

Charge

“The charge to this task force is to determine how to exploit the CTSI, clinical research infrastructure and faculty to grow T1, clinical, and T2 research. It also includes to integrate the Medical Center and educational enterprise, and build necessary cores, looking across and between Centers, Institutes, and the Medical Center.”

Situation: The following points to consider describe some general and specific aspects of the current situation at UCSF.

1. General

- Establishing UCSF as a hub for clinical and translational research (CTR) of the highest merit is a top priority for UCSF.
- Basic science is outstanding at UCSF but faces significant risk in an era of decreasing federal and state funding.
- Many outstanding CTR programs exist at UCSF. Suboptimal transition to new systems or requirements could hamper their continued success.
- Many Departments, Divisions and ORU's have invested significant resources in existing infrastructure and struggle financially to maintain these resources.
- Although UCSF is very collaborative, basic scientists and clinicians remain somewhat siloed. Campus geography exacerbates this problem.
- Successful mid and senior level investigators are often oversubscribed, leaving little time to mentor younger investigators.
- Significant obstacles (lack of mentoring, insufficient funding) hamper career development at UCSF.

2. Informatics

- UCSF has an incomplete electronic medical records (EMR) that does not include ambulatory care.
- Access to patient data for research is currently suboptimal and will be increasingly important.
- The Integrated Data Repository will need to link to the new EMR and does not meet the needs of many faculty.
- Access to biomedical informatics and bioinformatics are increasingly needed for CTR, driven by the increasing complexity of available clinical data and “omics” data.

3. Clinical Research

- Poor oversight for scientific quality and feasibility in clinical studies often leads to early study closure; related costs are sometimes never recovered and relationships with industry are jeopardized.
- Budgets for clinical trials are often prepared by faculty and staff who have sparse training and we do not have a centralized process for determining “usual care” cost within clinical trials. Legitimate recharges for start up costs are not always included in budget proposals.
- Outside of the Cancer Center, audits of investigator-initiated clinical trials are limited and thus we do not have an understanding about research compliance nor data quality.
- Existing infrastructure adopted by some units may have considerable capacity (i.e., Clinical Trials Management System) and consideration should be given to leveraging these assets.

4. Biospecimens

- Since we don't have a centralized biospecimen repository, specimen procurement and banking is distributed across programs and individuals with variable standard operating procedures and specimen protection and security.
- Patient care at UCSF is often episodic, with much co-management in the community or at other hospitals. Thus, building patient cohorts, accessing biospecimens, and retrieving key elements for outcomes are difficult and cumbersome tasks.

5. Partnerships

- UCSF is not considered by industry to be “user” friendly because of difficulties in finding faculty, delays in contract negotiations, and failure to deliver on promises.

6. Population and Health Services Research

- Selected clinical sites at UCSF, such as SFGH and SFVAMC, offer unique patient populations and opportunities to conduct health services research.
- Health care reform and cost containment pressures will require significant changes in health care delivery and create new research needs and opportunities.
- There is increasing need for knowledge on the broad determinants of health and ways to manage the health of populations, including prevention as well as chronic disease management.
- Little infrastructure is in place to study and implement improvements in healthcare delivery.

7. Core Technology

- Many specialized cores and core technology required for T1 and T2 research are missing or incompletely developed. These include cores, such as pharmacokinetics and pharmacodynamics, biomedical imaging, immune monitoring, and preclinical therapeutics on the T1 side. On the T2 side of the

CTR continuum technologies such as web-based systems for collecting data directly from patients, personal monitoring systems, smart-phone technologies, etc. are needed.

- Expanding CTR at UCSF may attract more patients and more need for ancillary services in radiology and pathology: this will create a strain on our existing capacity.

Target - UCSF should provide the services, infrastructure, and culture to grow clinical and translational research (CTR) so that UCSF becomes the national leader in CTR both in terms of high quality and impact.

- Barriers to performing CTR at UCSF should be minimized by ready availability of systems and resources and provide safeguards for patient safety, data security, data quality and compliance with good clinical research practice.
- CTR on biomarkers and targets for clinical intervention requires access to robust biorepositories with adequate clinical annotation.
- UCSF must be “user-friendly” to industry because many CTR studies (especially intervention research) require a partnership with the private sector.
- The metrics for success in CTR include: leadership on practice changing trials, accruals to investigator-initiated trials, federally sponsored awards that require CHR approval, and publications in top tier journals.
- Any new procedures and processes should result in shorter times to protocol approval and activation.
- Clinical care and health care policy should be integrated with the CTR mission and infrastructure.
- Clinical scientists and basic scientists need ready access to selected core technologies such as flow cytometry, genome analysis, pathology services, and so forth.
- Clinical service and clinical research should be tightly integrated.
- Services should serve the needs of all four Schools and the Graduate Division.
- Clinical and research informatics and data sharing should be integrated across the Campus with appropriate management of security risks. Data ownership should be the exception and openness should be the norm. Campus wide database architecture and interconnectivity should be a priority.
- Key determinants of disease, such as socioeconomic factors and lifestyle predictors, should be incorporated with clinical outcomes for selected cohorts.

Proposal

The following proposals have been placed in general order of priority, weighting perceived needs, potential impact, and the importance of an investment from campus leadership.

1. Create world-class programs in biomedical/clinical informatics and bioinformatics/computational biology that will include training programs and robust and diverse research programs that are aligned with the healthcare and discovery missions of the University. The program should:
 - Serve all four schools and the Graduate Division.
 - Include faculty with primary appointments across the University.
 - Partner with the Medical Center to identify research priorities that advance its mission.
 - Assure the rapid development of the Integrated Data Repository to support research on UCSF patients
 - Support development of functionality within electronic health records—inpatient and outpatient—to facilitate research.
 - Meet current demands for analyses of complex data (e.g., full sequencing, arrays) and anticipate informatics needs for the “New Biology for the 21st Century”.
 - Work closely with local software, Internet, and mobile health companies.
 - Support a campus-wide clinical trial management system.
 - Support informatics needs for biobanking including linkage to clinical data systems.
 - Continue to build informatics tools to support collaboration and identification of experts.
2. Create an integrated campus-wide clinical research organization drawing upon expertise and existing services across the campus to facilitate all aspects of clinical studies. Existing services should be integrated and gaps in services should be filled while reducing regulatory barriers. This should be organized to assure that support of components is matched with needs in those areas, and long-term, financial self sufficiency is assured. Where there is added value and favorable cost/benefit, services can be centralized. Priorities should include offering and advocating for services in the following areas:
 - Navigation (via personnel, a Website, a community of mentors and experts) across the entire spectrum of clinical research to assist investigators in finding services needed from the planning stage to study publication and data warehousing, which may be best achieved by creation of an office.
 - Assessment of feasibility and economic viability of protocols.
 - Budget preparation and financial management.

- Obtaining accessible and consistent research charges for clinical tests and services.
 - Access to appropriate systems to capture usual care costs of reimbursable tests and services from third party payers.
 - Protocol development, IND applications, IRB support, and assistance with other regulatory requirements.
 - Access to a supported campus-wide clinical trials management system that can integrate with our electronic medical record system.
 - Participant recruitment and retention services.
 - Access to expert research personnel at various levels.
 - Access to appropriate research space and infrastructure to support specimen handling and storage.
 - Access to timely IRB and contracting services.
 - Provide support for new models of clinical studies, such as Internet-based trials.
 - Providing support in the translation of findings, including dissemination through campus and external professional and media channels.
3. Implement a comprehensive program to support procurement, storage, access, and data management and integration for biospecimens.
- Assure availability of experts to assist investigators in obtaining biospecimen handling and storage services.
 - Create standard operating procedures for the procurement and storage of biospecimens and establish this as a requirement for CHR approval.
 - Build or acquire a data management platform for biospecimens that is integrated with electronic medical records.
 - Assure that all faculty have access to reliable biospecimen storage and tracking, either by providing a centralized service or by building on existing strengths in selected units.
 - Establish a “universal consent” process for research on biospecimens procured as part of routine diagnostic and therapeutic procedures.
 - Implement a process for procurement and storage of selected surgical samples for research that is seamlessly integrated with routine pathology practice.
4. Enhance programs that build partnerships between UCSF clinicians and scientists, and between UCSF investigators and external partners, including at other institutions and in industry.
- Continue to explore large-scale research partnerships with industry.
 - Create more opportunities that facilitate building multidisciplinary teams.
 - Pilot new models for creating multidisciplinary knowledge sharing.
 - Continue to build IT tools that support collaboration and identification of experts.
 - Enhance mentorship of junior faculty by senior investigators with established industry contacts.

- Establish models for broad master agreements and Material Transfer Agreements and provide a process to actively manage them.
 - Establish networking opportunities for former UCSF faculty and other personnel in industry, including participation in training, mentoring, and other translational efforts.
 - Develop training programs that involve faculty and students from industry.
 - Define new policies and procedures to recognize faculty contributions to team science.
 - Pursue further collaboration with a health maintenance organization, such as Kaiser, to build selected disease cohorts and collect related biospecimens linked to detailed medical records.
5. Enhance infrastructure to support research aimed at improving healthcare and community health.
- Define appropriate mechanisms (i.e., specialized teams, funding opportunities) to integrate our exceptional health services research with our clinical care delivery system in order to improve healthcare quality and safety. Maximize new opportunities to conduct health services research linked to clinical care as part of health care reform and efforts aimed at innovation to assure improved health outcomes.
 - Enhance partnerships for data sharing and problem solving with the community—including local hospitals, Kaiser, the San Francisco Department of Public Health, the school district, and local foundations and advocacy groups—to embrace and support their missions through research. Infrastructure should include a platform for exchange of clinical and research data, as well as opportunities for quality improvement, longitudinal research on integrated systems of care (e.g., outpatient and inpatient, physical and mental health services).
 - Support programs that direct UCSF expertise, collaboration, and research services toward health needs identified by the community.
6. Provide additional access to core services and technology supporting the full scope of clinical and translational science by filling current gaps. These might include:
- Clinical Laboratory Improvement Amendments (CLIA) conforming capability for assays such as whole genome sequencing and other core technologies.
 - Space and technology for specialized investigational imaging.
 - Immune monitoring capabilities.
 - Pharmacokinetics/pharmacodynamics capability within our CRC structure.
 - Enhanced exam and treatment space within our own CRC structure.