



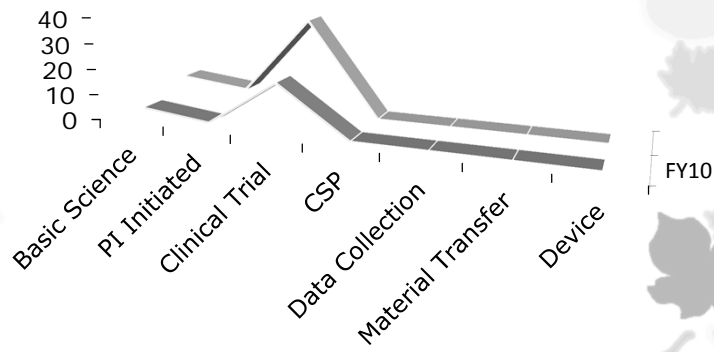
## Budgeting For Industry Sponsored Studies

***Real Budgets – Real Solutions***

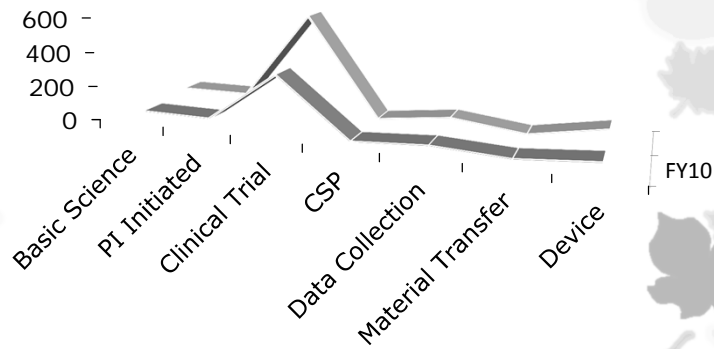
Brentwood Biomedical Research Institute  
VA Greater Los Angeles Healthcare System

- **Kenneth Hickman, PhD – Panel Moderator**  
Executive Director  
Brentwood Biomedical Research Institute  
VA Greater Los Angeles Healthcare System
- **Ron Waldorf, MS**  
Contracts & Grants Manager  
Brentwood Biomedical Research Institute  
VA Greater Los Angeles Healthcare System
- **Wendy Hill, RN, NP, MSN**  
Study Coordinator  
Pulmonary Arterial Hypertension Program  
VA Greater Los Angeles Healthcare System

## BBRI CRADA Activity FY10



## NAVREF CRADA Activity FY10



1. Facilities Human Protection Program (FHPP) Surcharge @ 10% of total direct costs for human studies
2. BBRI Indirect Cost Rate @ 20%
3. VA IRB Fee's
  - Initial Review @ \$1,500
  - Modifications @ \$500/ea.
  - Annual Continuations @ \$500/ea.
4. Pharmacy Fee's
5. Storage Fee's
6. Other
  - IRB Preparation
  - Start-Up (non-refundable)
  - Advance (refundable)
  - Patient Payments
  - Patient Travel & Lodging
  - VMU Costs
7. Coming - VA Attorney CRADA Review Fee

#### IRB Tracking for Modifications/Continuations

pi name	proj	submission	title	irbapproved	track no
B.A., MD	0021	Continuation Review		8/1/2011	2011-070722
E.R, MD	0028	Continuation Review		5/2/2011	2011-040428
E.R, MD	0028	Modification		5/2/2011	2011-030349
F.A, MD	0009	Continuation Review		7/20/2011	2011-060696
G.M., PhD	0017	Continuation Review		7/14/2011	2011-060625
H.A, PhD	0002	Continuation Review		7/14/2011	2011-060700
H.W., PhD	0004	Modification		8/18/2011	2011-080827
L.S., MD	0081	Continuation Review		7/14/2011	2011-060609
L.B., MD	0074	Continuation Review		5/2/2011	2011-040423
L.A., MD	0028	Continuation Review		7/14/2011	2011-060603
M.S., MD	0039	Modification		5/12/2011	2011-040514
M,C, PhD	0004	Continuation Review		5/18/2011	2011-040425
M,F, MD	0040	Continuation Review		5/18/2011	2011-040489
M,F, MD	0042	Continuation Review		7/14/2011	2011-060616
S.S, MD, PhD	0025	Continuation Review		6/9/2011	2011-050586
S.S, MD, PhD	0047	Modification		6/6/2011	2011-050560
S,S, MD, PhD	0048	Modification		5/18/2011	2011-040420
S,S, MD	0005	Modification		5/12/2011	2011-040463
S.D., MD	0014	Continuation Review		5/12/2011	2011-040449

## What is the IMPACT Process?

- Mechanism to reimburse the Medical Center for 'non-standard of care' services provided to research protocols

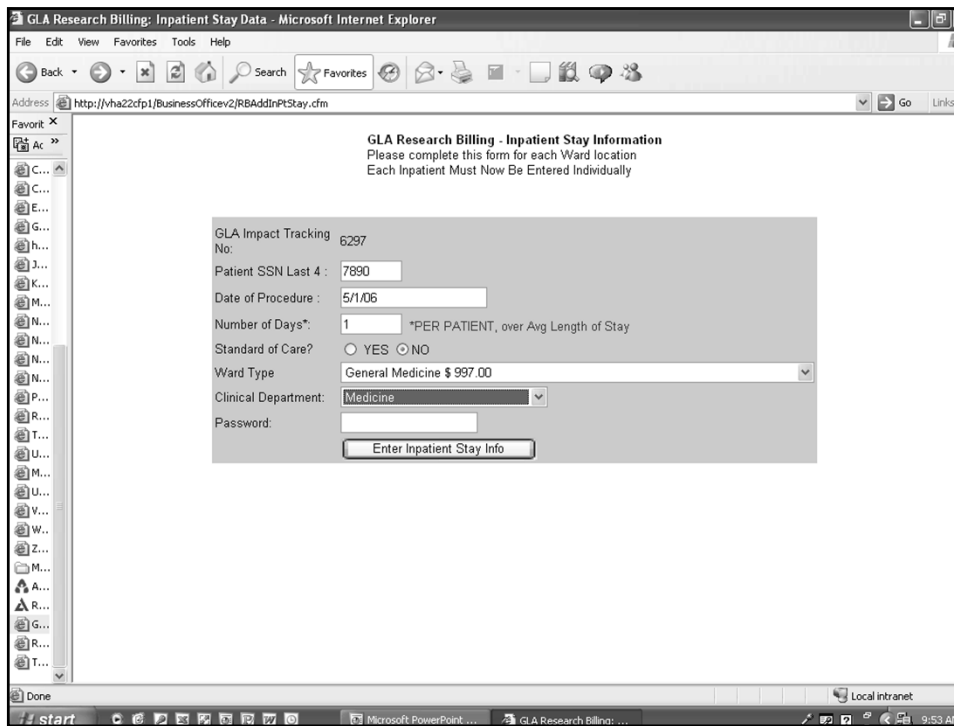
CPT Codes - Microsoft Internet Explorer

Address: http://vha22cftp1/BusinessOfficev2/RBAddProc2.cfm?ID=71010&WAProjectNum=6297

Click on the CPT Code to Select the CPT Code / Charge Set Combination  
Click on a Charge Set for Detailed Charge Set Information

CPT Code	Short Name	Charge Set (ID)	Unit Charge	Effective Date
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN FS PR 691GO (106)</a>	\$27.58	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN FS PR 691GK (84)</a>	\$27.76	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN FS PR 691GL (97)</a>	\$27.76	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN FS PR 691GR (67)</a>	\$28.36	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN FS PR 691GG (81)</a>	\$29.17	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN FS PR 691GD (76)</a>	\$30.15	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN OPT PR 691GC (74)</a>	\$32.66	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN FS PR 691GN (103)</a>	\$32.66	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN OPT PR 691A4 (59)</a>	\$33.61	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN OPT PR 691GA (65)</a>	\$35.83	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN INPT PR 691 (45)</a>	\$35.83	01/01/2006
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<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN OPT PR 691GF (89)</a>	\$35.83	01/01/2006
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<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-PHYSICIAN FS PR 691GM (100)</a>	\$37.80	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-OPT FAC PR 691A4 (55)</a>	\$313.39	01/01/2006
<a href="#">71010</a>	CHEST X-RAY	<a href="#">RC-OPT FAC PR 691 (49)</a>	\$332.84	01/01/2006

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**Summary Impact Data**

Project Title: A Multi-Center, Double-Blind, Randomized Study Comparing the Combined Use of  
Phase III  
GLA Tracking Number: 6426  
VA Study Number (ePROMISE): 008  
Administering Agency: BBRI

TOTALS

Total CPT Impact: **\$4,167.75**  
Total Inpatient Stay Impact: **\$0.00**  
**GRAND TOTAL: \$4,167.75**  
Date Started: 02/06/2006  
Projected End Date: 02/05/2007

Approval Period: 02/06/2006 through 02/05/2007

Days Left in One Year Window: NONE  
Number of Days in Project Timeline: 364  
Number of Days Left in Project Timeline: NONE

Actual Costs: Yes  
(yes means you're indicating that the cost data is final)

Finished: Yes  
(yes means impact form administrator indicated project is completed, no more edits)

Finish Date: 06/15/2007

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**PROJECT INFORMATION - Edit Project Info**

Principal Investigator: A Multi-Center, Double-Blind, Randomized Study Comparing the Combined Use of  
Study Title:  
Administrative Agency: BBRI  
Other Admin Agency:  
Contact Phone: 310-288-3  
Contact Email: nrd.v@va.gov

Est. Number of Pts: No. of Outpt. Visits: 180  
Proj. Start Date: 02/06/2006 Proj. End Date: 02/05/2007  
Other Information: corrections made to ERG charge back to Medicine corrections on MRI charges as per Imaging Quota List (updated OMAC rates)

EDIT	DELETE	CPT	Charge Set ID	Calculated CPT Cost	Qty/Pt	SSN4 Date	CRG	Other Visit	CRG	CRG	CRG	Total	
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## The Budget Process

*The Initial Offer To The Final  
Approved CRADA Budget*

*"Thinking On A  
Labor-Costing Basis"*

## Example #1

*Drug X, Phase II CRADA Budget*

*Initial Proposed Budget &  
Final Approved Budget*

## Sponsor Budget

1. This is the **INITIAL** Budget. It is the **Starting Point**
2. Think Cost and Time When Initially Reviewing the Budget
3. What Study Points will Need to be Analyzed and the Cost to Perform These Tasks or Procedures.
4. Allow For The Unexpected
5. Consider Costs Accrued by the Subject

**Drug X Phase 2 Clinical Study Site Budget – COLLABORATOR INITIAL BUDGET**

	Screening	Random-ization	Weeks 1, 3, 13, 15 Safety Visits	Weeks 2, 4, 8, 14, 16, 20 Clinic Visits	Weeks 12, 24, 36, 48, and 60	Long Term Safety Visit <sup>4</sup>	Long Term Clinic Visit <sup>4</sup>	Premature Discontinuation Visit	Change in Random Tx Visit <sup>5</sup>	Early Escape Visit <sup>6</sup>
Complete Medical History										
Physical Exam										
12-lead ECG <sup>1</sup>										
Six-minute Walk Test, Borg Dyspnea Index										
Blood Draws, UA, Lab Processing and Analysis <sup>2</sup>										
Study Coordinator Fees (includes below)										
Vital Signs, Patient Telephone Contacts,										
AE/Concomitant Medication Assessment										
Dispense Study Drug & Assess Compliance,										
CRF Completion, Subject Management,										
Informed Consent, Administer patient questionnaires										
WHO Functional Class, subject medical assessment for clinical worsening										
Sub-total per Visit Cost <sup>3</sup>										
Administrative Overhead Fees (25%)										
Total per Visit Cost <sup>3</sup>										
Total Cost per Evaluable Patient										
Total Subject for Full Study										

<sup>1</sup> Grant includes ECG at Screening and Weeks 4, 12, 16, 24, 36, 48, 60 and for up to 10 extension study visits  
<sup>2</sup> Includes all fees associated with phlebotomy and sample processing/shipment (central lab - clinic visits). Safety Visit labs are completed at central labs.  
<sup>3</sup> Payments will be quarterly and based on the completion of the CRFs for each visit (unscheduled visits are paid additionally upon receipt of blinded invoice of assessments completed).  
<sup>4</sup> Assumes up to 10 visits during extension: 5 safety and 5 clinic visits.  
<sup>5</sup> Total Cost per Evaluable Patient includes all scheduled visits and a premature discontinuation visit. Change in Rando Ix Visit and Early Escape Visit will be in addition to the standard budget.  
<sup>6</sup> Reimbursement for screen failures will be provided based upon screening procedures completed.

## Budget Discussions and Counters

- 1. Counter Back Offers to the Collaborator with numbers that will work with/in your Budget
- 2. Consider Cost per hour for Medical History & Exams, Coordinator, Research Assistant etc.
- 3. Make sure your overhead is correctly stated in the Final Budget
- 4. Make sure Final Budget is a figure per patient that makes sense and is enough to cover costs

## Budget Discussions and Counters

- 1. First Cost for PI oversight, PE, & H&P would need to increase approx. 33%
- 2. Study procedures would have to increase by approx. 25% to 50% depending on the procedure
- 3. Additional of Subject Stipend & Administrative cost
- 4. The budget overhead would have to increase from 25% to 30%
- 5. Changes in budget increased by 43%

	Screening	Randomization	Weeks 1, 3, 13, 15 Safety Visits	Weeks 2, 4, 8, 14, 16, 20 Clinic Visits and 60	Weeks 12, 24, 36, 48, and 60	Long Term Safety Visit4	Long Term Clinic Visit4	Premature Discontinuation Visit5	Change in Random Tx Visit5	Early Escape Visit 5
Complete Medical History										
Physical Exam										
Physician Supervision (if more than just lab)										
12-lead ECG1										
Six-minute Walk Test, Borg Dyspnea Index										
Blood Draws, UA, Lab Processing and Analysis2										
Study Coordinator Fees*										
WHO Functional Class, subject medical assess. for clinical worsening										
Adverse Events Assessment										
Patient Stipend										
Administrative cost										
Sub-total per Visit Cost3										
Overhead Fees (30%)										
Total per Visit Cost3										
Total Cost per Evaluable Patient										
Total Subject for Full Study										

## Amendments, Renewals, etc

Start Up Fee	IRB Fees
Pharmacy Set Up & per Use	
Regulatory Document Completion/Submission	
IRB Submission Fee ( Paid to IRB)	
Amendments (cost/submission)	
Amendments (site processing fee)	
Amendments (site processing fee)	
Amendments (site processing fee)	
Monitoring Visits	
IND Safety Reports	
Close out Submission	

## Additional Pass-Through Costs

### Additional Fees

- Storage Fees per year
- Pass Through fees to be paid by Invoice
- Travel expense reimbursement will be pre-approved and paid on a case-by-case basis
- Hotels (reasonable rates for location) on a pre-approved basis
- Diagnostic test (e.g., PFT, Labs, X-rays) will be reimbursed on a preapproved basis

## Exhibit #2 (Initial Budget Based on Forms)

Completed Case Report Form	Amount
Baseline Form	
Surgery Form	
1 Week Follow-up Form	
1 Month Follow-up Form	
3 Month Follow-up Form	
6 Month Follow-up Form	
12 Month Follow-up Form	
Long-Term Follow-up Form– every 6 months following the 12 Month Follow-up visit	
6 Minute Walk Test Section – performed at each required follow-up visit	
CAMPHOR Quality of Life Form	
Medication Form	
Adverse Event Form	
Adverse Event Update Form	

## Exhibit #2 (Final Budget Based on Forms)

Completed Case Report Form	Amount
Baseline Form	
Surgery Form	
1 Week Follow-up Form	
6-Week Follow-up Form	
3 Month Follow-up Form	
6 Month Follow-up Form	
12 Month Follow-up Form	
Long-Term Follow-up Form– every 6 months following the 12 Month Follow-up visit	
6 Minute Walk Test Section – performed at each required follow-up visit	Included in Visits
CAMPHOR Quality of Life Form	Included in Visits
Medication Form	Included in Visits
Adverse Event Form	
Adverse Event Update Form	

## Final Budget Approval

- 1. If the Collaborator counters back- Consider explaining your decisions before accepting the counter. For instance the amount of experience the PI and Coordinators have, location (CA, NY may be higher), the economy.
- 2. Set up conference calls to explain your stance to all decision makers.
- 3. When all fails and you are confident the numbers are fair, have the PI speak with the Collaborator or the person actually approving the budget.
- 4. Have a bottom line number in mind per visit in case you have to move items around.

## **FINAL APPROVED BUDGET**

Once budget has been approved

- 1. Signatures needed by the Collaborator  
(or financial organization)
- 2. Signature by the PI
- 3. Ready for insertion into the CRADA



Budgeting For Industry Sponsored Studies

*Q & A*

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