

Catawba Valley Med Cnt Institutional Review Board
IRB-Approved Research Study Closure Form

The Institutional Review Board must be informed once research studies under its review have been concluded. Upon study completion, it is the responsibility of the Primary Investigator (PI) to submit a Study Closure Form. After receipt and review of said form, the IRB will notify the PI that the Board has ceased its review of the research study.

Instructions: Complete and submit this form once your research is complete. This form must be submitted to the IRB within thirty (30) days of the study's completion. Your Study IRB Number, Approval Expiration Date and Approval Type are contained in the original IRB approval letter you received. Submit this form and attachments as appropriate to irb@cvmc.us.

	Date:	
Study Title:		
Primary Investigator (PI) Name:		
PI Email:	PI Phone:	
IRB Approval Expiration Date:		
Original Approval:	<input type="checkbox"/> Full Board Review	<input type="checkbox"/> Expedited Review

Study Status (choose one of the following)

1. Research complete
- All research activities, including data analysis, are concluded
 - Proceed to page 2, Study Summary Information
2. Research terminated
- Study closed
 - Subjects were enrolled and some data were collected – Complete the explanation below and proceed to Page 2, Study Summary Information
 - No subjects were enrolled – Complete the explanation below and proceed to Page 2, Item 4

Explain why the study was terminated[†].

Study Summary Information – Complete ALL Items

1. Number of subjects enrolled in the study since its inception:

If gender was not recorded, check this box:

Females _____ # Males _____ # Adults _____ # Minors _____ Total _____

2. Were any subjects withdrawn from the study, either investigator-initiated or subject- initiated?

YES NO

If YES, explain[†].

3. Summarize any unanticipated adverse events/complications that occurred in the course of the study[†]. If there were none, state "None."

[†] Continue explanations as needed in a separate document and attach to this form upon submission.

4. Electronic Signature: Disclaimer

By signing your name electronically below, you are agreeing that your electronic signature is the legal equivalent of your manual signature on this Study Closure Form.

Investigator Signature: _____ Date: _____

IRB Use Only

CATAWBA VALLEY MED CNT INSTITUTIONAL REVIEW BOARD SIGNATURE:

Date of Study Closure: _____