These notes are intended to provide a summary of action & follow up items; a few discussion highlights are included.
- The goal is to change the funding model to receive unrestricted philanthropy gifts only.
- Who will select and decide which scientists receive funding?
  - Barry will be part of an advisory board where applications will be reviewed and selected.

**Mandatory Trainings Update, Brian Smith**

- There are about 57 trainings with 45% of them housed under EH&S and 23% under IACUC.
- Campus trainings are focused for researchers and the number of trainings per individual vary depending on the type of their research.
- Brian is working with EH&S to update all trainings with a deadline of December 2017 to ensure the following:
  - Test out option is readily available
  - Regulations are updated
  - Broken links are fixed
  - Adding specifications for ADA requirements
- The original proposal to the RAB committee was to form a sub-committee, however, Brian would like to review the new proposed mandatory trainings then bring them to the RAB committee for final review. Other committees, such as the Chemical and Environmental Safety Committee will also be reviewing new trainings.

**Questions/Comments:**

- Is it possible for training notifications to be sent out in bulk as oppose to one at a time?
  - This is something Brian can look into for Phase 2 of the project for updating the trainings.
- What process will be put in place when a training is no longer required?
  - Brian will work closely with the safety committees and updates to the trainings will occur on a more regular basis.
Clinical Data Request Process
Presentation to RAB
June 6, 2016

David Dobbs, Kim Romero
Enterprise Information & Analytics
Clinical Data Request Intake Process

Main Objectives

• Provide requestors a simple and standardized online form to request clinical data
• Create a central place to track all requests
• Improve compliance with UCSF policies for controlling access to and releasing de-identified data, limited data sets, protected health information and personally identifiable information
• Standardize data use clauses and have them cover commercialization of UCSF data by external parties
High Level CDRP Flow

Research
- A systematic investigation to develop or contribute to generalized knowledge
- Typically grant or contract funded

Quality Improvement
- Activities to continuously evaluate and improve performance in a clinical area or department
- Typically hospital or department funded

Determine Quality or Research → Quality → Quality/Payment/Operations → Research → De-identified Approval → LDS/PKI/PIII Approval

LDS – Limited Data Set
PHI – Protected Health information
PII – Personally Identifiable Information
Quality/Payment/Operations Approval

- Manager/Director Approval
- Attestation form sent to requestor via DocuSign

Internal Employee

- Manager/Director Approval
- External contract established (see slides 7 & 8)
- Security assessment if taking possession of data

External Entity

- Same as Vendor
- External contract established (see slides 7 & 8) by Health Plan Strategy and ACO department

Vender

Payor
Research De-identified Approval

- Attestation form sent to requestor via DocuSign
- PI informed of request via email
- No data use agreement required

- External research contract for de-identified data established (see slides 7 & 8) with DUA
- No Attestation form required because of contract
- PI informed of request via email
- Security assessment if taking possession of data

Internal Researchers

- Same as Academic approval
- Contract is different if industry is paying us for data and there is a higher due oversight required.

External Researchers

Academic

Industry

UCSF Medical Center
UCSF Benioff Children's Hospitals
Research LDS/PHI/PII Approval

- LDS – Requestor and PI sign UCOP DUA via DocuSign
- PHI / PII - IRB approval. Requestor must be named on study team in iRIS
- Attestation form sent to requestor via DocuSign
- PI informed of request via email

LDS/PHI/PII Approval

- LDS / PHI / PII – IRB approval. External party must be named on study team in iRIS
- PI informed of request via email
- External research contract established (see slides 7 & 8) with DUA
- No attestation form required because of contract and standard data use language
- Security assessment if taking possession of data

- Same as Academic approval
- Contract is different if industry is paying us for data and there is a higher oversight required.
Clinical Data Request Process

- New, streamlined Clinical Data Request Process (CDRP) was implemented on March 29th.

- An easy-to-use way for faculty, staff and students to request clinical data for treatment, payment, operations, quality improvement and research purposes; while ensuring all UCSF privacy and security policies are followed.

- Replaces 2 existing processes:
  - APeX New/Modify Report Request Form
  - Clinical Data Research Consultations Request Form

- Learn more about CDRP at data.ucsf.edu
Innovation Ventures

Current Status and Goals

Barry Selick
VC of Business Development, Innovation & Partnerships

6/5/2017
Innovation at UCSF

- 2016 Research Expenditures were $1.3B
  - 80 filings of new patent applications
  - 72 licenses granted; 18 to UCSF start-ups
  - $30-35M license revenues earned
    - 15% to “Research Share” to Dean of relevant school
    - 37.5% to “School Share” to Dean of relevant school
    - 12.5% to Chancellor (most goes to UCOP assessments
    - 35% to Inventors
Ways in Which Inventions are Prosecuted

- Licensed to a pharma/existing company partner
- Licensed to a start-up company
  - Founded and run by non-UCSF entrepreneurs
  - Founded and run by UCSF faculty/students/staff
- Retained by inventor for maturation within UCSF
Ways in Which Inventions are Prosecuted

- Licensed to a pharma/existing company partner
- Licensed to a start-up company
  - Founded and run by non-UCSF entrepreneurs
  - Founded and run by UCSF faculty/students/staff
- Retained by inventor for maturation within UCSF
Ways in Which Inventions are Prosecuted

- Licensed to a pharma/existing company partner
  + Let’s inventor focus on their day job
  + Is typically associated with an up-front payment ($’s)
  + Credible partner can invest meaningful resources ($’s)
  - Inventor loses control of project
  - Up-fronts for early stage programs tend to be modest with modest milestones/royalties
  - Large companies tend to move at glacial speeds
  - Partner may have “different” vision for development of project
    • eg…“strategic decay”
Ways in Which Inventions are Prosecuted

- Licensed to a pharma/existing company partner
- Licensed to a start-up company
  - Founded and run by non-UCSF entrepreneurs
  - Founded and run by UCSF faculty/students/staff
- Retained by inventor for maturation within UCSF
Ways in Which Inventions are Prosecuted

- Licensed to a start-up company
  - Founded and run by non-UCSF entrepreneurs
    + Inventors are typically involved as advisors...more influence
    + Start-up entrepreneurs tend to be more closely aligned with the needs of inventors/university
    - Not all start-up entrepreneurs are capable
  - Founded and run by UCSF faculty/students/staff
    + Control/responsibility
    +/- Running a start-up is a full-time job
    - You cannot be a FT CEO and UCSF faculty member simultaneously
Ways in Which Inventions are Prosecuted

- Licensed to a pharma/existing company partner
- Licensed to a start-up company
  - Founded and run by non-UCSF entrepreneurs
  - Founded and run by UCSF faculty/students/staff
- Retained by inventor for maturation within UCSF
Ways in Which Inventions are Prosecuted

- Retained by inventor for maturation within UCSF
  + Control
  + Control
  + Control
  + Build greater value/generate greater upside before licensing ($’s)
  - Most faculty/staff do not have the expertise/resources to mature programs to POC
  - Manufacturing, IND-enabling studies, FDA interactions can be distracting
  - $’s required to prosecute programs internally
Potential Solution

- Raise $’s from visionary donors to fund internal programs to POC before licensing
  + Ongoing involvement of inventors
  + Accelerated enablement by dedicated technology developers who work in partnership with inventors
  + Utilize outside CROs with deep expertise in all aspects of technology development/POC demonstration
  + Alignment of interests between inventors, developers, donors, UCSF
  + Preserve greater upside for inventors and UCSF

*Goal is to raise $50M in commitments to fund this program*
What Constitutes a “Great” Invention?

- While discoveries at UCSF are expected to be transformative, not all discoveries become inventions...

...and not all inventions are expected to be transformative

Patrick Soon-Shiong, UCLA: HSA-conjugated paclitaxcel

sold to Celgene in 2010 for >$3B

net worth in November 2016: ~$9B

Queen & Selick: Humanized monoclonal antibody therapeutics

~15 approved drugs licensed technology

top 2 therapeutics (Herceptin & Avastin) had cumulative sales through 2016 of $127B
What Constitutes a “Great” Invention? (cont.)

Motion Preservation
Interlaminar Stabilization™
The 1st and only motion preserving, minimally invasive treatment approved for moderate to severe spinal stenosis post decompression. LEARN MORE

February 18, 2014
PDL BioPharma and Paradigm Spine Complete a $75 Million Financing Transaction
Paradigm Spine, LLC Announces Publication of 5 Year Long-Term Results of Level 1 Data for coflex® Interlaminar Stabilization® Compared to Fusion
Wednesday, January 27, 2016
How to Invent at UCSF?

- UCSF Innovation, Technology & Alliances
- Entreprenuership Center
- Industry Collaborations
- Office of Technology Management

WHERE STARTUPS GET STARTED

QB3 accelerates the science innovation and entrepreneurship. Learn how we can help your startup launch and grow.

QB3

WHERE STARTUPS GET STARTED

Ucsf Innovation, Technology & Alliances
Who to Talk to About Your Inventions at UCSF?

Cathy Tralau-Stewart

Hanmin Lee

Mike Blum
Partner or DIY?
Reg and QB3 are Start-Up Gurus
But be Sure to Protect Your Ideas First…Talk to Karin

The Clinic’s A Translational Science clinical and translational network in health. We do this by bringing into the clinic new ways.

Karin Immergluck

WHERE STARTUPS GET STARTED

UO3 accelerates the science innovation and entrepreneurship. Learn how we can help your startup launch and grow.

Karin Immergluck

University of California San Francisco

Office of Technology Management

UCSF OTM

@UCSFOTM

At the UCSF Office of Technology Management, our mission is to commercialize UCSF’s life science and medical technologies for public use & benefit.