# IDE Preparation and Submission


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# IDE Content (21 CFR 812.20 (b))

1. Cover Sheet – form 3514
2. Name and Address of the Sponsor
3. Report of Prior Investigations
4. Investigational Plan
5. Manufacturing Information
6. Investigators Agreement
7. Investigators Certification
8. IRB Information
9. Name and Address of Investigators Institution
10. Financial Claims
11. Environmental Assessment
12. Labeling
13. Informed Consent
14. Additional Information

http://tinyurl.com/ludu7p8

# 1. Cover Sheet – Form 3514

- used voluntarily
- same form is used for IDE, 510(k), PMA, meetings, 513(g) etc.
- captures the following information:

  - original submission, amendment, report or supplement

  **- device information (name, intended use)**

  - sponsor and manufacturer contact info

  - any previous discussion with the FDA

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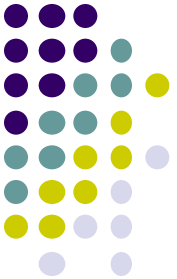
4. Investigational Plan

# 4. Investigational Plan

## (21 CFR 812.25)



- Purpose – name and intended use
- Protocol
- Risk Analysis
- Description of the Device
- Monitoring Procedures
- Additional Records and Reports

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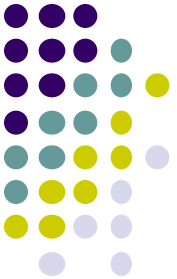
# 5. Manufacturing Information

## 21 CFR 812.20(b)(3)

- FDA-Approved Device – off label and/or modified
- Non-FDA Approved Device – from a company
- Non-FDA Approved Device – you control manufacturing

# 5. Manufacturing Information

## 21 CFR 812.20(b)(3)



- Refer to its approved label
- Refer to its approved label & describe changes that you make
- Refer to Letter of Authorization (LoA)

# What is a Letter of Authorization?

- This is a letter from a sponsor (company) to their IDE (or IND or MF) stating that confidential information from their submission can be used in support of your submission
- Thus, the FDA has “permission” to reference the named materials in support of your IDE
- Get copies of the letters to include in your submission

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# 6. Investigators Agreement (21 CFR 812.43)

- CV of the investigator
- Statement of investigator's relevant experience
- If investigator was involved in the investigation that got terminated, explain the circumstances
- Financial disclosure information
- Statement of investigators commitment to:
  - conduct the investigation according to the agreement
  - supervise all testing
  - ensure that requirements for obtaining of the IC are met

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# IDE Submission

IDE should be sent to:

- Food and Drug Administration
  Center for Devices and Radiological Health
  Document Mail Center - WO66-G609
  10903 New Hampshire Avenue
  Silver Spring, Maryland 20993-0002
- One paper and two 2 e-copies
  - http://tinyurl.com/99jtgle

# Medical Device Training Program

- The program is intended for anyone who either wishes to explore regulatory affairs as a potential career or to broaden their knowledge base
- Free of charge
- Remote participation via WebEx
- https://www.dtmi.duke.edu/dtmi-teams/regulatory-affairs/regulatory-affairs-training-programs

# Questions?