Investigational Devices

- Investigational devices are unique and potentially provide new treatments for diagnosing, treating or ameliorating disease processes.
- They are extraordinary when they first move into clinical trials.
- So thinking about them in black and white terms, is not useful. Each one is different.

What is considered a device?

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is used to diagnose, cure, mitigate, treat or prevent disease or other conditions, and does not achieve its purposes through chemical action within or on the body and is not dependent on being metabolized for the achievement of its primary intended purpose.

*CMS Pub 100-2, Ch. 14, § 10*
Device Classes

- Class I devices have the least regulatory control. They are not intended to help support or sustain life or be substantially important in preventing human health impairment to human health, and may not present an unreasonable risk of illness or injury.
- Class II devices are designed to perform as indicated without causing injury or harm to patient or user.
- A Class III devices are those for which insufficient information exists to assure safety and effectiveness. They usually support/sustain human life or prevent impairment.

Why do we have an IDE process?

An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully. Therefore an IDE exempts an unapproved device from the applicable law applied to interstate commerce.

Investigational Devices

- Significant risk (SR) device
  - Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject
  - Purported or represented for supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject
- Non-significant risk (NSR) device is one that does not meet the definition of a significant risk device
Who Determines SR/NSR?

- The sponsor makes the original determination to present to the IRB, who determine if the study involves a SR or a NSR device.
- In the case of significant risk studies, the sponsor submits the IDE application to FDA. FDA then approves, approves with conditions, or disapproves the IDE within 30 calendar days. If FDA does not respond within 30 days, the IDE is considered "deemed approved." The sponsor then obtains IRB approval. After both FDA and the IRB approve the investigation, the study may begin.

How Are Devices FDA-approved?

- 99% of new medical devices use the 510(k) process. The device is "substantially equivalent" to a previously legally marketed device can be "cleared" by the FDA for marketing. The 510(k) pathway rarely requires clinical trials.
- Premarket Approval (PMA) is the second pathway and is similar to the pathway for a new drug approval. Typically, clinical trials are required for the PMA approval pathway.

IDE Reimbursement Categories

- Category A-Experimental
- Category B-Non-experimental/Investigational
Can you submit the protocol the IRB while the sponsor is waiting to hear about FDA approval?  **NO**

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### Device Reimbursement

- Most devices are paid for by the patient or his/her insurer.
- Investigate whether pre-authorization is needed
- Medicaid only pays for investigational products (IP) in life-threatening circumstances when all other avenues have been tried and fail. This must be documented. Medicaid does not pay for injury as a result of the investigational product.

### CMS Notification-PRMO

- PRMO accesses the following documents from IRB submission:
  - CMS Check list
  - FDA full approval letter
  - Investigational Brochure (or equivalent)
  - Protocol/Research Summary
  - IRB Notification of Approval
  - Watermarked consent form
CMS Notification-Study Team

• The Study Team provides the following:
  – A fund code that is used to FEDEX documents to and from Palmetto GBA
  – CPT codes for all procedures performed as part of the research
  – Names of all providers participating in the trial
  – Performance site (DUH, DRH, DRAH)

Post IRB Approval Process

• Palmetto GBA takes 6-8 weeks to approve the Medicare application. You may not use the device prior to this approval.
• Complete the SAP Material Master Request Form and email to Bill Trofi.
Additional information for Procurement

- Manufacturer and any associated vendors
  - Vendors require approval in DUHS.
  - All manufacturer representatives are required to be enrolled in the DUHS vendor credentialing system “REPTRAX”.
- Where will products be used?
- Complete list of supplies (not just the IDE).
- Who is paying for what? If not provided by the sponsor, has the operational unit been informed
- Are the supplies used for other clinical indications
- Copy of the sponsor agreement (CTA) and IRB approval letter.

How does the device get to Duke?

- Devices need to be tracked from manufacturing to use/implant. This is a sponsor responsibility.
- Documentation of the “Chain of Custody” is required.
- Identify the person responsible for device accountability.
- Different information is needed-device name, the serial number, all manufacturer information and the contact at the manufacturer
- If the device is made of tissue, additional “tissue tracking” is required.

DUHS Device and Supply Contacts

- Supply Chain—Bill Trofi
- Heart Center—Helen Brann
- Duke OR—Mike Kivel or Jen Rosen
- Duke ASC—Mike Kivel or Connie Monroe
- DUAP and PDC Clinic—Alice Walker
- DUH Inpatient—Judy Prewitt or Alice Walker
Additional activities prior to device usage

• Obtain miscellaneous institutional approval (PERT committee for OR devices)
  http://periopexec.duhs.duke.edu/modules/periop_prp/index.php?id=1
• Notify the Patient Care Administrative staff about the device and your willingness to do whatever is necessary to get the information about the device disseminated. Judy Prewitt is very helpful.
• Arrange for/conduct clinical staff training. Some sponsor require all staff to be trained on the device.

Humanitarian Use Device (HUD)

• A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

Humanitarian Device Exemption (HDE)

• To obtain approval to use an HUD, the sponsor submits and HDE application to the FDA
• It is not research but requires IRB oversight
• CMS approval for HDE is generally on a case-by-case basis
• Each patient must sign a consent form in order to receive the device with the exception of the emergency use of the device.
• All the internal processes described for IDEs are the same for HDEs (Procurement, training, billing)
Resources

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