Clinical Research Administration and Compliance Meeting
Wednesday, May 10, 2017
Ball Conference Room, BioTech One
1:30 – 3:00 p.m.

Clinical Research Administration

- Grant and Contracts Update – Mark Roberts
- Office of Sponsored Programs Update – Tina Cunningham
- Wright Center Update – Alanda Perry
- Office of Environmental Health and Safety – Mike Elliot
- Self-monitoring of Full Board Studies – Betsy Ripley/Beth Collins
Annual FIR Update in AIRS

• Update period: May 10th-July 1st
  • For all PIs and COI investigators on active or pending proposals or protocols
  • No proposal/protocol progression until annual update completed
  • Annual update required even if no changes
  • Particular circumstances
    • Last update on 5/10/16 and we receive a COI review request on 5/15/17 = over a year old
    • Last update on 11/10/16 and we receive a COI review request on 7/15/17 = outside of update period
    • Last update on 5/10/16 and we receive a COI review request on 7/15/17 = over a year old and outside update period

• COI in Research training (required at least every 4 years) precedes FIR update automatically when due
Notable Changes

• To FIR
  • No SoEl option, just Research FIR
  • FIR questions – text more user friendly

• To COI in Research process
  • Competing Financial Interest (CFI) becomes Competing Interest (CI)
National Clinical Trials Day

Friday, May 19

- Table in Gateway 10 am- 2 pm.
- Community Health & Education Center (CHEC)- adjacent to Gateway table
  - Navigators to assist anyone interested in exploring Study Finder, ClinicalTrials.gov, etc
  - Educational materials during the week on CHEC table
- Various PR activities involving social media, VCU TelegRam, Mass Mail
Fee Establishment Proposal

Purpose/Rationale

• Initiative designed to increase uniformity in budgeting and establish mechanism for revenue to be recovered for units providing specialized support

Services Covered

• Study Activation/Start Up
  – Regulatory
  – Coverage Analysis
  – Budget Development and Negotiation
  – Data Management

• Amendments
  – Regulatory
  – Budget & Contract

• Other Administrative Fees
  – Ongoing Maintenance
  – Closeout
Compliance Notices

- [https://research.vcu.edu/secure/compliance_program/compliance_notices.htm](https://research.vcu.edu/secure/compliance_program/compliance_notices.htm)

The following VCU OVPRI Compliance Notices have been posted for comment:

<table>
<thead>
<tr>
<th>Draft Compliance Notice</th>
<th>Post Date</th>
<th>Comments Due By</th>
<th>Submit Comments To</th>
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<tbody>
<tr>
<td>DRAFT 17-003 Clinical Trials Registration and Results Reporting 4-28-17.docx</td>
<td>April 28, 2017</td>
<td>May 12, 2017</td>
<td>You Lee Kim</td>
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<td><strong>Related Forms:</strong></td>
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<tr>
<td>- Sponsored Project Research Volunteer Documentation Form - 4-24-17.docx</td>
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<tr>
<td>- Sponsored Project Research Volunteer Safety Form - 4-24-17.docx</td>
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<tr>
<td>DRAFT 17-004 Sponsored Project and Research Volunteers 4-24-17.docx</td>
<td>May 3, 2017</td>
<td>May 17, 2017</td>
<td>Lisa Ballance</td>
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<td>DRAFT 17-005 Compliance with Federal Funding and Transparency Act 5-3-17.docx</td>
<td>May 3, 2017</td>
<td>May 17, 2017</td>
<td>You Lee Kim</td>
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Other Initiatives

• Improvements to the Informed Consent Review Process
  – Pursuing review of OnCore to manage process

• Improvements to Obtaining Intellectual Property Assignments
RAMS-SPOT Update
RAMS-SPOT Phased Implementation

Phase 3: Subrecipients
- Implemented Subrecipient Project with March 31, 2017 patch
- Working to “back fill” existing subrecipient data
- It’s going well!
- We’ll send announcement when subrecipient actions can be processed by you, will be training

Phase 4: Closeout and Reporting
- Final aspects of RAMS-SPOT implementation

Refinements to existing underway and will be ongoing

Next patch – May 26, 2017
RAMS-SPOT Notes

Administrative Actions:

• Following items will route for School Approval for Clinical Trials only
  • Change in Scope
  • Decrease
  • New Subawardee
  • Agreement Modification
  • Personnel: Change in Committed Effort
  • Rebudgeting

• Once change in SPOT made, “Get Started” document for Administrative Actions will be published
Organizational Restructure

CRS Budget Development and SOM Budget Review Teams

BETTER TOGETHER

CRS budget staff will be joining the SOMCT team!
Institutional Biosafety Committee: “IBC”

• Required by National Institutes of Health (NIH) rDNA Guidelines for all Institutions receiving NIH funding

• Primary mission: review all research protocols involving rDNA applications to ensure protection of staff, public, and environment

• VCU expanded IBC mission: in addition to reviewing all rDNA applications, review all clinical trials involving biohazardous agents, and any procedures involving biological agents deemed to present significant hazards.

• VCU IBC Membership:
  - 5 Practicing Scientists (2 Microbiologists, Geneticist, Immunologist, Plant Biologist)
  - 2 Public Members
  - 3 Safety Professionals
  - Clinical Trial/Human Subjects Professional
  - Research Integrity and Ethics Expert
  - Attending Veterinarian
Memorandum of Understanding and Agreement: “MUA”

• Principal Investigators (PIs) must submit MUA whenever protocol involves:
  - ANY recombinant DNA (rDNA) application
  - Biohazardous Agents (BSL-1/RG-1 or >) including bacteria, viruses, fungi, prions, parasites, etc.
  - Potential exposure to Bloodborne Pathogens (BBPs).

• MUAs involving significant rDNA/biological hazards will require full IBC review and approval (IBC meets monthly)

• MUAs involving less significant hazards may be directly approved by “Biosafety Office” (me).
Memorandum of Understanding and Agreement: “MUA”

- Laboratory Research Protocols (“Nonhuman Use”):
  http://www.vcu.edu/oehs/chemical/biosafe/MUA061306.doc

- Clinical Trials (“Human Use”):
  http://www.vcu.edu/oehs/chemical/biosafe/MUAClinical.docx

- Both MUA “WORD” forms are available on Office of Environmental Health & Safety (OEHS) website:
  http://oehs.vcu.edu/chemical/index.html

- Submit completed MUA forms to Biosafety Office (mtelliot@vcu.edu)

- Call (804-400-4984) or email me (Mike Elliott) at any time for assistance.
VCU Quality & Study Monitoring

Beth Collins, MA, CCRP
Clinical Research Auditor
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**WHO/WHEN:**

- **[Pilot Phase]** All IND and IDE Studies
  - Started December 2016
- **[NEXT]** All Full Board Studies
  - Fall 2017 at time of continuing review
WHAT & WHERE:

REDCap Submission-  go.vcu.edu/submit/monitor

1. In the last year, has your study been monitored by a CRO, Massey Cancer Center, VCU Johnson Center, or other Internal/External Monitoring Group?
2. Has study monitoring identified any amendment that needs to be submitted or was submitted to the IRB?
3. Has monitoring identified any issues that need to be reported to the IRB?
4. During the review have you identified any problems or concerns that you are addressing which did not need to be reported or submitted as an amendment?

VCU Clinical Research QA Assessment Worksheet

   go.vcu.edu/indide
VCU Clinical Research Quality Assurance Assessment

**WHY:**

- To improve quality
- To identify future education needs
- To assure that studies are being conducted according to Federal Regulations, Policies, Guidance, VCU policies and conditions of IRB approval
Quality Assurance- Monitoring has always been a part of approvals, regulations, guidelines, and policies.

IRB Approval: “Conditions of Approval:

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must (as applicable):

1. Conduct the research as described in and required by the Protocol.
2. Obtain informed consent from all subjects without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate (unless Waiver of Consent is specifically approved or research is exempt).

... 
6. Monitor all problems (anticipated and unanticipated) associated with risk to research participants or others.

”
ICH Harmonized Guideline ICH E6(R2): Guideline for Good Clinical Practice

5.18 Monitoring

5.18.1 Purpose

The purposes of trial monitoring are to verify that:

(a) The rights and well-being of human subjects are protected.
(b) The reported trial data are accurate, complete, and verifiable from source documents.
(c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s)
21 PART 312 INVESTIGATIONAL NEW DRUG APPLICATION

- Subpart D--Responsibilities of Sponsors and Investigators
- Sec. 312.50 General responsibilities of sponsors.
  - Sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND, maintaining an effective IND with respect to the investigations, and ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. Additional specific responsibilities of sponsors are described elsewhere in this part.
9. COMMITMENTS

- I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

- I agree to personally conduct or supervise the described investigation(s).

- I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met...

- I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.
21 PART 812 INVESTIGATIONAL DEVICE EXEMPTIONS

- Subpart C--Responsibilities of Sponsors
- Sec. 812.46 Monitoring investigations.
  - (a) Securing compliance. A sponsor who discovers that an investigator is not complying with the signed agreement, the investigational plan, the requirements of this part or other applicable FDA regulations, or any conditions of approval imposed by the reviewing IRB or FDA shall promptly either secure compliance, or discontinue shipments of the device to the investigator and terminate the investigator's participation in the investigation. A sponsor shall also require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.
Clinical Research Quality Assurance Assessment

- Pilot Phase: All INDs and IDEs
- Next Step: Full Board Studies
- Current plan is to tie only to time of Continuing Review but not part of IRB process.
- Submissions through [go.vcu.edu/submit/monitor](go.vcu.edu/submit/monitor)
- [If needed] Assessment and Monitoring Template can be found at [go.vcu.edu/indide](go.vcu.edu/indide)
Clinical Research Quality Assurance Assessment

• Educational Sessions:

  – **May 16, 2017** from 8am-9am
    • Location: MMEC, 11-101 & 11-102
  – **May 31, 2017** from 12noon-1pm
    • Location: MMEC, 11-101 & 11-102
  – **June 15, 2017** from 4pm-5pm
    • Location: Sanger Hall, 1-050
  – By Appointment

ALSO
Self Monitoring Process Training Sessions TO COME
Contact Information

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Thanks!