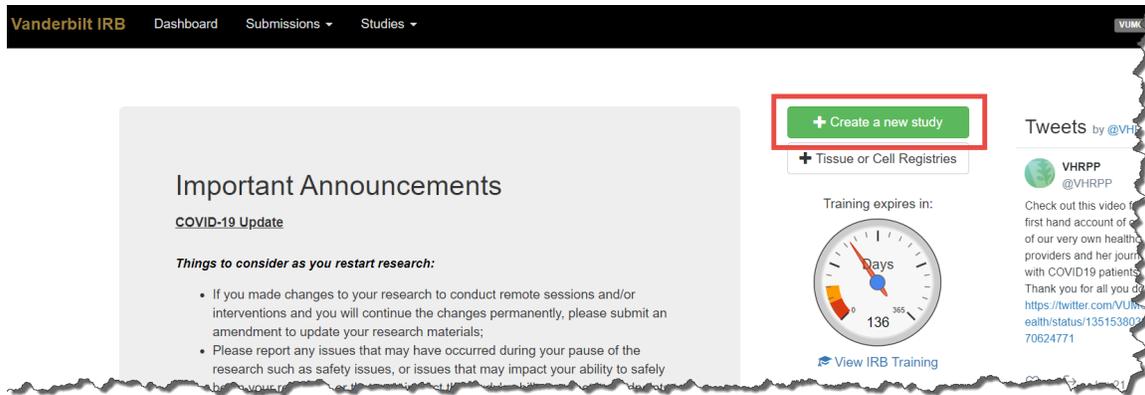


History
Implementation of Changes to the Common Rule for Research 1/30/2019
IRB Annual Training 2019 6/26/2019
IRB NYCU: Revised Common Rule sIRB Requirement 11/25/2019
Group 1. Biomedical Research Investigators and Key Personnel 1/16/2020
Group 2. Social Behavioral Investigators and Key Personnel 1/16/2020
VHRPP Annual Training - 2020 6/12/2020

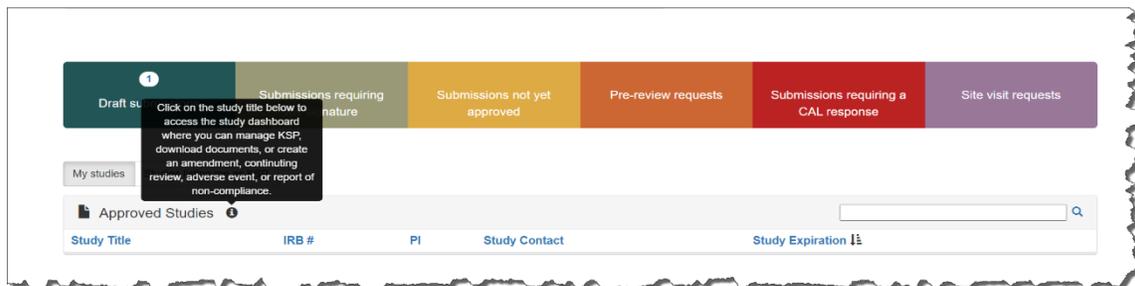
Look up another user:

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.



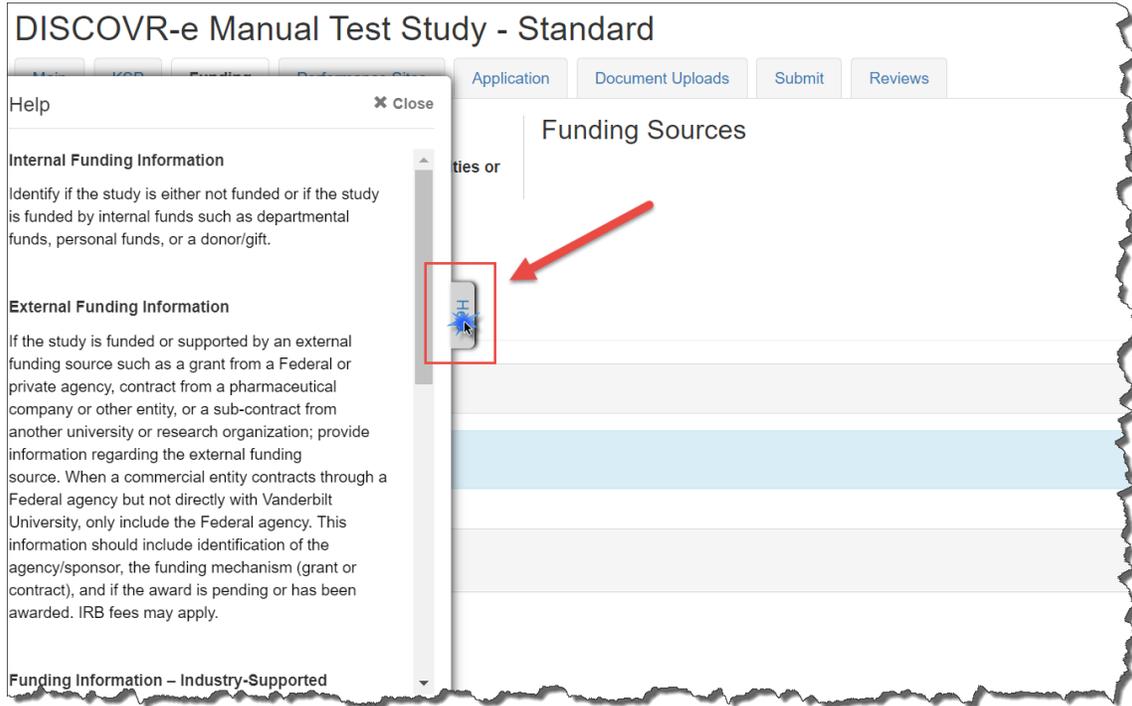
Throughout the website and application, you will find small black circle icons with an 'i' inside. These are information buttons. Hovering your mouse over these icons will display helpful information about that item. For example, hovering over this icon next to the Approved Studies heading displays information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



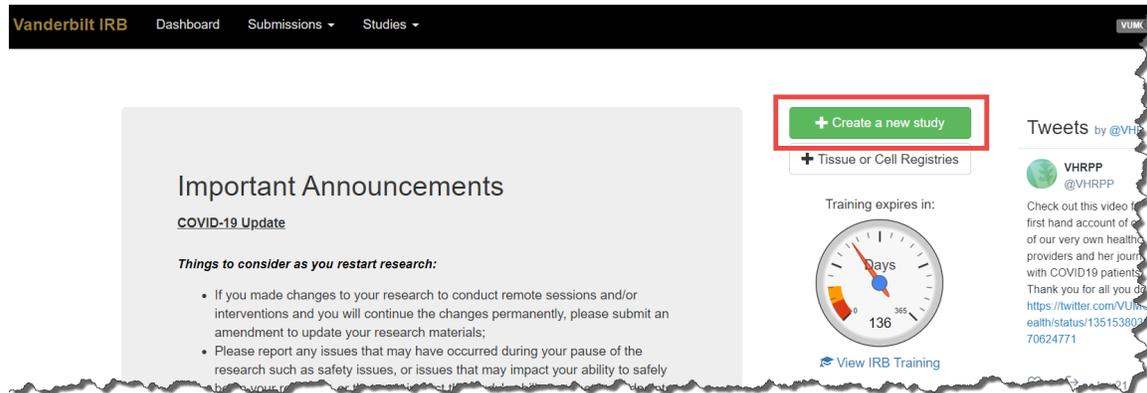
To expand the Help tab, click the [Help](#) tab which will slide out and provide information on how to complete the elements of each page from the KSP tab through Submit.



Submitting a New Study

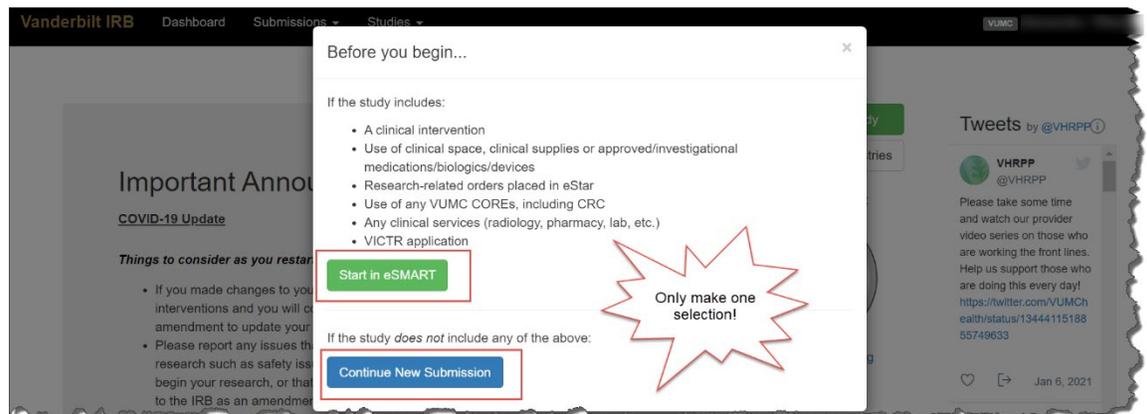
Submitting a new study through the DISCOVER-e portal does not require any special training. The following guide is a basic set of instructions and illustrations to help you in the submission process. If you have not logged into the system yet, please follow the instructions provided above.

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.*

The screenshot shows the 'New Study' form in the Vanderbilt IRB system. The form includes the following fields and options:

- Study Title
- Principal Investigator
- Is the PI a student, resident, or fellow? (Radio buttons for No and Yes)
- Study Coordinator
- Department Chair
- Division Chief
- Create New Study button (circled in red)

Annotations include:

- A blue box on the left with the text 'Complete your new study information here.' and red arrows pointing to the Study Title, Principal Investigator, and Study Coordinator fields.
- A blue box on the right with the text 'Include the name of the Department Chair or the Division Chief. Only one field is required for your new study submission.' and red arrows pointing to the Department Chair and Division Chief fields.

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

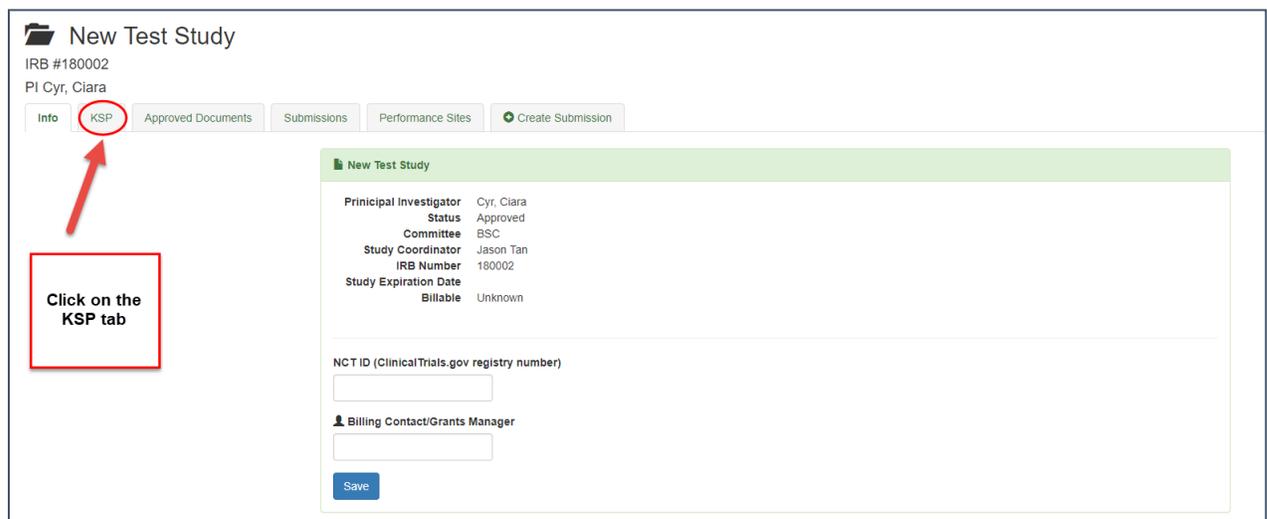
Selecting and Managing Key Study Personnel

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.

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...

IRB # [redacted]
PI [redacted]

Info KSP Approved Documents Submissions Funding Performance Sites Create Submission

Billing Contact/Grants Manager [redacted]

Current KSP History

VUNetID	First Name	Last Name	Department	Credentials	Phone	Role in Project	Accessing PHI (HIPAA)?	Human Subjects Training Expire	GCP Training Expire
[redacted]	[redacted]	[redacted]	Human Research Protection P	MD	615-875-9905	Principal Investigator	YES	13-Aug-2021	[N/A]
[redacted]	[redacted]	[redacted]	Human Research Protection P	BA, CIP	615-875-8961	[Select a Role]	Select	06-Jan-2024	23-Dec-2023

+ Add another:
Start typing to search by name, email, or VUnetID

Save

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.

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...

IRB # [redacted]
PI [redacted]

Info KSP Approved Documents Submissions Funding Performance Sites Create Submission

Billing Contact/Grants Manager [redacted]

Current KSP History

VUNetID	First Name	Last Name	Department	Credentials	Phone	Role in Project	Accessing PHI (HIPAA)?	Human Subjects Training Expire	GCP Training Expire
[redacted]	[redacted]	[redacted]	Human Research Protection P	MD	615-875-9905	Principal Investigator	YES	13-Aug-2021	[N/A]
[redacted]	[redacted]	[redacted]	Human Research Protection P	BA, CIP	615-875-8961	Research - Clinical	YES	06-Jan-2024	23-Dec-2023

+ Add another:
Start typing to search by name, email, or VUnetID

Save

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.

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...

IRB #180081
PI Alexander, Tiffany

Info | **KSP** | Approved Documents | Submissions | Funding | Performance Sites | Create Submission

Billing Contact/Grants Manager

Current KSP | History

You have the option of clicking the Restore button in the event you choose the wrong member of KSP to remove from the study. After selecting restore, click Save to document the

VUNetID	First Name	Last Name	Department	Credentials	Phone	Role in Project	Accessing PHI (HIPAA)?	Human Subjects Training Expire	GCP Training Expire
VUMC-LEXAT3	Tiffany	Alexander	Human Research Protection PI	MD	615-875-9905	Principal Investigator	YES	13-Aug-2021	[N/A]
VUMC-ARRINGJG	James	Arrington	Human-Research-Protection-PI	HA-GIP	616-874-6694	Research-Clinical	YES	06-Jan-2024	23-Dec-2023

+ Add another:
Start typing to search by name, email, or VUNetID

Save

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

New Test Study

IRB #180002
PI Cyr, Clara

Info | **KSP** | Approved Documents | Submissions | Performance Sites | Create Submission

Current KSP | **History**

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

Date Added	Date Removed	VUNetID	First Name	Last Name	Added By	Deleted By
02/05/2018		CYRC	Clara	Cyr		N/A
02/05/2018	03/02/2018	GUSTAVKD	Kevin	Gustavson		MILFORJ
03/20/2018		GUSTAVKD	Kevin	Gustavson	MILFORJ	N/A
02/05/2018		MILFORJ	Joshua	Milford		N/A
02/18/2019		STRAZNKL	Kristin	Straznicky	CYRC	N/A
02/05/2018		TANJW1	Jason	Tan		N/A

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.

DISCOVER-e Manual Test Study - Standard

Main | KSP | **Funding** | Performance Sites | Application | Document Uploads | Submit | **Funding Sources**

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

Funding Sources

Step 1: Answer these two questions.

Step 2: Click this button to Add a Funding Source

\$ Add or Import a Funding Source

Related Studies

No related studies have been added.

Add Related Studies

Step 3: Click this button to Add any Related Studies that also include this funding source.

← Back | Save | → Save and Continue

DISCOVER-e Manual Test Study

Main | KSP | Funding | Performance Sites

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 #
B.P. #

FACT# #
FACT# #

Import a Funding Source

Search by contract/grant number

Search

Or

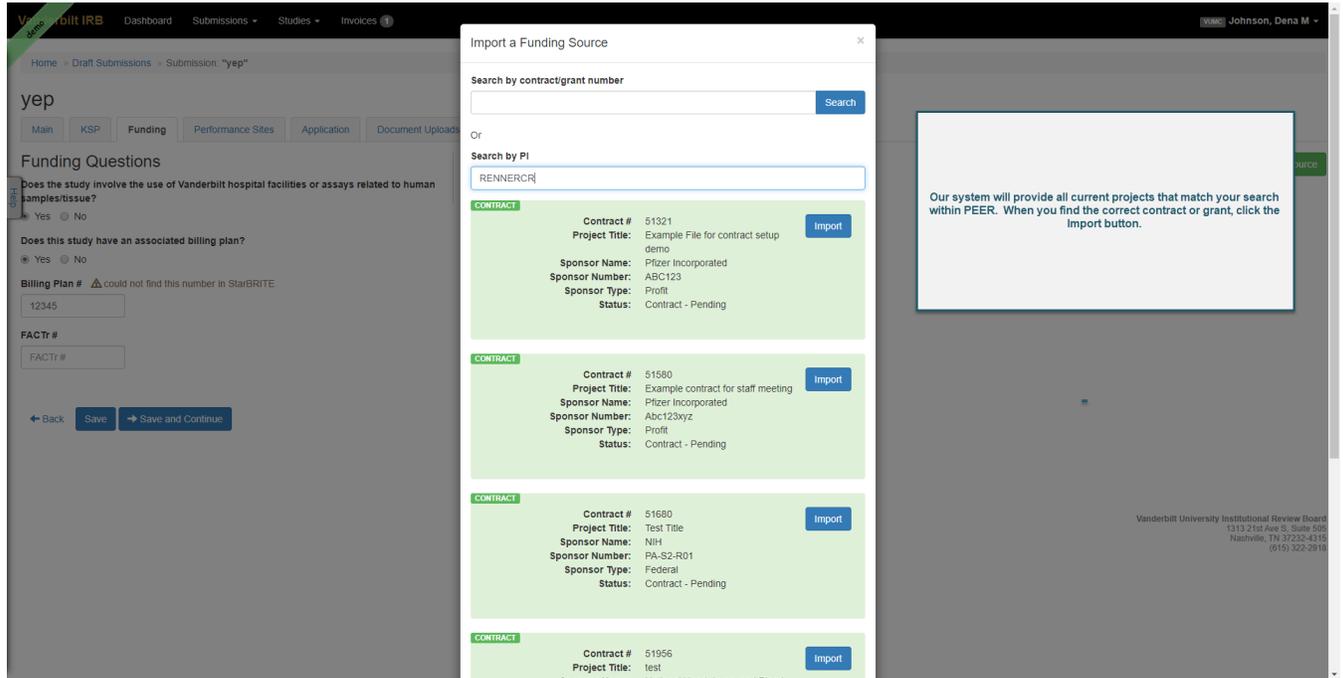
Search by PI

Add a new funding source Close

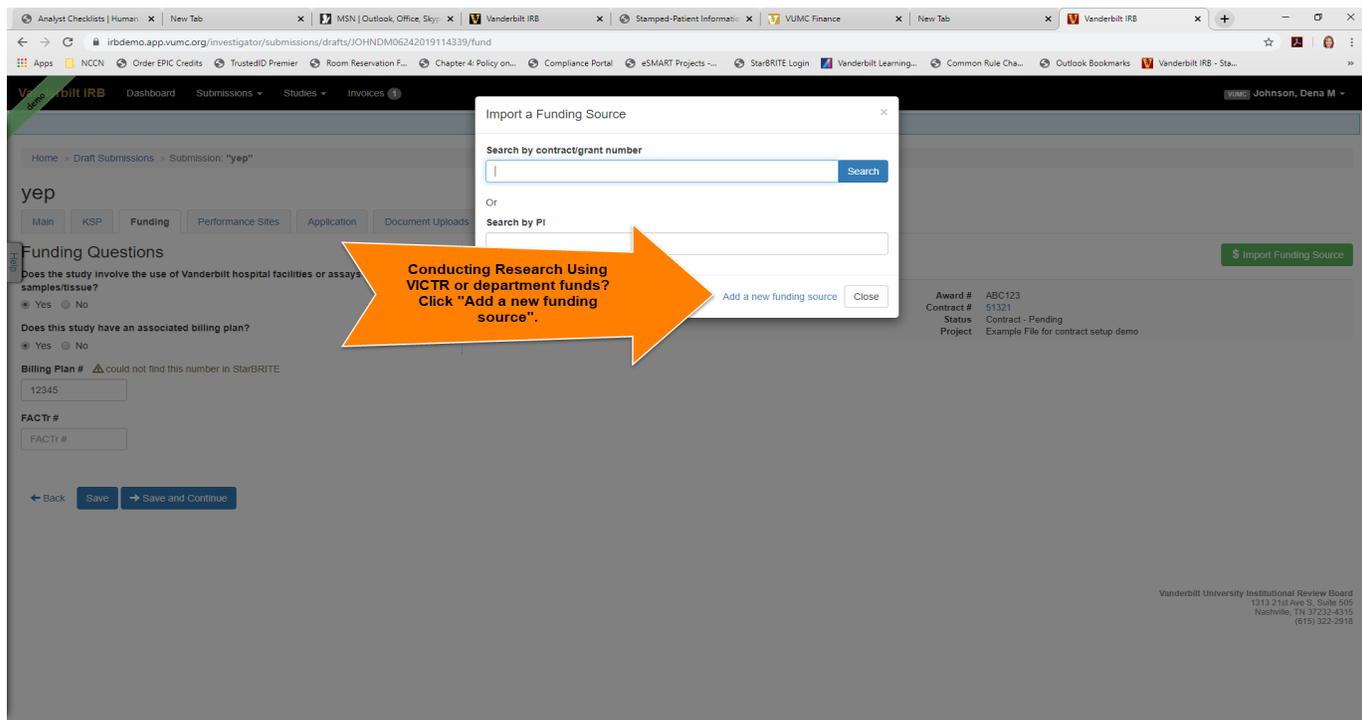
You can search by Contract or Grant number or Principal Investigator

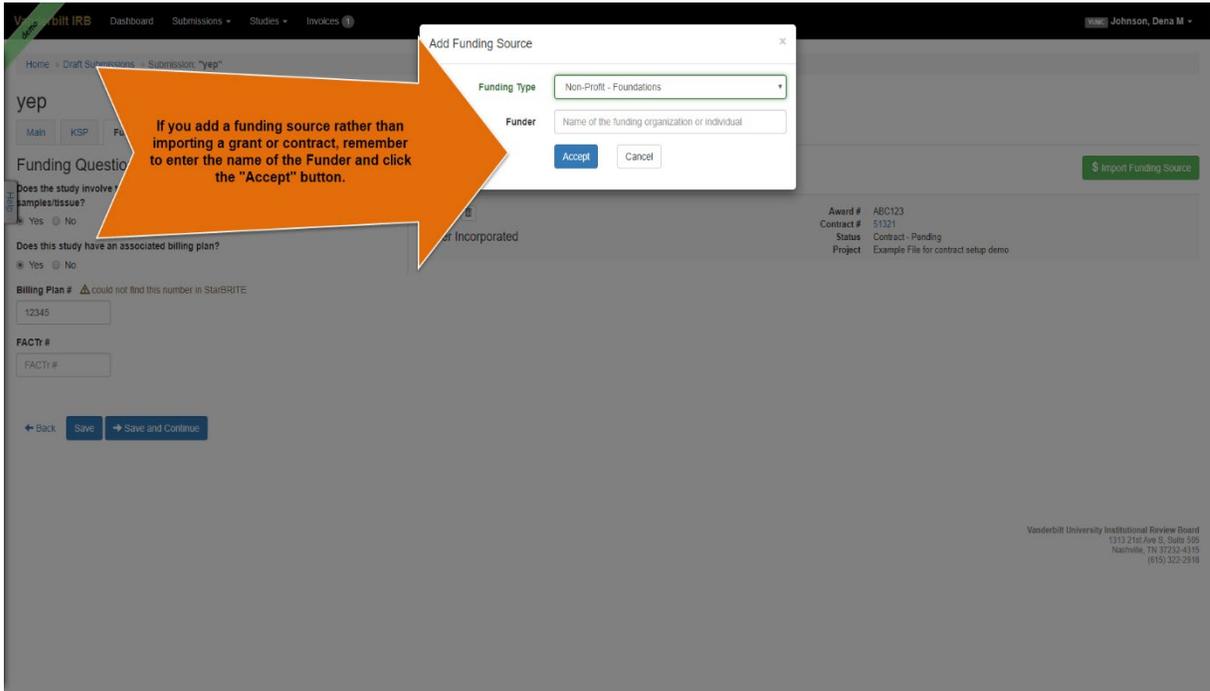
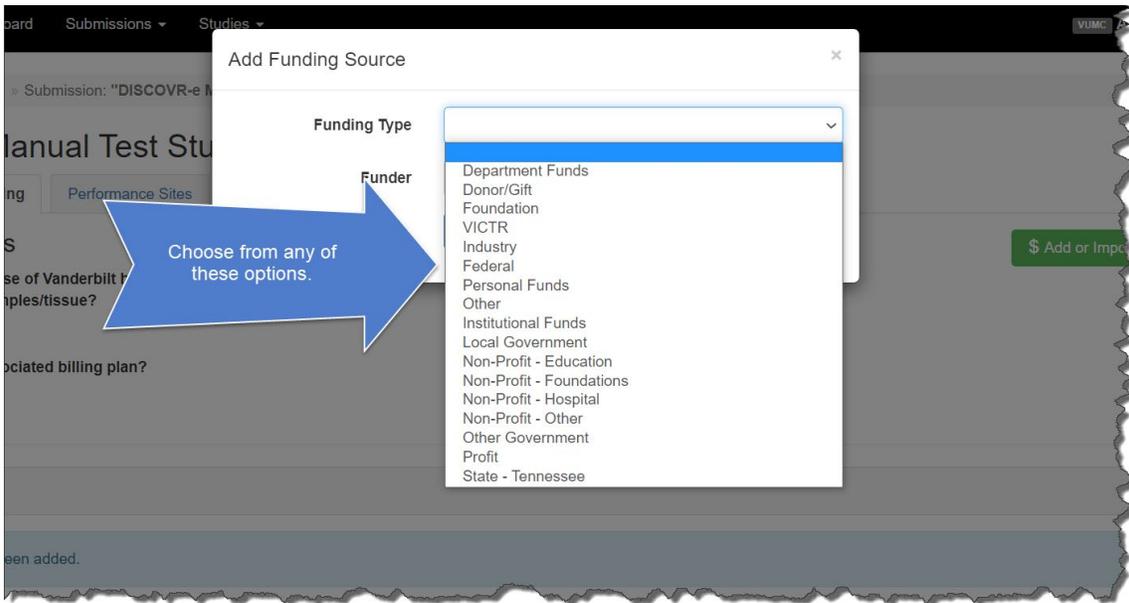
\$ Add or Import a Funding Source

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.





Vanderbilt IRB 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

FACTr #

← Back **Save** → Save and Continue

Funding Sources [\\$ Import Funding Source](#)

PROFIT	Award # ABC123
Pfizer Incorporated	Contract # 51321
	Status Contract - Pending
	Project Example File for contract setup demo

NON-PROFIT - FOUNDATIONS

NMNH

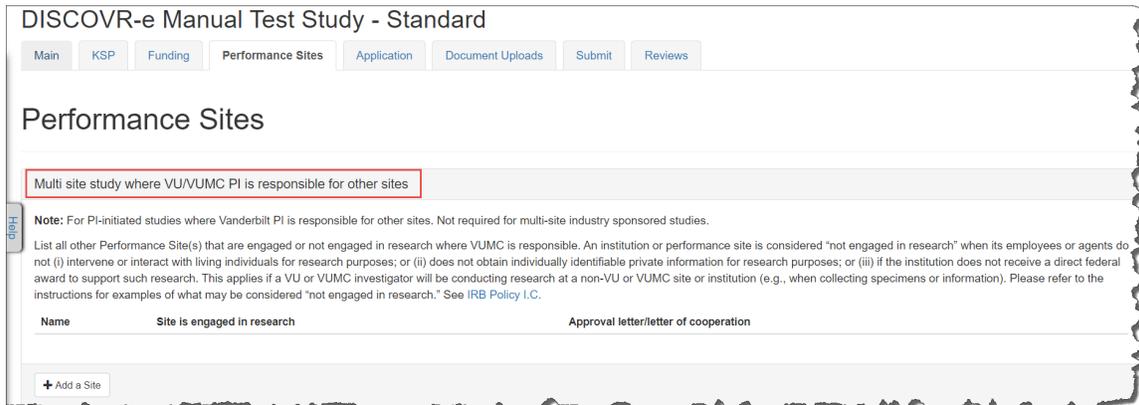
Remember to save your work!

Vanderbilt University Institutional Review Board
 1313 21st Ave S, Suite 505
 Nashville, TN 37232-4315
 (615) 322-2918

Completing the Performance Sites Tab

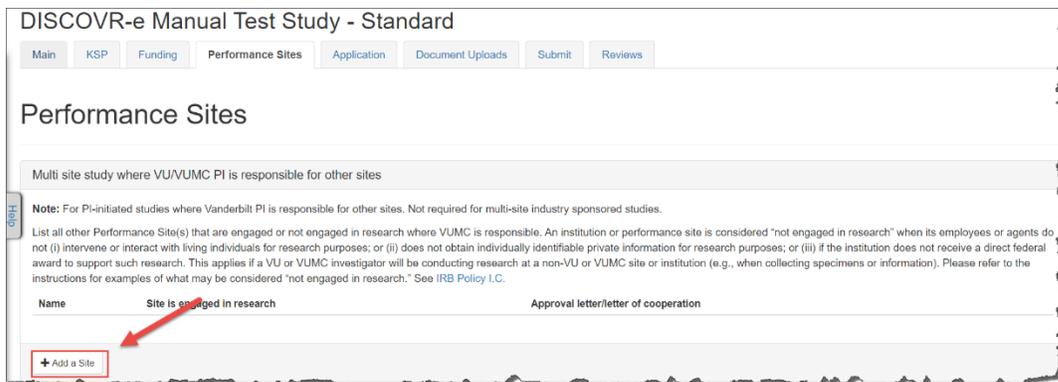
The Performance Sites tab will hold all the information about other sites involved in the study that are:

- 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/VUMC PI is responsible for other sites](#) section.



Enter the name of the site

Performance Sites

Multi site study where VU/VUMC PI is responsible for other sites

Note: For PI-initiated studies where Vanderbilt PI is responsible for other sites. Not required for multi-site industry sponsored studies.

List all other Performance Site(s) that are engaged or not engaged in research where VUMC is responsible. An institution or performance site is considered "not engaged in research" when its employees or agents do not (i) intervene or interact with living individuals for research purposes; or (ii) does not obtain individually identifiable private information for research purposes; or (iii) if the institution does not receive a direct federal award to support such research. This applies if a VU or VUMC investigator will be conducting research at a non-VU or VUMC site or institution (e.g., when collecting specimens or information). Please refer to the instructions for examples of what may be considered "not engaged in research." See IRB Policy I.C.

Name	Site is engaged in research	Approval letter/letter of cooperation	
<input type="text"/>	No	<input type="text"/>	<input type="button" value="Remove"/>

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

Performance Sites

Multi site study where VU/VUMC PI is responsible for other sites

Note: For PI-initiated studies where Vanderbilt PI is responsible for other sites. Not required for multi-site industry sponsored studies.

List all other Performance Site(s) that are engaged or not engaged in research where VUMC is responsible. An institution or performance site is considered "not engaged in research" when its employees or agents do not (i) intervene or interact with living individuals for research purposes; or (ii) does not obtain individually identifiable private information for research purposes; or (iii) if the institution does not receive a direct federal award to support such research. This applies if a VU or VUMC investigator will be conducting research at a non-VU or VUMC site or institution (e.g., when collecting specimens or information). Please refer to the instructions for examples of what may be considered "not engaged in research." See IRB Policy I.C.

Name	Site is engaged in research	Approval letter/letter of cooperation	
<input type="text"/>	No	<input type="text"/>	<input type="button" value="Remove"/>

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.

Performance Sites

Multi site study where VU/VUMC PI is responsible for other sites

Note: For PI-initiated studies where Vanderbilt PI is responsible for other sites. Not required for multi-site industry sponsored studies.

List all other Performance Site(s) that are engaged or not engaged in research where VUMC is responsible. An institution or performance site is considered "not engaged in research" when its employees or agents do not (i) intervene or interact with living individuals for research purposes; or (ii) does not obtain individually identifiable private information for research purposes; or (iii) if the institution does not receive a direct federal award to support such research. This applies if a VU or VUMC investigator will be conducting research at a non-VU or VUMC site or institution (e.g., when collecting specimens or information). Please refer to the instructions for examples of what may be considered "not engaged in research." See IRB Policy I.C.

Name	Site is engaged in research	Approval letter/letter of cooperation	
<input type="text"/>	No	Attached	<input type="button" value="Remove"/>

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

Performance Sites

Multi site study where VU/VUMC PI is responsible for other sites

Note: For PI-initiated studies where Vanderbilt PI is responsible for other sites. Not required for multi-site industry sponsored studies.

List all other Performance Site(s) that are engaged or not engaged in research where VUMC is responsible. An institution or performance site is considered "not engaged in research" when its employees or agents do not (i) intervene or interact with living individuals for research purposes; or (ii) does not obtain individually identifiable private information for research purposes; or (iii) if the institution does not receive a direct federal award to support such research. This applies if a VU or VUMC investigator will be conducting research at a non-VU or VUMC site or institution (e.g., when collecting specimens or information). Please refer to the instructions for examples of what may be considered "not engaged in research." See IRB Policy I.C.

Name	Site is engaged in research	Approval letter/letter of cooperation
<input type="text"/>	No	<input type="text"/>

+ Add a Site

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

Vanderbilt Serving as a Single IRB

This may apply when a VU or VUMC investigator collaborates with a non-VU or VUMC investigator or institution, or when VU or VUMC serves as a Coordinating Center. Note, if VUMC will not act as the IRB of record, those specific sites will require a letter of IRB approval. See IRB Policy IRB Policy I.C.

Site	Lead Site
------	-----------

+ Add a Site

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

Vanderbilt Serving as a Single IRB

This may apply when a VU or VUMC investigator collaborates with a non-VU or VUMC investigator or institution, or when VU or VUMC serves as a Coordinating Center. Note, if VUMC will not act as the IRB of record, those specific sites will require a letter of IRB approval. See IRB Policy IRB Policy I.C.

Site	Lead Site
------	-----------

+ Add a Site

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

+ Add a Site

Vanderbilt Serving as a Single IRB

This may apply when a VU or VUMC investigator collaborates with a non-VU or VUMC investigator or institution, or when VU or VUMC serves as a Coordinating Center. Note, if VUMC will not act as the IRB of record, those specific sites will require a letter of IRB approval. See IRB Policy IRB Policy I.C.

Site Lead Site

Remove

+ Add a Site

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

+ Add a Site

Vanderbilt Serving as a Single IRB

This may apply when a VU or VUMC investigator collaborates with a non-VU or VUMC investigator or institution, or when VU or VUMC serves as a Coordinating Center. Note, if VUMC will not act as the IRB of record, those specific sites will require a letter of IRB approval. See IRB Policy IRB Policy I.C.

Site Lead Site

Johns Hopkins Health System & Johns Hopkins Hospital - FWA00006087 Remove

Johns Hopkins Health System & Johns Hopkins Hospital - FWA00006067

Johns Hopkins University School of Medicine - FWA00005752

Johns Hopkins All Children's Hospital - FWA00005752

Additional Single IRB Information

Requested Sites

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.

Additional Single IRB Information

Requested Sites

Please list performance sites (including primary contact and phone number) not available above.

Type in any site that is not available from the list in the above section.

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.

Site	Lead Site	Remove
Johns Hopkins University School of Medicine - FWA00005752	<input type="checkbox"/>	<input type="button" value="Remove"/>
University of Utah - FWA00003745	<input type="checkbox"/>	<input type="button" value="Remove"/>
Vanderbilt University Medical Center - FWA00005756	<input checked="" type="checkbox"/>	<input type="button" value="Remove"/>
University of Maryland Baltimore - FWA00007145	<input type="checkbox"/>	<input type="button" value="Remove"/>

+ Add a Site

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*.

Site	Lead Site	Remove
Johns Hopkins University School of Medicine - FWA00005752	<input type="checkbox"/>	<input type="button" value="Remove"/>
University of Utah - FWA00003745	<input type="checkbox"/>	<input type="button" value="Remove"/>
Vanderbilt University Medical Center - FWA00005756	<input checked="" type="checkbox"/>	<input type="button" value="Remove"/>
University of Maryland Baltimore - FWA00007145	<input type="checkbox"/>	<input type="button" value="Remove"/>

+ Add a Site

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?*

Have you completed the Vanderbilt Reliance Interest Form to ask the VUMC IRB to serve as the Single IRB?

Yes No

Coordinating Center

Is a coordinating center managing IRB submissions?

Yes No

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

Have you completed the Vanderbilt Reliance Interest Form to ask the VUMC IRB to serve as the Single IRB?

Yes No

Coordinating Center

Is a coordinating center managing IRB submissions?

Yes No

[← Back](#) [Save](#) [→ Save and Continue](#)

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.

Have you completed the Vanderbilt Reliance Interest Form to ask the VUMC IRB to serve as the Single IRB?

Yes No

Please complete the Vanderbilt Reliance Interest Survey here: [Vanderbilt Reliance Interest Survey](#)

Coordinating Center

Is a coordinating center managing IRB submissions?

Yes No

[← Back](#) [Save](#) [→ Save and Continue](#)

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.

Coordinating Center

Is a coordinating center managing IRB submissions?

Yes No

Name **1**

Contact name **2**

Contact email **3**

Contact phone **4**

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.

Have you completed the Vanderbilt Reliance Interest Form to ask the VUMC IRB to serve as the Single IRB?

Yes No

Please complete the Vanderbilt Reliance Interest Survey here: [Vanderbilt Reliance Interest Survey](#)

Coordinating Center

Is a coordinating center managing IRB submissions?

Yes No 1

← Back Save → Save and Continue 2

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.

DISCOVER-e Manual

Main KSP Funding Performance Sites Application Document Uploads Submit Reviews

Application Submission Summary

Progress: [Progress Bar]

Application is saved and complete → Continue

Download Application

As you input information into the "Wizard," it will build a tailored IRB application based on your responses.

Once an application tab is complete and you are ready to proceed to the next, click the "Save and continue" button at the bottom of the form to start the next tab. Continue this process until you have reached the end of the application.

Study Type and Performance Site Information ✓ complete

Study Purpose and Description ✓ complete

Research, Activities, Procedures, and Schedule of Events for Study Participants ✓ complete

Data and Safety ✓ complete

Subject Population(s) ✓ complete

Recruitment

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.

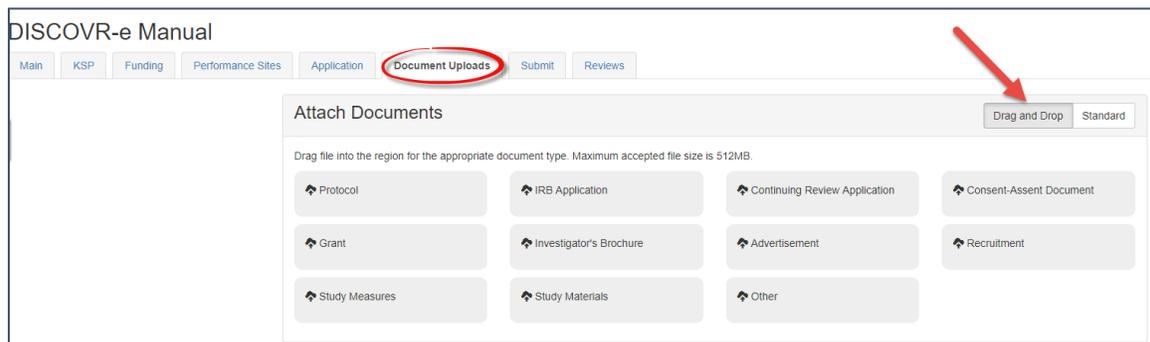
You may choose to download an electronic version of the IRB Application by clicking the *Download Application* button as shown in the example above.

To proceed to the next section of the submission process, click the [Continue](#) button.

Document Uploads

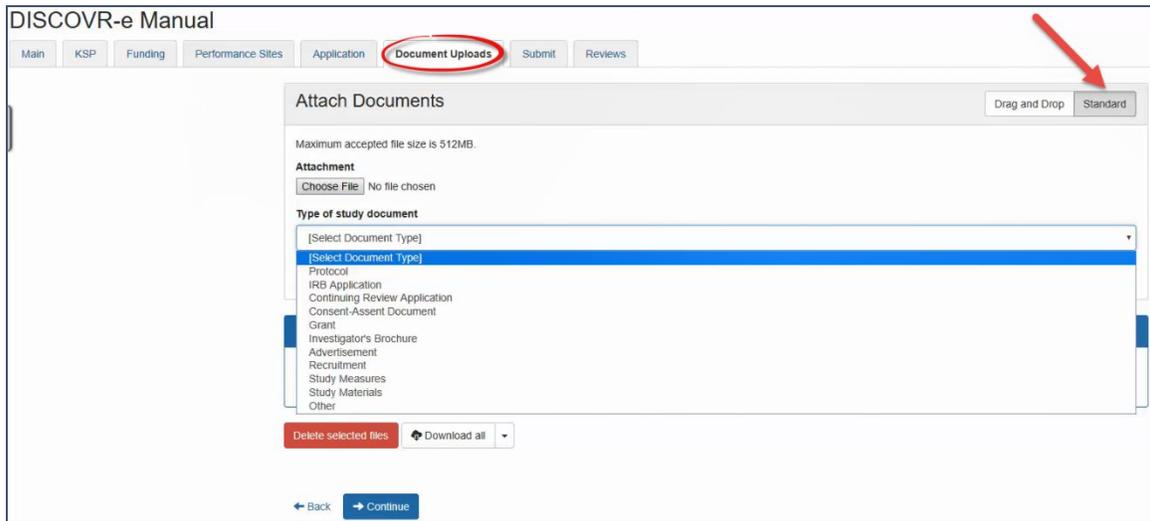
The Documents Uploads section is where you will attach/upload additional study documents such as consent forms, protocols, questionnaires, and any other study related documents or materials. Uploading documents is easy! You may upload/attach documents from locations saved on your computer by dragging 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.

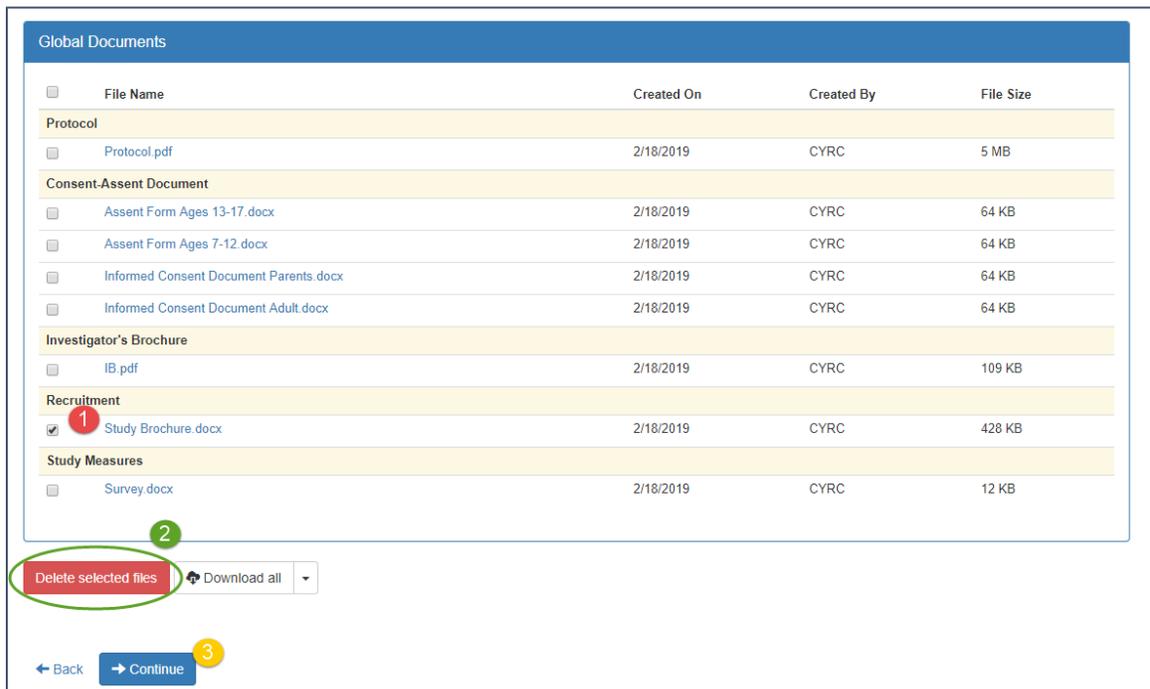


To upload/attach a document the standard way, click the [Standard](#) button to activate it. Click the [Choose File](#) button under the [Attachment](#) section to search your computer for the item you would like to attach. Select the item and then click the [Open](#) button. The item you selected will 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.



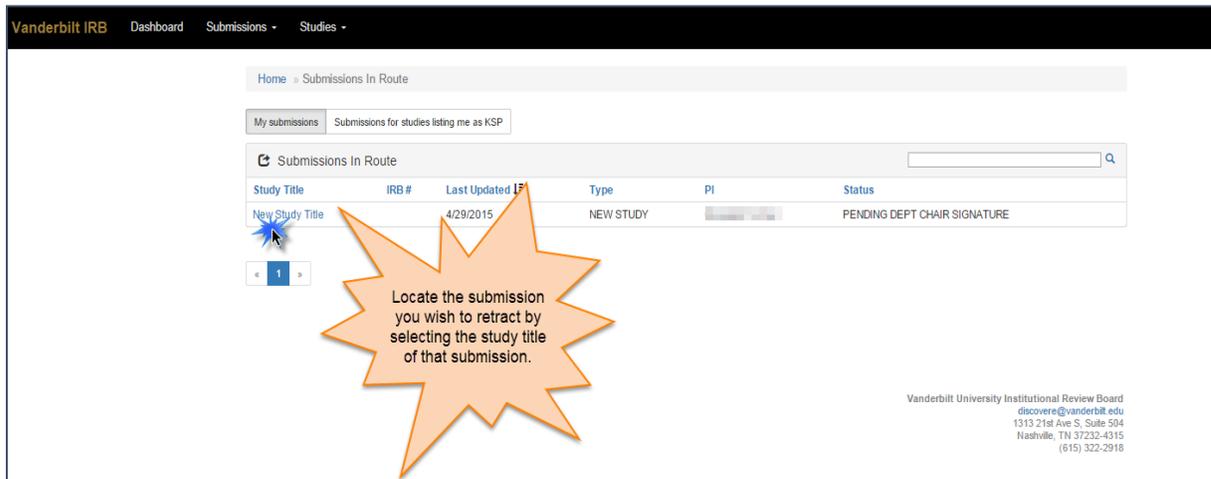
If you would like to delete an attachment, click the box next to item you wish to remove then click the *Delete Selected Files* button.



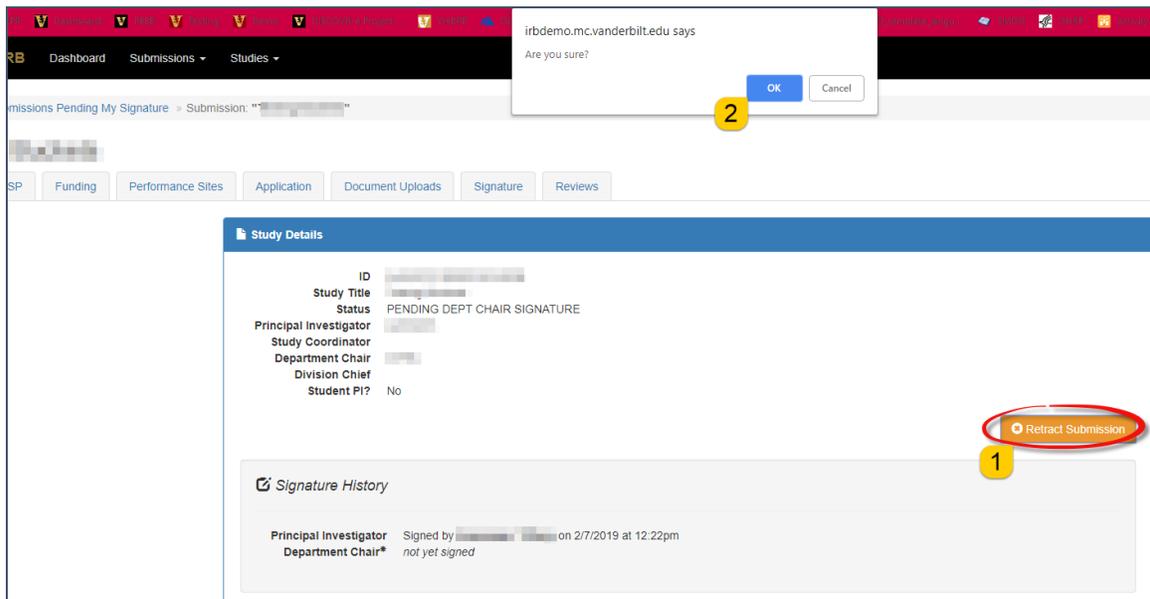
To continue with submission process, click the *Continue* button.

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

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.

Vanderbilt IRB Dashboard Submissions Studies

"New Study Title" has been retracted and sent back to draft status

Home > Draft Submissions

Create a new study submission

Draft Submissions

Study Title	IRB #	Last Updated	Type	PI	Status
New Study Title		4/29/2015	NEW STUDY		DRAFT
		4/28/2015	NEW STUDY		
		4/23/2015	CONTINUING REVIEW		
		4/22/2015	AMENDMENT		
		4/21/2015	AMENDMENT		
		4/13/2015	AMENDMENT		

Your submission should now be located within the "Draft Submissions" region.

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

Home > Draft Submissions > Submission: "DISCOVER-e Manual"

DISCOVER-e Manual

Main KSP Funding Performance Sites Application Document Uploads Submit Reviews

Study Title
DISCOVER-e Manual

Principal Investigator
Cyr, Ciara - CYRC - VUMC

Is the PI a student, resident, or fellow? No Yes

Study Coordinator

Department Chair
Cyr, Ciara - CYRC - VUMC

Division Chief

Save Save and Continue

Delete

Navigate through your study tabs to edit any information within your submission.

If you want to delete the submission, simply click the "Delete" button.

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.

Home » Draft Submissions » Submission: "DISCOVER-e Manual"

DISCOVER-e Manual

Main KSP Funding Performance Sites Application Document Uploads **Submit** Reviews

After making your edits and saving your work, advance to the "Submit" tab and submit your submission to re-route for appropriate signatures.

Your submission is ready to be submitted.

Click the submit button to start the signature process. Once all required parties have signed off on the submission, it will be sent to the IRB for review.

[Submit](#)

[Debug info](#)

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 number in this box reflects the number of items with a requested pre-review. Select this button to view all requests.

My studies Studies listing me as KSP

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
VICC NEU1424: Quantitative High-Field Magnetic Resonance...				11/30/2019
- New Study, VUMC, IRB of Record, Standard,...				12/12/2019
sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...				

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*.

Vanderbilt IRB Dashboard Submissions Studies

Home » Submissions in Pre-review

[My submissions](#) [Submissions for studies listing me as KSP](#)

Submissions in Pre-review

Study Title	IRB #	Last Updated	Type	PI	Status
Umbrella Test IRB# 141738 Autonomic: Angiotensin-(1-7)...	150093	4/1/2015	NEW STUDY	Kristin Straznicky	REQUESTING PRE-REVIEW CHANGES

1

All of your submissions that are currently in pre-review will appear on this page. This view can be sorted by study title, IRB#, date, type, and Principal Investigator.

Click on the study title to respond to the pre-review

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.

Test Expedited new study:

Submission Type: NEW STUDY
 Status: REQUESTING PRE-REVIEW CHANGES
 ID: STRAZNKL03302015124639

Please address the following items:
 General issues and comments Last update: 3/30/2015 2:57pm

A pre-review has been conducted on this submission. Please respond to the requested changes. Please keep in mind these are pre-review recommendations and you are free to disagree with any suggested change. If you do not wish to make a suggested revision, please consider providing a rationale for review by the committee/subcommittee.

Please submit an Assent Form for children 7-12.

Issues and comments on your application

Subject Population(s)

- If individuals under the age of 18 will be enrolled on this study, please select Children/minors.

Recruitment

- Please confirm if flyers will be used for recruitment.

Pre-Review History

Status	Changed By	Changed On	Emailed On	Comments
REQUESTING PRE-REVIEW CHANGES	Straznicki, Kristin Leigh	3/30/2015 2:57pm	3/30/2015 2:57pm	A pre-review has been conducted...

[Re-submit to Analyst](#)

Annotations:
 - Blue arrow: This item gives a summary of changes requested to the IRB electronic application.
 - Orange callout: This item shows general comments and changes requested to attached documents.

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.

Summary | [Download Application](#)

Pre-Review Comments

Study Type and Performance Site Information

- Type of study:
 - Regarding the study type, please consider changing this study to an Exempt study as this would best meet the description provided. 2019-02-19 08:21:59 (CYRC)

Study Purpose and Description

- Provide a brief abstract of the study in lay language. The IRB Committees are comprised of scientists with varied backgrounds, non-scientists, and community members.
 - Please include additional information including a purpose statement. 2019-02-19 08:22:16 (CYRC)

Sidebar (IRB 5):

- Study Type and Performance Site Information: complete, comments
- Study Purpose and Description: complete, comments (highlighted)
- Research, Activities, Procedures, and Schedule of Events for Study Participants: complete
- Data and Safety: complete
- Subject Population(s): complete
- Recruitment: complete
- Radiation Procedures and Radioactive Drugs: complete
- Drugs, Devices, Biologics: complete

Annotations:
 - Red arrow: Points to the highlighted 'Study Purpose and Description' section in the sidebar.
 - Blue box: Click on each tab to make changes and review comments.
 - Green box: Sections of the IRB Application with changes requested will be highlighted.

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.

Please identify ALL applicable recruitment methods:
* must provide value

- N/A
- Flyers
- Internet
- Letter
- Departmental Research Boards
- Mass E-mail Solicitation
- Newspaper
- Posters
- ResearchMatch (IRB 090207)
- Radio
- Telephone
- Television
- Social Media
- Other

Change History (1)

Comments (1)

Please confirm if flyers will be used for recruitment.
2015-03-30 14:56:17 (staznki)

Add comment

Changes made to the application will be recorded in the change history.

Add a comment for any changes requested but not made.

Requested changes will be included in the comments box for the specific item.

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.

Main | KSP | Funding | Performance Sites | Application | Document Uploads | Pre-review | Reviews

Attach Documents

Drag and Drop | Standard

Drag file into the region for the appropriate document type. Maximum accepted file size is 512MB.

- Protocol
- IRB Application
- Continuing Review Application
- Consent-Assent Document
- Grant
- Investigator's Brochure
- Advertisement
- Recruitment
- Study Measures
- Study Materials
- Other

Global Documents

File Name	Created On	Created By	File Size
Protocol			
PRO.pdf	8/15/2018	ALEXAT3	5 MB
Consent-Assent Document			
Part2_LocalConsent_v2.docx	8/15/2018	ALEXAT3	29 KB
Part1_MasterConsent_v2.docx	8/15/2018	ALEXAT3	29 KB
Investigator's Brochure			
IB.pdf	8/15/2018	ALEXAT3	109 KB
Study Materials			
Flyer.docx	8/15/2018	ALEXAT3	12 KB

Delete selected files | Download all

Back | Continue

Attach any documents with requested changes. Track changes to all documents.

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.

Submission Type: NEW STUDY
 Status: REQUESTING PRE-REVIEW CHANGES
 ID: [REDACTED]

Return to the pre-review tab once all comments have been addressed.

Please address the following items:
 Issues and comments on your application

Study Type and Performance Site Information

- Regarding the study type, please consider changing this study to an Exempt study as this would best meet the description provided.

Study Purpose and Description

- Please include additional information including a purpose statement.

Pre-review History

Status	Changed By	Changed On	Emailed On	Comments
REQUESTING PRE-REVIEW CHANGES	Cyr, Ciara	2/19/2019 8:22am	2/19/2019 8:23am	no comment
SUBMITTED	Ciara	8/15/2018 2:31pm		no comment
REQUESTING PRE-REVIEW CHANGES	Ciara	8/15/2018 2:31pm		
SUBMITTED	Alexander, Tiffany	8/15/2018 1:51pm	8/15/2018 1:51pm	Changed Study Type to: Request...
REQUESTING PRE-REVIEW CHANGES	Cyr, Ciara	8/15/2018 1:47pm	8/15/2018 1:47pm	This pre-review is opened for revisions...

Re-submit to Analyst

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.

Pre-Review Comments

Enter Comments Below

Comments are optional...

1

Cancel Re-submit to Analyst 2

After checking that all changes/comments have been addressed, insert any comments you would like to include and then 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.

Study Title	IRB #	PI	Study Contact	Study Expiration
VICC NEU1424: Quantitative High-Field Magnetic Resonance...				11/30/2019
- New Study, VUMC, IRB of Record, Standard,...				12/12/2019
sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...				

From the study page, click [Create Submission](#).

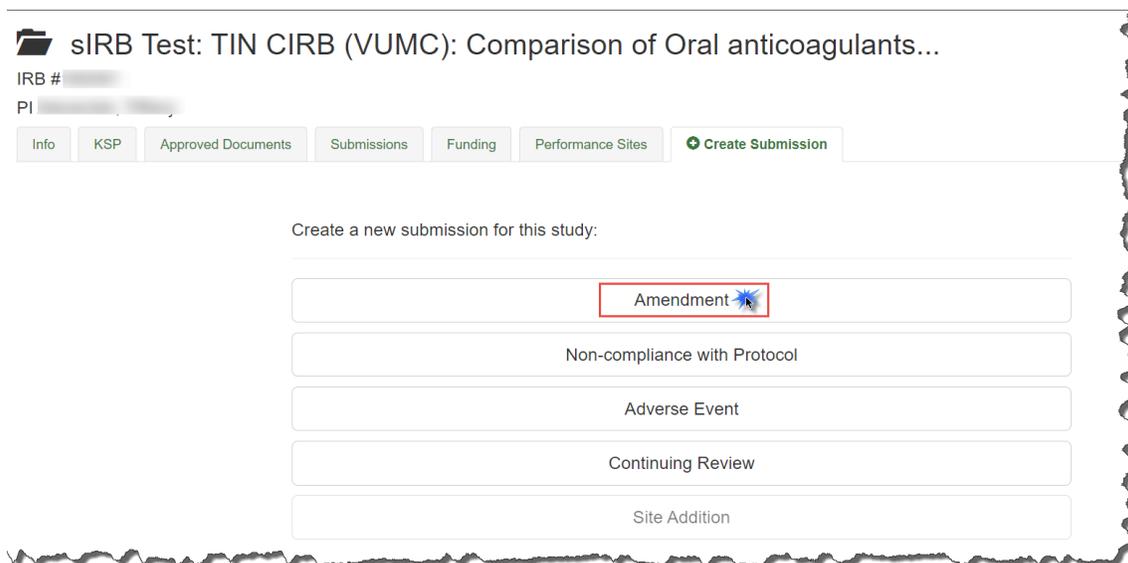
sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants for extended VEnous Thromboembolism (COVET)

Principal Investigator: [Redacted]
Status: Approved
Committee: HS2
Study Coordinator: None Listed
IRB Number: [Redacted]
Study Expiration Date: [Redacted]
Billable: No
Accrual Goal: 50

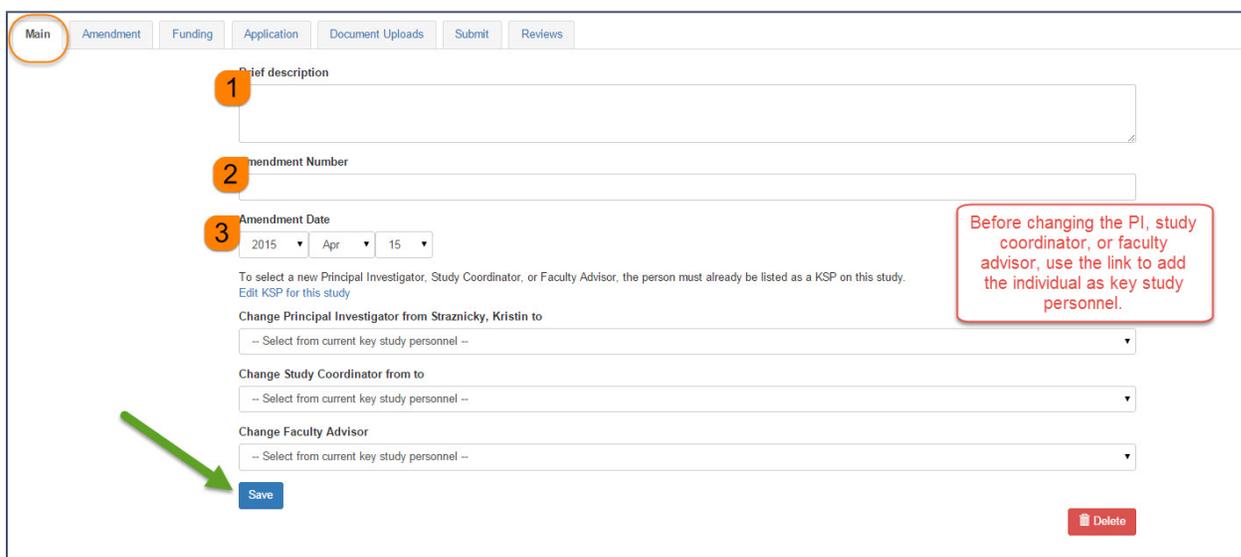
NCT ID (ClinicalTrials.gov registry number): [Redacted]

Save

This will open the study page. Using the [Create Submission](#) tab on the study page, select to create a new amendment submission.



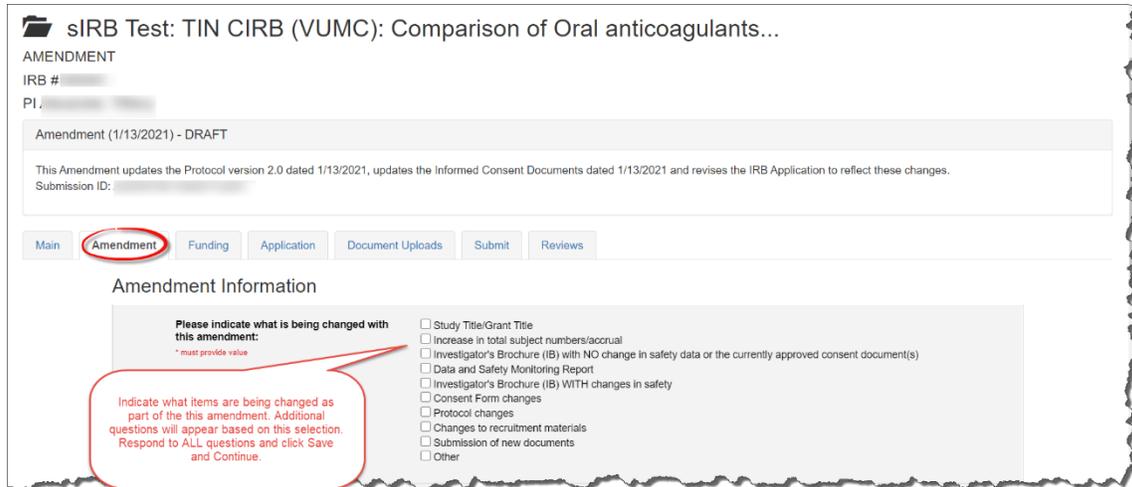
Begin by completing the [Main page](#) of the amendment. Save your changes at the bottom of the page before moving forward. Changes that are not saved before moving to a new tab may be lost.



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.



sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...

AMENDMENT

IRB # [REDACTED]

PI. [REDACTED]

Amendment (1/13/2021) - DRAFT

This Amendment updates the Protocol version 2.0 dated 1/13/2021, updates the Informed Consent Documents dated 1/13/2021 and revises the IRB Application to reflect these changes.
Submission ID: [REDACTED]

Main **Amendment** Funding Application Document Uploads Submit Reviews

Amendment Information

Please indicate what is being changed with this amendment:
* must provide value

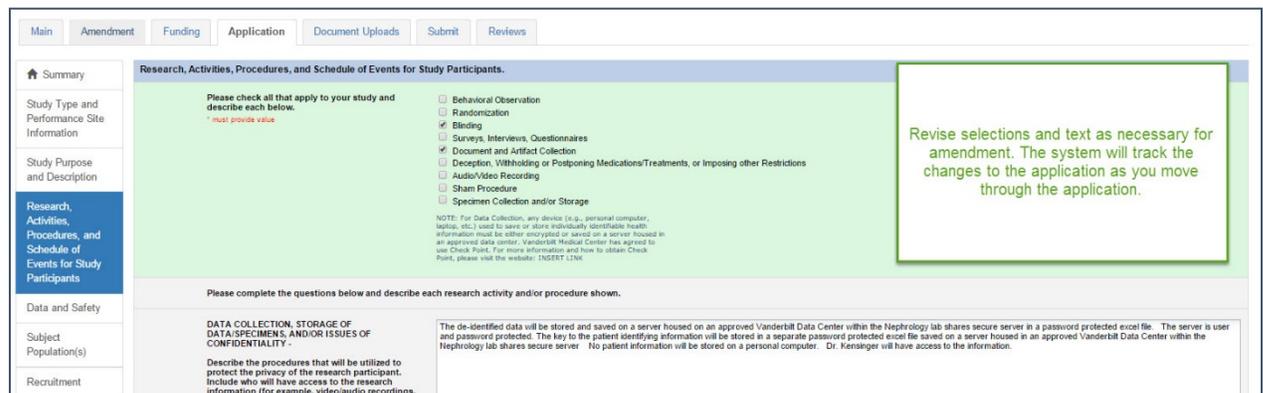
Indicate what items are being changed as part of this amendment. Additional questions will appear based on this selection. Respond to ALL questions and click Save and Continue.

- Study Title/Grant Title
- Increase in total subject numbers/accrual
- Investigator's Brochure (IB) with NO change in safety data or the currently approved consent document(s)
- Data and Safety Monitoring Report
- Investigator's Brochure (IB) WITH changes in safety
- Consent Form changes
- Protocol changes
- Changes to recruitment materials
- Submission of new documents
- Other

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.



Main Amendment **Application** Funding Document Uploads Submit Reviews

Summary

Study Type and Performance Site Information

Study Purpose and Description

Research, Activities, Procedures, and Schedule of Events for Study Participants

Data and Safety

Subject Population(s)

Recruitment

Research, Activities, Procedures, and Schedule of Events for Study Participants.

Please check all that apply to your study and describe each below.
* must provide value

- Behavioral Observation
- Randomization
- Blinding
- Surveys, Interviews, Questionnaires
- Document and Artifact Collection
- Deception, Withholding or Postponing Medications/Treatments, or Imposing other Restrictions
- Audio/Video Recording
- Sham Procedure
- Specimen Collection and/or Storage

NOTE: For Data Collection, any device (e.g., personal computer, tablet, etc.) used to store or store individually identifiable health information must be either encrypted or saved on a server housed in an approved data center. Vanderbilt Medical Center has agreed to use Check Point. For more information and how to obtain Check Point, please visit the website: INSERT LINK

Please complete the questions below and describe each research activity and/or procedure shown.

DATA COLLECTION, STORAGE OF DATA/SPECIMENS, AND/OR ISSUES OF CONFIDENTIALITY -

The de-identified data will be stored and saved on a server housed on an approved Vanderbilt Data Center within the Nephrology lab shares secure server in a password protected excel file. The server is user and password protected. The key to the patient identifying information will be stored in a separate password protected excel file saved on a server housed in an approved Vanderbilt Data Center within the Nephrology lab shares secure server. No patient information will be stored on a personal computer. Dr. Kensinger will have access to the information.

Describe the procedures that will be utilized to protect the privacy of the research participant. Include who will have access to the research information (for example, video/audio recordings,

Revise selections and text as necessary for amendment. The system will track the changes to the application as you move through 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 screenshot shows the 'Document Uploads' tab for an amendment (3/31/2015) - DRAFT. The submission ID is STRAZNKL03312015133028. The interface includes a navigation bar with 'Main', 'Amendment', 'Funding', 'Application', 'Document Uploads', 'Submit', and 'Reviews'. The 'Attach Study Files' section has two tabs: 'Drag and Drop' (selected) and 'Standard'. Below are categories for uploading files: Protocol, IRB Application, Continuing Review Application, Consent-Assent Document, Grant, Investigators Brochure, Advertisement, Recruitment, Study Measures, Study Materials, and Other. A blue arrow points to the 'Drag and Drop' tab with the text 'Drag and Drop revised documents into file type'. A yellow callout box points to the 'Standard' tab with the text 'The upload method can be changed to the standard format.' Below the categories is a 'Submission Documents' table with columns: File Name, Type, Created On, Created By, and File Size. The table contains one row: 'Revised ICD.docx', 'Consent-Assent Document', '3/31/2015', 'STRAZNKL', and '11 KB'. Below the table are buttons for 'Delete selected files', 'Download all', 'Back', and 'Continue'. A red box contains the text: 'Select continue after all affected documents have been attached.'

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 screenshot shows the 'Submit' tab for an amendment (4/15/2015) - DRAFT. The submission ID is STRAZNKL04152015143003. The navigation bar includes 'Main', 'Amendment', 'Funding', 'Application', 'Document Uploads', 'Submit', and 'Reviews'. A large grey box contains the text: 'Your submission is ready to be submitted. Click the submit button to start the signature process. Once all required parties have signed off on the submission, it will be sent to the IRB for review.' A green 'Submit' button is highlighted with a blue arrow. Below the box is a 'Debug info' link.

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.

	<p>Principal Investigator's Assurance Statement</p> <p>I certify that the information provided in this application is complete and accurate.</p> <p>I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to the study protocol and any stipulations imposed by the Vanderbilt University Institutional Review Board.</p> <p>I understand that should I use the project described in this application as a basis for a proposal for funding (either intramural or extramural), it is my responsibility to ensure that the human participants' involvement as described in the funding proposal(s), is consistent in principle to that contained in this application. I will submit modifications and/or changes to the IRB as necessary, in the form of an amendment, to ensure these are consistent.</p> <p>I agree to comply with all VU policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human participants in research, including, but not limited to:</p> <ul style="list-style-type: none">• Ensuring all investigators and key study personnel have completed the VU human subjects training program.• Ensuring the project is conducted by qualified personnel following the approved IRB application and study protocol.• Implementing no changes in the approved IRB application, study protocol, or informed consent document without prior IRB approval in accordance with VU IRB policy (except in an emergency, if necessary to safeguard the well-being of a human participant, and will report to the IRB within 5 days of such change).• Obtaining the legally effective informed consent from human participants or their legally responsible representative, using only the currently approved date-stamped informed consent documents, and providing a copy to the participant, if applicable.• Promptly report to the IRB, Data Safety and Monitoring Boards, sponsors and appropriate federal agencies any adverse experiences and all unanticipated problems involving risks to human subjects or others that occur in the course of the research in accordance with Vanderbilt University IRB Policies and Procedures.• If unavailable to conduct this research personally, as when on sabbatical leave or vacation, I will arrange for another investigator to assume direct responsibility for the study. Either this person is named as another investigator in this application, or I will notify the IRB of such arrangements.• Promptly providing the IRB with any information requested relative to the project.• Promptly and completely complying with an IRB decision to suspend or withdraw approval for the project.• Obtaining Continuing Review approval prior to the date the approval for the study expires. I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all study activity must cease until IRB approval is granted.• Maintain accurate and complete research records, including, but not limited to, all informed consent documents for 3 years from the date of study completion.• Maintain any authorization documents to use or disclose PHI for 6 years from the date authorization is obtained, and• Fully informing the VU IRB of all locations in which human participants will be recruited for this project and being responsible for obtaining and maintaining current IRB approvals/letters of cooperation when applicable. <p>Sign Here</p> <p>Please enter your e-password in order to electronically sign this submission. The system will process this submission upon signing.</p> <p><input type="password"/> <input type="button" value="Sign"/></p>	
--	---	--

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.

New Tools for Assessing Fracture Risk

Submission Type: NEW STUDY
 Status: PENDING FAC ADVISOR SIGNATURE
 ID: TURNERC903312015135019
 PI Name: Chaslety Turner
 PI VUNetID: TURNERC9
 Review Type: Standard
 Study Type: Health Science

Faculty Advisor's Assurance Statement

By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accordance with the approved protocol. In addition,

- I agree to meet with the student investigator on a regular basis to monitor study progress;
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the student investigator in solving them;
- I will ensure that all investigators and key study personnel have completed the VU human subjects training program;
- I will ensure that the project is performed only by qualified personnel according to the approved IRB application;
- I will ensure that the student investigator does not implement any changes to the approved IRB application or informed consent document without prior IRB approval in accordance with VU IRB policy (except in an emergency, if necessary to safeguard the well-being of human participants, and will report to the IRB within 5 days of such change);
- I will ensure that the student investigator only obtains legally effective informed consent from human participants or their legally responsible representative, only the currently approved date stamped informed consent documents for human participants are used, and a copy of the informed consent is provided to the participant;
- I will ensure that the student investigator promptly reports any unanticipated problems involving risks to participants or others, or any serious adverse events (whether anticipated or not) to the IRB in accordance with Vanderbilt University IRB Policies and Procedures;
- I will assume the responsibility for the accurate documentation, investigation and follow-up of all possible study-related adverse events and unanticipated problems involving risks to participants;
- If I will be unavailable to supervise this research personally, as when on sabbatical leave or vacation, I will arrange for an alternate Faculty Advisor to assume direct responsibility in my absence and I will advise the IRB by letter in advance of such arrangements;
- I will ensure that the student investigator promptly provides the IRB with any information requested relative to the project;
- I will ensure that the student investigator promptly and completely complies with an IRB Decision to suspend or withdraw approval for the project; and
- I will ensure that the student investigator obtains continuing review approval prior to the date approval for the study expires. Further, I understand that if the student investigator fails to apply for continuing review, approval for the study will automatically expire and I must ensure that all study activity ceases until IRB approval is obtained.

Sign Here
 Please enter your e-password in order to electronically sign this submission. The system will process this submission upon signing.

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.

Home » Submissions Pending My Signature » Submission: "Investigating immune responses in patients with advanced..."

Investigating immune responses in patients with advanced...

Main KSP Funding Application Document Uploads Signature Reviews

Study Details

ID: TURNERC903312015112747
 Study Title: Investigating immune responses in patients with advanced melanoma treated with immune-based therapy
 Status: PENDING DEPT CHAIR SIGNATURE
 Principal Investigator: TURNERC9
 Study Coordinator: VIGILKM
 Department Chair: STRAZNKL
 Division Chief:
 Student PI?: Yes
 Student Type: Emphasis
 Faculty Advisor: CYRC

Signature History

Principal Investigator: Signed by Turner, Chaslety on 3/31/2015 at 1:43pm
 Faculty Advisor: Signed by Cyr, Clara on 3/31/2015 at 4:06pm
 Department Chair*: not yet signed

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.

Main Amendment Funding Application Document Uploads Submit Reviews

Amendment Information

Please indicate what is being changed with this amendment:
* must provide value

- Study Title/Grant Title
- Increase in total subject numbers/accrual
- Investigator's Brochure (IB) with NO change in safety data or the currently approved consent document(s)
- Data and Safety Monitoring Report
- Investigator's Brochure (IB) WITH changes in safety
- Consent Form changes
- Protocol changes
- Changes to recruitment materials
- Submission of new documents
- Other
- ADD a participating site to the single IRB review.

Please provide the rationale for the amendment/changes:
* must provide value

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.

10 Draft submissions

Submissions requiring my signature

Submissions not yet approved

1 Pre-review requests

4 Submissions requiring a CAL response

Site visit requests

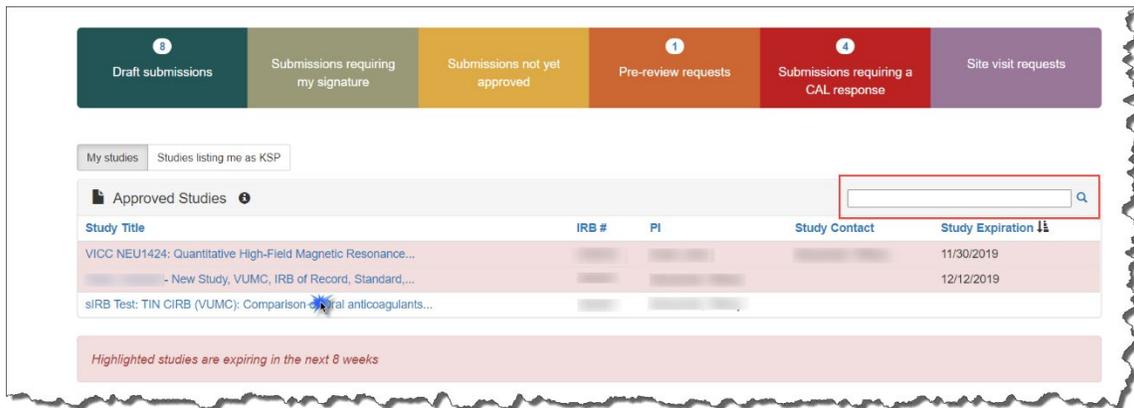
My studies Studies listing me as KSP

Approved Studies

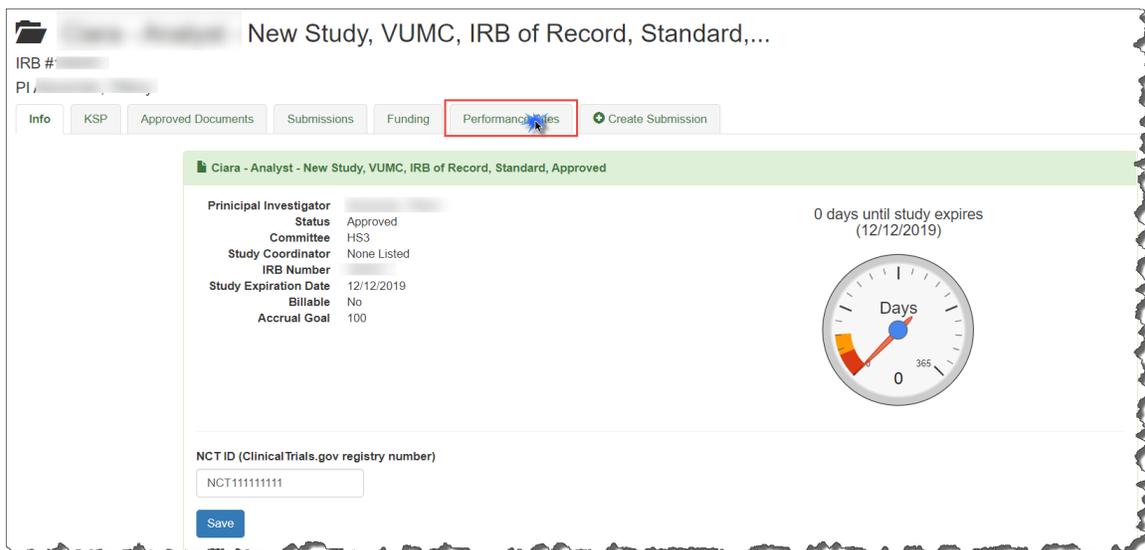
Study Title	IRB #	PI	Study Contact	Study Expiration
VICC NEU1424: Quantitative High-Field Magnetic Resonance...	140819	Ozier, Julie	Alexander, Tiffany	11/30/2019
Clara - Analyst - New Study, VUMC, IRB of Record, Standard,...	180051	Alexander, Tiffany		12/12/2019
siRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...	180081	Alexander, Tiffany		

Highlighted studies are expiring in the next 8 weeks

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](#).

IRB # [redacted] - New Study, VUMC, IRB of Record, Standard,...

PI [redacted]

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 - FWA0000000	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.

IRB # [redacted]
PI [redacted]

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 - FWA0000000	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 - FWA00002869	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

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.

Baylor College of Medicine - FWA00000286	SMART IRB	Yes	3/3 surveys complete -	Yes	--	Pending Review
Dignity Health - FWA00001499	SMART IRB	Yes	3/3 surveys complete -	Yes	--	Ready
Crossroads Eye Physicians - FWA000025426	SMART IRB	Yes	3/3 surveys complete -	Yes	--	Ready
MGH Institute of Health Professions - FWA00005721	SMART IRB	Yes	3/3 surveys complete -	Yes	--	Ready
Carnegie Mellon University - FWA00004206	SMART IRB	Yes	3/3 surveys complete -	Yes	--	Remove
Children's Hospital of Wisconsin - FWA00001809	--	No	1/3 surveys complete -	No	--	Remove

If there is an outstanding 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.

Billings Clinic	SMART IRB	No	2/3 surveys complete -	No	--	Remove
<div style="border: 1px solid red; padding: 5px;"> <input type="checkbox"/> Institutional Profile <input checked="" type="checkbox"/> PI Survey <input checked="" type="checkbox"/> HRP Survey </div>						
+ Add a Site						
Requested Sites						

To add a new site to this table, click [Add a Site](#).

Crossroads Eye Physicians - FWA00025426	SMART IRB	Yes	3/3 surveys complete	Yes	--	Ready
MGH Institute of Health Professions - FWA00005721	SMART IRB	Yes	3/3 surveys complete	Yes	--	Ready
Carnegie Mellon University - FWA00004206	SMART IRB	Yes	3/3 surveys complete	Yes	--	Remove
Children's Hospital of Wisconsin - FWA00001809	--	No	1/3 surveys complete	No	--	Remove
Brigham and Women's Hospital - FWA00000484	--	No	1/3 surveys complete	No	--	Remove
Spaulding Rehabilitation Hospital - FWA00000485	--	No	1/3 surveys complete	No	--	Remove

+ 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.

MGH Institute of Health Professions - FWA00005721	SMART IRB	Yes	3/3 surveys complete	Yes	--	Ready
Carnegie Mellon University - FWA00004206	SMART IRB	Yes	3/3 surveys complete	Yes	--	Remove
Children's Hospital of Wisconsin - FWA00001809	--	No	1/3 surveys complete	No	--	Remove
Brigham and Women's Hospital - FWA00000484	--	No	1/3 surveys complete	No	--	Remove
Spaulding Rehabilitation Hospital - FWA00000485	--	No	1/3 surveys complete	No	--	Remove
Johns Hopkins University School of Medicine - FWA	--	--	0/3 surveys complete	--	--	Remove

+ Add a Site

Start typing the name of the institution or organization here.

Requested Sites

Please list performance sites (including primary contact and phone number) not available above.

Save Sites

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



Baylor College of Medicine - FWA00000286	SMART IRB	Yes	3/3 surveys complete ▾	Yes	--	Pending Review
Dignity Health - FWA00001499	SMART IRB	Yes	3/3 surveys complete ▾	Yes	--	Ready
Crossroads Eye Physicians - FWA000025426	SMART IRB	Yes	3/3 surveys complete ▾	Yes	--	Ready
MGH Institute of Health Professions - FWA00005721	SMART IRB	Yes	3/3 surveys complete ▾	Yes	--	Ready
Carnegie Mellon University - FWA00004206	SMART IRB	Yes	3/3 surveys complete ▾	Yes	--	✕ Remove
Children's Hospital of Wisconsin - FWA00001809	--	No	1/3 surveys complete ▾	No	--	✕ Remove

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](#).

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...

IRB #180081
PI Alexander, Tiffany

Info | KSP | Approved Documents | Submissions | Funding | Performance Sites | **Create Submission**

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants for extended VEnous Thromboembolism (COVET)

Principal Investigator	Alexander, Tiffany
Status	Approved
Committee	HS2
Study Coordinator	None Listed
IRB Number	180081
Study Expiration Date	
Billable	No
Accrual Goal	50

NCT ID (ClinicalTrials.gov registry number)

Save

Select [Site Addition](#).

IRB # [redacted]
PI [redacted]

Info | KSP | Approved Documents | Submissions | Performance Sites | **Create Submission**

Create a new submission for this study:

- Amendment
- Non-compliance with Protocol
- Adverse Event
- Continuing Review
- Site Addition**

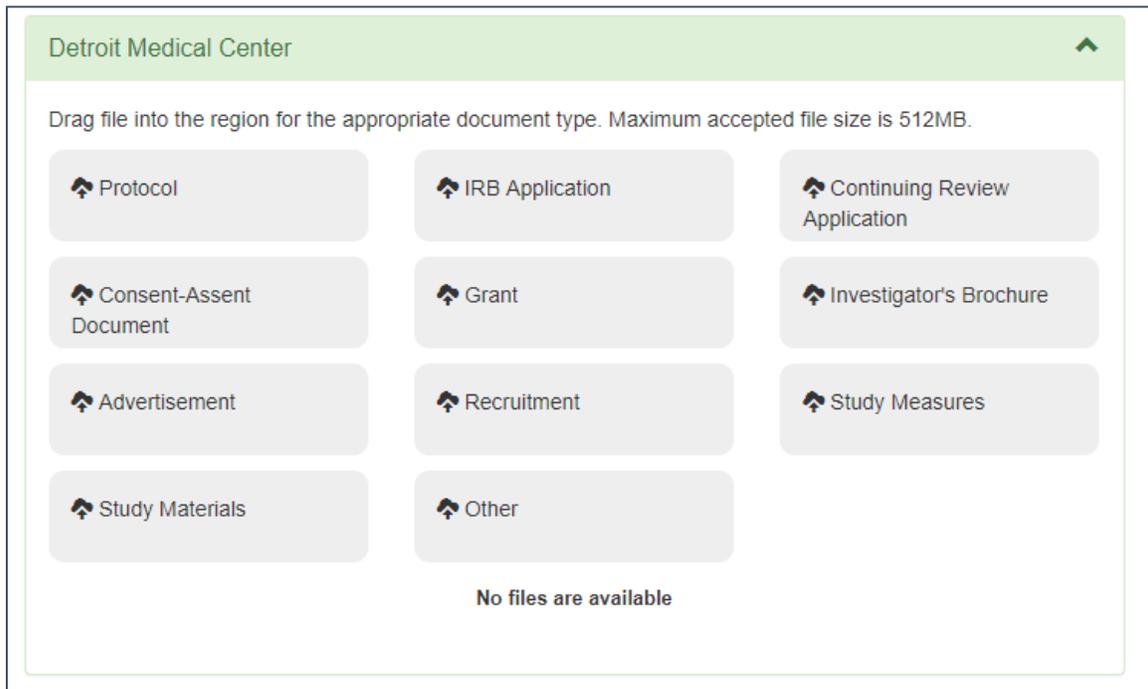
You will be prompted to select the sites to be added with this submission. Only the sites that have a status of Ready will appear in this section. Select the site(s) to be added by selecting the box next to the site name. Click save and continue when the sites have been selected to move forward to the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

The screenshot shows a web interface with a navigation bar at the top containing 'Main', 'Document Uploads', 'Submit', and 'Reviews'. Below the navigation bar is a section titled 'Sites Selected for Review'. Inside this section, there is a heading 'Select the sites to be added.' followed by a list item 'Detroit Medical Center' with a checkbox next to it. Below the list are two buttons: 'Save' and '→ Save and Continue'. At the bottom right of the section is a red button with a trash icon and the text 'Delete'.

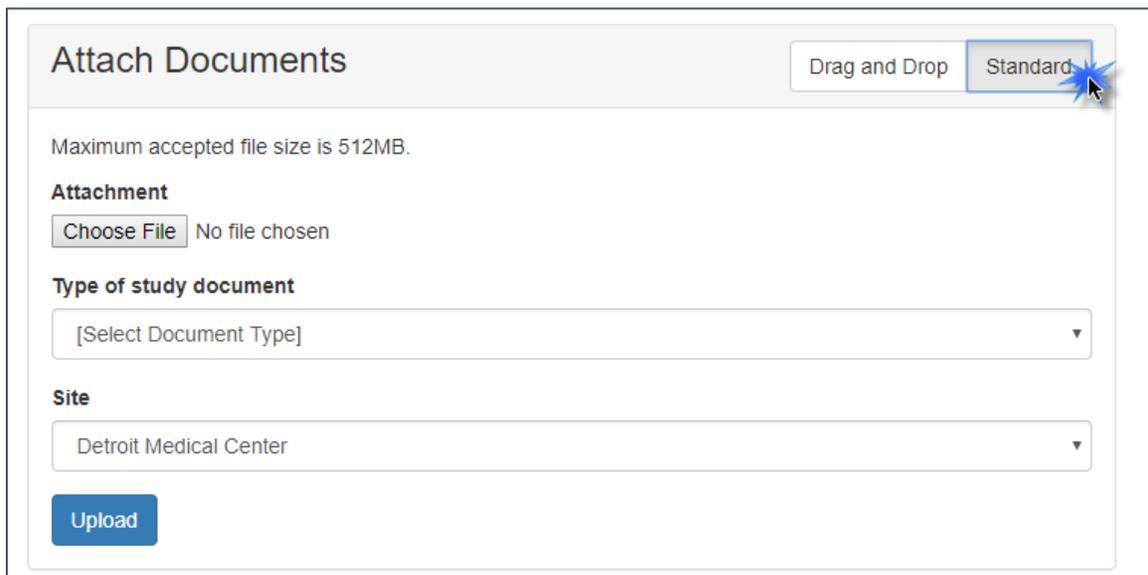
The system will create a section for documents to be uploaded for each site. In the Document Uploads tab you can 1) *expand or collapse each site section individually by clicking on the bar with the site name in it*, 2) *expand all sections by clicking Expand All*, and 3) *collapse all sections by clicking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

The screenshot shows a web interface with a navigation bar at the top containing 'Main', 'Document Uploads', 'Submit', and 'Reviews'. Below the navigation bar is a section titled 'Attach Documents'. At the top right of this section are two buttons: 'Drag and Drop' and 'Standard'. Below these are two green buttons: 'Select All in All Sites' and 'Collapse All' (with a blue circle containing the number 3). To the right of 'Collapse All' is another green button: 'Expand All' (with an orange circle containing the number 2). Below these buttons is a green bar representing a site section, labeled 'Detroit Medical Center' (with a red circle containing the number 1) and a dropdown arrow on the right. Below the site bar are two buttons: 'Delete selected files' (red) and 'Download all' (white with a dropdown arrow). At the bottom of the section are two blue buttons: '← Back' and '→ Continue'.

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.

Attach Documents Drag and Drop Standard

Maximum accepted file size is 512MB.

Attachment
 No file chosen

Type of study document
[Select Document Type]

Site
Detroit Medical Center

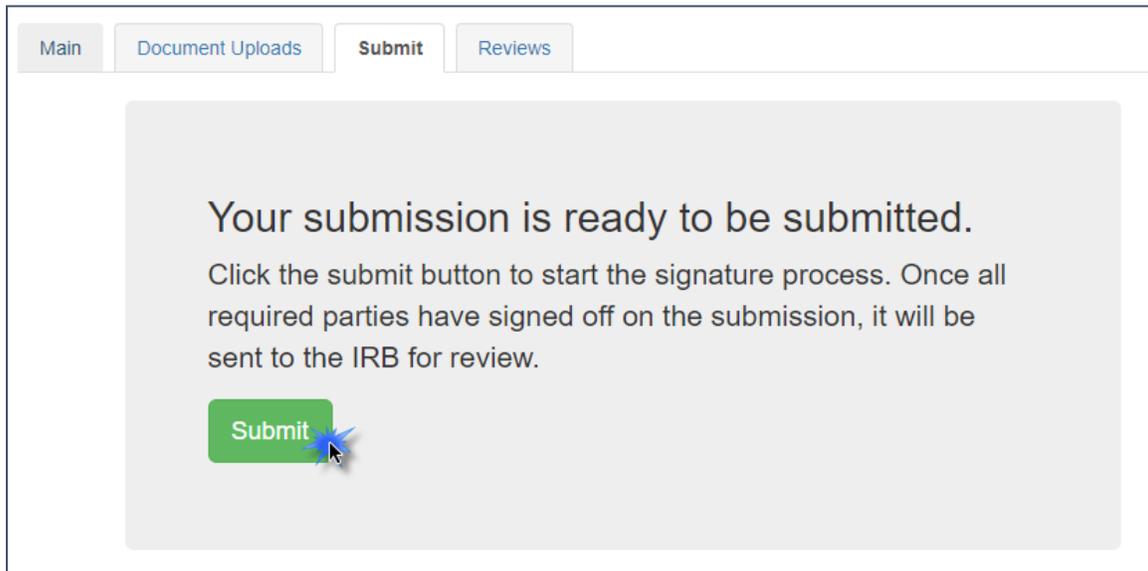
Once all documents are attached, click [Continue](#) to move forward to the Submit tab.

Main Document Uploads Submit Reviews

Attach Documents Drag and Drop Standard

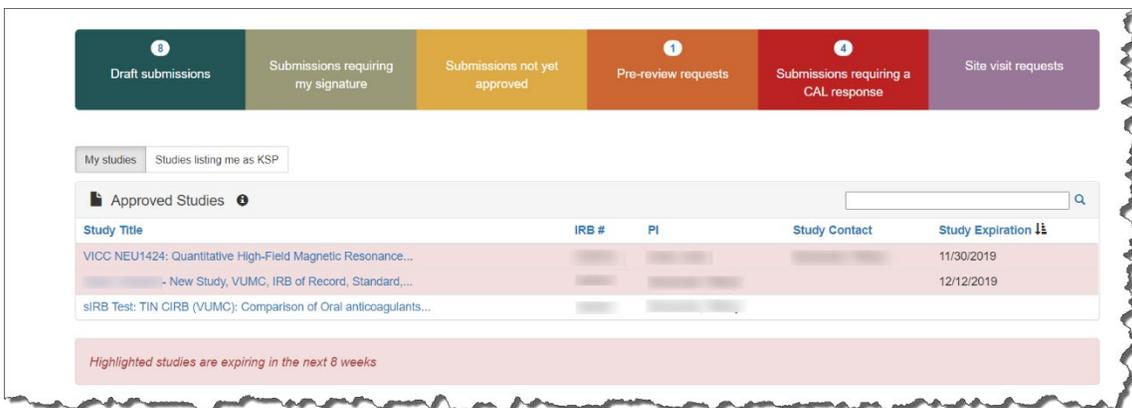
Detroit Medical Center

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

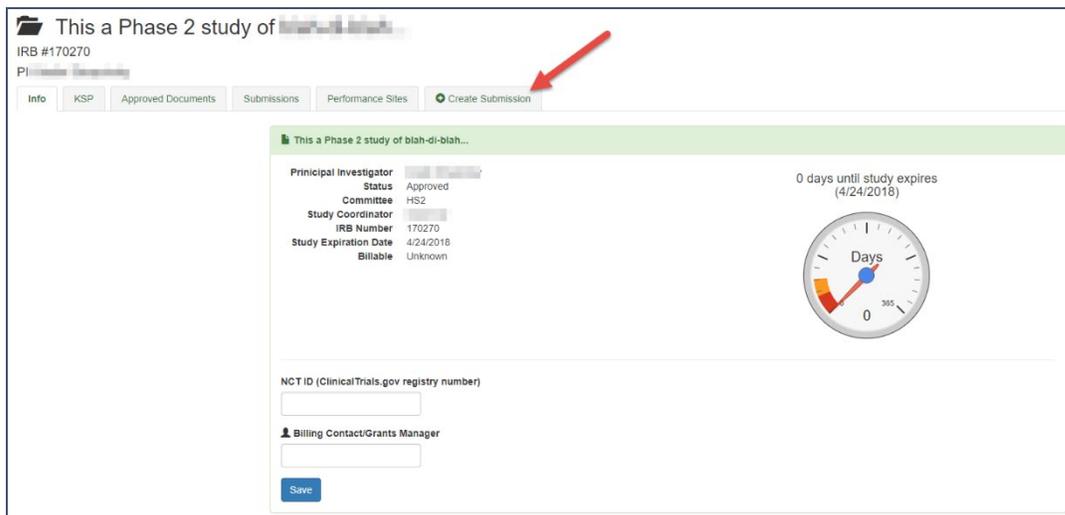


Submitting a Continuing Review

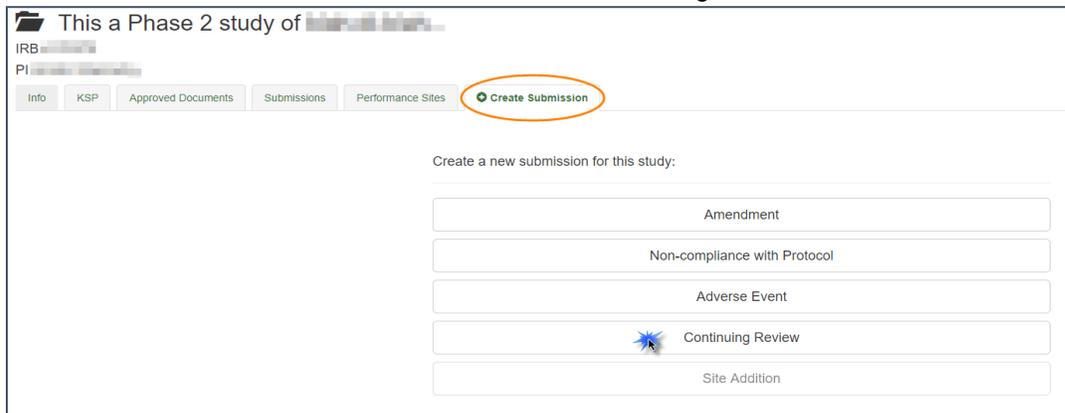
Submit a [Continuing Review](#) for continuing studies or to close a study with the IRB. To start a continuing review submission, access your approved studies and select the appropriate study. Note that any studies with approval expiring in the next 8 weeks will be highlighted red.



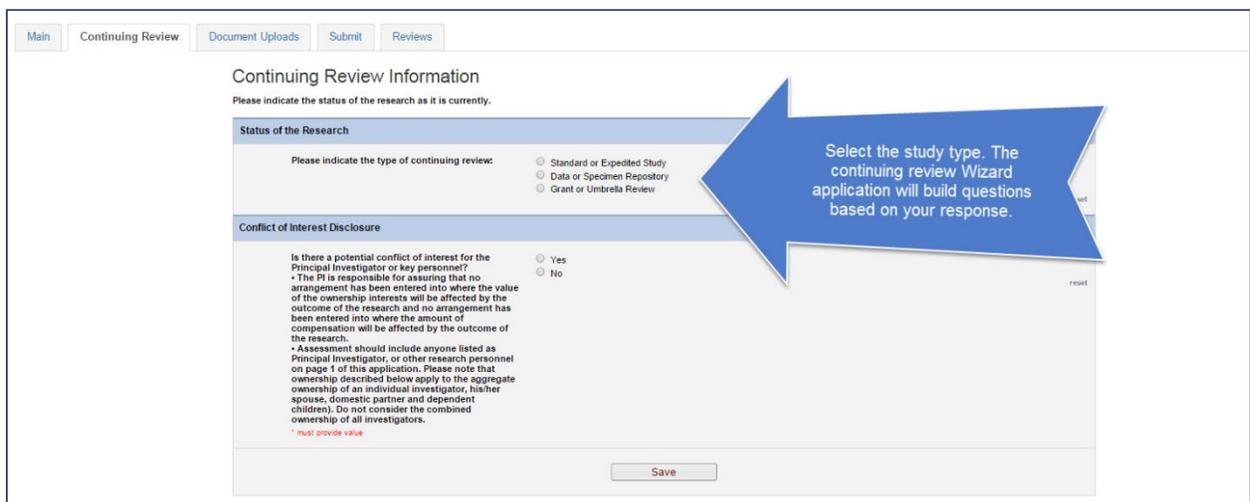
From the study page, click [Create Submission](#).



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.

Please indicate the status of the research as it is currently.

Status of the Research

Please indicate the type of continuing review:

Standard or Expedited Study
 Data or Specimen Repository
 Grant or Umbrella Review

[reset](#)

Please indicate the status of the study:

No participants have been enrolled to date.
 Recruitment and/or enrollment of new participants or review of records/specimens continue.
 Study is no longer enrolling but participants still receive research-related interventions (e.g., still receiving treatment, obtaining blood draws, etc.).
 Study is no longer enrolling and participant have completed research-related interventions. The study remains active only for long term follow-up.
 Study enrollment is permanently closed, participant have completed all research-related interventions, and long term follow-up has been completed. The remaining research activities are limited only to data analysis that may require contact with records or specimens.
 Close the study: Enrollment and follow-up are complete and no further contact with participants, records, or specimens is anticipated. Data queries are complete.

[reset](#)

Maximum number of participants approved to complete the study:
* must provide value

Please provide ALL information requested below.
NOTE: These numbers should reflect participants enrolled by the VU Principal Investigator and/or additional personnel involved in the study. "Number enrolled" means enrolled beyond screening.

Number enrolled within the last IRB approval period:
* must provide value

Number enrolled since the beginning of the study:
* must provide value

Has the adverse event profile experienced by participants differed from that expected since the most recent IRB continuing review?
* must provide value

Yes
 No

[reset](#)

Adverse event is defined here as any untoward or undesired outcome of the research, including both serious and non-serious events, expected and unexpected events, and events related and unrelated to the research.

Answers to subsequent questions will build the application so that only the necessary questions for your study type and enrollment status will appear.

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.

Continuing Review (4/3/2015) - DRAFT

Submission ID: STRAZNKL04032015105547

Main Continuing Review Funding Application Document Uploads Submit Reviews

Attach Study Files Drag and Drop Standard

Protocol	IRB Application	Continuing Review Application
Consent-Assent Document	Grant	Investigators Brochure
Advertisement	Recruitment	Study Measures
Study Materials	Other	

Submission Documents

There are no documents for this study

[← Back](#)
[→ Continue](#)

Drag and Drop documents (ex. ICD, publications) into the corresponding buckets.



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.

Submission Reviews

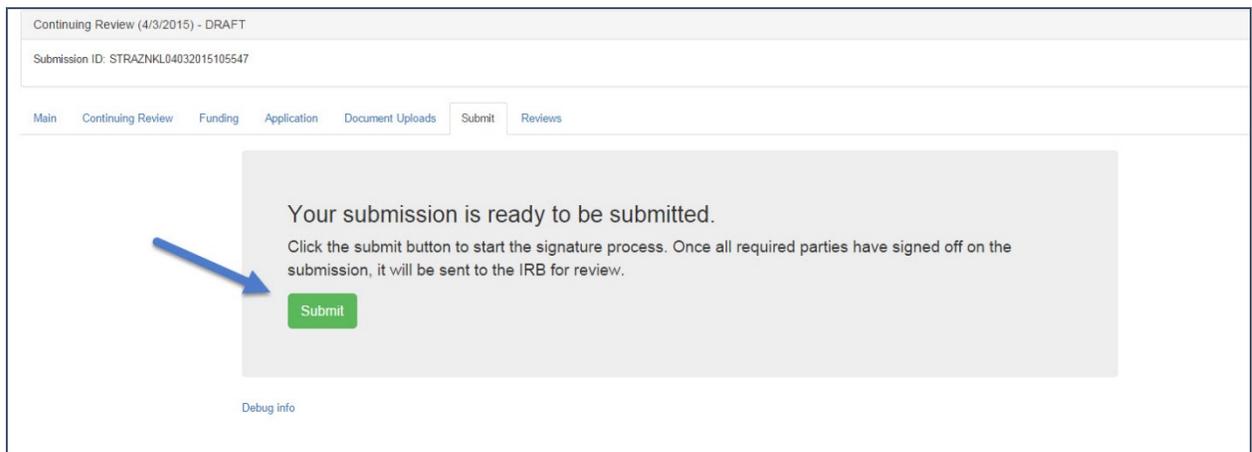
Updated On	Meeting Date	Committee	Review Type	Review Outcome	Letter
1/22/2019		HS3	Analyst Review	Approve	Download FAL
12/13/2018		HS3	Full Committee	Approve	Download FAL

Approved Documents

Global Documents ^

File Name	By	On
Continuing Review Application		
CR.pdf	HTMLDB_PUBLIC_USER	12/13/2018 14:25:53
Consent-Assent Document		
Stamped-Part1_MasterConsent_v2.pdf	HTMLDB_PUBLIC_USER	12/13/2018 14:25:53

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.

The screenshot shows a dashboard with six navigation tabs: Draft submissions (8), Submissions requiring my signature, Submissions not yet approved, Pre-review requests (1), Submissions requiring a CAL response (4), and Site visit requests. Below the tabs are two tabs: My studies and Studies listing me as KSP. The 'Studies listing me as KSP' tab is selected. Underneath is a section for 'Approved Studies' with a search bar. A table lists three studies with columns for Study Title, IRB #, PI, Study Contact, and Study Expiration. The first two studies are highlighted in pink. A message at the bottom states: 'Highlighted studies are expiring in the next 8 weeks'.

Study Title	IRB #	PI	Study Contact	Study Expiration
VICC NEU1424: Quantitative High-Field Magnetic Resonance...				11/30/2019
- New Study, VUMC, IRB of Record, Standard,...				12/12/2019
sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...				

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.

This screenshot is identical to the one above, but with a red box highlighting the search bar in the 'Approved Studies' section.

From the study page, click [Create Submission](#).

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...

IRB # [redacted]
PI [redacted]

Info KSP Approved Documents Submissions Funding Performance Sites **Create Submission**

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants for extended VEnous Thromboembolism (COVET)

Principal Investigator	[redacted]
Status	Approved
Committee	HS2
Study Coordinator	None Listed
IRB Number	[redacted]
Study Expiration Date	
Billable	No
Accrual Goal	50

NCT ID (ClinicalTrials.gov registry number)

Save

Click [Adverse Event](#). Clicking this button will create the Adverse Event submission.

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...

IRB # [redacted]
PI [redacted]

Info KSP Approved Documents Submissions Funding Performance Sites **Create Submission**

Create a new submission for this study:

- Amendment
- Non-compliance with Protocol
- Adverse Event**
- Continuing Review
- Site Addition

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.

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...

ADVERSE EVENT

IRB # [REDACTED]

PI [REDACTED]

Adverse Event/Unanticipated Problem (1/13/2021) - DRAFT

Submission ID: [REDACTED] 301132021114606

Main Adverse Event Document Uploads Submit Reviews

Is this a Cancer Center related AE that has been completed in OnCore? No Yes

Please indicate type of report. Initial Report of Event/Problem Follow-Up Report

Save Save and Continue

Step 1: Select "Yes" or "No"

Step 2: Select either Initial Report or Follow-up Report.

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) or check with your sponsor.

<p>Was this an event that requires prompt reporting to the sponsor in accordance with the protocol (e.g., serious adverse events)?</p> <p>* must provide value</p>	<p><input checked="" type="radio"/> Yes</p> <p><input type="radio"/> No</p>
<p>Unanticipated? (An event is "unanticipated" when it was unforeseeable at the time of its occurrence)</p> <p>* must provide value</p>	<p><input checked="" type="radio"/> Yes</p> <p><input type="radio"/> No</p>
<p>Serious? (An event is "serious" if it adversely alters the risk/benefit relationship of the research)</p> <p>* must provide value</p>	<p><input checked="" type="radio"/> Yes</p> <p><input type="radio"/> No</p>
<p>Related? (An event is "related" if it is likely to have been caused by the research procedures)</p>	<p><input checked="" type="radio"/> Yes</p> <p><input type="radio"/> No</p>

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

Participant Identifier:	<input type="text"/> <small>NOTE: DO NOT include a name or ANY personal identifiers.</small>
Participant Age:	<input type="text"/>
Identify Drug/Biologic/Device/Treatment/Intervention: <small>* must provide value</small>	<input type="text"/>

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.

List 3-4 keywords describing the event/problem:	<input type="text"/> <small>(e.g., loss of confidentiality, nausea, vomiting)</small>
Provide a description of the event/problem including the timing of the study treatment, dosing, or intervention with start and stop dates of relevant research interventions. <small>* must provide value</small>	<input type="text"/>
This study (choose one): <small>* must provide value</small>	<input type="radio"/> has a Data and Safety Monitoring Committee/Board (DSMC/DSMB) or Data Safety Monitor (DSM). <input type="radio"/> does not have a Data and Safety Monitoring Committee/Board (DSMC/DSMB) or Data Safety Monitor (DSM). <input type="radio"/> unknown.

reset

Once all required questions are complete, click the [Save](#) button at the bottom of the page.

Other event that is unanticipated-involved risk to participants or others and was possibly related to the research procedures.

NOTE: Events that do not fit into the above categories do not require reporting to the IRB at this time. However, the event may require reporting to the sponsor or data monitoring plan.

This event/problem is: (Choose one):
* must provide value

Currently described as a risk in the informed consent document and does not require submission of an amendment.
 Not listed as a risk in the informed consent document and requires submission of an amendment.
 Not listed as a risk in the informed consent document and submission of an amendment is not recommended at this time. reset

This study (choose one):
* must provide value

has a Data and Safety Monitoring Committee/Board (DSMC/DSMB) or Data Safety Monitor (DSM).
 does not have a Data and Safety Monitoring Committee/Board (DSMC/DSMB) or Data Safety Monitor (DSM).
 unknown. reset

Has the PI been notified of this event/problem and received a copy of this report?
* must provide value

Yes
 No reset

The PI should be notified of all noncompliances with the protocol, adverse events, and/or unanticipated problems involving risks to participants or others. The PI is responsible for the accurate documentation, investigation and follow-up of all noncompliances with the protocol, adverse events and/or unanticipated problems involving risks to participants or others that are possibly related to study participation.

Has the event been reported to the Sponsor?
* must provide value

Yes
 No reset

Please add any additional comments:

[Save](#)

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.

Home > Study: IRB#150080-Test Standard: 140026 A Phase 1 Study to Evaluate the... > Submission: ADVERSE EVENT

Test Standard: 140026 A Phase 1 Study to Evaluate the...
IRB # 150080
PI [REDACTED]

Adverse Event/Unanticipated Problem (4/3/2015) - DRAFT
Submission ID: [REDACTED]

Main Adverse Event Funding Application **Document Uploads** Submit Reviews

Adverse Event/Unanticipated Problem Information
Information provided here will be used to generate the Adverse Event/Unanticipated Problem report. The report will be reviewed by the IRB and does not require the signature of the Principal Investigator.

Is there a MedWatch Report to attach? Yes No reset
* must provide value

Date of Event: [REDACTED]
* must provide value

Participant Identifier: [REDACTED]
NOTE: DO NOT include a name or ANY personal identifiers.

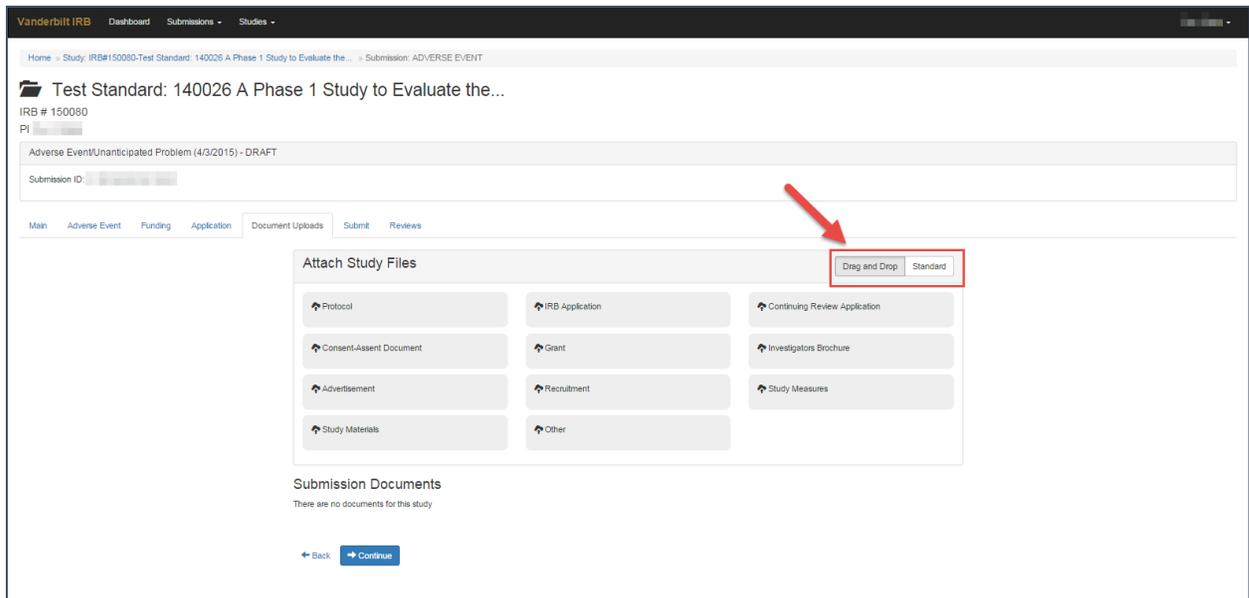
Participant Age: [REDACTED]

Identify Drug/Biologic/Device/Treatment/Intervention: [REDACTED]
* must provide value

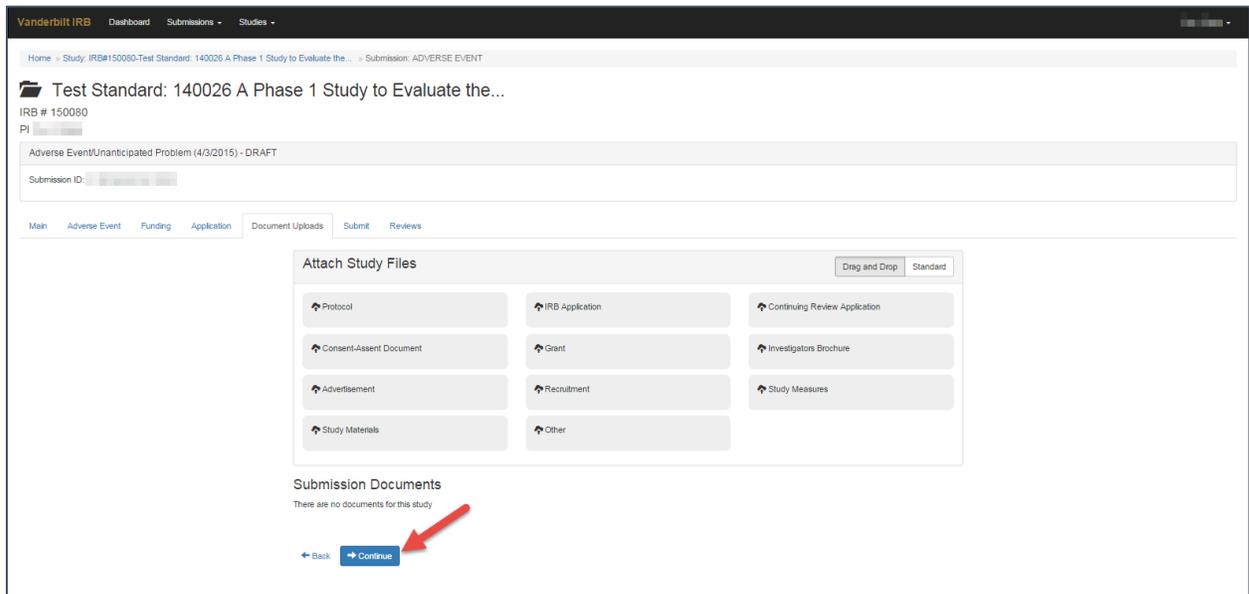
List 3-4 keywords describing the event/problem: [REDACTED]
(E.g., loss of confidentiality, nausea, vomiting)

Provide a description of the event/problem including the timing of the study treatment, dosing, or intervention with start and stop dates of relevant research interventions.
* must provide value

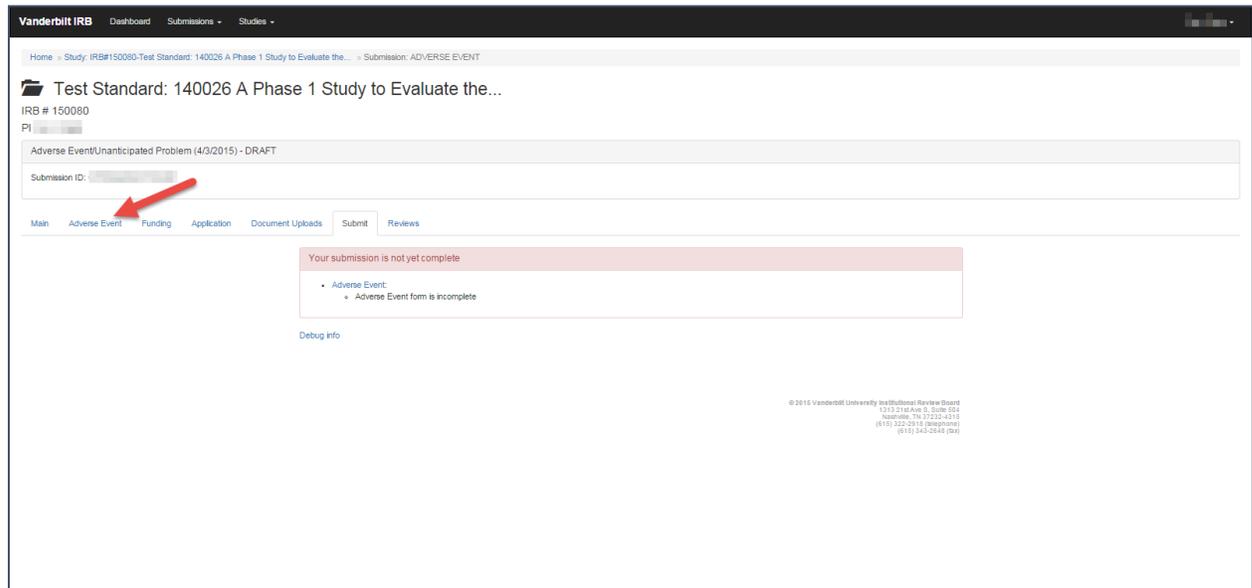
On the Document Uploads tab, documents can be submitted with either the Drag and Drop option, or the Standard option.



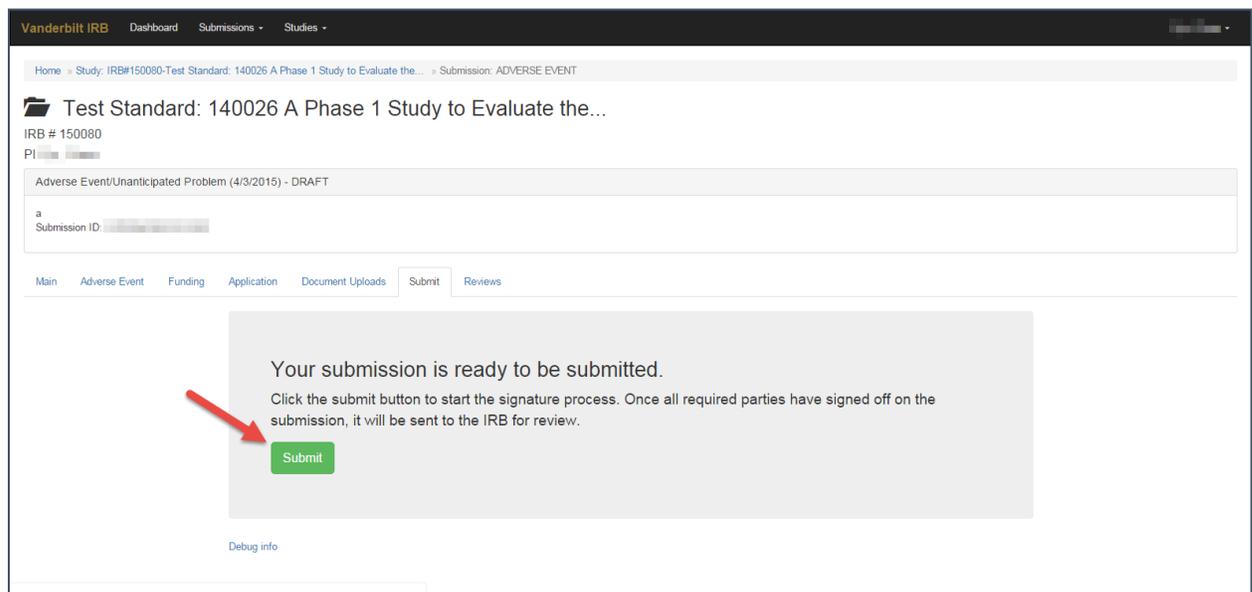
When all documents have been uploaded, click the *Continue* button at the bottom of the page. This button will bring you to the Submit tab.



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.



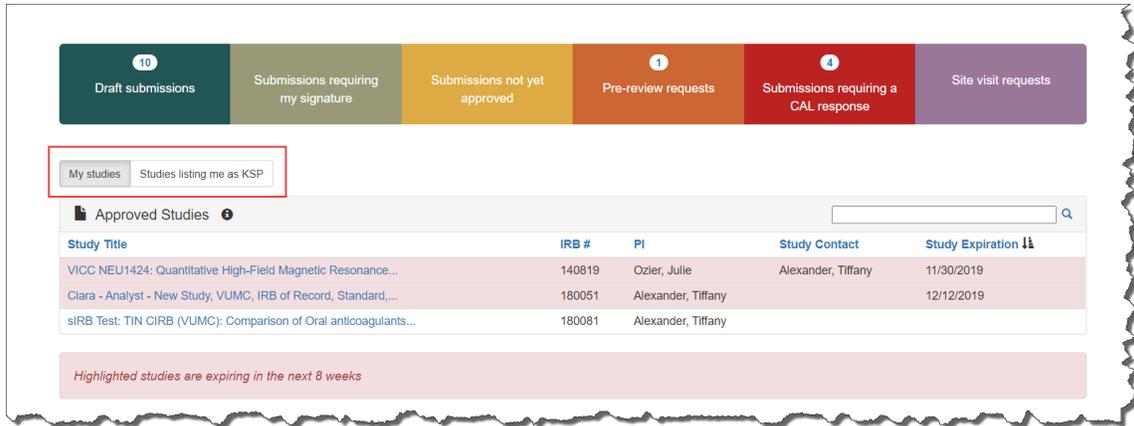
Once the required information is complete, you will be able to click the *Submit* button on the Submit tab.



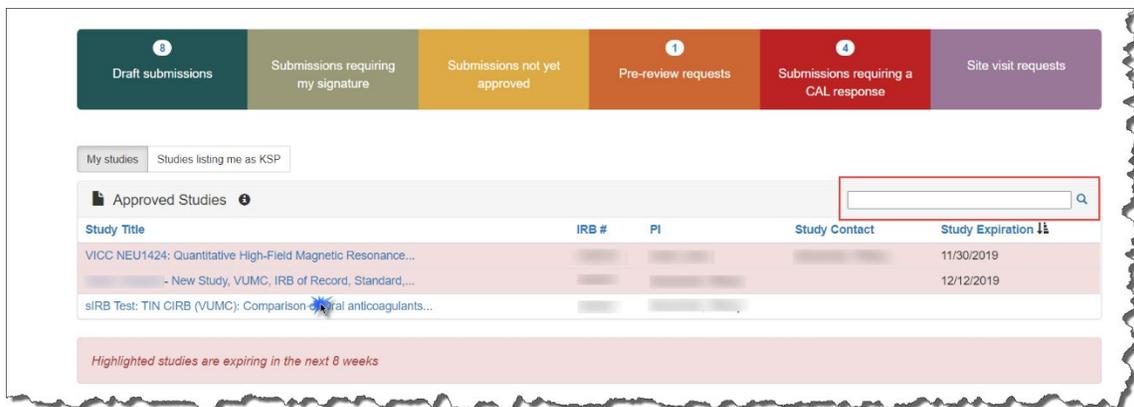
After a signature from the PI, the submission is automatically routed through the Wizard and ultimately ends its journey at the IRB where it will be sent to a team to start the review process.

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](#).

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...

IRB # [redacted]
PI [redacted]

Info KSP Approved Documents Submissions Funding Performance Sites **Create Submission**

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants for extended VEnous Thromboembolism (COVET)

Principal Investigator	[redacted]
Status	Approved
Committee	HS2
Study Coordinator	None Listed
IRB Number	[redacted]
Study Expiration Date	
Billable	No
Accrual Goal	50

NCT ID (ClinicalTrials.gov registry number)

Save

Click [Non-compliance with Protocol](#). This will create the non-compliance with the protocol submission.

sIRB Test: TIN CIRB (VUMC): Comparison of Oral anticoagulants...

IRB # [redacted]
PI [redacted]

Info KSP Approved Documents Submissions Funding Performance Sites **Create Submission**

Create a new submission for this study:

- Amendment
- Non-compliance with Protocol**
- Adverse Event
- Continuing Review
- Site Addition

Enter the description of the Non-compliance and the date of the event or problem. Click [Save](#).

Vanderbilt IRB Dashboard Submissions Studies

Home Draft Submissions Submission: "Test Standard: 140026 A Phase 1 Study to Evaluate the..."

Test Standard: 140026 A Phase 1 Study to Evaluate the...
IRB # 150080
PI [REDACTED]

Noncompliance with Protocol (4/13/2015) - DRAFT
Submission ID: [REDACTED]

Main Noncompliance Document Uploads Submit Reviews

Description of the Noncompliance with the Protocol

Date of event/problem
2015 Apr 13

Save Delete

Once you have saved the Main tab, click the [Non-Compliance tab](#) to continue.

Vanderbilt IRB Dashboard Submissions Studies

Home Draft Submissions Submission: "Test Standard: 140026 A Phase 1 Study to Evaluate the..."

Test Standard: 140026 A Phase 1 Study to Evaluate the...
IRB # 150080
PI [REDACTED]

Noncompliance with Protocol (4/13/2015) - DRAFT
Submission ID: [REDACTED]

Main Noncompliance Document Uploads Submit Reviews

Description of the Noncompliance with the Protocol

Date of event/problem
2015 Apr 13

Save Delete

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

The screenshot shows a form with four sections, each containing a question and radio button options:

- Section 1: "Did the Noncompliance with the Protocol affect the integrity of the study?" with options "Yes" and "No". A red asterisk and "must provide value" are below the question. A "reset" link is on the right.
- Section 2: "Please provide an explanation of the plan to prevent future Noncompliance with the Protocol events:" with a red asterisk and "must provide value" below. A large text input area is on the right.
- Section 3: "Has the PI been notified of the Noncompliance with the Protocol and received a copy of this report?" with options "Yes" and "No". A red asterisk and "must provide value" are below. A "reset" link is on the right.
- Section 4: "Has this Noncompliance with the Protocol been reported to the sponsor?" with options "Yes" and "No". A red asterisk and "must provide value" are below. A "reset" link is on the right.

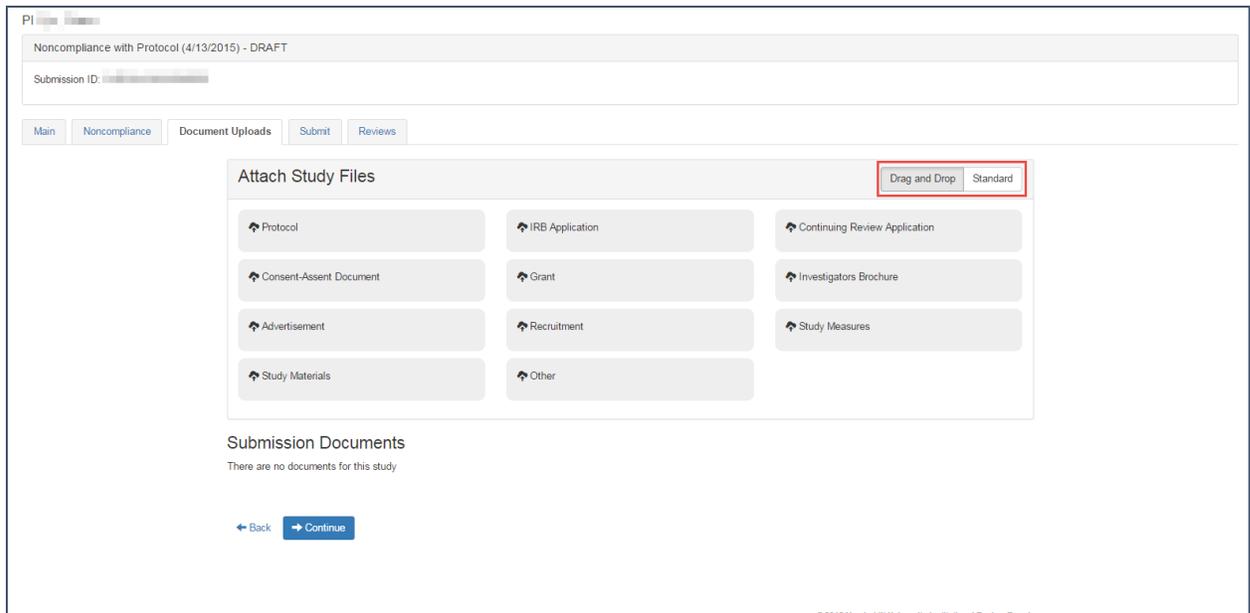
At the bottom center, there is a "Save" button, which is pointed to by a red arrow.

If you have additional documents to upload, click the [Document Uploads](#) tab. If you have no additional documents to upload, click the [Submit](#) tab.

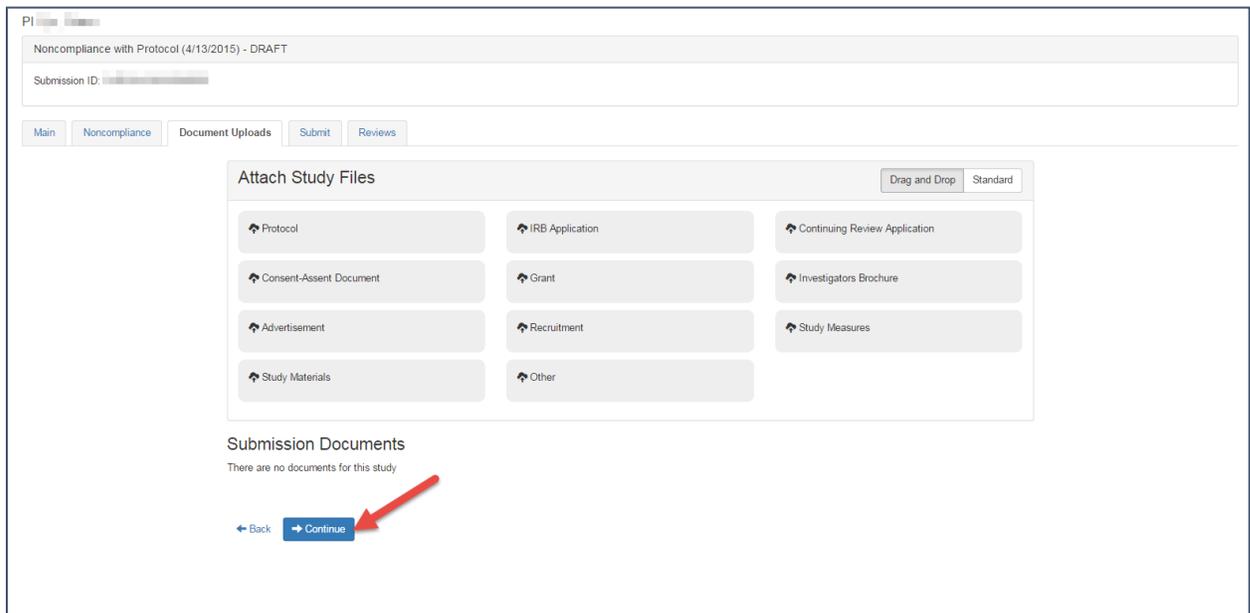
The screenshot shows the Vanderbilt IRB dashboard for a submission titled "Test Standard: 140026 A Phase 1 Study to Evaluate the...". The submission is in "DRAFT" status. The "Noncompliance with Protocol (4/13/2015) - DRAFT" section is active, showing a "Submission ID" field. Below this, there are four tabs: "Main", "Noncompliance", "Document Uploads", and "Submit". The "Document Uploads" and "Submit" tabs are highlighted with red boxes and red arrows. Below the tabs is the "Noncompliance with Protocol Information" section, which contains two questions:

- Question 1: "Is this a Cancer Center related report of Noncompliance with the Protocol that has been completed in OnCore?" with options "Yes" and "No". A red asterisk and "must provide value" are below. A "reset" link is on the right.
- Question 2: "Explain why or how the Noncompliance with the Protocol occurred:" with a red asterisk and "must provide value" below. A large text input area is on the right.

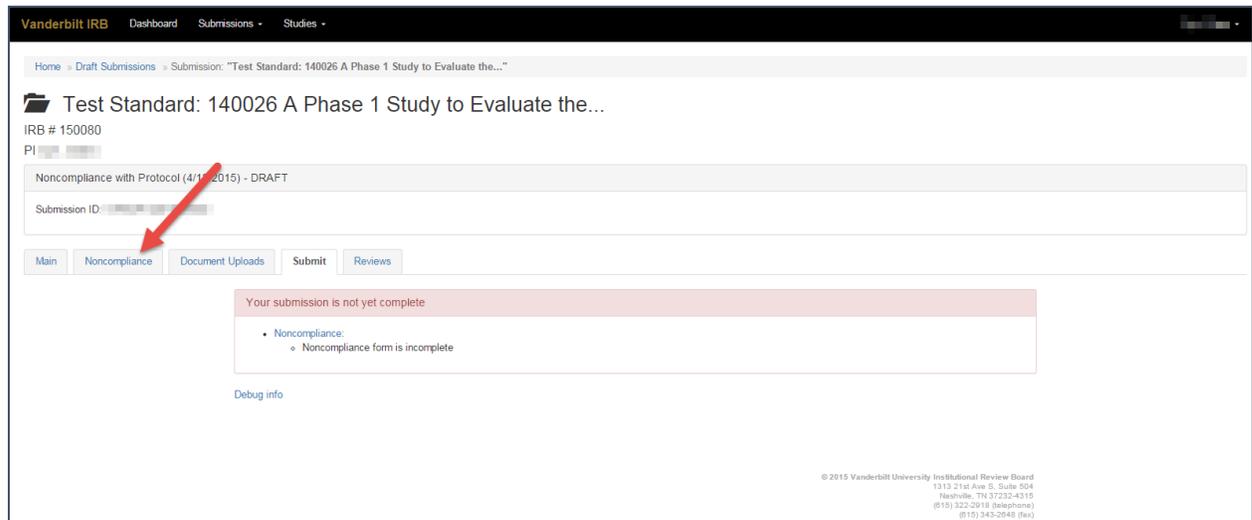
On the Document Uploads tab, upload additional documents using either the Drag and Drop or Standard method.



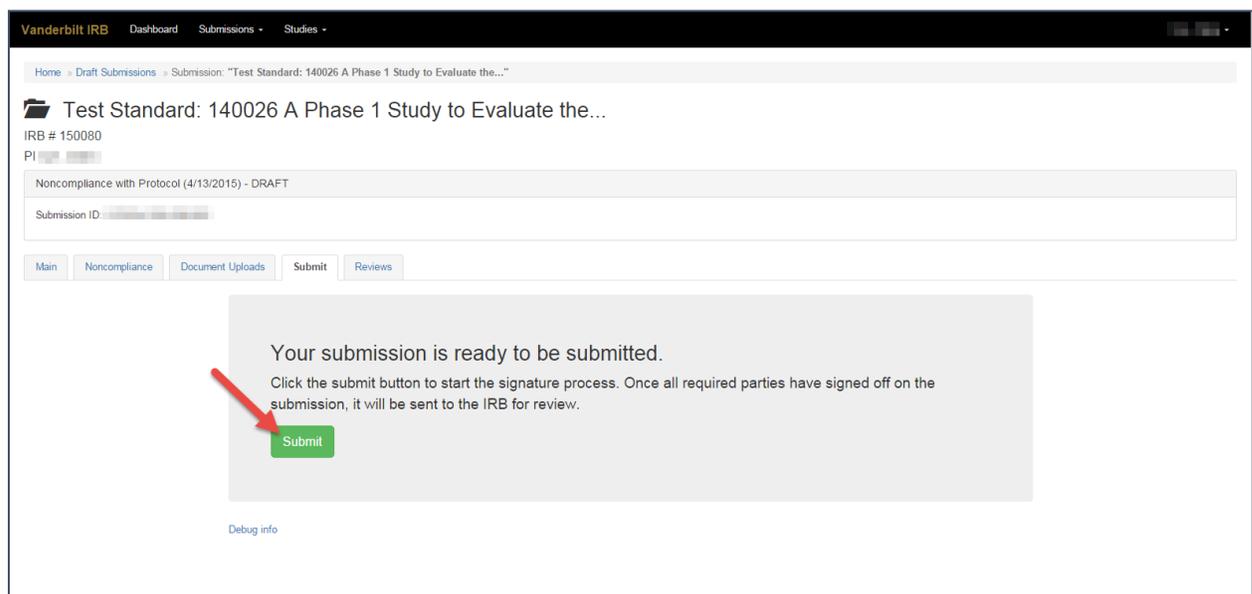
Once all documents are uploaded, Click *Continue*.



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.



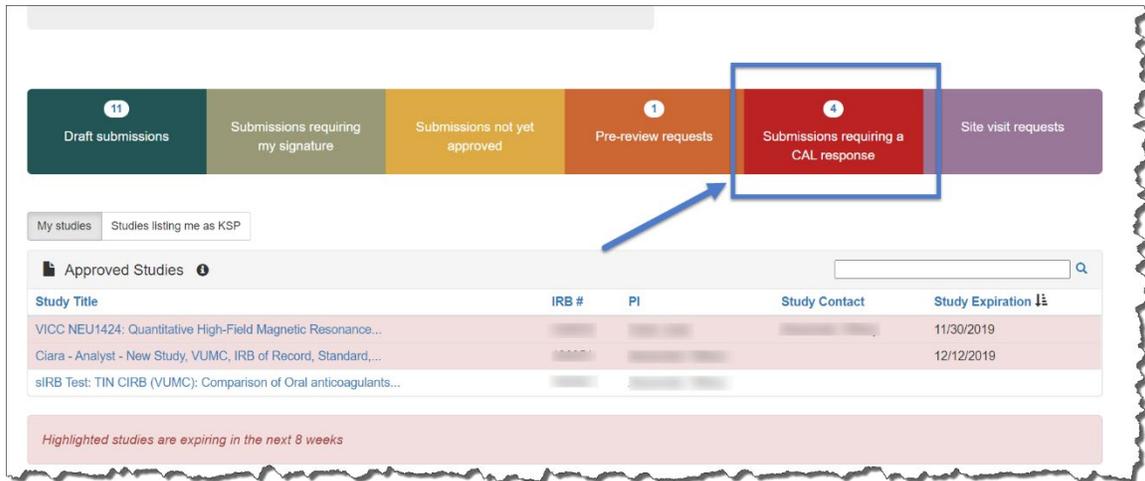
Once the form is complete, click the [Submit](#) button.



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)

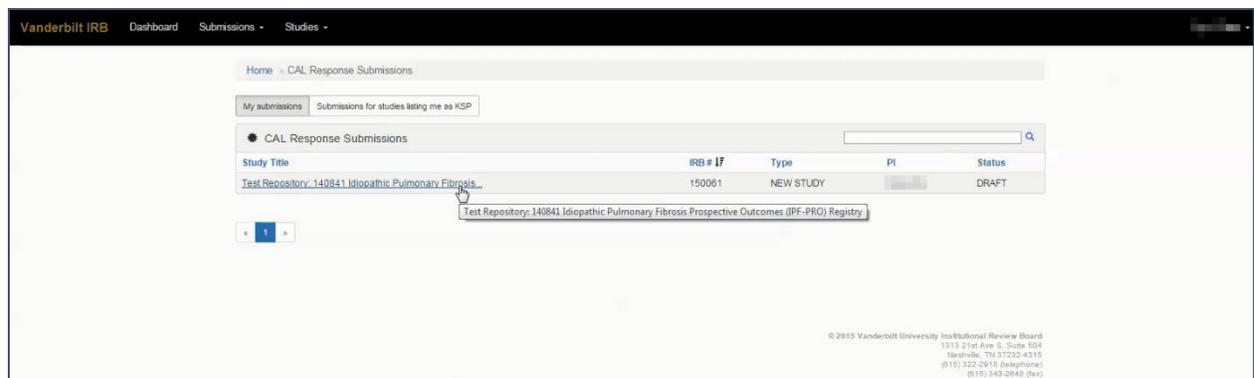
On the dashboard, the Submissions Requiring a CAL Response button will display a number indicating the number of outstanding items awaiting a response from you.



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.

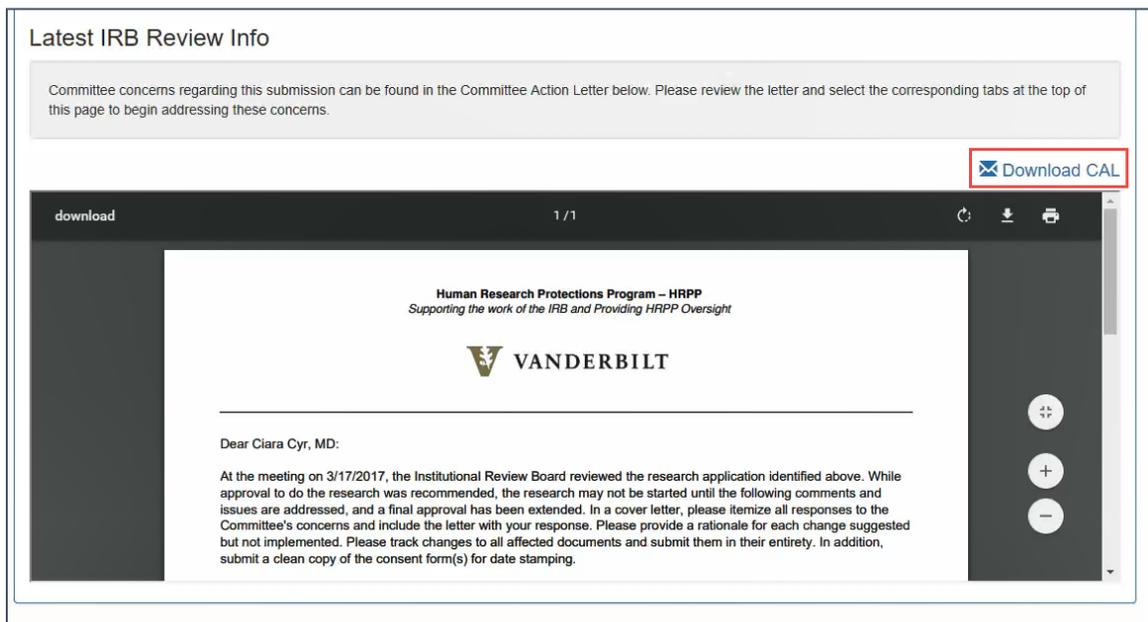


Select the appropriate response item.



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

1. Click the [Download CAL](#) button above the letter

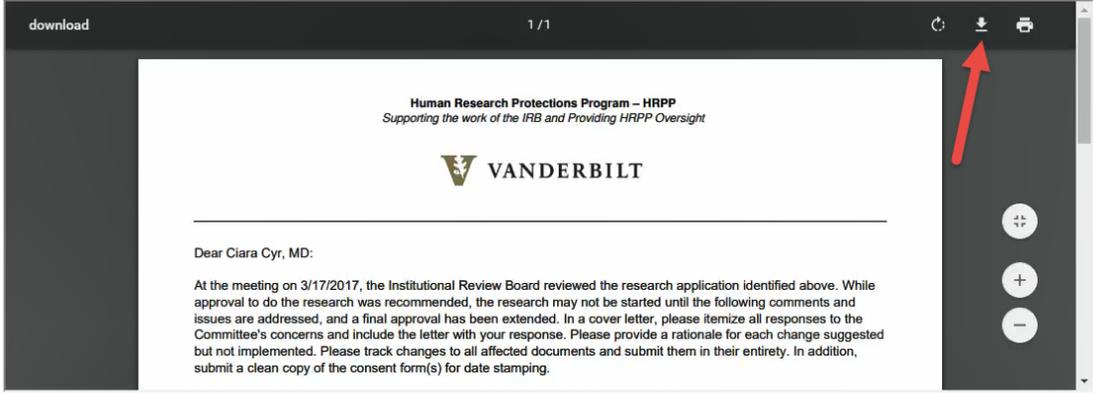


2. Click the [download](#) button in the PDF viewer

Latest IRB Review Info

Committee concerns regarding this submission can be found in the Committee Action Letter below. Please review the letter and select the corresponding tabs at the top of this page to begin addressing these concerns.

[Download CAL](#)



download 1 / 1

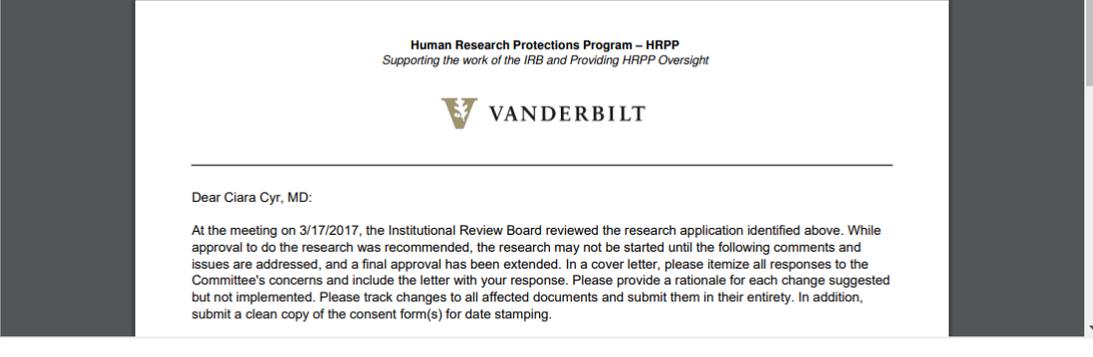
Human Research Protections Program – HRPP
Supporting the work of the IRB and Providing HRPP Oversight

VANDERBILT

Dear Ciara Cyr, MD:

At the meeting on 3/17/2017, the Institutional Review Board reviewed the research application identified above. While approval to do the research was recommended, the research may not be started until the following comments and issues are addressed, and a final approval has been extended. In a cover letter, please itemize all responses to the Committee's concerns and include the letter with your response. Please provide a rationale for each change suggested but not implemented. Please track changes to all affected documents and submit them in their entirety. In addition, submit a clean copy of the consent form(s) for date stamping.

3. Click the [Download CAL](#) link at the bottom of the page under Submission Reviews



Human Research Protections Program – HRPP
Supporting the work of the IRB and Providing HRPP Oversight

VANDERBILT

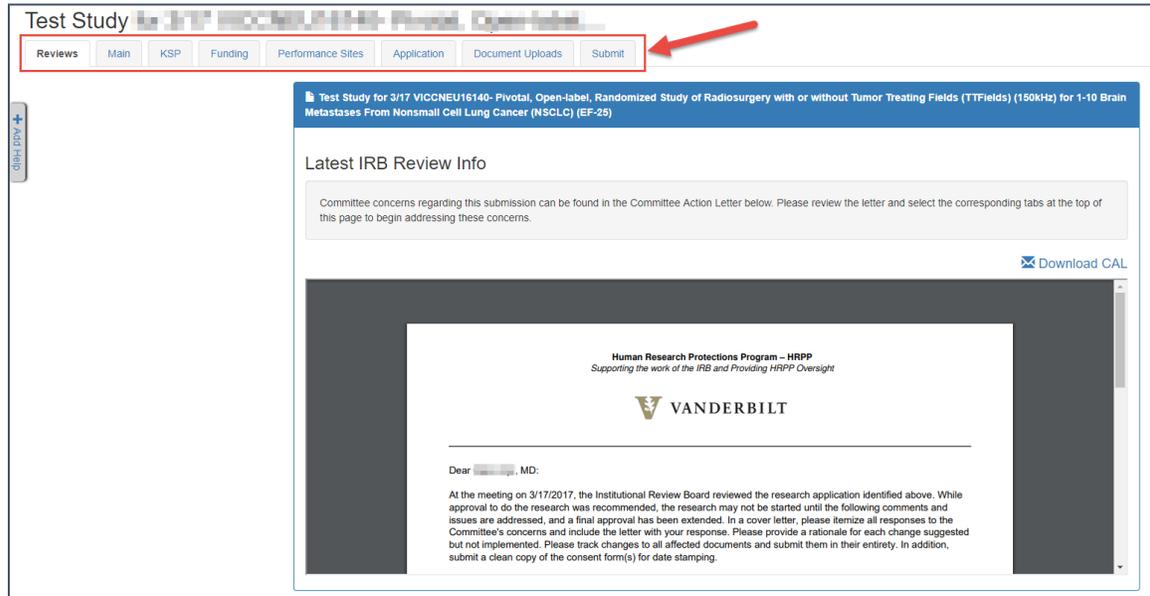
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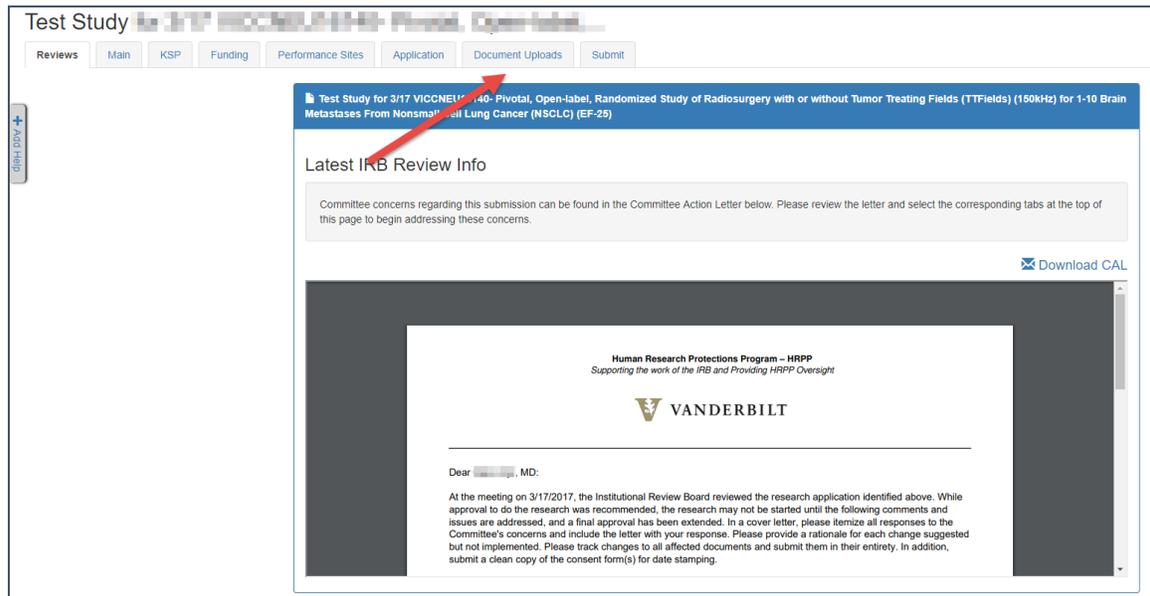
Submission Reviews

Updated On	Meeting Date	Committee	Review Type	Review Outcome	Letter
3/17/2017	3/17/2017	HS1	Full Committee	Approve Pending Changes	Download CAL

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.

Test Study for 3/17 VICCNEU16140- Pivotal, Open-label,...

Reviews Main KSP Funding Performance Sites Application Document Uploads Submit

Attach Documents

Drag file into the region for the appropriate document type. Maximum accepted file size is 512MB.

Protocol IRB Application Continuing Review Application Consent-Assent Document

Grant Investigator's Brochure Advertisement Recruitment

Study Measures Study Materials Other

Global Documents

File Name	Created On	Created By	File Size
Previously Submitted Documents			

Delete selected files Download all

Back Continue

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.

Attach Documents

Drag file into the region for the appropriate document type. Maximum accepted file size is 512MB.

Protocol IRB Application Continuing Review Application Consent-Assent Document

Grant Investigator's Brochure Advertisement Recruitment

Study Measures Study Materials Other

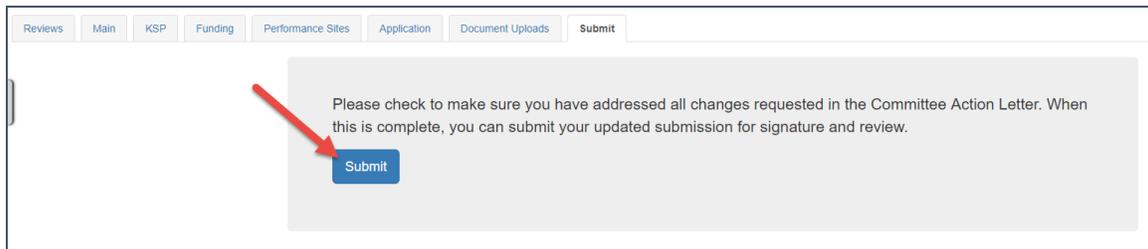
Global Documents

File Name	Created On	Created By	File Size
Previously Submitted Documents			

Delete selected files Download all

Back Continue

When you are sure every concern listed in the CAL has been addressed, click the [Submit](#) button.

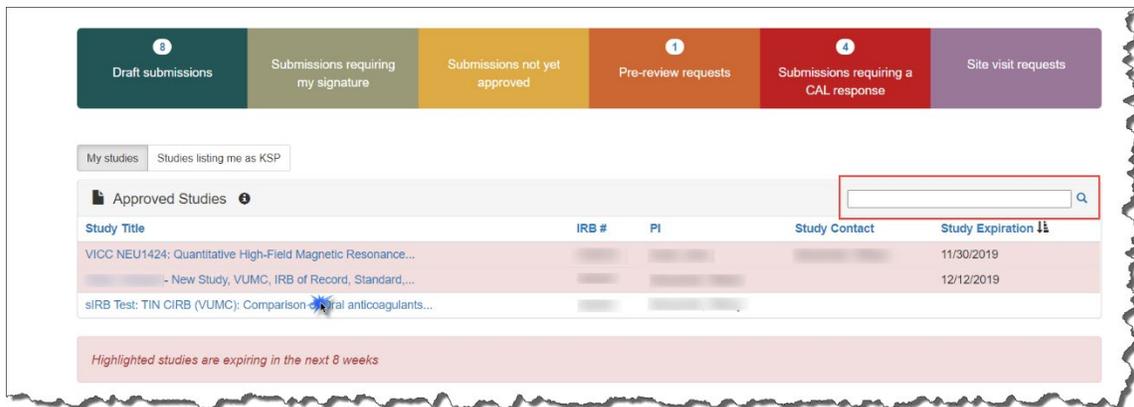
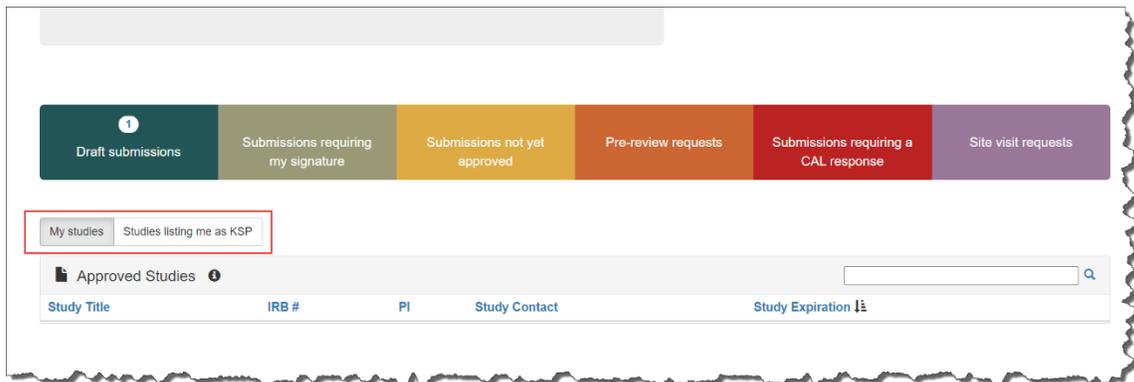


Once the CAL has been submitted, it will be routed for signature by the PI. If you need assistance, please do not hesitate to contact the IRB. Each team has a Regulatory Compliance Analyst that has been involved with the development of the Wizard system. These analysts are there to help you with any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

Home » Approved Studies » Study [Study ID]

Clara - Analyst - New Study, VUMC, IRB of Record, Standard, Approved

IRB # [Redacted]
PI [Redacted]

Info | KSP | Approved Documents | Submissions | Performance Sites | Create Submission

Principal Investigator [Redacted]
Status: Approved
Committee: HS3
Study Coordinator: None Listed
IRB Number: [Redacted]
Study Expiration Date: 12/12/2019
Billable: No

295 days until study expires (12/12/2019)

Days: 295

NCT ID (ClinicalTrials.gov registry number)

Billing Contact/Grants Manager

Save

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.

IRB # [Redacted]
PI [Redacted]

Info | KSP | Approved Documents | Submissions | Funding | Performance Sites | Create Submission

Clara - Analyst - New Study, VUMC, IRB of Record, Standard, Approved

Principal Investigator [Redacted]
Status: Approved
Committee: HS3
Study Coordinator: None Listed
IRB Number: [Redacted]
Study Expiration Date: 12/12/2019
Billable: No
Accrual Goal: 100

0 days until study expires (12/12/2019)

Days: 0

NCT ID (ClinicalTrials.gov registry number)

Save

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.

VUNetID	First Name	Last Name	Department	Credentials	Phone	Role in Project	Accessing PHI (HIPAA)?	Human Subjects Training Expire	GCP Training Expire
VUMC			Human Research Protection	MPH	615-875-9905	Principal Investigator	YES	13-Aug-2021	[NA]

IBC Subcommittee Submission

Subcommittee submissions 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.

Drugs, Devices, Biologics

Please check all that apply: *must provide value

- N/A
- Drug(s)/Biologic(s) or Placebo (inactive substance) Used for Research that HAVE an IND
- Drug(s)/Biologic(s) or Placebo (inactive substance) used for Research that DO NOT have an IND [only include drugs that are being used outside of package insert labeling for indication, route of administration, dose, dosing frequency, dosage form, and/or population in which the drug is being used (i.e., children)]
- IBC Review for Live, Recombinant, and/or Attenuated Microorganisms for Vaccination, Gene Transfer or Botox
- Device(s) Used for Research (devices may also include computer software, in vitro diagnostics, etc.)

Save

Powered by REDCap

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 DISCOVER-e dashboard.

Home » Draft Submissions

create a new study submission

Draft Submissions

Study Title	IRB #	Last Updated	Type	PI	Status
ow study, VUMC-IRB of Record, Expedited,...	180049	12/29/2020	AMENDMENT		DRAFT
IBC		12/19/2019	SUBCOMMITTEE		DRAFT
VICCGI15126: A Phase 1b/2 Study of Ibrutinib Combination...	151924	12/3/2019	ADVERSE EVENT		DRAFT

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

Home » Draft Submissions

create a new study submission

Draft Submissions

Study Title	IRB #	Last Updated	Type	PI	Status
ow study, VUMC-IRB of Record, Expedited,...	180049	12/29/2020	AMENDMENT		DRAFT
IBC		12/19/2019	SUBCOMMITTEE		DRAFT
VICCGI15126: A Phase 1b/2 Study of Ibrutinib Combination...		12/3/2019	ADVERSE EVENT		DRAFT

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

IBC

SUBCOMMITTEE

IRB #

PI

Subcommittee (12/19/2019) - DRAFT

Submission ID:

Subcommittee | Document Uploads | Submit | Reviews

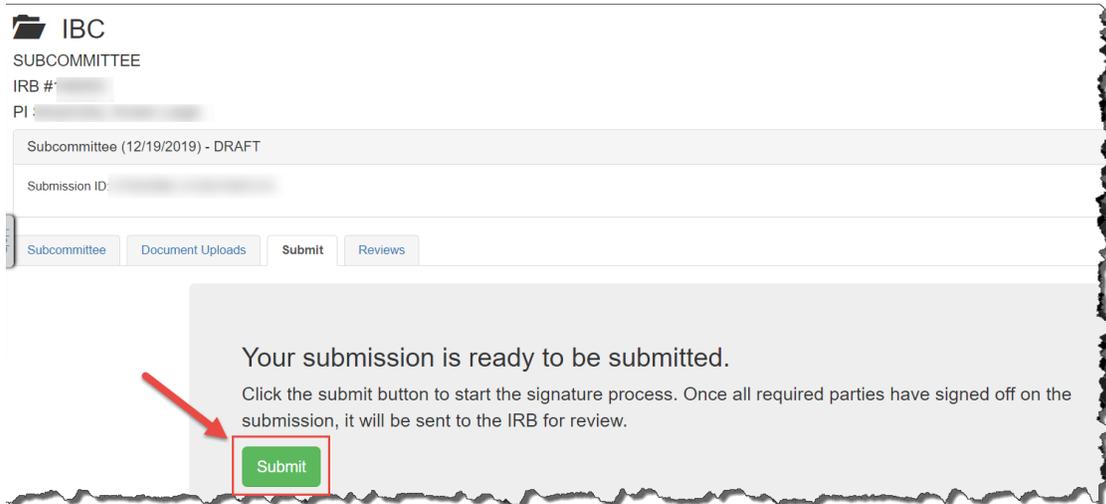
Subcommittee Information

Please describe the nature of the product including its history:
* must provide value

Please describe the agent, its function, expected shedding, and biodistribution:
* must provide value

Fill out each text box to provide information for IBC review.

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

DISCOVER-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 DISCOVER-e system

My Studies– The view within DISCOVER-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 DISCOVER-e system

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

View IRB Training– The dashboard in DISCOVER-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 DISCOVER-e