

Report on Research Compliance Volume 20, Number 6. May 25, 2023 Sample IRB Review Worksheet/Checklist

This tool, which was developed by Caroline Miner, appears in the Health Care Compliance Association's *Healthcare Compliance Forms and Tools*.^[1]

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"/>	<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"/>	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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