

## RESEARCH INVOLVING HUMAN SUBJECTS - CONTINUING REVIEW QUESTIONNAIRE

*Must be filled in:* SC #

<b>Principal Investigator:</b>	
<b>Project Title:</b>	
<b>Academic Title:</b>	

I. Dates covered by this progress report:  Previous 12 months  Other period as described:

II. Is this project currently active? Yes  No

A. Is this study a retrospective record/chart review? Yes  No

B. If not currently active, indicate the termination date of your project:

III. Is this project currently open to subject recruitment? Yes  No  N/A

If No, please indicate the date closed to recruitment:

IV. Do you wish to continue this protocol? Yes \* No

**If Yes, please complete the attached Project Summary and return to the PHDMC Research Review Panel. Attach copies of the appropriate informed consent and other relevant document(s).**

\*NOTE: If this study was approved as “exempt” and is unchanged, check here ; it is not necessary to complete Project Summary.

**PROJECT SUMMARY**

- A. Have there been any changes in leadership, responsibility or major personnel? Yes  No

If Yes, then fully describe:

- B. Concisely summarize any changes in Objectives, Procedures, or Informed Consent Documents that have occurred during the previous period. Provide documentation of IRB approval of these items. If no changes, enter “none.”

C. Research Subjects:

1. List each group, arm, cohort, etc., if applicable, including control groups, on separate lines. If only one group, description would be “All.”

Group	NUMBER OF SUBJECTS (at all sites for which you are the PI)			AGE RANGE OF SUBJECTS (at all sites for which you are the PI)		GENDER (of subjects to date)	
	This Period	Total Accrual to Date**	Next Period (anticipated)	This Period	Next Period (anticipated)	% Male	% Female

\*\* If the accrual of subjects has been lower than anticipated over the past year, explain how this will impact the ability to complete the protocol's research objectives:

2. Was the subject population representative of the population base from which subjects could be selected with respect to:

- a. Gender representation? Yes  No

If No, explain:

- b. Minority representation? Yes  No

If No, explain:

3. Have any subjects withdrawn from study since the study began? Yes  No

If Yes, explain:

4. Are you aware of any breach in confidentiality? (e.g., unauthorized access to medical record(s))

Yes  No

If Yes, describe:

D. **ADVERSE EVENTS:** [if the study is conducted at multiple sites, please include national trial information as well. If reported to an IRB, reference the reporting dates.]

1. **Have there been any unexpected toxicities or problems?** Yes  No

If Yes, please summarize these unexpected toxicities or problems, the number of occurrences, and indicate if they required consent document changes, particularly in the “risks” section. If risks are affected, describe how they are minimized and reasonable in relation to expected benefits. If available, attach copies of data safety monitoring reports.

2. **Were there major (e.g., severe or life threatening) toxicities?** Yes  No

If Yes, please summarize these major toxicities, the number of occurrences, and indicate if they required consent document changes.

3. **Have there been any deaths on study (from any cause)?** Yes  No

If Yes, list each separately and the apparent cause.

E. **NEGATIVE REACTIONS:**

**Have there been any unexpected/unusual negative responses as a result of subject recruitment?** (i.e., angry letters, phone calls, threats of legal action) Yes  No

If Yes, describe:

F. **Briefly summarize study findings to date. If findings to date are not available, explain why not.**

G. **Comment briefly about plans for the next twelve months:**

H. **Provide a listing of all publications, presentations and reports that have resulted from this work since the last review. If none, so state.**

**INVESTIGATORS STATEMENT:**

As PRINCIPAL INVESTIGATOR, I acknowledge that I am responsible for reporting any emergent problems or serious adverse effects or reactions. I will submit a continuing review for this research no less than annually.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

OR

\_\_\_\_\_  
Signature of PHDMC Collaborator

\_\_\_\_\_  
Date