# Research Administration and Compliance Meeting
# Wednesday, October 29, 2014 1:00 – 3:00 p.m.
# Larrick Hall, Court End Ballroom B

## Agenda

**Research Administration and Compliance (ORAC)**

- Controlled Substances Registration Requirement Changes
- Dual Use Research of Concern
- Integrity & Compliance Webpages

**Sponsored Programs Updates (OSP)**

- NIH Issues New Definition of Clinical Trial
- RAMS SPOT Testing, Pilot, and Implementation
- OMB Guidance (with Mark Roberts)

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

- PI Eligibility for Submitting to the IRB

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

- Research Misconduct – "Just the Facts"

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

- New Industry Clinical Trial 30% FACR Distribution Code
- New 90 Day Notice Follow Up
- Effort Reporting IBS Definition
- Training Update

**Clinical Research Services Updates (CRS)**

- Financial Console Implementation Update

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

- February 18, 2015
- April 29, 2015


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VIRGINIA COMMONWEALTH UNIVERSITY

# Research Administration And Compliance Update

October 29, 2014

# Controlled Substances Registration Requirements Changes

- Previous concession to allow Registrants to transport small amounts of substances to other buildings has been rescinded
- Registrants must store their inventory in the building where substances will be used
- We are attempting to identify space within DAR facilities for storage
- Have used “buddy” system to date

# Dual Use Research of Concern

- OSTP released policy on 9/24/2014
- 15 high-consequence agents and toxins
- 7 categories of experiments
- Policy available at:
- http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

# Dual Use Research of Concern

Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

# Dual Use Research of Concern Agents and Toxins

a) Avian influenza virus (highly pathogenic)

b) Bacillus anthracis

c) Botulinum neurotoxin

d) Burkholderia mallei

e) Burkholderia pseudomallei

f) Ebola virus

g) Foot-and-mouth disease virus

h) Francisella tularensis

i) Marburg virus

j) Reconstructed 1918 Influenza virus

k) Rinderpest virus

l) Toxin-producing strains of Clostridium botulinum

m) Variola major virus

n) Variola minor virus

o) Yersinia pestis

# Dual Use Research of Concern Categories of Experiments

a) Enhances the harmful consequences of the agent or toxin

b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin

without clinical and/or agricultural justification

c) Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies

d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin

e) Alters the host range or tropism of the agent or toxin

f) Enhances the susceptibility of a host population to the agent or toxin

g) Generates or reconstitutes an eradicated or extinct agent or toxin listed above

# Key Responsibilities

- Establish and implement internal policies and practices for identification and oversight of DURC
- Establish an institutional oversight process (including the establishment of an Institutional Review Entity) that:
  - Ensures appropriate review of research with DURC potential
  - Assesses the potential risks and benefits associated with DURC
  - Develops and implements risk mitigation plan, as necessary
- Ensure compliance with the institution's dual use research policies

# Key Responsibilities

- Provide education and training on DURC
- Consult the Federal funding agency for guidance on assessing risks or developing a risk mitigation plan
- Promptly inform Federal agencies funding the research of:
    - Research reviewed for DURC potential
    - Research determined to be DURC
    - The risk mitigation plans for research determined to be DURC
    - Instances of noncompliance with the Policy
- NIH is default for non-federal projects

# US Halts Funding for Gain-of-Function Studies

- http://news.sciencemag.org/biology/2014/10/u-s-halts-funding-new-risky-virus-studies-calls-voluntary-moratorium
- SARS, MERS, and influenza viruses

# Integrity and Compliance Webpages

http://www.research.vcu.edu/integrity_compliance/index.htm

**Integrity**

VCU is committed to fostering an environment of uncompromising integrity and ethical conduct of research. Questions about any aspect of research integrity are encouraged.
Contact orie@vcu.edu.

- » Responsible Conduct of Research
- » Conflict of Interests
- » Research Ethics Consultation
- » Research Misconduct

**Compliance**

VCU is committed to carrying out its education and research projects in compliance with all relevant laws, regulations, VCU policies and core values. Questions related to compliance requirements are encouraged. Please contact sarobb@vcu.edu with questions or concerns.

- » Export Control Laws and Trade Sanctions
- » Using Controlled Substances in Research
- » Federal Whistleblower Protections
- » VCU Faculty-Held IND or IDE


# Office of Sponsored Programs (OSP) Updates:

Melanie Wiggins

Director, OSP-Industry and Clinical Trials

October 29, 2014

# OSP Update Topics

NIH Announces:

A revision to the definition of a Clinical Trial

# Notice of Revised NIH Definition of "Clinical Trial"

## Notice Number:

NOT-OD-15-015

## Key Dates

**Release Date:** October 23, 2014

## Related Announcements

None

## Issued by

National Institutes of Health (NIH)

## Purpose

The purpose of this Notice is to inform the research community that NIH has revised its definition of "clinical trial." The revision is designed to make the distinction between clinical trials and clinical research studies clearer and to enhance the precision of the information NIH collects, tracks, and reports on clinical trials. It is not intended to expand the scope of the category of clinical trials. No changes have been made to the NIH definition of a "Phase III clinical trial."

In addition, because clinical trials are subject to additional oversight, a clearer definition will help investigators ensure that they are meeting all of their obligations, and it will help NIH ensure that the additional oversight is occurring when it is needed. For example, NIH policy requires clinical trials to be monitored, and applicants and offerors seeking NIH support are expected to describe their plans for data and safety monitoring in their applications and proposals. Final data and safety monitoring plans must be approved by the NIH prior to award. In addition, throughout the life of the award, NIH staff monitors the clinical trial's progress to ensure that milestones are met and that any safety concerns are addressed.

The revised definition will replace the current clinical trial definition in relevant extramural and intramural NIH policies, guidance, and instructional materials. It will apply to competing grant applications that are submitted to NIH for the January 25, 2015 due date and subsequent due dates and contracts proposals that are submitted to NIH on or after January 25, 2015.

The revised NIH definition of clinical trial is:

## NIH Clinical Trial Definition

A research study[1] in which one or more human subjects[2] are prospectively assigned[3] to one or more interventions[4] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.[5]

[1]See Common Rule definition of *research* at 45 CFR 46.102(d).

[2]See Common Rule definition of *human subject* at 45 CFR 46.102(f).

[3]The term "*prospectively assigned*" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[4]An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

[5]*Health-related biomedical or behavioral outcome* is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Further information and resource materials about the NIH definition of clinical trial are available on the NIH Office of Science Policy website at http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials.

# 45 CFR §46.102
# Common Rule Definitions

- *(d) **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.*
- *(f) **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains*

  *(1) Data through intervention or interaction with the individual, or*
  *(2) Identifiable private information.*

# NIH Definition of Phase III Clinical Trials

**NIH-Defined Phase III Clinical Trial**. An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

# Revision Applies to:

- Competing grant applications that are submitted to NIH for the January 25, 2015 due date and subsequent due dates
- Contract proposals that are submitted to NIH on or after January 25, 2015

# Impact of Revision to VCU

- VCU will adopt the revised NIH definition – this requires a change to policies/procedures which include the definition of a clinical trial.
- Observational studies – those where the investigator does not assign an intervention will no longer be considered a clinical trial. Mirrors information found on clinicaltrials.gov website.

# Impact of Revision to VCU

- From the CT.gov website**:** **Observational Studies**: In an observational study, investigators assess health outcomes in groups of participants according to a protocol or research plan. Participants may receive interventions, which can include medical products, such as drugs or devices, or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator (as in a clinical trial).
- In a clinical trial (also called an interventional study), participants receive specific interventions according to the research plan or protocol created by the investigators.
- Indirect costs for observational research studies will be assessed at the full indirect cost rate (currently 52.5%).

# Current VCU Definition

A clinical trial is an interventional or **observational** prospective research study involving human subjects that is designed to answer specific questions about biomedical (e.g., drugs, treatments, devices) or behavioral interventions (e.g., diet modifications, physical activity) through the compliant collection and analysis of safety and efficacy data as measurement for health outcomes.

In an interventional clinical trial, research subjects are assigned to a treatment or other intervention and their outcomes are measured.

**In an observational clinical trial, interventions given during the course of clinical care are observed and outcomes are measured by the researchers**

# Determining a Clinical Trial under the Revised Definition

Examples of Case Studies are available on the NIH Office of Science Policy website:

http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials

Additional information such as a decision tree is coming

# Examples from NIH Website

**Case #5:** A dose-escalation study is designed to determine the maximum tolerated dose of a new drug in healthy volunteers. The study will also measure the drug concentrations in the blood (pharmacokinetics (pK)). Is this study a clinical trial? 2

**Answer: Yes,**

☐**The study involves human subjects (healthy volunteers).**

☐**Subjects are prospectively assigned to an intervention.**

☐**The study identifies a health-related biomedical outcome (maximum tolerated dose).**

**Note: If the study was examining only pK, it would not be a clinical trial.**

# Examples from NIH Website

**Case #13:**

**A study aims to examine mechanisms of Serotonin 1A receptor neurotransmission in social anxiety disorder (SAD), by examining how human limbic neurocircuitry processes affect mood stimuli after acute perturbation of the serotonin 1A system. In a double-blind, counterbalanced, repeated- 4 measures design, both controls and subjects with social phobia will be randomly assigned to receive either 30 mg Buspirone 30-minutes prior to a functional MRI scan on one laboratory visit, or placebo. . Measures of amygdala and frontocortical responsiveness to affect cues will be compared between doses using functional MRI, as well as off-line measures of cognitive (reaction time) interference in an emotional-word Stroop task outside the scanner. The PIs will also examine brain and behavioral responsiveness to buspirone as a function of sex, diagnosis, and other individual differences. Is this study a clinical trial?**

**Answer: No,**

☐ **The study involves human subjects.**

☐ **Subjects are prospectively assigned to an intervention (drug or placebo).**

**o The study is not designed to examine the effects of Buspirone on individuals, but rather to determine the role of serotonin 1A receptor agonism in behavioral and brain intermediate phenotypes that may be linked to SAD.**

☐ **The study does not identify a health-related biomedical or behavioral outcome.**

**o Differences in brain activation or cognitive interference by emotional words as dependent measures cannot be reasonably construed to be proxies for actual clinical improvement in SAD.**

# Questions

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

Office of Sponsored Programs:

ospred@vcu.edu

828-6772

OR

mwiggins@vcu.edu

Melanie Wiggins

827-4992


# Research Administration & Compliance Meeting

October 29, 2014

Annie Publow, Director, OSP,
Government/NonProfit

# Office of Sponsored Programs Updates

Presentation Topics:

- Staffing Update
- RAMS-SPOT –Testing, Pilot and Implementation Status
- OMB Uniform Guidance - Update

# RAMS-SPOT

**R**esearch **A**dministration **M**anagement **S**ystem-**S**ponsored **P**rograms **O**nline **T**racking

- Database for sponsored projects administration and submission (Vendor= Click Commerce)
- Will replace “VCUeRA” (Vendor=InfoEd)
- Internal discussions began early 2013
- Currently in development and testing

# 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 Implementation Timeline

- Submission Pilot – December 2014- February 2015
  - —Demonstration Training sessions (December)
  - —Preparation, Routing, Review and Submission of selected proposals, CDAs, and Master Agreements (January-February)
- Phase 1 Implementation – March 1 – August 31, 2015
  - —Preparation, Routing, Review and Submission of ALL proposals, CDAs, and Master Agreements
- Phase 2 Implementation– September 1, 2015
  - — Everything else

# RAMS-SPOT Implementation Timeline

Submission Pilot Testing Goals:

- Test system functionality for all types of proposals and variety of sponsor submission types
- Involve Schools, College and proposal-submitting Centers

Proposals to Pilot:

- CAR members will coordinate selection of pilot proposals in consultation with OSP
- Pilot proposals must arrive timely to OSP for review and be complete with sufficient time for submission

# RAMS-SPOT Implementation Timeline

- Effective with proposal submission in RAMS-SPOT, we will be working in two systems (VCUeRA/InfoEd and RAMS-SPOT/Click Commerce)
- FY2015: InfoEd system of record (July 1, 2014- June 30, 2015)
- All awards will be processed in VCUeRA/InfoEd through August 2015
- FY2016: RAMS-SPOT system of record (July 1, 2015-June 30, 2016)
- Basic award data will be exported from InfoEd and imported into RAMS-SPOT end of August 2015

# 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 Summary

Top 5 Things You can do to Prepare for RAMS-SPOT

1. Work with OSP Post Award to close out existing sponsored projects 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
4. Anticipate proposals due during systems transition period: January 1-August 31, 2015.
5. Disseminate information to your PIs.

# RAMS-SPOT Implementation Summary

## Register for and Attend RAMS-SPOT…

## Demonstration/Training event (in person format):

- December 4, 2014 (Thursday) 9:30am-10:45am
- December 12, 2014 (Friday) 9:30am-10:45am

## Demonstration/Training event (webinar format):

- January 9, 2015 (Friday) 9:30am-10:45am

Registration will be announced via ResAdmin listserve.

# 2 CFR 200

- Review Process at VCU
- Update on Federal Agency Implementation
- Training @ VCU
- On-line Resources
- VCU Approach to some Major Issues

# Uniform Guidance Implementation

## Federal Regulations in Effect through December 25, 2014

OMB Circular A-21: Cost Principles for Educational Institutions (5/10/2004)

OMB Circular A-110: Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (09/30/1999)

OMB Circular A-133: Audits of States, Local Governments, and Non-Profit Organizations (06/26/2007)

OMB Circular A-87: Cost Principles for State, Local, and Indian Tribal Government (05/10/2004)

OMB Circular A-102: Grants and Cooperative Agreements with State and Local Governments (10/07/1994)

OMB Circular A-122: Cost Principles for Non-Profit Organizations (05/10/2004)

OMB Circular A-50: Audit Followup (09/29/1982)

OMB Circular A-89: Catalog of Federal Domestic Assistance (08/17/1984)

## Federal Regulation in Effect **December 26, 2014**:

# Uniform Guidance

2 CFR 200

- **Uniform implementation date for all federal agencies**
- **Date applies to all requirements except audit. The audit regulations become effective the first fiscal year after implementation, so July 2015 given our July-June fiscal year.**
- **Federal agencies submitted their implementation plans to OMB June 2014. Except for NSF, we will not hear more on agency implementation until December 26, 2014.**

# Uniform Guidance Implementation at VCU

- Evaluated existing circular requirements with VCU existing policies, procedures and responsible parties
- Identified areas changing and staying the same
- Closely monitoring advisory/professional resources:
  - Council on Government Relations (COGR)
  - National Council of University Research Administrators (NCURA)
  - Society of Research Administrators (SRA)
  - Huron Consulting
- Involving VCU stakeholders as needed
- Providing updates to CAR and RACM
- Develop training for VCU faculty and staff

# Overview of Uniform Guidance

## Presentation (in person format):

- December 4, 2014 (Thursday) 11:00am-12:00pm
- December 12, 2014 (Friday) 11:00am-12:00pm

## Presentation (webinar format):

- January 9, 2015 (Friday) 11:00am-12:00pm

Registration will be announced via ResAdmin listserve.

# Uniform Guidance Implementation at VCU

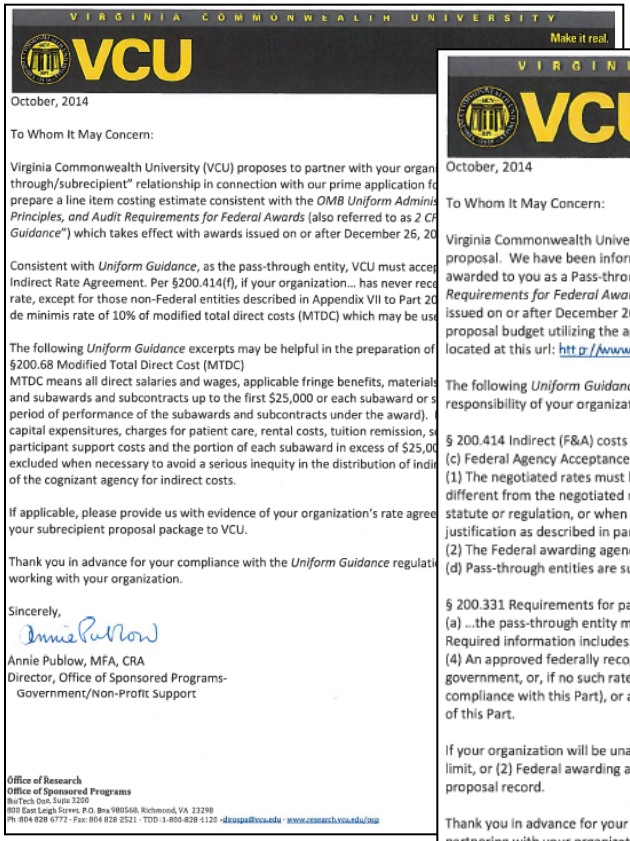
## Top 5 Things You can do to Prepare for UG:

1. Attend Training-Learn what is the same and what is different.
2. Monitor ResAdmin List serve for additional updates.
3. Disseminate information to your PIs.
4. Process final project expenses and corrections timely. (Federal agencies have already initiated stricter enforcement of 90 day close-out/final invoice federal requirement.)
5. Use current negotiated F&A rates when preparing proposals that include federal flow through with a start date on or after December 26, 2014.
   a. Utilize “VCU IDC Uniform Guidance Letter to Sponsor”
   b. Utilize “VCU IDC Uniform Guidance Letter to Subrecipient”

   Located on VCU OSP website under FORMS/Proposals at:

   http://www.research.vcu.edu/forms/index.htm#osp_forms

# Uniform Guidance Implementation at VCU



VIRGINIA COMMONWEALTH UNIVERSITY

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Make it real.

October, 2014

To Whom It May Concern:

Virginia Commonwealth University (VCU) proposes to partner with your organ
through/subrecipient" relationship in connection with our prime application fo
prepare a line item costing estimate consistent with the *OMB Uniform Adminis*
*Principles, and Audit Requirements for Federal Awards* (also referred to as *2 CF*
*Guidance*") which takes effect with awards issued on or after December 26, 20

Consistent with *Uniform Guidance*, as the pass-through entity, VCU must accep
Indirect Rate Agreement. Per §200.414(f), if your organization... has never rec
rate, except for those non-Federal entities described in Appendix VII to Part 20
de minimis rate of 10% of modified total direct costs (MTDC) which may be us

The following *Uniform Guidance* excerpts may be helpful in the preparation of
§200.68 Modified Total Direct Cost (MTDC)
MTDC means all direct salaries and wages, applicable fringe benefits, materials
and subawards and subcontracts up to the first $25,000 or each subaward or s
period of performance of the subawards and subcontracts under the award).
capital expenditures, charges for patient care, rental costs, tuition remission, s
participant support costs and the portion of each subaward in excess of $25,00
excluded when necessary to avoid a serious inequity in the distribution of indi
of the cognizant agency for indirect costs.

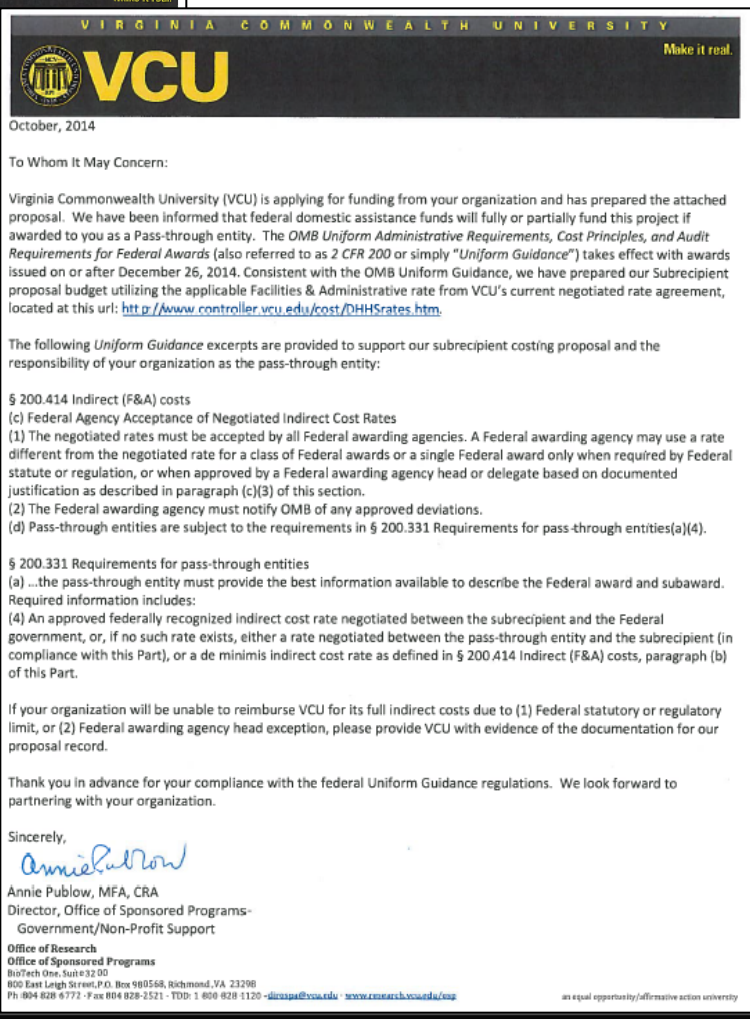
If applicable, please provide us with evidence of your organization's rate agree
your subrecipient proposal package to VCU.

Thank you in advance for your compliance with the *Uniform Guidance* regulati
working with your organization.

Sincerely,

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

**Office of Research**
**Office of Sponsored Programs**
BioTech One, Suite 3200
800 East Leigh Street, P.O. Box 980568, Richmond, VA 23298
Ph 804 828 6772 - Fax: 804 828 2521 - TDD: 1-800-828-1120 - dirosp@vcu.edu - www.research.vcu.edu/osp



VIRGINIA COMMONWEALTH UNIVERSITY

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

**Office of Research**
**Office of Sponsored Programs**
BioTech One, Suite 3200
800 East Leigh Street, P.O. Box 980568, Richmond, VA 23298
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an equal opportunity/affirmative action university

- Located on OSP Forms page under "Proposal Development" header.

When federal domestic assistance funds are involved…

- Use with sponsors or subrecipients who may be unfamiliar with changing federal guidance;
- Use with sponsors who may not have honored negotiated rates in the past.

# Uniform Guidance Implementation at VCU

**SECTION I: INDIRECT COST RATES**

RATE TYPES: FIXED FINAL PROV. (PROVISIONAL) PRED. (PREDETERMINED)

| | EFFECTIVE PERIOD | | | | |
|---|---|---|---|---|---|
| TYPE | FROM | TO | RATE(%) | LOCATION | APPLICABLE TO |
| FINAL | 07/01/2011 | 06/30/2012 | 49.50 | On-Campus | Organized Research |
| PRED. | 07/01/2012 | 06/30/2013 | 52.00 | On-Campus | Organized Research |
| PRED. | 07/01/2013 | 06/30/2015 | 52.50 | On-Campus | Organized Research |
| FINAL | 07/01/2011 | 06/30/2012 | 26.00 | Off-Campus | Organized Research |
| PRED. | 07/01/2012 | 06/30/2015 | 26.00 | Off-Campus | Organized Research |
| FINAL | 07/01/2011 | 06/30/2012 | 34.00 | On-Campus | Instruction |
| PRED. | 07/01/2012 | 06/30/2015 | 40.00 | On-Campus | Instruction |
| FINAL | 07/01/2011 | 06/30/2012 | 26.00 | Off-Campus | Instruction |
| PRED. | 07/01/2012 | 06/30/2015 | 26.00 | Off-Campus | Instruction |
| FINAL | 07/01/2011 | 06/30/2012 | 30.00 | On-Campus | Other Sponsored Activities |
| PRED. | 07/01/2012 | 06/30/2015 | 35.00 | On-Campus | Other Sponsored Activities |
| FINAL | 07/01/2011 | 06/30/2012 | 26.00 | Off-Campus | Other Sponsored Activities |
| PRED. | 07/01/2012 | 06/30/2015 | 26.00 | Off-Campus | Other Sponsored Activities |

- VCU Negotiated Facilities & Administration Rate Agreement
- Industry-Sponsored Clinical Trial rate 30%
- Will honor Commonwealth of Virginia “sister” agency rates so long as funding is state funds (if federal funds should be full F&A rate)
- Anticipate a transition period

# Research Misconduct:
## 'Just the Facts' at VCU and beyond

Monika S. Markowitz, PhD

Director, Office of Research Integrity and Ethics

VCU Research Integrity Officer

RACM

October 29, 2014

# Scientific/Research Misconduct Regulations

42 CFR Part 93

Applies to Public Health Service (PHS) conducted or supported biomedical or behavioral research, research training and applications and proposals for such activities.

45 CFR Part 689

Applies to research proposals submitted to and funded by the National Science Foundation (NSF).

VIRGINIA COMMONWEALTH UNIVERSITY

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# Misconduct in Research and Scholarly Activities

## *VCU POLICY*

## *Responsibility to Report Misconduct*

Anyone who becomes aware of a possible incident of research misconduct by a member of the university shall immediately report the information to the Research Integrity Officer (RIO).

***Protecting the Reputation of the Complainant***

***Protecting the Reputation of the Respondent***

****Confidentiality***

*[Policy applies to all allegations regardless of funding]*

http://www.assurance.vcu.edu/Policy%20Library/Misconduct%20in%20Research%20and%20Scholarly%20Activities.pdf

# **Research misconduct** is:

- fabrication,
- falsification, or
- plagiarism in
  - proposing,
  - performing,
  - reviewing research, or in
  - reporting research results.

- **Fabrication is making up data or results and recording or reporting them.** **[lying]**

- **Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results** such that the research is not accurately represented in the research record [i.e. the record of data or results that embody the facts emerging from the research, and includes, but is not limited to, research proposals, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and books]. **[cheating]**

- **Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.** **[stealing]**

# Research misconduct is NOT:

- Honest error or differences of opinion.
- Authorship disputes unless they involve Plagiarism.
- Research-related noncompliance such as protocol violations, IP violations, financial or contractual mismanagement, conflict of interest violations (other areas address these)

# 3 requirements to find RM

42 CFR 93.104

- Significant departure from accepted practices of the relevant research community
- Committed intentionally, knowingly, or recklessly
- Proven by a preponderance of the evidence
  - Misconduct is more likely to be true than not

# VCU RM process, briefly

## (Emphasis on confidentiality)

Allegation to RIO concerning faculty or staff

(RIO with Chair consider: align with definition? credible? enough evidence?)

**If YES:** → 1) Inquiry – warrant an Investigation?

**YES:** → 2) Investigation – did research misconduct occur (and who did it)?

**YES:**

- Appeal is possible
- Sanctions – given outcome of appeal, if any

VCU reports to ORI or NSF depending on funding – either may pursue further

# RM proceedings at VCU since September 2011

Allegations involved in proceedings:

- plagiarism;
- plagiarism and falsification

4 separate Schools

Inquiry Panels

- Spring 2012
- Fall 2012
- Fall 2013
- Spring 2014

Investigation Panels

- Summer 2012
- Spring 2013

Panel findings:

- Research misconduct occurred x 1

# Case Summaries

http://ori.hhs.gov/case_summary

**2014**

Case Summary: Ahvazi, Bijan

Case Summary: Chen, Li

Case Summary: Cokonis, Melanie

Case Summary: Freeman, Helen

Case Summary: Fu, Jun

Case Summary: Patel, Parag*

Case Summary: Zou, Zhihua

**2013**

Case Summary: Adibhatla, Rao M.

Case Summary: Aggarwal, Nitin

Case Summary: Aprikyan, Andrew

Case Summary: Doreian, Bryan W.

Case Summary: Han, Dong-Pyou

Case Summary: Karnik, Pratima

Case Summary: Poore, Matthew

Case Summary: Savine, Adam C.

Case Summary: Sheehy, Timothy

Case Summary: Wang, Hao

Case Summary: Xu, Baoyan

**2012**

Case Summary: Elton, Terry S.

Case Summary: Hauser, Marc

Case Summary: Kim, Sinae

Case Summary: Ma, Jian

Case Summary: Mayack, Shane

Case Summary: Miller, Michael W.

Case Summary: Muchowski, Paul J.

Case Summary: Ravindranath, Mepur H.

Case Summary: Smart, Eric J.

Case Summary: Thiruchelvam, Mona

Case Summary: Zach, Calleen S. *

Case Summary: Zhang, Shuang-Qing

**2011**

13 cases

**2010**

4 cases

**2009**

10 cases including 1 research coordinator

# The Research Clinic



TRICK
or
TREAT


# Research Administration and Compliance Meeting

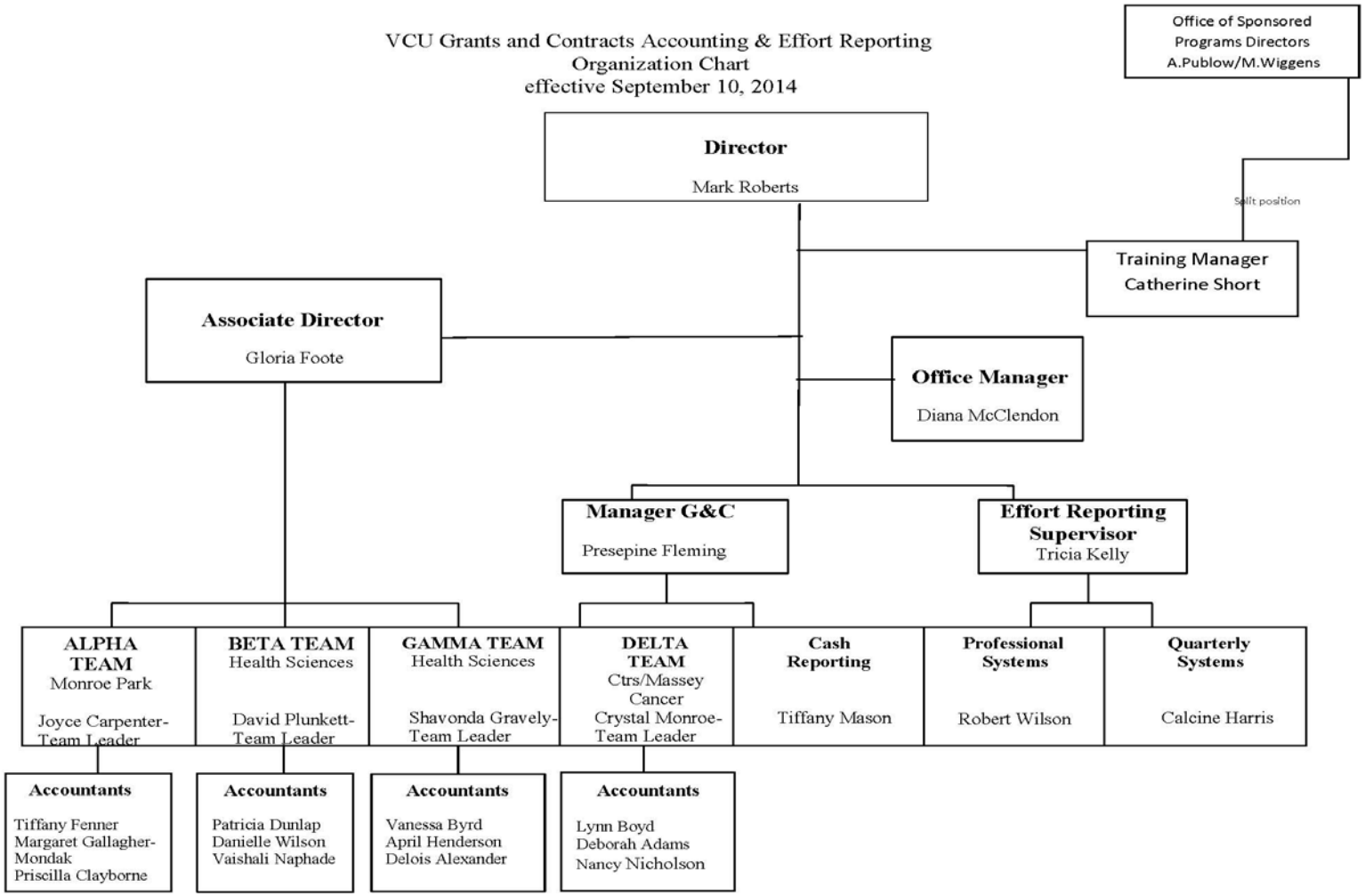
## October 29, 2014

Grants & Contracts Accounting Updates

# G&C staff and misc. updates

- Welcome Diana McClendon, Office Manager.
- Updated Org chart

# VCU Grants and Contracts Accounting & Effort Reporting
Organization Chart
effective September 10, 2014



# Industry Clinical Trial 30% FACR

- Trials negotiated and awarded with the new rate will require a new departmental FACR Distribution Code.
- Send a request (preferably electronic) to the Controller's Office, to the attention of Tricia Perkins.

# ECRT Institutional Base Salary (IBS) Definition

- "The annual compensation rate, as determined by University administrative procedures, for an employee's appointment ("University effort") devoted toward University-related activities. See G&C website link http://www.controller.vcu.edu/pdf/ECRTbasesalarycategories.pdf for the published listing of compensation codes included in ECRT.

# IBS Definition cont.

- IBS includes both compensation for University-related effort, and compensation from the MCV Physicians (MCVP) Practice Plan for clinical effort. However, some specific types of compensation are not included for the purposes of effort reporting. These types include bonuses, reward/recognition compensation, etc.”

# Training Update

- Review currently underway of training metrics to include offerings, registrations, and attendance.
- Increased offerings by Training Manager.
- Existing training documents as well as policies and procedures, will be reviewed and updated as needed to reflected VCU UG implementations.

VIRGINIA COMMONWEALTH UNIVERSITY

VCU Make it real.

**Grants and Contracts Accounting**
**P. O. Box 843039; 800 E. Leigh Street, Suite 3100**
**Richmond, Virginia 23284-3039**

**M E M O R A N D U M – 90 DAYS NOTICE**
**Grant/Contract and Fixed Price Agreement Close-out**

**FROM:**
**Grant Accountant**

**TO:**
**Fiscal Administrator**

**DATE:**

**RE: Index:** **Fund:** **Grant Code**:

**Principal Investigator**: **Sponsor**:

**PT/PD/SC Number:** **Type:**

Based on the monthly review of accounting records for VCU sponsored program indexes, the above referenced index has a budget period which terminates on _____. Please indicate which action is required by selecting (**X**) one of the following options:

**Options**: 1. Additional years/Additional funding; 2. Supplemental funding; 3. No-Cost Extension only; 4. Final year; 5. Close out and pool

_____1. There will be an additional budget year with additional funding. (Multi-year projects with annually awarded budgets-**DOES NOT INCLUDE EXTENSIONS**)

**If anticipated funding is not received, the **Department Chairperson/P.I.** (**circle one-Responsible Party for the committed Index**) agrees that the Alternative Non-sponsored Banner Index _____ will cover any charges of the project incurred after the expiration date of the current index. The alternative Non-Sponsored Banner Index will only be used if an award notice is not received by the University within 60 days after the current expiration date of the project, or if the index is in a deficit.

Note: If an individual will not be working on the continuation/renewal or extension of this project, please submit a Personnel Action Form (PAF) to change their labor distribution through the appropriate channels; or If there are individuals who should be charged to the additional year of this project, please submit the PAF with the proper labor distribution effective date through the appropriate channels.

_____
**FA Signature** **Date**

_____2. There will be Supplemental funding for this project and the end date on the award will be extended to _____. Alternative Non-sponsored Banner Index _____; (see #1** above for explanation). I understand that I will need to separately contact the Office of Sponsored Programs directly if an extension is needed. **The Banner Termination Dates will be extended to allow charges to continue to be processed, however, the Banner Budget Period End Date on FRMFUND will not be changed until G&C receives a Snapshot from OSP indicating an approved change in the end date.**

_____
**FA Signature** **Date**

_____3. There will be a No-Cost Extension (NCE) beyond the original end date of this project or sub-award/sub-Index without additional funding until _____ (Please insert new end date requested with (NCE). Alternative Non-sponsored Banner Index _____; (see #1** above for explanation).
I understand that I will need to separately contact the Office of Sponsored Programs directly if an extension is needed. **The Banner Termination Dates will be extended to allow charges to continue to be processed, however, the Banner Budget Period End Date on FRMFUND will not be changed until the G&C Accountant receives a Snapshot from OSP indicating an approved change in the end date.**

_____
**FA Signature** **Date**

_____4. This is the FINAL YEAR of the project. A new Banner Index is **not** required.

_____
**FA Signature** **Date**

_____5. Close-out this Fixed-Price Agreement (**G&C Accountant will electronically send the form directly to the FA regardless if the remaining cash balance is zero, or if there is a deficit cash balance. When the applicable, G&C will also email a copy the SOM Dean's Office at somresadmin@vcu)**:

**OSP Post-Award Certification** - "I certify that the above referenced project is a fixed price agreement."

_____ _____
**OSP Signature** **Date**

**G&C Certification** – "I certify that the fixed price agreement has been fully invoiced and that all payments have been applied towards the Index. If the final invoice is subject to final reporting or deliverables, the return of this Notice with the P.I. certification below will initiate the final invoice process by G&C."

_____ _____
**G&C Accountant Signature** **Date**

**FA Certification** - "I certify that the fixed price agreement has been charged for all work performed for the agreement and that no costs to be funded by the sponsor have been billed to other sponsored agreements, patient clinical trials, or absorbed by VCU, the VCUHS or VAMC. If this fixed price agreement is an Industry Clinical Trial, I am certifying that invoices have been submitted for all agreed payments. This leaves a cash balance of $ _____."

**(CHECK ONE)**

**_____** Please transfer the remaining funds to pool index number/s. **_____**

**_____** The P.I. does not have a pool index; please create an index.

_____ _____
**Fiscal Administrator Signature** **Date**

Please have the below responsible officials acknowledge review of this Notice/Fixed Price Close-out, certifying to the below statement, and returning this memo within 10 days to Grants and Contracts Accounting, or emailing it to GCAVCU@vcu.edu.

**PI Certification** - "I certify that all contractual obligations as required by this agreement have been completed to the satisfaction of the sponsor and approve the close-out of this award or sub-award/sub-index."

_____ _____
**Principal Investigator** **Date** **Department Chairperson** **Date**

# Questions???

Thanks for your continued assistance.

Grants and Contracts Accounting/Effort Reporting

Mark Roberts

# Research Administration and Compliance Meeting

## Clinical Research Services Update

## OnCore Financial Console Pilot Project
## and
## Plan For Implementation of Full Functionality of OnCore

**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**

**October 29, 2014**

# Why Use OnCore Clinical Trial Management System?

- Clinical Trial Database- We need a centralized clinical trial management system for oversight and tracking of all clinical research activities at VCU
- Clinical Trial Regulatory Compliance – We need a centralized, standardized approach to clinical trials compliance- eg, adequate auditing/monitoring of clinical trials, Investigator initiated Trials (IITs) and Those Involving INDs/IDEs
- Clinical Trial Financial Compliance and Cost Recovery – We need consistent and efficient budget negotiations with industry sponsors, consistent cost coverage analysis and accurate billing, invoicing and cost recovery of clinical study costs.
- Clinical Trial Education – We need a clearly defined career ladder and career development for clinical research coordinators; We need clinical trial education and GCP competencies for Principal Investigators and Research Staff.

s

# Using OnCore to Address Gaps in Clinical Trial Administration

- **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
- **OnCore Financial Console** Central Location for Clinical Trial Budgets, Cost Coverage Analysis, Billing Grids, and Invoicing Based on Chargemaster and Study Calendars

# Objective of Financial Console Pilot Project

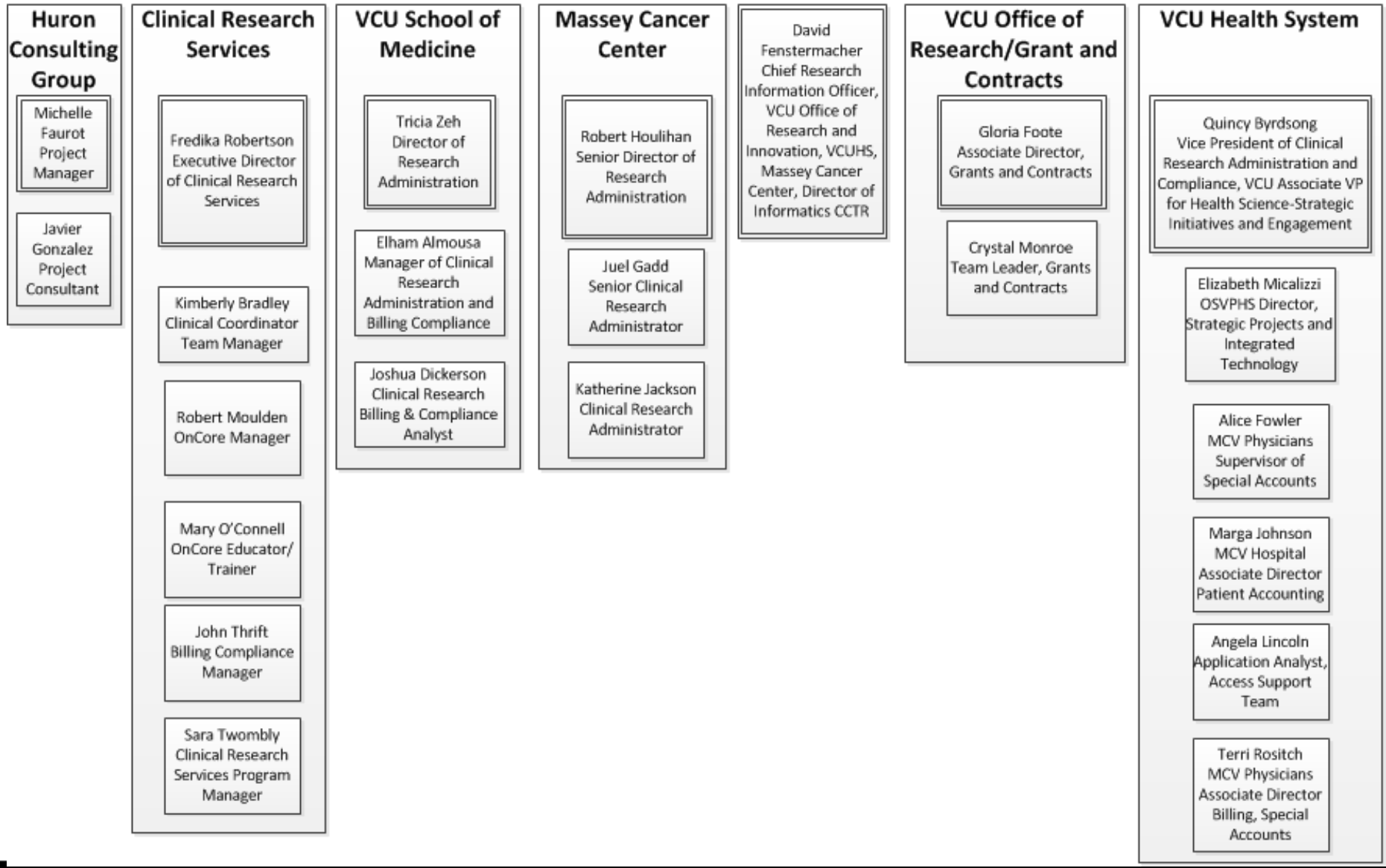
To **pilot** the implementation of the **OnCore Financial Console** which will facilitate more effective financial management of clinical research at VCU through the seamless **collaboration** of the critical components of clinical research across the **VCU/VCUHS enterprise**. This pilot project will identify processes that will allow for efficient and accurate retrieval of data to ensure appropriate and timely study billing/invoicing.

Lessons learned during this pilot will be applied to the further rollout of the full functionality of OnCore at VCU and VCUHS.

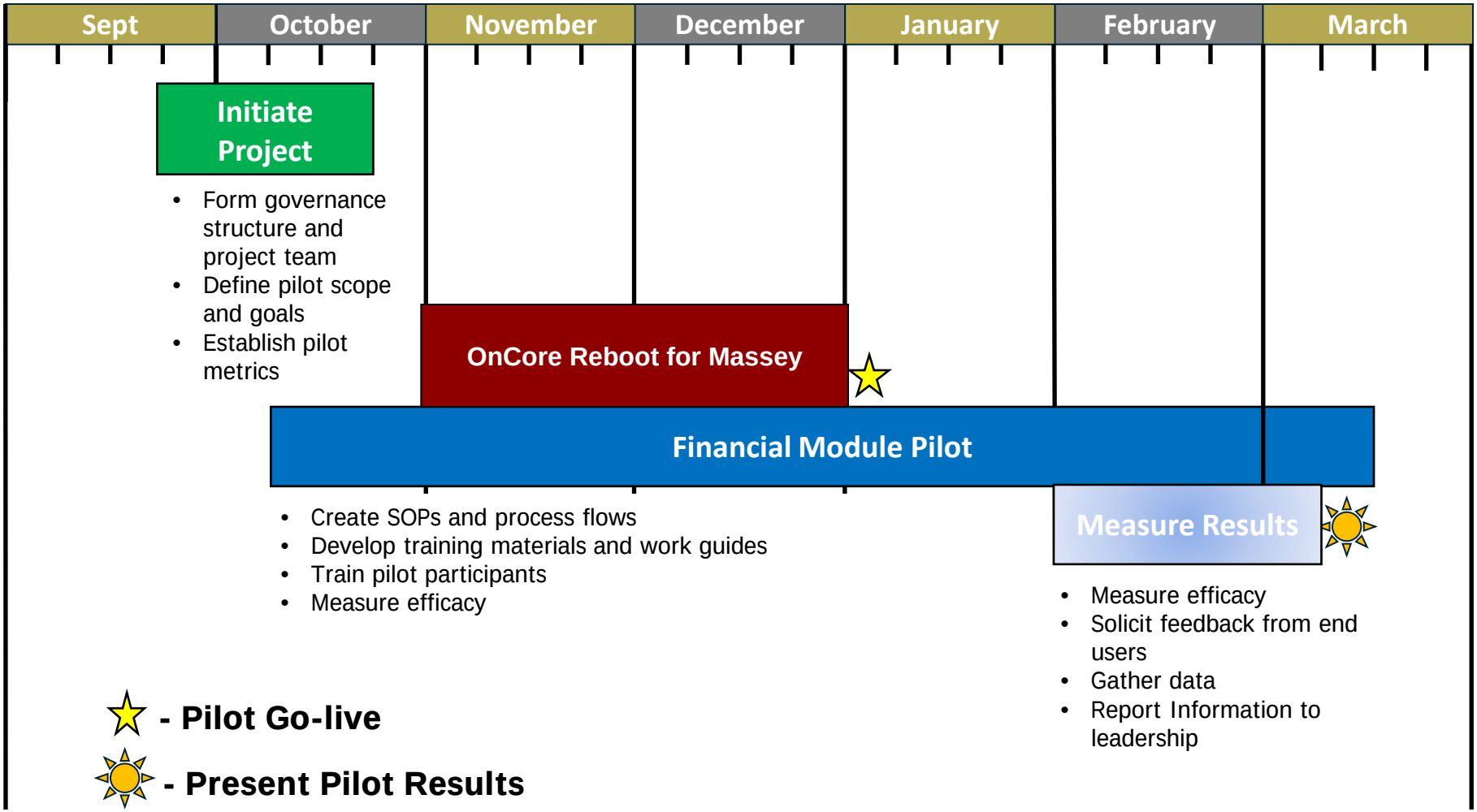
# Project Leadership

| Name | Title | Role | Affiliation |
|---|---|---|---|
| Fredika A Robertson, Ph.D. | VCU, Executive Director, Clinical Research Services | Project Operational Director and VCU Institutional Representative | VCU Center for Clinical and Translational Research |
| Robert Houlihan, DHA, FACHE, CCRP, CRA | MCC Senior Director of Research Administration | Project Director, Massey Cancer Center | VCU Massey Cancer Center |
| Quincy Birdsong, EdD, CIM, CIP, CCRP | VP, Clinical Research Administration, Associate VP for Health Sciences - Strategic Initiatives and Engagement | Project Leader, VCU Health System | VCUHS |
| David Fenstermacher, Ph.D. | VCU/VCUHS Chief Research Information Officer | Technical Director | CCTR Biomedical Informatics Core |
| Tricia L. Zeh, MS, CRA, CCRP | Director of Research Administration VCU School of Medicine | VCU School of Medicine Representative | VCU School of Medicine |

# Financial Pilot Project Team



# Timeline


Sept
October
November
December
January
February
March
Initiate Project
• Form governance structure and project team
• Define pilot scope and goals
• Establish pilot metrics
OnCore Reboot for Massey
Financial Module Pilot
• Create SOPs and process flows
• Develop training materials and work guides
• Train pilot participants
• Measure efficacy
Measure Results
• Measure efficacy
• Solicit feedback from end users
• Gather data
• Report Information to leadership
- Pilot Go-live
- Present Pilot Results

# Status Update 10-29-2014

| | Major Tasks | 9/22/2014 | 9/29/2014 | 10/6/2014 | 10/13/2014 | 10/20/2014 | 10/27/2014 | 11/3/2014 |
|---|---|---|---|---|---|---|---|---|
| 1 | Establish a working group dedicated to the Financial Module Pilot | ● | | | | | | |
| 2 | Define the frequency, content and audience for project updates | ● | | | | | | |
| 3 | Select departments, PIs and study teams to participate in pilot | ● | ● | ● | | | | |
| 4 | Develop a methodology for measuring success towards achieving the goals and outcomes established for the pilot | ● | ● | ● | | | | |
| 5 | Identify appropriate studies to include in the pilot | ● | ● | ● | | | | |
| 6 | Provide System Configuration Advice | | ● | ● | ● | ● | ● | ● |
| 7 | Measure baseline performance (as applicable and as possible) for the measures established for the pilot | | | ● | ● | ● | ● | |
| 8 | Develop SOPs, Field Definitions, and Workflows | | | ● | ● | ● | ● | ● |

1. Full Engagement of all parties
2. VCUHS Billing Practices
3. Communication about pilot to end users and research community

1. Hold smaller working group meetings to allow all voices to be heard and ensure strong leadership support for Massey, VCUHS and SOM
2. Immediate access to OnCore and the consoles that can help billing now and increased involvement of Massey and CRS billing compliance specialists.
3. In person meetings with pilot study team members. Vetting of ongoing communication plan.

# Financial Console Pilot Project Updates

- External website is live: https://wiki.vcu.edu/display/oncore/OnCore+Financial+Implementation

- 12 Pilot Trials identified – Massey, SOM Final list available on the wiki: https://wiki.vcu.edu/x/oB27Ag

- Project Emails sent to PIs and Study Team Members associated with Pilot Clinical Trials; Face: Face Meetings with Study Teams

- Data gathered from Study Teams- Budgets, CCA, Billing Grids, Full and Accurate Calendars Built in OnCore

# Next Steps

Definition of Future State Processes

- Define the future state process and
- Review suggested workflow with working groups

Pilot Team Engagement

- Baseline Satisfaction Survey

Financial Console Testing

- Loading/Testing Chargemaster
- Updating Calendars and entering budgets in OnCore

Measuring Baseline Performance

- Gathering data currently available from study teams and central resources
- Developing tools/reports to get information from OnCore during pilot

# Financial Console Pilot Project Updates

Ongoing Activities: Defining Current and Future State Workflows

Upcoming meetings

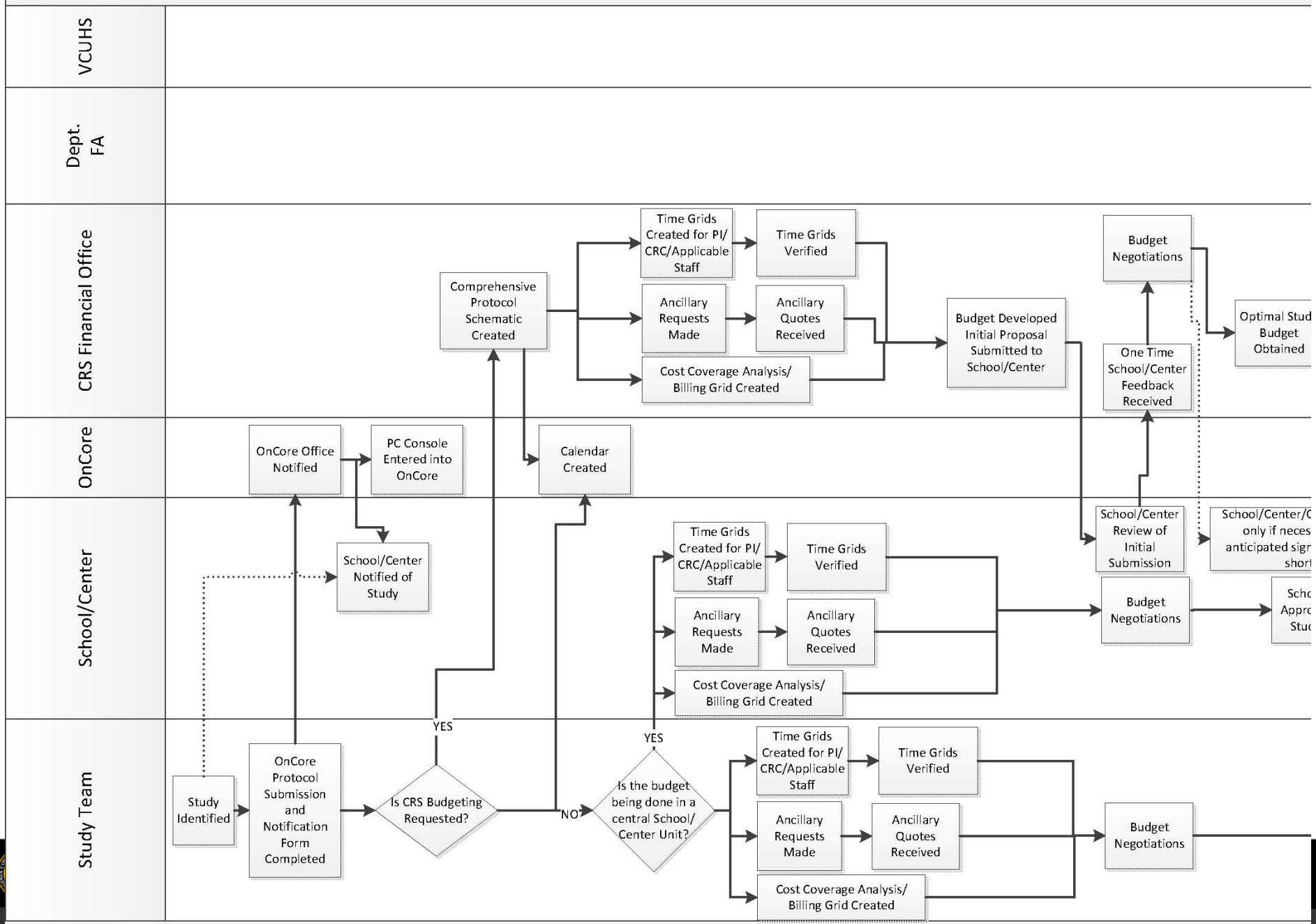
- 10/31 Meeting at Grants & Contracts Biotech 3061 Present and Future Workflows

Ongoing Activities: Load Chargemaster into OnCore, Upload Data for Pilots into OnCore, Begin Testing Function of System

Next Steps: Go Live 1/2015

Participant Visit tracking- visit occurred, invoicing/billing, then tracking process for accurate billing/invoicing

# OnCore Financial Workflow – All Units Pre-Award Current State Process



# Impact of Financial Pilot Project

- Teams involved in the pilot will have support from the Financial Project Team, and the OnCore Support Team during and following the pilot phase of this project.
- All OnCore consoles will be used in this pilot:
  - Study Calendars will be more detailed to show all procedures
  - Subject visit entry will be used to determine billing and invoicing
    - Less questions about which procedures occurred to address patient billing and finance
    - Need to update information within 24 hours
- Input from study teams will be valuable in helping us with the implementation and changes will be clearly communicated with our research community

# Training Plan For Pilot Project and Full OnCore Implementation

- **Training/Education/Support**
  - Massey Cancer Center [11/2014]
  - VCU SOM Study Teams/ One-on-One
  - OnCore Financials Training Manual, Videos, Process Flow Sheet, Pocket Information Card
  - Go- Live 1/2015
  - Lessons Learned and Next Steps 3/2015
  - CRS Outreach Activities- Schools, Centers and Institutes Performing Clinical Research and Implement OnCore

# 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**

# Contact our OnCore Support Team

- Oncore@vcu.edu
- **Kimberly Bradley, OnCore Coordinator Education Liaison and CRS Coordinator Manager**
  kbbradley@vcu.edu
- **Bobby Moulden, OnCore Program Manager**
  rbmoulden@vcu.edu
- **Mary O'Connell, BIC OnCore Protocol Entry, Calendar Builder, Certified OnCore Trainer** oconnellm@vcu.edu

# Study Coordinator/Team Roles & Responsibility-

# What Studies Go Into OnCore?

**1) STUDY MEETS THE DEFINITION OF CLINICAL RESEARCH *and***

**2) STUDY REQUIRES EXPEDITED OR FULL BOARD IRB REVIEW**

- **Submission of a study to the OnCore Support Team for entry of a protocol into OnCore IS REQUIRED to be completed no later than the time of IRB Approval**

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

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

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

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

3rd Wave: 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 [Subject and Financial Consoles]

1st Wave: Financial Console Pilot Project – Massey, Cardiology, Surgery

2nd st Wave: Massey Full Functionality of OnCore

2rd Wave: Implement Full Functionality of OnCore to SOM, across VCU

**Phase IV (upcoming):** Establish long-term management and governance strategy for ongoing OnCore Implementation