

The following new questions and new page were added by the FDA Regulatory Program to the RAMS-IRB Smartform in the 7/27/2022 patch

The RedCap portal previously used for VCU investigator-initiated IND/IDE submissions will begin to be phased out. Within the IRB system, you are now able to submit your IND/IDE submissions through the RAMS portal to the FDA program at VCU (this will replace the RedCap requirement but doesn't replace the actual submission required to be submitted to the FDA).

For studies that have existing IND/IDEs (previously submitted to RedCap): You will be prompted to create a FDA page next time you go to make changes to the IRB smart form. This new FDA page will provide you with a page to submit all future FDA submissions to VCU (instead of RedCap). You don't need to submit any submissions previously submitted in RedCap.

For new studies that will need an IND/IDE: you will be prompted to create a FDA page when you are completing the IRB smart form for a new study for the first time.

Other VCU Requirements

10. VCU Faculty-Held IND or IDE

For guidance, see <https://research.vcu.edu/human-research/regulatory-affairs/>.

1. * Is the study sponsored by an external party (not VCU - industry, consortium, etc.) where the sponsor would hold the IND/IDE: [Only displayed if Q1 on the Federal Regulations page=Yes]
 - Yes
 - No
 - [Clear](#)
2. * Has this study been given exempt status for an IND/IDE by the FDA: [Only displayed if Q#1=No]
 - Yes
 - No
 - [Clear](#)
3. * Is this submission for an IND or IDE: [Only displayed if Q#2=No]
 - IND
 - IDE
 - Other
 - [Clear](#)
4. Select an existing IND/IDE (if not listed, leave this question blank):

Mark if IND/IDE is not listed. This will need to be clicked the 1st time you are entering this study into the RAMS system even if previously submitted in RedCap:

[Checking this box will cause the smartform to branch to the New IND/IDE page]

New IND/IDE

This page is for the VCU FDA Regulatory Program's use only, which is independent of the IRB/HRPP's review. The IRB/HRPP does not evaluate or review information contained on this page.

Questions regarding this page or any FDA submission should be directed to Lauren Kanigher, FDA Program Manager at indide@vcu.edu.

1. IND/IDE Number (can be entered as 'TBD'):

2. Sponsor:

3. Study team contacts:

Last Name	First Name	Organization	E-Mail
There are no items to display			

4. Is this submission for an IND or IDE:

- IND [Selection branches to Q#6]
- IDE
- Other

[Clear](#)

5. Type of IND/IDE:

- Research study
- Expanded access/single patient
- Emergency use
- HUD

[Clear](#)

6. * Which office in the FDA is this being submitted to: [Only displayed if Q#4=IND]

- CDER
- CBER
- CDRH
- Other

[Clear](#)

7. * Serial number of submission. New submissions to the FDA will be 0000:

8. * Is this an existing IND/IDE previously submitted to RedCap:

- Yes
- No

[Clear](#)

9. Please upload the following documents:

1. * Cover letter:
2. 1571 (Only required for INDs):
3. 1572 (Only required for INDs):
4. 3674 (Only required for new FDA submissions or if a change is being made to this form):
5. Letter of authorization (If referencing industry application):

6. * Investigator brochure/package insert/device packet:
7. 3926 (Single patient IND only):
8. * Protocol:
9. * Consent:
10. * Investigator's CV:
11. * Investigator's ML:

Exit Save Submit IND/IDE

When investigators click "Submit IND/IDE" this page will be hidden and not editable.

To make changes, go to **Home** Then click on the "My IND/IDEs tab" and click on the FDA number for your IND or IDE.

Inbox	My IRB Studies	My IND/IDEs	Archive	Templates	
Filter by ? Name ▼ <input type="text" value="Enter text to search for"/> 🔍 + Add Filter ✕ Clear All					
Name	ID	IND/IDE Number	Type	▼ Date Modified	State
FDAN00000023	FDAN00000023	132512	IND	7/27/2022 9:06 AM	Active

The IRB cannot assist with completion of this page as it is not an IRB requirement.

Please direct any questions/concerns or requests for assistance with this new functionality to Lauren Kanigher, FDA Program Administrator, at indide@vcu.edu

For technical difficulties, email ERAHelp@vcu.edu