RESEARCH ADVISORY BOARD (RAB)
June 2, 2015
8:30-10:00am
Medical Sciences Building, Chancellors Conference Room S-30

Attendees: Diane Barber, Chip Chambers, Clarice Estrada, MC Gaisbauer, Jim Kiriakis, Larisa Kure, Steve Lazarus, Kathryn Lee, Georgina Lopez, Suzanne Murphy, Marge O’Halloran, Terri O’Lonergan, Michael Nordberg, Bill Seaman, Brian Smith, Matt Springer
On Phone: Gretchen Kiser

PRESENTATION: Clinical Research Services, Program Review and Progress Report; Chip Chambers, MD
• Chip Chambers presented on Clinical Research Services, Program Review and Progress Report (see PowerPoint Presentation)
• Current CRS Services
  o Adult and Pediatric Nursing and Phlebotomy
  o Pediatric Neurodevelopmental testing
  o Bionutrition
  o Sample Processing and Short-Term Storage
  o Body Composition, Exercise Physiology and Energy Metabolism
• Major Challenges:
  o Reduction in level of NIH funding
    • $10,000,000 total
  o Expensive inpatient research
  o Salary/benefit increases
    • Projected for FY15/16 $400K
• Planned changes:
  o Relocate in-patient services to Moffitt (new SFGH hospital opens 12/15)
  o New out-patient space at Moffitt ACC
  o Renegotiate space agreement at SFGH
  o Begin rebuild of coordinator core
  o Close Tenderloin Clinical Research Center
  o Begin phase out of Bionutrition
  o Revise recharge rate structure

Questions/Comments:
• To what extend is the recharge subsidized?
  o Currently 60%, having to increase it to cover the loss of institutional funding (Budget Outlook slide)
• How much will the K programs be cut?
  o At least half
    • 4 years to phase in, CRS will cease to exist in its current state, there will be a dispersal of these funds over the rest of CSI, there will be changes in administration to be non-site specific
• Discussions about what to use for medical records across the board, should use APEX, because while it is difficult to use, it can be very powerful
  o It is a major challenge to use on the out-patient side

Next Steps:
• None noted

PRESENTATION: RMS’ updated Service Partnership Agreement (SPA); Georgina Lopez & Marge O’Halloran
• Marge O’Halloran and Georgina Lopez gave an update on the RMS Service Partnership Agreement (see PowerPoint Presentation)
• Background
  o RMS has been providing service to all campus researchers for 3.5 years
  o Original RMS Service Level Agreement was put in place February 2012
  o RMS Satisfaction Survey results echoed RMS Leadership’s note that revisions and updates to the agreement were needed
These notes are intended to provide a summary of action & follow up items; a few discussion highlights are included.

- Workgroup launched in August 2014 included participants from all 4 schools, faculty, finance staff, department managers, RMS and other key stakeholder staff

  - Guiding principles:
    - Define successful pre-award support and how to maximize outcomes for all parties
    - Practical and pragmatic review
    - Efficiencies (including limited handoffs)
    - Ensure that issues identified are reflected in the updated document
    - Clarify pre- and post-award duties and outline responsibilities of the PI, RSC, Department and CGA (including handoffs)

Questions/Comments:
- Regarding themes, partnership is now represented, which adds a different/better tone between RMS, faculty and departments.
- It would be helpful to learn more about the use of UCSF Profiles for biosketch development
  - Maybe we could have the CTSI Profiles team and the Advance development team present to RAB to help with increased usage/capacity?
    - Having Profiles as the repository for all information could be very helpful, especially in terms of having all the correct PMCID numbers/codes.
  - Current limitation in Advance does not allow for modifications and changes to formatting
- Will it be easy to see what changes were made between the original and the current version?
  - No, the prior version was extremely cumbersome to navigate, we made major format changes to make it more usable, especially in terms of who owned which sections
- Will there be trainings for departments as well as faculty? Yes, training for end users is needed (as an example, how do complete Other Support documents).
  - Recognized the need for better trainings, not just for RMS but also for the departments
    - Will be developing trainings for RMS, departments and faculty

Next Steps:
- Communicate, communicate, communicate – we need to get the word out.
  - Share with Control Points (School of Medicine, School of Nursing, School of Dentistry, School of Pharmacy) by June 6
  - Present to the OSR Advisory Board on June 24
Clinical Research Services
Program Review and Progress Report

Chip Chambers, MD
Eunice Stephens, MPH
March 30, 2015
Current CRS Services

• Adult and Pediatric Nursing and Phlebotomy
• Pediatric Neurodevelopmental testing
• Bionutrition
• Sample Processing and Short-Term Storage
• Body Composition, Exercise Physiology and Energy Metabolism
Changes for FY09

- User and non-user survey completed
- Taskforce and External Advisory Panel reviews
- SPARC budget planning tool
- Phasing out Grandfathering as of January/July, 2015
- Reduce administrative costs
- PCRC/NCCU
  - PCRC/NCCU relocated to Mission Bay
  - NCCU reorganized: replacing nursing service with clinical coordinator
  - Neurodevelopment service re-organized through partnership with the department of Pediatrics
Changes for FY09 – con’t

• Mt. Zion
  – Unit closed, consolidating research nursing to 12Moffit.
  – Continue providing sample processing service

• SFGH
  • Medical Director position combined with TCRC (Margot Kushel)

• Cores
  – Body composition
    • In collaboration with Dr. John Shepherd and Department of Radiology developed a cost sharing agreement for cost efficiency and to provide investigators access to state-of-the-art equipment.
Major Challenges

• Reduction in level of NIH funding
  – $10,000,000 total
• Expensive inpatient research
• Salary/benefit increases
  – Projected for FY15/16  $400K
## Budget Outlook (Best Guess)

<table>
<thead>
<tr>
<th></th>
<th>Actual FY14-15</th>
<th>FY15-16</th>
<th>FY16-17</th>
<th>FY17-18</th>
<th>FY18-19</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenues</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTSA*</td>
<td>$7,587</td>
<td>$7,492</td>
<td>$5,619</td>
<td>$3,765</td>
<td>$1,882</td>
</tr>
<tr>
<td>Recharge**</td>
<td>$2,224</td>
<td>$1,907</td>
<td>$2,193</td>
<td>$4,166</td>
<td>$5,832</td>
</tr>
<tr>
<td>Misc</td>
<td>$133</td>
<td>$278</td>
<td>$278</td>
<td>$278</td>
<td>$278</td>
</tr>
<tr>
<td>Institutional</td>
<td>$780</td>
<td>0</td>
<td>$1,000</td>
<td>$1,000</td>
<td>$1,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$10,725</td>
<td>$9,677</td>
<td>$9,090</td>
<td>$9,209</td>
<td>$8,993</td>
</tr>
<tr>
<td><strong>Expenses</strong></td>
<td>$10,635</td>
<td>$10,646</td>
<td>$10,012</td>
<td>$10,005</td>
<td>$10,047</td>
</tr>
<tr>
<td><strong>Projected Gap</strong></td>
<td><strong>$89</strong></td>
<td><strong>($968)</strong></td>
<td><strong>($922)</strong></td>
<td><strong>($845)</strong></td>
<td><strong>($1,054)</strong></td>
</tr>
</tbody>
</table>

*CTSA reduction 20%, 50%, 75% for last 3 FY

** Recharge unchanged FY15-16 then increases by 15%, 50%, 30% over prior year
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
Some of the Changes Planned
CTSI Renewal Application Due 12/15

• Relocate in-patient services to Moffitt (new SFGH hospital opens 12/15)
• New out-patient space at Moffitt ACC
• Renegotiate space agreement at SFGH
• Begin rebuild of coordinator core
• Close Tenderloin Clinical Research Center
• Begin phase out of Bionutrition
• Revise recharge rate structure
# Bionutrition Core Cost Analysis

1. Projected utilization

   a. Number of studies: 6
   b. Number of studies projected to recruit beyond July 1, 2016: 3
   c. Number of investigators: 5
   d. Number of investigators with studies beyond July 1, 2016: 2

2. Projected costs to complete 6 studies

<table>
<thead>
<tr>
<th>Expenses</th>
<th>FY14-15</th>
<th>FY15-16</th>
<th>FY16-17</th>
<th>TOTALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff salary and benefits</td>
<td>735,000</td>
<td>585,000</td>
<td>289,000</td>
<td>1,609,000</td>
</tr>
<tr>
<td>Food, other costs</td>
<td>108,000</td>
<td>69,000</td>
<td>71,000</td>
<td>248,000</td>
</tr>
<tr>
<td>Total</td>
<td>843,000</td>
<td>654,000</td>
<td>360,000</td>
<td>1,857,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recharge</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator 1</td>
<td>--</td>
<td>133,000</td>
<td>67,000</td>
<td>200,000</td>
</tr>
<tr>
<td>Investigator 2</td>
<td>--</td>
<td>36,000</td>
<td>9,000</td>
<td>45,000</td>
</tr>
<tr>
<td>Total</td>
<td>202,000</td>
<td>179,000</td>
<td>76,000</td>
<td>457,000</td>
</tr>
</tbody>
</table>

| Balance                           | 641,000 | 475,000 | 284,000 | 1,400,000 |
Research Management Services

Service Partnership Agreement Update

Georgina Lopez – Global Health Sciences
Marge O’Halloran – Research Management Services

8/12/2015
Background

- RMS has been providing service to all campus researchers for 3.5 years
- Original RMS Service Level Agreement was put in place February 2012
- RMS Satisfaction Survey results echoed RMS Leadership’s note that revisions and updates to the agreement were needed
- Workgroup launched in August 2014 included participants from all 4 schools, faculty, finance staff, department managers, RMS and other key stakeholder staff
Service Partnership Agreement workgroup

- Melissent Zumwalt
- Christine Razler
- Bill Seaman (faculty)
- Sam Pleasure (faculty)
- Susan Noworolski (faculty)
- Catherine Garzio
- Ophir Klein (faculty)
- Larisa Kure
- Kathy Lee (faculty)
- Mounira Kenaani
- Millo Pasquini
- Stuart Gansky (faculty)
- Mark Seielstad (faculty)
- Pat Wirattigowit
- Sarah Glass
- Georgina Lopez
- Marge O’Halloran
- Samantha Yee
- Martha White
- John Radkowski
- Irene Shin
- Jim Kiriakis
Principles

Our guiding principles:

- Define successful pre-award support and how to maximize outcomes for all parties
- Practical and pragmatic review
- Efficiencies (including limited handoffs)
- Ensure that issues identified are reflected in the updated document
- Clarify pre- and post-award duties and outline responsibilities of the PI, RSC, Department and CGA (including handoffs)
Process

- Bi-weekly meetings from August 2014 – February 2015
  - Reviewed SPA sections, made changes, reached consensus on changes
  - Changes to Subcontracts Out deferred to the Subaward Business Process Improvement workgroup (this group has met and produced workplan)
- Final review to workgroup to solicit feedback from their stakeholders (April 2015)
- Incorporated changes in the final draft (May 2015)
Key Themes

- Key themes reflected throughout the updated Service Partnership Agreement:
  - Underlining the relationships between key parties (PI, RMS, department and CGA)
  - Accurately reflect the current process
  - Clarified roles and responsibilities
  - Focus on consistent service across all of RMS
    - New SPA helped to identify key areas for additional training
Feedback

- How we solicited input
  - Our workgroup members and their associates spent significant time and effort on changes
  - Other groups that have provided feedback:
    - Research Administration Think Tank
    - RMS Leadership
    - RMS Council
  - While we welcome feedback, we need it to be focused on general direction of the revised SPA
**Next Steps**


- Communicate, communicate, communicate – we need to get the word out.
  - Share with Control Points (School of Medicine, School of Nursing, School of Dentistry, School of Pharmacy) by June 6
  - Present to the OSR Advisory Board on June 24
APPENDIX: Key Changes & Details

- Introduction & Overview: Sections 1 – 3
- Roles & Responsibilities: Section 4
  - Example of Section 4 Format
  - Additions to Roles & Responsibilities
- Key Changes
  - Carryforwards, Re-budgeting Awards & Changes in Personnel on Awards
  - T32s & Other Project-Specific Tables/Lists
  - PubMed Central Identifiers (PMCIDs)
  - Other Support
  - Award (Fund) Advances
Introduction & Overview: Sections 1 - 3

- Updated and clarified language
- Established communication standards
- Removed duplicative language
- Outlines responsibilities of:
  - Units managing sponsored projects (RMS, GBC and ICD)
  - Roles on each RMS team (RSC, Associate and Team Manager)
Roles & Responsibilities: Section 4

- Added resources for improved navigation & comprehension:
  - Definitions of processes
  - Service expectations where applicable
  - Acronyms and terms are hyperlinked to a Glossary

- All processes were fleshed out to accurately reflect the work
- PI, RSC, Department and CGA responsibilities were aligned to allow for a procedural ‘flow’
- Service Expectations and Roles & Responsibilities from prior SLA incorporated
### Create Budget

**Definition:** The proposal budget is a detailed statement outlining estimated project costs to support the work under a grant or contract. Line items may differ but usually include salary, fringe benefits, materials and supplies, computer costs, travel, student support, equipment, subgrants or subcontracts, publications and other allowable miscellaneous costs. The RSC will be responsible for completing the budget guided by input from the PI and will answer specific questions about which costs are allowable.

For clinical trials, follow the guidance below in addition to that outlined in [Appendix D – Clinical Trial Budgets](#).

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Research Mgmt. Services Team</th>
<th>Department/Division</th>
<th>Contracts &amp; Grants Accounting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide input to create budget. For projects with animal or patient care expenses, supplies and procedures will be provided by PI or his/her study coordinator to ensure scientific accuracy.</td>
<td>Develop a draft of the project budget with input from the PI, request all cost details, e.g., animal and patient care costs, etc., verify with Dept. as necessary and complete the final budget pages in the application.</td>
<td>Verify budget input as requested; e.g., cost sharing, effort commitments and salary projections.</td>
<td></td>
</tr>
<tr>
<td>Provide personnel, supply, equipment, services, etc. information for budget development.</td>
<td>Confirm/obtain accurate salary/stipend information and appropriate benefit rate to use on proposal with UCSF systems or department when needed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prepare sponsor budget form pages, paper or online.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Additions to Roles & Responsibilities

Added sections to reflect RMS’ role in award acceptance as of April 2014:

- Award Triage
- Award Intake
- Negotiation
- Award Setup

Further defined the pre-award process by adding procedures that were previously omitted:

- Just-In-Time
- Transfer Awards In
- Biosketch
Key Changes

Carryforwards, Re-budgeting Awards & Changes in Personnel on Awards

- Fleshed out Carryforwards, Re-Budgeting Awards and Changes in Personnel on Awards to define and standardize RMS/post award relationships.

- Post award will provide the raw data in the form of BSR, spending plan or other applicable format.

- RSC will translate into the Sponsor-specific format and communicate with Sponsor.
### Carry Forward

**Definition:** Carry forward consists of unobligated funds remaining at the end of any budget period that, with the approval of the sponsor, may be carried forward to another budget period to cover allowable costs of that budget period (whether as an offset or additional authorization). When the sponsor is the NIH, carry-forward approval may be provided by either the GMO or UCSF’s expanded authority.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Research Mgmt. Services Team</th>
<th>Department/Division</th>
<th>Contracts &amp; Grants Accounting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inform RMS of the need to request a carry-forward.</td>
<td>At the request of the PI/Dept, confirm that prior approval is needed for carry-forward and submit request to sponsor.</td>
<td>Inform RMS of the need to request a carry forward.</td>
<td>Provide BSR spending plan to RSC and validate carry forward amount.</td>
</tr>
<tr>
<td>Write or confirm scientific and budget justifications specifying why a carry-forward is necessary, if required by Sponsor.</td>
<td>Work with PI to prepare request and budget justification for carry-forward request, if required by sponsor.</td>
<td>Verify information prepared by RSC and PI. Convey any relevant information to RSC.</td>
<td></td>
</tr>
<tr>
<td>Approve carry forward request.</td>
<td>Follow up with sponsor every 2 weeks until a response is received.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Key Changes

T32s & Other Project-Specific Tables/Lists

- Department is responsible for the information and formatting of T32 tables and other project-specific tables and lists required by the Sponsor, such as publications resulting from the grant or pictures where the Sponsor logo is displayed.

- From “Create a Proposal” (p.9):

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Research Mgmt. Services Team</th>
<th>Department/Division</th>
<th>Contracts &amp; Grants Accounting</th>
</tr>
</thead>
</table>
| Draft science.         | Complete the administrative sections of proposal:  
                           - OSR Approval Form  
                           - COI Forms  
                           - Face Page  
                           - Budget(s)  
                           - Budget Justification(s)  
                           - Key Personnel List (completed with information from PI)  
                           - Checklist | Provide project-specific information if required by sponsor. Collect data and complete tables for T32 applications and provide them to RMS in table format. Complete sponsor-specific tables and lists, such as publications resulting from the grant or pictures where Sponsor logo is displayed. |
Key Changes

*PubMed Central Identifiers (PMCID)*

- Updated to include PMCID responsibilities in regards to biosketches.
  - After much discussion, it was decided that PMCID sit with the PI and designated administrative staff, if available.
### Biosketch

**Definition:** A biosketch is used to highlight a PI’s education and accomplishments as a scientist. Reviewers use this information to assess each individual's qualifications for a specific role in the proposed project. This is a NIH form, but it is used by many sponsors including federal, state, and private.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Research Mgmt. Services Team</th>
<th>Department/Division</th>
<th>Contracts &amp; Grants Accounting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inform and educate PI on PubMed Central Identifiers (PMCIDs) requirements and resources as needed.</td>
<td>Inform and educate PI on PubMed Central Identifiers (PMCIDs) requirements as part of basic training and onboarding process.</td>
<td></td>
</tr>
<tr>
<td>Maintain publications in MyNCBI. If designated administrative staff available, assist with Section D “Research Support” of biosketch including looking up PubMed Central Identifiers (PMCIDs).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintain biosketch templates and update with PMCIDs as needed. Review MyNCBI bibliography for accuracy. Retain versions sent by RSC and work from updated document.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Key Changes

Other Support

- Previously the RSC reviewed Other Support for completeness, accuracy and consistency with UCSF records, communicated discrepancies to the Department and participated in resolution.

- It was agreed that it would be more efficient for Departments to own Other Support content, with RSCs providing guidance, relevant grant information and translating information into Sponsor-specific formatting.
Other Support

**Definition:** Other Support includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual’s research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts. Used by Grants Management to ensure a project is not being funded twice.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Research Mgmt. Services Team</th>
<th>Department/Division</th>
<th>Contracts &amp; Grants Accounting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Provide guidance regarding Other Support instructions.</td>
<td>Maintain Other Support page.</td>
<td></td>
</tr>
<tr>
<td>Provide major aims to RSC.</td>
<td>For grants submitted by RMS, provide title, grant number, amount, project period and other grant descriptors in a format that can be cut and pasted. Send this information to department, PI and any investigator listed on the grant.</td>
<td>Calculate effort and Total Direct Costs for each award listed.</td>
<td></td>
</tr>
<tr>
<td>Review Other Support content to verify support is accurate and identify scientific overlap.</td>
<td>Format Other Support into Sponsor-specific guidelines, conveying any specific level of detail required</td>
<td>Review Other Support page for effort overlap. Work with PI to complete overlap statement for Other Support (including maintaining/update Veterans Affairs effort).</td>
<td></td>
</tr>
<tr>
<td>Approve Other Support page and overlap statement.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Key Changes

Award (Fund) Advances

- Previously the Department requested a fund advance from the RSC, who completed the form and obtained signatures.

- Now the Department completes the award advance form and submits to the RSC for compliance review.
**Award Set-Up**

**Definition:** Award Setup is step 4 of 4 in Award Acceptance. RSC will route to CGA in CACTAS for **RAS** setup and **COA** assignment.

**Service Expectation:** RSC will forward a signed copy of the agreement to Sponsor within 2 business days of finalized agreement. RSC to notify CGA within 24 hours of award execution.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Research Mgmt. Services Team</th>
<th>Department/Division</th>
<th>Contracts &amp; Grants Accounting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Forward signed copy of agreement to Sponsor within 2 business days of finalized agreement.</td>
<td></td>
<td>Set up account in <strong>RAS</strong> system</td>
</tr>
<tr>
<td></td>
<td>Notify <strong>CGA</strong> via CACTAS for set-up within 24 hours of completion of negotiation and execution.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Review the assigned Posting level <strong>DeptID</strong> and request CGA to change within 2 business days, if required.</td>
<td></td>
<td>Notify the Department and PI once the award set-up is complete.</td>
</tr>
<tr>
<td></td>
<td>Request project ID for awards with multiple projects.</td>
<td></td>
<td>Provide the Award #, the primary Project ID, and Posting Level Dept ID.</td>
</tr>
<tr>
<td></td>
<td><strong>Supply information and documentation as requested by RSC.</strong></td>
<td>Complete Fund (Award) Advance form, obtain signatures and submit to RSC. Obtain commitment documentation from Sponsor.</td>
<td>Set up Fund (Award) Advance.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Mgmt. Services Team</th>
<th>Department/Division</th>
<th>Contracts &amp; Grants Accounting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verify Fund (Award) Advance compliance with all applicable regulations and forward to CGA via CACTAS.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>