

# Complete Healthcare Compliance Manual 2024

## Resource: Sample IRB Review Worksheet/Checklist

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### 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: \_\_\_\_\_

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

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

☐

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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