**Please note that all Duke-sponsored regulatory submissions to the FDA (or other federal regulatory agency) must be reviewed and submitted to FDA by the Duke Office of Regulatory Affairs and Quality (ORAQ).**

**General Instructions – IDE Template**

**What should I send?**

The IDE should be submitted in eCopy format, and the following technical standards must be followed:

* + All documents should be in Portable Document Format (PDF) when possible
  + Individual PDFs must be 50MB or smaller in size
  + Remove any password protections
  + No embedded attachments or attributes
  + If non-PDFs are required, zip all non-PDF content into one file and save within a folder labeled either “STATISTICAL DATA” or “MISC FILES”
  + Follow the eCopy PDF naming convention described in the eCopy guidance (see link below)
  + For volume-based eCopies, follow the volume (i.e., folder) naming convention described in the [eCopy guidance](https://www.fda.gov/media/83522/download)[[1]](#footnote-1)
  + Include a cover letter in the eCopy (The cover letter should either be the first page(s) of the PDF for merged PDFs, the first file if multiple PDFs are being submitted, or the first PDF in the first folder for a volume based eCopy.)
    - Include a handwritten or valid digital signature
    - Include the submission tracking number, if previously assigned
    - Use the company letterhead and include full contact information
    - Provide a brief description of the purpose of the submission along with submission type (e.g., IDE) and stage of review (i.e. original, amendment, supplement, or report)
    - The Form FDA 3514, if included, should name the **individual sponsor** in the fields for Company/Institution Name and Contact Name (Section B). **Duke should not be listed as the Company/Institution.**

**What is an eCopy and where can I find information on the eCopy program for medical device submissions?**

An electronic copy (eCopy) is an electronic version of your medical device submission. Including an eCopy with your submission has been required since January 1, 2013, and a final rule was issued by FDA on December 13, 2019 requiring medical device premarket submissions to be sent in electronic format, eliminating the need for paper submissions. A submission with an eCopy that does not meet the technical standards outlined in the eCopy guidance will be placed on eCopy hold until a valid eCopy is received.

The following resources will help you in understanding the eCopy program and how to successfully create and submit your eCopy:

* eCopy Guidance:

<https://www.fda.gov/media/83522/download>

* Video Tutorial on eCopy Basics:

<https://www.accessdata.fda.gov/cdrh_docs/presentations/eCopy/Module1.mp4>

* Frequently Asked Questions:

<https://www.fda.gov/about-fda/ecopy-program-medical-device-submissions-frequently-asked-questions>

* eSubmitter-eCopies Tool- a voluntary tool that formats your eCopy content and allows you to download onto a local drive:

<https://www.fda.gov/industry/fda-esubmitter/esubmitter-ecopies-tool>

* eCopies Validation Module- a voluntary tool that verifies the format of an eCopy you have already developed on your local drive

<https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions>

If you have additional questions about the eCopy program, please contact the eCopy Program Coordinators at CDRH- eCopyinfo@fda.hhs.gov or 240-402-3717.

**How do I Submit my IDE?**

At Duke University, device eCopy premarket submissions directed to the Center for Devices and Radiological Health (CDRH) at FDA are submitted through the CDRH Customer Collaboration Portal (CDRH Portal). All Duke-sponsored IDEs must be reviewed and submitted to FDA by the Duke Office of Regulatory Affairs and Quality (ORAQ).

For additional information on the CDRH Portal: <https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal>

For Device eCopy premarket submissions directed to the to the Center for Biologics, Evaluation, and Research (CBER), reach out to the assigned ORAQ Regulatory Affairs Scientist for information on how to submit.

For additional information on submissions to CBER: <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper-format-cber-regulated-products>

**Whom do I address in the submission?**

For submissions to CDRH, the initial submission is usually sent to the attention of the appropriate Division Director if you know where the subject device or similar devices are reviewed. For CBER submissions, the addressee may be the appropriate Office Director or Regulatory Project Manager where the subject device or similar devices are reviewed.

The CDRH Management Directory on the FDA website can be helpful in identifying the appropriate review division or Division Director to be addressed: <https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization>

The CDRH Office of Product Evaluation and Quality (OPEQ) website may also be helpful in identifying the appropriate review division:

<https://www.fda.gov/about-fda/cdrh-offices/office-product-evaluation-and-quality>

For CBER submissions, the CBER Key Staff Directory may be helpful in identifying the appropriate Office Director or Regulatory Project Manager:

<https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/center-biologics-evaluation-and-research>.

Additionally, you can contact our office and we can assist you in determining the correct contact information.

**What happens after I send my IDE application to the FDA?**

* FDA will notify you in writing of the date they received an original IDE application
* The “notification letter” will contain:
  1. The IDE number that has been assigned to your application
  2. The name of the project manager that you can address in future correspondence
* FDA actions on IDE applications
  1. Approval
  2. Approval with Conditions
  3. Staged Approval, with and without conditions
  4. Disapproval
* An investigation may begin:
  1. 30 days after FDA receives the application
  2. FDA approves an IDE for investigation

**Where can I get more information on the IDE submission and approval process?**

* Regulations: 21 CFR Part 812.19 – 812.30

[§812.19 Address for IDE correspondence](http://www.ecfr.gov/cgi-bin/text-idx?SID=63af1db546fdc694378f62c6ec6a03ee&mc=true&node=se21.8.812_119&rgn=div8)

[§812.20 Application](http://www.ecfr.gov/cgi-bin/text-idx?SID=63af1db546fdc694378f62c6ec6a03ee&mc=true&node=se21.8.812_120&rgn=div8)

[§812.25 Investigational plan](http://www.ecfr.gov/cgi-bin/text-idx?SID=63af1db546fdc694378f62c6ec6a03ee&mc=true&node=se21.8.812_125&rgn=div8)

[§812.27 Report of prior investigations](http://www.ecfr.gov/cgi-bin/text-idx?SID=63af1db546fdc694378f62c6ec6a03ee&mc=true&node=se21.8.812_127&rgn=div8)

[§812.30 FDA action on applications](http://www.ecfr.gov/cgi-bin/text-idx?SID=63af1db546fdc694378f62c6ec6a03ee&mc=true&node=se21.8.812_130&rgn=div8)

* “Device Advice” at the FDA Website:

IDE Application

<https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-application>

IDE Approval Process

<https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-approval-process>

IDE Responsibilities

<https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-responsibilities>

FDA Decisions for IDEs

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-decisions-investigational-device-exemption-clinical-investigations>

1. A volume-based eCopy is generally recommended for large or complex submissions in order to facilitate the review of the submission. This eCopy structure includes volumes (i.e., folders) at the root level. [↑](#footnote-ref-1)