**Continuing Review Form**

**(for use with protocols undergoing continuing review in eCompliance having previously been reviewed in eProtocol**

1. **Summary: Number of Participants Associated with the Protocol:**
2. *Total number of participants approved to date:*
   1. Click or tap here to enter text.
3. *Number of participants studied since the last approval date:*
   1. Click or tap here to enter text.
4. *Total number of participants studied since the beginning of the project:*
   1. Click or tap here to enter text.
5. *Number of participants remaining to recruit/enroll (total number of participants approved LESS the total number of participants studied to date):*
   1. Click or tap here to enter text.
6. *Please explain if there is a discrepancy in participant numbers (e.g., more participants responded to a survey than had been approved):*
   1. Click or tap here to enter text.
7. **Summary: Issues associated with the protocol**
8. *Reasons and number of withdrawals from the research (both subject and investigator initiated) since the last approval date.*
   1. Click or tap here to enter text.
9. *Number of subjects lost to follow-up since the beginning of the study.*
   1. Click or tap here to enter text.
10. *Description and number of any protocol deviations/violations or unanticipated problems (UPs)/adverse events (AEs), particularly those that may have affected the risks to subjects since the last approval date.*
    1. Click or tap here to enter text.
11. *Complaints about the research during the last year.*
    1. Click or tap here to enter text.
12. **A summary of any recent findings, literature, or other relevant information (especially pertaining to risks), if applicable.**
    1. Click or tap here to enter text.
13. **Description of the remainder of project:**
14. *Are research participants still being enrolled in the study?* 
    1. Choose an item.
15. *Have all enrolled research participants completed study participation?*
    1. Choose an item.
16. *Is the research active only for long-term follow-up of enrolled participants?*
    1. Choose an item.
17. *Do you plan to recruit more subjects?*
    1. Choose an item.

**If "No," have all subjects completed all research-related interventions? Note: Protocols must be renewed to continue recruiting participants and/or collect data from already recruited participants.**

* 1. Click or tap here to enter text.

1. *Are you in the data analysis stage?*
   1. Choose an item.
2. *Is the data de-identified?*
   1. Choose an item.

**(If you answered yes to these two questions you can stop and submit a Final Report. If you answered no to one of them please continue).**

1. **Has approval for this study expired?** Choose an item.
2. *Why did approval lapse?*
   1. Click or tap here to enter text.
3. *What will you do differently in the future to prevent this from happening again?*
   1. Click or tap here to enter text.
4. *Were any additional research participants enrolled or data collected after the expiration date?*
   1. Click or tap here to enter text.

**If Yes, describe all activities that continued including number of participants involved and any adverse event or incidents that occurred after expiration of approval.**

Click or tap here to enter text.

NOTE: If renewal of the study does not occur before the expiration date of study approval ALL enrollment of participants and DATA COLLECTION must stop at the expiration date. Procedures and treatment needed for the safety of participants should continue but data collected during this time period CANNOT be used for research purposes.

1. **Informed Consent:**
2. *Does this study use a consent form? Choose an item.*

**(if so please attach a copy of the previously approved "stamped" copy and a clean copy of the consent form)**

1. **Has there been additional or new information about this study which may affect a subject's willingness to continue their participation, or that may need to be given to prior participants? (Such as safety information, complaints about the research, revised procedures, duration of study, recent literature, etc.)**
   1. Choose an item.

**If YES, please explain and describe how information was provided or is being provided to current or prior participants.**

Click or tap here to enter text.

1. **If this is a multi-center trial, has the most recent data safety and monitoring report or other summary report been submitted to the IRB since the last review?**
   1. Choose an item.

**If No, submit a current report.**

1. **Summarize all changes in the protocol since it was last approved (e.g., have you amended your protocol during the past year?). Are you requesting to make any changes for the upcoming year?**
   1. Click or tap here to enter text.