### What is an IDE?

A Investigational Device Exemption (IDE) is the document submitted to FDA to allow for the conduct of a clinical study using a significant risk device that is new or not approved for a given use.

### Physician-sponsored IDE

- You are the “holder”
- You are the responsible for testing of the device
- The physician must conduct a clinical trial using the device in human subjects: “you are the investigator”

### Industry sponsored IDE vs. Physician Sponsored IDE

<table>
<thead>
<tr>
<th></th>
<th>IS-IDE</th>
<th>PS-IDE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intent</strong></td>
<td>Data collection, Device design &amp; approval</td>
<td>Research clinical importance</td>
</tr>
<tr>
<td><strong>Patient Enrollment</strong></td>
<td>Strict pt enrollment criteria</td>
<td>Typically less stringent</td>
</tr>
<tr>
<td><strong>Risks</strong></td>
<td>Reduced risk profile to evaluate true device impact</td>
<td>Higher risks</td>
</tr>
<tr>
<td><strong>Access</strong></td>
<td>Well selected sites with good results</td>
<td>May be broader</td>
</tr>
<tr>
<td><strong>Support</strong></td>
<td>Industry based direction</td>
<td>Money &amp; institutional support</td>
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Sponsor-investigator perspectives on manufacturer-sponsored studies, Mark A. Farber, MD

[Links to relevant FDA pages:](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/)
Contact information and mailing address for the CDRH at FDA

Contact Information for CDRH
1-800-638-2041
301-796-7100
Fax: 301-447-8149
dsmica@fda.hhs.gov
Food and Drug Administration
10903 New Hampshire Avenue
WO66-5429
Silver Spring, MD 20993

IDE submissions to CDRH
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G809
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA website for CDRH contact information
About the Center for Devices and Radiological Health. Available from: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/default.htm

Rational Use of institutional and external resources

- Division research coordinator(s)
- Use institutional facilities
- Venous access
- Institutional network and computers
- ECG
- Division research coordinator(s)
- Department research office
- Research compliance office
- Hospital purchasing office
- Research administration
- Clinic staff

- Department staff: SPIE, Co-I, external monitor, director of IDE, technicians: JEB
- Clinical specialists/associate
- Interventional plannings

PS-IDE Budget

- Electronic data capture system (EDC): $50,000
- Free access to software-EDC
- Biostatistician: $90-120/hr *9=1,080
- Research coordinator:
  - $44,000-Postdoctoral fellow MD, PhD
  - $45,680-Research associate

- Electronic data capture system (EDC)- $8,000-$60,000

Physician-sponsored Investigational Device Exemption (IDE)

Device manufacturing

- Clinical specialists/associate
- Interventional planners

Protocol Summary / Business Plan

Downstream revenues & hospital negotiations

- # patients
- Enrollment: # months
- Follow-up: # years
- Total Duration Time: # years

AlluraClarity

<table>
<thead>
<tr>
<th>Screening</th>
<th>CTA-chart review</th>
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<tbody>
<tr>
<td>Informed consent obtained</td>
<td></td>
</tr>
<tr>
<td>Baseline evaluations: abdominal ultrasound, labs</td>
<td></td>
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<tr>
<td>FEVAR + procedural Angiography</td>
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</tbody>
</table>
| Follow-up
  - 30d, 6m, 12m, 2-5y
  - CTA, US, Labs |
Conclusions

• With guidance and direction, the requirements and costs for an individual investigator who wants to do research with an FDA-approved or nonapproved device are readily met.
• Indeed, medical device research including the filing and maintenance of an IDE is well within the scope and the resources of physician investigators at academic and private medical centers.