

# Office of Clinical Research



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# Today's Topics

- **USF electronic Internal Form**
- **Clinical Research Contracts**

# ***USF Internal Form***

***For Industry Sponsored Contracts  
(Non-Federal Clinical Trials)***

# For Industry Sponsored (Non-Federal) Clinical Trials

- **Project Type = Pharmaceutical Contract**
- **Funding Source = For-Profit Corporation**
- **Indirect Cost Rate = 30%**
  - **Use the rate that was negotiated in your budget!**
- **Full Federal Indirect Costs? = No**

# What Must Be Attached to the eIF?

- **Final Budget**
- **Financial Management Plan from eCOI module**
  - If there is a financial COI with the research
- **ROAD**
  - If there is outside activity that is or could be perceived as conflicting with the research
- **Nepotism Memo**
  - If there are any relatives or related persons participating in the research

# Internal Form Example

- Test Int Form.pdf

Test Int Form.pdf - Adobe Acrobat Pro

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1 / 3 134% Find

3650 Spectrum Blvd., Suite 160 Tampa, FL 33612-9446 (813) 974-2897 Fax: (813)974-4962 Campus Mail Point: 30338 USF Holly Dr. <a href="http://www.research.usf.edu/sr/">http://www.research.usf.edu/sr/</a>	<b>University of South Florida</b> Division of Sponsored Research Proposal Authorization Form "Internal Form" Version Date 03102009	Please complete: Date Received: 7/5/2011 Due Date: USF ID#		
<b>PROJECT TYPE</b> <input type="checkbox"/> Competitive Renewal <input type="checkbox"/> Continuation <input type="checkbox"/> New Proposal <input checked="" type="checkbox"/> <b>Pharmaceutical Contract</b> <input type="checkbox"/> Supplemental Request				
Account Number, if continuation:	Date Proposal Submitted to Sponsor:	Previous Proposal Number, if any:	Recovery Act? <b>NO</b>	
<b>INVESTIGATORS</b>				
PI NAME	GEMS ID	PI PHONE	PI FAX	PI EMAIL ADDRESS
<b>Catherine Jahrsdorfer</b>	<b>00000010599</b>	<b>813-396-9172</b>	<b>813-905-9997</b>	<b>cjahrsdo@health.usf.edu</b>
Department Receiving Credit for Award: <b>Clinical and Translational Science Institute</b>				PI MAIL POINT
CO-PI NAME	GEMS ID	CO-PI PHONE	CO-PI FAX	CO-PI EMAIL ADDRESS
<b>SPONSOR</b>				
Sponsor/Agency Name: <b>Bristol Myers Squibb</b>				
Agency Program (I.e. Name, RFP, RFA, OR PA#): <b>Protocol #</b>				
Sponsor Contact: <b>Contract contact</b>		Title:		
Address:				
City:		State:		Zip:
Phone: <b>888-888-8888</b>	Fax:	E-Mail: <b>MUST INCLUDE</b>		
Funding Source: <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local FL Govt <input checked="" type="checkbox"/> <b>For-Profit Corp</b> <input type="checkbox"/> Nonprofit Org <input type="checkbox"/> Other				
<b>PROJECT TITLE / KEYWORDS / DESCRIPTION</b>				
Project Title: <b>MUST MATCH IRB PROJECT TITLE</b>				
Keywords: <b>PROTOCOL#</b>				

# When Should the eIF Be Completed?

- **When the following are complete**
  1. **Study is Approved by IRB**
  2. **Contract is Fully Executed**

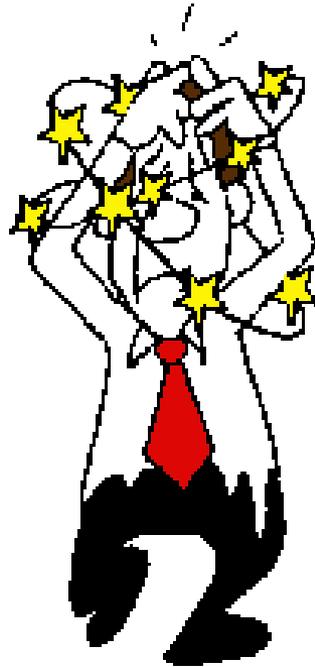
# ***Clinical Research Contracts-***

***Understanding the Terms?***

***Why This Is Important?***

# ***Pesky Details – “Exhibit B” Budget and Payment Terms***

- Start-Up
  - Non-refundable?
- Advance Payments
- Special Terms
  - Training/Meeting?
- Advertising
- Materials
- Travel Expense
- Payment Method



- Holdback
  - How much & until when?
- Who's paying, CRO or Sponsor?
  - How?
- Screen Fails?
- Subject discontinuation payments?
- Final Payment
- Remit Invoices?



# Included in Per Visit Payment

<b>A. Procedures</b>	vMRI	ApoE Genotyping
Informed Consent	PET	Immunogenicity
Medical History/ Prior Medication	Initial Physical Examination	Plasma A $\beta$
Inclusion/Exclusion Criteria	On -Study Physical Examination	Lab Handling
NINCDS/ADRA Criteria Review	Neurological Examination	<b>C. Optional Procedures</b>
DSM-IV Criteria Review	Vitals	CSF
Hachinski Score	12-lead ECG	PI CSF Time
MMSE	Adverse Events	PI SC Time
ADAS-Cog	24-hr Telephone Contact	CSF Immunogenicity Blood Draw
DAD	Concomitant Medications	CSF Plasma A $\beta$ Blood Draw
FAQ	Study Drug Preparation	CSF Lab Handling
CDR-SOB	Study Drug Administration	Molecular Profiling ICF
DS	Subject Stipend	Molecular Profiling Blood Draw
NPI	Caregiver Stipend	<b>D. Personnel</b>
Abbreviated RUD-lite v2.4	<b>B. Laboratory Tests</b>	PI Time
AD MACQ	Clinical Laboratory Testing (CBC, CMP)	Study Coordinator Time
NTB	Urinalysis	

# Budget Summary

			PER VISIT SUB-TOTAL	OVERHEAD	GRAND TOTAL PER VISIT
Screening	V1	Day -49 to Day -29	\$1,915	\$575	\$2,490
	V2a	Day -45 to Day -22	\$2,535	\$761	\$3,296
	V2b	Day -41 to Day -18	\$2,935	\$881	\$3,816
	V3	Pre Day 1 (Day -14 to Day -3)	\$2,390	\$717	\$3,107
Randomization	V4	Day 1	\$1,570	\$471	\$2,041
Treatment Period	V5	Wk 2	\$2,860	\$858	\$3,718
	V6	Wk 4	\$1,045	\$314	\$1,359
	V7	Wk 6	\$755	\$227	\$982
	V8	Wk 10	\$2,670	\$801	\$3,471
	V9	Wk 12	\$1,245	\$374	\$1,619
	V10	Wk 14	\$705	\$212	\$917
	V11	Wk 24	\$2,850	\$855	\$3,705
	V12	Wk 26	\$1,810	\$543	\$2,353
	V13	Wk 28	\$860	\$258	\$1,118
	V14	Wk 50	\$5,430	\$1,629	\$7,059
	V15	Wk 52	\$1,810	\$543	\$2,353
	V16	Wk 54	\$860	\$258	\$1,118
	V17	Wk 76	\$4,140	\$1,242	\$5,382
	V18	Wk 78	\$4,415	\$1,325	\$5,740
	V19	Wk 80	\$800	\$240	\$1,040
	V20	Wk 102	\$3,115	\$935	\$4,050
	V21	Wk 104	\$4,420	\$1,326	\$5,746
		TOTAL PER COMPLETER		\$51,225	\$15,368
	EARLY TERM		\$6,265	\$1,880	\$8,145
	Health Status		\$90	\$27	\$117

# Payable Upon Invoice

- What does this mean?
- Sponsor Special Conditions

With prior approval from Sponsor,

- ✓ the cost of the following items will be reimbursed within forty-five (45) days of
- ✓ receipt and approval of a detailed invoice including the specific documentation listed below for each item

Invoices must be submitted within

- ✓ 4 months from the time
- ✓ the cost of the service was incurred

Remit all invoices for pass-through expenses directly to Sponsor

# What does all of this mean?

## (Budget and Payment Terms)

- **To be paid**
  - eCRF – how the sponsor knows the visit happened
  - Study Status Logs – how OCR knows the visit happened
  - Must provide documentation requested for all “items” listed under “Payable Upon Invoice”
- **OCR must invoice the sponsor for visits and all time items payable upon invoice PLUS start-up, advertising, travel, screen fails, partial visits, study subjects who discontinue, unscheduled visits, document storage, pharmacy start-up, etc.**

# Other ‘Little Known Facts’

- **Watch expenses – OCR is willing to renegotiate budgets to cover unforeseen expenses, excessive monitor changes, unexpected or missing items**
- **Move non-recurring or unanticipated expenses into the “to be invoiced” or “payable upon invoice” lines**
  - Remember to add overhead
  - Keep the OCR in the loop

# Questions?