Stanford MEDICINE

Clinical Trial Research Management Group / Cancer Clinical Trial Office

Budget Amendment Intake Form*

Please fill out this form **completely** and email with required documents to RMG CT Intake rmg_ct_intake@stanford.edu or submit to CCTO as a **REDCap request** if the study budget was completed by CCTO. Contact ccto-finance@stanford.edu for any questions.

STUDY INFORMATION

PI_____SPO_____ eP _____ RedCap_____

PTA_____ 98/Mnemonic Account ID:_____

Protocol Amendment Version and Date _____

☐ Department Initiated Amendment

☐ Sponsor Initiated Amendment

IRB Review required? ☐Yes ☐No

Stanford IRB revision submitted? ☐Yes ☐No

Single IRB approved? ☐Yes ☐Pending

IRB Review/Approval Date: _____

PATIENT ENROLLMENT

of Patients Currently Active on Study: _____

PURPOSE OF AMENDMENT

Describe in detail all of the changes you will implement with this amendment. This information is required.

CHANGES WITH THIS AMENDMENT (select all that apply)

Protocol Amendment/Changes to Schedule of Events/Calendar:

☐ Cohort/Arm(s) Added (see Appendix A)

☐ Visits Added, Moved or Removed

☐ Hospital Services Added, Moved or Removed

Target Enrollment Change: Increased to:_____Reduced to_____

☐ Billing/Budget changes (ex. Sponsor offers payment for service that requires billing designation change in CA)

☐ Invoiceable Items added/amended

☐ Change in Effort (on existing arms) *please clarify in comments section below*

☐ Inpatient Component Added

☐ CTRU services Added/Removed CTRU Budget Builder updated: ☐Yes ☐No

** Internal SeRA Funding Increase, No Cost Extension, Sponsor or PI change only? Refer to processes:*
http://med.stanford.edu/rmg/clinical-trials/post-award-management.html

☐ Other Changes (please explain)

CONTACT INFORMATION

Department Contact:

Name_____
Email_____
Phone_____

Sponsor Contact:

Name_____
Email_____
Phone_____

TIMELINE

Requested Completion Date: _____

Rationale: _____

Does sponsor require the amendment be executed in order for Stanford to continue with enrollment or receive payment? ☐Yes ☐ No

LOCATION Will a new/additional location be involved? (e.g. CTRU/ValleyCare) ☐Yes ☐ No

Please List: _____

REQUIRED DOCUMENTS

1. Updated Protocol with Summary of Changes
2. Protocol with Tracked Changes *(if available*)
3. Updated Sponsor Budget/Payment Table (*if* provided by sponsor)
4. Contractual Amendment to original CTA (*if* provided by sponsor)
5. Active Budget and Billing Workbook currently being used for study enrollment (PHI removed)
6. Updated Stanford ICF (*if applicable*) with track changes
7. Updated CTRU Budget Builder document (*if applicable*)

Comments or explanation of changes covered above:

CT RMG / CCTO ONLY

Ankura's Internal Tracking number (ex. SHC-CA-XXX): _____

Is an amendment to the coverage analysis required? ☐Yes ☐ No

Explanation of required documents NOT attached: (e.g. "no sponsor agreement because ACTA used for the original)

APPENDIX A

Information on Additional Arms/Cohorts Being Added

Please describe (ex. new investigational product, new age group, other details):

EFFORT ESTIMATES FOR ADDITONAL ARMS:

Name of New Arm 1_____

Total Number of Patients in: New Arm 1_____

Patient Population: ☐ Adult ☐Pediatric

Coordinator: Hours Per Patient_____-OR- % Annual Effort Per Study _____

PI: Hours Per Patient_____-OR- % Annual Effort Per Study _____

Other Name:_____Hours Per Patient_____-OR- % Annual Effort per Study _____

Name of New Arm 2_____

Total Number of Patients in: New Arm 2_____

Patient Population: ☐ Adult ☐Pediatric

Coordinator: Hours Per Patient_____-OR- % Annual Effort Per Study _____

PI: Hours Per Patient_____-OR- % Annual Effort Per Study _____

Other Name:_____Hours Per Patient_____-OR- % Annual Effort per Study _____

Name of New Arm 3_____

Total Number of Patients in: New Arm 3 _____

Patient Population: ☐ Adult ☐Pediatric

Coordinator: Hours Per Patient_____-OR- % Annual Effort Per Study _____

PI: Hours Per Patient_____-OR- % Annual Effort Per Study _____

Other Name:_____Hours Per Patient_____-OR- % Annual Effort per Study _____

Please copy/add Arms as appropriate.