ARGUS IRB

ARGUS INDEPENDENT REVIEW BOARD
6668 S. HIDDEN FLOWER WAY • TUCSON, AZ 85756
(520) 298-7494 • FAX (520) 298-7494
www.argusirb.com • argusirb@gmail.com

STUDY STATUS REPORT FORM

General Information	
Protocol Number:	
Sponsor:	
Principal Investigator:	
Site Contact for this Study:	
Phone:	
Fax:	

I certify that I have thoroughly reviewed the information provided on this report form.
I also certify that the information provided in response to the questions of Argus is true and accurate.

_____ _____

Signature of Principal Investigator **(Required)** Date (mm/dd/yy)

1. Submit consent documents.
You must submit a copy of the most recent version of the informed consent document (ICD), addendum consent document, and sub-study consent document *signed and dated by the most recently consented subject.*

2. What TYPE of report are you submitting?

☐ Interim
☐ Continuing Review (when applying for **re-approval** of the study at your site)
☐ Final

(a) Provide date of final contact with the last study subject: _____ *(mm/dd/yy)*
(b) Are any subjects still participating in this study, including follow-up or subjects being followed until death for survival analysis? ☐ Yes ☐ No
NOTE: If any subjects are currently being followed, this cannot be a final report until all follow-up is completed.

3. Is enrollment OPEN at your site? ☐ Yes ☐ No

4. What was the DATE the 1st (first) subject was consented at your site? _____ *(mm/dd/yy)*

5. Calculate how many subjects are still ACTIVE in the study.

Subjects	Initial Study	Study Extension 1	Study Extension 2
		IRB#:	**IRB#:**
(a) # Consented			
(b) # Screen Failures			
(c) # *Dropped** (see note)			
(d) # Completed Study			
(e) # Still Active in Study			

Please calculate ACTIVE subjects: (e) = (a) – (b) – (c) – (d)
***NOTE:** List the specific reason for each dropped or withdrawn subject since your last submitted report. Please use subject initials or numbers when listing each specific reason.
Reasons: _____
_____
_____

6. List the number of CONSENTED subjects in each category below:

Gender:		# Male		# Female	
Ethnicity:		# Hispanic		# Non-Hispanic	
Race:		# Caucasian		# African-American	
		# Asian-American		# Native American	# Other

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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 Argus **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)?	☐ Yes	☐ 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?	☐ Yes	☐ 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?	☐ Yes	☐ 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?	☐ Yes	☐ 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?	☐ Yes	☐ No
13. Since your last report, has a state medical board taken disciplinary action against any investigator associated with this study?	☐ Yes	☐ No
14. Are there state medical board complaints and/or charges currently pending against any investigator associated with this study?	☐ Yes	☐ 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

(a) If Yes, by what entity? ☐ FDA ☐ IRB

(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)
☐ Anyone who cannot read (blind or illiterate subjects)
☐ Employees/immediate family members of employees
☐ Consented via legally authorized representative
☐ Non-English speaking persons

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.