

SOP: SC 504 Version No.:04 Effective Date: 12/3/10	DRUG, DEVICE AND BIOLOGIC STUDIES	Supersedes Document Dated: 7/1/08
---	--	--

Steering Committee approved 10/17/11

1. POLICY

When the research involves a drug or biologic (approved or unapproved), the reviewer will complete form SC 504-A to determine that FDA regulations are being followed.

When the research involves a device (approved or unapproved) being studied for safety or effectiveness, the reviewer will complete form SC 504-B to determine that the FDA regulations are being followed.

2. SCOPE

This policy applies to all research studies that involve the use of drugs, biologics and devices.

3. APPLICABLE REGULATIONS GUIDELINES, AND STANDARDS

21 CFR 312

21 CFR 812

Information Sheet Guidance for IRBs, Clinical Investigators and Sponsors: Significant Risk and Nonsignificant Risk Medical Device Studies (January 2006)
<http://www.fda.gov/oc/ohrt/irbs/devrisk.pdf>

Bluebook Memos – Significant and Nonsignificant Risk Medical Device Studies
<http://www.fda.gov/cdrh/d861.html>

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure
<http://www.fda.gov/ohrms/dockets/98fr/110998b.pdf>

AAHRPP Standard 1.7.A

4. REFERENCES TO OTHER APPLICABLE SOPS

This policy affects all drug and device research.