As part of the Continuing Review process, it is required that a progress summary be submitted along with the “Renewal Application for Continuing Review.” The progress summary provides information that helps the IRB in its determination of whether the proposed research continues to fulfill the criteria for continued approval. The summary should be a brief narrative regarding study activity since the beginning of the project and include risk/benefit information that may have an impact on the conduct or design of the research. An outline and an example of a “Progress Summary” are provided below.

In general, a progress summary should consist of a couple of paragraphs that address the following:

1. Accomplishments thus far in terms of study goals.
2. Enrollment information:
   a. Is recruitment and enrollment on schedule? If slower than expected, how is this being addressed?
   b. Is there a higher than expected number of withdrawals? If yes, how is it being addressed?
   c. What are the anticipated accruals for the coming year?
   d. What is the estimated date of study completion?
   e. What is the total number of “failed screens” and the reasons? (A “failed screen” occurs when an individual signs a consent document but does not meet screening procedures AND therefore, does not continue participation in the study.)
3. Number of problems or complaints and how they were addressed/resolved.
4. Serious Adverse Event (SAE) findings: A brief description of the SAEs and if/how they impacted the study (e.g., did they affect accruals, was a change in protocol or a revised consent form required, etc.
5. Findings that might affect a subject’s willingness to continue in the study: If yes, briefly discuss the findings and indicate whether subjects were notified of those findings.
6. Changes to protocol or personnel since last approval: Briefly discuss.

Example:

The IRB originally approved this study for enrollment of 160 subjects. To date, we have enrolled 80 subjects. We have had 3 withdrawals, 2 due to ongoing illness and the other because the subject moved out of the area. 3 subjects failed screening because their BP levels were too high. Although we had hoped to enroll 100 subjects during the past approval period, we were only able to enroll 80 due to a 2 month halt in enrollment while we replaced some testing equipment. Enrollment resumed in March and it is expected that we will complete enrollment during the next approval period.

We had one complaint regarding the amount of time it took for the subject to receive the compensation check. The subject was contacted by the project coordinator and the issue has been resolved to the subject’s satisfaction. There were 3 on-site SAEs: 1 unexpected and related, and 2 expected and unrelated. The DSMB determination was that the study would be continued. There were no findings that might change a subject’s willingness to continue in this study. It was noted that the study visit was taking significantly longer than expected. We were able to resolve this by hiring 2 additional staff. We expect to complete the study by May 2007, as originally approved.