

**Research Administration and Compliance Meeting**  
**Wednesday, August 26, 2015 1:00 – 3:00 p.m.**  
**Larrick Student Center, Court End Ballroom A**

**Agenda**

**Special Guest –**

- Dan Han – Chief Information Security Officer

**Office of Sponsored Programs (OSP)**

- RAMS SPOT
  - Implementation Update
  - Best Practice Use of Document Drop-off for agreements needing review
  - Cost-Share
- Sponsored Project Administration Certification Program
- Uniform Guidance – Use of Subrecipient de minimis F&A rate
- Accelerated Confidentiality Disclosure Agreement (ACDA)

**Office of Research Subjects Protection (ORSP)**

- WPP XI-5: Enrolling Subjects with Limited English Proficiency
- New Guidance: [Enrolling Limited English Proficiency \(LEP\) Subjects in Research](#)
- VA IRB Consortium: October 16

**Office of Research Integrity and Ethics (ORIE)**

**Office of Export Compliance**

- Existing Procedures and Future Plans

**Office of Research Administration and Compliance (ORAC)**

- Subject Injury Language

**Grants & Contracts (G&C)**

- Staffing Update
- How to Account for Budgeted Unrecovered F&A at financial report time
- Year End Grant Expenditure and Close-Out Statistics

**Clinical Research Services Updates (CRS)**

- Clinical Research Subject Registration and Arrival
- Enrollment Logs

**Upcoming RACM Meetings – 1 – 3 p.m., Larrick Student Center, Court End Ballroom A**

- October 28, 2015
- February 17, 2016
- April 27, 2016



Office of Sponsored Programs (OSP) Updates:

Melanie Wiggins

Director, OSP-Industry and Clinical Trials

Annie Publow

Director, OSP-Government/NonProfit

August 26, 2015

# OSP Update Topics

- OSP Staffing Update
- RAMS-SPOT
  - Implementation Update
  - Cost Share
  - Best Practice Use of Submit Document for Review
- Accelerated Confidentiality Disclosure Agreement (ACDA)
- Sponsored Projects Administration Certification Program
- Uniform Guidance—Use of Subrecipient *de minimis* IDC rate

# RAMS-SPOT Phased Implementation

## Phase 1: Submission new funding proposals

### ➤ Go Live: May 2015 Included...

- All task orders and new proposals including available Grants.gov opportunities
- Pre-proposals/Letters of Intent (LOI) that require OSP signature
- Reviews for Confidentiality Non Disclosure Agreements (CDA), Material Transfer Agreements (MTA), and Data Use Agreements (DUA), Just-in-Time (JIT), Export Control
- Agreements for negotiation including Unilateral/Bilateral/Master agreements

### ➤ Due to data reporting requirements, previously described “Phases 2 and 3” are updated with revised target date



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# RAMS-SPOT Implementation Update

## Phase 2: Awards, Post Award, Reporting activities

- Includes...
  - Award processing (initial and subsequent actions)
  - Funding Proposal Continuations/Supplements
  - Administrative Actions (Prior Approval, Expanded Authority, Progress Reports)
  - Subaward/Subrecipient (initial and subsequent actions)
  - Closeout
  - Reporting
  - Subaward/Subrecipient Actions (if not completed in Phase 2)
- Target Go Live: 1<sup>st</sup> Quarter 2016



# RAMS-SPOT Implementation Update

## Phase 2: Awards, Post Award, Reporting activities

### ➤ Thank you to...

- Controller's Office
- Grants & Contracts Accounting
- School of Medicine
- School of Social Work
- Massey Cancer Center
- College of Humanities & Sciences

for participating over the summer in RAMS-  
SPOT Awarding discussions



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## RAMS-SPOT Target Implementation Timeline

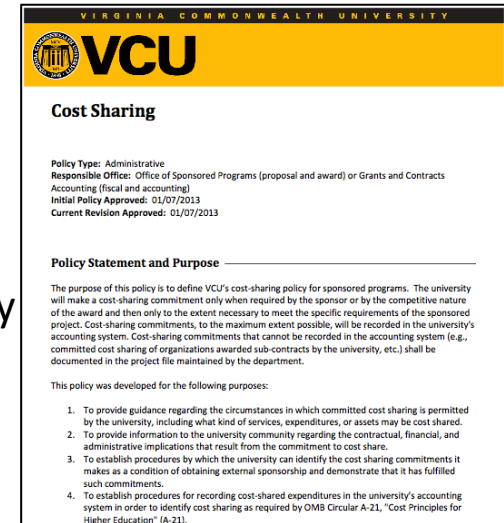
Implementation Phase	Activity	January 2015	February 2015	March 2015	April 2015	May 2015	June 2015	July 2015	August 2015	September 2015	October 2015	November 2015	December 2015	January 2016	February 2016	March 2016	April 2015	May 2015	June 2015
InfoEd	Continue InfoEd Use																		
	New Proposals (IAF package)																		
	Continuation Proposals (IAF package)																		
	Awards & Post Award Actions																		
	Data Conversion																		
RAMS-SPOT Phase 1	Funding Proposal (new proposals, pre-proposals and task orders)																		
	Pre-Award Review Projects: Unilateral/Bilateral/Clinical Trial/Master Agreements, CDAs, MTAs, DUAs, JIT, Export Control																		
RAMS-SPOT Phase 2	Awards-Initial & Subsequent																		
	Awards-Subsequent																		
	Funding Proposal Continuations																		
	Post Award Review Projects (prior approval, expanded authority, progress report)																		
	Subawards-Initial & Subsequent																		
	ODS/Dashboard Data Feed																		
RAMS-SPOT Phase 3	Closeout																		
	Reports																		
										version 2015-08-26									



# RAMS-SPOT and Cost Share

A couple of reminders:

- Cost share costs are those necessary for conduct of the sponsored project and provided by the institution (VCU)
  - Can be direct
  - Can be indirect costs (if sponsor approves)
- VCU has an approved policy on Cost Sharing
  - Mandatory Cost Share or Matching (required in writing by sponsor)
  - Voluntary Committed Cost Sharing (offered by entity, becomes condition of award)
    - These are verifiable and must be reported to sponsor
  - Voluntary Uncommitted
    - Should be avoided, arises from cost overrun
    - Should not be in budget





# Uniform Guidance: Subpart A—Acronyms and Definitions

## General Terminology: Cost Share

### [§200.29](#) **Cost sharing or matching**

means the portion of project costs not paid by Federal funds (unless otherwise authorized by Federal statute). See also §200.306 Cost sharing or matching.

[§200.99](#) **Voluntary committed cost sharing** means cost sharing specifically pledged on a voluntary basis in the proposal's budget or the Federal award on the part of the non-Federal entity and that becomes a binding requirement of Federal award.

### [§200.96](#) **Third-party in-kind**

**contributions** means the value of non-cash contributions (i.e., property or services) that—

- (a) Benefit a federally assisted project or program; and
- (b) Are contributed by non-Federal third parties, without charge, to a non-Federal entity under a Federal award.



# Cost Share Budget in RAMS-SPOT

## Entering a Cost Share Budget

- If cost share will be a factor in the funding proposal then a **Cost Share Budget** template will automatically be generated in RAMS-SPOT once you answer the cost share question.
- Applicable sections must be completed:
  - Budget Characteristics – Cost Sharing
  - Personnel Costs – Cost Sharing
  - Travel Costs – Cost Sharing
  - General Costs – Cost Sharing
  - Cost Sharing Details
  - Attachments

3. \* Will this budget have Cost Sharing (including salary cap):

☒ Yes

☐ No


[Clear](#)


FP00000478 Funding Proposal


### Test Proposal for Certification


**Current State**

**In Development**


 Edit Funding Proposal

 Printer Version

 View Differences

 View SmartForm Progress

**My Current Actions**

 Inactivate Proposal

**PROPOSAL INFORMATION**

PD/PI:



Fiscally Administering Unit:

Sponsor:

OSP Reviewer:

Team:

**Working Budgets**

<input checked="" type="checkbox"/> Name
 Primary Budget
 Cost Share Budget



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# Cost Share Budget Details

Add the name of the dept. that will be providing cost share.

Add a line for each dept. providing cost share for the funding proposal.

Enter total direct plus any allowable, associated indirect costs for each dept. providing cost share. Total should equal amounts reported on Cost Share Financials tab plus any salary over cap.

Add a line if any organization external to VCU will be providing cost share.

### Cost Sharing Details

1. \*At least one Cost Sharing Allocation is required:

**Enter Department/Unit Cost Sharing Allocation:**

Department	Total Dollars
Medicine	\$2,500.00

**Enter Third Party Cost Sharing Allocation:**

Entity
There are no items to display

2. \* Enter Total Cost Sharing F&A Dollars:  
\$0.00

3. \* Enter Total Unrecovered F&A Dollars:  
\$0.00

Question will be removed (because the information is available via Cost Share Financials Tab.) Enter \$0 for now.

Enter unrecovered cost dollars due to approved academic merit (F&A waiver exemption #2) or approved required match (F&A waiver exemption #3.) Enter \$0 if not applicable.



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# RAMS-SPOT Cost Share Budget Financials Tab

Cost Share/Match  
Example:  
This is verifiable  
cost share if  
project awarded  
(direct and  
indirect)

History	Change Log	Financials	Attachments
Spreadsheet Version:			
Current All-Period Totals		Period 1	Cumulative
<b>Personnel:</b>		<b>\$9,217</b>	<b>\$9,217</b>
Salaries:		\$6,762	\$6,762
Benefits:		\$2,455	\$2,455
<b>General:</b>		<b>\$128,271</b>	<b>\$128,271</b>
<b>Travel:</b>		<b>\$2,500</b>	<b>\$2,500</b>
<b>Trainee:</b>		<b>\$0</b>	<b>\$0</b>
<b>Patient Care:</b>		<b>\$0</b>	<b>\$0</b>
Inpatient:		\$0	\$0
Outpatient:		\$0	\$0
<b>Subrecipient:</b>		<b>\$0</b>	<b>\$0</b>
Subrecipient Direct:		\$0	\$0
Subrecipient Indirect:		\$0	\$0
<b>Total Direct less Subrecipient Indirect:</b>		<b>\$139,988</b>	<b>\$139,988</b>
<b>Total Direct:</b>		<b>\$139,988</b>	<b>\$139,988</b>
<b>Total F&amp;A:</b>		<b>\$38,024</b>	<b>\$38,024</b>
<b>Project Total:</b>		<b>\$178,012</b>	<b>\$178,012</b>
F&A Costs		Period 1	Cumulative
<b>Start Date:</b>		<b>7/1/2015</b>	
<b>End Date:</b>		<b>6/30/2016</b>	
<b>Research on Campus Indirect Cost Rate:</b>		<b>52.5%</b>	
<b>Research on Campus Indirect Cost Type:</b>		<b>MTDC</b>	
<b>Research on Campus Indirect Cost Base:</b>		<b>\$0.00</b>	
<b>Research on Campus Indirect Funds Req.:</b>		<b>\$0.00</b>	
<b>Instruction on Campus Indirect Cost Rate:</b>		<b>40%</b>	
<b>Instruction on Campus Indirect Cost Type:</b>		<b>MTDC</b>	
<b>Instruction on Campus Indirect Cost Base:</b>		<b>\$95,060.00</b>	
<b>Instruction on Campus Indirect Funds Req.:</b>		<b>\$38,024.00</b>	



# Cost Share Budget in RAMS-SPOT

## **Cost Share/Matching:**

- Direct Costs + Associated Indirect Costs (at applicable F&A rate)
- Reports in Financials Tab

## **Cost Share due to \$ Limit:**

- Direct Costs only
- Select 0% F&A
- Reports in Financials Tab

## **Cost Share/Matching:**

- Unrecovered F&A
- Does not reports in Financials Tab
- Report on C/S Budget Details

# Expanded Use of RAMS-SPOT for Incoming “Agreements”

- There is an broad, increased focus on “turnaround” time for sponsored project agreements
- Metrics are difficult to report due to multiple factors, chief among them for OSP:
  - Divergent points of entry to OSP

# Expanded Use of RAMS-SPOT for Incoming “Agreements”

## Divergent points of entry to OSP

Agreements for acceptance/review/negotiation currently arrive to OSP via:

- Email to OSP team (dirospa, ospred, ospgold, ospblue, ospgreen)
- Email to individual OSP staff
- Delivery by U.S. Mail
- Delivery by courier/express service
- Upload to Funding Proposal record (RAMS-SPOT)

**So many options will never lead to consistent metrics**

# Expanded Use of RAMS-SPOT for Incoming “Agreements”

## Divergent points of entry to OSP

- This best practice applies to all internally-forwarded “agreements”
- Exceptions to this practice are those “agreements” that are forwarded directly to OSP from the sponsor
  - Sponsor agreements can continue to arrive to team email and/or U.S. mail/courier

### Consequences of internal non-compliance with best practice:

- Longer turnaround time for your agreement to be logged in, i.e. for the “clock” to start on OSP acceptance/review/negotiation
- Return of your agreement for proper delivery
- Metrics will be calculated based on best practice only





# Use of Submit Document for Review in SPOT

- **Best practice**, beginning September 1, 2015 , OSP is expanding use of the “Submit Document for Review” function in SPOT for submission to OSP of all agreements which require acceptance/review/negotiation of terms and conditions by OSP.
- Specifically included in the expanded use are all bilateral agreements (signatures by both parties are required), contracts, subawards (where VCU is the subrecipient), clinical trial agreements, task orders, grant agreements, and unilateral agreements.
- Confidentiality agreements, material transfer agreements and data use agreements will also continue to be submitted through this mechanism **to the appropriate office** as originally intended.

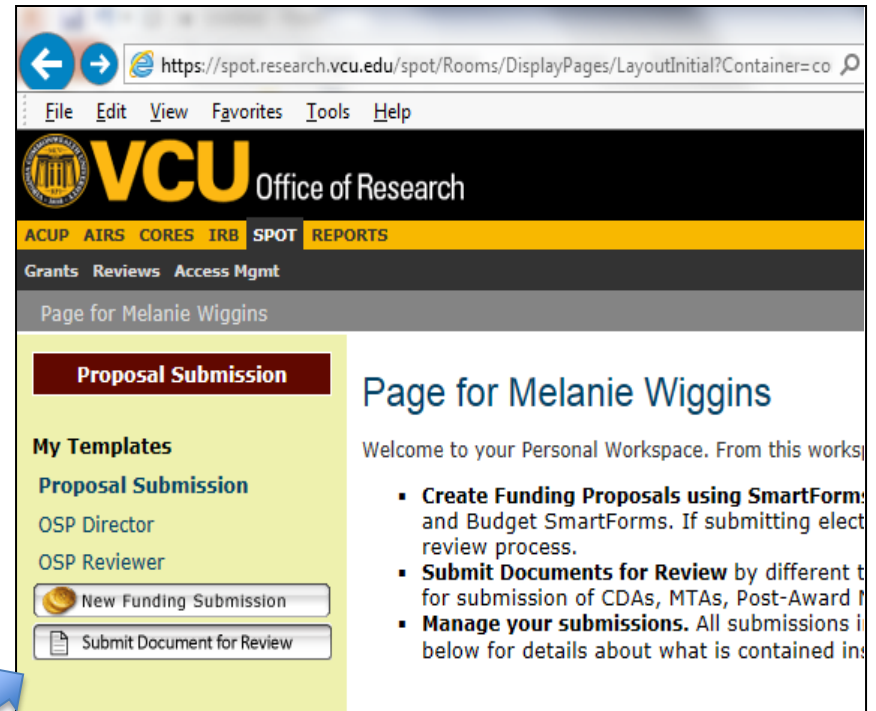


# Use of Submit Document for Review

- Log on to SPOT

<https://spot.research.vcu.edu>

- Forward agreements requiring acceptance/review/negotiation by OSP through “Submit Document for Review” process in SPOT.



# Submit Document for Review

## Submit Document for Review

1. \* **Name of Document:**

2. \* **Principal Investigator:**

 Select...

3. **Other Contacts (include yourself if submitting on behalf of PI or you will lose**

 Add

First Name

Last Name

There are no items to display

4. \* **Department Responsible for Administering / Fiscal Management of Project:**

 Select...

5. \* **Select Direct Sponsor or TBD if not listed:**

 Select...

6. \* **Select the Team that will review this submission:**

- ☐ Blue  
☐ Green  
☐ Gold  
☐ Red  
☐ Gray  
☐ Post Award  
[Clear](#)

7. \* **Upload document for review:**

Name

Owner

Modified

There are no items to display

- Answer all questions as appropriate.
- Be sure to include identifying information in the Name of the Document (e.g, FP# for linkage) and select the appropriate team.
- Select add to upload document.

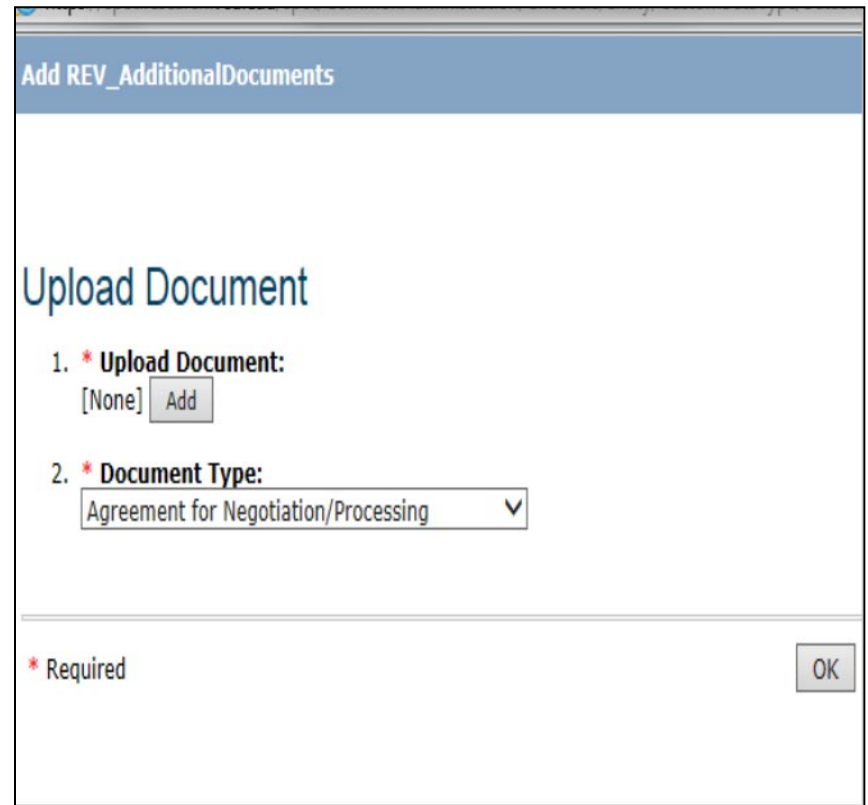


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# Submit Document for Review

- When uploading the document, select “Agreement for Negotiation Processing” as the Document Type.
- Note: An FP# drop down list, a Sponsor contact text box, and a comment field will be added with the next system patch (9/2/2015).
- Please use the comment field to include pending site visit dates (for clinical trials) or other information needed for OSP assessment of your agreement..



The screenshot shows a web application window titled "Add REV\_AdditionalDocuments". Inside, there is a section titled "Upload Document" with two required fields:

1. \* Upload Document: [None] Add
2. \* Document Type: Agreement for Negotiation/Processing

At the bottom left, there is a note "\* Required" and at the bottom right, there is an "OK" button.

# Submit Document for Review

- A review and an RV # is created upon submission to OSP.
- OSP will perform document triage, link review to associated funding proposal (as appropriate), take ownership and begin review.

VCU Office of Research

ACUP ADRS CORES IRB SPOT REPORTS

Grants Reviews Access Mgmt.

Page for Melanie Wiggins > FP00000000 Test Document for Review

FP00000000 Test Document for Review

RV00000856 Reviews

**Current State**

**Pending Review Action**

Edit Review  
Printer Version

**My Current Actions**

- Agreement Executed or Accepted
- Send for Review - Approval(s)
- Withdraw
- Upload Documents
- Upload Administrative Documents
- Set Reminders for Review
- Assign Ownership
- Log Public Comment
- Log Private Comment
- Not Executed
- Notify Export Control Reviewer
- Upload Email
- Link Funding Proposals

**History** Documents Personnel Changes Linked Proposals Pending Actions

Activity	Author	Activity Date
Review Began	Wiggins, Melanie A	8/12/2015 6:00 PM
Testing system - please ignore email		
Take Ownership	Wiggins, Melanie A	8/12/2015 5:59 PM
I will review		
Updated Linked Funding Proposals	Wiggins, Melanie A	8/12/2015 5:52 PM
Testing linkage for document review		
Document Triage	Wiggins, Melanie A	8/12/2015 5:23 PM
Expedited Review Eligible		
Review Created	Wiggins, Melanie A	8/12/2015 5:14 PM

PI: Melanie Wiggins  
Approver(s): There are no items to display  
Direct Sponsor: Abbvie, Inc.  
Fiscal Admin Unit: Office of Research  
Clinical Trial: Yes  
Team: Red  
Date Created: 8/12/2015 5:14 PM  
Last Modified: 8/12/2015 6:03 PM  
Submission Type: Bilateral Agreement Review  
Review Priority: Expedited Review  
Owner: Melanie Wiggins

# Why Use Submit Document for Review

Use of this mechanism will:

- Streamline receipt of agreements by OSP
- Identify agreements for priority processing (e.g. clinical trials)
- Increase efficiency by cutting down on email exchange through Team Email
- Please do not upload agreements to the FP (proposals and awards are structured differently in VCUeRA RAMS-SPOT than in VCUeRA InfoEd.)



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# OSP Update Topics

## Use of Accelerated Confidential Disclosure Agreement (ACDA) Template





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# Compliance Notice 15-005: Use of ACDA for Industry Sponsored Clinical Trials

<div> <a href="#">Research Compliance / OVPRI Research Compliance Notices</a></div> <div><h2>Final Compliance Notices</h2></div> <div> Created by Lisa R Ballance, last modified on Jul 07, 2015</div> <div><a href="#">Watch</a> <a href="#">Share</a> <a href="#">Tools</a></div>					
Number	Date	Status*	Title	Notes	Prior Version History / Access
15-005	6/30/2015	Active	<a href="#">Use of Accelerated Confidentiality Disclosure Agreement Template for Industry-Sponsored Clinical Trials</a>	Use of the VCU-CTSA national standard template for accelerated CDAs with potential clinical trial sponsors.	



# Use of Accelerated Confidential Disclosure Agreement (ACDA) Template

## Compliance Notice

Research Administration and Compliance

No. 15-005

June 30, 2015

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**NOTICE: USE OF ACCELERATED CONFIDENTIALITY DISCLOSURE AGREEMENT TEMPLATE FOR  
INDUSTRY-SPONSORED CLINICAL TRIALS**

Effective immediately, VCU has adopted the use of the Accelerated Confidentiality Disclosure Agreement (ACDA) template. This template was developed by Clinical and Translational Science Award (CTSA) recipient institutions and partnering industry sponsors as a mechanism to streamline the negotiation process between institutions and industry, thereby enabling researchers to obtain protocols in a timely manner for evaluation of their inclusion as a site in potential industry-sponsored clinical trials.

### **Use of the Agreement**

As a registered user, VCU encourages investigators to download the template and provide it to potential clinical trial Sponsors for disclosure of sponsor provided confidential information (e.g., the study protocol) rather than requesting or accepting a sponsor-provided confidentiality template. The investigator shall provide the template to the sponsor as is with instructions to contact the Office of Sponsored Programs with any questions.

Please note that use of the term “Accelerated Confidential Disclosure Agreement” or “ACDA” is only permitted when referring to the unmodified template. Any changes made to the template by the Sponsor shall require review and negotiation by the Office of Sponsored Programs (OSP) and negates the use of the ACDA template as is.



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# Use of Accelerated Confidential Disclosure Agreement (ACDA) Template

- Effective 6/30/2105, in accordance with Compliance Notice 15-005, VCU adopted use of the ACDA template.

<https://wiki.vcu.edu/display/ResearchCompliance/Final+Compliance+Notices>

- Compliance Notice 15-005 outlines the use of the ACDA and describes the process.
- Template was developed by Clinical and Translational Science Award (CTSA) institutions in coordination with partnering industry sponsors to streamline the negotiation process of confidential disclosure agreements for potential industry sponsored clinical trials.
- Use of template will enable VCU to obtain protocols from potential industry sponsors faster and without negotiation of contract language.
- VCU reviewed the template and is listed as a registered user on the accelerated contracting website (hosted by Vanderbilt ) <https://ara4us.org/acda/>
- In order to use the term Accelerated Confidential Disclosure Agreement , the template cannot be altered.
- Any edits to the template will require negotiation by OSP.



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# Use of ACDA Template by VCU Investigator

- PI/Study Staff is encouraged to send the ACDA Template to the Sponsor in lieu of OSP negotiating a Sponsor CDA. Please do not send a downloaded version of the ACDA to Sponsors (as described in compliance notice).
- OSP created a fillable PDF “locked” version which should be sent to the Sponsor. This version will be posted on the OSP website and should be sent to Sponsor for consideration of use.
- If Sponsor has any questions, please refer them to OSP.

## **ACCELERATED CONFIDENTIAL DISCLOSURE AGREEMENT** **(FOR PURPOSES OF OBTAINING STUDY PROTOCOL)**

This ACCELERATED CONFIDENTIAL DISCLOSURE AGREEMENT (the “Agreement”) is made by and between:

Virginia Commonwealth University, a non-profit, educational, research and healthcare institution (“Institution”) with an address of 800 East Leigh Street, Suite 3200, Richmond, VA 23298 and

\_\_\_\_\_, a corporation having its principal place of business located at \_\_\_\_\_ (“Sponsor”).

Sponsor and Institution are herein referred to collectively as “Parties.” Individually, each of Sponsor and Institution is a “Party.”

WHEREAS, Sponsor is seeking to identify potential investigative sites for a study relating to \_\_\_\_\_ {DISEASE OR DRUG/DEVICE BEING STUDIED} pursuant to Protocol Title or Protocol Number: \_\_\_\_\_ the “Study”), and Institution desires to review information about the Study on behalf of \_\_\_\_\_ (“ PRINCIPAL INVESTIGATOR”) in order to determine whether it would be interested in participating in the Study (“Purpose”); and

WHEREAS, in consideration for the opportunity to be considered as an investigative site, Institution is willing to receive the Confidential Information subject to the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the benefits set forth herein, the Parties hereby agree as follows:



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# Use of ACDA Template by VCU Investigator

- If Sponsor agrees to use ACDA, the template information should be filled in and signed by Sponsor and PI and forwarded to OSP through “Document Submission for Review” process in SPOT for OSP processing.
- OSP reviewer will complete CDA checklist in SPOT, obtain AOR signature, submit to Sponsor, and upload a fully executed copy to the review in SPOT. A copy of executed ACDA will be accessible under Documents tab.
- Please be sure to include contact information for the Sponsor when submitting the request so OSP can return the fully executed version.

**NOTE: A Sponsor contact text field will be available after the next patch to SPOT (scheduled for September 2, 2015).**

The screenshot shows the VCU Office of Research SPOT system interface. The browser address bar displays the URL: <https://spot.research.vcu.edu/spot/Rooms/DisplayPages/LayoutInitial?Container=co>. The page features a navigation menu with tabs for ACUP, AIRS, CORES, IRB, SPOT, and REPORTS. Below this, there are links for Grants, Reviews, and Access Mgmt. The main content area is titled "Page for Melanie Wiggins" and includes a "Proposal Submission" section. This section contains a "My Templates" list with links for "Proposal Submission", "OSP Director", and "OSP Reviewer". There are also two buttons: "New Funding Submission" and "Submit Document for Review". To the right, a welcome message states: "Welcome to your Personal Workspace. From this workspace, you can:" followed by a bulleted list of actions: "Create Funding Proposals using SmartForm: and Budget SmartForms. If submitting elect review process.", "Submit Documents for Review by different t for submission of CDAs, MTAs, Post-Award I", and "Manage your submissions. All submissions i below for details about what is contained in".



# Direct Use of ACDA by OSP

- If Sponsor contacts OSP directly, OSP will submit “locked” version of the ACDA template to Sponsor for their consideration in lieu of Sponsor CDA. PI/Study staff will be copied on correspondence.
- If Sponsor agrees to use template, OSP will set up a review in SPOT, complete checklist, forward template for PI signature, execute and forward to Sponsor.
- A copy of executed ACDA will be uploaded to the review in SPOT and will be accessible under documents.

# Sponsored Projects Administration Certification Program

Fall, 2015:

- Fully enrolled with ~50 students
- Course runs September-December, 2015

Winter/Spring, 2015:

- Sufficient interest expressed to Cathy Short's emailed survey, program will be offered
- Will publish dates on OSP Training website:  
<http://www.research.vcu.edu/osp/training.htm>
- Will announce registration for spring via Research Administration list serve

**Course updated to include RAMS-SPOT and Uniform Guidance**



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# Uniform Guidance 2 CFR 200: Indirect Cost Recovery

## §200.414 Indirect (F&A) costs

“(c) Federal Agency Acceptance of Negotiated Indirect Cost Rates.

(1) The **negotiated rates must be accepted by all Federal awarding agencies**. A Federal awarding agency may use a rate different from the negotiated rate for a class of Federal awards or a single Federal award **only when required by Federal statute or regulation, or when approved by a Federal awarding agency head or delegate** based on documented justification as described in in paragraph (c)(3) of this section.

(2) The Federal awarding agency head or delegate must notify OMB of any approved deviations.

3) The Federal awarding agency must implement, and make publicly available, the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviation from negotiated rates.

(4) As required under 200.203 Notices of funding opportunities, the Federal awarding agency must include in the notice of funding opportunity the policies relating to indirect cost rate reimbursement, matching, or cost share as approved under paragraph (e)(1) of this section.”

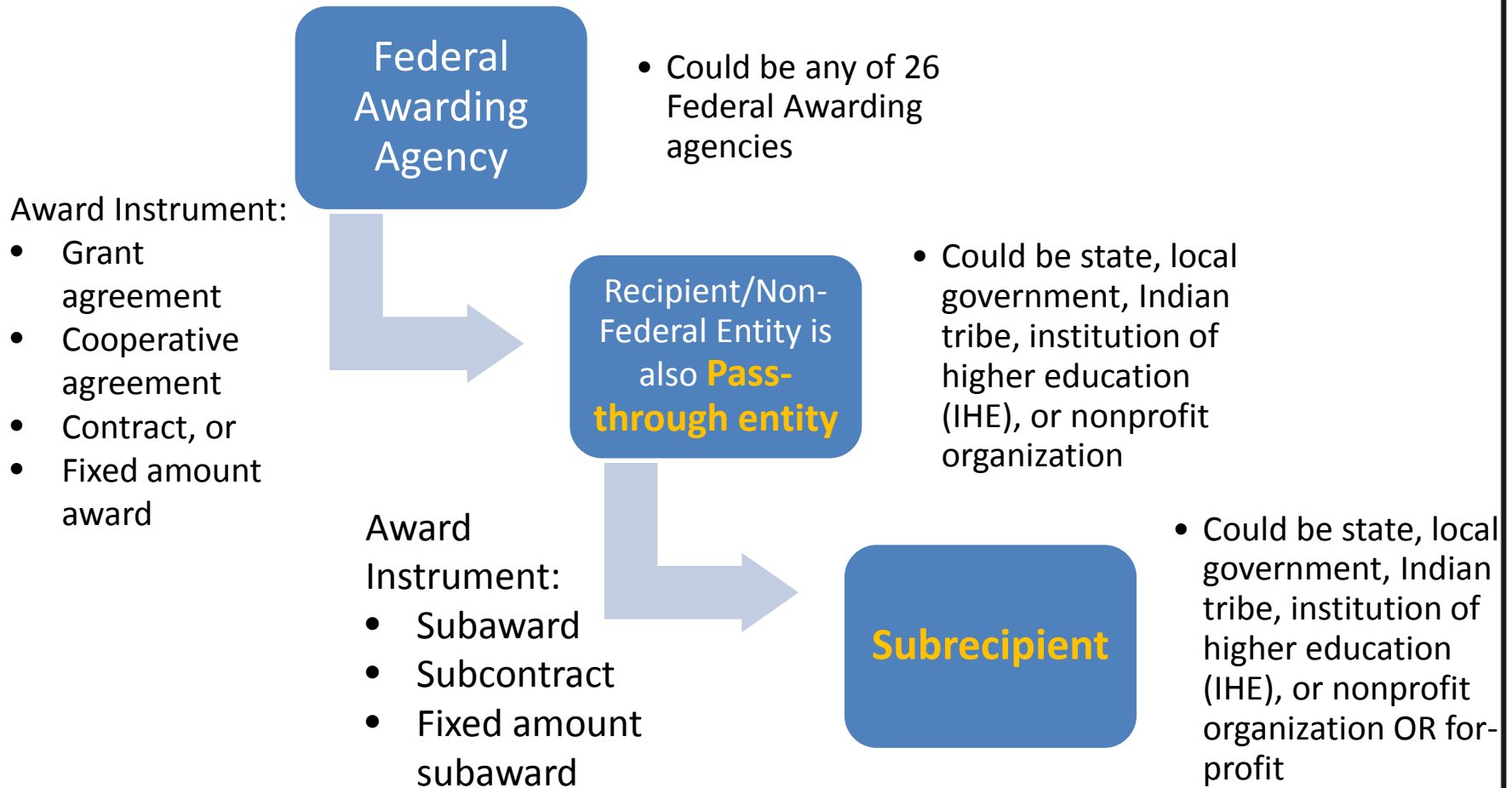
- Adhere to negotiated rate agreement F&A rates when preparing cost estimates for proposals unless statutory or federal agency head exception that limits recovery
- Document exception at proposal time in Funding Proposal (Federal statute or agency head exception)- should be in program announcement



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# Uniform Guidance 2 CFR 200: To “de minimis” or not to “de minimis”?





# Uniform Guidance 2 CFR 200: To “de minimis” or not to “de minimis”?

[§200.414 Indirect \(F&A\) costs....](#) (d) Pass-through entities are subject to the requirements in §200.331 Requirements for pass-through entities, paragraph (a)(4).... (see box below)

(f) In addition to the procedures outlined in the appendices in paragraph (e) of this section, any non-Federal entity that has never received a negotiated indirect cost rate, except for those non-Federal entities described in Appendix VII to Part 200—States and Local Government and Indian Tribe Indirect Cost Proposals, paragraph D.1.b, may elect to charge a **de minimis rate of 10% of modified total direct costs (MTDC)** which may be used indefinitely. As described in §200.403 Factors affecting allowability of costs, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time.

[§200.331 Requirements for pass-through entities....](#)All pass-through entities must ensure that every subaward includes either...(a) (4) An approved federally recognized indirect cost rate negotiated between the subrecipient and the Federal government **or**, if no such rate exists, either a rate negotiated between the pass-through entity and the subrecipient (in compliance with this part), or a de minimis indirect cost rate as defined in §200.414 Indirect (F&A) costs, paragraph (b) of this part.



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# Uniform Guidance, 2 CFR 200

## Indirect Cost Recovery



October, 2014

To Whom It May Concern:

Virginia Commonwealth University (VCU) proposes to partner with your organization in a through/subrecipient relationship in connection with our prime application for Federal funding. We have prepared a line item costing estimate consistent with the OMB Uniform Administrative Principles, and Audit Requirements for Federal Awards (also referred to as 2 CFR 200 or "Uniform Guidance") which takes effect with awards issued on or after December 26, 2014.

Consistent with Uniform Guidance, as the pass-through entity, VCU must accept your Indirect Rate Agreement. Per §200.414(f), if your organization... has never received a rate, except for those non-Federal entities described in Appendix VII to Part 200... (you determine) a de minimis rate of 10% of modified total direct costs (MTDC) which may be used instead.

The following Uniform Guidance excerpts may be helpful in the preparation of support for §200.68 Modified Total Direct Cost (MTDC)

MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, and subawards and subcontracts up to the first \$25,000 of each subaward or subcontract period of performance of the subawards and subcontracts under the award. MTDC excludes capital expenditures, charges for patient care, rental costs, tuition remission, scholarship, participant support costs and the portion of each subaward in excess of \$25,000. Other excluded when necessary to avoid a serious inequity in the distribution of indirect costs of the cognizant agency for indirect costs.

If applicable, please provide us with evidence of your organization's rate agreement attached to your subrecipient proposal package to VCU.

Thank you in advance for your compliance with the Uniform Guidance regulations. We look forward to working with your organization.

Sincerely,

*Annie Publow*

Annie Publow, MFA, CRA  
Director, Office of Sponsored Programs-  
Government/Non-Profit Support

Office of Research  
Office of Sponsored Programs  
BioTech One, Suite 2200  
800 East Leigh Street, P.O. Box 980568, Richmond, VA 23298  
Ph: 804 828 6772 - Fax: 804 828 2521 - TDD: 1-800-828-1120 - [disinfo@vcu.edu](mailto:disinfo@vcu.edu) - [www.research.vcu.edu/osp](http://www.research.vcu.edu/osp)

[http://www.research.vcu.edu/forms/index.htm#osp\\_forms](http://www.research.vcu.edu/forms/index.htm#osp_forms)



October, 2014

To Whom It May Concern:

Virginia Commonwealth University (VCU) is applying for funding from your organization and has prepared the attached proposal. We have been informed that federal domestic assistance funds will fully or partially fund this project if awarded to you as a Pass-through entity. The OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (also referred to as 2 CFR 200 or simply "Uniform Guidance") takes effect with awards issued on or after December 26, 2014. Consistent with the OMB Uniform Guidance, we have prepared our Subrecipient proposal budget utilizing the applicable Facilities & Administrative rate from VCU's current negotiated rate agreement, located at this url: <http://www.controller.vcu.edu/kost/DHHSRates.htm>.

The following Uniform Guidance excerpts are provided to support our subrecipient costing proposal and the responsibility of your organization as the pass-through entity:

§ 200.414 Indirect (F&A) costs

(c) Federal Agency Acceptance of Negotiated Indirect Cost Rates

(1) The negotiated rates must be accepted by all Federal awarding agencies. A Federal awarding agency may use a rate different from the negotiated rate for a class of Federal awards or a single Federal award only when required by Federal statute or regulation, or when approved by a Federal awarding agency head or delegate based on documented justification as described in paragraph (c)(3) of this section.

(2) The Federal awarding agency must notify OMB of any approved deviations.

(d) Pass-through entities are subject to the requirements in § 200.331 Requirements for pass-through entities(a)(4).

§ 200.331 Requirements for pass-through entities

(a) ...the pass-through entity must provide the best information available to describe the Federal award and subaward. Required information includes:

(4) An approved federally recognized indirect cost rate negotiated between the subrecipient and the Federal government, or, if no such rate exists, either a rate negotiated between the pass-through entity and the subrecipient (in compliance with this Part), or a de minimis indirect cost rate as defined in § 200.414 Indirect (F&A) costs, paragraph (b) of this Part.

If your organization will be unable to reimburse VCU for its full indirect costs due to (1) Federal statutory or regulatory limit, or (2) Federal awarding agency head exception, please provide VCU with evidence of the documentation for our proposal record.

Thank you in advance for your compliance with the federal Uniform Guidance regulations. We look forward to partnering with your organization.

Sincerely,

*Annie Publow*

Annie Publow, MFA, CRA  
Director, Office of Sponsored Programs-  
Government/Non-Profit Support

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an equal opportunity/affirmative action university

When federal domestic assistance funds are involved...

- Use these letters with sponsors or subrecipients who may be unfamiliar with Uniform Guidance;
- Use with sponsors who may not have honored negotiated rates in the past;
- Located on OSP Forms page under "Proposal Development" header.



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# Uniform Guidance, 2 CFR 200

## Indirect Cost Recovery

### When VCU is Pass-through Entity

- Honor subrecipient's federally negotiated rates to the extent allowed by sponsor
- When subrecipient has no negotiated rate and program dollars are federal with no limitations, best practice is to allow subrecipient 10% de minimis of modified total direct costs (MTDC)

### When VCU is Subrecipient

- Calculate indirect costs based on our negotiated rate agreement (research, instruction or other, on/off campus)
- VCU's negotiated rate agreement applies when we do work as a subrecipient or as a contractor



# Questions

**For information about OSP review criteria contact:**

Industry-funded projects:

[ospred@vcu.edu](mailto:ospred@vcu.edu), 826-6772

Melanie Wiggins, Dir, OSP/Industry, [mwiggins@vcu.edu](mailto:mwiggins@vcu.edu), 827-4992

Government/Nonprofit-funded projects:

[ospblue@vcu.edu](mailto:ospblue@vcu.edu), [ospgold@vcu.edu](mailto:ospgold@vcu.edu), [ospgreen@vcu.edu](mailto:ospgreen@vcu.edu)

Annie Publow, Dir, OSP/Govt, [ajpublow@vcu.edu](mailto:ajpublow@vcu.edu), 828-6772



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# Introduction to Export Controls

Quinton Johnson

Director, Export Compliance Office

Office of the Vice President for Research and Innovation

# U.S. Export Controls Regulations

## Background and Purpose

- Export Regulations have been around since the mid 1970's and have been changed and updated ever since. The regulations are administered by the Departments of State, Commerce, Treasury, Energy, Defense, and Homeland Security.
- U.S. export control laws govern the transfer of Information, Items, and Technologies to foreign countries and foreign persons.
- Public information -> Export Controlled information -> Classified information



# U.S. Export Laws

## VCU's Compliance Policy and Procedures

- VCU's Compliance with U.S. Export Control Laws Policy
- Export Compliance Updates/Handouts
- Export Compliance Trainings
  - Dangerous Goods Training
  - NCURA Videos
  - Department/School Trainings
- UPDATE: Export Controls and Trade Sanctions Webpage
- Export Compliance Committee
  - Export Compliance Office is responsible for enterprise wide export compliance
  - The individuals on the committee will serve to represent the interests of their school, department, or office and will hopefully become a first point of contact for questions regarding export issues in their areas.

# Export Compliance Committee

## Membership Roster

College of Humanities and Sciences	Edith Allin
Fixed Assets	Lynne Trice
Global Education	Paul Babitts
Human Resources	Cathleen Burke & Laurie Bourne
Integrity and Compliance Office	Jacqueline L Kniska
Office of Environmental Health and Safety	Mary Beth Taormina & Larry Mendoza
Office of Procurement	Brenda Mowen & Nick Fetzer
Office of Sponsored Programs	Andrea J Publow & Melanie A Wiggins
Provost Office	Heidi Jack
School of Engineering	Ram B. Gupta
School of Medicine	Tricia Zeh
VCU Qatar	Gary L Huff
VCU Technology Services	Dan Han



# Dual Use Research of Concern (DURC)

- This Policy is to establish regular review of research (regardless of the source of funding) with certain high consequence pathogens and toxins for its potential to be Dual Use Research of Concern (DURC) as defined by the US Government Policy on Institutional Oversight of Life Sciences Dual Use Research of Concern.
- The DURC review is designed to:
  - (a) mitigate risks where appropriate; and
  - (b) collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC.
- Requires the establishment of an Institutional Review Entity (IRE)

## Dual Use Research of Concern Review Process:

Any individual working with any of the 15 DURC Agents should immediately notify the Institutional Review Entity (IRE) via an expanded Memorandum of Understanding (MUA)

The IRE reviews research to determine if it involves any of the 7 experimental effects

No

*Experimental effects not involved*, the IRE still must notify and has 30 calendar days to notify the appropriate USG funding agency of the outcome of the review

The MUA is appropriately marked and signed by the IRE and the researcher agrees in writing to notify the IRE if the research changes in a way that would implicate one of the 7 Experimental Effects

The IRE and researcher establish a plan for a periodic review of the research moving forward

Yes

*Experimental effects involved*, the IRE has 30 calendar days to notify the appropriate USG funding agency of the outcome of the review

The IRE considers the previously identified risks and the anticipated benefits in order to develop a draft risk mitigation plan

The IRE works with the USG funding agency to complete the draft risk mitigation plan within 90 calendar days of the IRE's initial determination that research is DURC

The USG funding agency finalizes the risk mitigation plan within 60 calendar days of receipt of the draft plan

VCU and the IRE implement the approved risk mitigation plan and provide ongoing oversight of DURC

### 15 DURC Agents & Toxins:

1. Avian influenza virus (high-path)
2. Bacillus anthracis
3. Botulinum neurotoxin
4. Burkholderia mallei
5. Burkholderia pseudomallei
6. Ebola virus
7. Foot-and-mouth disease virus
8. Francisella tularensis
9. Marburg virus
10. Reconstructed 1918 influenza virus
11. Rinderpest virus
12. Toxin-producing strains of Clostridium botulinum
13. Variola major virus
14. Variola minor virus
15. Yersinia pestis

### 7 Experimental Effects:

1. Enhances harmful consequences of agent or toxin
2. Disrupts immunity or effectiveness of immunization without clinical/agricultural justification
3. Confers resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions or facilitates ability to evade detection methodologies
4. Increases the stability, transmissibility, or the ability to disseminate the agent
5. Alters the host range or tropism
6. Enhances the susceptibility of a host population
7. Generates or reconstitutes an eradicated or extinct agent or toxin previously listed

# Contact Information for DURC

- **Mike Elliott**

Senior Safety Engineer

Office of Environmental Health and Safety

- [mtelliot@vcu.edu](mailto:mtelliot@vcu.edu)
- 804-400-4984

- **Larry Mendoza**

Sr. Safety Engineer/Chemical Safety

Office of Environmental Health and Safety

- [lgmendoz@vcu.edu](mailto:lgmendoz@vcu.edu)
- 804-828-2596

# Contact Information

- **Quinton Johnson**

Director, Export Compliance Office

- [exportctrl@vcu.edu](mailto:exportctrl@vcu.edu)
- [qjohnson3@vcu.edu](mailto:qjohnson3@vcu.edu)
- (804) 827-6088

- **VCU Webpage**

- [http://www.research.vcu.edu/export\\_control/](http://www.research.vcu.edu/export_control/)

## BILLING QUESTIONS AND ANSWERS

This information should be considered as answers “for now.” We continue to work with the Health System to address issues as they arise and encourage all to submit concerns or additional questions to sarobb@vcu.edu.

1) Is the five (5) trial limit per patient for active studies or for the lifetime of the patient? Will trials be deactivated when they are closed and how are we going to coordinate that? – At this time, I believe the answer would be lifetime. It was discussed that as a patient goes off study and on to a new one, the information will get updated. Once a patient exceeds 5, we had discussed the only study be removed and the new one added. I believe that we may need additional discussion if it is expected that patients will have more than 5 active at one time.

2) What does FSC mean? - FSC is the patient insurance. It stands for Financial Status Classification. Everyone that uses IDX has been trained on this piece so that they recognize it.

3) How should they answer the "bill to insurance or study" question if the visit is a "mixed visit," i.e., both routine care and research services will be conducted? Include the NCT#.

4) Do all of the schedulers have this same information and have they been trained? Have the individuals who "arrive" the subjects been trained to ask and enter the information? – All schedulers use the same screen. Notification has been sent out to them and they have access to the fields. They rely on being told how to answer the questions.

5) What happens if the follow-up visit is scheduled by the patient directly (some do this even though asked not to)? - It is my understanding that the patients are provided a form with the study information if they are scheduling the appointment themselves. I

assume that the form would instruct the patient to tell the scheduler that it is research related and for what study.

6) Is the process the same for all areas of the Health System? We have already received reports that Radiology has their own process and will not be doing this. – The process is the same for everyone who schedules in IDX. For Radiology, they are moving to Cerner Scheduling. As part of that project, the NCT will be assigned by the doctor on the order. I have validated with Sharon Grow that the “will this be billed to Insurance” has also been built in Cerner Radiology Scheduling with FSC one and FSC two. The only difference between that and GE/IDX is Cerner does not have FSC three.

## Research Appointment Scheduling Form

**Purpose:** To ensure Research Staff provide complete information when scheduling appointments for a research subject. This form can be used over the phone or faxed to the scheduler.

<b>Patient Name/MRN:</b>
<b>NCT #/Protocol Name:</b>
<b>Procedure/Services Requested:</b>
<b>Special Instructions:</b>

1. In which clinic will the subject receive services?

\_\_\_\_\_

2. What is the desired date for the appointment?

\_\_\_\_\_ ± \_\_\_\_\_ Days/Weeks

3. Will the services be billed to the patient's insurance or to the study?

\_\_\_\_\_

### **\*\*Note\*\***

- If the services will be billed to the patient's insurance, skip to step 6 and answer "Y."
- If the Sponsor/Study will be billed, advise the scheduler that the following FSC information needs to be entered in the Generic Carve Out page of the Registration screen and answer step 6 with "N."

4. Which FSC should be used?

- ☐ **421** – Study was set up prior to 1/1/14
- ☐ **644** – Non-Industry funded study set up after 1/1/14 with the new Fee Schedule (Skip to step 6)
- ☐ **645** – Industry funded study set up after 1/1/14 with the new Fee Schedule (Skip to step 6)

5. Provide/Verify the following information:

Carrier Dictionary: 10140 (only use for FSC 421, leave blank for FSC 644 & 645)

**Carrier Name:** (Study Short Name) \_\_\_\_\_

**Addr 1:** (Billing Street Address) \_\_\_\_\_

**Cty,St:** Richmond, VA

**Zip:** 23298

**Tel:** (Research Coordinator's #) \_\_\_\_\_

**Eff Dt:** (On Study Date) \_\_\_\_\_

**Carrier ID #:** (Study Short Name) \_\_\_\_\_

**Billing Contact:** \_\_\_\_\_

**Contact Tel:** (Billing Contact's #) \_\_\_\_\_

**PI:** \_\_\_\_\_

**Study #:** (IRB #) \_\_\_\_\_

6. On the Appointment Data Form (ADF), the Scheduler will ask "Do you want to bill insurance?"

Y – Services are to be billed as Routine Care to the patient's insurance

N – Services are to be billed as Sponsor Billed to the study

**\*\*Note\*\*** If you answered "Y," the patient's insurance pulls to the visit. If you answered "N," the study information from the Generic Carve Out page pulls to the visit.

7. If visit is related to a clinical trial (Sponsor Billed or Routine Care), populate the NCT # on the ADF. The study can be found by the NCT # or Protocol Name. The NCT # will copy forward to the visit screen.
8. If study cannot be found, request the Scheduler file the appointment without the NCT #.
9. Research Coordinator forwards the Billing Set up Forms and patient/appointment information to ClinicalTrialsBilling@mcvh-vcu.edu to have the study added to the system and the patient's appointment to be updated.



## Research Appointment Arrival Form

**Purpose:** To make sure that research appointments/visits contain necessary Clinical Trials information. All fields should already be complete in registration and on the appointment from the scheduling process.

1. Validate the Insurance and NCT# fields are correct on the appointment:

**Edit Appointment 1 Primary - MCV General**

**2.**

<b>Patient:</b> TEST,ANGELA 1 ANY WAY			<b>MRN:</b> 8403475 <b>DOB:</b> 12/06/1973			<b>FSC:</b> HEALTHK MDIPA/O			
<b>Date</b>	<b>Day</b>	<b>Time</b>	<b>Stat</b>	<b>Typ</b>	<b>Provider</b>	<b>Dept</b>	<b>Loc</b>	<b>Dur</b>	<b>Appt #</b>
08/19/2015	WED	8:00A	<span style="background-color: #007bff; color: white;">PEN</span>	<span style="border: 1px solid black;">FUV</span>	Q EYER MD,CHARLES	<span style="border: 1px solid black;">HEM</span>	<span style="border: 1px solid black;">DOC</span>	30	310003286

**Should this service be billed to your health insurance (Y/N):** N

**FSC 1 for Appt:** PRE-PPM NC **FSC 2 for Appt:**  **FSC 3 for Appt:**

**Referring Phy:** SELF REFERRAL

**Referring Clinic:**  **NCT #:** 01816776

**Reason for Appt:**

**Comment:**

**Actual Provider:**  **Disease Site:**

**Resident Phy:**  **DX Code:**

**Referring Agcy:**  **Patient Tracking?:** ☐

Generic Carve Out page is populated on the Registration screen.

**Add/Edit Registration 2 - VCU HEALTH SYSTEM [Test UCI 4] - Generic Carve Out 1**

<b>Inv FSC1:</b> <span style="background-color: #007bff; color: white;">PRE-PPM NON-INDUSTRY</span> # 644	<b>Auto Liability AOB Dt:</b> <span style="border: 1px solid black; padding: 2px;"></span>
<b>Carrier Dict:</b> <span style="border: 1px solid black; padding: 2px;"></span>	<b>Auto Liability AOB Loc:</b> <span style="border: 1px solid black; padding: 2px;"></span>
<b>Carrier Nm:</b> <span style="border: 1px solid black; padding: 2px;">STUDY NAME</span>	<b>Rel:</b> <span style="border: 1px solid black; padding: 2px;"></span>
<b>Addr1:</b> <span style="border: 1px solid black; padding: 2px;">1 BILLING LANE</span>	<b>Insured Nm:</b> <span style="border: 1px solid black; padding: 2px;"></span>
<b>Addr2:</b> <span style="border: 1px solid black; padding: 2px;"></span>	<b>Insured Sex:</b> <span style="border: 1px solid black; padding: 2px;"><input type="checkbox"/></span>
<b>Cty,St:</b> <span style="border: 1px solid black; padding: 2px;">RICHMOND,VA</span>	<b>Insured DOB:</b> <span style="border: 1px solid black; padding: 2px;"></span>
<b>Zip:</b> <span style="border: 1px solid black; padding: 2px;">23298</span> <b>Tel:</b> <span style="border: 1px solid black; padding: 2px;">804-555-1212</span>	<b>Billing Contact:</b> <span style="border: 1px solid black; padding: 2px;">LINCOLN,ANGELA</span>
<b>Carrier Code #:</b> <span style="border: 1px solid black; padding: 2px;"></span>	<b>Contact Tel:</b> <span style="border: 1px solid black; padding: 2px;">804-555-1212</span>
<b>Group #:</b> <span style="border: 1px solid black; padding: 2px;"></span>	<b>Crime Date:</b> <span style="border: 1px solid black; padding: 2px;"></span>
<b>Eff Dt:</b> <span style="border: 1px solid black; padding: 2px;">08/01/2015</span> <b>Exp Dt:</b> <span style="border: 1px solid black; padding: 2px;"></span>	<b>Generate Claim?:</b> <span style="border: 1px solid black; padding: 2px;"><input type="checkbox"/></span>
<b>Carrier ID#:</b> <span style="border: 1px solid black; padding: 2px;">STUDY NAME</span>	<b>Auth #:</b> <span style="border: 1px solid black; padding: 2px;"></span>

<b>Comments:</b> <span style="border: 1px solid black; padding: 2px;"></span> <span style="border: 1px solid black; padding: 2px;"></span> <span style="border: 1px solid black; padding: 2px;"></span> <span style="border: 1px solid black; padding: 2px;"></span> <span style="border: 1px solid black; padding: 2px;"></span>	<b>IDX User Init:</b> <span style="border: 1px solid black; padding: 2px;">AEL</span> <b>Date Added/Updated:</b> <span style="border: 1px solid black; padding: 2px;">08/13/2015</span> <b>Payer Requires ICD-9 Code?:</b> <span style="border: 1px solid black; padding: 2px;"><input type="checkbox"/></span> <b>PI:</b> <span style="border: 1px solid black; padding: 2px;">GEYER,CHARLES</span> <b>STUDY#:</b> <span style="border: 1px solid black; padding: 2px;">IRB #</span>
---	---

- If on the appointment, "Should this service be billed to your health insurance (Y/N):" was answered "Y", validate the patient's Insurance is on the visit. If it was answered "N"

**Patient: TEST,ANGELA MRN: 8403475 DOB: 12/06/1973 Age: 41 Sex: F**  
**Patient: TEST,ANGELA MRN: 8403475 DOB: 12/06/1973 Age: 41 Sex: F**  
**Adm #: 310003286 Adm Dt: PTPY: OREC REVFC: 644 Prog: \*NA**  
**This visit has been Auto Final Verified**

PR	Plan	Company Name	Plan Description	FSC
1	Q644	STUDY NAME	PRE-PPM NON-INDUSTRY	644
			AUTO ASSIGNED SELF PAY	1

and a "FSC 1" was assigned, validate Insurance was assigned to the visit as seen below.

- If data on the appointment was missed, it can be added on the visit. During the arrival process, validate the NCT # and Study have been assigned on the visit screen.

**Patient: TEST,ANGELA MRN: 8403475 PTPY: OREC - Additional Visit Information**

**ADDITIONAL VISIT INFORMATION**

ADDITIONAL DATA 1		ADDITIONAL DATA 2	
Missing Copay Reason:	<input type="text"/>	Transfer Call ID:	<input type="text"/>
Arrival Mode:	<input type="text"/>	Hospital Do Not Bill Insurance:	<input type="checkbox"/>
Program:	NOT ASSIGNED	Alt Visit #:	<input type="text"/>
Outreach Org:	<input type="text"/>	TCR Flag:	<input type="checkbox"/>
<b>FLAGS/INDICATORS</b>		<b>CLINICAL TRIALS</b>	
Trauma Visit?	<input type="checkbox"/>	NCT #:	01816776
		Study:	CR-1005
		Back to Main Screen (Y):	<input checked="" type="checkbox"/>

\*\*\* NOTE\*\*\* If study cannot be found, file the visit without the NCT #. The Research Coordinator should forward the Billing Set up Forms and patient/appointment information to [ClinicalTrialsBilling@mcvh-vcu.edu](mailto:ClinicalTrialsBilling@mcvh-vcu.edu) to have the study added to the system and the patient's appointment updated.