2011 UC-wide Biomedical Research Acceleration, Integration & Development Program (UC BRAID) Retreat
September 23, 2011

MEETING PURPOSE:

The UC BRAID group led by the CTSA (Clinical Translational Science Award) Principal Investigators at the 5 UC medical school/center campuses made considerable progress during its inaugural year, including harmonization of IRB and MTA processes, expanding the number of master agreements with many industry sponsors for clinical trials, and developing a plan to link clinical data warehouses for research at the five campuses.

At this meeting the progress made by UC BRAID in the areas of Contracting, Informatics-UC ReX, IRBs and Metrics and plans for the upcoming year were presented and discussed. New efforts to improve UC-wide collaboration in the area of Drug and Device Discovery and Development (D4) were also presented.

Dr. Susan Old, scientific director of the NIH TRND (Therapeutics in Rare and Neglected Diseases) provided insight into NCATS (National Center for Advancing Translational Sciences) (Refer to presentation "NIH Drug Discovery and Development – NCTT and CTSAs"). TRND, and the CTSAs, are scheduled to become part of NCATS in October, 2011.

RETREAT MAJOR THEMES and NEXT STEPS:

Collaboration: UC system needs to recognize itself as THE largest academic medical center in the world. Out-competing other medical centers is a matter of working together. Investigators should be able to easily find potential collaborators in their field across UC; Equipment, facilities, and shared resources should be easy to find and access across the UC system. Becoming the leading provider of health in the country requires a UC-wide union versus a group of city-states.

Infrastructure: There is a need to develop administrative infrastructure to increase efficiencies and productivity. These concepts could be expanded to include: CORES; Access to expertise; system for consultations and knowledge at each campus. Work to ensure investigators learn from others' mistakes. UCOP can pull together all campuses and negotiate better contracts; this only works if we actually come together and work with each other (increase support and decrease opportunity costs).

System for Clinical Trials: UC BRAID has ongoing efforts in Informatics, Contracting and IRB to accelerate clinical research. As a system we need to demonstrate that we can be more efficient as a team and build appropriate infrastructure to support working across campuses.

Future Efforts: BIOSPECIMEN BANKING we don't have the capacity to make huge advances in one year in this space. As a group we could develop a plan coming into next year to learn from each other before investing individually in this issue.

Future Efforts: WHO DOES WHAT and HOW? This group accomplished a huge amount by cobbling together ideas, funding/staffing effort from the CTSAs and getting external funding from UCOP in support of development efforts (UC ReX investment $5M over 5yrs). In the long-term the group needs a funding plan and consistent administrative support. Support for this effort should be distributed and include UCOP.

UCOP Closing Remarks: Collaboration across UC medical centers in support of clinical trials has to be a UC priority. UCOP had been trying to enable this (Master CTAs; IRB policy for UC-wide; website for FAQs); but this effort is largely driven by UC BRAID. A high priority for UCOP is to facilitate UC BRAID efforts and provide resources to expand UC BRAID. Working as a system UC can rapidly address barriers to accelerating biomedical research.

WORKING GROUP UPDATES:

CONTRACTING

The Contracting working group was established to reduce the barriers to clinical research contracting and accelerate the contracting process at UC. The group: provides a forum for strategic input that includes end-users of the contracting process; reinforces the benefits of UC-wide cooperation; encourages development of new technologies/approaches to address challenges in contracting; and focuses efforts on acceleration and innovation.

Clinical Trial Master Agreements (CTAs): UCOP led efforts worked to increase the number of UC-wide Master CTAs. The initial goal of establishing Master CTAs with 5 major companies was met and 2 additional are in negotiation. YR02 goals include continued increase of Master CTAs; increased Master Confidentiality Agreements; and resolving issues with key sponsors

Shared Database of Contract Terms: UCSF led efforts to develop an easy to use, secure, pilot version of a UC-wide centralized repository of contracts searchable to find companies, terms and types of studies. This database was piloted in Spring/Summer 2011. YR02 goals include establishing definitions; evaluating implementation at each campus; and deploying at each campus.

Shared Clause Library: UC Irvine led efforts to develop a prototype version of a clause library. Prototype is expected to be complete in December 2011. YR02 goals include testing and refining of prototype.

UC-wide Training Program for Contracting: UCOP led in the development of the curriculum for this online training program, divided into interactive modules. Content includes: definition of clinical trial, drugs and devices; distinction between phases; sponsor vs investigator initiated trials; overview of regulating bodies of clinical trials; UC principles in contracting; components to clinical trial; and negotiating a clinical trial agreement. Agreement from UCOP leadership that this effort is best served from a central resource. YR02 goals include wide adoption of training program.

Material transfer Agreements (MTAs): UCSD led efforts for all UC campuses to have a single consolidated office for managing MTAS. UC-wide agreement to use the UBMTA template as the default agreement has been reached. This effort will be retired in YR02.

Metrics: A UC BRAID Metrics Working Group was created to identify and develop the process and organizational metrics that all participating institutions agree to track and report. The Metrics Working Group will continue working in YR02.

Drug and Device Discovery and Development (D4)

With the soon to be official new NIH center–NCATS (National Center for Advancing Translational Sciences) there is increasing importance for the UC system to develop robust, collaborative infrastructure among the CTSAs. The overall goal of BRAID D4 is to explore the potential for shared resources and economies of scale across the UC campuses in order to achieve the broad goals of enhancing therapeutic drug discovery and development.

Opportunities for UC Collaboration: Sharing education and workforce development; Complementary facilities and infrastructure; Collaborative translational activities; Master Research/CT agreements; Linking EMR; Multicenter Clinical Trials; Disease Consortiums

Opportunities for Collaboration in D4: UC has strong position in target ID and Validation; a reasonable position in small molecule screening and assay development; and a limited position in Preclinical development

D4 Challenges in working with Industry: Explore ways to streamline how to best work with Industry. A major challenge in translational work with industry partnership is centered on IP including: publication of lead structure issues; and co-ownership of invention with parties spending too much time keeping track of who owns what IP. These can be barriers to successful partnerships. Handoff to industry partners for the successful development of drugs, diagnostics and devices that improve health is essential. These UC Policy related issues should be addressed to make contracts

workable. Industry has different mode of purpose than academia; UC policies are set by the Regents and Academic Senate (ie faculty) not UCOP. Policies aim to convey that development of drugs, diagnostics and devices is not the main focus of the University.

YR02 Goals: Explore NIH list of animal models and fund individuals at each UC to catalog animal models (useful to both internal and external collaborators); catalog and define potential shared resources at each screening center; review MedChem and ADME/Tox outsourcing practices; explore UC-wide website to describe resources/facilities/services available at each campus

INFORMATICS-UC ReX

The Informatics working group has had huge success during the inaugural year. The UC-Research eXchange (UC-ReX) Informatics consortium was funded for $5m over five years by UCOP through UCBRAID. UC ReX will build the first cross-campus clinical query system capable of exchanging patient-level data as well as aggregates (counts and descriptive statistics) across the five UC Medical Centers, and a subset of their key partner institutions.

Immediate Needs: The timeframe to hire a technical person would lead to a delay in starting the UC ReX efforts. Out of necessity an external vendor should be contracted to complete the work (less than 20% of the budget; source code would be owned by UC ReX). UC BRAID should expedite contracting the selected vendor.

Informatics and IRB Working Groups
Should the system be designed for Single IRB for all queries or should guidelines be established for each institution for dissemination to the individual IRBs? This requires further discussion. UC ReX is not building an IRB information system; feedback from the IRB working group is needed. Creating a pathway for access is equally as important as creating a system to be accessed.

Partnership beyond UC BRAID: The focus of the working group is on development and deployment of the system. While external partnerships are not the focus of the upcoming year, the group was encouraged to construct a cost breakdown for institutions wanting to participate at a future date.

Future Funding: Most of the sustaining funding for this effort will be coming from healthcare reimbursements not NIH grants. As such, the focus shouldn't solely be on IRBs. Consider expanding to include quality issues.

IRB

The IRB Working Group of the UC-Wide Biomedical Research Acceleration Initiative is tasked with identifying policy changes, new infrastructure, or processes that will reduce the barriers to IRB approval for the institution, for individual researchers, and external partners. During the inaugural year The IRB working group began development of online registry to share among and between UC campuses; expanded and enhanced the Memorandum of Understanding among the UC medical campuses to include greater than minimal risk studies; and established a timeline to complete major milestones.

IRB Reliance Registry: UCOP led effort is progressing well – 80% complete**.** Registry is essential in expanding MOU to greater than minimal risk studies – fundamental to have a centralized system for staff to know what study has been approved at which campus. Similar to central IRB model each site would be charged a cost after the IRB is approved. It is currently designed for industry funded research ways to apply it to NIH funded research should be explored

Potential Challenges: How do we use expertise in the room *IRB/Informatics/etc)
Lack of a designated IRB project manager; Ease of applicability Industry v. NIH; Communication issues (PIs with off-campus IRB; IRB to IRB)

AHARP : AHARP is a private IRB accreditation entity; It is expensive and not perceived to add much value beyond best practices (cost is both financial and administrative burden) AHARP is currently not required. Group should

explore the possibility of generating a clarification letter to AHARP. Main issue is ensuring that partnering institutions (non-AHARP) have a standardized IRB process that is just as robust as that of an AHARP institution. Who should own the process of clarifying and negotiating the details of AHARP requirement for UC BRAID members?

YR02 Goals: Complete IRB electronic clearinghouse; effectively publicize UC-wide IRB process as an option to researchers; Explore possibility of linking IRB Registry database to Contracts and Grants database; clarify AHARP requirements (will UC BRAID want all members to have AHARP accreditation?)

Metrics

The mission of the Metrics Working Group is to harmonize the IRB approval and contract negotiation and execution process between centers across UC, thus ensuring a high level of service with nationally competitive start-up times for investigational studies. The objectives are to define metrics to assess processes and outcomes; develop a pilot system for tracking across institutions based on the CTSA metrics collection project; and implement an initial study to collect initial performance data and monitor ongoing impact.

Contracting Metrics: Initial study is in process. Started September 1, 2011 (with goal of collecting data on 50 studies) and will end on October 31, 2011 at the UC BRAID participating campuses.

IRB Metrics: Metrics were based on those used for the CTSA IRB study. Data collection for 50 protocols was September 1, 2010 to November 1, 2010. Data has been provided by 3 of the 5 UC BRAID participating campuses. Instead of replicating – for IRB using CTSA measures – some campuses had the data prepared while others are pulling it together.

YR02 Goals: Include complete phase I data analysis; design of phase II study; and design of operation map to predict optimal phasing of administrative processes. IRB and Contracting are only two of the processes that need to work together – have to design an optimal administrative process – to get optimal time to completion.

Aligning Services to Support the Mission: A new area for UC BRAID. Addressing the management issues associated in providing services to "customers" (both internal and external) to ensure efforts are adequately resourced. do A study concierge could play a purely project management role to coordinate all of the administrative processes required to get a study started and track it at every stage. This person would shepherd a study starting from CDA.