

## STUDY AUDIT CHECKLIST

Principal Investigator:		Contact Person (if different from PI):	
Employee/Student#:	Phone:	Employee/Student#:	Phone:
Email:			Email:
Department:			Department:
Campus Address:			Campus Address:
Co-Investigator(s) (Name & affiliation or "None"):			
Title of Study:			

<b>STUDY STATUS:</b>
<b>#SUBJECTS ENROLLED:</b>
<b>LOCATION OF STUDY:</b>
<b>ALL SITES PI IS DIRECTLY RESPONSIBLE</b>
<b>DATE OF AUDIT:</b>
<b>AUDITOR:</b>

**Audit worksheets completed for this audit:**

- 1. Regulatory Documentation
- 2. Site Operations
- 3. Protocol Compliance
- 4. Informed Consent Documentation
- 5. Subject Records
- 6. Safety Monitoring
- 7. Drug/Device/Test Article Accountability