Frequently Asked Questions

In this section, you will find some questions most commonly asked by people using DISCOVR-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 <u>discovere@vanderbilt.edu</u>.

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 DISCOVR-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 DISCOVR-E system and the other IRB application on the "Forms" link that I find on your website?

The IRB Applications within the DISCOVR-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 DISCOVR-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 DISCOVR-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 DISCOVR-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.

Where can I find the repository application?

The repository application is now part of the Standard/Expedited study type to improve efficiency with committee review. Many times, the committee needs information for a repository that correlate to the standard/expedited application and repositories will fall into a minimal/greater than minimal risk category based on the activities conducted so utilizing the standard wizard application for these projects appears to be the best fit.

Where can I find submissions that are not approved but pending pre-review?

These submissions can be found in the "Submissions not yet approved" section of your investigator dashboard under the Submissions drop down list.