PRESENTER: Research Initiatives at UCSF

Keith Yamamoto

Keith Yamamoto presented a slide deck on current Research Initiatives that are ongoing at UCSF. 2013 initiatives come from the following three areas - local, federal/international and research education, local being the largest. Keith then provided examples for each.

UCSF is focused on three main local initiatives: Precision Medicine, the Lawrence Berkeley National Laboratory (LBNL) Alliance, and the opening of the Research Development Office. The Precision Medicine initiative grew out of a report that was set up by the National Academy of Science which recommended building an enabling tool which would allow us to access data from huge databases about all aspects of biological research, health, and disease – an information commons and knowledge network – and then begin to draw relationships between different points in that network.

The UCSF Precision Medicine Platform consists of 6 overlapping components: Basic Discovery, Omic Medicine, Institute for Computational Health Sciences (ICHS), Center for Digital Health Innovation, Clinical Discovery, and Knowledge Networks. Keith presented a slide on each component, detailing the main goals and leadership for each.

Questions/Comments:

- The idea of bringing all this information sounds great but also difficult to implement. How does the group envision bringing all the stakeholders together? Keith explained that the goal would be for an accessible cloud of information, which would be sortable in many ways, and would serve as a UCSF knowledge base. This would include an expansion of Profiles. This would allow people to identify new partnerships and new intersections with individuals on campus which would advance innovation and research.

- One of the goals for the ICHS is to establish tools to build computational literacy across the UCSF community – what does literacy mean in this instance? Keith explained that they are referring to everything - molecules to systems. Everyone does not have to know everything, but the hope would be that people have the knowledge that they need within their field of expertise.

For the LBNL Alliance, Terri O’Brien has been coordinating work on building a sustained, robust interface between LBNL and UCSF, through three main areas: high performance computing, omics, and imaging. The LBNL has recently announced that they will be building a second campus on Richmond Bay focused on health and biosciences.

The newly established Research Development Office (RDO) runs a series of programs designed to enable UCSF researchers at all levels – large grants, individual researchers, research teams, etc. Executive Director Gretchen Kiser runs the Research Allocation Program (RAP), the Limited Submission Program (LSP), as well as the BTIR – Building Teams for Innovative Research Program, and the LGDP – Large, Multi-Investigator Grant Development Program out of the RDO office.

Keith also briefly discussed the efforts being made towards Federal and International Research Initiatives. We have hired Jennifer Wickre as the Director of the Federal Government Relations Office, working out of the UC DC office, and she will work to identify and shape policy priorities at NIH and other government agencies as well as doing outreach on Capitol Hill.
Janhavi Bonville, EVCP Jeff Bluestone’s Chief of Staff, acts as the coordinator for International Alliances, seeking to facilitate research collaborations through institutional coordination, criteria and standards. In both of these areas, we have been reactive in the past, but are hoping to move towards a more proactive approach.

Keith also discussed **Research Education Initiatives**. There are several ongoing programs, and Keith brought specific attention to Graduate Student Internships for Career Advancement (GSICE), which is run by Terri O’Brien, and offers internships in business law, communication and other areas outside the academic track.

**Questions/Comments:**

- The suggestion was made that, specifically in relation to GSICE, faculty buy-in is key – faculty should encourage students who may be interested in areas outside academics to participate.
- The group also expressed interest in bringing the information presented today back to their constituents, and Keith encouraged this.

**Action:** Keith asks the group to continue to provide feedback on these initiatives, as most of them are in the beginning stages. He also encouraged the group to send on any contacts that would be advantageous to these initiatives.

**PRESENTATION:** New COI (conflict of interest) Regulations

Elizabeth explained some of the changes that have been put into place since the old PHS regulations changed in August, 2012. She provided a handout for the group which lists the old and new regulations for easy reference. Key changes under the new PHS regulations include:

1. **The definition of investigator** has changed, and now includes project directors, PIs on center grants, and any other individuals who have responsibility for the design, conduct and reporting of the research being funded. These individuals are all required to disclose conflicts of interest. This generally corresponds with the key personnel on individual grants, and the basic rule to follow is that if the individual is making independent decisions on the research, they should disclose. This may now include individuals such as collaborators who are not key personnel, and students who attend a conference and report research results. The advice from Elizabeth’s office is to over-disclose, if in doubt.

2. **Institutional responsibilities** - The disclosure of outside income now includes any financial interests above 5K – not just those related to research. The definition is much broader now, and includes teaching, training grants, etc. Exclusions to this include any reimbursements, honoraria, or other income from academic institutions. The timeframe for what should be included in the disclosure is 12 months before the grant.

These changes have made the work for Elizabeth’s office much more complex, but they have made every effort to make it seamless on the front end for investigators. In MyAccess, investigators are able to access a disclosure system called **COI Smart** which allows them to disclose once for the year, and as long as nothing changes, they do not have to go in and disclose again. Because we are now casting a much larger net for disclosures, Elizabeth’s office now waits for award notices before proceeding, and they do a lot more in-office review, saving the review committee for more complicated issues.

Elizabeth also called attention to the fact that there is **no threshold for disclosures on travel**. This should be reported within a month of when the travel takes place.

Finally, Elizabeth discussed the next steps her office is working on, with focus on their plan to incorporate a fillable 700U form which will accept an electronic signature into the COI Smart system in the next year.

**Questions/Comments:**

- The broadening of the definition of investigator seems to need a lot of clarification in order for it to be workable, is this being looked at? Yes, the NIH is working to add clarification, and we are providing feedback to them on a regular basis.
**Charge to the Research Advisory Group (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.

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- Are all disclosures dealt with in pre-award stages? Yes, everything must be completed before submitting the proposal, and will be reviewed later.
- Is there a way with the new COI Smart system that we would be able to see who within our department has filled out their disclosures? Eric Mah is the point person on this, and could answer this question.
- Who fills out the disclosure form for spouses and children? The PI would fill out this form.
- Do we accept FTPs from other institutions? Elizabeth explained that there is a database where we are supposed to be able to go to see if other schools have adopted the new standards and vice versa, but so far we have found that it is not working, and that other schools are not accepting our form there. We are hoping this will improve with time and experience.

**Action:** Elizabeth encouraged the group to contact her office with any questions.
Update
UCSF Research Initiatives

Keith Yamamoto
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Provost's Research Advisory Board
March 5, 2013

Integrate practices and policies across three planes

- Transdisciplinary science:
  Merge physics/chemistry/engineering/computation theory, concepts, methods into biomedical research

- Biomedical continuum:
  Build seamless links between basic discovery, translation, clinical care, patients, citizens

- Stakeholder synergy:
  Cooperate across .edu, .com, .org and .gov sectors
UCSF 2013 Research Initiatives

- Local
- Federal/International
- Research Education

Local Research Initiatives

- Precision medicine
- LBNL alliance
- Research Development Office
Building a biomedical continuum

Integrate rapidly expanding range and detail of biological, behavioral and experiential information to:

- facilitate basic discovery
- drive the development of a more accurate and precise classification of disease
- reach toward "precision medicine"

An enabling tool

Build an "Information Commons" and "Knowledge Network" that correlate and align disparate information; extend acquisition of molecular data from lab to point-of-care settings.

TOWARD PRECISION MEDICINE
Building a Knowledge Network for Medical Research and a New Taxonomy of Disease

http://www.nap.edu/catalog.php?record_id=13284

Board on Life Sciences
NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES
The UCSF Precision Medicine Platform

- Basic Discovery
- Omic Medicine
- Institute for Computational Health Sciences
- Center for Digital Health Innovation
- Clinical Discovery
- Knowledge Networks

Basic Discovery

- Conduct innovative investigations of fundamental biological processes
- Develop instrumentation or software that improve rates or resolution of analysis
- Establish new connections between ideas or observations thought previously to be unrelated
Omic Medicine

- Bob Nussbaum, Director
- Collect and analyze human subject genomic and other omic data in validated, secure environment
- Coordinate nextgen sequencing in IHG, CAT and CLIA-certified Applied Genomics Core (AGC); extend to other omics
- Ensure HIPAA-compliant data storage and access
- Education programs: Genomic Med, Genomic Tumor Board, certificate or Masters in Precision Medicine

ICHIS: Institute for Computational Health Sciences

- Michael Fischbach, Neil Risch, Interim Directors
- Aggregate and integrate: computer science, bioinformatics, hardware/software engineering, basic/clinical/population science
- Research developing and using computational tools and approaches
- Education: establish learning programs/tools to build computational literacy across UCSF community
CDHI: Center for Digital Health Innovation

- Mike Blum, Director

- Motivate, partner, develop, implement, validate tools that collect, aggregate, analyze and report health information in the course of normal life

- Aggregate expertise of engineers and computer scientists with basic/clinical/population scientists

- Coordinate with Office of Innovation, Technology and Alliances (ITA) and SOM ISU

- Organize clinical trials of dHealth devices, apps and technologies

Clinical Discovery

- Susanne Hildebrand-Zanki, Interim Director

- Conduct innovative clinical trials that integrate clinical and molecular information

- Build virtual data warehouse to advance selection of disease targets and patient cohorts

- Identify and address barriers to clinical discovery across clinical operations, data management, bioinformatics, regulatory, patient privacy, clinical care
Knowledge Networks

- Joe Hesse, Sorena Nadaf, Laura Van't Veer, Directors

- Primary enabling tool for precision medicine, nucleated from neurological disease, cancer

- Build integrated, visualizable access to campus, Kaiser, VA, LBNL basic, translational, clinical, population data

- Combine expertise and infrastructure resources of computer scientists, bioinformaticians, commercial partners, clinical and basic scientists

UCSF Precision Medicine

- Patients & Citizens
- Computational Health Science
- Digital Health
- Basic Discovery
- Information Commons
- Clinical Discovery
- Knowledge Network

New Correlations
New Hypotheses
New Transdisciplinary Links

New Diagnoses
New Therapy Implications
New Health Outcomes

New knowledge
Lawrence Berkeley National Lab Alliance

- Terri O'Brien, UCSF Coordinator; Horst Simon, LBNL Coordinator

- Develop extensive collaborative and cooperative interactions in three broad, overlapping areas of biosciences:
  - High performance computing
  - Omics
  - Imaging

RDO: Research Development Office

- Gretchen Kiser, Director; gretchen.kiser@ucsf.edu; 415.502.1655, Genentech Hall 116

- RAP: Resource Allocation Program

- LSP: Limited Submission Program

- BTIR: Building Teams for Innovative Research Program

- LGDP: Large, Multi-Investigator Project Grant Development Program

http://officeofresearch.ucsf.edu/rdo/home
Federal/International Research Initiatives

- Federal Government Relations Office
- International Alliances

Federal Government Relations Office

- Jennifer Wickre, Director; jwickre@gmail.com; 202.974.6315; UCDC; 1608 Rhode Island Ave, Washington DC

- Identify and help shape new research and policy priorities, programs and mechanisms at NIH, and also other federal agencies, e.g., NSF, DOE, DOD, OSTP

- Active outreach and communication on Capital Hill, especially with California delegation and relevant committee members

- Active relationships with private nonprofits, e.g., Coalition for Life Sciences, Research!America, CHI, BIO, AAMC, CHA, AHA

- Information conduit to UCSF faculty, RDO and administration
International Alliances

- Janhavi Bonville, Coordinator; j.bonville2@ucsf.edu; 415.514.0266

- For majority of our international alliances, UCSF has been reactive to approach from other countries/institutions

- Goals: Research collaborations, resources, funds; research and education outreach

- Developing institutional coordination, criteria and standards

Research Education Initiatives

- Workforce and diversity
  - Look @ implementation plans

- Team science; Design Science

- Rethinking how and what we teach

- Internships for Career Exploration
UCSF 2013 Research Initiatives

- Local
  Precision medicine
  LBNL alliance
  Research Development Office

- Federal/International
  Federal Government Relations Office
  International alliances

- Research Education
  Workforce and diversity
  Team and Design science
  Rethinking how and what we teach
  Internships for career exploration