

# Healthcare Compliance Forms and Tools 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 institutional review board (sIRB).

Study Title: \_\_\_\_\_

Study ID Number: \_\_\_\_\_

sIRB Name: \_\_\_\_\_

sIRB Registration Number: \_\_\_\_\_

sIRB Study ID Number: \_\_\_\_\_

Reviewer: \_\_\_\_\_

<input type="checkbox"/>	1. The sIRB is qualified to serve (Quality Standard): <input type="checkbox"/> Accredited <input type="checkbox"/> Current Self-Assessment <input type="checkbox"/> Other (provide rationale)
<input type="checkbox"/>	2. sIRB is qualified to serve (Expertise Standard): <input type="checkbox"/> IRB membership is appropriate for the research being conducted <input type="checkbox"/> Other (provide rationale)

<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"/>	8. All listed investigators have appropriate privileges and credentials?  <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other (describe)
<input type="checkbox"/>	9. Any investigator financial interests that need to be managed?  <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other (describe)

I recommend institutional approval

I recommend institutional approval pending

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