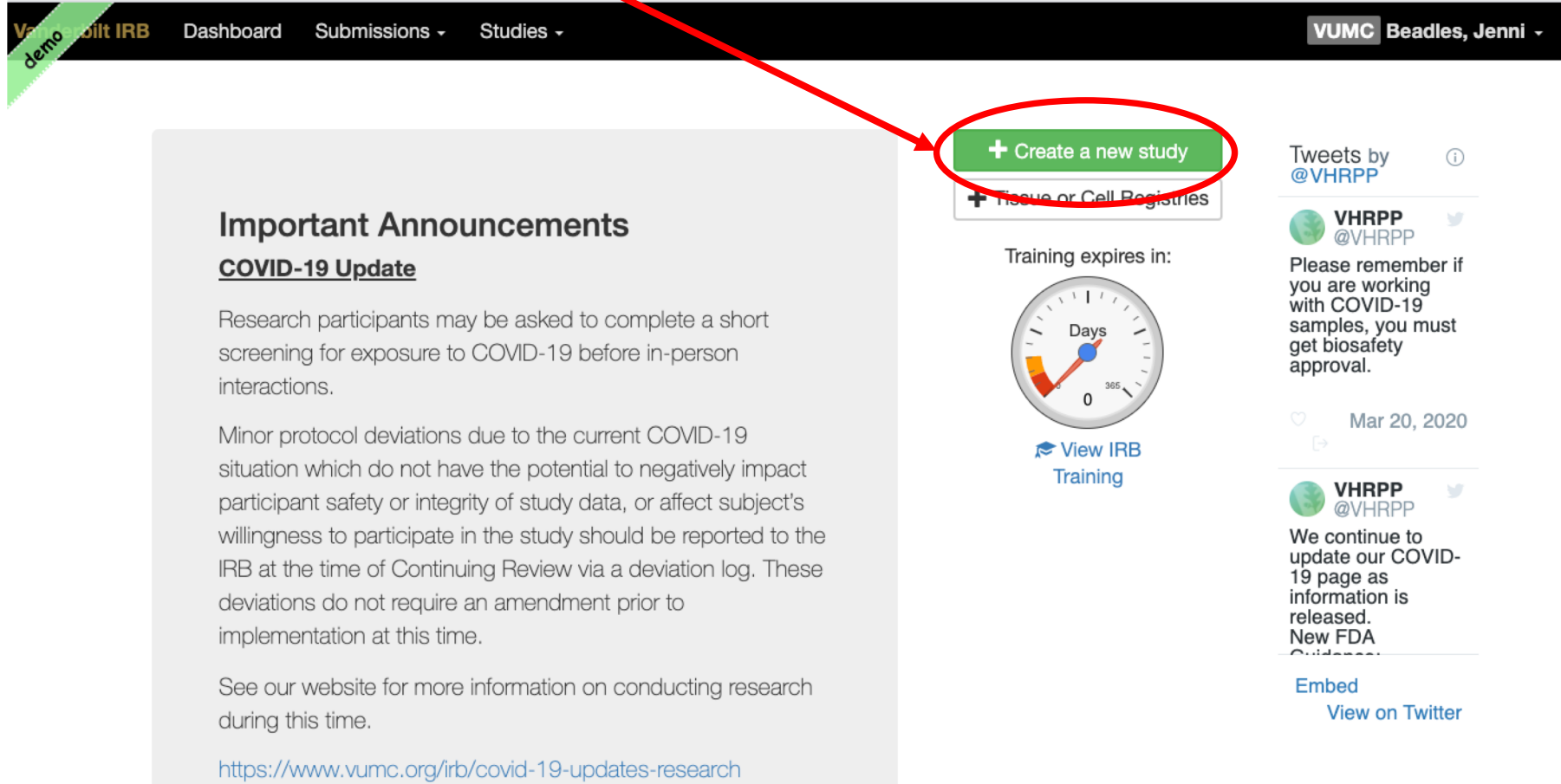


How to 'Request Review by Another IRB'

A Guide for VU/VUMC Principal Investigators and Study Teams
Using Another IRB for Multi-Site Studies

Create a new study submission in DISCOVER-e



The screenshot shows the VUMC IRB dashboard. At the top, there is a navigation bar with 'VUMC IRB' (with a 'demo' tag), 'Dashboard', 'Submissions', and 'Studies'. On the right, the user is identified as 'VUMC Beadles, Jenni'. A red arrow points from the text 'Create a new study submission in DISCOVER-e' to a green button labeled '+ Create a new study' in the main content area. Below this button is a section for 'Important Announcements' with a 'COVID-19 Update' and a 'Training expires in:' section featuring a clock icon and a 'View IRB Training' link. On the right side, there are two tweets from @VHRPP regarding COVID-19 biosafety and updates.

VUMC IRB [Dashboard](#) [Submissions](#) [Studies](#) **VUMC** Beadles, Jenni

+ Create a new study

Important Announcements

COVID-19 Update


Research participants may be asked to complete a short screening for exposure to COVID-19 before in-person interactions.

Minor protocol deviations due to the current COVID-19 situation which do not have the potential to negatively impact participant safety or integrity of study data, or affect subject's willingness to participate in the study should be reported to the IRB at the time of Continuing Review via a deviation log. These deviations do not require an amendment prior to implementation at this time.

See our website for more information on conducting research during this time.

<https://www.vumc.org/irb/covid-19-updates-research>

Training expires in:



[View IRB Training](#)

Tweets by @VHRPP

VHRPP @VHRPP
Please remember if you are working with COVID-19 samples, you must get biosafety approval.
Mar 20, 2020

VHRPP @VHRPP
We continue to update our COVID-19 page as information is released.
New FDA Guidance
[Embed](#)
[View on Twitter](#)

Begin the application as you normally would and complete all tabs except Performance Sites...

VUMC IRB demo | Dashboard | Submissions ▾ | Studies ▾ | VUMC | Beadles, Jenni ▾

Home > Draft Submissions > Submission: "How to Submit a 'Request Review by Another IRB' Application"

How to Submit a 'Request Review by Another IRB' Application

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

Study Title
How to Submit a 'Request Review by Another IRB' Application

Principal Investigator
× Beadles, Jennifer - BEADLEJG - VUMC

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

Study Coordinator
[Empty text box]

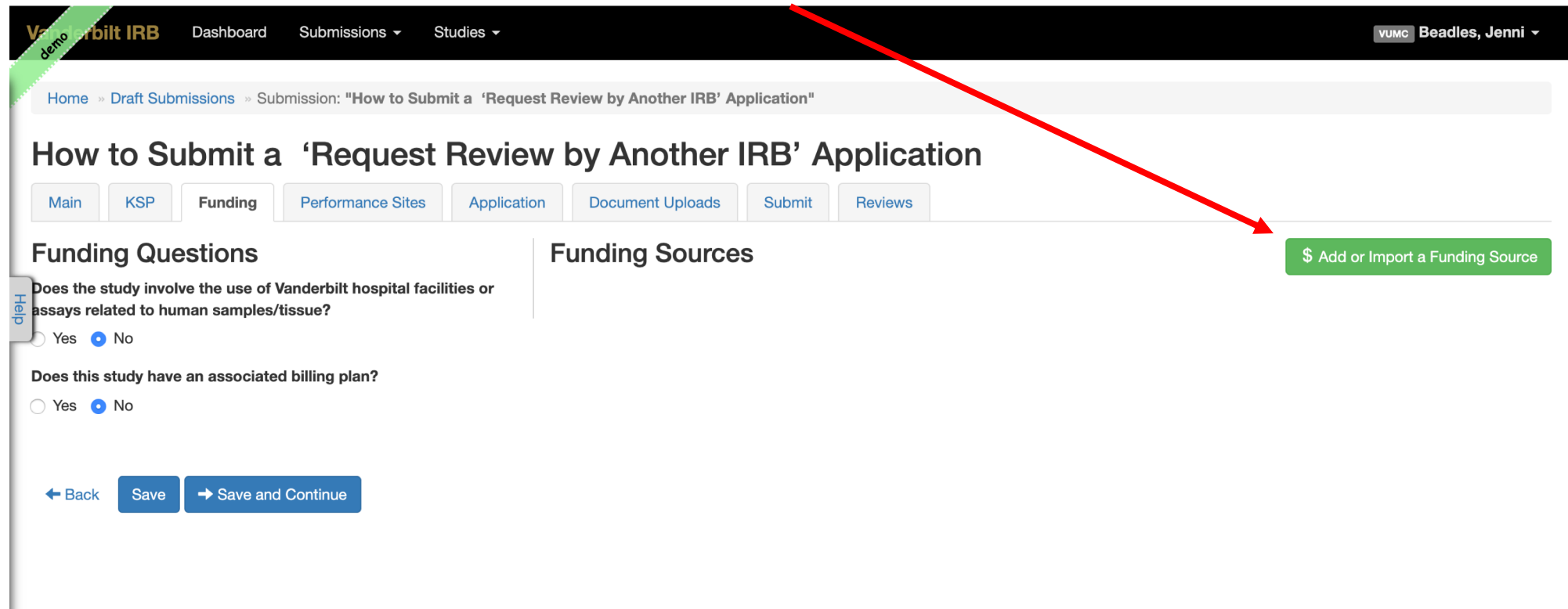
Department Chair
× Beadles, Jennifer - BEADLEJG - VUMC

Division Chief
[Empty text box]

Save | → Save and Continue

Delete

Funding Tab: Import if available



The screenshot shows the Vanderbilt IRB application interface. At the top, the navigation bar includes 'Vanderbilt IRB', 'Dashboard', 'Submissions', and 'Studies'. The user is logged in as 'VUMC Beadles, Jenni'. The breadcrumb trail is 'Home » Draft Submissions » Submission: "How to Submit a 'Request Review by Another IRB' Application"'. The main title is 'How to Submit a 'Request Review by Another IRB' Application'. Below the title are several tabs: 'Main', 'KSP', 'Funding', 'Performance Sites', 'Application', 'Document Uploads', 'Submit', and 'Reviews'. The 'Funding' tab is active. On the left, under 'Funding Questions', there are two questions: 'Does the study involve the use of Vanderbilt hospital facilities or assays related to human samples/tissue?' and 'Does this study have an associated billing plan?'. Both have 'No' selected. At the bottom left are 'Back', 'Save', and 'Save and Continue' buttons. On the right, under 'Funding Sources', there is a green button labeled '\$ Add or Import a Funding Source'. A red arrow points from the top right of the page to this button.

Note: The VUMC HRPP prefers to rely on another IRB for only studies that are federally funded. Contact the VUMC HRPP office to discuss any exceptions.

Performance Sites Tab: **SKIP IT!** Does not apply

The screenshot shows the Vanderbilt IRB application interface. At the top, there is a navigation bar with 'Vanderbilt IRB' on the left and 'VUMC Beadles, Jenni' on the right. Below the navigation bar, there is a breadcrumb trail: 'Home » Draft Submissions » Submission: "How to Submit a 'Request Review by Another IRB' Application"'. The main heading is 'How to Submit a 'Request Review by Another IRB' Application'. Below the heading, there are several tabs: 'Main', 'KSP', 'Funding', 'Performance Sites', 'Application', 'Document Uploads', 'Submit', and 'Reviews'. The 'Performance Sites' tab is selected. The content area is titled 'Performance Sites' and contains a section for 'Multi site study where VU/VUMC PI is responsible for other sites'. This section includes a note and a list of sites. A large red 'X' is drawn over the entire 'Performance Sites' section, indicating that this section is to be skipped. Below the 'Performance Sites' section, there is a section for 'Vanderbilt Serving as a Single IRB'.

Vanderbilt IRB Dashboard Submissions ▾ Studies ▾ VUMC Beadles, Jenni ▾

Home » Draft Submissions » Submission: "How to Submit a 'Request Review by Another IRB' Application"

How to Submit a 'Request Review by Another IRB' Application

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

Performance Sites

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

Note: For PI-initiated studies where Vanderbilt PI is responsible for other sites. Not required for non-VU/VUMC PI-initiated studies.

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

Name	Site is engaged in research	Letter of cooperation
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+ Add a Site

Vanderbilt Serving as a Single IRB

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

Application Tab

- For Study Type and Performance Site Information, select **Request review by another IRB**
- Then complete the rest of the application sections

The screenshot shows the Vanderbilt IRB application interface. The top navigation bar includes 'Vanderbilt IRB', 'Dashboard', 'Submissions', and 'Studies'. The user is logged in as 'vumc Beadles, Jenni'. The breadcrumb trail is 'Home » Draft Submissions » Submission: "How to Submit a 'Request Review by Another IRB' Application"'. The main heading is 'How to Submit a 'Request Review by Another IRB' Application'. Below the heading are tabs for 'Main', 'KSP', 'Funding', 'Performance Sites', 'Application', 'Document Uploads', 'Submit', and 'Reviews'. The 'Application' tab is active. On the left, a sidebar shows a 'Summary' section with a 'Help' icon and a list of application sections: 'Study Type and Performance Site Information' (incomplete), 'Study Purpose and Description' (incomplete), 'Research, Activities, Procedures, and Schedule of Events for Study Participants' (incomplete), 'Data and Safety' (incomplete), 'Subject Population(s)' (incomplete), and 'Recruitment'. The main content area is titled 'Study Type and Performance Site Information' and contains several sections with radio button options. A red arrow points from the 'Study Type and Performance Site Information' section in the sidebar to the 'Request review by another IRB' radio button in the main content area, which is highlighted with a red box. The other options in this section are 'Standard or Expedited', 'Exempt', 'Umbrella Review for funds release', 'Comparative Effectiveness Research', 'Non-Human Subject Determination', 'Quality Improvement/Non-Research Determination', and 'Coordinating Center ONLY'. Below this section are three more sections: 'Please indicate which Committee is most appropriate to review your project:' (options: Social and Behavioral Sciences, Health Sciences), 'Are there any international sites involved in this study in which the PI is responsible?' (options: Yes, No), and 'Is this project cancer-related?' (options: Yes, No). A 'Save' button is located at the bottom right of the form.

Study Type and Performance Site Information

Type of study:
* must provide value

Standard or Expedited
 Exempt
 Umbrella Review for funds release
 Comparative Effectiveness Research
 Non-Human Subject Determination
 Quality Improvement/Non-Research Determination
 Request review by another IRB
 Coordinating Center ONLY

Please indicate what type of study you are doing. [reset](#)

Please indicate which Committee is most appropriate to review your project:
* must provide value

Social and Behavioral Sciences
 Health Sciences

NOTE: If any of the research interventions are medical in nature, please choose the "Health Sciences" option. [reset](#)

Are there any international sites involved in this study in which the PI is responsible?
* must provide value

Yes
 No

Note: Outside of the US. Please list these site on the performance sites tab. [reset](#)

Is this project cancer-related?
* must provide value

Yes
 No

NOTE: All cancer-related studies are required to be reviewed by the VICC Scientific Review Committee (SRC) prior to opening to accrual. [reset](#)

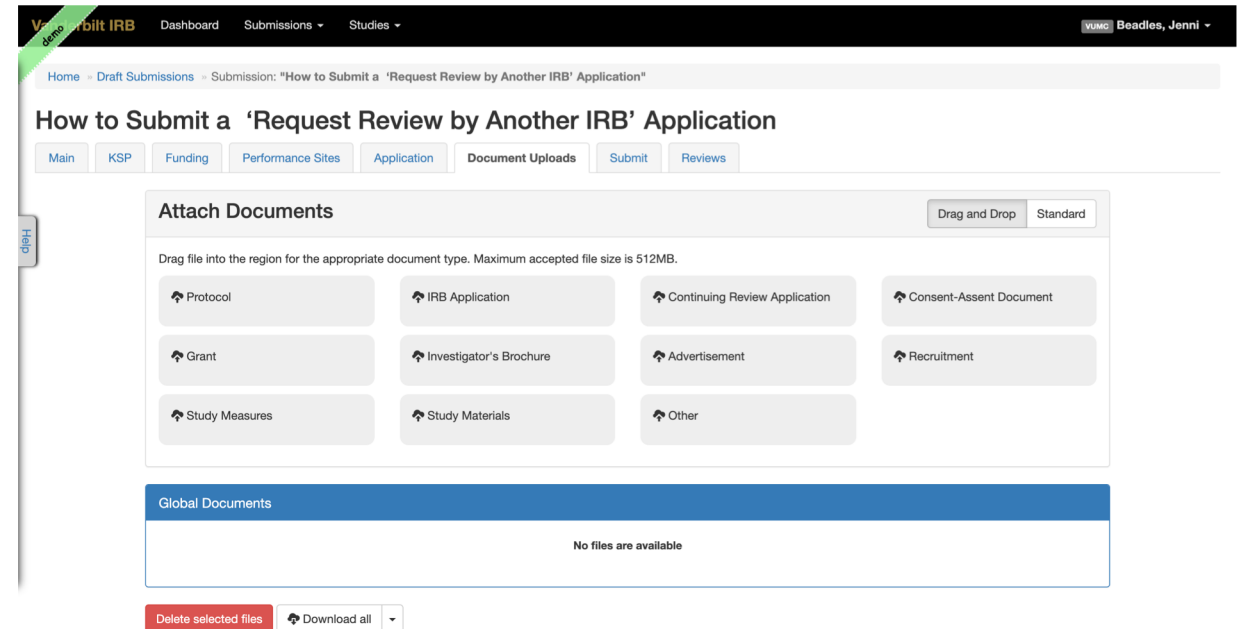
[Save](#)

https://irbdemo.app.vumc.org/investigator

Document Uploads Tab

The VUMC HRPP needs the following for local review:

- **Local context forms/questionnaires** for the VUMC HRPP to complete from the IRB of Record
- Current study **IRB approval letter** from the IRB of Record
- **Consent form(s)**
 - Copy of ICD approved by the IRB of Record; and
 - Tracked copy with Vanderbilt local consent language included (see Local Information document on the Single IRB Help page)
- Any **Vanderbilt-specific study documents** (e.g. recruitment materials applicable to only Vanderbilt)
- **IRB-approved study documents** from the IRB of Record (as applicable):
 - Protocol
 - Investigational Brochure(s)
 - Study Measures and Materials
 - Recruitment materials and Advertisements



Next Steps

- When all tabs have been completed, submit via the Submit Tab
- Amendments/Continuing Review (Annual Enrollment Report)/Reportable Events
 - **Amendments** that affect IRB-approved study documents are reviewed and approved by the IRB of Record BEFORE local submission in DISCOVER-e.
 - **Continuing Review** information is reviewed and approved by the IRB of Record BEFORE local submission in DISCOVER-e. The local submission should occur **within 30 days of receipt of CR approval from the IRB of Record.**
 - **Unanticipated problems** are reviewed and approved by the IRB of Record BEFORE local submission in DISCOVER-e. Please note that the IRB of Record may have differing reporting timelines and requirements for documentation.
- **For questions about Relying on another IRB:**
 - Visit our Single IRB Help page: <https://www.vumc.org/irb/node/28>
 - Contact the VUMC HRPP at (615) 322-2918

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Human Research Protections Program

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Single IRB Help

Request the VUMC IRB to be the Single IRB

Request to rely on another Institution's IRB

Currently, VHRPP will only cede review or serve as the single IRB for federally funded research studies in order to comply with the Single IRB mandate. If you have any questions about single IRB review, please contact Jenni Beadles, Assistant Director, Single IRB at jenni.beadles@vumc.org.

Networks



- ▶ 2-Part Consent for sIRB
- ▶ Grant Resources
- ▶ Additional Information

Reliance Platforms

