

DISCOVER-e USER MANUAL

Vanderbilt University Human Research Protection Program

The screenshot shows the Vanderbilt IRB DISCOVER-e investigator dashboard. At the top, the navigation bar includes 'Vanderbilt IRB', 'Dashboard', 'Submissions', and 'Studies'. The user is logged in as 'Johnson, Dena M.'. A welcome message states: 'Welcome, Dena! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions.' A green button labeled '+ Create a new study' is visible.

Below the welcome message are four circular action items with counts:

- Pre-review requests: 2
- Submissions requiring my signature: 11
- Submissions requiring a CAL response: 0
- Draft submissions: 49

To the right of these items is a 'Training expires in:' clock showing 2061 days remaining, with a link to 'View IRB Training'.

The 'My studies' section is active, showing a list of 'Approved Studies' for 'Studies listing me as KSP'. The table below lists the studies:

Study Title	IRB #	PI	Study Contact	Study Expiration
Test study 3	051201	Johnson, Dena M.	Beades, Jenni	1/3/2007
Phase II study test 5- test-test-test	040302	Berlin, Jordan D.	Johnson, Dena M.	2/8/2009
Test Study 02052012 Dena	120005	Johnson, Dena M.		4/18/2014
Using this study for more CAL testing...changed for...	140018	Boeing, Chris	Briggs, Don	11/29/2015
David Hillers Test Study	150118	Hiller, David A.	Johnson, Dena M.	4/6/2016
IRB test#150036 MEL 1400: Stand Up To Cancer Consortium...	150148	Vigil, Karen	Hutchins, Erin	4/8/2016
VICCOMEL1451-A Phase Ib/2, Multicenter, Open-label...	150003	Turner, Chaslety		
Dena - Radiation (Administrative review)-Approve/HSC...	120031	Berlin, Jordan D.	Johnson, Dena M.	
IRB 1-141887	10...	Johnson, Dena M.	Hiller, David A.	

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Introduction

Welcome to the Vanderbilt University Institutional Review Board's new electronic submission system called DISCOVER-e (the Data Integrated Study Console of Vanderbilt's Research Enterprise. 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.

As you work your way around DISCOVER-e, please feel free to share your thoughts, comments, and suggestions by sending an email to the address shown below.

discovere@vanderbilt.edu

Overview

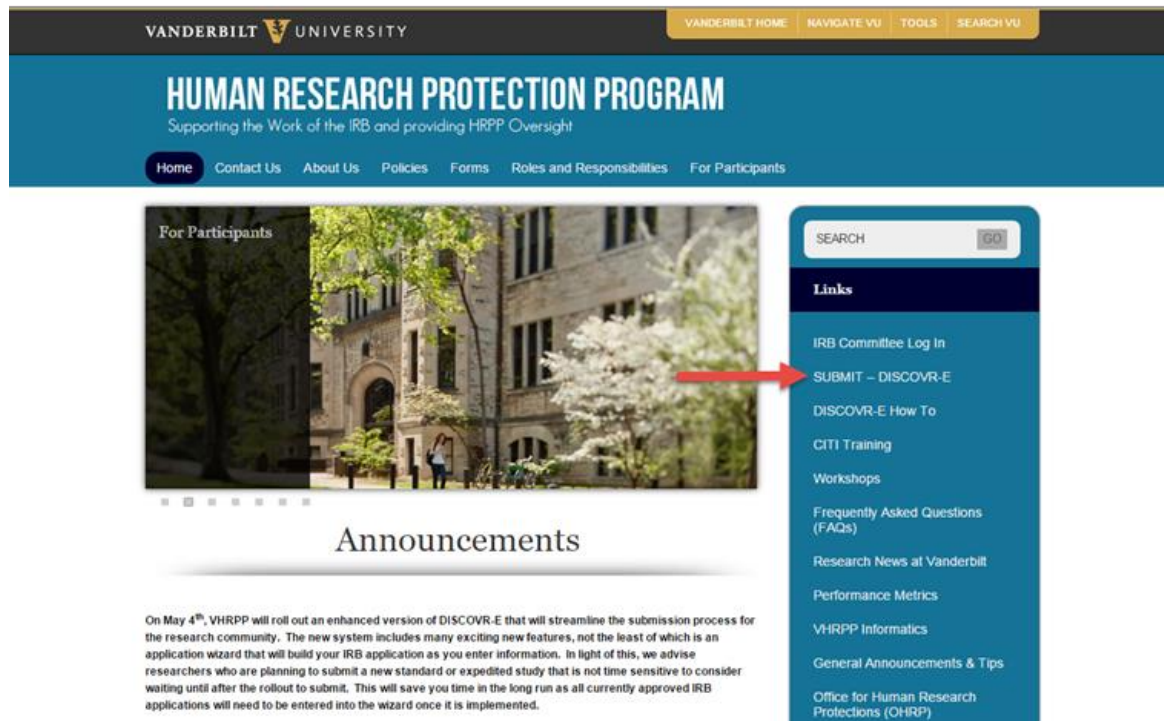
The DISCOVER-e portal is a web-based system. You can log in and submit documents or check the status of a previous submission anywhere in the world where you have a connection to the Internet. This section of the manual will give you an overview of the system and provide highlights of its capabilities.

To access the system, please visit the Vanderbilt IRB website at <https://www4.vanderbilt.edu/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!!!

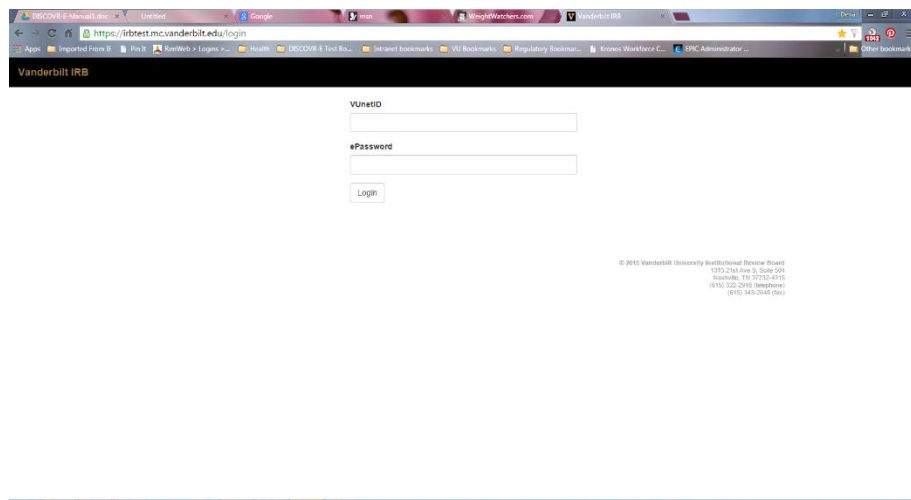
After logging in, you will see your Investigator Dashboard. This is your home page which shows all of your outstanding action items and approved studies. The following pages will provide step-by-step screenshots for creating and responding to outstanding submissions, as well as navigation tips for the site. We plan to provide video tutorials following the rollout as a secondary training tool for the research community so check back often!

Log into the System

You can access the system by going to the IRB website, <https://www4.vanderbilt.edu/irb/> and clicking on the DISCOVER-E link.



You can also access the system by typing the following internet address into your browser: <https://irb.mc.vanderbilt.edu/>. 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 e-password.



Investigator Dashboard Overview

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

Vanderbilt IRB Dashboard Submissions Studies

Welcome, [User]! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [Create a new study](#)

12 Pre-review requests

Submissions requiring my signature

1 Submissions requiring a CAL response

39 Draft submissions

Training expires in: 2732 Days [View IRB Training](#)

My studies Studies listing me as KSP

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
ECOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test: 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test: 140067 HDL Function in Human Disease	150058			4/1/2016
Test Expedited: 140050 Retrospective Review of Coagulation...	150087			4/1/2016
Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016

The different colored buttons across the top of the page show items requiring action from you.

Vanderbilt IRB Dashboard Submissions Studies

Welcome, [User]! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [Create a new study](#)

12 Pre-review requests

Submissions requiring my signature

1 Submissions requiring a CAL response

39 Draft submissions

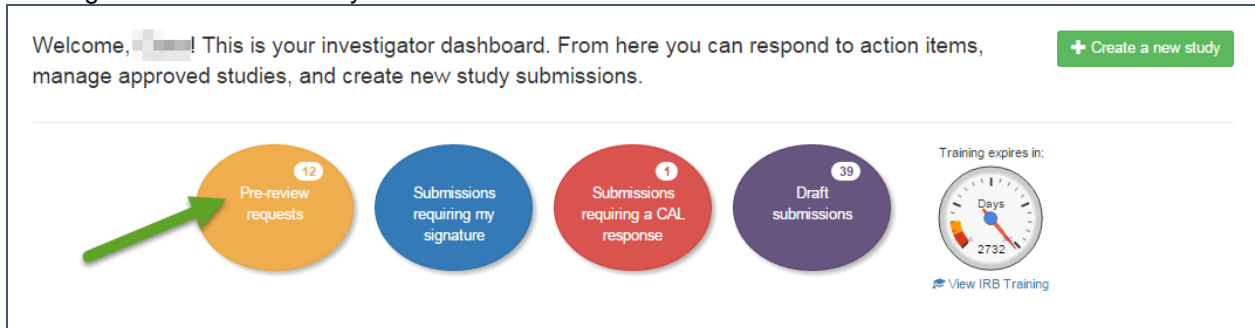
Training expires in: 2732 Days [View IRB Training](#)

My studies Studies listing me as KSP

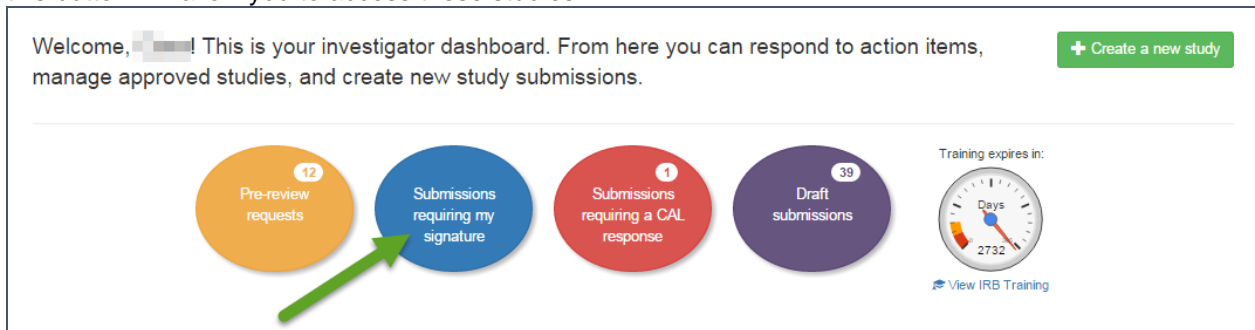
Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
ECOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test: 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test: 140067 HDL Function in Human Disease	150058			4/1/2016
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Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016

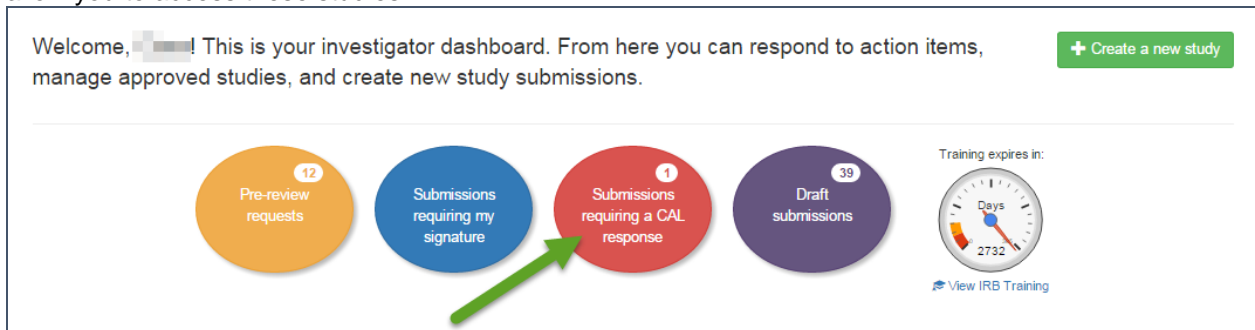
Notice the number in the top, right corner of each button. This number indicates how many items are requiring that particular action. The first button (yellow) is the pre-review requests button. The number in the corner indicates how many submissions require a pre-review response. Clicking this button will allow you to access these studies.



The next button (blue) is the Submissions Requiring My Signature button. The number in the corner indicates how many submissions require your signature before moving forward. Clicking this button will allow you to access these studies.



The next button (red) is the Submissions Requiring a CAL Response button. The number in the corner indicates how many submissions require a response to a CAL. Clicking this button will allow you to access these studies.



The final button (purple) is the Draft Submissions button. The number in the corner indicates how many submissions have been started but have not been completed or sent to the IRB. Clicking this button will allow you to access these studies.


Welcome, [User]! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [+ Create a new study](#)

12
Pre-review requests

Submissions requiring my signature

1
Submissions requiring a CAL response

39
Draft submissions

Training expires in:  2732 Days
[View IRB Training](#)

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.

My studies

Studies listing me as KSP

Study Title	IRB #	PI	Study Contact	Study Expiration
ECOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test: 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test: 140067 HDL Function in Human Disease	150058			4/1/2016
Test Expedited: 140050 Retrospective Review of Coagulation...	150087			4/1/2016
Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016

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

My studies

Studies listing me as KSP

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration ⓘ
ECOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test; 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test; 140067 HDL Function in Human Disease	150058			4/1/2016
Test Expedited: 140050 Retrospective Review of Coagulation...	150087			4/1/2016
Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016

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.

and Study Contact by clicking on the heading.

My studies

Studies listing me as KSP

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration ⓘ
ECOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test; 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test; 140067 HDL Function in Human Disease	150058			4/1/2016
Test Expedited: 140050 Retrospective Review of Coagulation...	150087			4/1/2016
Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016

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 on the right.

My studies Studies listing me as KSP

Approved Studies ?

Study Title	IRB #	PI	Study Contact	Study Expiration ⌵
ECOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test, 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test, 140067 HDL Function in Human Disease	150058			4/1/2016
Test Expedited: 140050 Retrospective Review of Coagulation...	150087			4/1/2016
Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016

The views accessed 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.

Vanderbilt IRB **Dashboard** Submissions Sub Studies

Welcome, This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [+ Create a new study](#)

12 Pre-review requests

Submissions requiring my signature

1 Submissions requiring a CAL response

29 Draft submissions

Training expires in: 2732 days [View IRB Training](#)

My studies Studies listing me as KSP

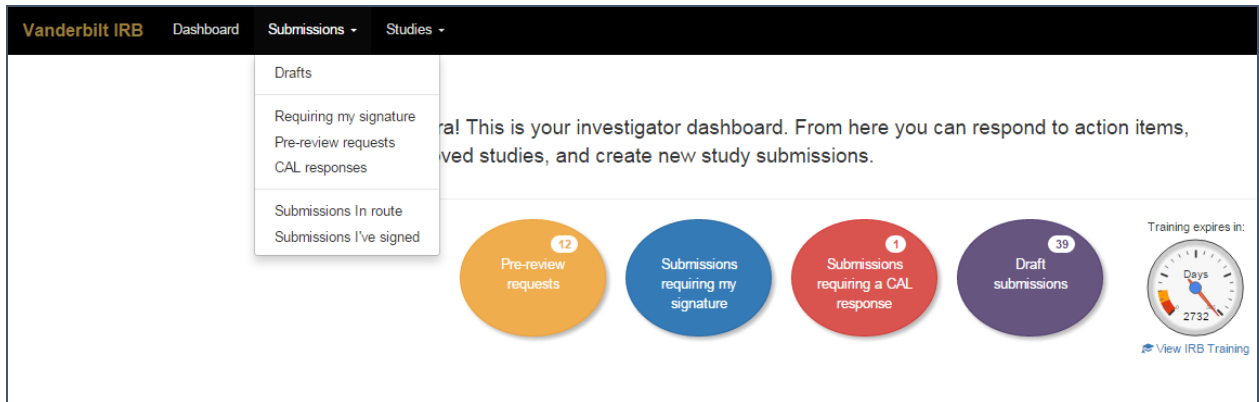
Approved Studies ?

Study Title	IRB #	PI	Study Contact	Study Expiration ⌵
ECOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test, 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test, 140067 HDL Function in Human Disease	150058			4/1/2016
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Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
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Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016

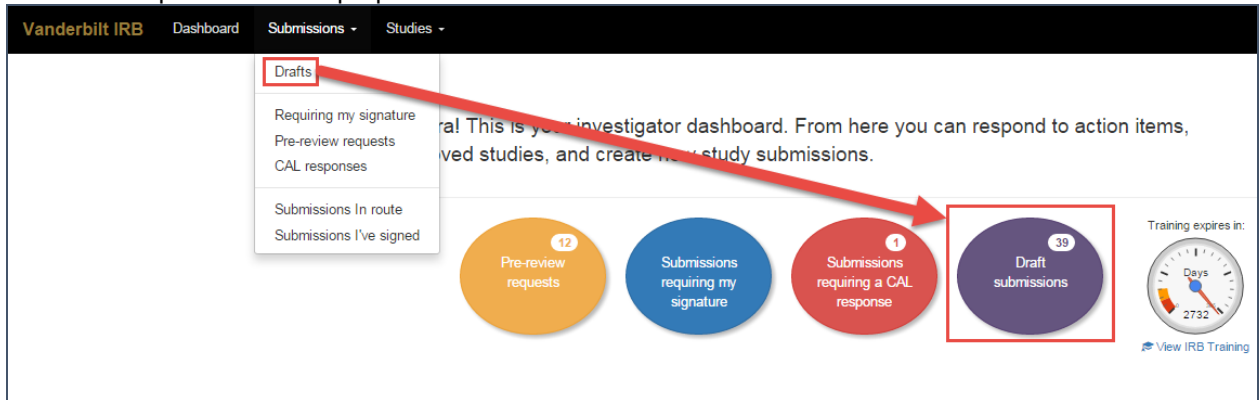
Clicking on Dashboard will return you to your Investigator Dashboard.

Vanderbilt IRB **Dashboard** Submissions Sub Studies

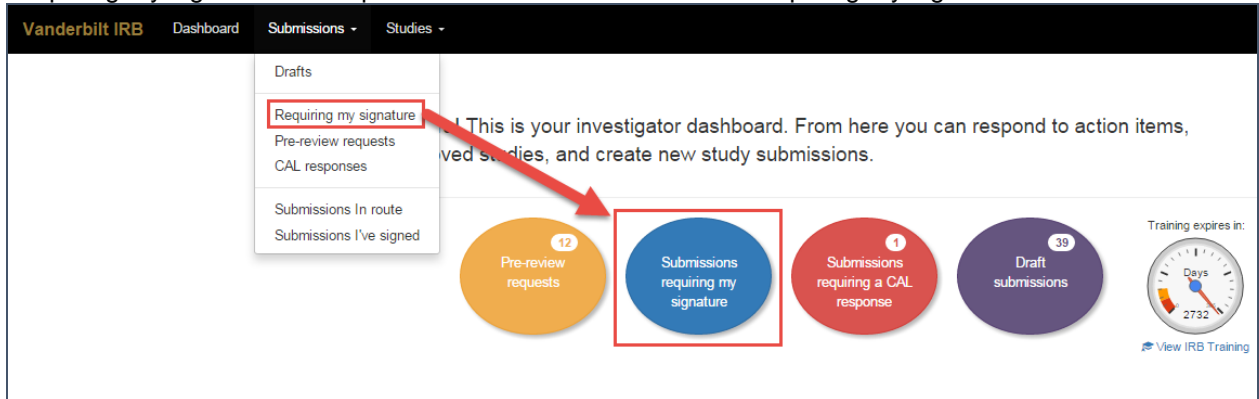
Clicking Submissions will display a drop down menu. This menu holds items corresponding with the buttons on the dashboard, as well as other study views.



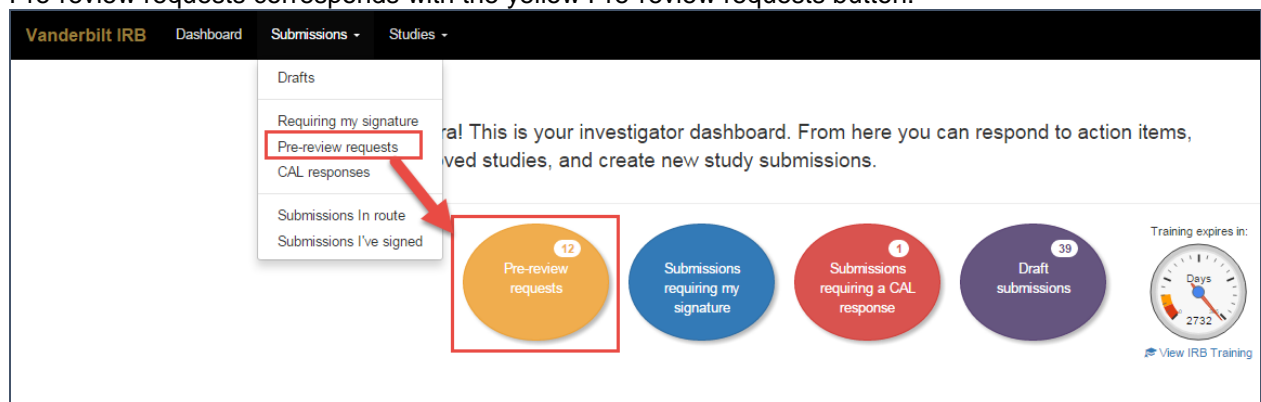
Drafts corresponds with the purple Drafts button.



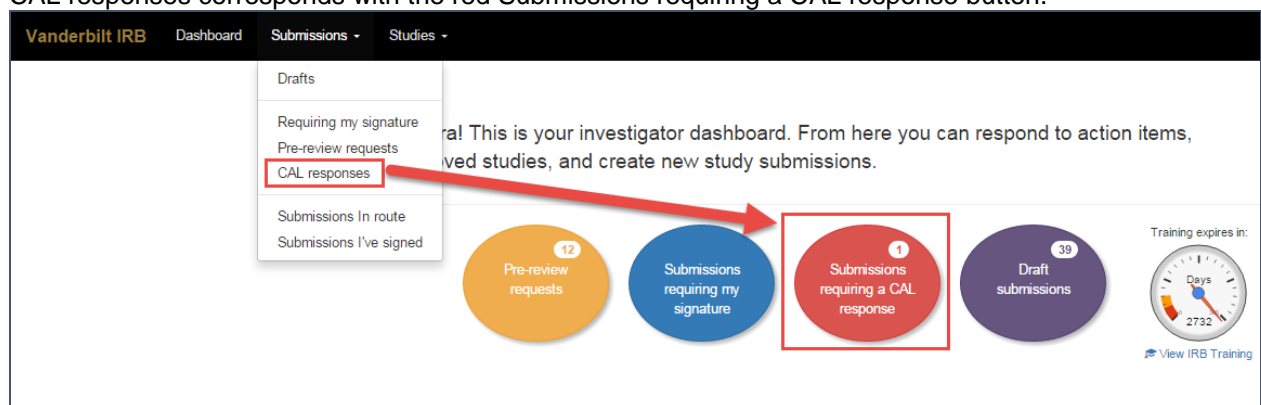
Requiring my signature corresponds with the blue Submissions requiring my signature button.



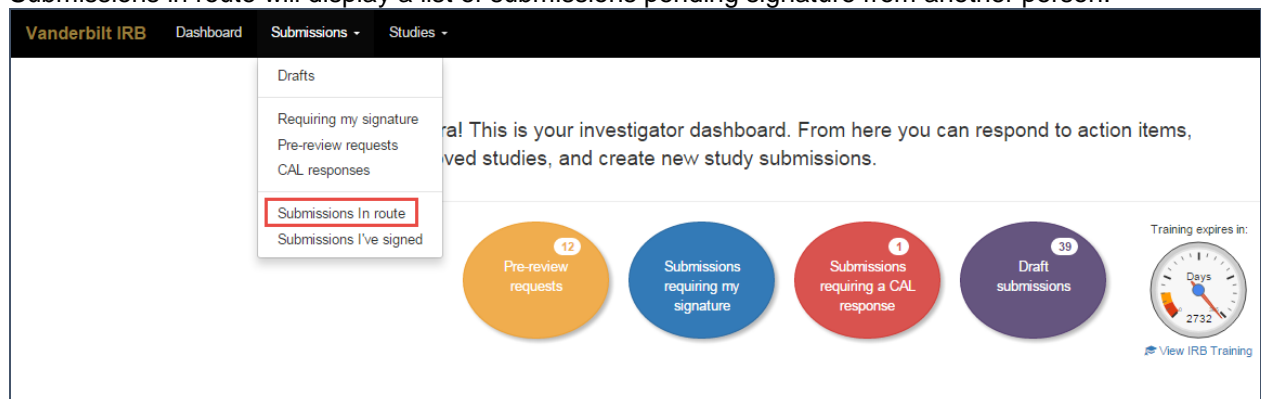
Pre-review requests corresponds with the yellow Pre-review requests button.



CAL responses corresponds with the red Submissions requiring a CAL response button.



This dropdown 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.

The screenshot shows the Vanderbilt IRB Dashboard. The top navigation bar includes 'Vanderbilt IRB', 'Dashboard', 'Submissions', and 'Studies'. The 'Submissions' dropdown menu is open, showing options: 'Drafts', 'Requiring my signature', 'Pre-review requests', 'CAL responses', 'Submissions In route', and 'Submissions I've signed' (which is highlighted with a red box). The main dashboard area contains a welcome message, four circular buttons for 'Pre-review requests' (12), 'Submissions requiring my signature', 'Submissions requiring a CAL response' (1), and 'Draft submissions' (39). A 'Training expires in:' clock shows 2732 days remaining. A 'View IRB Training' link is at the bottom right.

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.

The screenshot shows the Vanderbilt IRB Dashboard with the 'Studies' dropdown menu open. The menu options are 'My studies', 'Studies listing me as KSP', and 'Inactive studies'. The rest of the dashboard interface is identical to the previous screenshot.

My Studies corresponds with the My Studies button.

The screenshot shows the Vanderbilt IRB Dashboard with the 'My studies' button highlighted by a red box and a red arrow pointing to it. Below the button is a table titled 'Approved Studies' with the following data:

Study Title	IRB #	PI	Study Contact	Study Expiration
EOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014	[REDACTED]		1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080	[REDACTED]		4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071	[REDACTED]		4/1/2016

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

Vanderbilt IRB Dashboard Submissions Studies

Welcome, [Name]! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [+ Create a new study](#)

My studies Inactive studies

Pre-review requests (12) Submissions requiring my signature Submissions requiring a CAL response (1) Draft submissions (39) Training expires in: 2732 days [View IRB Training](#)

My studies Studies listing me as KSP

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
EOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014	[Redacted]		1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080	[Redacted]		4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071	[Redacted]		4/1/2016

Clicking Inactive will display a list of your inactive studies.

Vanderbilt IRB Dashboard Submissions Studies

Welcome, [Name]! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [+ Create a new study](#)

My studies Inactive studies

Pre-review requests (12) Submissions requiring my signature Submissions requiring a CAL response (1) Draft submissions (39) Training expires in: 2732 days [View IRB Training](#)

My studies Studies listing me as KSP

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
EOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014	[Redacted]		1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080	[Redacted]		4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071	[Redacted]		4/1/2016

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

Submissions Studies

Welcome, [Name]! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [+ Create a new study](#)

Pre-review requests (12) Submissions requiring my signature Submissions requiring a CAL response (1) Draft submissions (39) Training expires in: 2732 days [View IRB Training](#)

Clicking on the link under the gauge titled View IRB Training will open the view of your training status.

Submissions ▾ Studies ▾


Welcome, [redacted]! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [+ Create a new study](#)

12
Pre-review requests

Submissions requiring my signature

1
Submissions requiring a CAL response

39
Draft submissions

Training expires in:

[View IRB Training](#)


This view displays your IRB Training status and expiration date.


Vanderbilt IRB Dashboard Submissions ▾ Studies ▾

Home » Training Summary

IRB Training Summary

Name: [redacted]
 IRB Training Status: REQUIREMENT IS MET
 Expiration Date: 10/21/2022




[View Latest IRB Training Certificates](#)
 View your five most recent IRB training certificates

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

Submissions ▾ Studies ▾


Welcome, [redacted]! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [+ Create a new study](#)

12
Pre-review requests

Submissions requiring my signature

1
Submissions requiring a CAL response

39
Draft submissions

Training expires in:

[View IRB Training](#)

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.

Click on the study title below to access the study dashboard where you can manage KSP, download documents, or create an amendment, continuing review, adverse event, or report of non-compliance.

My studies

Approved Studies ⓘ

Study Title	IRB #	PI	Study Contact	Study Expiration ⓘ
ECOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test: 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test: 140067 HDL Function in Human Disease	150058			4/1/2016
Test Expedited: 140050 Retrospective Review of Coagulation...	150087			4/1/2016
Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016

Pre-review requests 12

Submissions requiring my signature

Submissions requiring a CAL response 1

Draft submissions 39

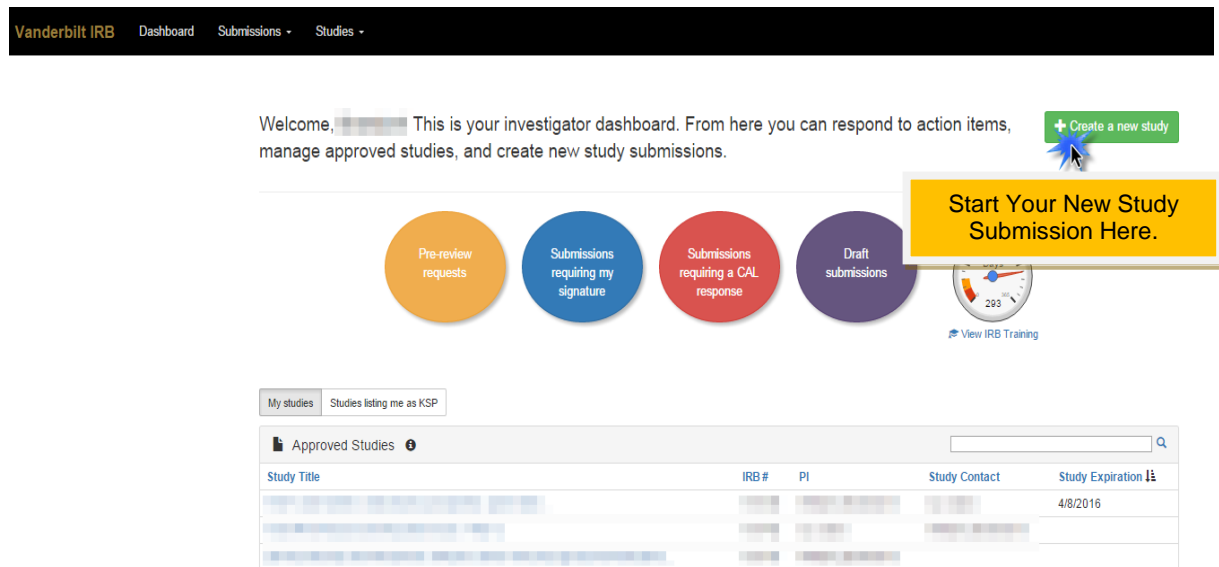
Training expires in: 2732 Days

View IRB Training

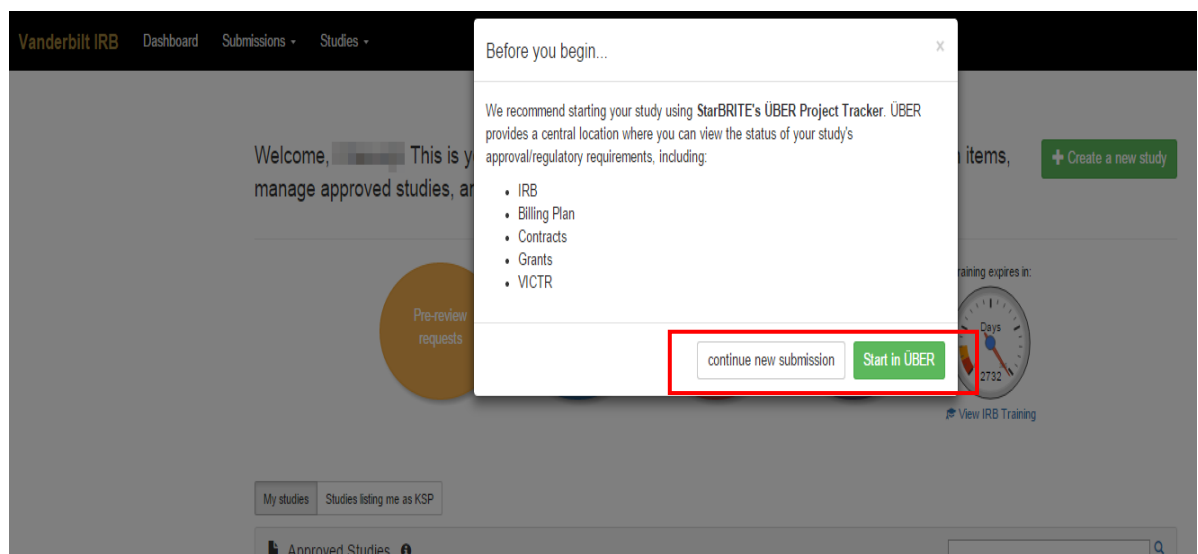
Submitting a New Study

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 StarBRITE’s ÜBER Project Tracker. This feature provides a central location to view the status of your study’s approval/regulatory requirements. To proceed in ÜBER, click the “Start in ÜBER” button. To bypass this feature, click the “Continue New Submission” button.



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 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 322-2918 for assistance.

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

- Study Title**: A text input field.
- Principal Investigator**: A dropdown menu.
- Is the PI a student, resident, or fellow?**: Radio buttons for 'No' and 'Yes'.
- Study Coordinator**: A dropdown menu.
- Department Chair**: A dropdown menu.
- Division Chief**: A dropdown menu.
- Create New Study**: A blue button at the bottom, circled in red.

Annotations on the form:

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

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

Selecting 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 access the CITI Basic and Refresher Courses at <https://www.citiprogram.org>.

The screenshot shows the Vanderbilt IRB investigator dashboard. At the top, there is a navigation bar with 'Vanderbilt IRB', 'Dashboard', 'Submissions', and 'Studies'. The user's name 'Hutchins, Erin L.' is in the top right. Below the navigation bar, a welcome message states: 'Welcome, Erin! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions.' A green button labeled '+ Create a new study' is to the right. Below the welcome message, there are four circular icons representing different study stages: 'Pre-review requests' (1), 'Submissions requiring my signature' (blue), 'Submissions requiring a CAL response' (red), and 'Draft submissions' (4). To the right of these icons is a 'Training expires in:' gauge showing 2723 days. Below the icons, there are two tabs: 'My studies' (selected) and 'Studies listing me as KSP'. Below the tabs is a table titled 'Approved Studies' with columns: 'Study Title', 'IRB #', 'PI', 'Study Contact', and 'Study Expiration'. The table contains four rows of study data. A red box with a blue arrow points to the first row of the table, with the text 'Click on the study title to add/remove KSP.' Below the table, a pink banner states 'Highlighted studies are expiring in the next 8 weeks'.

Vanderbilt IRB Dashboard Submissions Studies Hutchins, Erin L.

Welcome, Erin! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. + Create a new study

1 Pre-review requests
Submissions requiring my signature
Submissions requiring a CAL response
4 Draft submissions
Training expires in: 2723 Days

My studies Studies listing me as KSP

Click on the study title to add/remove KSP.

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
- test - test - test - test - test - test - ...	050615	Hiller, David A.	Hutchins, Erin	10/11/2006
Metabolic and CD4+ T Cell Dysregulation in Post-Transplant...	150013	Hutchins, Erin		1/21/2016
IRB test#150036 MEL 1460: Stand Up To Cancer Consortium...	150148	Vigil, Karen	Hutchins, Erin	4/8/2016
Test IRB# 130393 A Phase 2, Randomized, Double-Blind...	150151	Hutchins, Erin	Johnson, Tiara B.	4/9/2016

Highlighted studies are expiring in the next 8 weeks

Click on the KSP tab

Vanderbilt IRB Dashboard Submissions Studies Hutchins, Erin L

Home » Approved Studies » Study: "IRB test#150036 MEL 1460: Stand Up To Cancer Consortium..."

IRB test#150036 MEL 1460: Stand Up To Cancer Consortium...

IRB # 150148
PI Vigil, Karen


Info **KSP** Approved Documents Submissions Create Submission

Click on the KSP tab

IRB test#150036 MEL 1460: Stand Up To Cancer Consortium Genomics-Enabled Medicine for Melanoma (G.E.M.M.): Using Molecularly-Guided Therapy for Patients with BRAF Wild-Type (BRAFWt) Metastatic Melanoma

Principal Investigator	Vigil, Karen
Status	Approved
Committee	HS3
Study Coordinator	Erin Hutchins
IRB Number	150148
Study Expiration Date	4/8/2016

345 days until study expires (4/8/2016)



NCT ID (ClinicalTrials.gov registry number)

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.

IRB test#150036 MEL 1460: Stand Up To Cancer Consortium...

IRB # 150148

PI Vigil, Karen

Info **KSP** Approved Documents Submissions Create Submission

Current KSP History

Please list your staff's highest degree level. If someone does not have a degree, you may enter N/A.

Pager numbers will be auto-filled if available. If we cannot find one for a KSP who has a pager, please provide the number in case of urgent issues

Select the role in the project: Clinical, Non-Clinical, Sub-Investigator

Indicate whether the member of KSP is accessing

VUNetID	First Name	Last Name	Department	Credentials	Phone	Pager	Role in Project	Accessing PHI (HIPAA)	Training Expire
VIGILKM	Karen	Vigil	Human Research Protection	MD	615-875-9905		Principal Investigator	YES	21-Oct-2022
HUTCHIEL	Erin	Hutchins	Human Research Protection	MD	615-322-2918		Study Coordinator	YES	06-Oct-2022
JOHNSTB7	Tiara	Johnson	Human Research Protection	MD	615-322-2918		Research - Clinical	YES	03-Feb-2026
HUBBARTM	Tyler	Hubbard	Human Research Protection	MD	615-875-8716		Research - Clinical	YES	31-Oct-2022
ARRINGJG	James	Arrington	Human Research Protection	BA	615-875-8961		Research - Non-Clinical	YES	31-Mar-2022
CYRC	Ciara	Cyr	Human Research Protection		615-875-9704		[Select a Role]	Select	21-Oct-2022

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

Save KSPs

Hit the Save KSPs button to save your changes

Hit the “Save KSP’s” 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.

IRB test#150036 MEL 1460: Stand Up To Cancer Consortium...

IRB # 150148

PI Vigil, Karen

Info KSP Approved Documents Submissions Create Submission

Current KSP History

Click on the trash icon of the KSP member you wish to remove from the study.

VUNetID	First Name	Last Name	Department	Credentials	Phone	Pager	Role in Project	Accessing PHI (HIPAA)?	Training Expire
VIGILKM	Karen	Vigil	Human Research Protect	MD	615-875-9905		Principal Investigator	YES	21-Oct-2022
HUTCHIEL	Erin	Hutchins	Human Research Protect	MD	615-322-2918		Study Coordinator	YES	06-Oct-2022
JOHNSTB7	Tiara	Johnson	Human Research Protect	MD	615-322-2918		Research - Clinical	YES	03-Feb-2026
HUBBARTM	Tyler	Hubbard	Human Research Protect	MD	615-875-8716		Research - Clinical	YES	31-Oct-2022
ARRINGJG	James	Arrington	Human Research Protect	BA	615-875-8961		Research - Non-Clinical	YES	31-Mar-2022
CYRC	Clara	Cyr	Human Research Protect	MS	615-875-9704		Research - Clinical	YES	21-Oct-2022

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

Save KSPs

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.

IRB test#150036 MEL 1460: Stand Up To Cancer Consortium...

IRB # 150148

PI Vigil, Karen

Info KSP Approved Documents Submissions Create Submission

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.

VUNetID	First Name	Last Name	Department	Credentials	Phone	Pager	Role in Project	Accessing PHI (HIPAA)?	Training Expire
VIGILKM	Karen	Vigil	Human Research Protect	MD	615-875-9905		Principal Investigator	YES	21-Oct-2022
HUTCHIEL	Erin	Hutchins	Human Research Protect	MD	615-322-2918		Study Coordinator	YES	06-Oct-2022
JOHNSTB7	Tiara	Johnson	Human Research Protect	MD	615-322-2918		Research - Clinical	YES	03-Feb-2026
HUBBARTM	Tyler	Hubbard	Human Research Protect	MD	615-875-8716		Research - Clinical	YES	31-Oct-2022
ARRINGJG	James	Arrington	Human Research Protect	BA	615-875-8961		Research - Non-Clinical	YES	31-Mar-2022
CYRC	Clara	Cyr	Human Research Protect	MS	615-875-9704		Research - Clinical	YES	21-Oct-2022

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

Hit the Save KSPs button to save your changes

Save KSPs

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

Vanderbilt IRB Dashboard Submissions ▾ Studies ▾Hutchins, Erin L ▾

Home > Approved Studies > Study: "IRB test#150036 MEL 1460: Stand Up To Cancer Consortium..."

IRB test#150036 MEL 1460: Stand Up To Cancer Consortium...

IRB # 150148
PI Vigil, Karen

Info **KSP** Approved Documents Submissions ➕ Create Submission

Current KSP **History**

Date Added	Date Removed	VUNetID	First Name	Last Name	Added By	Deleted By
04/22/2015		ARRINGJG	James	Arrington	HUTCHIEL	N/A
04/27/2015		CYRC	Clara	Cyr	HUTCHIEL	N/A
04/10/2015		HUBBARTM	Tyler	Hubbard	SYSTEM	N/A
04/10/2015		HUTCHIEL	Erin	Hutchins	SYSTEM	N/A
04/10/2015	04/27/2015	JOHNSTB7	Tiara	Johnson	SYSTEM	HUTCHIEL
04/22/2015	04/22/2015	PFLUMAE	Amy	Pflum	HUTCHIEL	HUTCHIEL
04/22/2015	04/22/2015	TURNERC9	Chasiety	Turner	HUTCHIEL	HUTCHIEL
04/10/2015		VIGILKM	Karen	Vigil	SYSTEM	N/A

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

Adding a Funding Source

Indicate whether the study is funded by external support, VICTR funding support/use of VICTR facilities, internal funds or not funded.

[Main](#) [KSP](#) [Funding](#) [Application](#) [Document Uploads](#) [Submit](#) [Reviews](#)

Funding Questions

Indicate whether the study involves (check all that apply):

- ☒ External Support of any kind (funding, drug, supplies, equipment or personnel) from Government, Foundation or Industry
- ☐ VICTR funding support or use of VICTR facilities
- ☐ Internal funds
- ☐ No funds

Please specify this study's funding sources. [\\$ Add Funding Source](#)

Next, specify the study's funding source by clicking the "Add Funding Source" button.

Add Funding Source

Funding Type: ▼

Funder:

- Department Funds
- Donor/Gift
- Federal Foundation
- Industry
- Personal Funds
- VICTR

To add a funding source for your study, select the funding type within the dropdown menu.

Funding Questions

Indicate whether the study involves (check all that apply):

- ☒ External Support of any kind (funding, drug, supplies, equipment or personnel) from Government, Foundation or Industry
- ☐ VICTR funding support or use of VICTR facilities
- ☐ Internal funds
- ☐ No funds

Please specify this study's funding sources. [\\$ Add Funding Source](#)

Is there a grant application or proposal required for the external support?
☐ Yes ☐ No

Will the external support require the signing of a written letter/MOU/agreement/contract?
☐ Yes ☐ No

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

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

You are currently logged in as an investigator

Vanderbilt IRB Dashboard Submissions Studies

Chemistry: Human Cell Imaging (HPI-2014)

Main KSP **Funding** Application Document Uploads Sub

Funding Questions

Indicate whether the study involves (check all that apply):

- ☒ External Support of any kind (funding, drug, supplies, equipment or personnel) from Government, Foundation or Industry
- ☐ VICTR funding support or use of VICTR facilities
- ☐ Internal funds
- ☐ No funds

Please specify this study's funding sources. [\\$ Add Funding Source](#)

Is there a grant application or proposal required for the external support?
☐ Yes ☐ No

Will the external support require the signing of a written letter/MOU/agreement/contract?
☐ Yes ☐ No

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

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

Add Funding Source

Funding Type: Department Funds

Funder: Vanderbilt ✓

[Accept](#) [Cancel](#)

Add the funder for your research and select "Accept".

Vanderbilt IRB Dashboard Submissions Studies

Chemistry: Human Cell Imaging (HPI-2014)

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

Funding Questions

Indicate whether the study involves (check all that apply):

- ☒ External Support of any kind (funding, drug, supplies, equipment or personnel) from Government, Foundation or Industry
- ☐ VICTR funding support or use of VICTR facilities
- ☐ Internal funds
- ☐ No funds

Please specify this study's funding sources. [\\$ Add Funding Source](#)

Is there a grant application or proposal required for the external support?
☐ Yes ☐ No

Will the external support require the signing of a written letter/MOU/agreement/contract?
☐ Yes ☐ No



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

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



Funding Sources

[\\$ Add Funding Source](#)

DEPARTMENT FUNDS  

Vanderbilt

Your funding source will be found under "Funding Sources".
You may click the "pencil" icon to edit your funding source or the "trashcan" icon to delete it.

DEPARTMENT FUNDS  

Vanderbilt

[\\$ Add Funding Source](#)

Once all funding-related questions have been completed and you are ready to proceed with the creation of your new study submission, click the “Save and Continue” button at the bottom of the form.

The screenshot shows a web form titled "Funding Questions". At the top, a navigation bar contains buttons for "Main", "KSP", "Funding" (circled in red), "Application", "Document Uploads", "Submit", and "Reviews". The "Funding" section includes a heading "Indicate whether the study involves (check all that apply):" followed by four checkboxes: "External Support of any kind (funding, drug, supplies, equipment or personnel) from Government, Foundation or Industry" (checked), "VICTR funding support or use of VICTR facilities", "Internal funds", and "No funds". Below this is a green box with the text "Please specify this study's funding sources." and a green button labeled "\$ Add Funding Source". To the right, a sidebar titled "Funding Sources" has a green button "\$ Add Funding Source" and a list of "DEPARTMENT FUNDS" with "Vanderbilt" listed. Below the funding questions are four radio button questions: "Is there a grant application or proposal required for the external support?" (Yes/No), "Will the external support require the signing of a written letter/MOU/agreement/contract?" (Yes/No), "Does the study involve the use of Vanderbilt hospital facilities or assays related to human samples/tissue?" (Yes/No), and "Does this study have an associated billing plan?" (Yes/No). At the bottom, a navigation bar contains buttons for "Back", "Save", and "Save and Continue" (circled in red).

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

Funding Questions

Indicate whether the study involves (check all that apply):

- ☒ External Support of any kind (funding, drug, supplies, equipment or personnel) from Government, Foundation or Industry
- ☐ VICTR funding support or use of VICTR facilities
- ☐ Internal funds
- ☐ No funds

Please specify this study's funding sources. [\\$ Add Funding Source](#)

Is there a grant application or proposal required for the external support?
☐ Yes ☐ No

Will the external support require the signing of a written letter/MOU/agreement/contract?
☐ Yes ☐ No

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

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

Funding Sources

[\\$ Add Funding Source](#)

DEPARTMENT FUNDS [✎](#) [🗑](#)

Vanderbilt

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.

New Study Title

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

Summary

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

Application Submission Summary

Application is saved and complete

Download Application

Continue

Progress:

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.

Data and Safety

Subject Population(s)

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.

Home > Draft Submissions > Submission: "New Study Title"

New Study Title

Main KSP 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

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 choice 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.

[Main](#)
[KSP](#)
[Funding](#)
[Application](#)
[Document Uploads](#)
[Submit](#)
[Reviews](#)

Attach Study Files

[Drag and Drop](#)
[Standard](#)

Attachment

No file chosen

Type of study document

[Select Document Type]

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

[← Back](#)
[→ Continue](#)

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.

Submission Documents

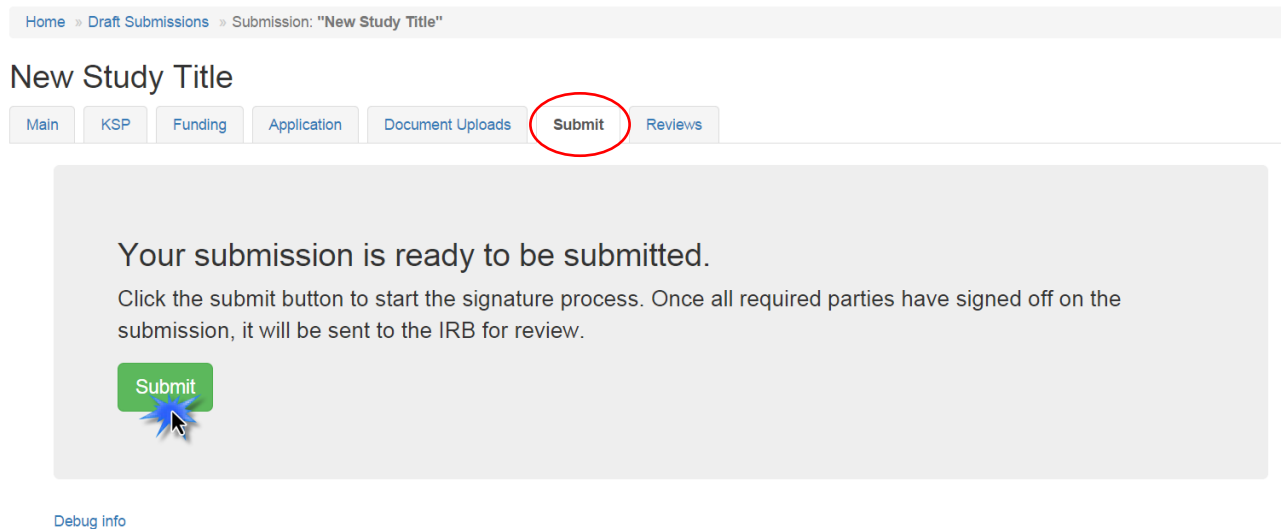
	File Name	Type	Created On	Created By	File Size
<input type="checkbox"/>	ICD.pdf	Consent-Assent Document	4/16/2015		879 KB
<input checked="" type="checkbox"/>	IND Letter.pdf	Other	4/16/2015		879 KB
<input type="checkbox"/>	PRO.pdf	Protocol	4/16/2015		879 KB
<input type="checkbox"/>	Survey.pdf	Study Measures	4/16/2015		879 KB
<input type="checkbox"/>	Patient Card.pdf	Study Materials	4/16/2015		879 KB

[Delete selected files](#)
[Download all](#)

[← Back](#)
[→ Continue](#)

To continue with submission process, click the “Continue” button.

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



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

How to Retract a Submission

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

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

The screenshot shows the top navigation bar of the Vanderbilt IRB system. The 'Submissions' dropdown menu is open, and the 'Submissions In route' option is highlighted with a red box. A yellow arrow points to this option with the text: 'Select the “Submissions” dropdown menu at the top of the screen and click the “Submissions in Route” button.' Below the menu, a table lists submissions with columns for Date, Type, PI, and Status.

Date	Type	PI	Status
4/21/2015	NEW STUDY	[Redacted]	PENDING DEPT CHAIR SIGNATURE
4/16/2015	CONTINUING REVIEW	[Redacted]	SUBMITTED
4/15/2015	NEW STUDY	[Redacted]	SUBMITTED
4/9/2015	NEW STUDY	[Redacted]	SUBMITTED
4/8/2015	NEW STUDY	[Redacted]	SUBMITTED
4/8/2015	NEW STUDY	[Redacted]	SUBMITTED
4/6/2015	NONCOMPLIANCE WITH THE PROTOCOL	[Redacted]	SUBMITTED

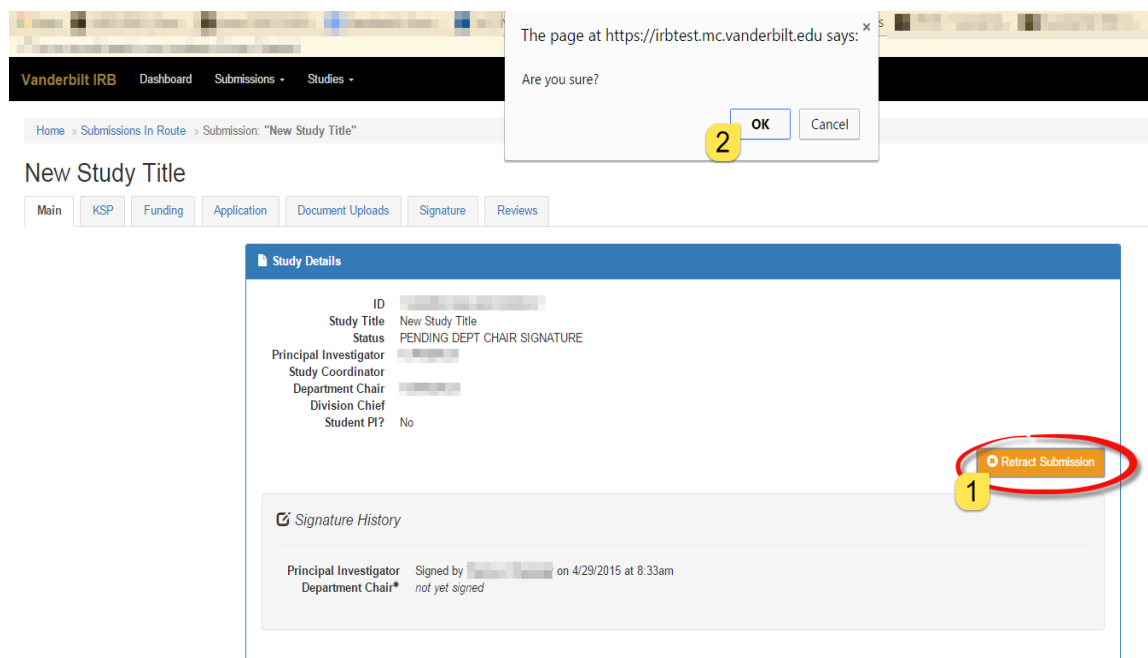
Locate the submission you wish to retract by selecting the study title of that submission.

The screenshot shows the 'Submissions In Route' page. A starburst callout points to the 'New Study Title' link in the 'Study Title' column of the submission list. The callout contains the text: 'Locate the submission you wish to retract by selecting the study title of that submission.'

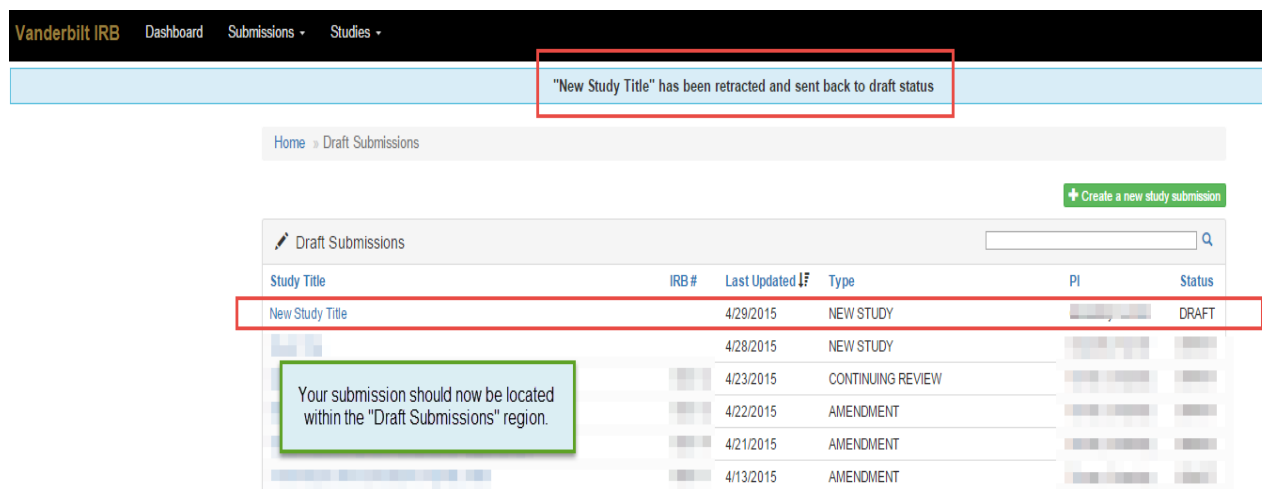
Study Title	IRB #	Last Updated	Type	PI	Status
New Study Title		4/29/2015	NEW STUDY	[Redacted]	PENDING DEPT CHAIR SIGNATURE

Vanderbilt University Institutional Review Board
discover@vanderbilt.edu
1313 21st Ave S, Suite 504
Nashville, TN 37203-4315
(615) 322-2918

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 located in your “Drafts Submissions” view within your Investigator’s Dashboard.



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

The screenshot shows the 'Vanderbilt IRB' dashboard with a navigation bar containing 'Dashboard', 'Submissions', and 'Studies'. Below this, a breadcrumb trail reads 'Home > Draft Submissions > Submission: "New Study Title"'. The main heading is 'New Study Title'. A row of tabs includes 'Main', 'KSP', 'Funding', 'Application', 'Document Uploads', 'Submit', and 'Reviews'. A red box highlights the 'Main' tab. An orange starburst callout points to the tabs with the text: 'Navigate through your study tabs to edit any information within your submission.' The form fields include: 'Study Title' (text input with 'New Study Title'), 'Principal Investigator' (dropdown menu), 'Is the PI a student, resident, or fellow?' (radio buttons for 'No' and 'Yes'), 'Study Coordinator' (text input), 'Department Chair' (dropdown menu), and 'Division Chief' (text input). At the bottom are 'Save' and 'Save and Continue' buttons. A red circle highlights a 'Delete' button in the bottom right corner, with a green callout box stating: 'If you want to delete the submission, simply click the "Delete" button.'

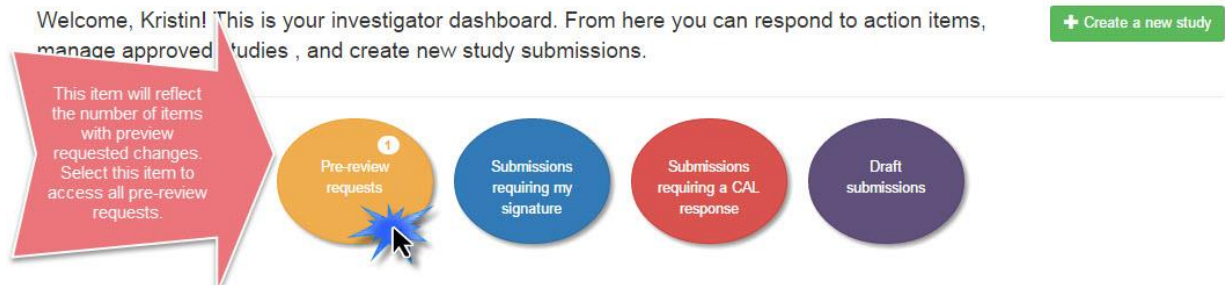
If you would like to delete your submission, simply click the "Delete" button.

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.

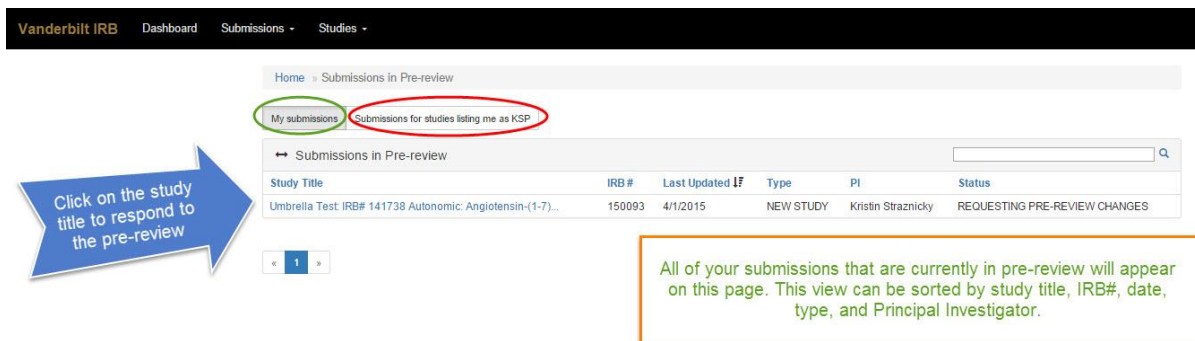
The screenshot shows the 'New Study Title' page with the 'Submit' tab selected and circled in red. An orange callout box on the left says: 'After making your edits and saving your work, advance to the "Submit" tab and submit your submission to re-route for appropriate signatures.' The main content area has a grey background with 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.' Below this text is a green 'Submit' button with a mouse cursor clicking it. A 'Debug info' link is visible at the bottom left of the main content area.

How to Respond to a Pre-review

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



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



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

Test Expedited new study

[Main](#)
[KSP](#)
[Funding](#)
[Application](#)
[Document Uploads](#)
[Pre-review](#)
[Reviews](#)

This item gives a summary of changes requested to the IRB electronic application.

Test Expedited new study:

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

This item shows general comments and changes requested to attached documents.

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](#)

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.

Home > Submissions in Pre-review > Submission: "Test Expedited new study"

Test Expedited new study:

[Main](#)
[KSP](#)
[Funding](#)
[Application](#)
[Document Uploads](#)
[Pre-review](#)
[Reviews](#)

Click on each tab to make changes and review comments

[Download Application](#)

Summary
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 ■ comments
Recruitment ✓ complete ■ comments
Radiation Procedures and Radioactive Drugs ✓ complete

Sections of the IRB application with changes requested will be highlighted.

Pre-Review Comments

Subject Population(s)

- Check all that apply ("Complete the appropriate supplemental information as applicable):
 - If individuals under the age of 18 will be enrolled on this study, please select Children/minors. 2015-03-30 14:53:53 (STRAZNKL)

Recruitment

- Please identify ALL applicable recruitment methods:
 - Please confirm if flyers will be used for recruitment. 2015-03-30 14:55:17 (STRAZNKL)

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 (STRAZNLK)

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 Application Document Uploads Pre-review Reviews

Attach Study Files

Drag and Drop Standard

Protocol

Consent-Assent Document

Advertisement

Study Materials

IRB Application

Grant

Recruitment

Other

Continuing Review Application

Investigators Brochure

Study Measures

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

Submission Documents

<input type="checkbox"/>	File Name	Type	Created On	Created By	File Size
<input type="checkbox"/>	Assent-Form.doc	Consent-Assent Document	3/30/2015	STRAZNLK	36 KB
<input type="checkbox"/>	PRO.docx	Protocol	3/30/2015	STRAZNLK	920 KB

Delete selected files Download all

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.

[Main](#)
[KSP](#)
[Funding](#)
[Application](#)
[Document Uploads](#)
[Pre-review](#)
[Reviews](#)

Test Expedited new study:

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

Address the following items:

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](#)

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.

Please submit an Assent Form for children 7-12.

Issues and comments on your a

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

Pre-Review History

Status

REQUESTING PRE-REVIEW CHANGES

[Re-submit to 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. The administrative amendment and standard amendment forms will no longer be utilized. Changes to key study personnel no longer require the submission of an amendment.

To initiate an amendment submission, select from the study in your dashboard and select the study that requires an amendment.

Vanderbilt IRB Dashboard Submissions Studies

Welcome, Kristin! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [+ Create a new study](#)

Pre-review requests Submissions requiring my signature Submissions requiring a CAL response Draft submissions

My studies Studies listing me as KSP

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
A Phase 1b, Open Label, Dose Finding Study to Evaluate...	150007	Straznicki, Kristin		1/21/2016
3/13/2015 CAL testing Preliminary Assessment...	150035	Straznicki, Kristin		3/11/2016
Expedited Study Test: Study of Prophylaxis...	150055	Straznicki, Kristin		3/30/2016
Do those with generalized neck pain also have undiagnosed...	150077	Straznicki, Kristin		3/31/2016

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

IRB # 150007
PI Straznicki, Kristin

Info KSP Approved Documents Submissions Reviews **Create Submission**

Create a new submission for this study:

- Amendment
- Non-compliance with Protocol
- Adverse Event
- Continuing Review

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.

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

Completing the Amendment Tab

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

Making Changes to the IRB Application

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

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

[Main](#)
[Amendment](#)
[Funding](#)
[Application](#)
[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, laptop, etc.) used to save 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 -

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,

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. Kersinger will have access to the information.

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.

Amendment (3/31/2015) - DRAFT

Submission ID: STRAZNKL03312015133028

[Main](#)
[Amendment](#)
[Funding](#)
[Application](#)
[Document Uploads](#)
[Submit](#)
[Reviews](#)

Attach Study Files

Drag and Drop Standard

Protocol

Consent-Asent Document

Advertisement

Study Materials

IRB Application

Grant

Recruitment

Other

Continuing Review Application

Investigators Brochure

Study Measures

Submission Documents

File Name	Type	Created On	Created By	File Size
Revised ICD.docx	Consent-Asent Document	3/31/2015	STRAZNKL	11 KB

[Delete selected files](#)
[Download all](#)

[Back](#)
[Continue](#)

Drag and Drop revised documents into file type

The upload method can be changed to the standard format.

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.

Amendment (4/15/2015) - DRAFT

Submission ID: STRAZNKL04152015143003

Main

Amendment

Funding

Application

Document Uploads

Submit

Reviews

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

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.

Principal Investigator's Assurance Statement

I certify that the information provided in this application is complete and accurate.

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.

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.

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:

- 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.

Sign Here

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

Password

Sign

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, advisor, chair, or chief) would like to make changes before the submission is sent to the IRB for review, the amendment can be placed in draft mode 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

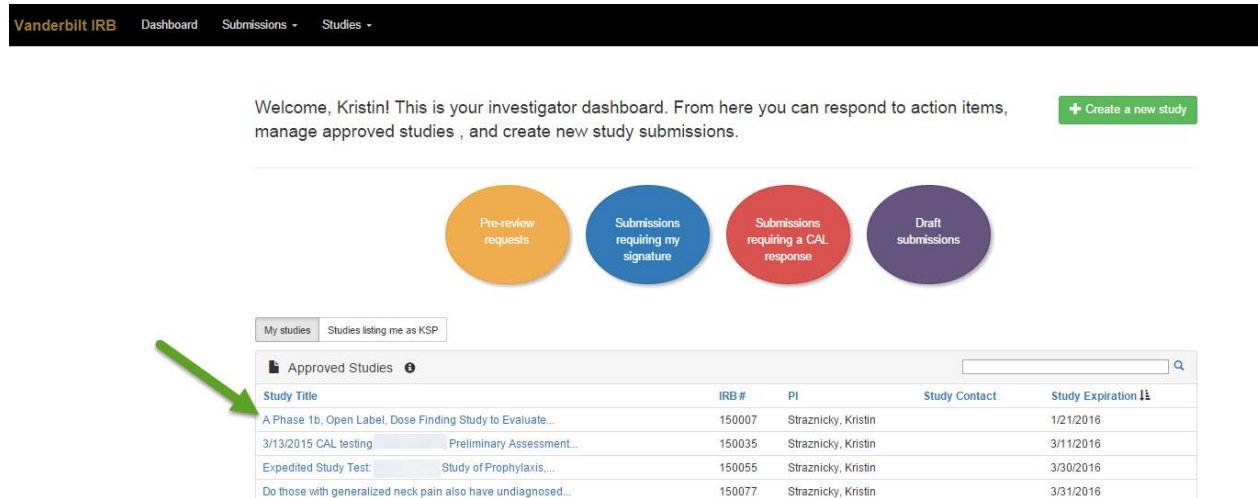
Department Chair*

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.

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.



My studies Studies listing me as KSP

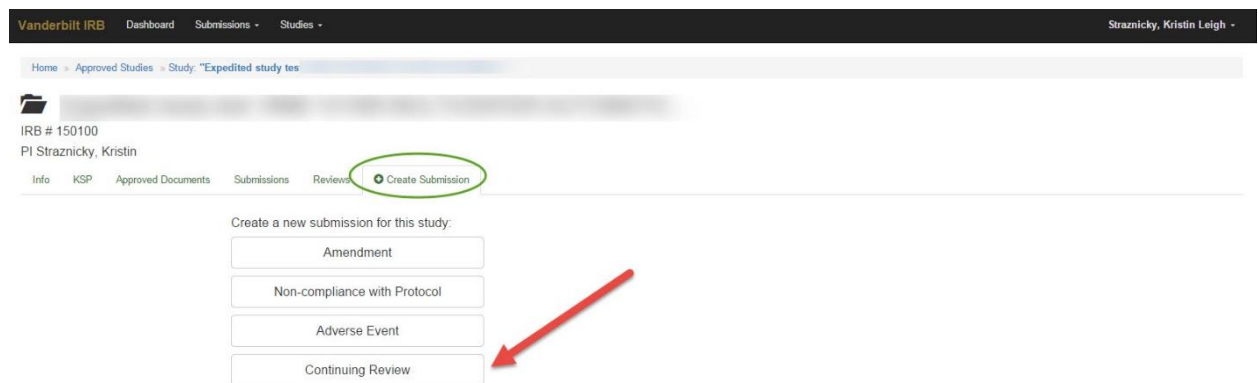
Welcome, Kristin! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions. [+ Create a new study](#)

Pre-review requests Submissions requiring my signature Submissions requiring a CAL response Draft submissions

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
A Phase 1b, Open Label, Dose Finding Study to Evaluate...	150007	Straznicki, Kristin		1/21/2016
3/13/2015 CAL testing Preliminary Assessment...	150035	Straznicki, Kristin		3/11/2016
Expedited Study Test: Study of Prophylaxis...	150055	Straznicki, Kristin		3/30/2016
Do those with generalized neck pain also have undiagnosed...	150077	Straznicki, Kristin		3/31/2016

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



Vanderbilt IRB Dashboard Submissions - Studies - Straznicki, Kristin Leigh

Home > Approved Studies > Study: "Expedited study tes

IRB # 150100
PI Straznicki, Kristin

Info KSP Approved Documents Submissions Reviews **Create Submission**

Create a new submission for this study:

- Amendment
- Non-compliance with Protocol
- Adverse Event
- 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.

[Main](#) [Continuing Review](#) [Document Uploads](#) [Submit](#) [Reviews](#)

Continuing Review Information

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

Conflict of Interest Disclosure

Is there a potential conflict of interest for the Principal Investigator or key personnel?
• The PI is responsible for assuring that no arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research and no arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.
• Assessment should include anyone listed as Principal Investigator, or other research personnel on page 1 of this application. Please note that ownership described below apply to the aggregate ownership of an individual investigator, his/her spouse, domestic partner and dependent children. Do not consider the combined ownership of all investigators.
* must provide value

☐ Yes
☐ No

Save

Select the study type. The continuing review Wizard application will build questions based on your response.

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

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.

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

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

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

Attach Study Files

Drag and Drop Standard

Protocol

Consent-Assent Document

Advertisement

Study Materials

IRB Application

Grant

Recruitment

Other

Continuing Review Application

Investigators Brochure

Study Measures

Submission Documents

There are no documents for this study

← Back → Continue

The *Reviews* tab allow you to review the currently approved study information. To make changes to this information, please see the amendment submission section of this manual.

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

Continuing Review (4/3/2015) - DRAFT

Submission ID: STRAZNKL04032015105547

Main Continuing Review Funding Application Document Uploads Submit Reviews

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

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.

Submissions ▾

Studies ▾

Welcome, [User]! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions.

Create a new study

12

Pre-review requests

Submissions requiring my signature

1

Submissions requiring a CAL response

35

Draft submissions

Training expires in:

Days 2739

My studies

Studies listing me as KSP

Approved Studies

Study Title	IRB #	PI	Study Contact	Study Expiration
ECOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test; 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test; 140067 HDL Function in Human Disease	150058			4/1/2016
Test Expedited: 140050 Retrospective Review of Coagulation...	150087			4/1/2016
Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016
Test Using patient data to transform care and improve...	150133			4/8/2016

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.

Submissions ▾
Studies ▾

Welcome, ! This is your investigator dashboard. From here you can respond to action items, manage approved studies , and create new study submissions.

Create a new study

12

Pre-review requests

Submissions requiring my signature

1

Submissions requiring a CAL response

35

Draft submissions

Training expires in:

Days

2739

My studies

Studies listing me as KSP

Approved Studies ⓘ

Study Title	IRB #	PI	Study Contact	Study Expiration ⓘ
ECOGIEA2131- A Phase I and Randomized, Double-Blind...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test; 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test; 140067 HDL Function in Human Disease	150058			4/1/2016
Test Expedited: 140050 Retrospective Review of Coagulation...	150087			4/1/2016
Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016
Test Using patient data to transform care and improve...	150133			4/8/2016

From the study page, click “Create Submission.”

Home » Approved Studies » Study: “Test Standard: 140026 A Phase 1 Study to Evaluate the...”

Test Standard: 140026 A Phase 1 Study to Evaluate the...


IRB # 150080
PI [redacted]

Info KSP Approved Documents Submissions **Create Submission**

Test Standard: 140026 A Phase 1 Study to Evaluate the Safety and Pharmacokinetics of Panitumumab in Children with Solid Tumors [Study VICCPED 1395/Amgen 20050252]

Principal Investigator	[redacted]
Status	Approved
Committee	HS1
Study Coordinator	None Listed
IRB Number	150080
Study Expiration Date	4/1/2016

345 days until study expires (4/1/2016)



Update NCT ID (ClinicalTrials.gov registry number)

Save

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

Home » Approved Studies » Study: “Test Standard: 140026 A Phase 1 Study to Evaluate the...”

Test Standard: 140026 A Phase 1 Study to Evaluate the...

IRB # 150080
PI [redacted]

Info KSP Approved Documents Submissions **Create Submission**

Create a new submission for this study:

Amendment

Non-compliance with Protocol

Adverse Event

Continuing Review

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1313 21st Ave S, Suite 504
Nashville, TN 37232-4315
(615) 322-2018 (telephone)
(615) 343-2948 (fax)

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.

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]

Adverse Event/Unanticipated Problem (4/13/2015) - DRAFT

Submission ID: [REDACTED]

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

Delete

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.

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

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

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.	<div><input type="text"/></div>
<small>* must provide value</small>	
This study (choose one):	<div><input type="radio"/> has a Data and Safety Monitoring Committee/Board (DSMC/DSMB) or Data Safety Monitor (DSM).</div> <div><input type="radio"/> does not have a Data and Safety Monitoring Committee/Board (DSMC/DSMB) or Data Safety Monitor (DSM).</div> <div><input type="radio"/> unknown.</div>
<small>* must provide value</small>	<div>reset</div>

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

does not require the signature of the Principal Investigator.

Is there a MedWatch Report to attach?
* must provide value

☐ Yes
☐ No [reset](#)

Date of Event:
* must provide value

[Add](#) [Today](#) [Help](#)

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

Participant Age:

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

List 3-4 keywords describing the event/problem:
(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.

The screenshot shows the 'Document Uploads' tab in the Vanderbilt IRB system. At the top, there is a navigation bar with 'Vanderbilt IRB', 'Dashboard', 'Submissions', and 'Studies'. Below this is a breadcrumb trail: 'Home > Study: IRB#150080-Test Standard: 140026 A Phase 1 Study to Evaluate the... > Submission: ADVERSE EVENT'. The main header area displays 'Test Standard: 140026 A Phase 1 Study to Evaluate the...', 'IRB # 150080', and 'PI [redacted]'. Below this, a box contains 'Adverse Event/Unanticipated Problem (4/3/2015) - DRAFT' and 'Submission ID: [redacted]'. A horizontal menu includes 'Main', 'Adverse Event', 'Funding', 'Application', 'Document Uploads' (which is active), 'Submit', and 'Reviews'. The 'Attach Study Files' section features a grid of document categories: Protocol, IRB Application, Continuing Review Application, Consent-Assent Document, Grant, Investigators Brochure, Advertisement, Recruitment, Study Measures, Study Materials, and Other. Each category has an upload icon. To the right of this grid, the 'Drag and Drop' button is highlighted with a red box and a red arrow points to it. Below the grid, the 'Submission Documents' section states 'There are no documents for this study'. At the bottom, there are 'Back' and 'Continue' buttons.

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.

This screenshot is identical to the one above, showing the 'Document Uploads' tab. However, the red arrow now points to the 'Continue' button at the bottom of the page, which is located next to the 'Back' button. The 'Drag and Drop' button is no longer highlighted.

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.

The screenshot shows the Vanderbilt IRB interface. At the top, there's a navigation bar with 'Vanderbilt IRB', 'Dashboard', 'Submissions', and 'Studies'. Below this, a breadcrumb trail reads 'Home > Study: IRB#150080-Test Standard: 140026 A Phase 1 Study to Evaluate the... > Submission: ADVERSE EVENT'. The main header area displays 'Test Standard: 140026 A Phase 1 Study to Evaluate the...' and 'IRB # 150080'. Below this, a section titled 'Adverse Event/Unanticipated Problem (4/3/2015) - DRAFT' contains a 'Submission ID:' field. A red arrow points to the 'Adverse Event' tab in the navigation bar. A red error message box states: 'Your submission is not yet complete' with a bullet point: 'Adverse Event: Adverse Event form is incomplete'. At the bottom right, there is copyright information for 2015 Vanderbilt University Institutional Review Board.

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

This screenshot shows the same Vanderbilt IRB interface but with a success message. The breadcrumb trail and header information are identical. The 'Adverse Event/Unanticipated Problem (4/3/2015) - DRAFT' section now shows a 'Submission ID:' field with a small 'a' icon. A red arrow points to a green 'Submit' button. A large grey box contains the message: '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.' The 'Submit' button is located within this box. The bottom right corner still shows the 2015 copyright information.

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.

Submissions ▾Studies ▾

Welcome, [User]! This is your investigator dashboard. From here you can respond to action items, manage approved studies, and create new study submissions.

Create a new study

12Pre-review requests

Submissions requiring my signature

1Submissions requiring a CAL response

35Draft submissions

Training expires in:
Days
2730

My studies

Studies listing me as KSP

Approved Studies ⓘ

Study Title	IRB #	PI	Study Contact	Study Expiration ⓘ
ECOGGIEA2131- A Phase I and Randomized, Double-Blinded...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test; 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test; 140067 HDL Function in Human Disease	150058			4/1/2016
Test Expedited: 140050 Retrospective Review of Coagulation...	150087			4/1/2016
Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016
Test Using patient data to transform care and improve...	150133			4/8/2016

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.

Submissions ▾
Studies ▾

Welcome, ! This is your investigator dashboard. From here you can respond to action items, manage approved studies , and create new study submissions.

Create a new study

12

Pre-review requests

Submissions requiring my signature

1

Submissions requiring a CAL response

35

Draft submissions

Training expires in:

Days

2739

My studies

Studies listing me as KSP

Approved Studies ⓘ

Study Title	IRB #	PI	Study Contact	Study Expiration ⓘ
ECOGIEA2131- A Phase I and Randomized, Double-Bl...	150014			1/21/2016
Test Standard: 140026 A Phase 1 Study to Evaluate the...	150080			4/1/2016
Test Repository: 140916 IRMH Recruitment Repository	150071			4/1/2016
Grant Review Test; 140279 Cardiac structure and function...	150068			4/1/2016
Grant Review Test; 140067 HDL Function in Human Disease	150058			4/1/2016
Test Expedited: 140050 Retrospective Review of Coagulation...	150087			4/1/2016
Test Study: A randomized study of the effect of chocolate...	150103			4/2/2016
New Tools for Assessing Fracture Risk	150110			4/5/2016
IRB 130808The Establishment of the Genotype/Phenotype...	150113			4/5/2016
Investigating immune responses in patients with advanced...	150109			4/8/2016
Test A multi-center, randomized, prospective, open-label...	150145			4/8/2016
Test Using patient data to transform care and improve...	150133			4/8/2016

From the study page, click “Create Submission.”

Home » Approved Studies » Study: “Test Standard: 140026 A Phase 1 Study to Evaluate the...”

Test Standard: 140026 A Phase 1 Study to Evaluate the...


IRB # 150080
PI [redacted]

Info KSP Approved Documents Submissions **Create Submission**

Test Standard: 140026 A Phase 1 Study to Evaluate the Safety and Pharmacokinetics of Panitumumab in Children with Solid Tumors [Study VICCPED 1395/Amgen 20050252]

Principal Investigator	[redacted]
Status	Approved
Committee	HS1
Study Coordinator	None Listed
IRB Number	150080
Study Expiration Date	4/1/2016

345 days until study expires (4/1/2016)



Update NCT ID (ClinicalTrials.gov registry number)

Save

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

Home » Approved Studies » Study: “Test Standard: 140026 A Phase 1 Study to Evaluate the...”

Test Standard: 140026 A Phase 1 Study to Evaluate the...

IRB # 150080
PI [redacted]

Info KSP Approved Documents Submissions **Create Submission**

Create a new submission for this study:

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

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1313 21st Ave S, Suite 504
Nashville, TN 37232-4315
(615) 322-2018 (telephone)
(615) 343-2648 (fax)

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.

Did the Noncompliance with the Protocol affect the integrity of the study?
* must provide value

☐ Yes
☐ No

reset

Please provide an explanation of the plan to prevent future Noncompliance with the Protocol events:
* must provide value

Has the PI been notified of the Noncompliance with the Protocol and received a copy of this report?
* must provide value

☐ Yes
☐ No

reset

Has this Noncompliance with the Protocol been reported to the sponsor?
* must provide value

☐ Yes
☐ No

reset

Save

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

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

Noncompliance with Protocol Information

Is this a Cancer Center related report of Noncompliance with the Protocol that has been completed in OnCore?
* must provide value

☐ Yes
☐ No

reset

Explain why or how the Noncompliance with the Protocol occurred:
* must provide value

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

The screenshot shows a web application interface for document uploads. At the top, there's a header with 'PI' and a status bar indicating 'Noncompliance with Protocol (4/13/2015) - DRAFT'. Below this is a 'Submission ID' field. A navigation bar contains tabs: 'Main', 'Noncompliance', 'Document Uploads' (which is active), 'Submit', and 'Reviews'. The main content area is titled 'Attach Study Files' and features a grid of document categories: Protocol, IRB Application, Continuing Review Application, Consent-Assent Document, Grant, Investigators Brochure, Advertisement, Recruitment, Study Measures, Study Materials, and Other. Each category has an upload icon. To the right of this grid are two buttons: 'Drag and Drop' and 'Standard', with 'Drag and Drop' highlighted by a red box. Below the grid, the section 'Submission Documents' states 'There are no documents for this study'. At the bottom, there are 'Back' and 'Continue' buttons.

Once all documents are uploaded, Click Continue.

This screenshot is identical to the one above, showing the 'Document Uploads' tab. However, a red arrow points directly to the 'Continue' button at the bottom of the page, indicating the next step in the process.

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.

The screenshot shows the Vanderbilt IRB submission interface. At the top, there's a navigation bar with 'Vanderbilt IRB', 'Dashboard', 'Submissions', and 'Studies'. Below this is a breadcrumb trail: 'Home > Draft Submissions > Submission: "Test Standard: 140026 A Phase 1 Study to Evaluate the..."'. The main heading is 'Test Standard: 140026 A Phase 1 Study to Evaluate the...'. Below the heading, it shows 'IRB # 150080' and 'PI [redacted]'. A section titled 'Noncompliance with Protocol (4/13/2015) - DRAFT' contains a 'Submission ID: [redacted]'. A red arrow points to the 'Noncompliance' tab in the navigation bar. Below the tabs, a red error message box states: 'Your submission is not yet complete'. It lists a non-compliance item: 'Noncompliance: Noncompliance form is incomplete'. A 'Debug info' link is visible below the error message. At the bottom right, there is copyright information for the Vanderbilt University Institutional Review Board.

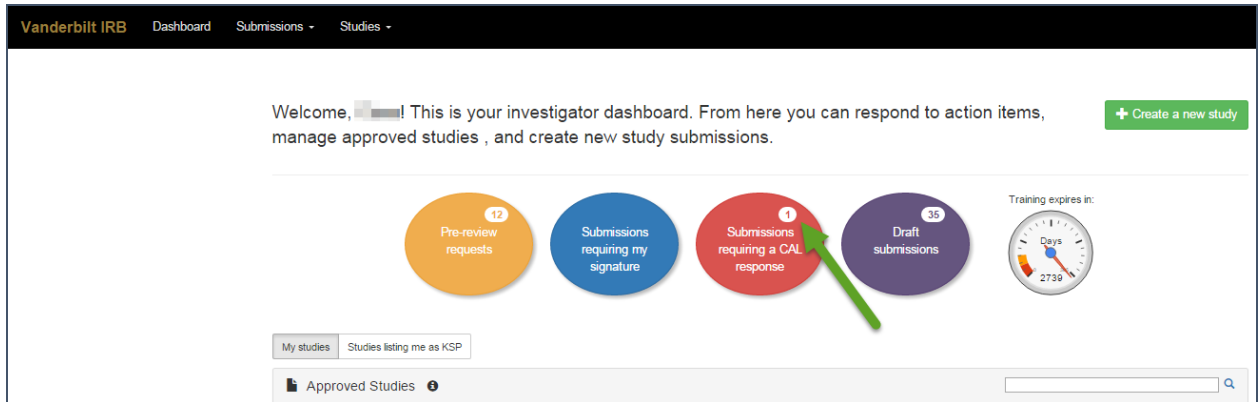
Once the form is complete, click the Submit button.

This screenshot shows the same Vanderbilt IRB submission interface as the previous one, but with a successful status. The 'Noncompliance' tab is still selected. A large grey box in the center of the page contains the message: '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 red arrow points to a green 'Submit' button located within this grey box. The 'Debug info' link remains at the bottom.

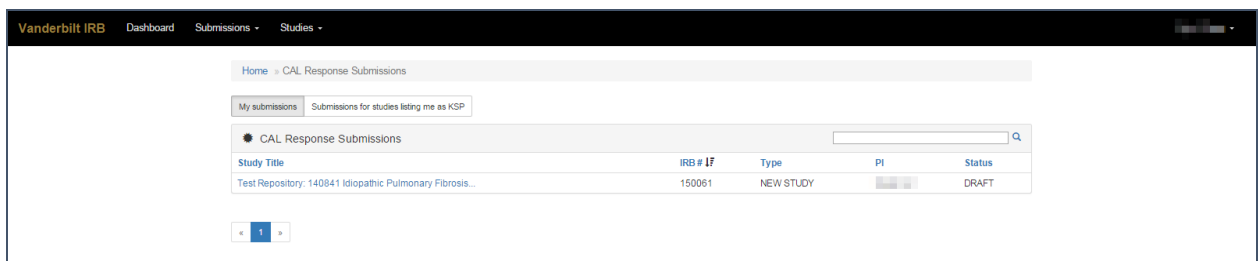
After a signature from the PI, the submission is automatically routed through the Wizard and ultimately ends its journey at the IRB where it will be sent to a team to start the review process.

Submitting a Response to a Committee Action Letter (CAL)

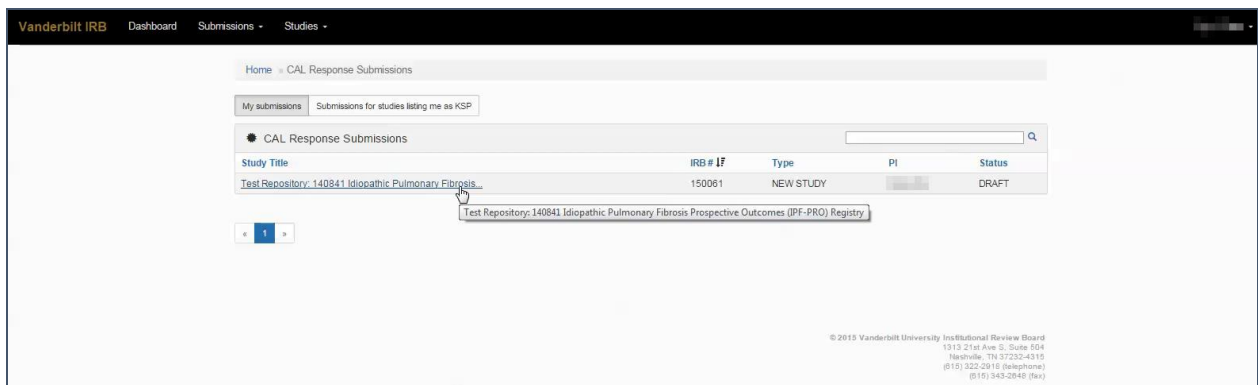
On the dashboard, the Submissions Requiring a CAL Response button will display a number indicating the number of outstanding items awaiting a response from you.



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.

The screenshot shows the 'Vanderbilt IRB' dashboard with the 'Submissions' menu selected. The page title is 'CAL Response Submissions'. Below the title, there are tabs for 'My submissions' and 'Submissions for studies listing me as KSP'. A table lists the submissions:

Study Title	IRB #	Type	PI	Status
Test Repository: 140841 Idiopathic Pulmonary Fibrosis...	150061	NEW STUDY		DRAFT

A green arrow points to the first row of the table.

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

1. Click the Download CAL button above the letter

The screenshot shows the 'Vanderbilt IRB' dashboard with the 'Submissions' menu selected. The page title is 'Test Repository: 140841 Idiopathic Pulmonary Fibrosis...'. Below the title, there are tabs for 'Reviews', 'Main', 'KSP', 'Funding', 'Application', 'Document Uploads', and 'Submit'. The 'Reviews' tab is selected. The page displays 'Latest IRB Review Info' and a 'Download CAL' button. A red arrow points to the 'Download CAL' button.


2. Save the save button in the PDF viewer

Test Repository: 140841 Idiopathic Pulmonary Fibrosis Prospective Outcomes (IPF-PRO) Registry

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](#)

**Vanderbilt University**
Institutional Review Board
504 Oxford House Nashville, Tennessee 37232-4315
(615) 322-2918 Fax: (615) 343-2648
www.mc.vanderbilt.edu/irb


April 2, 2015

Human Research Protection Prog

RE: IRB# 150061 "Test Repository: 140841 Idiopathic Pulmonary Fibrosis Prospective Outcomes (IPF-PRO) Registry"



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

**Vanderbilt University**
Institutional Review Board
504 Oxford House Nashville, Tennessee 37232-4315
(615) 322-2918 Fax: (615) 343-2648
www.mc.vanderbilt.edu/irb

April 2, 2015

Human Research Protection Prog

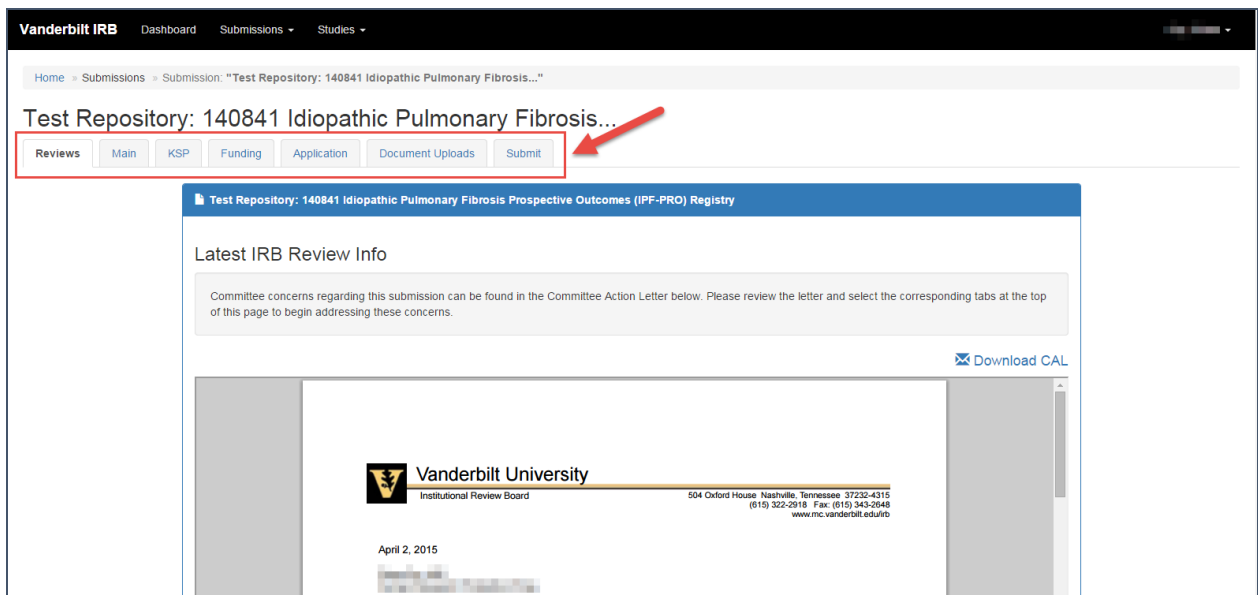
RE: IRB# 150061 "Test Repository: 140841 Idiopathic Pulmonary Fibrosis Prospective Outcomes (IPF-PRO) Registry"

Dear [REDACTED]

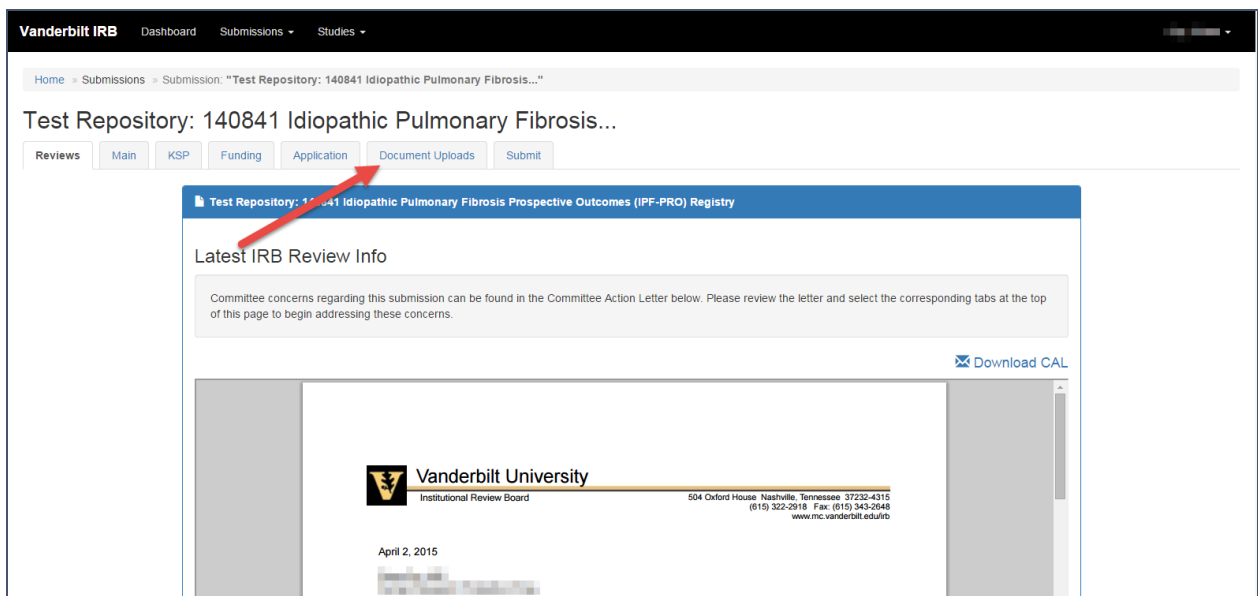
Submission Reviews

Updated On	Meeting Date	Committee	Review Type	Review Outcome	Letter
		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.

The screenshot shows the 'Vanderbilt IRB' dashboard with the 'Submissions' tab selected. The breadcrumb trail is 'Home > Submissions > Submission: "Test Repository: 140841 Idiopathic Pulmonary Fibrosis..."'. The page title is 'Test Repository: 140841 Idiopathic Pulmonary Fibrosis...'. Below the title are tabs for 'Reviews', 'Main', 'KSP', 'Funding', 'Application' (selected), 'Document Uploads', and 'Submit'. The 'Attach Study Files' section has two buttons: 'Drag and Drop' (highlighted with a red box and a red arrow) and 'Standard'. Below these are upload buttons for 'Protocol', 'IRB Application', 'Continuing Review Application', 'Consent-Assent Document', 'Grant', 'Investigators Brochure', 'Advertisement', 'Recruitment', 'Study Measures', 'Study Materials', and 'Other'. The 'Submission Documents' section states 'There are no documents for this study'. The 'Previously Submitted Documents' section is empty. At the bottom are 'Back' and 'Continue' buttons.

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.

This screenshot is identical to the one above, showing the 'Attach Study Files' section and the 'Continue' button at the bottom. A red arrow points to the 'Continue' button.

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

Home > Submissions > Submission: "Test Repository: 140841 Idiopathic Pulmonary Fibrosis..."

Test Repository: 140841 Idiopathic Pulmonary Fibrosis...

Reviews Main KSP Funding Application Document Uploads Submit

Please check to make sure you have addressed all changes requested in the Committee Action Letter. When this is complete, you can submit your updated submission for signature and review.

Submit

[Debug info](#)

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(615) 343-2048 (fax)

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 for 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:


Home » Approved Studies » Study: [Study Name]

IRB # [IRB Number]
PI [PI Name]

Info KSP Approved Documents Submissions Create Submission

Principal Investigator [Name]
Status Approved
Committee HS1
Study Coordinator [Name]
IRB Number [Number]
Study Expiration Date 4/5/2016

342 days until study expires (4/5/2016)



NCT ID (ClinicalTrials.gov registry number)

Business Officer

Save

Study updated successfully


Home » Studies » Study: [Study Name]

IRB # [IRB Number]
PI [PI Name]

Info KSP Approved Documents Submissions Create Submission

Principal Investigator [Name]
Status Approved
Committee HS1
Study Coordinator [Name]
IRB Number [Number]
Study Expiration Date 4/5/2016

342 days until study expires (4/5/2016)



NCT ID (ClinicalTrials.gov registry number)

Business Officer

Save

Study updated successfully


Home » Studies » Study: [REDACTED]

IRB # [REDACTED]
PI [REDACTED]

Info KSP Approved Documents Submissions Create Submission

Principal Investigator [REDACTED]
Status Approved
Committee HS1
Study Coordinator [REDACTED]
IRB Number [REDACTED]
Study Expiration Date 4/5/2016

342 days until study expires (4/5/2016)



NCT ID (ClinicalTrials.gov registry number)

Business Officer
Turner, Chaslety (TURNERC9)

Save

Study updated successfully


Home » Studies » Study: [REDACTED]

IRB # [REDACTED]
PI [REDACTED]

Info KSP Approved Documents Submissions Create Submission

Principal Investigator [REDACTED]
Status Approved
Committee HS1
Study Coordinator [REDACTED]
IRB Number [REDACTED]
Study Expiration Date 4/5/2016

342 days until study expires (4/5/2016)



NCT ID (ClinicalTrials.gov registry number)

Business Officer
Turner, Chaslety (TURNERC9)

Save

Frequently Asked Questions

In this section, you will find some questions most commonly asked by people using DISCOVER-E. As additional questions come in, we will update this part of the manual. If you have any questions not addressed here, please send them to discovere@vanderbilt.edu.

How do I know when my submission has been approved?

When the review of your submission has been finalized, the Principal Investigator, Study Coordinator, and/or Faculty Advisor will receive an email which contains a link to the letter and study associated documents.

What if I delete the email link that tells me the status of my submission?

You can always access the status of any submission by logging into DISCOVER-E and viewing information in the approved study dashboard. . Click on the approved study link in the investigator dashboard to locate statuses of submissions.

What is the difference between the IRB Application within the DISCOVER-E system and the other IRB application on the “Forms” link that I find on your website?

The IRB Applications within the DISCOVER-E portal now include all the questions necessary for review of standard, expedited, exempt, non-human/non-research determinations, repository, and grant reviews. Supplemental forms including forms for vulnerable populations, investigator held IND's, devices, radiation, et cetera, have also been added to this application wizard. Other documents required for review can be uploaded into the submissions portal using a convenient drag and drop feature. There is a standard browse to file feature available as well. These documents will include consent forms, protocol, investigator's brochure, recruitment materials, measures, etc. You will also be able to manage KSP in DISCOVER-E without submitting amendment. The only key study personnel changes that require an amendment are changes to PI, Study Contact and Faculty Advisor. As long as an individual has completed CITI training, they can be added to the study.

My PI deleted his/her link to sign off on a study submission, now what do I do?

You can instruct your PI to log in to DISCOVER-E through the IRB website. If they have any submissions that require their signature, they will see a section, called, “Submissions Requiring My Signature” at the very top of the page. They can access and sign off on all submissions that may require their signature by clicking the button or link under the menu at the top of the page.

Will I be able to add photos or diagrams to my application?

At this time, photos and diagrams cannot be added to the application wizard itself. However, you are free to attach them as supporting documents or reference their location in the protocol.

Will I be able to use standard formatting such as bold, italics, super/sub scripts?

At this time, the system does not support text formatting in the wizard responses. You may refer to the appropriate sections in the protocol for this information (i.e., references). Please also consider if the additional information that requires formatting answers the question being asked by the IRB application.

Can I access a collective list of all my currently approved study documents?

Yes, by clicking on the link in the approved studies dashboard for that study. Select the "Approved Documents" tab. There you will see a tab for "Current Documents" that includes links for currently approved documents, as well as a tab for "Documents History" for a historical view of all previously approved study documents. If you need to see a document(s) associated with one particular submission, click on the "link" beside the study item that you wish to review to download the document.

Where can I find my list of key study personnel since it is no longer included in the IRB application?

When you log in to DISCOVER-E, simply click the link for the study you wish to review in the "Approved Studies" dashboard. Click on the "KSP" tab to review the KSP currently listed on the study. You can manage KSP, as well as Business Officer on this tab. You will not that there are new required fields prior to saving the information. These include, the credentials of your KSP, their role in the project, and whether they will be accessing PHI while working on the study. Credential information will help the IRB Committees assess the appropriateness of study staff. The role in project has been limited to three selections: "Research - Non-clinical", "Research - Clinical", and "Sub-Investigator". When you click on the KSP tab, you will see current KSP. To add new KSP, start by searching for their name, email, or VUnetID in the "Add another" field. Select the appropriate individual and enter the required information. Our system has been programmed to automatically enter an individual's phone number and pager. You may make edits to phone number, if the number automatically pulled from People Finder is not the best contact number. Make sure to click "Save KSPs" before navigating away from the page. The "History" tab shows everyone who has been listed as KSP on the study, the date they were added or removed (if applicable), and the information on who added or deleted the individual. Both views are easily printable in your browser.

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 R-E