



## ADIRONDACK HEALTH

TITLE:	Study Closeout or Early Closure by the Sponsor	POLICY #: SOP-6
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 1
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 1/22/14	REVIEWED/REVISED: 12/8/14, 2/16	
APPROVED BY:		
Patricia Druzba, PhD (Chair, IRB)		
Chandler Ralph (President & CEO)		

### POLICY:

1. There must be a final report from the Principal Investigator (PI) when the study is closed to enrollment either because the study has been completed or the sponsor has closed the study early.
2. The format for the report will be supplied by the IRB to the PI as soon as he/she has notified the IRB in writing of the circumstances of the closure along with the notice from the sponsoring company.
3. All Safety Reports which the Investigator has received from the sponsor since the last submission to the IRB must be submitted at the time of notice of closure.
4. All investigational product or device must be returned to the sponsor or destroyed at site per the Institution policy and proof of the final disposition must be submitted to the IRB. In the case of a controlled substance, the proof of disposition must be signed by two responsible individuals.
5. If there is to be an abstract or a publication coming out of the study, the IRB must be sent a copy of it for the IRB files.

### REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 312.64  
NYCRR: N/A  
HFAP: N/A