Research Administration and Compliance Meeting
Wednesday, August 27, 2014 1:00 – 3:00 p.m.
Larrick Hall, Court End Ballroom B

Agenda

Sponsored Programs Updates (OSP)

- RAMS SPOT Testing, Pilot, and Implementation
- Website Updates

Grants & Contracts Updates (G&C)

- Training Manager - Introduction
- Uniform Guidance Update (with OSP)
- Staffing Update
- Final Audit Results
- Institutional Base Salary Categories in ECRT

Research Administration and Compliance (ORAC)

- NIH Notice NOT-OD-14-113 – Use of IDPs for Graduate Students and Postdoctoral Researchers Required in Annual Progress Reports
- Updated Subrecipient Commitment Form
- NSF RCR Policy – Addition of Disallowances for Non-compliance
- IND/IDE Webpage and Assistance
- OnCore Audit Console
- Updated Clinical Research Compliance Checklist
- Virtify

Clinical Research Services Updates (CRS)

- OnCore Subject Console Roll-out
- Clinical Research Advisory Board Report

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

- October 29, 2014
- February 18, 2015
- April 29, 2015

Research Administration & Compliance Meeting

August 27, 2014

Annie Publow, Director, OSP,
Government/NonProfit

Office of Sponsored Programs Updates

Presentation Topics:

- Staffing Update
- RAMS-SPOT – Development/Implementation Status
- OMB Uniform Guidance - Update

RAMS-SPOT

Research **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

Preparation, Approval Routing, Review and Submission of selected…

  - New Proposal Submissions
  - CDA (Confidentiality NonDisclosure Agreements)
  - Master Agreements
  - Pre-Award Reviews

- Phase 1 – March 1 – August 31, 2015

Preparation, Routing, Review and Submission of ALL proposals, CDAs, and Master Agreements

- Phase 2 – September 2015

RAMS-SPOT Implementation Timeline

Goals of Submission Pilot Testing:

- Test system functionality for all types of proposals and variety of sponsor submission types
- Ideally will involve all Schools, the 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

Submission Pilot Notes:

- Pilot proposals are “live” proposals in “live” system
- As of December 1, 2014, we are working in two systems (VCUeRA/InfoEd and RAMS-SPOT/Click Commerce)
- What will determine which system a project is entered in?
  - Proposals submitted in RAMS-SPOT between December 1, 2014 and August 31, 2015 that have an award start date of September 1, 2015 or later will never (need to) be entered into VCUeRA/InfoEd
  - Proposals submitted between December 1, 2014 and August 31, 2015 that are awarded prior to September 1, 2015 will need to be entered into VCUeRA/InfoEd.

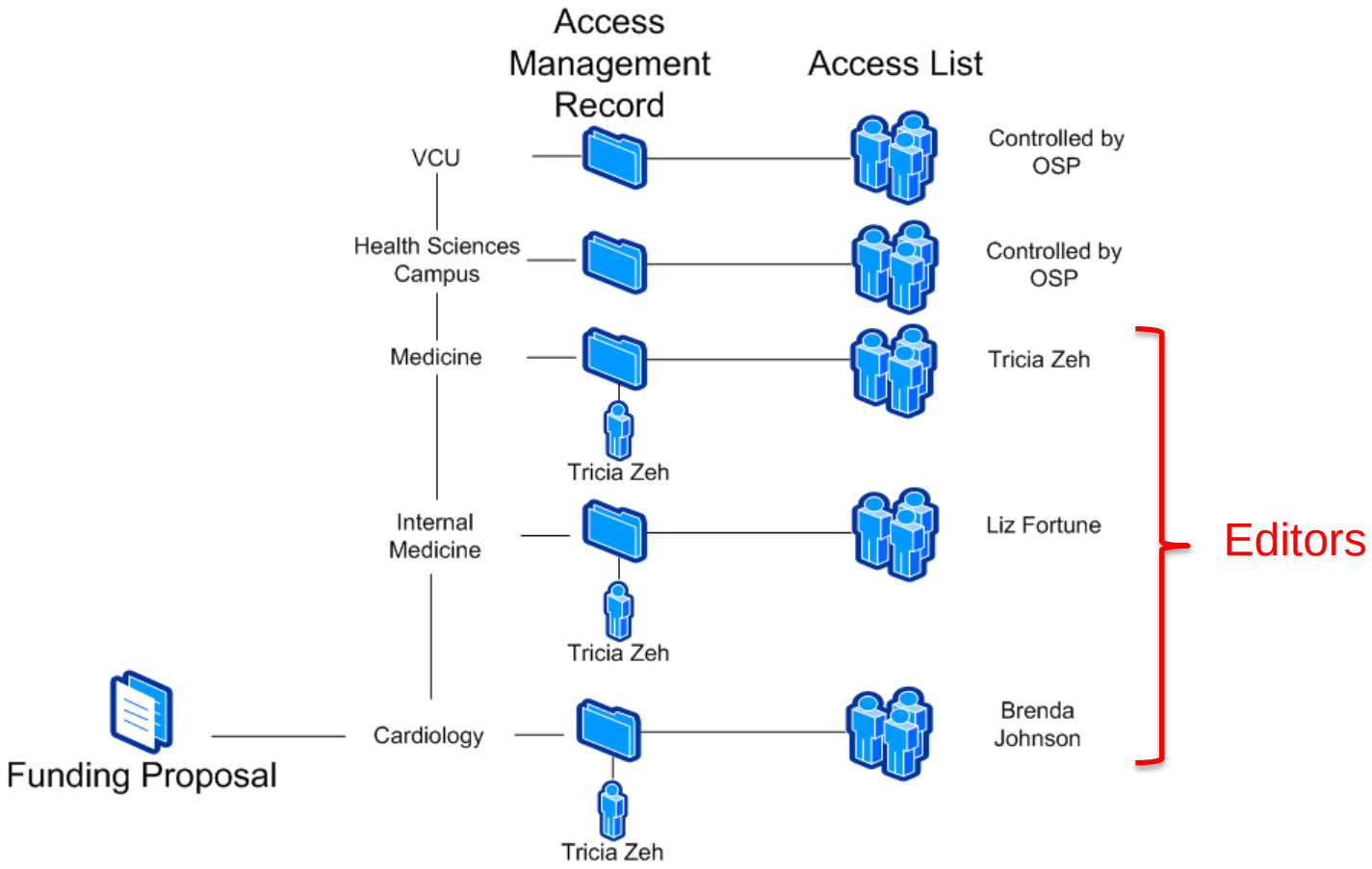
RAMS-SPOT Implementation Timeline

- Phase 2 System Functionality will include:
  - Award Processing
  - Continuation/Supplemental Proposals
  - Prior Approval/Expanded Authority Actions
  - Closeout
- Additional Phase 2 Notes :
  - GoLive: September 1, 2015
  - Basic award data from InfoEd will be imported into RAMS-SPOT
  - FY2015: InfoEd system of record (July 1, 2014- June 30, 2015)
  - FY2016: RAMS-SPOT system of record (July 1, 2015-June 30, 2016)

RAMS-SPOT Org Structure

- Maintain existing ORG Structure provided by HR (as best as possible).
- Create VPR Org Structure limited to the following five levels for Access Management (no exceptions):
    1. Organization
    2. Executive
    3. Senior
    4. Business
    5. Division

Example FP in Cardiology



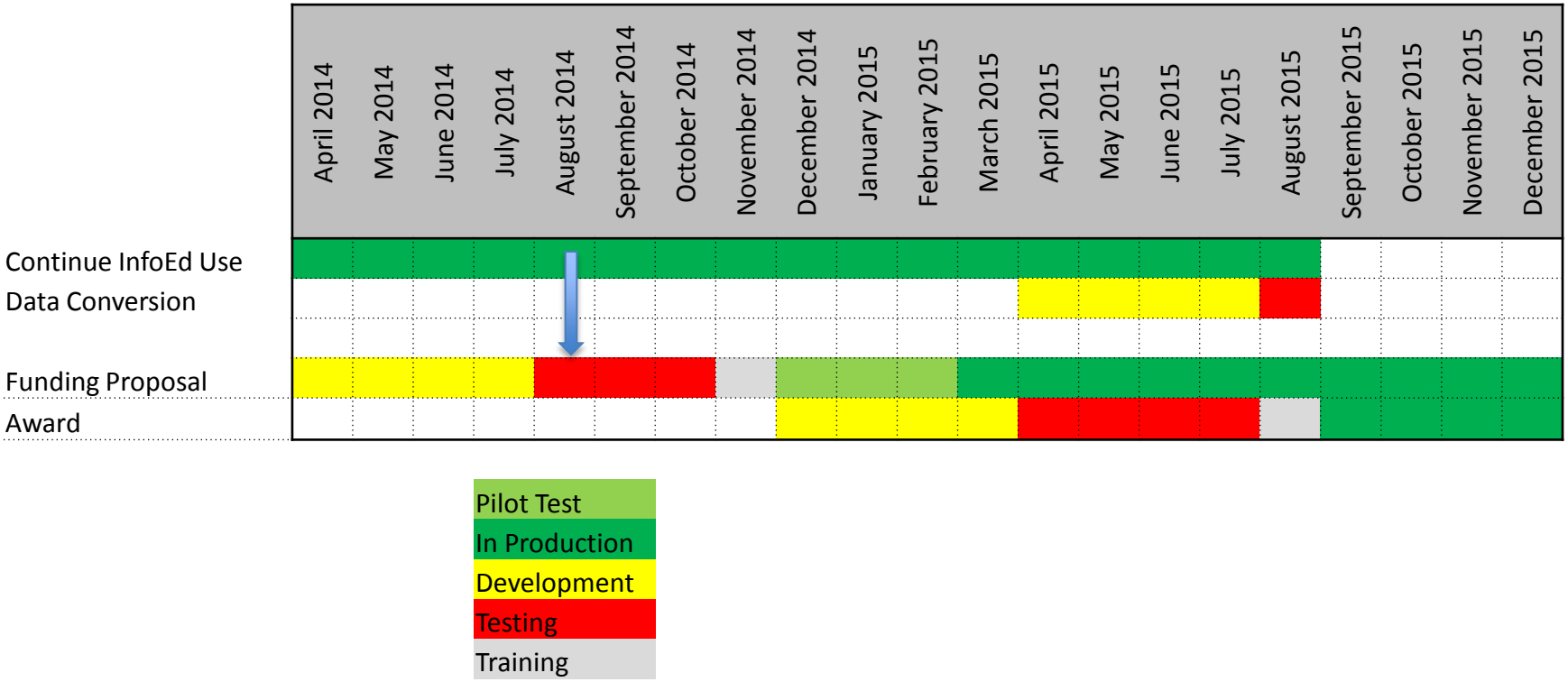
RAMS-SPOT Implementation Summary

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

1. For all existing records with completed period of performance, work with OSP Post Award to close out.
2. Know who your CAR member(s) is and how they will communicate about RAMS-SPOT for your School, College or Center.
3. Anticipate proposals due during transition period:

   December 1, 2014-August 31, 2015.
4. Communicate with your PIs.
5. Monitor OSP website and ResAdmin Listserve announcements for Training Updates.

SPOT Implementation Timeline



2 CFR 200

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

Uniform what?

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

Gil Tran, Office of Management & Budget:

Uniform Guidance…. "maintains general principles of grants management while revising existing policies. The policy revisions are designed to:

- increase accountability for recipient performance;
- promote the efficient use information technology;
- provide consistent and transparent treatment of costs;
- implement standard business processes and data definitions;
- encourage family-friendly policies;
- strengthen oversight; and
- mitigate the risk of waste, fraud, and abuse to federal funding.

2 CFR 200 – Basic Layout

- 6 Subparts: A-F
  - Subpart A – Acronyms & Definitions
  - Subpart B – General Provisions
  - Subpart C – Pre Award
  - Subpart D – Post Award
  - Subpart E – Cost Principles
  - Subpart F – Audit Requirements
- 11 Appendices – I through XI

Committee on the Administration of Research

Committee on the Administration of Research (CAR) subcommittee appointed to evaluate Uniform Guidance and make recommendations for implementation at VCU

CAR Member Subcommittee Participation:

Annie Publow, Chair

Mark Roberts, Chair

- Stacey Garnett (SoN)
- Robert Houlihan (Massey Cancer Center)
- Brigette Pfister (College of Humanities & Sciences)
- Margaret Poland (School of Dentistry)
- Catherine Short (G&C/OSP Training)
- Sandra White (Purchasing)
- Tricia Zeh (School of Medicine)

VCU Approach

- 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

VCU Approach

Uniform Guidance training

- October/November timeframe – Initiate in-person training sessions @ VCU
- OSP website - Will provide url references, and updated guidance announcements
  - COFAR website: https://cfo.gov/cofar/
- Federal "Workforce Development" efforts-- Monitoring OMB/COFAR issuance

VCU Approach to Major Issues – Today

Procurement	Compare existing VCU procurement procedures to new federal standards. Try to coordinate with other Virginia public universities. 12 month grace period for implementation anticipated.
Subrecipient Risk Assessment & Monitoring	Analyze Uniform Guidance and VCU processes. Utilize pending FDP templates for subaward agreements and risk assessment. Focus on risk of subs not subject to Single Audit. Strengthen existing internal controls.
Closeouts	90 days means 90 days: Monitor guidance from OMB and DHHS. Prepare for NIH subaccounts in 2015. Improve internal timelines for closeout.

VCU Approach to Major Issues – Today

Fixed Amount Awards	Fixed price subawards limited to Simplified Acquisition Threshold (currently $150,000). Prior Federal Agency approval required. How to handle current FP clinical trials and subaward situations?
Administrative / Clerical	Salaries still normally treated as indirect cost. Direct charge only if (1) integral, (2) allocable, (3) justified in budget and has agency approval, and (4) not also recovered as indirect cost.
Compensation - Fringe Benefits	Monitor for anticipated OMB FAQ clarification. VCU (cash basis) unused terminal leave sometimes direct charged to grants. Prepare for improved tracking.

VCU Approach to Major Issues – Today

MTDC	"Participant support costs" to be added to exclusions list. Monitor for clarification that "subcontractor" refers only to subrecipient relationships (and not also procurement.)
Subrecipient vs. Contractor Determination	No change to characteristics of a subrecipient vs. contractor (vendor.) Substance of the relationship more important than form of the agreement; must document.
Supplies / Computers	Direct charge of computing devices allowable, must be "essential and allocable", but not necessarily solely dedicated to federal award.

VCU Approach to Major Issues – Today

Effort Reporting	Continue to use current Effort Reporting / ECRT system. Monitor outcome of FDP demonstrations on payroll confirmation.
Cost Share	Federal Agency must have OMB approval and publish in program announcement.
Indirect Cost Rate	Federal Agency / Pass Through Entity must honor negotiated rates unless limited by law or regulation or approved by agency head. "De minimis" rate of 10% MTDC when no rate agreement / new.

VCU Approach to Major Issues – Today

Single Audit Requirement	Threshold in FY expenditures in Federal awards increasing from ≥ $500K to ≥ $750K.
Performance Management	OMB-approved governmentwide standard information collections are acceptable. Research Performance Progress Report (RPPR) meets standard.
So much that is…SAME SAME	(But different, so be sure to come to offered training later in the fall)

Research Administration and Compliance Meeting

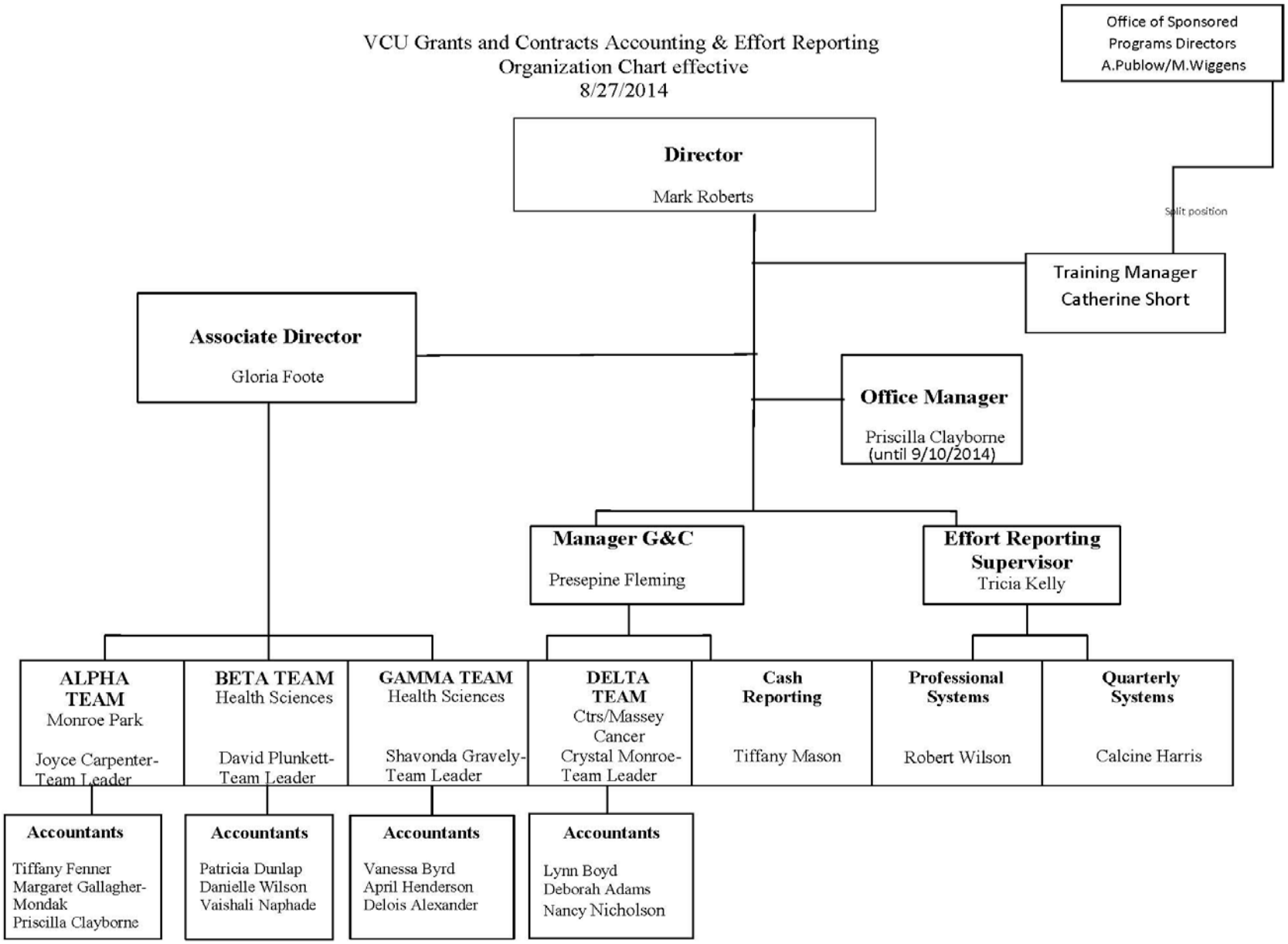
August 27, 2014

Grants & Contracts Accounting Updates

G&C staff and misc. updates

- Welcome April Henderson and Shavonda Gravely.
- Updated Org chart

VCU Grants and Contracts Accounting & Effort Reporting
Organization Chart effective
8/27/2014



FY14 Compliance Audit of G&C

Concluded recently with the auditor's opinion that "the university complied in all material respects, with the types of compliance requirements described in the OMB Circular A-133 Compliance Supplement".

Congratulations to you!

ECRT Institutional Base Salary (IBS) Definition

- Proposed university definition will be reviewed by Committee for the Administration of Research (CAR)
- See G&C website link http://www.controller.vcu.edu/pdf/ECRTbasesalarycategories.pdf for the published listing of compensation codes included in ECRT.

Other update…..Transition to subaccounting by NIH

For domestic, non-competing awards, transition has been delayed by one year; this implementation will now occur between October 1, 2015 and September 30, 2016

Questions???

Thanks for your continued assistance.

Grants and Contracts Accounting/Effort Reporting

Mark Roberts

Research Administration And Compliance Update

August 27, 2014

NIH Notice NOT-OD-14-113

- Revised Policy: Descriptions on the Use of Individual Development Plans (IDPs) for Graduate Students and Postdoctoral Researchers Required in Annual Progress Reports beginning October 1, 2014
- IDPs Not Required but Strongly Encouraged
- October 1, 2014 – RPPR must include description of whether the institution uses IDPs or not and how they are employed to help manage training and career development

IDPs

- Report in Section B. Accomplishments, B.4.
- VCU has not mandated use of IDPs as of this date; however, final decision has not yet been made
- Notice available at:
- http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-113.html

Subrecipient Commitment Form

- Subrecipient Commitment Form updated
- Rare instance when a subrecipient PI does not meet the definition of COI Investigator
- VCU PI can check the box
- Requires corroboration of ORIE Director

Clinical Research Compliance Checklist 8-26-14

- Now includes box for Original or Revised
- Moved the indication of device, non-device, or clinical research
- Added preliminary and final checkboxes to those areas where preliminary documents may be acceptable

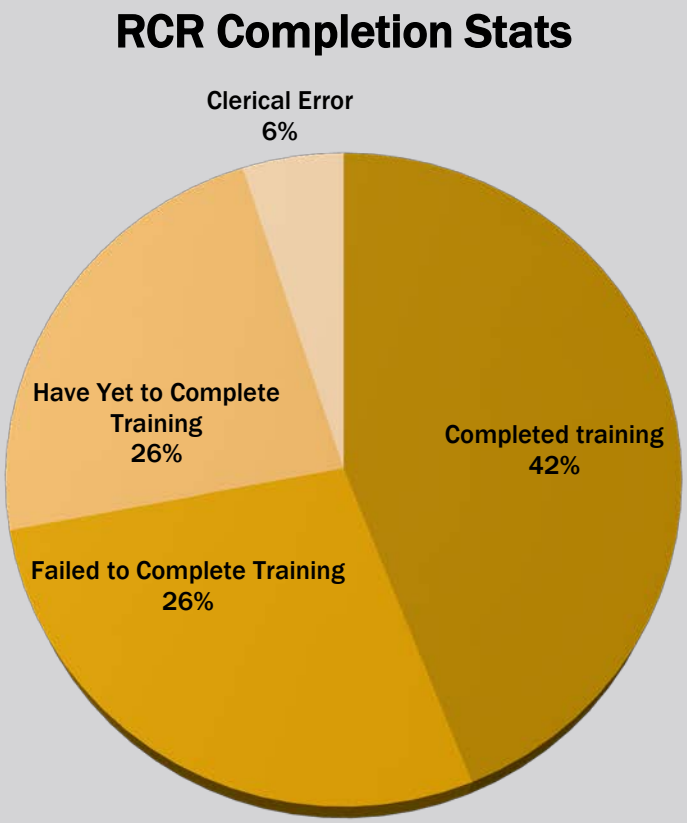
Clinical Research Compliance Checklist 8-26-14

- School/Center will be required to distribute billing documents to VCUHS for external funding if final documents were not provided to OSP prior to award
- OnCore Data Entry: Added a checkbox for "Holding: Protocol Development Pending" School/Center will need to track this

NSF AND NIH RCR TRAINING COMPLIANCE UPDATE

Office of Research Update 2014

CURRENT NSF RCR COMPLIANCE



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."

QUESTIONS?

- VCU RCR Course Matrix
- RCR Training Completion Form

Clinical Research Compliance Officer: Betsy Ripley
Faculty Held IND/IDE

Investigational New Drug/Investigational Device Exemption

- Oversight of investigator compliance activities related to FDA regulated research including Investigative New Drugs (IND) and Investigative Device
- Education and training needs for IND and IDE compliance
- Oversee and report on inventory, including status profile, of all VCU Sponsor-Investigator Investigational New Drug and Investigational Device Exemptions.
- Collaborate with the VCU CCTR on Clinicaltrials.gov registration and reporting
- Develop and oversee an institution-wide tracking process for VCU investigator-held applications for FDA approval of IND and IDEs, approvals, SAE reporting, and annual reporting.

Faculty Held IND/IDE

Investigational New Drug/Investigational Device Exemption

- Website

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

Tools, Templates, Links, Handbook

- REDCap for submissions:

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

Contact: Betsy Ripley, MD, MS at eripley@mcvh-vcu.edu
804-828-1955, 804-687-3062

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 this Fall: Audits of all protocols related to these

OnCore Audit Console

- Part of VCU's Quality System for Clinical Research
- It is the institutional format/documentation for Monitoring and Auditing at VCU
- Console allows for setup of a Monitor or Audit visit, Documenting Observations, Creating reports to study teams, Tracking for education and QA/QI
- Items are GCP, regulations, VCU Policy based
- Wiki page has the information about the console and checklist items www.go.vcu.edu/wiki Compliance
- Contact Betsy Ripley if your area conducts (or would like to start) monitoring or auditing of clinical research/clinical trials.

*Compliance Documentation Checklist (For All Clinical Research)

PI Name: 5T	**STATUS OF THIS COMPLIANCE SUBMISSION:** ☐ **Original** *or* ☐ **Revised: 5T**
PI Department: 5T	
PT/PD/SC #: 5T	
HM #: 5T	**Clinical Trial Registration (NCT #): 5T**

Protocol Type *(select one)*:

☐ Clinical Trial

☐ Clinical Research *with a clinical trial component* (select one):
- ☐ scheduled to begin at initiation of the award
- ☐ proposed for later in the project

☐ Clinical Research *with no clinical trial component*

Initiator *(select one)*:

☐ Investigator-Initiated Protocol: 5T

☐ Sponsor-Initiated Protocol: 5T

Resource Types *(select all that apply)*:

External
- ☐ Financial Resources: 5T
- ☐ Executed Materials Transfer Agreement (see requirements): 5T

Internal
- ☐ Financial Resources: 5T

Document Checklist: This study involves: ☐ *A device trial* ☐ *A non-device trial* ☐ *Not a clinical trial (CR)*

☒ This checklist		☐ VCU Internal Approval Form (IAF) -- *placed behind this form*	
☐ Prepared Internal Budget		☐ External/Sponsor's Budget, if provided -- *placed behind internal budget*	
VCU Clinical Research Cost Coverage Analysis: ☐ Study Qualification Form (including NCT#) ☐ Billing Grid (including NCT#) ☐ Billing Set-Up Form (including NCT#) ☐ Prepared **Enrollment Log (including NCT#)	☐ *Preliminary* ☐ *Final*	☐ Contract if provided by Sponsor (Industry/other)	☐ *Preliminary* ☐ *Final*
☐ Protocol/Synopsis or Proposal Submission	☐ *Preliminary* ☐ *Final*	☐ Other: 5T	
☐ Informed Consent Document Draft	☐ *Preliminary* ☐ *Final*	**Notes:** 5T	

Budgeting / Billing Responsibilities:

Budget developed by: ☐ CCTR Clinical Research Services ☐ SOM Central ☐ MCC Central ☐ Other: 5T

Initial billing documents to be submitted to VCUHS by: ☐ School/Center (Internal /or/ Ext. Funding) ☐ OSP (External Funding)

External sponsors to be billed by: ☐ Research Team ☐ Department Administration ☐ Grants and Contracts

Clinical Service Providers:

☐ VCUHS/MCVP ☐ VCU Dentistry ☐ Other: 5T

OnCore:

Study entered into OnCore by: ☐ CRS ☐ MCC ☐ SOM OR ☐ Holding: *Protocol Development Pending*

Compliance Document Package Verified By:

Name: First and Last Name Email Address: 5T

*See second page for definitions/instructions

**Inclusion of the enrollment log is recommended, but not required at this time.

*Compliance Documentation Checklist (For All Clinical Research)

Purpose	To facilitate and record school/center receipt and review of key compliance documents supporting clinical research, applying these standards uniformly to both internally-supported and externally-sponsored/proposed clinical research.
Preparation & Submission	The school/center should define who utilizes this checklist to document final 'clinical research package preparation' prior to school/center review. The submission workflow: • **SOM** preparers submit this checklist to SOM Office of Research Administration (in accordance with their requirements). • **MCC** preparers submit this checklist to the MCC Office of Research Administration (in accordance with their requirements). • **All other schools** submit this checklist to the CCTR Clinical Research Services Office (with complete clinical research package).
Definitions and Resources (by checklist section)	
Heading	• **Identifiers:** PI Name and Department should match other documents, no format requirement. • **Status:** Differentiates between initial and revised/amended submissions. • **PT/PD/SC #:** *(If available)* - A unique number assigned by the Office of Sponsored Programs database. • **HM #:** *(If available)* - A unique number assigned by the VCUIRB database. Resources: IRB/Human Research Protections • **Clinical Trial Registration NCT#:** VCU Clinical Trial Registration Policy, clinicaltrials.gov Account Create Form
Protocol Type	• **Clinical Trial:** 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. Preclinical laboratory studies or studies in animals are not considered clinical trials. • **Clinical Research with no trial component:** Patient-oriented research conducted on material of human origin (tissue, specimens, and cognitive phenomena). If checked, the protocol should not otherwise meet the definition of clinical trial. The research may include epidemiological and behavioral studies, outcomes research, and health services research. • **Clinical Research with a clinical trial component:** If checked, the protocol should meet the definition of clinical research, but have a future clinical trial component. Indicate if the clinical trial component is scheduled to begin (a) at the time the award is made or (b) at a later time during the project.
Initiator	• **Investigator-Initiated Protocol:** When the principle investigator has initiated or designed/authored the research protocol independently or collaboratively. • **Sponsor-Initiated Protocol:** When the intended sponsor initiated or designed/authored the research.
Resource Types	• **External:** Note origin of financial resources. If materials are provided outside of the scope of a Clinical Trial Agreement, a Materials Transfer Agreement must be negotiated between VCU Innovation Gateway and the provider of materials. • **Internal:** Identify financial resources committed, as specified by the school/center requirements (e.g., departmental funds, pool accounts, internal research awards, account detail).
Document Checklist	***Please note document status. Please ensure all critical documents are 'final' prior to approval.*** **All:** (Necessary documents for internally-supported *and* externally-supported/proposed research): • **Budgeting and Clinical Cost Coverage Analysis** Guidance and forms: Clinical Trial Budgeting Best Practices; Sample Internal Budget - Template, Ancillary Pricing Structure and Process; VCU Clinical Cost Coverage Analysis Process (Clinical Research Coverage Analysis Documentation, Billing Grid, VCU Billing Set-Up Form, Enrollment Log (recommended, to ensure preparation with correct NCT#). **Protocol/Synopsis or Proposal Submission:** Recommended format for a human research protocol (World Health Organization); Proposal Writing Resources (compiled by VCU Research Development), PI Proposal Checklist (via OSP). • **Informed Consent Draft:** Best practice is to include the draft of the informed consent document submitted for IRB review for research which could be activated promptly following school/center processes (when internally-sponsored) or VCU OSP processes (when externally-sponsored, e.g., industry contract). For more informed consent drafts/requirements, see: VCU Institutional Review Board. • **Other:** This space is provided as an option to document additional requirements (e.g., controlled substances). **ADDITIONAL:** (These documents are necessary ONLY FOR externally-supported/proposed research): • **IAF:** VCU Internal Approval Form (IAF), IAF Instructions (IAF) • **External Budget:** As applicable, budget in sponsor-required format or on sponsor required forms. The final budget figures/plan must match the internal budget (VCU format). • **Contract:** If applicable, written agreement between the Institution (VCU) and the sponsor (typically applies to industry-sponsors).
Budgeting & Billing	Identify the groups responsible for budget development, VCUHS initial billing document submission, and billing of any external sponsors.
Clinical Providers	Identify groups within VCU responsible for providing clinical services. Please note VCUHS Policy 4PC.CP.004 (v1) Conduct of Clinical Research In Patient Care Areas.
OnCore	Identify the group that entered basic data into OnCore for this clinical research protocol. *NOTE:* The CRS is currently the data-entry point for all non-SOM and non-MCC studies. If the clinical research described a future protocol, check 'Holding'.
Verification	Identify the individual verified completion of the compliance documentation checklist/package (include email).

Research Administration and Compliance Meeting
RACM
August 27, 2014

Clinical Research Services Updates
OnCore Subject Console Roll-out
Clinical Research Advisory Board Report

Fredika M Robertson, Ph.D.
Executive Director
Professor, Department of Internal Medicine,
Division of Hematology/Oncology and Palliative Care

What You Always Wanted to Know About OnCore And More

Coordinator Council Meeting
August 20, 2014

Fredika A. Robertson, Ph.D.
Executive Director, Clinical Research Services/CCTR
Professor, Internal Medicine, Division of Hematology, Oncology and Palliative Care

Kimberly B. Bradley, E.M.T., CCRP
Manager, CRS Coordinator Team
OnCore Coordinator Liaison
Member, OnCore Support Team

Why Use OnCore Clinical Trial Management System?

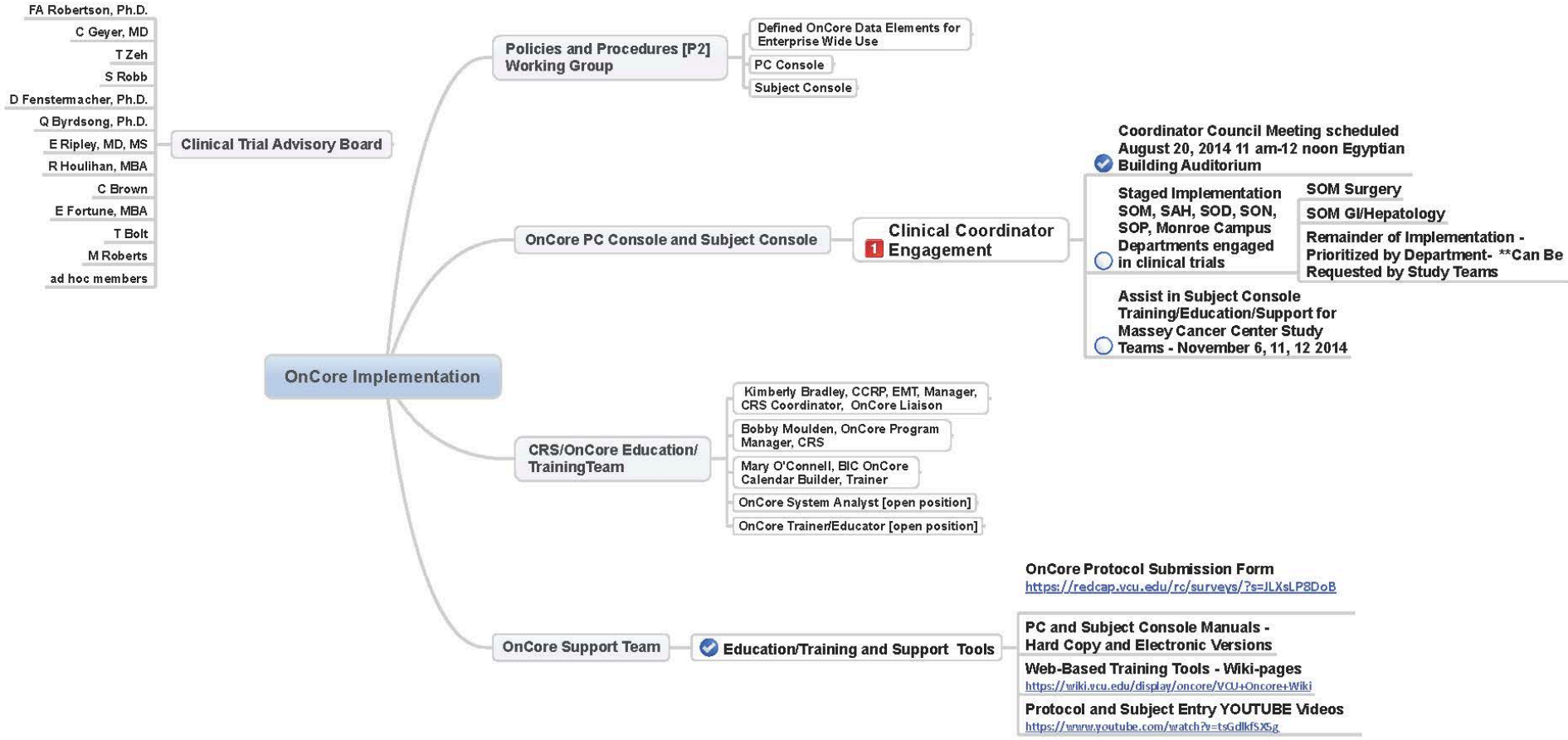
- Clinical Trial Database- We need a centralized clinical trial management system for oversight and tracking of all clinical research activities at VCU
- Clinical Trial Regulatory Compliance – We need a centralized, standardized approach to clinical trials compliance- eg, adequate auditing/monitoring 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 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

#1 Mission Critical Priority: Educate and Support Study Coordinators During OnCore Implementation of Subject and Financial Consoles



Study Coordinator/Team Roles & Responsibility- Submission of New Study Protocol or Amendments

- Fill Out Redcap OnCore Protocol Submission and Notification Form
- Upon submission, the study information will automatically be sent to the OnCore Support Team for protocol entry into PC Console

http://go.vcu.edu/oncoresubmission

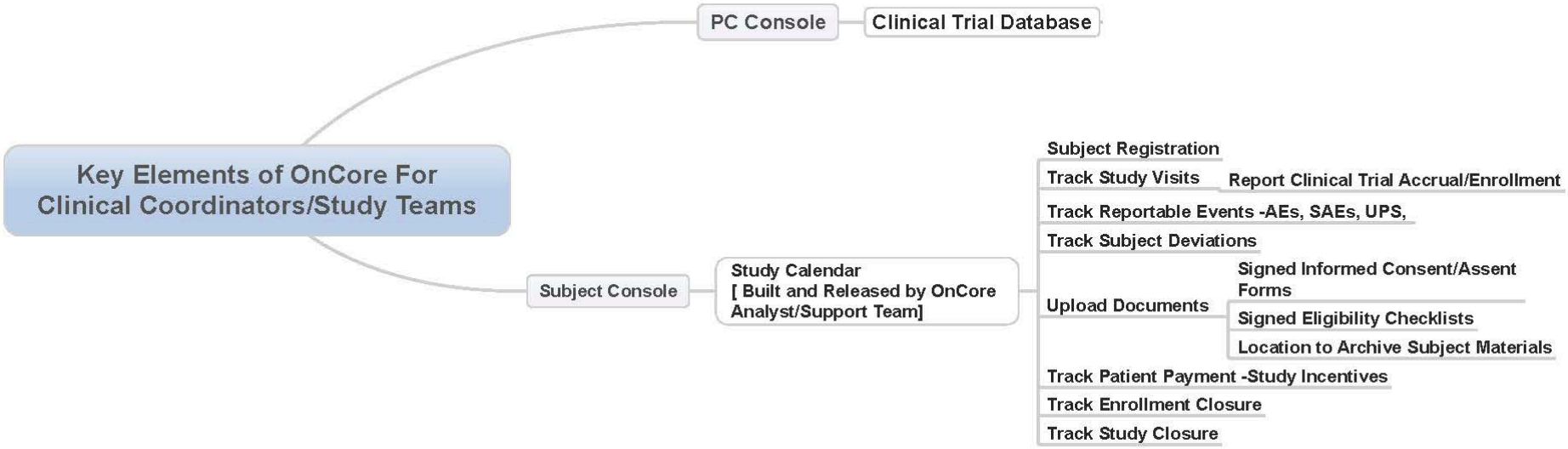
Contact our OnCore Support Team

- 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- When Should a Study be submitted to the OnCore Support Team?

- For Industry Studies- Submission of the OnCore Protocol Submission Form –Required At Time of Site Selection
- For All Other Studies- Submission of the RedCap OnCore Protocol Submission Form- Required at latest at time of IRB approval

Key Elements of OnCore for Coordinators



Study Coordinator/Team Roles & Responsibility- Subject Console Elements

Subject Console Data Entry may include:

- **Subject Registration**
- **Track Study Visits**
- **Reportable Events AE, SAE, UPs**
- **Subject Deviations**
- **eCRFs [IITs] –Data Monitoring for IITs**
- **Repository for Documents- Signed Informed Consent/Assent Forms, Eligibility Checklists, Archive Subject Materials**
- **Track Patient Payments-Study Incentives**
- **Track Enrollment Closure**
- **Track Study Closure**

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

Plan For Coordinator Training/Education/Support

- **Training/Education/Support**
  - SOM Department/Division Training [1st, Surgery, 2nd GI/Hepatology; remaining departments starting 8/2014]
  - Massey Cancer Center [11/2014]
  - SAH, SOD, SON, SOP, SOBE, Monroe Campus,
  - Small Study Team Groups / One-on-One
  - OnCore Training Manual, Videos, Process Flow Sheet, Pocket Information Card

Agenda
Clinical Research Advisory Board
Thursday August 21, 2014
11 am-12 pm MMEC 12-102

1. **Update on Progress by Policies and Procedures Working Group (P2)**

- Data Definitions for PC and Subject Console - Bob Houlihan

- Demonstration of Definitions in OnCore Consoles- Sara Twombly
- OnCore/Study Interactions Worksheet – Sara Twombly

2. **Update on VCU Enterprise Wide Clinical Trial Administration**

- Demonstration of OnCore Training/Education Tools –Bobby Moulden

  OnCore Protocol Entry Template
  OnCore Wiki pages
  Web based training tools
  System Navigation/Console Manuals

3. **Update on Compliance Working Group and OnCore Audit Console Implementation**

- Discussion of Audit Console – Betsy Ripley
- Bobby Moulden – demonstration of OnCore Audit Console Checklists

4. **Plans for Financial Console Implementation –**

    - **Huron Engagement Status –Quincy Byrdsong/ David Fenstermacher/**
    - **Partnership with Quincy Byrdsong – Vice President for Clinical Research Administration and Compliance, VCUHS**

Study Coordinator/Team Roles & Responsibility-
Accessing OnCore

- **To Request Access to OnCore as a New User**
  http://go.vcu.edu/oncorenewuser

- **Accessing OnCore with One Click**
  http://go.vcu.edu/oncore

Study Coordinator/Team Roles & Responsibility-

What Studies Go Into OnCore?

- **IF THE STUDY REQUIRES IRB SUBMISSION IT MUST BE SUBMITTED FOR ENTRY INTO ONCORE**
- **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**

OnCore Education/Training Tools- OnCore Subject Entry Manual

Purpose

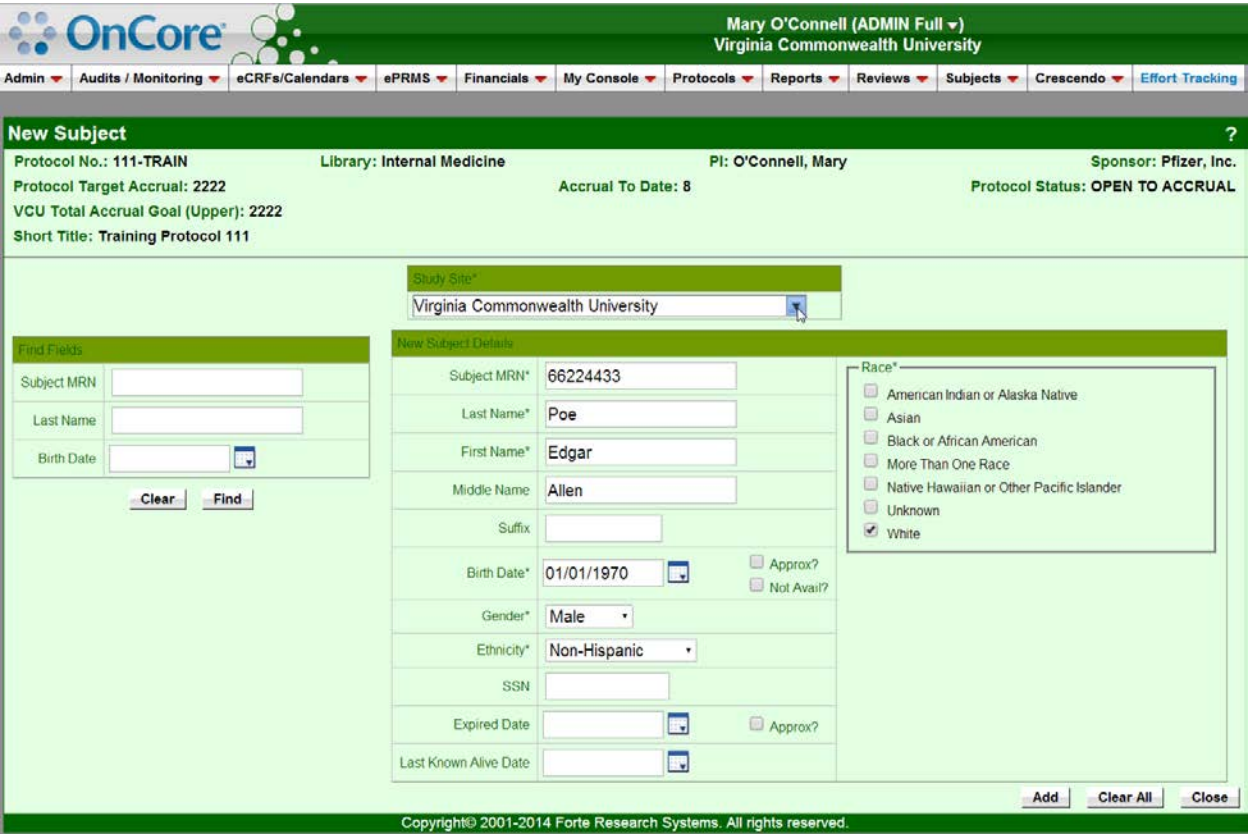
- **Provides visual training materials for entry of information into the Subject Console of OnCore**

- **Manual is available online and can be printed**

  http://go.vcu.edu/oncoretraining

- **For additional support with the subject console contact the OnCore Support Team at oncore@vcu.edu**

New Subject- Details



Select the study site where the subject is registered from the drop down menu. Enter the subject's MRN, Last Name, First Name and other information in the fields under New Subject Details.

Subject MRN (Required)

Field Definition

A unique participant MRN.

Field Notes

If a VCUHS MRN exists or can/should be created for this participant, that information should be entered in this field. For studies that do not have, or cannot obtain a VCUHS MRN, HM Number-Sequential number of registration in OnCore will be entered.