**Formatting and Submission Requirements for IDE Submissions**

***(****This document serves as a quick reminder as you prepare your submission. It should not be considered a substitute for the IIS Policies and Procedures, which provide a thorough overview of university-based IND and IDE applications).*

* 8.5 in x 11 in (US letter Size)
* Black font
* 12-point font
* Times New Roman; Verdana; Arial; Tahoma; or Helvetica
* Ensure at least one-inch margins

**Requirements for Preparing Submission to IIS**

* All University-based IND and IDE applications and all documents relevant to such applications shall be submitted to the FDA **through** **IND and IDE Support (IIS).**

.     As of January 1, 2013, and as part of the MDUFA III agreements, IDEsubmissions to FDA are now required to include a valid electronic copy (eCopy) of the submission in a specific format.  We have a link below to the new FDA guidance document on e-Copies for your reference.

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

1. An electronic copy (eCopy) is an electronic version of your medical device submission created and submitted on a compact disc (CD), digital video disc (DVD), or a flash drive.
2. **An eCopy is accompanied by a paper copy of the signed cover letter.** The cover letter should also be included within the PDF in your eCopy**. IIS will print a copy of your cover letter to send to FDA.**
3. **The signed cover letter must be written on letterhead and include the purpose of the submission, contact information (including phone number and email address), along with your signature. You should also include submission tracking number if one has been assigned.**
4. **PDF files are the primary file format used for an eCopy.** You must create the PDF file from the source document. No PDFs should require a password to open.
5. The total submission package should not exceed 1GB. No individual PDF file may exceed 50MB. If file size is greater than 50 MB, then you must split the contents into multiples files. For instance, 001\_Mechanical testing Part 1 and 002\_Mechanical testing Part 2.

1. **The eCopy has a specific Naming Convention that must be followed**. Failure to do so will result in an eCopy Hold. Please see pages 19-25 of the FDA guidance document for further instructions. The link is provided below.

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

1. All IDE Submissions must include the following:

* 1 eCopy, **which must include a signed cover letter** on digital media

Following receipt, the IIS will promptly forward, to the FDA, all University-based IDE applications and all related communications initiated by the IDE Sponsor (i.e., unless an IIS review of the application is requested prior to its submission to the FDA).

**Additional reminders for eCopy:**

* Compassionate use submissions, emergency use authorizations, and adverse reports do not require an eCopy.
* Be sure to check your flash drive, CD, and DVD for pre-loaded files and delete them before you burn your eCopy to the media. Pre-loaded files may cause your eCopy to fail the loading process.
* The free eCopy Validation module is available on FDA’s website. The module will ensure that your eCopy meets the technical standards before submitting to FDA. IIS will also review the eCopy before sending to FDA.

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

* A non-volume-based eCopy is generally recommended for small submissions.
* eCopies that are comprised of only a single PDF need to have the 3-digit prefix of 001\_.
* Only eCopies using Adobe Acrobat II or below will be accepted.