

### 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"/>	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"/>	3. IRB Reliance Agreement Status: <input type="checkbox"/> Fully Executed <input type="checkbox"/> In progress <input type="checkbox"/> Institutional Point of Contact: <input type="checkbox"/> Institutional signatory:
<input type="checkbox"/>	4. There is documentation that the sIRB review includes this site. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other (describe)

<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>
<input type="checkbox"/>	<p>9. Any investigator financial interests that need to be managed?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Other (describe)</p>

I recommend institutional approval

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