Clinical Research Administration and Compliance Meeting  
Wednesday, October 11, 2017  
Founders Room, BioTech One  
1:30 – 3:00 p.m.

Clinical Research Administration

- Clinical Trial Definition: Updates – Alanda Perry Jones
- Subject Injury Review Process – Melanie Wiggins
- Clinical Research Coordinator Education Task Force – Lydia Klinger
- TriNetX – Shirley Helm
- Draft VCU Employee and Facility Use Requirements and Recommendations for the Conduct of Clinical Research – Sue Robb/Shirley Helm
- IIT Roles and Responsibilities Webinar – Susan Robb

Future Dates for RACM Meetings

- November 29, 2017 - University Student Commons, Richmond Salons, 1:30-3:00  
  o General RACM
- January 17, 2018 - BioTech One, Founders Room, 1:30-3:00  
  o Clinical RACM
- February 21, 2018 – BioTech One, Founders Room, 1:30-3:00  
  o General RACM
- March 21, 2018 - BioTech One, Founders Room, 1:30-3:00  
  o Clinical RACM
NIH Clinical Trials & Training

Expanded Definition

• **Case Studies (#9, 14, 18c, 18e)**

• **FAQs**

• If *any* outcome measure meets definition
• Short-term/transient outcomes
Joint Letter from AAMC/AAU/APLU/COGR

- Break from October 2014 Notice (explicitly did not intend to expand scope)
- Case studies lack sufficient clarity
- Significant consequences
  - ClinicalTrials.gov – reduced utility for public
  - GCP requirements
  - Potential funding limitations (fellows, trainees)
  - New Forms
  - Single IRB
Rationale

“We have an ethical mandate to assure the public that the results of all NIH-funded trials will be made available in a timely manner. We know that under the current state of affairs, over half of all completed NIH-funded trials are not reported out within 2.5 years of completion; the problem is widespread and pervasive. This is an unacceptable state of affairs; it should not be optional to report results. We look forward to continuing to work with you as we move towards higher levels of trust and transparency.”

-Dr. Michael Lauer, NIH Deputy Director for Extramural Research

Continuing to Clarify the NIH Definition of a Clinical Trial
Challenges

• Short timeline
  – **October 25, 2017** - FORMS-E Application Packages will start being published for FOAs with due dates on or after January 25, 2018.
  – **January 25, 2018** – First due dates for new FORMS-E Application Packages

• Identifying clinical trials consistently
• Regulatory compliance (esp for areas new to clinical trials)
• Impact on the selection of NIH clinical trial funding opportunities
Guidance

• NIH Program Officer
• Clinical Trials Decision Tree Tool

• TBD Training (Massey, OSP, SOM, Wright Center)
  – Form E Samples
  – Live Case Study Sessions (December/January)
Clinical RACM: Office of Sponsored Programs – Industry Update

Melanie Wiggins
Director, Office of Sponsored Programs – Industry and Clinical Trials – October 11, 2017
Revised Process for Subject Injury Language Review
Subject Injury Language Review Process – Key Points

• Draft Informed Consent Forms (ICF’s) for subject injury language review are uploaded into OnCore by Study Team/School (as appropriate) for OSP review.

• Reports are generated from OnCore and sent to OSP Red Team email based on completion of the following tasks on the Subject Injury Language Review Task List in OnCore.
  - Uploading the consent in OnCore,
  - Uploading the contract in SPOT and
  - Indicating the completion dates of those activities on the Subject Injury Task List in OnCore.

• Red Team accesses OnCore, reviews/negotiates the subject injury language in consent/contract and uploads the ICF version with the approved subject injury language and the WIRB Memo in OnCore for submission to IRB.
OSP Subject Injury Review Process - Overview

BEGIN process by logging in to OnCore. Under Protocol Tab, click on FC Console.

Select the appropriate Protocol.

Click on Status, Task Lists. Then find the OSP Subject Injury Language Review Task List.

Click on the Task List.

Complete Task 1 (Draft Consent Uploaded to OnCore) as follows:
- Attach a copy of the draft ICF which needs OSP subject injury language review.
- Add a comment in the Communications Section indicating ICF has been updated.
- Select contact name in the Owner Section.
- Enter the date in the Completed Date Section.

Upload the contract in SPOT through the Submit Document for review mechanism and link to the funding proposal. (Note: The review record should include the contact information for the Sponsor and the CRO, to include email address, for review of the ICF and contract.)

Log a Public Comment in SPOT in the Funding Proposal that consent form is available through OnCore for review.

Complete Task 2 (Draft Contract Uploaded to SPOT) as follows:
- Indicate the date in Completed Date Column that contract was uploaded in SPOT.
- Select contact name in the Owner Section and provide a comment in the Communications Section that contract has been uploaded.
- Please provide the associated funding proposal number in the comment.

Under Task 5: Study Team Notified of IRB Approval and Availability of Documents, School enters date in Completed Date Column and selects contact name in the Owner Section. School notifies Study team of availability of documents.

OSP completes Task 3, OSP Review Start. A report is generated and sent to IRB when OSP completes Task 3A, OSP Approved and Upload of Approved Injury Language ICP and Memo, and the approved subject injury review forms (Redline ICP and External IRB Memo) have been uploaded to OnCore.

Process Complete.
OSP Subject Injury Task List Reports

OSP Subject Injury Language:

1) OSP Red receives an email report generated from OnCore listing studies requiring OSP subject injury evaluation of the informed consent form (ICF).

The first report, Document Upload, is generated from OnCore when new consent is uploaded in Oncore and contract information is uploaded in SPOT, and the report will contain the following information requiring OSP assessment/review:

<table>
<thead>
<tr>
<th>Department</th>
<th>FP Number</th>
<th>Protocol Number</th>
<th>Sponsor</th>
<th>PI</th>
<th>Study Site Contact</th>
<th>Consent Uploaded</th>
<th>Contract Uploaded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massey Cancer</td>
<td>FP000006355</td>
<td>GPT-CRE-003H</td>
<td>OncoQuest Inc.</td>
<td>M</td>
<td>H</td>
<td>05/12/2017</td>
<td>05/15/2017</td>
</tr>
</tbody>
</table>

The Studies under Review report will be generated from OnCore on a weekly basis and will contain the following information under review by OSP:

<table>
<thead>
<tr>
<th>Department</th>
<th>FP Number</th>
<th>Protocol Number</th>
<th>Sponsor</th>
<th>PI</th>
<th>Reviewer</th>
<th>OSP Review Start</th>
</tr>
</thead>
<tbody>
<tr>
<td>School of Medicine</td>
<td>null</td>
<td>CER-1042-10522</td>
<td>Georgetown</td>
<td>S</td>
<td>H</td>
<td>08/07/2017</td>
</tr>
<tr>
<td>School of Medicine</td>
<td>null</td>
<td>CLCZ096BUS13</td>
<td>Novartis</td>
<td>S</td>
<td>H</td>
<td>08/08/2017</td>
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<tr>
<td>School of Medicine</td>
<td>null</td>
<td>GAM10-08</td>
<td>Octapharma</td>
<td>V</td>
<td>L</td>
<td>08/09/2017</td>
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</table>
### OSP Subject Injury Language Review Task List

<table>
<thead>
<tr>
<th>Task Lists</th>
<th>Status</th>
<th>Previous Task</th>
<th>Completed Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Oncology - CDA/Site Qualification - GS1840</td>
<td>In Progress</td>
<td>Site Selected</td>
<td>05/22/2017</td>
</tr>
<tr>
<td>2 Oncology - Feasibility - GS1840</td>
<td>Complete</td>
<td>Approved by Feasibility Committee</td>
<td>08/03/2017</td>
</tr>
<tr>
<td>3 Oncology - Calendar/CRFs - GS1840</td>
<td>In Progress</td>
<td>Calendar Drafted; Reviewing Teams Notified</td>
<td>10/02/2017</td>
</tr>
<tr>
<td>4 Oncology - Coverage Analysis - GS1840</td>
<td>New</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Oncology - Regulatory - GS1840</td>
<td>In Progress</td>
<td>Rec’d Negotiated Consent(s) from Research Admin</td>
<td>09/19/2017</td>
</tr>
<tr>
<td>6 Oncology - Budget - GS1840</td>
<td>In Progress</td>
<td>Draft Budget Received from Sponsor</td>
<td>05/24/2017</td>
</tr>
<tr>
<td>7 Oncology - CTA - GS1840</td>
<td>In Progress</td>
<td>Draft Contract Received</td>
<td>05/24/2017</td>
</tr>
<tr>
<td>8 Oncology - Activation - GS1840</td>
<td>In Progress</td>
<td>Register trial with CTRP</td>
<td>09/07/2017</td>
</tr>
<tr>
<td>99 OSP - Subject Injury Language Review - GS-US-406-1840</td>
<td>Complete</td>
<td>Study team notified of SIL approval and availability of documents</td>
<td>09/19/2017</td>
</tr>
</tbody>
</table>
## Task List – In Process

### OSP - Subject Injury Language Review - 017

**Status:** In Progress

<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>NA</th>
<th>Target Date</th>
<th>Completed Date</th>
<th>Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Draft Consent Uploaded to OnCore</td>
<td></td>
<td></td>
<td>10/02/2017</td>
<td>Rivers, Leslie - Virginia Commonwealth University</td>
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<tr>
<td>2</td>
<td>Draft Contract Uploaded to SPDP</td>
<td></td>
<td></td>
<td>10/09/2017</td>
<td>Sok, Meagan - Virginia Commonwealth University</td>
</tr>
<tr>
<td>3</td>
<td>OSP Review Start</td>
<td></td>
<td></td>
<td>10/10/2017</td>
<td>Hill, Amanda - Virginia Commonwealth University</td>
</tr>
<tr>
<td>4</td>
<td>OSP Approval and Upload of Approved Injury Language ICF and Memo</td>
<td></td>
<td></td>
<td>10/10/2017</td>
<td>Hill, Amanda - Virginia Commonwealth University</td>
</tr>
<tr>
<td>5</td>
<td>Study Team notified of SIL approval and availability of documents.</td>
<td></td>
<td></td>
<td></td>
<td>Owner</td>
</tr>
</tbody>
</table>

**VCU**
OSP SIL Status Update: Review Complete

<table>
<thead>
<tr>
<th>Organization Unit</th>
<th>Department</th>
<th>Protocol Number</th>
<th>PI</th>
<th>Study Site Contact</th>
<th>OSP Documents Uploaded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Center</td>
<td>Internal Medicine</td>
<td>017</td>
<td>Smallfield, George.</td>
<td>Demro, Elizabeth</td>
<td>10/10/17 12:00 AM</td>
</tr>
</tbody>
</table>
### Completed Task List in OnCore

**OSP - Subject Injury Language Review - GS-US-406-1840**

Status: Complete

<table>
<thead>
<tr>
<th>#</th>
<th>Task Description</th>
<th>NA</th>
<th>Target Date</th>
<th>Completed Date</th>
<th>Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Draft Consent Uploaded to OnCore</td>
<td></td>
<td>09/12/2017</td>
<td></td>
<td>Children, Victoria - VCU Clinical Research</td>
</tr>
<tr>
<td>2</td>
<td>Draft Contract Uploaded to SPIDT</td>
<td></td>
<td>09/11/2017</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>OSP Review Start</td>
<td></td>
<td>09/07/2017</td>
<td></td>
<td>Wiggins, Wekarie - Virginia Commonwealth University</td>
</tr>
<tr>
<td>4</td>
<td>OSP Approval and Upload of Approved Injury Language ICF and Memo</td>
<td></td>
<td>09/19/2017</td>
<td></td>
<td>Wiggins, Wekarie - Virginia Commonwealth University</td>
</tr>
<tr>
<td>5</td>
<td>Study team notified of SL approval and availability of documents</td>
<td></td>
<td>09/19/2017</td>
<td></td>
<td>Children, Victoria - VCU Clinical Research</td>
</tr>
</tbody>
</table>
Points of Contact for Contracting

Contact Information

• When providing contact information for negotiation of the contract, please provide an email contact for the Sponsor/Contract Research Organization (CRO).
• We will need separate contacts for consent form and contract review. Contact for consent form can be added as a Public Comment to the funding proposal.

Submit Document for Review

6. Sponsor Contact Information:
Sheryl Fross | RCO- Grants Manager
Global Clinical Operations|RCO, Americas

Rt 206 & Provinceline Rd,
Princeton, NJ 08543
E (609) 252-3181

sheryl.fross@bms.com

The Bristol Myers Squibb Site Manager:

Dr. Michael Keats
Clinical Site Manager
Bristol-Myers Squibb
Rt 206 & Province Line Road
Princeton, NJ 08540
Direct Office Phone 609-252-4947
E-Mail: michael.keats@bms.com
Questions??

Contact Red Team Liaison:
Amanda Hill at OSPRED@vcu.edu

Melanie Wiggins
Director
OSP-Industry and Clinical Trials
Phone: 827-4992
mwiggins@vcu.edu

Juanita Lawrence, M.Ed.
Assistant Director
OSP-Industry and Clinical Trials
Phone: 827-4993
juanita@vcu.edu
**TriNetX**
A global federated health research network connecting BioPharma, CRO, HCO

https://research.vcu.edu/compliance_program/trinetx.htm
VCU/TriNetX Partnership

• A robust feasibility and recruitment resource by exploring VCU institutional data with the goal of fully enrolling clinical research studies and bringing new therapies to our patients

• Increased opportunities to participate in industry-sponsored clinical trials which are **feasible** and of scientific interest and merit

• Expanded research opportunities with other health care organizations through collaborative networks
VCU/TriNetX Partnership

How it works:
TriNetX allows VCU researchers to query the VCUHS EHR system (Cerner), IDX, OnCore, and Tumor Cancer Registry for a specific patient/potential participant population in a de-identified manner for study feasibility and to help with study design. Currently, data in VCU TriNetX is updated on a monthly basis and spans back to 2010 (data expansion in future).
How Potential PI are contacted for Clinical Research Opportunities

From: YourEmailHere@edu.com
To: <PI Email Here>
Cc: 
Subject: Response Required: Investigator Research Opportunity From Sponsor Goes Here

Dear Dr. PI First Name Here PI Last Name Here,

The VCU Wright Center for Clinical and Translational Research has received information regarding an industry-sponsored clinical research study for which you have been identified as a possible principal investigator.

Please click on the link for detailed study information and to indicate your interest.

You may open the survey in your web browser by clicking the link below.

Clinical Research Study Opportunity

If the link above does not work, try copying the link below into your web browser:
https://redcap.vcu.edu/survey

This link is unique to you and should not be forwarded to others.
Clinical Research Opportunity Info & Response

Clinical Research Study Opportunity

Dear Dr. [Name],

The VCU Wright Center for Clinical and Translational Research has received a clinical research study opportunity from an Industry Sponsor with VCU identified as having a competitive patient population for this study opportunity.

You are being contacted as an investigator/physician with a patient population and/or interest area for this clinical research study opportunity. The TEST SPONSOR study information/description we have received is as follows:

TEST STUDY INFO HERE

Should you indicate an interest in this clinical research study opportunity, the Wright Center will connect you with the sponsor or CRO for more detailed information. Should you choose to decline this study opportunity, please indicate the reason(s) why you are declining as this assists us in developing more robust clinical research processes. If you know of another investigator who might be interested in this clinical research study opportunity, please provide the name and email address in the areas indicated on the response form.

Thank you for your consideration of this clinical research study opportunity and please do not hesitate to contact me directly if you have questions or need clarification.

Shirley L.T. Helm, MS, CCRP
Clinical Research Industry Liaison
Wright Center for Clinical and Translational Research
Phone: 804-628-2942
Email: shirley.helm@vcuhealth.org
Clinical Research Opportunity Info & Response

<table>
<thead>
<tr>
<th>Interest Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you interested in this study opportunity?</td>
</tr>
<tr>
<td>* must provide a response</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Need more information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cohort Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCUH Patient Cohort Count: _____</td>
</tr>
<tr>
<td>Time Interval (months) for VCUH Patient Cohort Count: _____</td>
</tr>
<tr>
<td>Predicted Annual Patient Cohort Arrivals: _____</td>
</tr>
<tr>
<td>Indication: TEST INDICATION</td>
</tr>
<tr>
<td>Intervention/Treatment: _____</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General Inclusion/Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion: _____</td>
</tr>
<tr>
<td>Exclusion: _____</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Study Documents for Your Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Synopsis</td>
</tr>
</tbody>
</table>

Today's Date:
10-15-2017

Submit
Clinical Research Opportunity Info & Response

Interest Response

Are you interested in this study opportunity?
* must provide value

Yes

No

Need more information

Please indicate why you are not interested in this study opportunity.

- Competing Studies
- General Disinterest in Conducting Clinical Trials
- Inadequate or Limited Patient Population
- Lack of Infrastructure
- Insufficient Expertise in Research Area
- Not Interested in Study
- Study Design Concerns
- Time Constraints/Limited Bandwidth
- Other

Is there another investigator you would recommend for us to contact regarding this clinical research study opportunity?

Yes

No

reset
Request a TriNetX Account

- [http://www.go.vcu.edu/bicrequest](http://www.go.vcu.edu/bicrequest)
- TriNetX support: trinetx@vcu.edu
- Wright CCTR TriNetX Liaison: shirley.helm@vcuhealth.org
- Wright CCTR Clinical Research Informatics TriNetX Analyst: shipy@vcu.edu