OPTIMUM ETHICS REVIEW BOARD

STUDY STATUS REPORT FORM

INSTRUCTION SHEET:

INSTRUCTIONS FOR COMPLETION OF THIS FORM:

ICH Regulations recommend interim review of ongoing studies, final review of completed studies, and require re-approval of all research studies at least annually. **If you are submitting this form for Annual Review, please submit it 4 weeks before the annual approval is required (see DUE DATE on form) by email to optimumerb@yahoo.com, or fax to Optimum at 1-800-878-9494.**

PLEASE NOTE: ***"Approval date" is the date that the protocol was approved. Your site may have received approval at a later date, but all sites must submit the annual report for the same renewal date, for re-approval of the protocol, regardless of when the site received approval.***

A. Please read this form carefully. All sections of this form must be completed.

B. Please make a photocopy of this blank form BEFORE you complete it, for use for your final report, if needed prior to the next annual review.

C. Please ensure that the numbers in section #3 are accurate and correctly add up (see instructions within section box).

D. Failure to submit an Annual Report prior to the due date will result in suspension of your site from "approved" status and will delay any further enrollment of subjects into the study, at your site.

E. Please note that 6 Month Reports are only required if specifically requested by the Board, in your initial approval letter.

OPTIMUM ETHICS REVIEW BOARD

STUDY STATUS REPORT FORM

Due in Optimum ERB office:_____ Date Returned to Optimum ERB:_____

SIX MONTHS☐ *(Only if requested)* **ANNUAL☐** ***(Annual and Final Reports are required)*** **FINAL REPORT☐**

1. Site Information

SITE NAME: (If applicable) _____

ADDRESS:_____

PRINCIPAL INVESTIGATOR: _____

RESEARCH CO-ORDINATOR/CONTACT PERSON_____

Telephone _____ email:_____

(Please note, if you provide an email address, your response letter will be sent via this email)

2. Protocol Information

APPROVAL DATE: _____

OUR FILE NO. _____

TITLE: _____

_____

SPONSOR: _____

PROTOCOL NO. _____

STUDY STATUS: (please check one) ☐ Ongoing (currently enrolling)

☐ Ongoing (enrollment complete, but subjects currently ongoing)

☐ Complete (enrollment closed, all subjects completed)

☐ On Hold

☐ Cancelled

3. Enrollment Statistics (PER SITE) *please note the total of b) + c) + d) +e) must equal a)

a) NUMBER OF SUBJECTS ENROLLED (to date): _____Screen Fail (if applic)___

b) NUMBER OF SUBJECTS COMPLETE: _____

c) NUMBER OF SUBJECTS ONGOING: _____

d) NUMBER OF SUBJECTS WITHDRAWN: _____

e) NUMBER OF SUBJECTS LOST TO FOLLOW-UP: _____

* NUMBER OF SERIOUS ADVERSE EVENTS: _____(If SAEs occurred, you must check one below)
AT YOUR SITE

☐ SAE(s) Previously reported to Optimum

☐ SAE Information is attached to this form

4. Event Reporting

As an investigator, you have the responsibility to report to the Board all of the events/new documents listed below. By signing this form, you confirm that if these events occurred/materials were used, they were reported to the ERB. ***If an event occurred but was not reported***, please provide an explanation of what happened and why it was not reported.

Serious Adverse Events
Significant Protocol Deviations
Protocol Amendments
Advertisements/Recruiting Material
Changes of Investigators (Principal, Co- or Sub-)
Change of Site Location
Change in Subject Compensation.

5. For <u>ANNUAL REPORT ONLY</u>, you MUST return a copy of the signed informed consent. (N/A for Final Report)

Check One:

☐ Attached is a copy of the signed informed consent of the last subject enrolled (all pages)(for **Annual Report ONLY**).

Please black-out the patient's name with a black marker. All other writing must be visible on the signature page. The Board requests a copy of the signed consent form with the Annual Report to ensure that: (a) the proper version of the consent form was used, (b) to check that all signatories dated the consent form individually (c) to ensure that each page was initialed by the subject or person providing consent. Please note that the consent form "Confidentiality" section indicates that the ERB has access to study documents.

☐ Informed Consent of last subject enrolled not attached - (same form as attached to previous annual report).

☐ No subjects enrolled; Informed Consent not available.

☐ Other: _____

_____ _____
Signature of Principal Investigator or Designee Date