Research Administration and Compliance Meeting
Wednesday, November 2, 2016  1:30 – 3:30 p.m.
Ball Conference Room, BioTech I

Agenda

Office of Sponsored Programs Update
- Tina Cunningham
- Annie Publow
- Melanie Wiggins

Grants & Contracts Accounting Update
- Mark Roberts

Special Movie Presentation
- Dishonesty: The Truth About Lies
Office of Sponsored Programs (OSP) Updates:
Annie Publow
Director, OSP-Government/NonProfit
RACM, November 1, 2016
OSP Update Topics

- OSP Staffing Update
- RAMS-SPOT Implementation
- Status of Administrative Actions Guidance & Training
- Submitting Closeout documentation to OSP
- NIH: Reminders
RAMS-SPOT Phased Implementation

Phase 1: Submission new funding proposals

- Went Live: May 1, 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
RAMS-SPOT Phased Implementation

Phase 2: Compliance Data, Awards, Continuation/Supplement Proposals, and Administrative Actions

➢ Went Live: May 31, 2016...Included these functions:

• Compliance Data (Subjects Protection, Intellectual Property, Export Control, Hazardous Materials, rDNA, HIPAA, Controlled Substances, Clinical Trial)
• Award processing (initial and subsequent actions)
• Funding Proposal Continuations/Supplements
• Administrative Actions (No Cost Extension, Progress Report, Effort Change, Change to Fiscally Administering Unit (FAU), Change of PI, Grant Relinquishment, etc.)
VPRI System-wide change affecting RAMS-SPOT implementation schedule

- Patch will be applied three times a year (January, May and September) about 2-3 weeks before the major NIH deadlines. This is targeted to allow for the incorporation of new forms and functionality from our vendor for the SF424.

- Patch schedule affects further RAMS-SPOT implementation.
RAMS-SPOT Phased Implementation

Phase 3: Subrecipients
- Target Go Live: January, 2017...to include:
  - Subrecipient Actions

Phase 4: Closeout and Reporting
- Target Go Live: May, 2017...to include:
  - Closeout (expanded options)
  - Reporting
OSP Update

- Administrative Actions (AA)
  - Guidance document and training still in development.
  - Anticipated before the end of the year.
  - In all cases, we certainly need whatever is called for by the sponsor terms and conditions, NOA, or executed agreement.
OSP Update

- Submitting Closeout documentation
  - No change to previous process
  - Use e-closeout forms available on OSP website:
    http://www.research.vcu.edu/forms/index.htm#osp_forms
OSP Update

• If you have processed a CP (continuation proposal) because your project will be continuing with more time and money...
• If you have processed a no cost time extension...
• If, for any reason, your project is not ending...

Then, please don’t process the e-closeout form
NIH: Reminders

Question:

When we submit a funding proposal to NIH, why do we usually select the “National Institutes of Health” (the collective agency) as our sponsor?
NIH: Reminders

Answer: We submit funding proposals to the National Institutes of Health collectively when the PA identifies more than one institute or center that supports that mechanism and/or announcement.
NIH: Reminders

23 of 27 NIH institutes and centers support PA 16-160 (parent announcement for R01)
Note: Not all NIH Institutes and Centers (ICs) participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest at the R01 IC-Specific Scientific Interests and Contact website. ICs that do not participate in this announcement will not consider applications for funding.
NIH: Reminders

Question:
When would we submit a funding proposal to a specific institute at NIH?
NIH: Reminders

Answer: We would submit a funding proposal to a specific institute at NIH when it is identified in the PA as the only institute supporting that mechanism and/or announcement.
<table>
<thead>
<tr>
<th>Participating Organization(s)</th>
<th>National Institutes of Health (NIH)</th>
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<tr>
<td>Components of Participating Organizations</td>
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<td>Funding Opportunity Title</td>
<td>New Computational Methods for Understanding the Functional Role of DNA Variants that are Associated with Mental Disorders (R01)</td>
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| Related Notices | - NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)  
- NOT-OD-16-006 - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015)  
- NOT-OD-16-011 - Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications (November 18, 2015)  
- June 4, 2014 - Notice NOT-14-074 supersedes instructions in Section III.3 regarding applications that are essentially the same. |
NIH: Reminders

Question:
Who has the primary responsibility to evaluate a program announcement’s applicability to any given proposal?
NIH: Reminders

Summary:

1. It is the responsibility of the PI/SS to select the correct PA for any given funding proposal.
2. Select “NIH” as your sponsor in RAMS-SPOT if the program announcement is supported by more than one NIH institute or center.
3. Select the specific institute or center at NIH if the PA is only supported by one institute or center.
Office of Sponsored Programs (OSP) Updates:
Melanie Wiggins
Director, OSP-Industry and Clinical Trials
November 2, 2016
OSP Industry Update Topics

Use of Accelerated Agreement Templates

(1) Approval to use Accelerated Clinical Trial Agreement (ACTA)

(2) Reminder: Confidential Disclosure Agreement (ACDA) Template
Accelerated Clinical Trial Agreement (ACTA)

- The ACTA is a clinical trial agreement template that was developed with input from approximately 25 Clinical and Translational Science Award (CTSA) institutions. The template initiative is being led by The CTSA Consortium Coordinating Center at Vanderbilt and has been coordinated with industry sponsors and the University Industry Development Partnership (UIDP).

- Similar to the ACDA, the ACTA serves as a mechanism to provide a standardized clinical trial agreement template to streamline and reduce contract negotiation between the parties.

- The ACTA is intended for use in industry sponsor-initiated multicenter trials. In order to use the ACTA template, both parties must agree to use the language as is without further negotiation.

- After several rounds of review by offices within VCU, including the General Counsel’s office, VCU is now registered as a voluntary user of the ACTA.

- [https://www.ara4us.org/acta/about](https://www.ara4us.org/acta/about)
How It Began

Contract negotiations are a complex process and are often identified as a major barrier to efficient study initiation. Data from a 2010 CTSA sites contracts processing study showed that an average contract terms negotiation time of 55 days could be reduced to 22 days if a ‘master agreement’ was used. As an attempt to remedy this hurdle, the CTSA Master Contracts Working Group, made up of legal experts from ~25 CTSA institutions, collaborated with industry and the University Industry Demonstration Partnership to develop a standardized clinical trial agreement – a single agreement to be used (voluntarily) by each participating institution and sponsor, to reduce contract negotiations for industry sponsored multi-site studies.

Benefits

The ACTA was prepared with the intent to facilitate relationships with industry sponsors that are interested in expediting the contract process thus optimizing lag time for research. The underlying principles used in the construction of the ACTA are that it represents a straightforward and unambiguous position which clearly sets forth the regulatory and contractual obligations of both parties, and presents language while perhaps not ideal to either party, is acceptable to both.

The ACTA has now been reviewed by several external sources (Pfizer, Epixyme, Shire) and feedback has been incorporated. There has been considerable interest from regional collaborations (e.g., MARCH, PACT, Ohio) as well as other groups (e.g., WIRB, Copemicus Group and MAGI) in regards to advancing this initiative.

The ACTA is now ready for broad dissemination and adoption. More than 50 organizations representing over 225 sites, including academic medical centers, universities, hospitals and physician practices, have agreed that the terms would be acceptable. Outreach has begun to approach Industry sponsors to initiate opportunities to pilot the use of the ACTA with 5 pilots currently active.
ACTA

- Currently, you can download a copy of the ACTA using your name, Institution and email
- [www.ara4us.org](http://www.ara4us.org)
Accelerated Clinical Trial Agreement

This Accelerated Clinical Trial (ACTA) Agreement ("Agreement") is made as of this {DAY} day of {MONTH}, {YEAR} (the "Effective Date") by and between {INSTITUTION NAME}, a non-profit, educational, research and healthcare institution ("Institution") with an address at {INSTITUTION ADDRESS} and {COMPANY NAME}, a corporation having its principal place of business at {COMPANY ADDRESS} ("Sponsor"). Sponsor and Institution are herein referred to collectively as "Parties." Individually, each of Sponsor and Institution is a "Party."

WHEREAS, the Institution and Sponsor have agreed to use the ACTA, to accelerate the process of translating laboratory discoveries into treatments for patients, to engage communities in clinical research efforts, and to train a new generation of clinical and translational researchers;

WHEREAS, Sponsor is a for-profit organization that intends to conduct a sponsored multicenter clinical trial, described in 1.1 below, involving the use of certain diagnostic(s), drug(s), device(s), or biologic(s) provided by Sponsor;

WHEREAS, the Institution has appropriate facilities and personnel with the qualification, training, knowledge, and experience necessary to conduct such a clinical trial; and

WHEREAS, the Study contemplated by this Agreement is of mutual interest and benefit to Institution and Sponsor, and will further the instructional and research objectives of Institution in a manner consistent with its status as a nonprofit educational, research and health care institution;

NOW, THEREFORE, in consideration for the mutual promises made in this Agreement and for valid consideration, the Parties agree as follows:
Use of the ACTA

OSP will develop a “locked” fillable PDF version of the ACTA to send to industry Sponsors to streamline contract negotiation.

Issue a compliance notice describing use of ACTA. Notice will be sent to via Research Administrator List Serve. Will post ACTA template on our website.

OSP will “target” smaller companies and those companies where we do not have Master Agreements in place.
Other ACTA Initiatives

- ACTA-CRO is intended for use when the Contract Research Organization (CRO) is the party to the clinical trial agreement rather than the Sponsor of the clinical trial. VCU has currently not yet vetted or registered to use.

- ACTA Prime plus Subcontract is intended for use when an Institution is the coordinating center and contracting with industry. **VCU has agreed to terms but template is not yet available for use.**

- FDP Fixed Price Clinical Trial Sub-award Agreement (F-CTSaA) for use when VCU is 1) either a pass through entity (we have received a grant from a federal source) and we want to subcontract to another University or 2) VCU is a subrecipient from another University on a federal funded clinical trial. A fillable PDF version is **now available for download:** [https://www.arq4us.org/downloads/fsct-download/](https://www.arq4us.org/downloads/fsct-download/)
Dear [Name]:

Attached as Exhibit A and incorporated herein, please find the Accelerated Clinical Trial Agreement - Coordinating Center ("Agreement") for the above referenced Study between [Institution], serving as the coordinating center ("Coordinating Center") for the Study Sites and [Sponsor].

Coordinating Center will reimburse Study Site in accordance with the Study specific payment synopsis that has been provided to Study Site separately by the Coordinating Center. It is understood by Study Site that Sponsor has retained Coordinating Center to administer the payments due Study Site hereunder and to coordinate and/or perform other Study activities. Payment to Study Site is contingent upon receipt of payment from Sponsor by Coordinating Center. Coordinating Center and Study Site agree that Sponsor shall have no obligation to provide any compensation directly to Study Site, and that once Sponsor pays Coordinating Center the compensation due for its activities hereunder, Sponsor's payment obligations regarding the activities shall be fully discharged.

By signing this Letter Agreement, Study Site agrees to be bound by the terms and conditions applicable to Study Site outlined herein and in the attached Agreement.

Sincerely,

[Signature]
FDP Fixed Price Clinical Trial Subaward Agreement

### FDP Fixed Price Clinical Trial Subaward Agreement

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<td>Cost Sharing (Attachment 5)</td>
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### Terms and Conditions

1. PTE hereby awards a fixed price subaward, as described above, to Subrecipient. The statement of work for this subaward is (check one) [ ] as specified in Subrecipient’s proposal dated [ ], or [ ] as shown in Attachment 5. In its performance of subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.

2. PTE shall provide funding in accordance with the Payment Schedule shown in Attachment 5. All invoices shall be submitted using Subrecipient’s standard invoice, but at a minimum shall include deliverables completed and milestone payment amount, subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments should be directed to the appropriate party’s Financial Contact, as shown in Attachments 3A and 3B.
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 “Submit Document 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.
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](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/](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.
Accelerated CDA Template

- The ACDA Template can be found on The Office of Research and Innovation website under Industry and Clinical Trial forms: http://www.research.vcu.edu/forms/index.htm

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**Industry & Clinical Trial**

- Accelerated CDA Template
- Clinical Research Compliance Documentation
- ClinicalTrials.gov Account Create Form
- WIRB Checklist
- Sample Clinical Trial Worksheet
- Clinical Research Coverage Analysis Forms
- E-Closeout Form-Industry Research
- E-Closeout Form-Clinical Research

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**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 [Name of Sponsor], a corporation having its principal place of business located at [Address of Sponsor] (“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: [Protocol Title or Protocol Number], and Institution desires to review information about the Study on behalf of [Name of Sponsor] (“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:

1) “Confidential Information” refers to information of any kind which is disclosed to the Institution by Sponsor to evaluate the Purpose which:

a) by appropriate marking, is identified as confidential and proprietary at the time of disclosure, or
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.
Questions

Office of Sponsored Programs:
ospred@vcu.edu
828-6772

OR

mwiggins@vcu.edu
Melanie Wiggins
827-4992