**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?**

One eCopy and one paper cover letter:

* + One original hard copy of the cover letter
		- 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 (i.e. IDE) and stage of review (i.e. original, amendment, supplement, or report)
	+ One electronic copy (eCopy) of the submission on digital media
		- All documents should be in Portable Document Format (PDF)
		- 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)
		- It is recommended that the cover letter also be included as a PDF in the eCopy, but it is not required.

**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 stored on a compact disc (CD), digital video disc (DVD), or a flash drive. 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.

**Where do I send my IDE?**

**These are current addresses, but please confirm on the FDA website**

**For devices regulated by the Center for Devices and Radiological Health (CDRH):**

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Mail Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, Maryland 20993-0002

**For devices regulated by the Center for Biologics Evaluation and Research (CBER):**

U.S. Food and Drug Administration

Center for Biologics Evaluation and Research

Document Control Center - WO71-G112

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

**Important note:**

You must state on the outer packaging (e.g. The FedEx label) of each submission what the submission contains. For example, an “IDE application”, a “supplemental IDE application” or a “correspondence concerning an IDE application”. This should also be clearly stated on your cover letter in the “RE:” section.

**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>