NOVA SOUTHEASTERN UNIVERSITY

Institutional Review Boards

Overview, Regulatory Support and References:

The Principal Investigator is ultimately responsible for all study activity, including data integrity, operations, recruitment, scheduling and many other things including ultimately the protection of the rights and well-being of the research subjects. The IRB is an independent administrative body, however, that focuses exclusively in the area of protection of the rights and well-being of human subjects. The membership represents the community and statutorily includes, among other things, both scientific and non-scientific members. A critical component of any clinical trial is the review of the study by the IRB. Although no committee can ever be a substitute for a concerned Principal Investigator exercising integrity in his/her decisions, a properly run IRB offers an objective, multi-disciplined, publically oriented and (most importantly) binding concern to all aspects of the research that pertain to the protection of human subjects.

- 21CFR56.107; 56.114; 312.64; 312.66
- 45CFR46.107(a); 46.114
- 21 CFR 50
- 21 CFR 56
- 45 CFR 46
- FDA Information Sheet (1998): Non-Local IRB Review (http://www.fda.gov/oc/ohrt/irbs/nonlocalreview.html)
- FDA Information Sheet (1998): Cooperative Research (http://www.fda.gov/oc/ohrt/irbs/research.html)
- FDA Information Sheet (1998): Sponsor-Investigator-IRB Relationship (http://www.fda.gov/oc/ohrt/irbs/toc4.html)
- PHRP Accreditation Standard ONR(HRP)1B7; ONR(HRP)2; IRB6