AGENDA

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenter</th>
<th>Time</th>
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</table>
| 1. Office of Clinical Trial Activation (OCTA) Update | Winona Ward  
Director, Office of Sponsored Research  
Director, Office of Clinical Trials Activation | 8:30 – 9:15 a.m. |
Interim Director  
Human Research Protection Program | 9:15 – 9:45 a.m. |
| 3. Roundtable Discussion | All | Remainder of meeting |

2019 Meetings Remaining: 2nd Tuesday of each month
- October 8
- November 12
- December 10
Office of Clinical Trial Activation (OCTA) Update**

Clinical trials processing efforts at UCSF have largely been focused on compliance, including mitigation of billing and cost policy risks. To that end, UCSF formed the Office of Clinical Research (OCR) in 2016 to centralize coverage analysis and budget development, implement use of a clinical trial management system (CTMS), cover costs, increase enrollments, and increase Clinical Trials (CT) revenue. In 2018, a group of key stakeholders participated in a 3-day KAIZEN and conducted a review of best practices and benchmarking at UCLA, Duke, and Yale to understand issues still challenging clinical trials processing. A task force was convened with the goal of improving administration and processing of clinical trials, and shortening the time to trial activation. In FY19, the Office of Clinical Trial Activation (OCTA) was formed and is accountable for end-to-end trial processing, and continued compliance.

FY19 Accomplishments include:

- Augmented staff to deal with budget backlog of 86 items, clearing them in eight weeks.
- Newly branded OCTA includes four distinct teams: Intake/Operations; Calendar-Oncore; Coverage Analysis; and Budget Development and negotiation. Ideally, faculty and study teams will rely on Intake/Operations to navigate the pipeline process.
- Secured budget augmentations for additional IRB and ICD staffing – 9 FTE; recruitments are in process.
- Coverage analysis and billing compliance is still being addressed. OCTA may now turn attention to improved activation timelines via end-to-end processing.
- Creation of resource account clinicaltrials.help@ucsf.edu to provide a single point of contact for assistance.
- All pipeline units: IRB, OCTA(OCR), ICD now report to the Vice Chancellor of Research.
- A Budget Development Pilot embeds full time OCTA staff within the Department of Medicine; what is learned in the pilot will be applied to all of OCTA.
- Oncore: Research Insights will provide Investigators with a tracking mechanism for their protocols; OCTA is also working on new triage methods.
- OCTA has set a target for UCSF Clinical Trial processing at 120 days from protocol receipt to activation.

OCTA’s FY20 pledge is dramatic improvement of timeline to activation with continued compliance, and fiscal stewardship. OCTA’s goals include increasing master agreements, negotiating rate cards, and coding them into OnCore. FY20 Action Items include development and implementation of reports and dashboard for protocols processed through IRB, OCTA and ICD, and QICO plan development and implementation for service areas.

Quick Wins (Jim Kiriakis): OCTA worked with a large pharmaceutical company’s attorneys to develop mutually agreeable Indemnification/Subject Injury and facilitated agreements for several investigators. Sponsor negotiations are very complex and involve many constituents; we cannot anticipate all issues, but we can now see where bottlenecks exist, and work to resolve.

Department of Medicine (DoM) Pilot (Jon Rueter): Together with OCTA and OR leadership, the DOM budget pilot launched on in December 2018 to study the trial activation process. Key findings:

- Time for corrections is a big contributors to delays; defect rate is consistently high (75%).
Calendar builds are a source of errors for many subsequent steps.
UCSF’s method for escalating costs is unique and complex.
Combined roles (e.g. budget + MCA or calendar builder + MCA) are relatively common at other institutions.

2. Human Research Protection Program Institutional Review Board: Status and Initiatives**  Sherry Felchlin

The UCSF Human Research Protection Program (HRPP) Institutional Review Board (IRB) does more than protocol reviews, in addition to the review and committee support functions, there is also the QUI unit which supports audits, subject complaints and protocol violations as well as educational activities to the research community. The full committees reviews are a small component of IRB work. Expedited, exempt, Not Human Subjects and quality improvement projects protocols comprise a significant amount of the work with the largest volume of protocols coming through the office being expedited and exempt. These submission are often the most challenging and poorly developed as they are submitted by research naïve investigators, as such there is a significant amount of time taken to assist in the preparation of a study that may be reviewed and approved. The committees are not involved in expedited reviews; those get assigned to an individual staff person. Additionally, research now is more complex and innovative.

Due to understaffing, funding was secured for recruitments; however these positions are niche and difficult to fill. HRPP leadership is now very stable and high turnover has subsided.

The HRPP is assessing all initial review submissions to look for processing trends; typically most submission currently require two “touches” by the IRB analyst prior to being able to perform a review either by staff or full committee with some as many as 5. The HRPP is trying to understand why this is & to improve the efficiency of the review preparations as well as ensure the appropriate allocations of staff based upon the volume of the workload.

The HRPP gets a significant number of Just in Time protocols, which are assigned to team managers. Time between protocol receipt in the HRPP and assignment to an analyst (sometimes six weeks) is a frustration. The HRPP will develop & set expectations for protocol committee assignments as well as improved cycle times for the expected reviews.

Summary Assessment:
- The volume of expedited, exempt and NHS submissions continues to increase.
- Adjustments in processes and/or documents can positively impact cycle times by allowing for more efficient workflow routing.
- Providing additional resources to assist the research community in their submissions helps reduce direct contact impact on the IRB staff.
- There is an increasing complexity of the research.

Current HRPP Initiatives:
- Further evaluation of staffing,
- Provide a framework for consistent business processes,
- Consideration of work flow adjustments, and
- Enhance the service aspect to the research community.

Action: Sherry will attend an Academic Senate Committee on Research meeting; Sharmila Majumdar will gather questions from faculty about delays. Sherry will consider visiting other venues, too.

3. Roundtable Discussion  All
 Deferred due to time constraints.

* Attendance by phone  ** Contains excerpts from PowerPoint presentation; see presentation for detail.
Office of Clinical Trials Activation (OCTA)

Update to Research Advisory Board

October 8, 2019

Winona Ward, Interim Director
UCSF Clinical Trials

1. FY19
   - Objectives
   - History & Funding
   - Accomplishments

2. FY20
   - Action Items
   - Recent “Wins” – Jim Kiriakis
   - DOM Pilot and Metrics – Jon Rueter
   - OCTA Role & Broader Impact
FY19 Objectives

1. Clinical Research Billing Compliance (ongoing)
   - Began in 2016
   - Office of Clinical Research (OCR) Formed
   - Goal: Ensure regulatory and billing compliance.

2. Industry Funded Clinical Trial Activation
   - Began with 3-day “Kaizen” in June 2018.
   - Task Force Created
   - OCR became Office of Clinical Trial Activation
   - Goal: Improve administration/processing of clinical trials, and shorten time to trial activation.
Clinical Research Billing History

**Objectives:**
- Centralized CA and budget in OCR
- Substantial decrease in bill hold and write offs
- Increase Clinical Trial revenue

**Issues:**
- Inadequate coverage analysis (CA)
- Disconnected clinical budgeting and billing
- Inadequate charge segregation

**Impact:**
- Cost policy and billing compliance risk
- Millions in UCSF Health bill hold and write offs
- Financial impact to UCSF unknown

1 UCSF Clinical Research Financial Update March 2017
Funding History

- **FY16 $5.3M** initial investment to ensure federal compliance and appropriate revenue capture in UCSF’s clinical research billing process;

- **FY17 increased to $8.2M** for additional compliance needs and use of consultants to backfill slow hiring.
  - Additions based on compliance needs $2.72M, including:
    - Aegis audit-ready baseline project $1.8M
    - Additional 4 billing scrubbers for bill hold compliance $920K
  - Due to slow hiring, Aegis backfill through Dec 30 2017 $200K

- **$8.2M shared investment: (5.3M+2.72M+200k)**

<table>
<thead>
<tr>
<th></th>
<th>UCSF Health</th>
<th>Core</th>
<th>SOM</th>
<th>Total</th>
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<tbody>
<tr>
<td>Option 3</td>
<td>33.3%</td>
<td>33.3%</td>
<td>33.3%</td>
<td>100%</td>
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<tr>
<td>FY 16/17</td>
<td>$ 1,003,675</td>
<td>$ 1,003,675</td>
<td>$ 1,003,675</td>
<td>$ 3,011,025</td>
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<tr>
<td>FY 17/18</td>
<td>$ 1,726,491</td>
<td>$ 1,726,491</td>
<td>$ 1,726,491</td>
<td>$ 5,179,475</td>
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<tr>
<td>Total</td>
<td>$ 2,730,167</td>
<td>$ 2,730,167</td>
<td>$ 2,730,167</td>
<td>$ 8,190,700</td>
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- March 2017: Approved FY18/19 at $7,641,443; Projected actual $7,966,304
- **FY 20 Projected OCTA Budget $7,991,889; ~4.0% increase over plan; ~0.3% over actual**

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1 UCSF Clinical Research Billing Briefing and Funding Request August 2016

OCTA Update October 2019
FY19 Accomplishments

1. **All Pipeline Units: IRB, OCTA(OCR), ICD report to VCR**

2. **Created the Office of Clinical Trial Activation (OCTA)** accountable for end-to-end trial processing.

3. **Quality Improvement and Compliance Officer** to ensure consistent, accurate and efficient services are provided.

4. **Conducted review of** best practices and benchmarking of UCLA, Duke and Yale; onsite visits and consults.

5. **Created single point of contact** for help and escalation: clinicaltrialshelp@ucsf.edu

6. Augmented budget staff and **cured budget backlog** (n=86) in less than 8 weeks.
FY19 Accomplishments (2)

6. **Budget Development pilot**, with FTE budget support in SOM.

7. **Federated** model charter drafted in collaboration with Department of Medicine and Pediatrics (e.g. decentralized budget development).

8. Secured funding for Clinical **Trial dashboard from the IT Governance Committee** (FY20 funding).

9. **Accelerated implementation of Task Management** for tracking of pipeline studies and metrics.

10. Secured budget augmentations for **additional IRB and ICD staffing** – 9 FTE; recruitments are in process.

11. **Set target for UCSF Clinical Trial processing at 120 days** from protocol receipt to activation. (See metrics from HDFCCC)
FY 20 Action Items

- OCTA pledge is dramatic improvement of timeline to activation with continued compliance, and fiscal stewardship

- OCTA responsible for:
  - Maintaining regulatory and fiscal compliance and implementation of QA Program for all centralized services (e.g. CA, budget dev, billing)
  - Quality assurance & improvement program for services & compliance
  - Systems, reporting & development/deployment of dashboards
  - Escalation protocols for critical trials and sponsors
  - Staff recruitment, retention, training and development
  - Federated service models; Research Pricing Policy
  - Master Agreements and Rate/Pricing Agreements with sponsors
  - Post-Award Billing Improvements (TBD)
FY 20 Action Items

How will success be measured?

- Development and implementation of reports and dashboard for protocols processed through IRB, OCTA and ICD
  - Number of new protocols and amendments processed
  - Number of days to activation, by task for dept./PI/Sponsor, etc.
  - Number of subjects enrolled, compared to target
  - Continued reporting on charge review and bill hold
  - Number of Master Agreements and Rate Agreements with sponsors

- QICO plan development and implementation for service areas
  - SOPs for processing; CA, Calendar, Budget, and Contracting
  - QI for compliance with federal and institutional policy
  - Escalation and prioritization protocols
# Recent Wins – Jim Kiriakis

<table>
<thead>
<tr>
<th>PI</th>
<th>Sponsor</th>
<th>Protocol</th>
<th>Issues and Solutions</th>
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<tbody>
<tr>
<td>Tom Martin</td>
<td>Janssen</td>
<td>Sponsor</td>
<td>Indemnification/Subject Injury (CAR-T). IP.</td>
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<tr>
<td>Nina Shah</td>
<td>Janssen</td>
<td>Sponsor</td>
<td>Replicated Martin solution locally.</td>
</tr>
<tr>
<td>Vadim Koshkin</td>
<td>Janssen</td>
<td>Sponsor</td>
<td>Replicated Martin solution locally.</td>
</tr>
<tr>
<td>Rahul Agarwal</td>
<td>Janssen</td>
<td>Sponsor</td>
<td>Replicated Martin solution locally.</td>
</tr>
<tr>
<td>Rahul Agarwal</td>
<td>Janssen</td>
<td>PI Initiated</td>
<td>Liability issues vetted by Risk Mgt, appv’d by SOM.</td>
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<tr>
<td>Jo Chien</td>
<td>Amgen</td>
<td>PI Initiated</td>
<td>Sponsor refused to honor master.</td>
</tr>
<tr>
<td>Larry Fong</td>
<td>Amgen</td>
<td>PI- Initiated</td>
<td>Negotiated in parallel with Chien terms.</td>
</tr>
<tr>
<td>M. Melisko</td>
<td>JHU/TBSRC</td>
<td>Consortium</td>
<td>JHU flow down liability, IP terms, Seattle Genetics drug.</td>
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</table>
DOM Budget Pilot – Jon Rueter

- The DOM budget pilot launched on in December 2018 and is funded wholly by the central Department of Medicine in order to study the trial activation process.

- 7 participating PI’s across 4 disease programs in Hematology-Oncology with 14 studies activated, 17 current studies in pilot, 20 more studies will soon enter the pipeline.

- Key Findings:
  
  - Time for corrections is one of the biggest contributors to delays; defect rate has consistently high in the DOM pilot.
  
  - Although times for Calendar build are within target timeframes they are also a source of errors for many subsequent steps.

  - UCSF’s method for escalating costs is unique and complex.

  - Combined roles (e.g. budget + MCA or calendar builder + MCA) are relatively common at other institutions.
Key Steps: Targets v. Actuals

- DOM Budget Pilot target = 120 days;
- Average time to activation last 90 days = 107 days
- Current sum of the average actual days for DOM budget pilot = 103 days
OCTA Role & Broader Impact
Compliance, Financial Stewardship & Trial Activation

Compliance
Federal/DHHS Regulations
Medicare

Financial
Research Pricing
Accurate Billing for Internal & Sponsor Trials

Activation Impact
Data/ROI/Activation
UCSF & Research, Patients & Faculty; CTSI renewal
UCSF Health Competitive advantage
HRPP
Institutional Review Board
Status and Initiatives

Sherry Felchlin
Interim Director, HRPP
11/7/2019
HRPP – More than just the IRB
IRB Activity by Numbers
Active IRB Studies vs. FTEs

<table>
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<tr>
<th>Year</th>
<th>Total Active Studies</th>
<th>FTEs</th>
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<tbody>
<tr>
<td>2010</td>
<td>4800</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>5200</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>5600</td>
<td></td>
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<tr>
<td>2013</td>
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</tr>
<tr>
<td>2017</td>
<td>7600</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>8000</td>
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New Full Committee Time to Review and Approval in Calendar Days vs. Number of Submissions

- New Studies Received
- New Studies Approved
- Time to First Review - Clean Submissions
- Time to First Review - Corrected Submissions
- Median Time to Approval

Calendar Days:
- Jan '17
- Feb '17
- Mar '17
- Apr '17
- May '17
- Jun '17
- Jul '17
- Aug '17
- Sep '17
- Oct '17
- Nov '17
- Dec '17
- Jan '18
- Feb '18
- Mar '18
- Apr '18
- May '18
- Jun '18
- Jul '18
- Aug '18
- Sep '18
- Oct '18
- Nov '18
- Dec '18
- Jan '19
- Feb '19
- Mar '19
- Apr '19
- May '19
- Jun '19
- Jul '19
- Aug '19
- Sep '19

Number of Submissions:
- 0
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100
- 110
- 120
- 130
- 140

UCSF
New Expedited Median Time to Approval vs. Number of Submissions

- Submissions Received
- Submissions Approved
- Median Time to Approval (T2A)
What does this mean?
### Time to Approval in Days & Number of Approvals by Month

<table>
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<tr>
<th>Full Committee</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
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<tr>
<td>Median of monthly medians: 87 days</td>
<td>Median of monthly medians for:</td>
<td></td>
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<tr>
<td>Average of monthly medians: 86 days</td>
<td>• 2018 all months: 102 days</td>
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<tr>
<td></td>
<td>• Jan-April: 116 days vs. May-Dec: 93 days (contractors hired)</td>
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<tr>
<td></td>
<td>Average of monthly medians for</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>• 2018 all months: 99 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Jan-April: 113 days vs. May-Dec: 92 days (contractors hired)</td>
<td></td>
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<tr>
<td>Median T2A for studies approved in that month</td>
<td>Jan</td>
<td>Feb</td>
<td>Mar</td>
</tr>
<tr>
<td>293 studies total</td>
<td>26</td>
<td>24</td>
<td>25</td>
</tr>
<tr>
<td>2019</td>
<td>Jan</td>
<td>Feb</td>
<td>Mar</td>
</tr>
<tr>
<td></td>
<td>98</td>
<td>97</td>
<td>74</td>
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<table>
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<th>Expedited</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
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<tr>
<td>Median of monthly medians for 2018: 40 days</td>
<td>Average of monthly medians for 2018: 41 days</td>
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<tr>
<td>N of studies approved in that month</td>
<td>Jan</td>
<td>Feb</td>
<td>Mar</td>
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<tr>
<td>838 studies total</td>
<td>96</td>
<td>64</td>
<td>71</td>
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<td>71</td>
<td>43</td>
<td>35</td>
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11 Kinetiq contractors hired May 2019, Lost 1 FTE expedited analyst January 2019, Expedited contractors reduced Feb 2019
Summary Assessment

- The volume of expedited, exempt and NHS submissions continues to increase
  - This often is more challenging work to process
- Adjustments in processes and/or documents can positively impact cycle times by allowing for more efficient workflow routing
- Providing additional resources to assist the research community in their submissions helps reduce direct contact impact on the IRB staff
  - Metrics have indicated that these resources are under utilized and greater community outreach is needed
- Finally what is recognized without metric is an increasing complexity of the research
What is being done?
Initiatives under the HRPP

- Further evaluation of staffing
  - increased funding allocation for additional personnel received and hiring endeavors are in progress
  - Is the allocation of staff to specific roles appropriate?

- Provide a framework for consistent business processes
  - SOPs and standard procedural instructions

- Consideration of work flow adjustments
  - Opportunities in modifications to documents or processes

- Enhance the service aspect to the research community
  - Increase focus on education in the understanding of process and mechanics of engagement with the IRB
  - Develop collaborative relationships with our colleagues in the research community