CDER NextGen Portal for Research INDs

Notes for University of Colorado Anschutz and Affiliate Submitters
Version Date: 6/19/2020 | Author: Erin McDonagh, Clinical Research Support

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/lut/p/z0/04_Sj9CPyksy0xPLMnMz0vMAfijo8ZifQxdnA2dgg18_UNdHA0CDd0CXCxdPQwM3i30C7dFQFcUl7r/

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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)

<table>
<thead>
<tr>
<th>Research IND Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have an IND Number for this submission?*</td>
</tr>
<tr>
<td>Please provide the IND Number provided by the FDA for this Research IND.*</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Does the submission contain clinical study/protocol trial information?</td>
</tr>
<tr>
<td>Is this submission COVID-19 treatment related?*</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Research IND Documents</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Document Type</strong></td>
<td><strong>File Name</strong></td>
</tr>
<tr>
<td>Form 1571 or 3926</td>
<td>Form 3926_Withdrawal_PDF_no fields Signed.pdf</td>
</tr>
<tr>
<td>Cover Letter</td>
<td>Single Patient IND_Closeout letter to FDA.pdf</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><em>Research IND Information</em></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question</strong></td>
<td><strong>Response</strong></td>
</tr>
<tr>
<td>Do you have an IND Number for this submission?</td>
<td>Yes</td>
</tr>
<tr>
<td>Please provide the IND Number provided by the FDA for this Research IND</td>
<td>IND - 145186</td>
</tr>
<tr>
<td>Does the submission contain clinical study/protocol trial information?</td>
<td>No</td>
</tr>
<tr>
<td>Please provide all the National Clinical Trial (NCT) number(s) for this Research IND, if available</td>
<td>N/A</td>
</tr>
<tr>
<td>Is this submission COVID-19 treatment related?</td>
<td>No</td>
</tr>
</tbody>
</table>