Catawba Valley Med Cnt Institutional Review Board
Research Study Amendment Request

The Institutional Review Board must be informed of any change(s) to a study it has approved. It is the responsibility of the Primary Investigator (PI) to submit to the IRB a Study Amendment Request PRIOR to making any change in the informed consent process, collection of additional data, study protocol, recruitment materials, study personnel, etc. After receipt and review of said request, the IRB will notify the PI of the Board's decision regarding the proposed changes. The PI must be aware that the IRB may approve or reject the study changes, change the review type, and/or the review time interval.

Instructions: Complete and submit this form when you propose to make changes to your research study. Be aware that it is MANDATORY the IRB receive this form and make its decision(s) BEFORE any changes can be implemented. The 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:	☐ Full Board Review	☐ Expedited Review

Study Status (choose one of the following)

☐ 1. Research as yet NOT initiated

- No research activity has begun
- Proceed to Page 2 and complete items as applicable

☐ 2. Research in progress

- Subject enrollment is ongoing, and data are being collected

  Number of Subjects enrolled to date:

- Subject enrollment is complete and data collection and/or analysis has been undertaken

  Number of Total Study Subjects:

- Proceed to Page 2 and complete items as applicable

Study Amendment(s) Being Requested

Amendment Type – Check all that apply.

☐ 1. Research personnel change(s). Describe below.

☐ 2. Additional data to be collected. Delineate each new variable below.

☐ 3. Protocol procedural change(s). Attach the **revised protocol** with a **new version number** to this Amendment Request submission. Detail changes below.

☐ 4. Informed Consent (IC) additions or deletions. Attach the **revised IC** to this Amendment Request submission. Provide detail of proposed changes below.

☐ 5. Study questionnaire or survey changes. Attach **revised study questionnaire or survey** to this Amendment Request submission. Briefly note changes below, e.g., question/item number(s).

☐ 6. Recruitment material (fliers, email text, advertisements, etc.) changes. Attach **revised recruitment material(s)** to this Amendment Request submission. Describe changes below.

7. Has awareness of any new information, through the study itself (if applicable), or available via published literature, conferences, colleague conversation, etc. had a bearing on this request?

☐ YES ☐ NO

If YES, describe.

8. Summarize any unanticipated adverse events which have occurred during the study. If not applicable, check this box: ☐

9. 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 Amendment Request Form.

Investigator Signature:_____Date:_____

IRB Use Only

Approval Type: Expedited ☐ Full Board ☐ Study Now Exempt ☐

CATAWBA VALLEY MED CNT INSTITUTIONAL REVIEW BOARD SIGNATURE & DATE:

_____

Approval Period: From_____To_____