

Research Administration and Compliance Meeting
Wednesday, February 18, 2015 1:00 – 3:00 p.m.
Larrick Hall, Court End Ballroom A

Agenda

Special Guests - OEHS

- Office of Environmental Health and Safety Services

Research Administration and Compliance (ORAC)

- Compliance Notices Webpage
- Material Transfer and Data Use Agreements
- Principal Investigator Eligibility Policy
- NSF and NIH RCR Policy
- Investigator-Initiated IND/IDE Program Update

Sponsored Programs Updates (OSP)

- RAMS SPOT Testing, Pilot, and Implementation
- OMB Guidance (with Mark Roberts)

Office of Research Subjects Protection (ORSP)

- IACUC Process for Congruency Requests

Office of Research Integrity and Ethics (ORIE)

Grants & Contracts Updates (G&C)

- Staffing Update
- Current Data Entry and Accuracy Improvement Tasks in Progress
- Assistance Needed on Outstanding Checks

Clinical Research Services Updates (CRS)

- OnCore Financial Implementation Project
- CRS Education and Outreach Activities

Future Meeting Dates, 1-3 p.m., Larrick Hall, Court End Ballroom A

- April 29, 2015



Material Transfer and Data Use
Agreements:
Change in Process

Material Transfer Agreements

An MTA (Material Transfer Agreement) is a written contract that establishes legally binding terms and conditions whereby materials (pieces of technology, biological agents, or other tangible goods) may be transferred between the University and an external entity for academic or research purposes.

- Legal protections against certain types of liability
- Protects Researcher's right to publish results
- Protects Intellectual Property rights in which researcher and/or University may have an interest
- May require IRB, IACUC, and/or OEHS approval prior to execution

Data Use Agreements

A DUA (Data Use Agreement) is a written contract that establishes legally binding terms and conditions whereby Data may be transferred between the University and an external entity.

- Legal protections against certain types of liability
- Sets Confidentiality and security requirements
- Protects IP and publication rights
- May require IRB approval if PHI is included

General Purpose

- Obtain pilot data
- Verify results - compare with results already obtained with other materials or data
- Complete analysis or research per executed sponsored agreement

Process Change

Office of Research Administration and Compliance is responsible for all MTAs & DUAs as of January 1, 2015

“The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.”

Process Change

An MTA or DUA Submission form must accompany each request

- General questions to inform negotiation
- For projects not externally funded, Department Chair approval required – signifies Chair's approval and commitment of resources

Forms

http://www.research.vcu.edu/forms/mta_form.pdf

http://www.research.vcu.edu/forms/dua_form.pdf

Process Change

Submission form is needed *even when there is no negotiation required*

- On-line Orders from Research Repositories (e.g., NCI, Addgene) automatically generate an MTA that requires approval of the Authorized Official
- Access to certain datasets (e.g., DBGaP) requires agreeing to certain terms

Process Change

If possible, use our Standard Agreements when requesting materials or data

- Attach appropriate agreement template to initial request
- Will speed up negotiation process

Will be posted on website very soon.

Upcoming Process Change

- Ultimately, MTAs and DUAs will be submitted via the RAMS SPOT system.
- RAMS SPOT will replace InfoEd as VCU's proposal submission system this Spring and award database this Fall.
- Timeframe announcements will be sent to the ResAdm List Serve when available.

Outgoing Materials or Data

- Outside entity wants to obtain data or materials from one of our faculty
- Ensure adequate handling and protection of data or materials
- Ensure proper shipping
- Most often involve Innovation Gateway and/or OEHS in review of these agreements

Inappropriate Use

An MTA or DUA should not be used to do work that ought to be a Sponsored Project

- Conducting research or data analysis for an outside entity that cannot afford to pay
- Doing work as a “favor” for a previous Sponsor

What's In A Name?

Any agreement that involves the transfer of materials or data that is not a sponsored research agreement fall under the MTA/DUA process. Some examples:

- Confidentiality Agreement
- Non-Disclosure Agreement
- Memorandum of Agreement

Contact

MTA/DUA Contract Manager

Kristin L. Schmidt

828-6488

mtadua@vcu.edu

If in doubt, please ask!

Questions are always welcome.



VCU

VIRGINIA COMMONWEALTH UNIVERSITY

Principal Investigator Eligibility

Purpose

- Best practice for IHEs
- Ensure Chairs and Deans are aware of exceptions
- Obtain commitment from individual

Principal Investigator Eligibility

- Sponsored Projects
 - Full-time faculty member
 - Pre- or post-doctoral scholar on a trainee grant
- Human Subject Protocols
 - Permanent, full-time or part-time employee of Virginia Commonwealth University or the Virginia Commonwealth University Health System Authority
- Animal Protocols
 - Full-time faculty member
 - Pre or post-doctoral scholar on a trainee grant
- Effective immediately for all new proposals and protocols

Exceptions

- Sponsored Projects
 - Case-by-case approval by VPR*
- Human Subject Protocols
 - Non-employee with a VCU faculty appointment who will conduct research within the scope of his/her appointment and provides the following to the IRB for review:
 - a) a copy of the appointment letter and
 - b) the VCU IRB PI Eligibility Request form**
- Animal Protocols
 - Individuals who have a contractual relationship with VCU*
 - Case-by-case approval by VPR*

*Principal Investigator Eligibility Exception Form (must be approved by Chair and Dean to be considered by VPR).

**VCU IRB PI Eligibility Request Form (must be approved by Chair and Dean)

Exception Request Reviews

- In making the case-by-case determination, several factors are considered; however, special attention will be applied to:
 - 1. Commitment of proposed PI to project timeline and project administration
 - 2. Academic quality of proposal
 - 3. Qualifications of proposed PI
 - 4. Relevance and importance of proposal to other University interests

Policy and Forms

- [Principal Investigator Eligibility Policy](#)
- [Principal Investigator Eligibility Exception Form](#)
- [VCU IRB Principal Investigator Eligibility Exception Form](#)



VCU

VIRGINIA COMMONWEALTH UNIVERSITY

NSF AND NIH RCR TRAINING COMPLIANCE UPDATE

Quinton Johnson

Senior Research Compliance Analyst

Office of Research

Background

This policy describes requirements for compliance with Responsible Conduct of Research Training for undergraduate students, graduate students, and postdoctoral researchers funded by NSF and NIH grants.

NSF's OIG Report

■ RCR Training in the Spotlight

- “Report on Research Compliance” Jan 2014 Conducted by NSF's OIG:
 - “The NSF faces eight ‘issue areas that reflect fundamental program risk’ and that are ‘likely to require management’s attention for years to come’... The areas include... ‘encouraging ethical conduct of research’ among others. NSF’s Office of Inspector General also said its ‘site visits and investigations’ indicate that awardee institutions may not be complying with NSF’s requirement for training in the responsible conduct of research.”

VCU Legal counsel advice

- VCU Legal Counsel has recommended we add additional consequences for non-compliance
 - The “NSF and NIH Responsible Conduct of Research (RCR) Training Requirements” now states:
 - “In the event that an undergraduate student, graduate student, or postdoctoral researcher fails to complete the required RCR training, the salaries and/or wages along with any associated fringe benefits for that individual must be removed from the NSF funded project. The PI’s program or department will be responsible for covering any salary, wages, and fringe benefits determined unallowable as a result of noncompliance with this policy.”

Additional Major Changes to the Policy

1. The distinction between Education and Training

Education: is administered at the program level and represents VCU's commitment to conduct responsible and ethical research

Training: is tracked by the Office of Research and Innovation and is intended to meet specific NSF compliance standards.

2. Updates to CITI course availability

CITI courses represent an online training alternative for RCR that can be completed at any time. CITI offerings have been expanded to all undergraduate level researchers.

3. New system for tracking RCR training completion

A RedCap survey will be used to track RCR training completion

Questions?

- [VCU RCR Course Matrix](#)
- [RCR Training Completion Form](#)

VCU Faculty Held IND/IDE

The “Elizabeth Program”

- Elizabeth (**Betsy**) Ripley
- Elizabeth (**Beth**) Stoddert

Faculty Held IND/IDE

Investigational New Drug/Investigational Device Exemption

- **Website** (Tools, Templates, Links, Handbook):

http://www.research.vcu.edu/IND_IDE

- **REDCap** for submissions:

<https://redcap.vcu.edu/rc/surveys/?s=Xbd3YgHxFe>

- **Contacts:**

– Betsy Ripley, MD, MS at eripley@mcvh-vcu.edu

804-828-1955, 804-687-3062

– Beth Stoddert at estoddert@vcu.edu 804-828-0819

Faculty Held IND/IDE

Investigational New Drug/Investigational Device Exemption

- **August 1, 2014**

All IND/IDE applications must be submitted to the VCU Clinical Research Compliance Officer prior to submission to FDA.

- Not a formal review. Once submitted and acknowledged can be sent to FDA
- All communication with the FDA needs to be sent to the CRCO.

- **September 15, 2014**

All current IND/IDEs must be reported to the CRCO

- **Starting last Fall**

Audits of all protocols related to these

IDE: Investigational Device Exemption

- **Significant Risk SR:** Requires submission and approval of both IRB and FDA
- **Nonsignificant Risk NSR:** Requires submission and approval of the IRB which acts as a surrogate for the FDA.

**BOTH SR and NSR IDEs
need to be reported to the CRCO.**

VCU Mandatory Good Clinical Practice (GCP) Training

What is the Training?

Effective Feb. 1, 2015, the Good Clinical Practice Module “The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices” from the Collaborative Institute Training Initiative (CITI) will be required. This requirement supports the VCU Quest for Distinction goal to enhance VCU Clinical Research/Clinical Trial quality.

Who Does this Training Requirement Apply To?

All study personnel* listed on a new or continuing review IRB protocol involved in executing a drug, device, biologic and/or behavioral intervention that meets the NIH definition of clinical trial** are required to complete the **Good Clinical Practice (GCP)** module through the Collaborative Institute Training Initiative (CITI) course. This training will be required every three years.

Definitions:

***Study Personnel:** Individuals listed on the IRB protocol. This includes all VCU and VCUHS employees, all VCU students and Community Research Partners that are involved with clinical interventions.

****Clinical Trial:** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Additional Contact Information

<http://go.vcu.edu/indide>

indide@vcu.edu



Research Administration & Compliance Meeting

February 18, 2015

Annie Publow, Director, OSP,
Government/NonProfit

Office of Sponsored Programs Updates

Presentation Topics:

- RAMS-SPOT –
 - Implementation Status
 - System Access for Administrators
 - Messaging and Communications
- OMB Uniform Guidance - Update

VPRI Click Commerce Modules

Research Administration Management System (RAMS)

- **In Production**

- IACUC – live April 2011 – 300 approved protocols
- COI (AIRS) – live August 2012 – 3700 financial interest reports
- IRB – live September 2013 – 2500 approved protocols

- **In Development**

- Sponsored Projects
 - Phase 1 (proposal submissions and pre-award) – May 1, 2015
 - Phase 2 (awards) – target October 1, 2015
- Animal Operations / CORE Services
 - Animal Ordering / Billing / CORE Services – 3rd quarter 2015
 - Census – 1st quarter 2016



RAMS-SPOT

Research Administration Management System-Sponsored Programs Online Tracking

- Database for sponsored projects administration and submission (Vendor= Click Commerce)
- Will replace “VCUeRA” (Vendor=InfoEd)
- Internal discussions began early 2013
- All records will be electronic

RAMS-SPOT

Goals of the System include:

- Paperless routing (all major project transactions)
- Paperless record storage
- Budgeting in system (including revisions)
- Communications in system
- All documents can be scanned directly to record
- Improved task management for all users
- Will streamline processes and reduce need for forms
- Establishes Office of Research and Innovation Organizational Structure and improves security

RAMS-SPOT Phased Implementation

Phase 1: Submission new funding proposals

➤ Includes...

- 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

➤ Target for Pilot Testing: March 2015

➤ Target Soft Launch: April 2015

➤ Target Go Live: May 2015



RAMS-SPOT Phased Implementation

Phase 2: Awards and Post Award activities

- Includes...
 - Award processing (initial and subsequent actions)
 - Funding Proposal Continuations/Supplements
 - Post Award Actions (Prior Approval, Expanded Authority, Progress Reports)
 - Subaward/Subrecipient (initial and subsequent actions)
- Target Go Live: October 1, 2015
- Basic award data from InfoEd will be imported into RAMS-SPOT (late summer/early fall)



RAMS-SPOT Phased Implementation

Phase 3: Closeout and Reporting

- Includes...
 - Closeout
 - Reporting
 - Subaward/Subrecipient Actions (if not completed in Phase 2)
- Target Go Live: December 1, 2015

- Effective with proposal submission in RAMS-SPOT, we will be working in two systems (VCUeRA/InfoEd and RAMS-SPOT/Click Commerce)
- InfoEd system of record for FY2015 (ending June 30, 2015)
- RAMS-SPOT system of record for FY2016 (July 1, 2015-June 30, 2016)



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 |
|----------------------|---|--------------|---------------|------------|------------|----------|-----------|-----------|-------------|----------------|--------------|---------------|---------------|
| InfoEd | Continue InfoEd Use | Green | Green | Green | Green | Green | Green | Green | Green | Green | Blue | Blue | Blue |
| | New Proposals (IAF package) | Green | Green | Green | Green | Blue | Blue | Blue | Blue | Blue | Blue | Blue | Blue |
| | Continuation Proposals (IAF package) | Green | Green | Green | Green | Green | Green | Green | Green | Green | Blue | Blue | Blue |
| | Awards & Post Award Actions | Green | Green | Green | Green | Green | Green | Green | Green | Green | Blue | Blue | Blue |
| | Data Conversion | White | White | White | White | White | Blue | Blue | Blue | Blue | Red | White | White |
| RAMS-SPOT Phase 1 | Funding Proposal (new proposals, pre-proposals and task orders) | Grey | Green | Green | Purple | Green | Green | Green | Green | Green | Green | Green | Green |
| | Pre-Award Review Projects: Unilateral/Bilateral/Clinical Trial/Master Agreements, CDAs, MTAs, DUAs, JIT, Export Control | Grey | Green | Green | Purple | Green | Green | Green | Green | Green | Green | Green | Green |
| RAMS-SPOT Phase 2 | Awards-Initial & Subsequent | White | White | White | Yellow | Yellow | Blue | Blue | Red | Grey | Green | Green | Green |
| | Awards-Subsequent | White | White | White | Yellow | Yellow | Blue | Blue | Red | Grey | Green | Green | Green |
| | Funding Proposal Continuations | White | White | White | Yellow | Yellow | Blue | Blue | Red | Grey | Green | Green | Green |
| | Post Award Review Projects (prior approval, expanded authority, progress report) | White | White | White | Yellow | Yellow | Blue | Blue | Red | Grey | Green | Green | Green |
| | Subawards-Initial & Subsequent | White | White | White | Yellow | Yellow | Blue | Blue | Red | Grey | Green | Green | Green |
| RAMS-SPOT Phase 3 | Closeout | White | White | White | White | White | White | White | White | Yellow | Blue | Red | Green |
| | Reports | White | White | Yellow | Yellow | Yellow | Blue | Blue | Red | Grey | Green | Green | Green |

version 1/29/2015

Design Work
Development
Testing

Pilot Test
Soft Launch
In Production

Training
Out of Service



| Activity | VCUeRA InfoEd | RAMS-SPOT | Timing of Transition to RAMS-SPOT |
|--------------------------------------|--|---|-----------------------------------|
| Internal Approval Form (IAF) | Required for all new proposals, task orders, LOI/preproposals requiring OSP signature. | Will be replaced by Funding Proposal (FP) Smart Form (in system). | April (soft launch), May |
| | Required for all continuation proposals until transition to RAMS-SPOT. IAF will be updated in April to allow for "continuation" and "supplement" only. | TBD | Transition target October, 2015 |
| Advance PT# Request | Required for all proposals until transition to RAMS-SPOT. (E-form option will be removed from website late April.) | Will be replaced by FP#-issued by system when PI/admin creates funding proposal. | April (soft launch), May |
| Advance SC# Request | Required for all new task orders until transition to RAMS-SPOT. (E-form option will be removed from website late April.) | Will be replaced by FP#-issued by system with PI/admin creates funding proposal. | April (soft launch), May |
| NIH proposal submission (non-ASSIST) | PD# assigned by system when PI/admin creates proposal shell in InfoEd. | Will be replaced by FP#-issued by system when PI/admin creates funding proposal. | April (soft launch), May |
| New proposal, non Grants.gov | Advance PT# request, IAF, budget worksheet, cost share form. | Will be replaced by FP-Smart Form, Budget Grid and Cost Share Budget Grid (in system). FP#-issued by system when PI/admin creates funding proposal. | April (soft launch), May |
| Grants.gov proposals | Non-NIH Grants.gov proposals are created as separate packages and sent to OSP through File drop or email (Advance PT#, IAF required). | Grants.gov opportunity can be selected in Funding Proposal-Smart Form. Grants.gov package will be built by RAMS-SPOT. Will be replaced by FP-Smart Form, Budget Grid and Cost Share Budget Grid (in system). | April (soft launch), May |
| Budget Worksheet (excel) | Required when sponsor budget template does not provide sufficient detail of costing estimates. | Will be replaced by Budget Grid (in system). Note that OSP must always receive a costing estimate/budget that provided sufficient level of detail. | April (soft launch), May |
| Transaction Routing Form | Used to categorize document/action request, provided at drop off to OSP or when sent to dirospa@vcu.edu. | In-system document drop off becomes an option and would replace need for form. In-system drop off intended for non-proposal documents such as agreements. Proposal-related documents will be uploaded by PI/admin to the proposal itself. | April (soft launch), May |



System Access and Edit/Approval Management RAMS-SPOT

- RAMS-SPOT enabled for all VCU faculty and staff with EID access
- Committee on the Administration of Research (CAR) members for each School/College/Massey will manage Edit and View access privileges for records in the system



The screenshot shows the VCU Office of Research and Innovation website. The header includes the VCU logo and the text "VIRGINIA COMMONWEALTH UNIVERSITY" and "Make it real.". Below the header is a navigation bar with "Office of Research and Innovation" and "Integrity & Compliance". The main content area is titled "Integrity & Compliance » Meeting Information - CAR and RACM". It features a section for the "Committee on the Administration of Research (CAR)" with a description: "The Committee on the Administration of Research (CAR), established by the Research Development Advisory Council (ReDAC) in May 2009, meets bi-monthly from 3:00 – 4:30 p.m. in Room 3060 BioTech One. Members are appointed by research deans and directors. Meeting dates are posted below." There are also links for "Purpose" and "Membership" with document icons.

RAMS-SPOT Org Structure

Customized ORG Structure based on HR data

- Create VPR Org Structure limited to the following five levels for Access Management (no exceptions to 5 levels):
 1. Organization--→VCU
 2. Executive-----→MCV/MP Campuses
 3. Senior-----→CAR members-School/College/Massey
 4. Business-----→Department
 5. Division-----→Division

RAMS-SPOT Implementation

Messaging and Communications

- Will continue to communicate directly with CAR members
- Will continue to provide updates via Research Administration and Compliance Meetings (general audience)
- OSP website resources <http://www.research.vcu.edu/osp/rams-spot.htm>
 - Training Library of online video tutorials
 - Implementation Updates
- RAMS-SPOT Demonstration/Training events will be announced via ResAdmin listserve

RAMS-SPOT Implementation Summary

Top 5 Things to Prepare for RAMS-SPOT

1. Work with OSP Post Award to close out existing sponsored projects (in InfoEd) with completed period of performance
2. Understand how your CAR member will authorize edit access to RAMS-SPOT for your School, College or Center
3. Attend RAMS-SPOT Demonstration and Training events and utilize OSP website resources <http://www.research.vcu.edu/osp/rams-spot.htm>
4. Anticipate proposals due during systems transition period:
April - September 2015
5. Disseminate information to PIs



Uniform Guidance Implementation at VCU

Top 5 Things You can do to Acclimate to UG:

- Utilize Federal Uniform Guidance Implementation at VCU resources on OSP and G&C websites:
 1. Uniform Guidance Training Presentation (25 minutes)--Learn what is the same and what is different.
 2. Quick Reference #1 [Topics include Indirect Costs, Direct costing of Administrative/Clerical salaries, Participant Support Costs, Equipment, Computing Devices, Performance Measurement and Reporting, Fixed Amount Awards, and Fixed Amount Subawards]
 3. Utilize explanatory letters: “VCU IDC Uniform Guidance Letter to Sponsor” and VCU IDC Uniform Guidance Letter to Subrecipient”
 4. Process final project expenses and corrections timely. (Federal agencies have already initiated stricter enforcement of 90 day close-out/final invoice federal requirement. Some agencies moving to 120 days-just enough time if subrecipients are involved.)
 5. Monitor ResAdmin List serve for additional updates and disseminate information to your PIs.



Research Administration and Compliance Meeting

Clinical Research Services Update

Fredika A Robertson, PhD
Executive Director, Clinical Research Services
Center for Clinical and Translational Research
Centralized Clinical Trial Administration
Professor, Hematology/Oncology and Palliative Care

February 18,2015

Use of OnCore Clinical Research Management System at VCU

- OnCore Provides a Clinical Research Database for the VCU Enterprise
- OnCore Allows for Audit/Monitoring of Applicable Clinical Research to Ensure FDA IND/IDE Regulatory Compliance with VCU Compliance Officer, OVPRI
- OnCore Provides Oversight of Sponsor Invoicing for Clinical Research Financial Compliance
- OnCore will serve as IRB Approved Protocol Documents, Informed Consentss

OnCoreFinancial Pilot is Ongoing with the Goal to Address Gaps in Clinical Trial Administration

- **OnCore Financial Console** Central Location for Clinical Trial Budgets, Cost Coverage Analysis, Billing Grids, and Sponsor Invoicing Based on Chargemaster and Study Calendars
- **OnCore PC Console** Central Repository for IRB Approved Documents- eg, Protocols, ICF.
- **OnCore Subject Console** Central Location for Participant Registration and Study Calendars to Track Study Visits and Procedures Performed.
- **OnCore Audit Console** Central Location for Audit/Monitoring Documents, FDA IND/IDE Documents

Financial Pilot Project Team

Huron Consulting Group

Michelle Faurot
Project Manager

Javier Gonzalez
Project Consultant

Clinical Research Services

Fredika Robertson
Executive Director of Clinical Research Services

Kimberly Bradley
Clinical Coordinator
Team Manager

Robert Moulden
OnCore Manager

Mary O'Connell
OnCore Educator/
Trainer

John Thrift
Billing Compliance
Manager

Sara Twombly
Clinical Research
Services Program
Manager

VCU School of Medicine

Tricia Zeh
Director of
Research
Administration

Elham Almousa
Manager of Clinical
Research
Administration and
Billing Compliance

Joshua Dickerson
Clinical Research
Billing & Compliance
Analyst

Massey Cancer Center

Robert Houlihan
Senior Director of
Research
Administration

Juel Gadd
Senior Clinical
Research
Administrator

Katherine Jackson
Clinical Research
Administrator

David Fenstermacher
Chief Research
Information Officer,
VCU Office of
Research and
Innovation, VCUHS,
Massey Cancer
Center, Director of
Informatics CCTR

VCU Office of Research/Grant and Contracts

Gloria Foote
Associate Director,
Grants and Contracts

Crystal Monroe
Team Leader, Grants
and Contracts

VCU Health System

Quincy Byrdsong
Vice President of Clinical
Research Administration and
Compliance, VCU Associate VP
for Health Science-Strategic
Initiatives and Engagement

Elizabeth Micalizzi
OSVPHS Director,
Strategic Projects and
Integrated
Technology

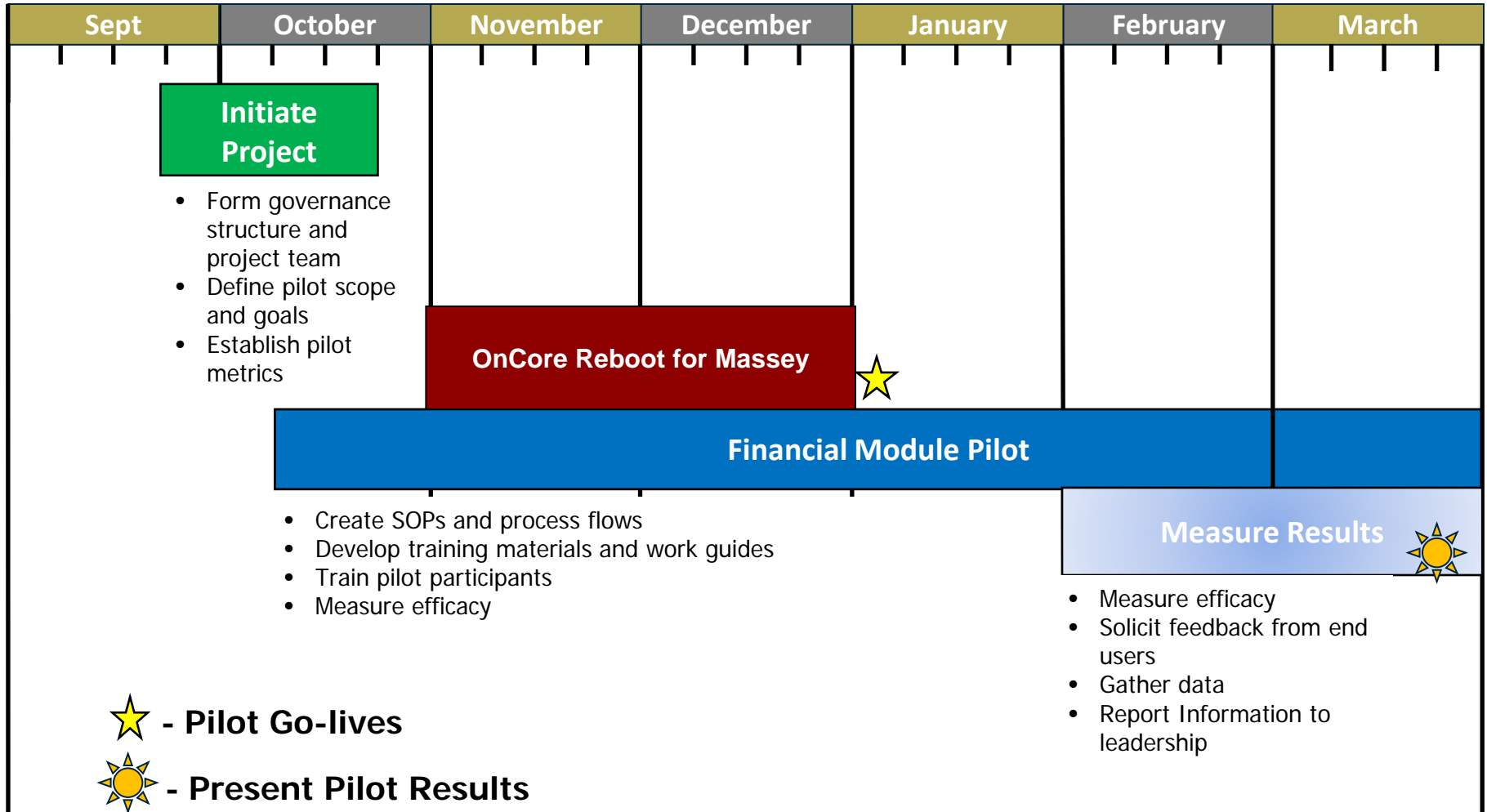
Alice Fowler
MCV Physicians
Supervisor of
Special Accounts

Marga Johnson
MCV Hospital
Associate Director
Patient Accounting

Angela Lincoln
Application Analyst,
Access Support
Team

Terri Rositch
MCV Physicians
Associate Director
Billing, Special
Accounts

Timeline



Phase I (complete): Completed MCC Implementation of OnCore Protocol Management and Subject Management Consoles

Phase II (complete): Collaborative harmonization of VCU Enterprise-wide standards for clinical research administration and management.

1: SOM Pediatrics, Cardiology, and Surgery early adoption of primary modules supporting evaluation of scope of standards/needs

2: CRS Pilot Test of Harmonized Standards (Protocol and Subject Management Consoles)

3: RedCap 'registration' process in place to support registration of all clinical research and clinical trials (qualifying for expedited or full board VCU IRB/WIRB review).

Phase III (ongoing): Concurrent Goals:

Expand implementation of Full Functionality of OnCore PC, [Subject and Financial Consoles]

1: Complete Financial Console Pilot Project – Massey, SOM

2: Massey and SOM – Implement Full Functionality of OnCore

3: Enterprise Wide VCU:

– Implement Full Functionality of OnCore

Phase IV (upcoming): Establish long-term management and governance strategy for OnCore Use Across VCU Enterprise

OnCore Education/Training Tools- OnCore Wiki Pages and Online Web-based Training Tools

Purpose

- **Provides on-line 24/7 accessible training for all OnCore Consoles**
- **Provides support for study team members for use of OnCore**
- **Provides Training Videos for Subject Entry Shortcuts for study teams –"widgets"**

<http://go.vcu.edu/wiki>

CCRA Wiki Pages- OnCore



VCU

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Make it real.

[OnCore](#) / [Restricted](#)

VCU OnCore Wiki

[Edit](#) [Watch](#) [Share](#) [Tools](#)

Created by wikiadmin, last modified by Robert B Moulden about 3 hours ago

[Submit/Update your Study](#)

[New OnCore User Form](#)

[OnCore Password Reset](#)

[Comments or Questions?](#)

About OnCore

[Introduction to OnCore](#)

[What kind of studies will be tracked in OnCore?](#)

[OnCore Financial Implementation](#)

[OnCore/Study Interactions Flowsheet](#)

OnCore Training Materials

- [Documents](#)
 - [Protocol and Subject Entry Manual](#)
 - [OnCore Budget/Contract Entry](#)
 - [OnCore CPT Code Entry](#)
 - [OnCore Sponsor Invoicing](#)
 - [Non Oncology Subject Entry](#)
 - [Massey Employees Subject Entry](#)
 - [Massey Affiliate Subject Entry](#)
- [Field Definitions](#)
 - [Audit Console - Field Definitions](#)
 - [PC Console - Field Definitions](#)
 - [Subject Console - Field Definitions](#)
- [Extra Materials](#)
 - [Frequently Asked Questions \(F.A.Q.s\)](#)
 - [Training Videos](#)
 - [Onsemble](#)

Need Help? - Email: oncore@vcu.edu

| Name | Email | Phone | Department |
|----------------|--|--------------|------------|
| Bobby Moulden | rbmoulden@vcu.edu | 804-628-1991 | CRS |
| Mary O'Connell | oconnellm@vcu.edu | 804-828-0228 | CRS |
| Linda Walker | lmwalker2@vcu.edu | 804-628-1810 | CRS |
| Travis Oakes | toakes@vcu.edu | 804-628-1920 | Massey |
| Daniel Hudson | djhdson@vcu.edu | 804-628-2682 | Massey |

Group Pages

- [Audit and Monitoring Group](#)
- [OnCore Financial Pilot](#)
- [Virtify Implementation](#)
- [Clinical Research Advisory Board \(CRAB\)](#)
 - [CRAB Sub-Committee: Clinical Research Activation](#)

Other Wiki Areas

- [Centralized Clinical Research Administration](#)
 - [Clinical Research Services](#)
 - [Clinical Research Coordinator Support Wiki](#)
 - [CITI Training: Human Subjects Protection and Good Clinical Practice](#)
 - [Compliance Notices](#)
- [Massey Cancer Center Wiki Page](#)

OnCore Support Team

- Oncore@vcu.edu
- Bobby Moulden, OnCore Program Manager
rbmoulden@vcu.edu
- Mary O'Connell, Certified OnCore Trainer/Educator
oconnellm@vcu.edu
- Kimberly Bradley, OnCore Coordinator Education Liaison
and CRS Coordinator Manager
kbb Bradley@vcu.edu
- Linda Walker, OnCore Analyst/Calendar Builder

Update on Clinical Research Services Education and Outreach Activities

**Provides Information About Services
Provided by CRS and CRS Unit and How We
Facilitate Clinical Research
Across the VCU Enterprise**

Presentation Content

- **CRS Mission & Vision**
- **CRS Structure**
- **CRS Resources and Services: The Who, Where, What and How**
 - Financial Office: Budget, Sponsor Liaison
 - Regulatory Services
 - Clinical Research Unit Services
 - Clinical Research Coordinators
- **Institutional Resources & Requirements**
 - Clinical Research Management System (CRMS): OnCore
 - Good Clinical Practice (GCP) Training
 - CCTR “TriCore”- bioinformatics support
- **CRS Information, Policies, Procedures, Processes & Pricing:**
 - How to Access CRS Resources & Services
 - WIKI

CRS Mission & Vision

The Bridge to Success in Clinical Research

- CRS strives to be the model of excellence for the conduct of clinical research
- CRS provides:
 - Exceptional customer service
 - Highest quality of safety & care for research participants
 - Assurance of Clinical Research data quality & integrity
 - Actively engaged & responsive extension of study team

CRS Structure

- In 2010, NIH awarded the Clinical & Translation Science Award (CTSA) to VCU.
- The CCTR is the VCU home for the CTSA award under which CRS is a component.
- Current NIH mandates cost recovery for all CRS resources and services.
- The CTSA does **NOT** provide funding for CRS Clinical Research Unit Services (North 8 facilities, clinical staff).
- CRS is an Ancillary Service and the VCUHS charge-master rates apply as with Radiology, Pathology, and other Ancillary Services.

CRS Resources and Services: Who, Where, What

- Financial Office: Budget & Sponsor Liaison
- Regulatory Services
- Clinical Research Unit Services
 - North 8 Facilities & Equipment
 - Nursing Services
 - Bionutrition Services
- Clinical Research Coordinators

CRS Resources and Services:

Whom do we serve?

- K Scholars & Junior Investigators
 - support & education for clinical research
- Senior Investigators
 - specific research study needs (e.g. Clinical Coordinators, Budget Development, Regulatory, Clinical Research Unit Services)
- All Investigators/Study Teams
 - OnCore support
 - GCP training
 - SoCRA certification
- VCU Institutional Clinical Research Infrastructure

Requesting CRS Resources & Services

- Requests for **ANY** CRS Resource/Service must be initiated by completing the VCUHS ancillary service request form.

<http://go.vcu.edu/ancillaryrequest>

- Click on Clinical Research Services under ancillary service requested and a short additional form specific to the CRS is needed.

CCRA Wiki Pages- Home

 Spaces ▾ People Browse ▾ [Create](#)

Home

- Ancillary Service Request
- ✓ Clinical Research Budgeting and Financial Management
 - Budgeting Best Practices Working Group
- ✓ Clinical Research Coordinator Support
 - Coordinator Conversations
 - CRCC By Laws
 - Regulations
 - Clinical Trial Educational Materials
 - Past Meetings
- ✓ Clinical Research Services
 - Cite the grant
 - CRS key contacts
 - CRS Leadership
 - For research teams
 - For sponsors
 - For Study Participants
 - Policies, Procedures, Processes, and Pricing
 - Research Ethics and Responsible Conduct of Research
 - Services
 - VCU-VCUHS Joint Clinical Research Institutional Billing Procedure
 - VCU Vision for Clinical Trials
 - CRS Outreach Working Group
- ✓ Good Clinical Practice (GCP)
 - GCP Topic of the week
- ✓ Wiki Training
 - Confluence Training

 **VCU** VIRGINIA COMMON

 [Centralized Clinical Research Administration](#)

Centralized Clinical Research Administration Home

Created by wikiadmin, last modified by Robert B Moulden on Jan 26, 2015

CCRA Pages

- [VCU Oncore Wiki](#)
- [Clinical Research Coordinator Support](#)
- [Clinical Research Budgeting and Financial Management](#)
- [Ancillary Service Requests/Providers](#)
- [Clinical Research Services](#)
- [Good Clinical Practice \(GCP\)](#)
- [Research Compliance](#)

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CCRA Wiki Pages- CRS



Clinical Research Services

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The Center for Clinical and Translational Research at Virginia Commonwealth University established the Clinical Research Services to support investigators in the conduct of clinical research studies

Our mission is to augment, cultivate, facilitate, and refine high-quality, subject-oriented clinical research. We partner with the VCU Health System, Office of Sponsored Programs, the IRB and other university and hospital service providers to standardize, streamline and support clinical research efforts.

The safety and support of research participants is paramount. We provide clinical research training, expertise and opportunities; enhance administrative, operational and resource efficiencies to support clinical research; and support the discovery of safe, effective and timely treatment options for the communities we serve.

While our mission is to provide mechanisms for quality clinical research, the overarching goal is to improve the overall health and wellness of our community.

Links

[Policies, Procedures, Processes, and Pricing](#)

[For research teams](#)

[For sponsors](#)

[For Study Participants](#)

[Services](#)

Resources

[Cite the grant](#)

[Research Ethics and Responsible Conduct of Research](#)

[VCU-VCUHS Joint Clinical Research Institutional Billing](#)

Clinical Trials at CRS

[What is a Clinical Trial?](#)

[VCU Vision for Clinical Trials](#)

[CRS key contacts](#)

CRS Leadership Area

Contact us

[View the Clinical Research Services staff »](#)

Clinical Research Services is an ancillary service and requests for resources and services are accessed through the [VCUHS Ancillary Service Request Form](#). Following the electronic submission of this form, the [CRS resources and services requested will be reviewed](#). If any additional information is needed, a CRS representative will contact you.

If you are a sponsor and would like to consider VCU as a site for a study, please contact the [Clinical Research Services Program Manager](#) or [Manager of Clinical Trial Administration](#) or email CRSAdmin@vcu.edu.

News & Events

[SoCRA Exam and CRS Prep Program](#)

Are you interested in becoming a Certified Clinical Research Professional?

VCU's Center for Clinical and Translational Research (CCTR) is hosting The Society of Clinical Research Associates (SoCRA) certification exam again this

Clinical Research Information



- go.vcu.edu/ccra
- Enter eID
- All CRS policies, pricing, standard operating procedures
- Institutional requirement information
- All CRS Clinical Research related activities

go.vcu.edu/ccra