NOVA SOUTHEASTERN UNIVERSITY

Investigator Initiated Versus Off Label Use-Overview, Regulatory Support

- FDA Information Sheet (1998): "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices (http://www.fda.gov/oc/ohrt/irbs/offlabel.html)
- FDA Information Sheet (1998): Use of Investigational Products When Subjects Enter a Second Institution (http://www.fda.gov/oc/ohrt/irbs/investigational.html)
- FDA Information Sheet (1998): Emergency Use of an Investigation Drug or Biologic (http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html#emergency)
- FDA Information Sheet (1998): Emergency Use of Unapproved Medical Devices (http://www.fda.gov/oc/ohrt/irbs/devices.html#emergency)
- Humanitarian Device Exemptions (HDE) Regulation: Questions and Answers; Final Guidance for Industry (July 12, 2001) http://www.irb-irc.com/theirb/3.5.3.C.__FDA_HDE_Guidance.pdf
- 21CFR 814.124 Subpart H: Humanitarian Use Devices/Institutional Review Board requirements
- 21 CFR 361.1 Radioactive drugs for certain research uses