NOVA SOUTHEASTERN UNIVERSITY

# General Administrative Policies

## Overview, Regulatory Support and References:

- FDA Debarment List (http://www.fda.gov/ora/compliance_ref/debar/)
- FDA Disqualified/Restricted/Assurances Lists For Clinical Investigators (http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm)
- 21 CFR 56.108(b)
- 21 CFR 46.108(b)
- OHRP Guidance on Written IRB Procedures (July 11, 2002): (http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm)
- 21 CFR 312.53 Selecting investigators and monitors
- 21 CFR 312.60 General responsibilities of investigators
- 21 CFR 312.61 Control of the investigational drug
- 21 CFR 312.62 Investigator recordkeeping and record retention
- 21 CFR 312.64 Investigator reports
- 21 CFR 312.66 Assurance of IRB review
- 21 CFR 312.68 Inspection of investigator's records and reports