

CDER NextGen Portal for Research INDs

Notes for University of Colorado Anschutz and Affiliate Submitters

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These notes are intended to supplement the FDA NextGen Portal user guides with instructions specific to University of Colorado Anschutz and affiliate institution researchers. These are not comprehensive instructions for using the NextGen Portal.

FDA Account Registration/Multifactor Authentication User Guide:

<https://www.fda.gov/media/128774/download>

FDA Research IND User Guide (login to portal, then copy/paste link into browser):

https://edm.fda.gov/wps/myportal!/ut/p/z0/04_Sj9CPykssy0xPLMnMz0vMAfljo8zifQxdnA2dgg18_UNdHA0CDd0CXcxdPQwM3I30C7IdFQFcul7r/

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What can the NextGen Portal be used for?

The NextGen portal may only be used for **CDER** (not CBER) **research INDs**:

A **research IND** (also called a non-commercial IND) is one for which the sponsor (generally an individual investigator, academic institution or non-profit entity) does not intend to later commercialize the product. These studies are strictly for research, are usually shorter in duration and may result in publications in peer-reviewed journals. In comparison, a commercial IND is one for which the sponsor (usually a corporate entity) intends to commercialize the product by eventually submitting a marketing application.

The NextGen portal can be used to submit IND applications, amendments, supplements, reports, and master files (MF), as well as for requesting an IND number.

Creating a User Account:

Creating a user account with the NextGen portal is free. Go to the [NextGen Portal page](#) and click the “Don’t have an account? Sign up” link under the Login fields. Refer to the [FDA Registration/MFA User Guide](#).

- Use your work email as your username.
- Create a password. Password requires capital, lowercase, number, and special character.
- For CU Anschutz research, see below for DUNS # and company information:

DUNS: 041096314

Company name: University of Colorado Denver-Anschutz Medical Center

Country: USA

State: CO

Address line 1: 13001 East 17th Place

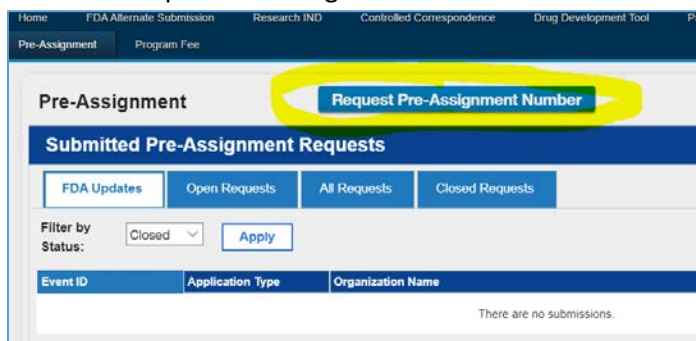
City: Aurora

Zip: 80045

Requesting a Pre-Assigned IND Number

IMPORTANT: If you already have an IND number, skip this section, even if you’ve never submitted via NextGen for this IND before.

1. Log in at the [NextGen Portal page](#).
2. Click “Pre-Assignment”
3. Click the “Request Pre-Assignment Number” button at the top of the page.

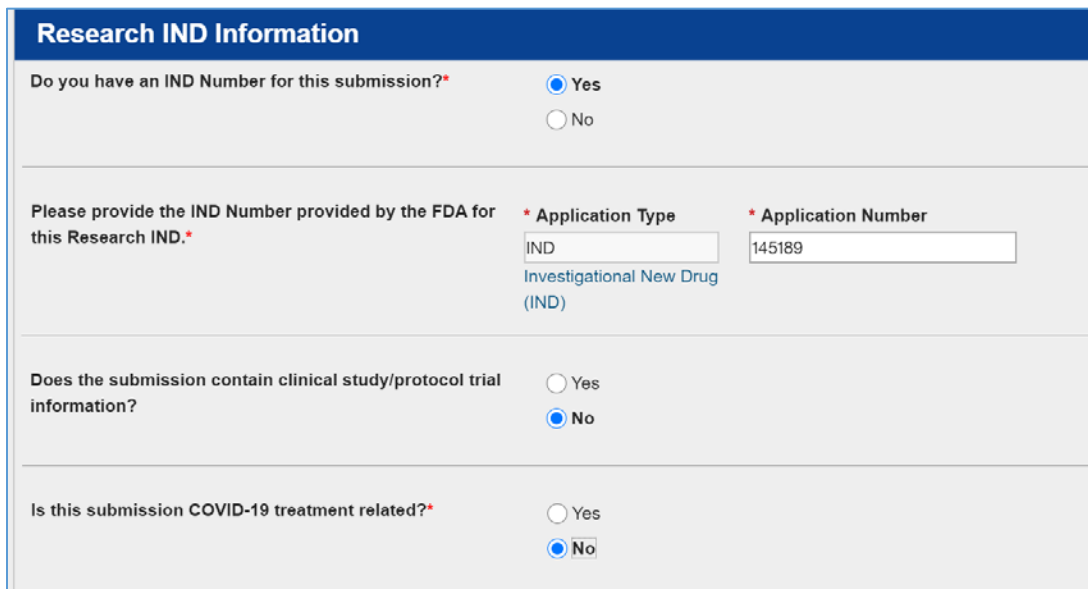


4. Select “IND” and “Sponsor”, then click “Next”
5. Submit your request to FDA. FDA will then send you two emails. The first will be an acknowledgement of your request. The second will contain your Pre-Assigned IND number. Use this IND number for all future submissions to this IND.

Submissions for Research INDs with Assigned IND Numbers

The following process can be used for all submissions once CDER has assigned an IND number to the project, such as Annual Reports, IND Amendments, and IND withdrawals. Refer to the [FDA Research IND User Guide](#) for more information (*login required*).

1. Log in at the [NextGen Portal page](#).
2. Click “Research IND”.
3. If you have an IND number, click “Create New Submission” even if you’ve never submitted anything via the NextGen portal for that IND number before (for example, if this is an APR, etc, for an existing IND).
4. Complete the Research IND information according to your protocol ([sample screenshot below](#))



The screenshot shows a form titled "Research IND Information" with the following fields and options:

- Do you have an IND Number for this submission?*** with radio buttons for Yes and No.
- Please provide the IND Number provided by the FDA for this Research IND.*** with a dropdown menu for *** Application Type** (selected: IND, options: Investigational New Drug (IND)) and a text input for *** Application Number** (value: 145189).
- Does the submission contain clinical study/protocol trial information?** with radio buttons for Yes and No.
- Is this submission COVID-19 treatment related?*** with radio buttons for Yes and No.

5. Next, upload your cover letter (this is mandatory), and confirm the attachment.
6. Click Attach Document and upload form 3926, 1571, etc. (specify type of submission in description). Confirm the attachment.
7. Use the Attach Document function to upload any other documentation you need to submit and specify the document type in the description.
8. Finally, review everything, check the acknowledgement, and submit to FDA
9. Access your submission as described in the next section and capture a screenshot for your records.

Documentation

To view your submission and capture a screenshot as documentation for your records, log in and click “Research IND”, then “View Submission”.

- **Only the person who created the submission will be able to view it later.**

- Clinical Research Support recommends capturing the information shown below in a screenshot of the “View Submission” screen (Event ID, Research IND documents, and Research IND information)
 - Please **email this screenshot to clinicalresearchsupportcenter@ucdenver.edu and include the COMIRB number, IND number, and submission type** in your email.
 - Please also attach the documents you submitted to FDA.
 - CRS will use this as confirmation of report submission to update our IND tracking information.

Review Recent Activity for Event ID: RI-02939

Research IND Documents

Document Type	File Name	Submitted Date (EST)
Form 1571 or 3926	Form 3926_Withdrawal_PDF_no fields Signed.pdf	06/04/2020, 03:53 PM
Cover Letter	Single Patient IND_Closeout letter to FDA.pdf	06/04/2020, 03:53 PM

[View Selected Document](#)

Research IND Information

Question	Response
Do you have an IND Number for this submission?	Yes
Please provide the IND Number provided by the FDA for this Research IND.	IND - 145189
Does the submission contain clinical study/protocol trial information?	No
Please provide all the National Clinical Trial (NCT) number(s) for this Research IND, if available.	N/A
Is this submission COVID-19 treatment related?	No