

ARGUS IRB

ARGUS INDEPENDENT REVIEW BOARD
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7. Indicate whether any of the following have occurred at your site since your last report:

- (a) Advertisements / Recruiting Materials Yes No
- (b) Significant Protocol Deviations Yes No
- (c) Protocol Amendments Yes No
- (d) Change of Site Location Yes No
- (e) Change of Principal Investigator Yes No
- (f) Change of Sub-Investigator Yes No
- (g) Change in Compensation Yes No
- (h) Serious Adverse Events (SAEs) Yes No

→ If Yes, how many SAEs have occurred?

of SAEs:

→ SAEs must be reported to Schulman **within 3 business days** of the site becoming aware of the SAE.

8. Since your last report, have there been any unanticipated problems involving risk to subjects or others (such as breach of confidentiality or increased cost to the subject)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
9. Since your last report, have you provided your subjects with any additional information not contained in an SAIRB approved document that may affect their willingness to stay in the study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
10. Since your last report, has an IRB terminated, suspended, imposed restrictions or sanctions upon research at your site, or refused to review a protocol for any investigator associated with this study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
11. Since your last report, have any subjects at this site sought compensation for injury or made complaints regarding the conduct of the study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
12. Since your last report, has anything occurred in this study, which, in your opinion, would alter the initial risk/benefit analysis of this study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
13. Since your last report, has a state medical board taken disciplinary action against any investigator associated with this study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
14. Are there state medical board complaints and/or charges currently pending against any investigator associated with this study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

NOTE: If you answered **Yes** to any questions numbered **#8** through **#14**, you must provide a detailed explanation and submit any pertinent documentation.

15. Has your site been AUDITED during this study?

- Yes No
 FDA IRB

(a) If Yes, by what entity?

(b) What was the date of the audit? _____(mm/dd/yy)

(c) Name of the physician/investigator who was the subject of the audit:

(d) Copy of audit report or findings attached:

- Yes Previously Submitted Will submit when available

16. Since your last report, have you consented subjects from the following VULNERABLE groups? Yes No

If **Yes**, check ALL that apply:

- Children (anyone under the age of majority in your state) Consented via legally authorized representative
- Anyone who cannot read (blind or illiterate subjects) Non-English speaking persons
- Employees/immediate family members of employees

NOTE: Submit *one signed and dated copy* of the **informed consent** document (and child's assent, if applicable) from each marked category by the most recently consented subject.