

Complete Healthcare Compliance Manual

Resource: Sample IRB Review Worksheet/Checklist

By Caroline Miner,^[1] CIP

Institutional sIRB Review Worksheet/Checklist

INSTRUCTIONS:

1. Use this worksheet/checklist to conduct the institutional review of an external, single IRB (sIRB).

Study Title: _____

Study ID Number: _____

sIRB Name: _____

sIRB Registration Number: _____

sIRB Study ID Number: _____

Reviewer: _____

☐	1. The sIRB is qualified to serve (Quality Standard): ☐ Accredited ☐ Current Self-Assessment ☐ Other (provide rationale)
☐	2. sIRB is qualified to serve (Expertise Standard): ☐ IRB membership is appropriate for the research being conducted ☐ Other (provide rationale)
☐	3. IRB Reliance Agreement Status: ☐ Fully Executed ☐ In progress ☐ Institutional Point of Contact: ☐ Institutional signatory:

☐	4. There is documentation that the sIRB review includes this site. ☐ Yes ☐ No ☐ Other (describe)
☐	5. Does the sIRB review for HIPAA considerations? ☐ Yes ☐ N/A ☐ No ☐ Protocol needs waiver(s) ☐ Authorization document contains all required elements and statements ☐ Authorization is acceptable
☐	6. Is the protocol information specific to this site (e.g., Local Context Supplement) complete, sufficient and appropriate? ☐ Yes ☐ No ☐ Other (describe)
☐	7. All listed investigators have completed training? ☐ Yes ☐ No ☐ Other (describe)
☐	8. All listed investigators have appropriate privileges and credentials? ☐ Yes ☐ No ☐ Other (describe)

☐

9. Any investigator financial interests that need to be managed?

☐ Yes

☐ No

☐ Other (describe)

☐ I recommend institutional approval

☐ I recommend institutional approval pending

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