



## Opus Institutional Review Board

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### Final Closeout Report

#### Protocol Information

	Protocol Name
	Protocol Number
	Opus IRB #
	Name of Principle Investigator
	Sponsor Name

#### Final Report Summary

	Date of study closure at site
	Date last subject completed study (This must include all follow-up visits/phone calls)
	Total number of subjects consented
	Total number of screen failures (could not meet eligibility requirements)
	Total number of subjects completing study
	Total number of subjects withdrawn/early terminated from study

#### Final Report Detail

(TOTAL NUMBER OF SUBJECTS CONSENTED : This should include all completed subjects plus all screen failures, plus all subjects that withdrew or had early termination for any reason)

List each subject and the reason for withdrawal or early termination in section below:

Name of Subject:

Reason for withdrawal or termination:

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Diversity of Subjects	Male	Female	Caucasian	Native American	African American	Hispanic	Asian/Pacific Islander	Other
# of Subjects								

Comments:

Yes <input type="checkbox"/> No <input type="checkbox"/>	Have there been any Significant Protocol Deviations that have NOT previously been reported to OPUS IRB?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Have there been any Unanticipated Problem involving risks to subjects that have NOT previously been reported to OPUS IRB?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Have there been any Serious Adverse Events that have NOT previously been reported to OPUS IRB?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Has the site been audited by the FDA OR OHRP since your last report?

**Audit Information (Complete this section if there has been any audit of your site)**

List the agency that performed the audit(s)                      Date each audit was performed

Yes  No  If you received an FDA audit, was a 483 issued?

Yes  No  If you received a 483, was it about a study under the approval of OPUS IRB?

If Yes, list the protocol number, name, and OPUS IRB #

Protocol name

Protocol Number

OPUS IRB #

\*If Yes, attach a copy of the 483 and any related correspondence

Yes  No  If you received an OHRP audit, was it regarding a study under the approval of OPUS IRB?

If yes attach a copy of the findings related to the OPUS approved study and any related correspondence

Yes  No  Have there been any events that make you feel the risk/benefit ratio should change?

Yes  No  Has there been any new information that you feel OPUS IARB should be made aware of?

Name of person completing this form

Email Address

Phone Number

I acknowledge and certify that the information provided on this Final Closeout Site Form is accurate and true to the best of my knowledge. I request that this protocol be closed out by OPUS IRB.

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Signature of Principle or Sub-Investigator

Date