# HEALTH SCIENCES FACULTY COUNCIL
## 2013 - 2014
### Tuesday, September 3, 2013
### Meeting Minutes

**Present:** Chair: L. Martin; D. Granet; L. Hill; T. Savides; C. Saenz; B. Best; R. Mehta; S. Huang; J. Resnik; D. Sears; B. Smith; J. Hirsch; A. Ries; T. Bronner *(arrived late)*

**Unable to attend:** B. Cosman; R. Clark; L. Eyler; C. Miller; T. Handel; D. Brenner; L. Friedman; R. Smith; R. Espiritu; H. Kimmons; M. Savoia; J. Dixon

**Guests & Speakers:** J. Ford; T. Koures; G. Young; A. Barker; G. Firestein

**Recorder:** D. Romano

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<th>Call to Order and Approval of Minutes</th>
<th>Dr. Martin called the meeting to order at 5:00 pm.</th>
<th>The HSFC June and July meeting minutes were approved.</th>
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<td>Chair Announcements</td>
<td>Dr. Martin introduced herself as the new chair for the 2013 – 2014 HSFC year and did a round table for everyone to introduce themselves and mention the department that they represented.</td>
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| **Gary Firestein, Dean and Associate VC for Translational Medicine, Director, CTRI** | Dr. Firestein reported on the CTRI Updates and discussed the following topics:  
- Clinical and Translational Research Unit:  
- Organized Research Unit developed in 2010  
- Funded by institutional funds, CTSA, CTSA supplements, UCOP, industry funding and NHLBI U54  
- See attached presentation for the 2010-2013 timeline for the Center for Clinical Research; Pilot Project Grant Program; Translational Research Technology and Biomedical Informatics  
- The Informatics and Biomarker services have been | |

HSFC 2013 fall.pptx
developed since 2011 and include Velos, biosamples collection and storage, and biomarker assays.
 Clinical services include space, coordinators, nurses, infusions, skin biopsies, IRB submission consultation,
Dr. Firestein reported on plans the following new CTRI programs break down silos to include the following:
 Development of the Galvanizing Engineering in Medicine (GEM Program) to bring engineers and clinicians together to apply technology to unmet medical needs.
 Altman CTRI Building – designed to break down silos
 Phase I unit:
  o Collaboration with the Cancer Center
  o Standard of Care billing
  o Experimental Pharmacy
  o Overnight stays
  o Begin in ECOB, then move to ACTRI
Jennifer J. Ford, MBA, Director of Office of Clinical Research Administration (OCRA); Includes Offices of Clinical Trials and Coverage Analysis Administration (OCTA/OCAA)

Jennifer Ford reported on the New Clinical Research Billing (CRB) Process Overview and Update and discussed the following areas:
  - Background and Policy
  - New CRB Process
  - Office of coverage analysis (OCAA)
  - Velos System
  - Study Team Responsibilities with Velos
  - Updates since May 2013
  - Refer to the attached powerpoint presentation for CRB process details

Jennifer discussed that in 2010 the University’s office of the President began discussions about reviewing the Clinical Research Billing policies and processes.

- Resulted in Merging Clinical Research and Medical Billing

The MCP 342.2 Clinical Research Billing Policy:
  - New and renewal clinical studies submitted to IRB
  - The Office of Coverage Analysis Administration (OCAA) was developed as the central office to facilitate the new CRB process
  - The Principal Investigator plays an active and vital role
  - The IT solution utilizing the CTMS System is called “Velos”
  - Refer to the attached presentation for a flow diagram the New CRB Process

The UCSD policy is now implemented (July 1, 2013) for the campus and Moores Cancer Center (January 1, 2013).

- Determining which Clinical Study requires a Coverage Analysis (CA):
  - Studies that **generate a charge** to either **patient/payor** or the research bulk account regardless of funding source
• Determining which Clinical Study **does not** require a Coverage Analysis (CA):
  ➢ Retrospective studies
  ➢ Data studies
  ➢ Subset of blood processing studies
  ➢ Refer to the attached presentation for Coverage Analysis (CA) samples

How the Faculty will communicate with the Office of Coverage Analysis Administration (OCAA):

➢ IRB Application: New question
  • Involves procedure(s) billable to sponsor/insurance subject?

  • If the question is marked “Yes”
    ➢ Office of Coverage Analysis Administration (OCAA) will be notified when a study whether new, renewal, expedited is submitted to HRPP

  • Pre-Award Activity (Federal/Non-profit): JIT or NOA
  • Clinical Trial Activity: Parallel with HRPP and Contract Office

After Coverage Analysis (CA) is finalized:

• Final Coverage Analysis (CA) is sent to the CTRI Velos Team
  ➢ The CTRI Velos team will create a calendar in Velos

Study Team Responsibilities:

• Enroll subjects into Velos *within 48 hours* a subject signs a consent
• Check off when visits occur *within 7 calendar days*
• Alert OCAA when there is a study amendment or budget changes

EPIC Billing System:
• **EPIC billing system will launch October 2013**
- Active studies will have their participants registered in Velos and linked to the study
- This process is an alternative short-term solution until renewal under the new CRB process

Unvalidated Procedures Process

- Policy states that the study team must validate visits within 7 days
- Leadership concerns about non-compliance
- Developed and Unvalidated Procedures Process
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<th>Tony Koures, PhD UCSD CTRI IT Director; Division of Biomedical Informatics</th>
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<td>• Tony Koures reported the Clinical Trial Management System Overview and CRB Update:</td>
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<td>Some of the benefits of utilizing Velos would include:</td>
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<td>Velos has been designated as the System of Record for Clinical Research studies. Please refer to the attached Velos presentation for complete details.</td>
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<td>• Tony Koures presented an overview of how Velos is used in the CRB process to include the following:</td>
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Study Coordinator Responsibilities (once notified that Study has been activated in Velos) to include the following:

- Register patient in Velos within 48 hours of patient signing consent
- Import Patient Demographics from Epic
- Associate the patient to the study
- Associate patient to appropriate calendar
- Update event status for all events on a visit within 7 calendar days of the visit occurring
- Update the scheduled date of the visit, if needed
- Add any unscheduled events to a visit, as needed.

Tony Koures also reported on the current CRB study status in Velos to include:

- MCC Retrospective studies:
  - 167 received
  - 164 completed
  - 3 pending
  - CA Amendments:
    - 31 received
    - 31 completed

- PI Driven, Bulk Event studies:
  - Designated by (PICAL) in the study title
  - 72 received
  - 72 completed

The support provided by the CTRI Velos Team includes the following:

- Training
- Application Support
- Management of Access Rights to the Velos Application
- Study and Calendar Creation in the Velos system upon receipt of an approved Coverage Analysis from OCAA
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<td>• Custom forms and report creation as needed.</td>
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<td>• eCRF Creation for Investigator Initiated Studies.</td>
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<td>• Data Migration from other databases to Velos (e.g. REDCap, Access Databases)</td>
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Dr. Ries discussed the Bylaws 55 and reported on the following topics:

- The Principles of Academic Review at UCSD to include:
  - Shared governance
  - Regular peer review: based on academic merit
  - Accountability (peers, department, school, university, state, public)

- Problems:
  - Large percentage of Non-Senate faculty in Health Sciences
  - Non-Senate faculty are critical to clinical and research missions for the University
  - Adjunct faculty are denied representation in the peer academic review process (CAP)
  - Distinct academic cultural differences between Health Sciences and General Campus faculty
  - Strict application of current University voting policies disenfranchises Non-Senate faculty
  - Unintended consequences of motivating many non-Senate faculty to change to Academic Senate series
  - Refer to presentation for graph displays

- Academic Senate Bylaw 55 – Departmental Voting Rights
  - All tenured faculty have right to vote on new appointments / advancements in Academic Senate series
  - Professors vote on Professors, Professors and Associate Professors vote on Associate Professors
Voting rights cannot be delegated to a committee
Voting privileges may be extended to Emeritus faculty upon 2/3 vote of eligible faculty
Voting rights cannot be delegated to a committee
Voting privileges may be extended to Emeritus faculty upon 2/3 vote of eligible faculty
No mention of non-Senate faculty
Refer to presentation for Legislative Rulings
University Committee on Rules and Jurisdiction

The challenge:
Changing University-wide voting policies is very difficult
Voting policies were established in a different era when there were many fewer non-Senate faculty
In the long-term, the University’s survival may depend upon adapting to new economic and academic realities
Refer to presentation for Voting Rights in United States

UCSD HSFC Voting Proposal for Non-Senate Faculty
Modify Senate Bylaw 55
Similar to extension of voting rights to Emeritus faculty
Allow (but not require) each HS department to extend voting rights for academic appointments and reviews to career (>50%) non-Senate faculty upon 2/3 vote of eligible Senate in that department
Refer to presentation for UCSD HSFC Voting Proposal for Non-Senate Faculty
**Final Remarks by Dr. Martin**

- Dr. Martin stated that the next HSFC would be held on Tuesday, October 1, 2013. She also stated that on November 7th, 2013 there will be an “All Faculty / New Faculty” welcome meeting at the Faculty Club.

**OLD BUSINESS:**

- NO OLD BUSINESS WAS DISCUSSED

**New Business**

- NO NEW BUSINESS WAS DISCUSSED

**ACTION ITEMS**

- *Dr. Firestein should be invited back bi-annually to present CTRI updates*

**Adjournment**

- The meeting was adjourned at 6:30 p.m.

**NEXT MEETING**

- Tuesday, October 1, 2013, 5:00 to 6:30 pm
  Dean’s Large Conference Room BSB 1320