

2011

## 2011 Device Advice from the FDA: IRB case study questions

Human Research Protection Office, Washington University School of Medicine in St. Louis

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**DEVICE ADVICE FROM THE FDA**  
**Friday, June 24, 2011**

HRPO Conference Room  
22 N. Euclid Ave., Ste. 233

**AGENDA:**

**8:30 am – 10:30 am                      Device Advice**

Lynn Henley, Center for Devices and Radiological Health

Ms. Henley has degrees in Biology, Biotechnology and Business. She has spoken to numerous groups at academic institutions (Stanford University, University of Pittsburgh Medical Center), conferences (Columbia University IRB Conference, MD&M West), government research facilities (National Institutes of Health, Fort Detrick) and regulatory workshops (Regulatory Affairs Professional Society, AdvaMed) concerning Investigational Device Exemptions and Humanitarian Device Exemptions. At CDRH, she serves on the Clinical Expert Review Committee, participate in the Level of Evidence Project, and represent the Office of Device Evaluation at CDISC.

***Topic for IRB staff and members (2 hours)***

**Case Study questions around:**

- How to distinguish when “standard care” use of a device is research.
- Determining if a device is “exempt” from the IDE regulations
- When using a device for an approved indication, when does it become investigational? Who determines whether the use is consistent with FDA approval? Where is this information found?
- Who makes first determination regarding risk – FDA or IRB? If the IRB is the one making the first determination regarding risk can or will this be overturned by the FDA?
- What is the Pre-IDE application? What does it look like? How is this used in an IRB review?
- Off-label use of devices. Are they always treated as investigational devices?
- Off-label use of devices cleared for marketing under a 510K. Is there more than one type of 510K clearance? Does the 510K act as an approval for research purposes?
- Off-label use of a significant-risk device. Is an IDE needed? Are there other requirements? What is the investigators’ responsibility? What is the IRB’s responsibility?
- When a study is just collecting data on an approved device do risk determinations apply? Does off-label use apply?
- Humanitarian Use Devices
  - Responsibilities of the IRB and investigator when there is a Premarket Approval
  - Responsibilities of the IRB and investigator when there is not a Premarket Approval
  - What is a Premarket approval?
  - FDA wants additional safety data on a HUD. What does this mean? Is this research? Responsibilities of the investigator and IRB.
- Transitional Devices – what are they?



## **CASE STUDIES**

1. An investigator wants to compare the effectiveness of two mesh reinforcement devices in preventing leaks after liver surgery. One device is approved by the FDA for use in liver surgery. The other device has a 510k clearance for use in “soft tissue”. The investigator claims both devices are approved for use in liver surgery.

Questions: How much flexibility does the IRB have in determining if the requested use falls under the 510k clearance or FDA approval? Must the 510k state the specific organ, in this case, the liver? Or is the term “soft tissue” sufficient?

2. An investigator proposes a prospective longitudinal study of biologic mesh prosthetics used during gastric bypass surgery. The study will allow surgeons to use their preferred biologic mesh. If the surgeon has no preference they will use Company X’s mesh product. The study is funded by the Company X. Company X’s mesh product is approved for this use under a 510K. This study will allow the investigator to assess the use and efficacy of Company X’s mesh product compared to other similar products.

Questions: Does Company X’s device require an IDE in this scenario? In general, if an investigator wants to assess the safety and/or efficacy of an approved device, being used for the approved indications, is an IDE ever required? If yes, under what circumstances? What if the study only involved use of Company X’s device and the collection of safety and/or efficacy data?

3. An investigator is conducting a study to better understand a genetic disorder that greatly decreases a person’s ability to sweat. One test that will be performed as part of the study utilizes a device that measures the amount of sweat produced on a specified area of the skin. There is no therapeutic or diagnostic intervention in this study. The device is approved to measure sweat production for the diagnosis of cystic fibrosis. However, there is no mention of approval to measure sweat production in individuals with this genetic disorder.

Questions: Is this considered an investigational device? Does the IRB need to determine if the device is SR or NSR? Are there other considerations for the IRB when reviewing studies using devices to collect physiologic data? Is this study regulated by the FDA?

4. A device company that manufactures surgical forceps would like to perform usability and preference testing on their angled and straight forceps. Information about the surgeon’s experience and preferences will be collected along with information about the patients undergoing the surgery. Both surgical forceps are approved by the FDA.

Questions: Are the forceps considered investigational devices in this instance? Is a SR/NSR determination required by the IRB? Is this study regulated by the FDA? How does the IRB differentiate between consumer preference testing and the collection of efficacy data?

