# ROAR Research Operations and Administrative Rounds

ROAR - Clinical Research Workshop
January 10, 2012
9:00-10:00 am
Lecture Room D



## **ROAR Research Operations and Administrative Rounds**

#### Future ROAR meetings:

- February 14, 2012 Lecture Room D
  - Grants and Clinical Research
- March 13, 2012 Lecture Room C-Grants
- April 10, 2012 Lecture Room B –
   Clinical Research



# **ROAR Research Operations and Administrative Rounds**

#### Agenda

- ORA announcements Paul Primrose
- Contract Terms Paul Primrose and Stacey Cleary
- Technology Development announcement Jill Wagner
- CTO announcements Terri Novchich
- HSPO announcements Kathy Hay
- Controller's Corner Kellen Takoch
- Research Quality Assurance announcements- Bill Pogash and Ray Scheetz



#### **ORA Announcements**

# Paul Primrose Contracts & Proposal Specialist



#### ORA ANNOUNCEMENTS

# PIAF / Hershey Blue reminders





#### PIAF / Hershey Blue

 On page 1, box 5 of the PIAF, even though the box reads "Consortium/Institute" do not list Cancer Institute, HVI, or Neuroscience Institute.

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1110	POSAL INTI
College Proposal ID N	0.:
Principal Investigator/P	roject Correspondent
3. College/Unit	
Medicine	
5. Department/Subunit (Co	onsortium/Institute/Center, etc.)
<u>-</u>	



#### PIAF / Hershey Blue

# List Academic Departments in box 5.

- Biochemistry and Molecular Biology
- Comparative Medicine
- Public Health Sciences
- Humanities
- · Microbiology and Immunology
- Neural and Behavioral Sciences
- Pharmacology
- Cellular and Molecular Physiology
- Anesthesiology
- Dermatology
- Emergency Medicine
- Family Medicine
- Medicine
- Neurology
- Neurosurgery
- Obstetrics and Gynecology
- Ophthalmology
- Orthopaedics
- Pathology and Laboratory Medicine
- Pediatrics
- Psychiatry
- Radiology
- Surgery



#### PIAF / Hershey Blue

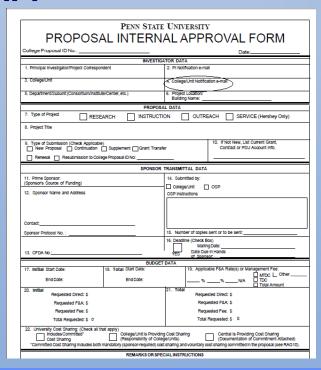
Institute information should be provided on the Hershey Blue Sheet:

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Investigator		Project Effort			tor Name/Title
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Pathology	Clinical Labs		Cen	ter for NMR Research	Spec
Radiology	Core Endocrine La			lic Health Sciences	Gene
	Clinica	al Research Sub	mission	& Contact Informati	on
Sponsor's Contract Conta	ect:			Fax:	
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ALSO: PIAF / Hershey Blue contact (box 4 on PIAF, and Dept. Contact on Blue) information should be the person who ORA should contact if issue w/ forms:

#### PIAF:



#### **Hershey Blue:**

Research Hours	Browing Compliance	MS#	Dop	PARTMENT CONTAC t. Contact to & Ext.	TINFORMATION	
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Chair Department of	f Comparative Medicine,	for IACLIC	IRB Protoc	ol #		
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Core Facilities	Microbiology Lab	,	Cardiology Services	Investigation	nal Pharmacy	
Pathology	Clinical Labs		Center for NMR Resear	ch Special Hem	natology Lab	
Radiology	Core Endocrine L		Public Health Sciences		ical Research Center	
	Clinic	al Research Submi:	ssion & Contact Inform	ation		
Sponsor's Contract Co	ontact:		Fax:			
Phone:		E-mai				
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Phone:		E-mai				
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Phone:	LS OFFICE (CTO)/OFFI			TED REVIEW DOCUME	ENT CHECKLIST	
Paper Electronic	Form (Paper accepted O	LY if electronic version	not available)	ORA	СТО	
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Paul Primrose
Contracts & Proposal Specialist
Stacey Cleary
Contracts & Proposal Specialist



What happens during clinical trial contract negotiations?





- What are some of the terms ORA negotiates?
- How do these terms benefit you?



- Some issues are "deal-breakers." Other issues depend on individual circumstances.
- College personnel, department personnel, investigators, and central contracting personnel need to understand each other's goals in order to facilitate solutions.
- Communication and unified approach facilitate win-win solutions.



#### Indemnification:

If we are sued because we did our job, the sponsor will cover costs and liabilities.



#### Insurance:

How do we make sure risk can be paid for?



## Subject Injury:

Sponsor will reimburse for treatment of injuries.

Your consent form must reflect the contract language.



#### **AAHRPP Clauses:**

They're all about the safety of our patients who are enrolled in our trials.



#### **Confidentiality:**

Some things shouldn't be discussed, but what sorts of things and for how long?



#### Publication:

Some things should be discussed. How do you go about doing that?



#### Termination:

When does the trial end?

If the trial ends early, what costs are reimbursed?





Successful Negotiations:

All of these clauses are important, but not all equally so.

Negotiation delays can negatively impact faculty and students.

By working together, we can balance the competing interests.



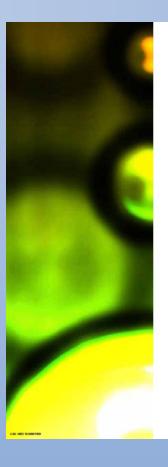
## QUESTIONS?



#### Technology Development Announcement

Jill Wagner
Contracts & Proposal
Specialist





#### nnovationCafé

FORUM AND NETWORKING EVENT

#### **GUEST SPEAKER**

#### Stephen Tang, Ph.D.

President and CEO of the University City Science Center in Philadelphia and member of the Harrisburg University Board of Trustees

#### NEW THERAPEUTIC TECHNOLOGY PRESENTATION

Gavin Robertson, Ph.D., Director, Penn State Hershey Melanoma Center and Tom Lytle, interim CEO, Melanomex Oncology Inc.

#### Wednesday, January 11, 2012 | 8:00 a.m.

Hershey Center for Applied Research 2nd floor, 1214 Research Park Blvd., Hummelstown

The presentation begins at approximately 8:30 a.m. following a networking opportunity with light breakfast fare.

This event is sponsored by the Penn State Hershey Office of Technology Development.

PLEASE RSVP TO 717-531-8496 OR KROBEY@HMC.PSU.EDU.







#### **CTO Updates**

Terry Novchich, RN, CCRC
Director, COM Clinical Trials Office
January 10, 2012



#### Infonet & CTO Resources

- Research department lists standardized
- Orientation checklist & competencies
- Many additions to generic forms
- Regulatory documents
  - Updates to lab director and certificates
- Standard Operating Procedures
  - All researchers responsible for content
  - Document staff review
  - Review checklist template available with SOP GA- 101



#### Clinical Research Skills Workshop

#### Clinical Research Skills Workshop

(Recommended for new investigators, clinical research associates/coordinators, regulatory coordinators, and research budget administrators)

Presentations by <u>special content experts</u> at each Session

Thursdays, February 2, 9, 16, 23 and March 1, 2012 Room T3007 (Third floor Cancer Institute) 1:00 - 3:00 pm

Participation is limited by room availability.

Please RSVP as soon as possible to:

Paula Navagato (x3779) or pnavagato@psu.edu

2.0 Contact hours awarded per session.



Penn State Milton S. Hershey Medical
Center, Nursing Education and Professional
Development is an approved provider of
continuing nursing education by the PA
State Nurses Association, an accredited
approver by the American Nurses
Credentialing Center's Commission on
Accreditation.

PENNSTATE HERSHEY

College of Medicine

- Presentations covering IRB, contracts, budgets, IDS, institutional SOPs, and competencies
- Contact hours awarded
- Call or email to reserve a space

SHEY e of Medicine

Good People. Great Medicine.<sup>™</sup>
PennStateHershey.org

#### **CTMS Update**

- Clinical Trials Management System to aid in the tracking of all clinical research studies, subject enrollment, and finances
  - Vendor selection complete Click™
     Portal (formerly Click Commerce)
  - Negotiating contract
  - Projected start date early 2012



#### State College Regional Medical Campus

- Now five clinical sites
- 60+ providers
- 100+ staff members
- 9,000 patient visits a month!
- Clerkships (medical student rotations) starting Summer 2012





#### State College Regional Medical Campus

- Business plan to include conduct of research studies in therapeutic areas
  - Oncology/hematology cooperative group studies
  - Heart & Vascular
  - Dermatology
  - Family & Community medicine
- Discussion points are many and include allocation of space, personnel, IDS, and IRB



#### Kathy Hay

Associate Director and Human Protection Administrator



#### **IRB Seminar and Workshops:**

- Using the PRAMS Online System for Research
  - Wed., Jan. 11, 2012, 9:00 a.m.-12 noon, Rm.C2610A
- IRB Process Overview for Researchers
  - Thur., Jan. 19, 2012, 9:00-11:00 a.m., Rm. C1830
  - Tues., Mar. 6, 2012, 11:00 a.m.-1:00 p.m., Rm. C1832

Registration required for these sessions.

Call HSPO at x5687 to register







# Change in education requirement as of January 1, 2012

- Research personnel involved in exempt research activities
  - Required to complete the CITI Course: Protection of Human Research Subjects
  - Training will be checked during prescreening of eSubmission



- Data Security and Integrity Policy now in effect
  - Current policy posted on the IRB website
    - Allows research studies to have more than one level of data
      - Coded, de-identified dataset Level 1
      - List linking code numbers to identifiers Level 2/3
  - FAQs and links to REDCap web site



- New protocol templates available on the IRB web site
  - Template Drug Study with IND
  - Template Drug Study without IND
  - Template Medical Device Study
  - Template Non-drug, Non-medical device Study
  - Template Research Tissue and/or Data Repository (coming soon)



#### **Controller's Corner**

# Announcements & Reminders Kellen Takoch





## **Industry-Sponsored Clinical Trials:**

 All accounts assigned a budget number beginning with 517- (industry-sponsored) are now being handled in the Controller's Office by Kellen Takoch. Debbie Musser and Tressa Jilek will continue to manage all other agreements, as specified by the current departmental assignments.



For Industry-Sponsored Clinical Trials, all correspondence will now be directed to Kellen.

- This includes:
  - Approval of AURAs
  - Approval of BARAs
  - Execution of ACE forms for trial extensions or close-outs
  - Payments received for clinical trials verification that payments align with sponsors' budgets and payment schedules
  - Follow-up with departmental financial analysts to ensure that PI effort on trials is appropriately applied in a timely manner to comply with regulations
  - Monthly clinical trial patient charges:
    - Verification of accurate application to the correct budget/fund number
    - Verification of account end dates to ensure that charges can be applied to clinical trial accounts



#### Reminders

- Send copies of all invoices sent to sponsors via email to ktakoch@hmc.psu.edu.
- When completing AURA documents in IBIS, remember to place a "Q" in the INDCOST CODE field on page 1 of the AURA. (This field is no longer populated with an "A".)



#### Reminders

- When completing BARAs for industrysponsored clinical trials, it is important to utilize the IBBW specifically for ensuring that the current fringe rate is reflected for PIs.
- If the IBBW was created prior to the current fringe rate, you will need to back into the salary in order to apply the current fringe rate.



#### Reminders

#### ACE Forms

- When a clinical trial is being closed, it is the responsibility of the departmental financial analyst to accurately complete sections 1, 3, and 4 prior to returning the form to the Controller's Office.
- Please be timely in completing and returning the ACE form to the Controller's Office by the "Form Due" date.



## **Updates**

- Over the past several months, Clinical Trial Process Review meetings were held with departments with active industry-sponsored clinical trials.
  - A forum of representatives from the ORA, the CTO, the CCTO, and the Controller's Office met with departmental financial analysts and study coordinators to learn about current practices for the management of clinical trials.
  - The forum of representatives is currently formulating best practice guidelines to streamline account management and activity across the campus.



## **Updates**

- There will be upcoming workshops to provide further education of the management of industry-sponsored clinical trials.
- The attendance of departmental financial analysts and study coordinators is highly encouraged.
- As you may already know, these best practice guidelines are being compiled as a result of an internal audit that took place in the Fall of 2010.



#### **Contact Information**

Kellen Takoch
Clinical Research Financial and Compliance Coordinator

ktakoch@hmc.psu.edu

531-1156



#### Questions





## **RQA Update**

## Research Quality Assurance





## **Biosafety Survey**

- >100 complete 30+ to go
  - Verifies correct Bioassurance protocol on file
  - Correct Biosafety Level of Lab
  - Correct training of Lab personnel
  - Overview of
    - BRDC(IBC)
    - IACUC
    - IRB





## **Equipment Service Agreement**

# Asset Management of vital Lab equipment Base level of service on COM equipment

- Biological Safety Cabinets
- Fume Hoods
- Centrifuges
- Autoclaves
- Pipettes
- Balances
- Limited Specialty Equipment
- Clinical area will be addressed in 2012
- 5 Year agreement with MicroClean Inc.





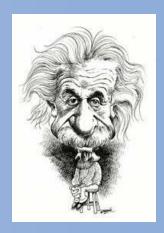
#### Freezer Maintenance

- PM(Preventative maintenance and Calibration
  - All ultra low freezers campus wide
- Annual service provided by the Administration
- Increase the reliability of freezers and reduce repairs over life of the freezer
- 3 Year Agreement with Energy Plus Inc.



## LabManager GIS

- GIS system
  - Current surveys
  - Emergency Contacts
  - Lab Placard Information
  - Equipment inventory
  - PI and Departmental Information
  - Increase collaboration of all labs
  - On line in first quarter of 2012





#### **Lunchtime Lecture Series**

- Monthly PI lecture initiated to provide information on the exciting research at Penn State Hershey
- Open to all faculty, staff and students
- Will highlight techniques and current research goals

