UCSF Clinical Research Infrastructure
Based on Recommendations from two 2010 Task Forces

updated December 7, 2012

Recommendations	Status	Next Steps/Actions	Due Date
SYSTEMS			
Implement a CRMS	in progress	The multi-disciplinary version of OnCore has been approved for rollout to the campus. Implementation has been developed. Identify funding sources and finalize funding model. (Note: Challenge is adoption by users in face of uncertain funding model and ongoing support)	March 2013
Optimize the use of APeX for clinical research; support development of functionality within electronic health records to facility research		Workgroup looking at optimizing process for identifying and routing of study participants	June 2013
Link APeX and the CRMS		Working on API for extraction of APeX data into OnCore for early 2013	Spring 2013
Develop a strategy for clinical research data management	in progress	Office of Research is currently functional owner of IDR. Oversigh Committee has been formed. Charge to the Committee is to provide vision and direction for research data repository needs at UCSF. In October 12, External Advisory Board made recommendation for enterprise-wide data warehouse initiative. Recommendations to be vetted by oversight committee and presented to leadership for action. Work is ongoing to build out IDR to expsoe additional fields and add new data sources. The IDR/MyResearch environment has been rebuilt and moved to Minnesota Street. The MyResearch desktop has been redesigned to increase utility.	Ongoing
Strengthen and expand the IDR			Ongoing
Create enterprise-wide data warehouse for clinical and research data			Ongoing
Develop and deploy the Charge Master for laboratory and medical assessments	partially done	Provisional charge master has been published in iMedris CHR and notification has been sent out to all users of the system. Additional notifications have gone out via the Clinical Coordinator and Contracts and Grants listserves. Charge Master will be available by June 2013. Industry trials will be billed at 150% of the research rate.	June 2013
Finance and Regulatory			
Establish models for broad master agreements and Material Transfer Agreements and provide a process to actively manage them.	in progress	Industry Contract Division is working on these issues.	Ongoing
Create shared service centers for clinical research administration, with trained personnel that can provide high levels of pre-and post-award services to the faculty.	partially done	Based on workgroup recommendations, the Clinical Trail Business Support Center has been created within Industry Contracts to create budgets for industry sponsored trials and to perform coverage analysis for all clinical trials. The unit started operation in July 12. Two position have been approved to work on clinical research compliance in the Clinical Compliance Office. Active recruitment for these positions is underway.	Various
Develop a standard template for clinical research budgets that includes all items that can be charged as a direct cost to the study			
Implement a budget review process prior to submission to the sponsor.			
Hire and train staff to carry out Coverage Analysis of all relevant studies	done		
Develop a regulatory and compliance oversight program of clinical studies	in progress	Plans are being developed on how to develop, fund, and implement such programs.	March 2013
Develop Patient Reimbursement SOP and mechanism	inactive	The recommendation is not being actively worked on because of the introduction of the subject reimbursement credit card initative	
Develop and deploy a regulatory and compliance training program for the research teams	not started	The compliance oversight program is just getting started and responsibility for developing the training will rest with that unit. However, there are compliance issues that need to be addressed before there is bandwidth to create a training program.	TBD
INVESTIGATOR SUPPORT SERVICES			
Continue the development of the Patient Recruitment and Retention currently ongoing in the CTSI	in progress	CTSI is the lead on this effort.	Ongoing
Strengthen and expand the IND/IDE Preparation and Filing service currently provided by CTSI	in progress	Bill Balke and Susanne Hildebrand-Zanki are engaged with CTSI Consult Services to ascertain current availability of materials available to faculty.	Ongoing
Provide strategic support for clinical studies involving IND/IDE filing	done		
Provide clinical trial project management, with a goal-oriented view of the entire arc of the project	inactive	Not clear that there is a demonstrated need for this activity	
Publicize and expand the Clinical Coordinator Service currently being developed in the CRS	the CRS has started the service	CRS will develop a training that will be available to all clinical coordinators and will have certification levels. This effort will take the proposed job family into consideration. The goal is for the CRS to be the home for Clinical Coordinators	available 6/30/2012
Develop and deploy campus-wide training for Clinical Coordinators	inactive	The CC Service has undergone some organizational changes that have resulted in not enough bandwidth to develop the training	TBD
Develop a feasibility analysis tool	done	A feasibility analysis tool has been developed and a modifed process for feasibility analysis	January 2013
Develop process and templates for scientific review of protocols	done	A revised scientific review process has been developed	January 2013
Enhanced exam and treatment space within our own CRS structure.	in progress	Process of reassessment of space utilization and reassigning space based on identified needs is underway.	Ongoing
Develop a business plan for the Research Pharmacy Service that addresses the needs and will provide a path to a sustainable model	done		Implemented 7/1/2012
Develop appropriate recharge rates and ensure that these rates are consistently included in study budgets			
Identify additional space to meet the needs of the RPS			