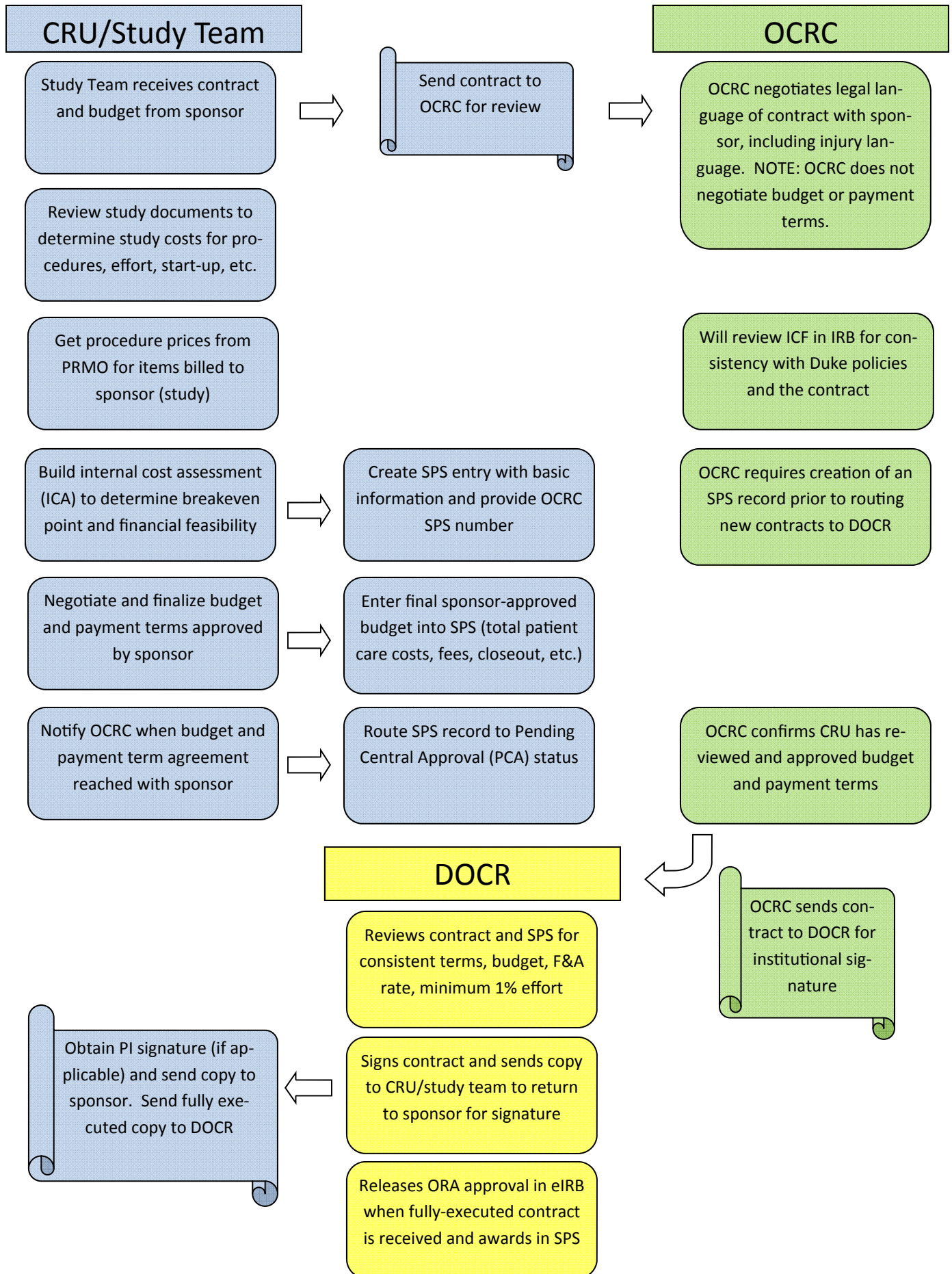


DUKE MEDICINE
Clinical Research Contacts

Service	Contact	E-mail	Phone	Website
Radiology	Steve Shipes	steven.shipes@duke.edu	919-684-7732	http://radiology.duke.edu/research/research-support/
Institutional Review Board (IRB)			919-668-5111	http://irb.duhs.duke.edu/modules/irb_fees/index.php?id=1
Duke Clinical Research Unit (DCRU)	Donna Hamel	donna.hamel@duke.edu	919-684-9966	http://dcru.org/investigators-0
Cardiac Diagnostic Unit (CDU)	Kris Arges	kristine.arges@duke.edu	919-668-0927	
Pathology Research Histology & Immunohistochemistry Lab	Wayne Terrell	terre004@mc.duke.edu	919-684-6207	http://pathology.duke.edu/experimental-pathology/research-immunohistology-lab
Investigational Drug Services (IDS) Pharmacy		Pharmacy-Grp_IDS@dm.duke.edu	919-684-3543	
Hospital Finance	Revenue Manager	Contact information is available on the intranet site		https://intranet.dm.duke.edu/ent/prmo/Revenue%20Management/revenuemanagement/SitePages/Home.aspx
Ophthalmology	Cecile Santiago -Turla Ali Hall	maria.santiagoturl@dm.duke.edu ali.hall@duke.edu	919-668-0634 919-684-8652	
Brain Imaging and Analysis Center (BIAC)		research@biac.duke.edu	919-681-9337 (Front Desk)	https://www.biac.duke.edu/research/gettingstarted.asp
Biospecimen Repository & Processing Core (BRPC)		brpc@duke.edu	919-684-2555	http://biobank.duke.edu/brpc/
Procurement		Procurement@Duke.edu	919-681-5900	http://finance.duke.edu/procurement/departments/
PRMO Clinical Trials		prmoclin@dm.duke.edu		https://duke.service-now.com https://intranet.dm.duke.edu/ent/prmo/clinicaltrials/SitePages/Home.aspx
Pharmaceutical Research (Investigational Chemotherapy Service and PK/PD Lab)	Beth McLendon-Arvik Ivan Spasojevic	beth.mclendon@duke.edu ivan.spasojevic@duke.edu	919-668-0657 919-684-8311	http://www.dukecancerinstitute.org/research/shared-resources/pharmaceutical-research
Central Offices	Contact	E-mail	Phone	Website
Duke Office of Clinical Research (DOCR)	Lindsey Spangler or Tracy Kerby	DOCR-Contracts@dm.duke.edu	919-681-6665 (front desk)	http://docr.som.duke.edu
Office of Research Administration (ORA)		Contracts.Management@mc.duke.edu	919-684-5175 (front desk)	http://research.som.duke.edu
Office of Corporate Research Collaborations (OCRC)	Marti Salguero (or your CRU's established agreement manager)	margi.salguero@duke.edu	919-681-0867 (front desk)	
Institutional Review Board (IRB)			919-668-5111 (front desk)	https://irb.duhs.duke.edu/
School of Medicine - Finance	Catee Mullen (as of 12/1/15)	TBD	919-668-4037	
School of Medicine - Finance	Ellen Kelly	ellen.kelly@dm.duke.edu	919-684-3239	
SOM Implementation Team	Laura Jensen	SOM.Implementation@dm.duke.edu		

Industry-funded Contract Process Flow



Closeout Tasklist - Section 6. Human Subjects/IRB

Section Overview

At the time when the clinical research study is complete, the [Closeout Tasklist](#) must be completed in accordance with GAP 200.180, Closeout of Sponsored Projects. The Clinical Research Closeout Policy should be referenced throughout the closeout process.

About Section 6. Human Subjects/IRB

- A clinical research study involves research using human volunteers (also called participants) and is intended to add to medical knowledge.
- Human subjects research includes activities such as:
 - ✓ consenting patients to research studies
 - ✓ gathering a specimen for inclusion in a repository
 - ✓ analyzing research data
 - ✓ processing research patient charges
 - ✓ studying records or repositories to determine which option has the best outcome
 - ✓ interpreting institutional policies governing human subjects research

[GAP 200.180, Closeout of Sponsored Project](#) • [Clinical Research Closeout Policy](#)
[DukeMedicine IRB](#) • [DOCR Clinical Research Closeout Policy & Procedure Definitions](#) • [Duke Office of Research Support](#)

Determine the required subsection

- Determining the IRB category for your project ensures the appropriate Closeout Tasklist subsection (and associated questions related to human subjects research) is generated.
- You can determine the appropriate IRB subsection by reviewing the programmatic attribute, IRB review type, WBSE, and BFR for the project.

Programmatic Attribute (ZF600)	IRB Review Board and Review Type (SPS)	BFR	Sponsor Type	WBSE	Required Tasklist Subsection
SCE - Sponsored Clinical Research w/ Exempt IRB	MEDICAL CENTER IRB Exempt	6840XXXXXX 6860XXXXXX	Non-Industry Industry	20x-29x 30x-39x	6.A. Exempt
SRF - Sponsored Research Federal SRN - Sponsored Research Non-Government	CAMPUS IRB Full Board Review Expedited Review Exempt	60XXXXXXXX	Non-Industry Industry	20x-29x 30x-39x	6.B. Campus IRB
SCI - Sponsored Clinical Research w/ IRB	MEDICAL CENTER IRB Full Board Review Expedited Review	60XXXXXXXX 6840XXXXXX 6860XXXXXX	Non-Industry	20x-28x 30x-38x	6.C. Non-Industry Sponsored Clinical Research
SCI - Sponsored Clinical Research w/ IRB	MEDICAL CENTER IRB Full Board Review Expedited Review	6840XXXXXX 6860XXXXXX	Industry	28x-293 38x-393	6.D. Industry Sponsored Clinical Research
SCI - Sponsored Clinical Research w/ IRB SDC - Coordinating Center Clinical Research	MEDICAL CENTER IRB Full Board Review Expedited Review	6860505XXX 6860450XXX	Non-Industry Industry	20x-29x 30x-39x	6.E. DCRI / DTMI
SNC - Sponsored Non Clinical Research SRF - Sponsored Research Federal SRN - Sponsored Research Non-Government	None	All	Non-Industry Industry	20x-29x 30x-39x	N/A

Programmatic Attribute: programmatic attribute designates the mission of a WBSE (Education, Clinical Service, Sponsored Research, Department Research, Administration, Other).

IRB Review Board and Review Type: all human subjects research review is done either through Medical Center or Campus IRB and is required to complete IRB review prior to project start.

WBSE (Fund Code): hierarchical model of a project that can be split into manageable units and have attributes that help to further categorize based on Project Type, Responsible Person, Funding Type, etc.

BFR (Budget & Financial Reporting Code): the BFR code is a series of ten digit codes within the general ledger that provides a five level organizational hierarchy structure. Every cost object at Duke is linked to a BFR code within the hierarchy.

Sponsor Type: all externally funded sponsored human subjects research will be funded by either Non-Industry or Industry Sponsors.

Required Tasklist Subsection: human subjects research closeout tasks are determined by the IRB type associated with the project.

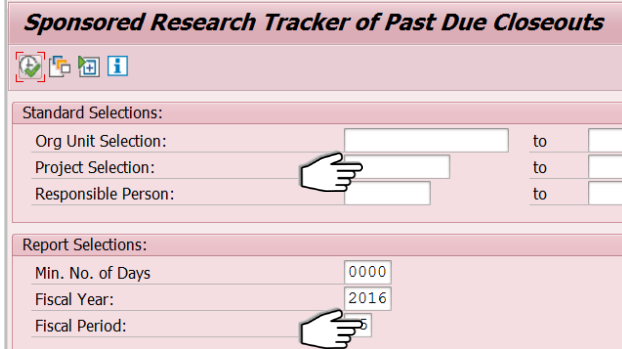
Closeout Tasklist - Section 6. Human Subjects/IRB

Guidance on choosing appropriate subsection

Determining Programmatic Attribute

- SAP transaction ZF600 and the Protocol Tab in SPS Web will give the research administrator some key data needed to assist with determining the IRB category for the project closeout.
 - ✓ ZF600 identifies the programmatic attribute assigned to each specific WBSE
 - ✓ SPS Web Protocol Tab identifies the type of IRB review assigned to the project

1 In the SAP GUI, launch transaction ZF600. Enter applicable WBSE(s) into the **'Project Selection'** field and the current fiscal period into the **'Fiscal Period'** field and execute the transaction (F8).



2 A row displays for each WBSE entered. Scroll to the right until the last column, **'PRGM ATTR'** is visible.

Resp. Uni	BillingSec	PreAwdOfc	Spon DueDt	OSP Due Date	LOC ATTR	PRGM ATTR
DEPT	A	ORA	08/29/2016	07/30/2016	YG	A CI

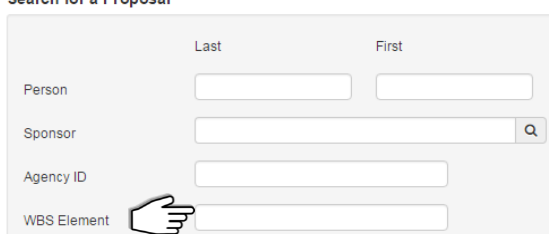
A. Programmatic Attribute: Programmatic Attribute designates the mission of a WBSE (Education, Clinical Service, Sponsored Research, Department Research, Administration, Other).

- **SCI:** Sponsored Clinical Research w/ IRB
- **SCE:** Sponsored Clinical Research w/ Exempt IRB
- **SDC:** Coordinating Center Clinical Research
- **SNC:** Sponsored Non Clinical
- **SRF:** Sponsored Research Federal
- **SRN:** Sponsored Research Non-Government

Determining IRB Review

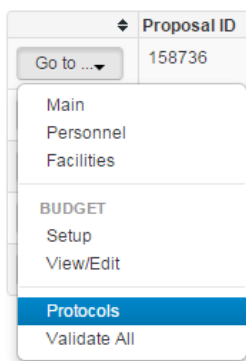
- At time of pre-award preparation, SPS is used to identify whether human subjects will be part of the proposed project. Upon award, the IRB protocol number and review type should be updated in SPS.

1 In the SPS Web Proposal Module, enter the WBSE into the **'WBS Element'** field and select the 'Search' button.

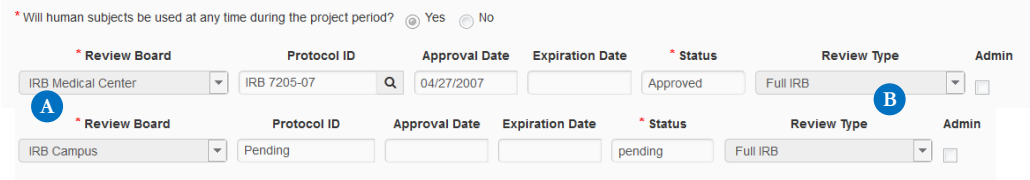


2 A row displays below the search criteria for each proposal matching the WBSE.

Find the appropriate proposal and select the **'Go to...'** drop-down menu on the left of the row. Then select **'Protocols'** in the list of options in the drop-down.



3 IRB information is displayed for the proposal. **'Review Type'** is displayed toward the right side of the window.



Review Board	Protocol ID	Approval Date	Expiration Date	Status	Review Type	Admin
IRB Medical Center	IRB 7205-07	04/27/2007		Approved	Full IRB	
IRB Campus	Pending			pending	Full IRB	

A. Review Board – Medical Center or Campus IRB Review

B. Review Type

- **Full IRB:** Full Board Review-Research that does not qualify for expedited or exempt review and/or presents more than minimal risks to subjects
- **Expedited Review:** Research that can be approved as 'expedited' if it is no more than 'minimal risk' and fits in one of 9 federally designed expedited review categories
- **Exempt:** Research that can be approved as 'exempt' if it is no more than 'minimal' risk' and fits into one of 6 federally designated exempt review categories

PREFERRED FORMAT FOR BUDGET ENTRY FOR INDUSTRY-FUNDED CLINICAL TRIALS IN SPS

It is strongly suggested that only the Excluded and Included direct cost categories be used when preparing the SPS budgets for industry-funded clinical trials.

When the agreement has a stated value or its budget is created in a way that reflects the total amount of the project, the contract value should match the SPS budget total. A 5% variance between the contract value and the SPS budget total is acceptable.

If you choose “Modular” as the budget template, the budget categories on the left will populate into the budget. Delete “Consortium cost” line by using the << button, add “Indirect cost” from the left by using the >> button.

The image displays two screenshots of a budgeting software interface, illustrating the process of customizing a budget template. Both screenshots show the 'Budget Template' set to 'Modular'.

Left Screenshot (Initial State):

- Available Categories:** Advertising Fees, Alterations and Renovations, CME Activity - Duke, Clinical - Non-Routine Care, Communications, Computer Services Cost, Consultant Costs, Equipment, Facility Rental Fee, Facility User Fee, Fellowship Stipend, Genomic Arrays Over 50K, Health Insurance, IRB Fees and Charges.
- Selected Categories:** Salary, Fringe Benefits, Included Direct, Excluded Direct, Consortium/Subaward Costs.

Right Screenshot (Customized State):

- Available Categories:** Consortium/Subaward Costs, Consultant Costs, Equipment, Facility Rental Fee, Facility User Fee, Fellowship Stipend, Genomic Arrays Over 50K, Health Insurance, IRB Fees and Charges, Laboratory Charges, Margin, Medical Procedure Charges, Modular Grant Offset.
- Selected Categories:** Salary, Fringe Benefits, Included Direct, Excluded Direct.

A red arrow points from the left screenshot to the right screenshot, indicating the transition. In the right screenshot, 'Consortium/Subaward Costs' has been removed from the 'Selected Categories' list, and 'Modular Grant Offset' has been added to the 'Available Categories' list.

PREFERRED FORMAT FOR BUDGET ENTRY FOR INDUSTRY-FUNDED CLINICAL TRIALS IN SPS

Preferred budget template...

Salary Summary Budget Income Justification

Show Periods: 1 Show All: Totals Only: Show Base Categories:

Category	Budget Period 1		Total
	Sponsor Amount	Sponsor Amount	Sponsor Amount
<input checked="" type="checkbox"/> Salary	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
<input checked="" type="checkbox"/> Fringe Benefits	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Salary and Fringe Benefits	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
<input checked="" type="checkbox"/> Included Direct	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
<input checked="" type="checkbox"/> Excluded Direct	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Other Budget Categories	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Total Direct Costs	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
F&A Costs	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Total Project Costs	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>

Calculate F&A Costs Show Base Info Show NIH Recap

PREFERRED FORMAT FOR BUDGET ENTRY FOR INDUSTRY-FUNDED CLINICAL TRIALS IN SPS

You can enter more detailed budgets by adding individual line items to the included/excluded categories:

Salary			
Summary Budget			
Income			
Justification			
Show Periods:	<input checked="" type="checkbox"/> 1	Show All:	<input type="checkbox"/>
Totals Only:	<input type="checkbox"/>	Show Base Categories:	<input type="checkbox"/>
Category	Budget Period 1	Total	
	Sponsor Amount	Sponsor Amount	
✕ Salary	<input type="text" value="0"/>	<input type="text" value="0"/>	
✕ Fringe Benefits	<input type="text" value="0"/>	<input type="text" value="0"/>	
Salary and Fringe Benefits	<input type="text" value="0"/>	<input type="text" value="0"/>	
✕ Included Direct	<input type="text" value="84,766"/>	<input type="text" value="84,766"/>	
✕ Excluded Direct	<input type="text" value="2,750"/>	<input type="text" value="2,750"/>	
Other Budget Categories	<input type="text" value="87,516"/>	<input type="text" value="87,516"/>	
Total Direct Costs	<input type="text" value="87,516"/>	<input type="text" value="87,516"/>	
F&A Costs	<input type="text" value="23,734"/>	<input type="text" value="23,734"/>	
Total Project Costs	<input type="text" value="111,250"/>	<input type="text" value="111,250"/>	

Calculate F&A Costs Show Base Info Show NIH Recap

Included Direct

Show Periods: 1 Show All: Hide All:

Period 1

Description	Sponsor Amount
✕ Per Subject Costs (10 subjects)	<input type="text" value="78,125"/>
✕ CRU Start-up Fees	<input type="text" value="3,906"/>
✕ Closeout Fee	<input type="text" value="1,563"/>
✕ Pharmacy Fee	<input type="text" value="1,172"/>

+ Add Included Direct Item

Remember to back out the F&A percentage when entering included directs

Excluded Direct

Show Periods: 1 Show All: Hide All:

Period 1

Description	Sponsor Amount
✕ IRB Review Fee	<input type="text" value="2,000"/>
✕ IRB Continuing Review	<input type="text" value="750"/>

+ Add Excluded Direct Item

PREFERRED FORMAT FOR BUDGET ENTRY FOR INDUSTRY-FUNDED CLINICAL TRIALS IN SPS

Budget Justification


Notes and Attachments x

Budget Justification


Expected enrollment of 10 subjects. Sponsor paying \$10,000/subject plus IRB and other fees detailed below.

\$10,000 x 10 subjects = \$100,000
CRU fee: \$5,000
Closeout: \$2,000
Pharmacy: \$1,500
IRB fee: \$2,000
IRB continuing review fee: \$750

TOTAL: \$111,250

 Printer Friendly

Budget Justification

None attached  Attach

- Provide \$/subject, number of expected subjects, other fees (e.g., \$10,000/subject x 10 subjects = \$100,000 + 11,250 other fees. Total of \$111,250.
- Do not list effort for clinical trials unless it matches with salary worksheet
- Please enter budget into justification box (not as an attachment)