You Want to Do Physician Based Research: Where Do You Begin?

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DISCLOSURES

Billi Tatum, RN, CCRC

- **Stock Option:** Aortica Corporation

Learning points

- How to get started
- Costs
- Reporting requirements

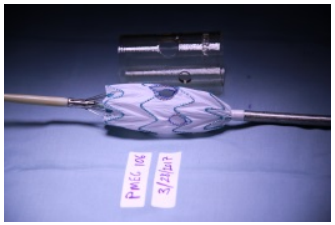
Getting started- the “what”

What do you want to do:

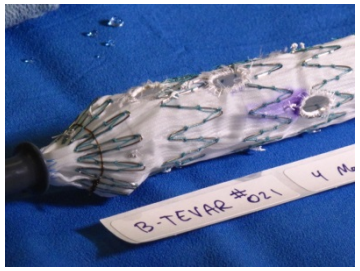
- Are you proving that something works better than something else?
- Are you introducing a new product/device?
- Are you finding a different use for an already approved product?
- Have there been other studies done?

Examples of studies

- We have two physician initiated investigational device exemption trials (IDE) in Vascular surgery
  - PMEG (Physician Modified Endovascular Graft) study with Dr. Starnes



  - BTEVAR (Branched Thoracic Endovascular Aortic Repair) study with Dr Sweet



After the “what” comes the “how”

- Writing the protocol
  - Call the FDA to ask to speak with someone that works in your area of interest for an IDE (Investigative Device Exemption)
  - Go to the FDA website https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm
  - Talk to others who have written a protocol
  - Do a background search on your topic

More of the “how”

- Create **C**ase **R**eport **F**orms(CRFs)- forms that collect the data or information that is important to your study
- Start putting out feelers for people to be on your Clinical Events Committee (CEC)
- Find a group that will monitor your study
- Write, re-write, repeat

Costs associated with an IDE

- Research coordinator salary
- Data base creation
- Monitor fees- usually come once a month
- Supplies-binders, paper
- Storage space –cabinets, cupboards

Getting approval

- Submissions:
  - Submit to your local IRB (Institutional Review Board)
  - Submit to the FDA after you have received the conditional approval from your IRB
  - The FDA will send an email that they have received your application
    - The FDA may approve, approve with modification, or disapprove an IDE application. They may also request additional information about an investigation
    - An investigation may begin **30 days** after FDA receives the IDE application for the investigation of a device if IRB approval has been obtained unless FDA notifies the sponsor that the investigation may not begin.

More approval

- Once the FDA has sent you the official letter with your approval, submit the approval letter to the local IRB for their “final” approval
- Now one more submission to the FDA with the IRB final approval.
- CMS (Centers for Medicare and Medicaid Services) submission
- You are now off an running with your study

Reporting requirements

- Once your study has been approved and you have started enrolling subjects, there are lots of reporting requirements to both the FDA, IRB and the CEC
  - Annual, or more frequent reporting, to the FDA. Some beginning studies may require a report after every 5th subject. The FDA website lists the format for these reports.
  - Reporting to the FDA,IRB and the CEC when certain events happen such as a death, paralysis, kidney failure

Conclusion what was learned

1. How to start an IDE- the “what”
2. What’s involved –the “how”
3. Costs
4. Reporting requirements

Any questions???