*To be completed for all grant application submissions involving the Clinical Trials Office.*

*Please return completed form to* *CTOBudgeting@health.ucsd.edu*

**Draft Budget Request Form**

**Investigator:** **Funder/Sponsor Name:**

**Study Title:**

**Duration of study (months):** **Accrual Period (months):**

**Number of anticipated cycles per patient: Estimated # of patients enrolled:**

**Will subsites be used for this study?** Yes [ ]  No [ ]  If yes, how many?

**Will network sites** *(Hillcrest, Encinitas, etc.)* **be used for this study?** Yes [ ]  No [ ]  If yes, specify which sites?

**Will you need to budget for screen failure patients or rescreened patients?** Yes [ ]  No [ ]  If yes, please estimate: # of rescreens \_\_\_\_\_\_\_\_\_\_\_\_\_ # of screen failures \_\_\_\_\_\_\_\_\_\_\_\_

**Estimated % effort for Study Coordinator, if applicable:** \_\_\_\_\_\_\_\_\_\_\_\_

**Ancillary Departments**

**Will the UCSD DSMB need to be involved in this study?** Yes [ ]  No [ ]

**Will the IBC be needed for this study?** Yes [ ]  No [ ]

**Will biorepository be involved?** Yes [ ]  No [ ]  If yes, confirm what is needed:

**Does the study require biostatistics?** Yes [ ]  No [ ]

**Will the study require IDS (research pharmacy)?** Yes [ ]  No [ ]

Please complete the following table for drugs that will be used for this study:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Drug(s) | Route of Administration | Billed to Insurance or Study |
| Investigational |  |  |  |
| Non-Investigational |  |  |  |

**Will drug need to be shipped to subsites?** Yes [ ]  No [ ]  N/A [ ]

If yes, please specify estimated costs for drug depot:

**Will we need to label the study drug?** Yes [ ]  No [ ]

If yes, please specify estimated costs for labelling:

**Will pharmacy monitoring be required?** Yes [ ]  No [ ]  If yes, estimate total # of visits across the study (including subsites, if applicable)?

**Patient Costs**

**What are the non-SOC patient care costs anticipated with the study (please also provide study calendar and label nonstandard research procedures)?** ­­­­­­

**Will there be any costs for patient related equipment (BP cuffs, iPads, etc)?** Yes [ ]  No [ ]  If yes, estimate cost?

**Will there be patient stipends/reimbursements?** Yes [ ]  No [ ]  If yes, estimate cost:

**Miscellaneous Costs**

**Will tumor assessment (radiology) costs need to be included on this study?** Yes [ ]  No [ ]  If yes, please estimate average # of timepoints per patient:

**Will a central pathology vendor be used for this study?** Yes [ ]  No [ ]  If yes, please estimate cost:

**Will a non-CTO data monitor be needed for this study?** Yes [ ]  No [ ]  If yes, please estimate cost:

**Will there be any correlatives sciences that need to be budgeted for the study (“central” labs, tissue, etc.)?** Yes [ ]  No [ ]  If yes, please estimate costs for reagents, tubes, materials:

**Are funds needed for publications?** Yes [ ]  No [ ]  If yes, how much?

**Are funds needed for PI/study team travel?** Yes [ ]  No [ ]  If yes, how much?

**Are funds needed for recruitment?** Yes [ ]  No [ ]  If yes, how much?

**Will translations be needed?** Yes [ ]  No [ ]  If yes, how much?

**Are there any other fees that should be added to the budget? ­** Yes [ ]  No [ ]  If yes, please elaborate:

**Guidance / Notes**

1. Accrual Period is not necessary for budgeting, but can be helpful in understanding the study as a whole.
2. # of anticipated patients cycles should indicate the average # of cycles patients will be on the trial. This helps determine how to budget for RECIST, drug dispensation, etc., as applicable
3. Study Coordinator Effort will default to 25% at the highest CRC salary in the CTO office if a CRC effort is not estimated. Efforts beneath 25% may need to be reviewed by the PM for accuracy.
4. Non SOC procedures refers to items that are anticipated to be billed to the study rather than insurance. For budgeting purposes, it is helpful if the protocol follows standard of care to avoid additional funding being pulled to pay for procedures. When writing the protocol, the following verbiage may permit OCAA to find items billable to insurance instead of to study:
	1. “Imaging at Screening/EOT is not required if done in the previous 6 weeks (or whatever cadence matches the treatment or the SOC for this indication)”
	2. (any procedure) – "as clinically indicated" *or* "if patient exhibits symptoms" *or* "if patient has hx of…" *or* "based on physician discretion".
	3. (if you just want tissue from a SOC biopsy) – "tissue will be requested if the patient has a SOC biopsy while on study (or until progression, etc.) based on physician discretion" *or* "if a biopsy is performed while on study as clinically indicated, tissue from the biopsy will be requested for the study"
5. Subsites include any sites that are external to the UCSD system. If you want a patient treated at a non-MCC UCSD location with investigational drugs, there may be additional pharmacy fees related to satellite sites. Please specify above if this is the case.
6. DSMB (Data Safety Monitoring Board) – this is required for studies that do not have a safety monitoring board set up. This can be waived if we are using an external DSMB.
7. Biorepository only needs to be used if we need to provide fresh tissue same day or if there is special processing. The CTO has a freezer that may be used for storage (unless the amount of samples and time to store is high) so please clarify the need if you want to use this as an option.
8. Biostatistics can vary per trial. If you do not provide a quote from this group but will need biostatistics on the trial, we will default to $30k for startup and $25k/year annually (average costs we’ve seen).
9. Pharmacy monitoring fees are required for any studies that require accountability of drug, whether the monitor is external or internal. We will budget for quarterly pharmacy visits unless specified otherwise.
10. Tumor Assessments (RECIST, Lugano, RANO, etc), if not done by the study team, are charged per timepoint. If a patient is estimated to get imaging done every 2 cycles and goes off treatment after 2 cycles, there will be two reading timepoints budgeted (Screening + End of Cycle 2).
11. If there is no external monitor, there will be a per patient charge of $1,250 for the QA team to review patient charts/monitor.
12. Correlative sciences cover both the supplies to obtain specimens as well as the cost to run the tests on the specimens. If this budget is associated with a grant and will go through the Business Office then lab fees will need to be estimated through their budget only. The CTO budget will need to include supplies to obtain the specimens only (tubes, cryovials, etc.)
13. Publications will default to $2,500 if another amount is not specified and will not need to be included in the CTO budget if it is a grant going through the Business Office.
14. Travel is meant to cover the costs for the study team for conference attendance or monitoring, not the patient.
15. Translations cost an average of $1,500 per language for the initial translation. We will default to this amount unless otherwise specified.