

**Affinity Health System  
Institutional Review Board  
Monitoring Form**

**Progress Report for Continuing Review**

Principle Investigator Name:

Research Title:

PI Office Address:

Phone:

Fax:

E-mail:

Signature of Principal Investigator

Date

**ENROLLMENT**

1. Number of subjects who have completed participation in the study, or number of samples that have been collected for research purposes:
  
2. Number of subjects currently participating:
  
3. Number of subjects yet to be recruited, or samples still to be collected:

## **PROGRESS REPORT**

1. Total number of deaths of subjects at your site on protocol **since the last continuing review**:

Were these deaths reported to the IRB?  Yes  No  
Were any possibly related to study participation?  Yes  No  
If yes, please describe:

2. Total number of serious adverse occurrences of subjects at your site on protocol since its initiation:

3. Total number of serious adverse occurrences of subjects at any site on protocol since its initiation:

4. Excluding subjects who have completed study participation, what is the total number of subjects who have withdrawn **since the last continuing review**:

Please describe the reasons for withdrawal:

5. Briefly summarize any serious adverse occurrences, as defined in study protocol (physical, psychological, social) that were BOTH serious and unexpected **since the last continuing review**. Does the consent form or protocol require changes to include these adverse effects?

6. Total number of serious adverse occurrences of subjects at your site on protocol since its initiation:

7. Total number of serious adverse occurrences of subjects at any site on protocol since its initiation:

8. Date of IRB notification? When occurred?

9. Please summarize any new information affecting the risks, benefits, or alternatives to study participation that has developed **since the last continuing review**. Please consider the relevant literature in your field of research in your response.

10. Study summary to-date: