



Appeal of Study Closure (Form Date 7/2012)

Federal regulations and CHS CIRB policies mandate continuing review of all open research studies involving human subjects at least annually. The Office of Human Research Protection (OHRP) recently issued guidance to IRBs for considerations in evaluating the progress of the research at the time of continuing review. One item requiring attention relates to low enrollment of subjects or a disparity between projected and actual enrollment, which may indicate a problem with the research. In these cases, further evaluation is necessary to assess whether the project continues to possess the integrity and merit to provide quality data to answer the scientific questions being studied.

The Principal Investigator must provide an explanation to justify the continued possibility of exposing subjects to the risks of the test article since the study itself may no longer provide sufficient data to answer the scientific question at hand. Your justification for keeping this study open for an additional year is important. This form should accompany your Request to Renew a Research Study. Please note that failure to respond will result in withdrawal of over-site and closure of the research study by the CHS CIRB.

1. Does the study continue to seek the answer to a relevant question or are there more current studies that should be considered?
2. Do you have sufficient resources to conduct this study?
3. Have factors outside of your control contributed to the lack of enrollment?
4. What methods did you employ to assess the surrounding patient population to ascertain that there are a sufficient number of prospective subjects who may meet the eligibility criteria?
5. What methods of recruitment have you employed in the past? What methods do you plan to implement in the future?
6. What is the actual study-wide (versus local) enrollment compared to the projected? In other words, is the study accruing subjects nationally at a rate that would justify keeping the study open locally?

Signature of Principal Investigator

Date