

# Budget Building Basics

ITHS Research Coordinator Networking &  
Education Day

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# Overview

- What documents you need for a budget
- The steps to put the budget together
- Work on a simple study budget
- Frequently asked questions

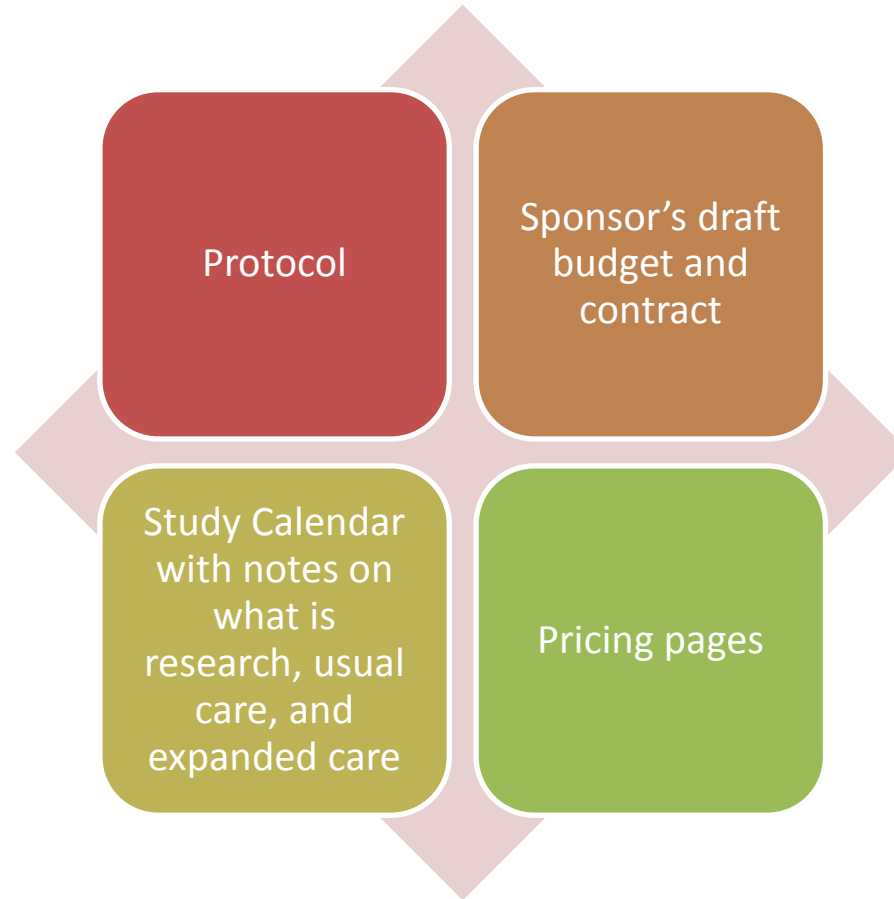


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# What documents should I have?



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# Protocol

- Read the protocol
  - Study design
  - Treatments
  - Study drug
  - Assessments/procedures

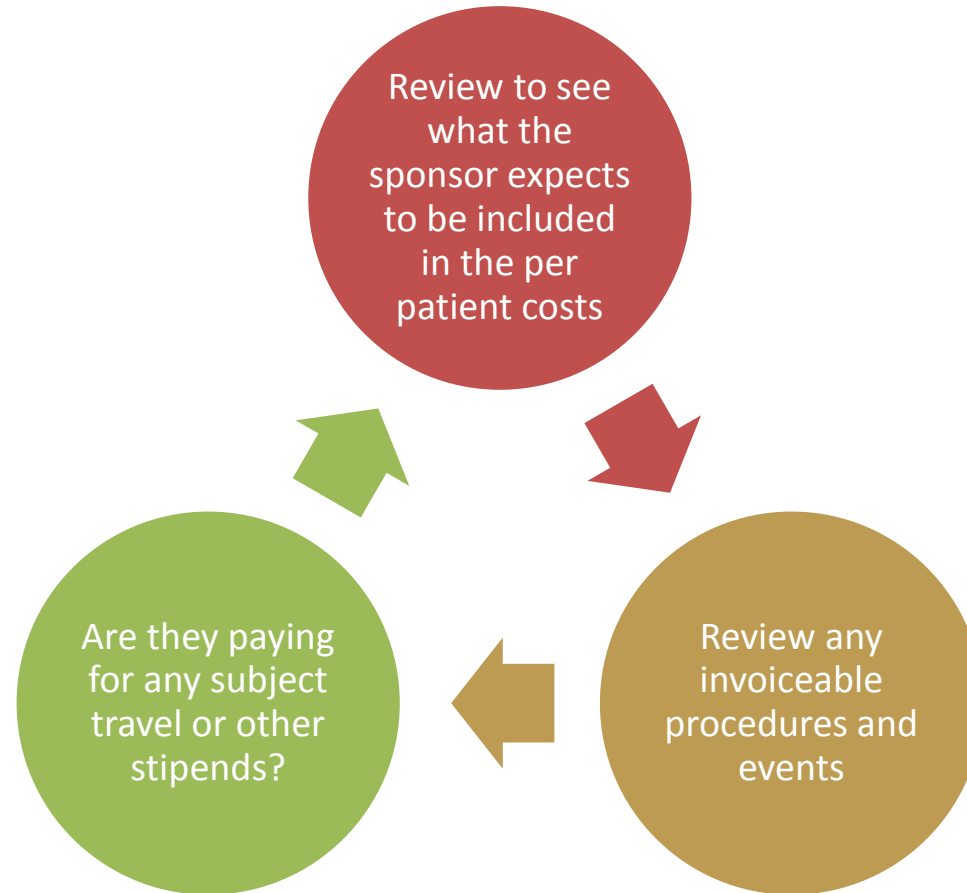


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# Sponsor Budget and Contract



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# Study Calendar

- Sit down with PI and review what is research, usual care and expanded care
- Make sure clearly marked on the calendar to refer back to
- If PI and sponsor have a procedure noted differently, discuss
- Discuss any invoiceables



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# Study Calendar

R = Research  
S = SOC

## Appendix A: Schedule of Events

Procedures	Screen	Day 1	Assessment 1 Week 5-11	Assessment 2 Week 13-19	Assessment 3 Week 24-30	Assessment 4 One Year End of Study
Informed consent	R X					
Inclusion/Exclusion	R X					
Melanoma Treatment History	S X					
HD IL-2 Eligibility Review <sup>(a)</sup>	S X					
Ipilimumab Eligibility Review <sup>(a)</sup>	S X					
Demographics & Body Measurements	S X					
ECOG PS & SOC Clinical Labs <sup>(b)</sup>	S X					
Targeted Physical Exam <sup>(c)</sup>	S X	S X	S X	S X	S X	S X
Adverse Events	? X	? X	? X	? X	? X	? X
Treatment Arm 1 <sup>(d)</sup> (Record ECOG prior to dosing)		R X HD IL-2	R X	R X	R X	
Treatment Arm 2 <sup>(e)</sup> (Record ECOG prior to dosing)		IPI	R First Tx: ██████████, up to 4 Cycles Second Tx: ██████████, up to 4 doses	R First Tx: ██████████, up to 4 doses Second Tx: ██████████, up to 4 Cycles		
Response Assessment			R X	R X	R X	R X

- Assessment for ██████████ and ██████████ eligibility performed according to the Institution Standard of Care.
- Standard of Care Labs per institutional normal procedures for treatment of ██████████ patients (include LDH, absolute neutrophils, absolute lymphocytes, and CRP as available in the medical record).
- Targeted Physical Examination includes: Neurological, cardiovascular (including peripheral edema), pulmonary, gastrointestinal, non-tumor skin, tumor-related palpable lymph nodes or tumor masses, skin nodules and location of metastases at baseline. Subsequent assessments record changes from previous visit.
- ██████████: Two cycles per course of therapy. Up to 4 Cycles at the discretion of the investigator. Patients may be switched over to treatment with ██████████ if progression is observed at the Response Assessment visit. Allow time for resolution of ██████████ treatment related toxicities and discontinuation of any treatment required (e.g., corticosteroids) prior to beginning ██████████ ab.
- ██████████: Up to four doses as tolerated. Allow time for resolution of ██████████ treatment related toxicities and discontinuation of any treatment required (e.g., corticosteroids) prior to beginning ██████████. Corticosteroids must be discontinued at least 14 days prior to dosing with ██████████.

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# Pricing pages

- UW and HMC– RRR form
- SCCA – Clinical trial implementation and planning form (CTIP), clinical trial assessment summary (CTAS), Coverage Analysis checklist (CPT), protocol, IB, and consent form



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# Pricing pages

- SCCA has a CTIP meeting as part of submission for pricing
- Always go to the CRBB and the SCCA research staff resources page to get current forms.



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# Budget

Study information

Staff compensation

Pre-study costs

Billing grid

On study costs

Post study costs

Salary review

Negotiation



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# Large invoicable example

Screen Failure					iSF
Unscheduled visit					iUSV
Chest CT					iCT-CH
Abdomin CT					iCT-A
Pelvis CT					iCT-P
Abdomin/Pelvis CT					iCT-AP
Head CT					iCT-H
Chest MRI					iMRICH
Abdomen MRI					iMRI-A
Pelvis MRI					iMRI-P
Brain MRI					iMRI-B
Neck CT					iCT-N
Neck MRI					iMRI-N
Bone Scan					iBone
Punch biopsy					iPBx
Additional Punch biopsy					iA PBx
Excisional biopsy trunk arms or legs					Excis1
Excisional Biopsy Scalp neck hands feet genitalia					Excis2
Excisional biopsy Face areas, eyelids nose lips					Excis3
CT guidance					iCTG
US guidance					iUSG
Liver biopsy					iLiver
Lung biopsy					iLung
Lymph biopsy					iLymph
Peritoneal/abdominal biopsy					iP/A
Soft tissue/muscle biopsy					iST/M
Conscious sedation, first 30 minutes					iCS
MUGA					iMUGA
ECHO					iECHO



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# Review

Documents  
you need  
for the  
budget

The steps  
to put the  
budget  
together

Worked on  
a simple  
study  
budget

Reviewed  
frequently  
asked  
questions



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# Questions?



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# What do I take into account when I'm setting up a budget (DBT)?

Review the sponsor provided budget, contract and the study calendar. Is there anything that you want to be able to invoice for?



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# What is the best way to set up a budget?

Look at the proposed budget from the sponsor and what the study visits are (study calendar) and go from there. Usually you are better off matching the sponsor budget template. The other thing you need to look at when setting up a budget is whether there are procedures or items that you want to be able to invoice the sponsor for, such as CT scans. Procedures or lab invoiceables need to be set up in the beginning.



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