Catawba Valley Med Cnt Institutional Review Board
IRB-Approved Research Continuing Review Request

All research studies must undergo, at least at a minimum, annual IRB review. Some research is required to be reviewed at more frequent intervals, e.g., quarterly. The Research Study Primary Investigator (PI) must submit this form, at the IRB-designated time interval for their approved research. The original approval notification details the review requirement. **All research must CEASE on the approval expiration date unless approval to continue has been obtained from the IRB in writing.**

Instructions: Complete this form to request continuing review of your study. This form must be submitted to the IRB at least two (2) weeks prior to the study approval expiration date. 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 by choosing "Send File" and then "Attach to email" from the Adobe File menu (delete this portion if it is not currently possible with the PDF program in use at CVMC).

	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. Study recruiting/enrolling subjects
- Attach Informed Consent Form in use
- If informed consent was waived by the IRB, check this box: ☐

☐ 2. Post-enrollment
- Subject enrollment complete
- Data collection complete
- Data analysis NOT initiated

☐ 3. Post-enrollment
- Subject enrollment complete
- Data collection complete
- Data de-identified
- Data analysis in progress

Study Summary Information – Complete ALL Items

1. Number of subjects enrolled in the study since the last IRB review. Provide number of subjects enrolled during the current approval time interval. If this is the second or subsequent review period, report the number of subjects added to the study since the last time you submitted a continuing review request.

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

   If gender was not recorded, check this box: ☐

2. TOTAL number of subjects enrolled since the study began:

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

3. Have any subjects been withdrawn from the study during this approval interval, either investigator-initiated or subject- initiated?

   ☐ YES ☐ NO

   If YES, explain. _____

4. Are you aware of any new information, either as a result of the study itself, or available through journal articles, conferences, information from colleagues, etc., that may indicate a possible increased risk of social, psychological, or physical harm to subjects in this study?

   ☐ YES ☐ NO

   If YES, explain. _____

5. Summarize any unanticipated adverse events/complications that could affect the risk/benefit assessment of the study. If none, state "None."

   _____

6. Investigator Signature _____

IRB Use Only

☐ Continuing Expedited ☐ Continuing Full Board

CATAWBA VALLEY MED CNT INSTITUTIONAL REVIEW BOARD SIGNATURE:

_____

Period of Continuing Approval: from _____ through _____