PRESENTATION: Introduction and Discussion of RAB Priorities – Brian Smith

Brian Smith introduced himself as the new Associate Vice Chancellor for Research Infrastructure and Operations, and presented several slides regarding his background, key approaches toward his position, and responsibilities in his new role. Brian was most recently with the University of California, San Diego (UCSD), and has experience in both public and private institutions. He has worked in research administration at UCSD and the University of Oregon, with a focus on sponsored research, affiliations, technology transfer, and clinical trials. Brian holds an MBA, and a JD. At UCSF, he oversees four main areas: Research Management Services (RMS), Government & Business Contracts (GBC), Laboratory Animal Resource Center (LARC), and Environment, Health and Safety (EH&S). He is also responsible for representing the Office of Research in campus-wide planning efforts, and on select UC system-wide committees and councils. Brian also discussed the current organizational chart for the EVCP office, and explained that he will be reporting to Vice Chancellor Keith Yamamoto.

Questions/Comments:
- Will Brian’s position continue to have a connection to the associate deans? Yes – the org chart does not include all connections, only those related to reporting.
- The group questioned the dotted line connection to the EVCP position, as well as the decision to have the new AVC for Clinical Research report not to Keith Yamamoto, but to the Chancellor. Suzanne Murphy explained that there are currently a number of discussions going on at a high level regarding the reporting structure, and that the dotted line represents this uncertainty, and will be likely be changing.
- There was a brief discussion regarding the upcoming AAALAC accreditation, and Eric Mah explained that emails with information will be sent out soon. The group suggested copying department administrators on those communications.

PRESENTATION: Update on Clinical Research Services (CRS) – Chip Chambers

Chip discussed the budget, and explained that while the CRS has been able to solve their revenue shortfall in the short term, they are currently looking for ways to implement changes so that their operation is sustainable in the long term. Challenges include: too many sites and services, expensive inpatient research, salary/benefit increases, and a decrease in NIH budget. In order to deal with these challenges, a number of changes have already been implemented, including:

- Creation of a task force to examine issues and provide recommendations
- Elimination of grandfathering – select group of investigators no longer receive free services
- Closing of the coordinator and participant recruitment cores
- Reduction in personnel effort
- Reconfiguration of facilities – implementation of scatter bed models

Two main changes that are currently being implemented now are:
- Restructuring of support at Mount Zion
- Restructuring of inpatient at 12 Moffitt

The task force has provided recommendations as to which services are essential for CRS to provide, as well as recommendations regarding a peer review process to allocate scarce and expensive resources, and the recommendation that a
clinical coordinator core be established to provide training, share best practices, create a sense of community, and make coordinator services available to UCSF investigators.

Chip also provided an overview of the NCATS U54 CTSA RFA, which came out last month, and is due in late fall, early winter 2015. It is a three part application consisting of: UL1 (core of services from CTSI) the K12 program, and the T component, for training. Budget considerations = 2.5% of FY13 institutional funding up to 10M.

The section that is most relevant to the CRCs is the section titled: Research Implementation and Participation. Requirements are as follows, and are divided into 3 components:

- Pilot Translational and Clinical Studies – 400K suggested budget, and no support beyond Phase IIA
- Integrating Special Populations – pediatrics, geriatrics
- Participant and Clinical Interactions – space, beds, patient care costs, testing or patient evaluations cannot be charged to CTSA except for voucher program; funding in addition to CTSA support must come from sources outside of CTSA

Questions/Comments:
- How many investigators use the CRCs? Currently there are 350, but this number is in flux, and is dominated by heavy users.

PRESENTATION: Update on CTSI – Deborah Grady

Deborah provided an overview of the services that CTSI provides, which include:
- Education and training for undergraduates, professional students (T32), residents, fellows and faculty (K12)
- Career development through workshops, mentoring programs, and team science
- Research Infrastructure and services, including:
  - CRS
  - Pilot Funding - Resource Allocation Program (RAP), Strategic Opportunity Support (SOS)
  - Consultation services
  - UCSF Profiles – resource for finding collaborators

Recent transitions include the departure of Director Clay Johnston and Executive Director Mini Kahlon, and the appointment of Jennifer Grandis who will arrive in January as the new CTSI Director.

In order to plan for the next grant in advance of the RFA, town hall meetings at various campuses were held, and from those meetings, two main ideas emerged:

1. NextGen Research – an exploration of what research will look like in 2020 and beyond, with a focus on electronic data, electronic platforms and remote measurements
2. Ensuring that CRS is the right size for success – plan to expand to support start-up activities

Demonstration projects around NextGen Research have begun, and the expansion to support start-up aims to include support for IRB and other regulatory submissions, recruitment and coordinators.

Deborah also discussed the new RFA from NCATS. The general aim, as laid out in the RFA, is to build a national clinical trials consortium, through cohort identification, participant recruitment and site qualification, with a focus on uniformity across sites.

The new budget is limited to 2.5% of NIH total direct funding and partners, and is limited to 10M total. This is much less than expected, constituting a ~50% reduction. There is also limited funding for pilot studies and the K program, and no funding for research space, research staff, or laboratory services.

Charge to the Research Advisory Board (RAB)
- To provide input to the Office of Research, and ultimately the EVC&P, about the needs of investigators and administrators in conducting research and administering extramural funds.
- To guide priority setting and critical assessment of quality improvement efforts in the Office of Research
- To work with the Office of Research staff to ensure the successful implementation of the current Quality Improvement Project
CTSI will respond to the budget reduction by continuing with the current organizational structure, while scaling back the K program and pilot awards. They also plan to continue to improve efficiency, expand recharges, expand engagement with partners (Cancer Center, Center for Digital Health, and others) and seek institutional and other non-NIH funding.

Since the CTSI’s structural budget has been reduced in recent years in preparation for a budget reduction, money exists for the short term, and then there will be a glide path for further reductions over the next few years.

Questions/Comments:

- Can pilot funding be used for new databases and other similar projects? Yes, we believe so. Pilot funding for NextGen Research, Catalyst, and team science pilots should be okay. Funds for junior investigators may have to be reduced, but we plan to pursue this as much as we can.
- Have we considered partnering with companies such as Twitter? Yes, partnering with tech companies is part of the plan, and we also plan to pursue partnerships with Kaiser, Berkeley, and others.
- Are there any current programs within CTSI that can help with big data analysis? This may be part of NextGen Research; we recognize that there is a gap here currently.
- Many departments currently pay for pieces of clinical research services on their own, and it would be great if we could somehow leverage this – take the money currently spent for these pieces and put it in a central fund for CTSI in ways that would more greatly benefit UCSF as a whole.
- The Medical Center should play a larger role – we should be better about asking for things we need from them.
- Consider Julie Auger’s strategic plan for cores, as well as other various efforts and how they intersect with this. This will be one of the things that Jennifer Grandis will be tasked with in her position.
- Gretchen Kiser noted that the RDO symposium in December will look at what large center grant resources currently exist, and may tie into some of these ideas.

Charge to the Research Advisory Board (RAB)

- To provide input to the Office of Research, and ultimately the EVC&P, about the needs of investigators and administrators in conducting research and administering extramural funds.
- To guide priority setting and critical assessment of quality improvement efforts in the Office of Research.
- To work with the Office of Research staff to ensure the successful implementation of the current Quality Improvement Project.
Brian Smith
Associate Vice Chancellor, Research Infrastructure and Operations

Research Advisory Board
November 4, 2014
Background

• Experience in private and public organizations
• Research administration at both University of Oregon and University of California, San Diego
  – Sponsored research
  – Affiliations
  – Technology transfer
  – Clinical trials
• JD and MBA
Keys

• Enhance the research enterprise

• Promote a safe research, patient care, and work environment

• Effective communications

• Continuous improvement
Responsibilities

• Organization:
  – Research Management Services (RMS)
  – Government & Business Contracts (GBC)
  – Laboratory Animal Resource Center (LARC)
  – Environment, Health and Safety (EH&S)

• Other:
  – Represent the Office of Research in campuswide planning and on selected UC systemwide committees and councils.
EXECUTIVE VICE CHANCELLOR & PROVOST
ORGANIZATION
10.01.2014

CHANCELLOR
Hawgood

EXECUTIVE VICE
CHANCELLOR & PROVOST
BLUESTONE

*AVC
Ethics & Compliance
Vacant
MAH - Interim

VC Research-Direct
Office
YAMAMOTO

AVC - Clinical
Research
GTSM
GRADY (Interim)

Bonville, Asst. Executive Vice
Chancellor & Provost

Academic Affairs
ALLDREDGE

Student Academic Affairs
& Graduate
Division
WATKINS

Library
BUITER

*Proctor Fdn
LIETMAN
(Interim)

Clinical
Compliance
KAHANER

Research
Compliance
MAH

HRFP
Vacant
DENNEY - Interim

IACUP
BROVARNEY

Conflict of
Interest
KENNON-FRINK

Research Resource
Program
AUGER

Research Dev
Office
KISER

A VC Research -
Infra Structure
Brian Smith

**Innovation
Technology &
Alliances
Kiriakis Interim

E VCP Business
Services
MURPHY

OMBUDS Office
DARON

Industry Contracts
KIRIAKIS

Technology Mgt.
IMMERGLUCK
(Interim)

Entrepreneurship
MARRUS

Clinical Trial
Business Support
Kellen

Cell Culture Facility
TBD (Vacant)

8 Additional Core
Ops

LARC
WILKERSON

Research Management
Services
OHALLORAN

Business Contracts
RADKOWSKI

EH&S
EATON

*Reporting realignment in process
**Elements of work focused on business development under review
potentially moving to new-yet-to be established organization
Research Management Services (RMS)

• Support researchers, from pre-award through the award process, on all grant mechanisms.
• Collaborate with the Principal Investigator, his/her department and our sponsors.
• Ten teams housed at many campus sites. Each team includes a Pre-Award Manager, Research Service Coordinators (RSCs) and RMS Associates.

> Marge O’Halloran, Director
Government & Business Contracts (GBC)

• Proposal development, *contract* negotiation and award acceptance for faculty seeking *contracts* with federal, state, municipal or foreign governments.

> John Radkowski, Director
Laboratory Animal Resource Center (LARC)

• Provide quality care for all animals used at UCSF.
• Assist faculty in their mission of quality research with respect to the use of laboratory animals.
• Act as a resource center on all issues relating to laboratory animals.
• Assist the University to meet its goal of humane treatment of laboratory animals.

> James Wilkerson, Executive Director
Environment, Health and Safety (EH&S)

- Ensure a safe and healthy work environment
- Promote a safe research and patient care environment
  - Train UCSF employees.
  - Develop and implement proper health and safety procedures.
  - Conduct environmental and personnel monitoring to verify effectiveness of EH&S programs.
  - Maintain regulatory/administratively required records.
  - Develop and maintain an effective emergency response program.

> Robert Eaton, Director
Approach

• Listen

• Involve stakeholders

• Develop and strengthen networks

• Use data-informed decision making (analytical culture)
Questions?
Clinical and Translational Science Institute / CTSI
at the University of California, San Francisco

Research Advisory Board

Deborah Grady, MD, MPH
Interim Director, UCSF CTSI
Associate Dean for Clinical and Translational Research
UCSF CTSI

- Currently 2nd largest of 60 awards
- Renewed in 2011 for $100 million direct costs over 5 years
CTSI Provides

Education and training
- Summer workshop, 1y Certificate, 2y Masters
- Training programs for undergraduates, professional students (T32), residents, fellows and faculty (K12)

Career development
- Workshops
- Mentor training and mentoring
- Team science

Research infrastructure and services
Research Infrastructure and Services

- Clinical Research Services
- Pilot funding (SOS, RAP)
- Consultation Services
- Early Translational Research
- Regulatory Knowledge and Support
- Community Engagement
- Secondary/clinical/big data access
- Profiles
CTSI Plans for Next Grant (before the RFA)

- NexGenResearch – C&T Research in 2020 and beyond
- Expansion of CRS to support start-up
- Team science
NexGenResearch

• Efficient, electronic research
  – Electronic data (clinical and many others)
  – Electronic platforms
  – Remote, electronic measurements

• Demonstration Projects
  – Migraine headache in children
  – Quality improvement for management of CKD
Early Ideas about Process

<table>
<thead>
<tr>
<th>Component</th>
<th>Website</th>
<th>Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort ID</td>
<td>Research Browser</td>
<td>Consultation Service to ARS, ReX</td>
</tr>
<tr>
<td>Recruitment</td>
<td>Information, pre-approved ads, etc.</td>
<td>Recruitment Service</td>
</tr>
<tr>
<td>Informed consent</td>
<td>Information, commercial apps</td>
<td>CS to tailor apps or to company</td>
</tr>
<tr>
<td>Baseline measures</td>
<td>Remote devices</td>
<td>CS to CDHI</td>
</tr>
<tr>
<td>Etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tied together seamlessly to support a broad range of research
Current CRS Services

• Scientific review of protocols
• Inpatient and outpatient space
• Trained research staff
• Specimen processing and laboratory services
• Special services
  – Body composition, DEXA
  – Exercise physiology
  – Bionutrition
Expansion to Support Start-up

- IRB submission
- Other regulatory submissions
- Staff training and certification
- Development of case report forms
- Database development
- Biospecimen processing and storage
- CRS … Access to space, staff, services
Team Science

• Education and training
  – New didactic, online courses
  – New modules in training programs
• Changes in promotion guidelines and processes
• Team science pilot awards
• Team science recognition awards
New RFA from NCATS

• General aim is to build a national clinical trials consortium
  – Cohort identification
  – Participant recruitment
  – Site qualification

• Organizational changes/challenges
  – Emphasis on uniformity across sites
  – Reorganization of some programs
  – Not a good model for the organization
New Budget

• Overall
  – 2.5% of NIH total direct funding + partners
  – Limited to total of $10M per year

• Limited funding for:
  – Pilot studies (methodologic pilots only)
  – K Program (limit of 8 total scholars)

• No funding for:
  – Research space
  – Research staff
  – Laboratory services
How Will CTSI Respond?

• Write a good grant - $10M is still a lot…

• Aim to:
  – Continue current organization
  – Provide current services, infrastructure and didactic education, but scale back K Program
  – Develop NexGen and team science, expand CRS

• Budget is the main challenge
Budget

- Improve efficiency and cost-effectiveness
- Expand recharges
- Engage partners
- Seek non-NIH funding
# Overall CRS Budget (Past / Present)

<table>
<thead>
<tr>
<th></th>
<th>FY13-14 Budget</th>
<th>FY14-15 Budget</th>
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</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTSA</td>
<td>6,575,937</td>
<td>6,515,208</td>
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<tr>
<td>Recharge</td>
<td>1,419,823</td>
<td>1,663,505</td>
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<td>Standard of Care</td>
<td>972,087</td>
<td>-</td>
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<tr>
<td>Misc Funds</td>
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<tr>
<td><strong>Expense</strong></td>
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<td>10,428,283</td>
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<tr>
<td><strong>Operating Loss</strong></td>
<td>(3,329,313)</td>
<td>(2,114,786)</td>
</tr>
</tbody>
</table>
Current CRS Services

• Nursing: hourly out-patient, daily inpatient, facility use only, phlebotomist
• Neurodevelopmental testing
• Bionutrition: meals, specialized meals, consultation
• Sample processing: serum, plasma, blood, csf, short-term storage, shipping, PMC, custom (limited)
• DEXA, body composition, exercise physiology
Major Challenges

• Too many sites (n=7) and services
  – Moffitt Adult, Peds CRC (6M), Neonatal CRC, Mt. Zion, SFGH, VA, TCRC

• Expensive inpatient research
  – Inpatient services cost $2M a year
  – In-patient bed rate at UCSF is $1,953

• Salary/benefit increases
  – Projected for FY15/16  $400K

• Shrinking NIH budget
  – New RFA cap at $10,000,000
Accomplishments and Changes Implemented

• Surveyed users and convened a task force
• Eliminated Grandfathering
• Closures
  – Coordinator Core
  – Participant Recruitment Core
• Reduced Personnel Effort
  – Director and Faculty Leaders (Two Scientific Committees)
  – Administrative staff
  – SFGH staff
  – Bionutrition core staff
• Reconfigured facilities
  – Moffitt adult: scatter bed and identification OP space in ACC
  – Pediatric CRC: scatter bed
  – Neonatal CRC
  – CHORI (1/3 budget reduction)
  – TCRC (Closure in Sept 2015)
• New PCRC and NCRC director: Barbara Moscicki
• Aligned Neurodevelopment Core with Pediatrics
Strategic Measure Covering Operating Loss

• Restructure support at Mount Zion Outpatient
  • In FY13-14, 20% of protocols are NIH
  • Site supports 12 investigators with NIH protocols

• Restructure Inpatient at 12 Moffit
  • In FY13-14, 349 inpatient bed days for research cost $681,597 at the DHHS daily rate $1,953 per day.
  • In FY13-14 cost of inpatient bed is 50% of site budget.
## CRS Budget Outlook

<table>
<thead>
<tr>
<th></th>
<th>FY14-15 Budget</th>
<th>FY14-15 Budget (Further reductions)</th>
<th>FY15-16 Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
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<td>Revenue</td>
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<td>8,313,497</td>
<td>8,431,980</td>
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<td>CTSA</td>
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<td>6,515,208</td>
<td>6,515,208</td>
</tr>
<tr>
<td>Recharge</td>
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<td>1,663,505</td>
<td>1,781,988</td>
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<tr>
<td>Misc Funds</td>
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<td>134,784</td>
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<tr>
<td><strong>Expense</strong></td>
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<tr>
<td>Expense</td>
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<td>Salaries and Benefits</td>
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<td>Other Expense</td>
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<td>2,021,621</td>
<td>1,564,255</td>
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<tr>
<td><strong>Operating Loss</strong></td>
<td>(2,114,786)</td>
<td>(974,312)</td>
<td>(668,023)</td>
</tr>
</tbody>
</table>
Summary of CRS Taskforce Recommendations

• CRS should provide the following essential services:
  – Phlebotomy, including after hours and mobile.
  – Sample processing, routine and specialized; short-term specimen storage, and shipping.
  – Space to conduct participant interviews and exams.
  – Basic nursing functions such as vital signs, patient intake, specialized blood draws.

• There should be an overnight stay unit that offers a flexible level of nursing and support services.

• A peer review process should be established to allocate scarce and expensive resources.

• A clinical coordinator core should be established to provide training, share best practices, create a sense of community, and make coordinator services available to UCSF investigators.
Overview of NCATS U54 CTSA RFA

• Key words: national network, translational workforce, catalytic approach, synergy, team science, informatics
• 3 part application: UL1, KL2, T
• Budget considerations
  – 2.5% of FY13 institutional funding up to $10M
CRCs: Research Implementation and Participation

• Pilot Translational and Clinical Studies
  – $400,000 suggested budget (directs) total for pilot programs
  – No support beyond Phase IIA
  – Rigorous review process

• Integrating Special Populations
  – Pediatrics, geriatrics, special populations

• Participant and Clinical Interactions
  – Space, beds, patient care costs, testing or patient evaluations cannot be charged to CTSA except for voucher program
    • Voucher program capped at $300,000 and support ranges between $1,000 to $5,000
  – Funding in addition to CTSA support must come from sources outside CTSA
  – CTSA funding can be used only for oversight and quality assurance
  – Study specific staff must be covered by non-CTSA funds
CRCs: Optional Modules

• One or two only such modules allowed
• Examples
  – Phase 1 unit
  – Genomics
  – Preclinical
  – Imaging
• Suggested budget of $400,000