UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Budget Workbook - Forms & Templates	
Relates to Policy/Procedures: 2006-07	
SOP#: 903-11	Version 2.0
Prepared by: Judie Fine	Original date: 8/9/11
Approved by: Judi Kulko	Date approved: 8/19/16

Purpose and Applicability: Documents and templates in this section are used in conjunction with the Budget Workbook and related activities.

Background and Significance: Please see SOP 900-11.

Scope: These forms and templates facilitate interaction between the OCTR, the PIs and/or PI Designee and the IRB.

Responsibilities: OCTR Administrative & Clinical Research Coordinator under the direction and supervision of the OCTR Executive Administrator is responsible for the Budget Workbook and correspondence related to the Budget Workbook.

Procedural Steps:

NOTE: The header in this SOP is applicable only to this leading page listing forms, and not to individual documents, which are routinely edited to reflect changes in usage and/or procedures. Changes to individual documents are noted on each document page.

Form labeled A:	Budget Workbook Checklist
Form labeled B:	Budget Negotiation Checklist
Form labeled C:	OCTR memo to IRB documenting completion of a Budget Workbook
Form labeled D:	Medicare Coverage Analysis
Form labeled E:	Expedited Budget Memo

Revision date: 8/19/16	Revised by: J. Kulko
Reason for revision: 2.0 Name change and addition D&E	
Date revised version sent to archives & current revision version # advanced: 8/19/16	

Budget Workbook checklist

A

Internal form

1. Correct Payor Selected	☐
2. Check IDC rate	☐
3. Check proper fringe rate	☐
4. Refresh other costs	☐
5. If multiple arm, costs included for all arms	☐
6. If multiple arms, payment included for all arms?	☐
7. check # of units x price on other costs tab	☐
8. type of account designated on "other costs?"	☐
9. no IRB fees to be applied if Investigator Initiated study	☐
10. correct staff line up with roles on Admin and patient T & E	☐
11. empty lines in patient T & E	☐
12. empty lines in Admin T & E	☐
13. Admin T & E complete to bottom of study years?	☐
14. check study notes to make sure all ancillary notes have been accounted for	☐
15. proper discount rate applied to UMG charges?	☐
16. proper discount rate applied to JDH charges?	☐
17. records retention accounted?	☐
18. No IRB continuation should be displayed in first year	☐
19. payment page account for screen failures?	☐
20. check quantity x price on payment screen	☐

Study Name: _____
PI: _____
Reviewer: _____
Date: _____
_____

P.I._____

Name of Study_____

Date_____

Company contact_____

B

Internal form

Budget Negotiation Checklist

	UCHC cost	Sponsor offered	Difference of	To be paid by invoice	Sponsor agrees to
Non-refundable start up costs					
IRB initial application fee	Invoice				
IRB continuation fee	Invoice				
Add cost for full board amendment	Invoice				
Pharmacy Fee Initial set up	600.00				
Pharmacy continuation	300.00				
Correct IDC rate					
Start up expenses					
Per patient fee					
Procedure/visit fee					
Screen failures					
Scans (to be paid by invoice?)					
P.E.'s					
T & E					

Notes: _____

_____

OCTR memo to IRB documenting completion of a Budget Workbook **C**

To: UCHC Institutional Review Board

From: Office of Clinical and Translational Research

Date:

RE: Completed Budget Workbook, Protocol ###,
Sponsor XXXX:
Title YYYYYYYYY

PI: ZZZZZZZ

A budget workbook has been completed on the above-referenced clinical trial per UCHC policy 2006-11. The OCTR requirement has been fulfilled, and the IRB application may now be submitted.

Clinical Trial Coverage Analysis Worksheet

Drug and Procedure Study Information

Study Title:_____

Principle Investigator: _____ IRB#:_____ Protocol#: ___

Sponsor:_____ Protocol Version Date:_____

Name of Investigational Item or Procedure: _____ICF Version Date: ____ _____

Clinicaltrial.gov#: _____Phase:_____

1. Is the item under investigation for the evaluation of an item or service that falls within a Medicare benefit category (e.g. drugs and biologicals, inpatient or outpatient services, physician services, diagnostic test)?

If Yes the category is: _____ Continue to step 2 If No – **Stop, trial doesn't qualify**

2. Does the study have therapeutic intent?

If Yes include statement – Continue to step 3 If No – **Stop, trial doesn't qualify**

Statement:

3. Does the study enroll subjects with a diagnosed disease (not healthy volunteers only)?

If Yes the disease under study is: _____ Continue to step 4

If No – **Stop, trial doesn't qualify**

4. Is the study funded by NIH, CDC, AHRQ, CMS, DOD or the VA?

If Yes include funding source – **This is a Qualifying Clinical Trial** If No – Go to step 5

Funding Source:

5. Is the study supported by cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD or the VA?

If Yes include cooperative group – **This is a Qualifying Clinical Trial** If No – Go to step 6

Cooperative Group:

6. Is the study conducted under an investigational new drug (IND) application reviewed by the FDA?

If Yes the IND # is:_____ **This is a Qualifying Clinical Trial** If No – Go to step 7

7. Is the study exempt from having an IND under 21 CFS 312.2(b)(1)? (see IND exemption worksheet)

If Yes – **This is a Qualifying Clinical Trial** If No – Go to step 8

8. If the answer to steps 4, 5, 6 and 7 were All **NO**, then this is **Not a Qualifying Clinical Trial**.

Informed Consent Document **What if any, items and/or services are promised free in the Informed Consent Document? Does the study appear to have therapeutic intent?**

Signature:

Name of person completing form:

Date:

Clinical Trial Coverage Analysis Worksheet

Device Study Information

Study Title:_____

Principle Investigator: _____ IRB#:_____ Protocol#: _____

Sponsor:_____ Protocol Version Date:_____

Name of Investigational Item:_____ICF Version Date: _____

Clinicaltrial.gov#: _____Phase:_____

1. Is the device being studied under an investigational device exemption (IDE) category A or B status assigned by the FDA?

If Yes and Category A – Go to step 2 If Yes and Category B – Go to step 3 If No – Go to step 4

2. Is the device intended for the use in the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition (i.e. a "stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment") and has the Medicare Contractor approved the request for the Category A device trial?

If Yes – Go to Step 7 If No – **Stop, Routine Costs cannot be billed**

3. Has the Medicare Contractor approved the request for the Category B device trial?

If Yes – Go to Step 8 If No – **Stop, Routine Costs cannot be billed**

4. Is device marketed under Humanitarian Device Exemption (HDE)?

If Yes – **Routine Costs can be billed** If No – Go to step 5

5. Is device approved by FDA through pre-market approval (PMA) process?

If Yes – **Routine Costs can be billed** If No – Go to step 6

6. Is device cleared by the FDA through the 510(k) process?

If Yes – **Routine Costs can be billed** If No – **Stop, Routine Costs cannot be billed**

7. If a Category A device is used, the routine costs will be covered if the trial is FDA approved and the device is determined to be intended for the use in the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition. The device itself is never covered by Medicare. Medicare Contractor approval is required for Category A trial routine costs coverage.

8. If a Category B device is used, the routine costs and possibly the device will be covered if the Medicare Contractor approves the study. When determining whether to cover routine costs on a study, the Medicare Contractor will consider: 1) medical necessity, 2) if device is appropriate for patient needs, 3) if device is being used in a FDA approved trial, 4) NCD and LCD determinations.

Informed Consent Document **What if any, items and/or services are promised free in the Informed Consent Document? Does the study appear to have therapeutic intent?**

Signature:

Name of person completing form:

Date:

Study Title:	
Principle Investigator:	

This Coverage Analysis is intended as a general guideline for use in determining which items and services are
determinations, coverage decisions, and physician determinations. All items and service

Items & Services	Protocol Location	Cpt Codes	Q1/Q0 Modifiers	Informed Consent	Screening		
Time and Effort:							
Procedures:							
Device and Sham:							
Coverage Code Key							
T&E: Time and Effort							
RC: Routine Care							
SP: Provided by Sponsor							
Footnotes							
PI Signature							
OCTR Signature							

E

Memo

To:
Principal Investigator

From:
Office of Clinical and Translational Research (OCTR)

Date:

RE:

_____

The above referenced research study has been reviewed according to UConn Health policy 2006-07. As no UMG or JDH research related charges have been identified as part of the study, a budget workbook is not required.
If the design of the study should change to include JDH/UMG charges, please notify the OCTR for a study budget re-evaluation.

Please upload a copy of this memo with your IRB application.

If you have further questions, do not hesitate to contact me at x1395.