UCSF Clinical Research Infrastructure Report
from the Clinical Research Infrastructure Taskforce
January 10, 2011

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1) **Background**

Conducting clinical research is a critical component of UCSF's mission to improve health worldwide. Currently there are over 5,000 active studies underway. Clinical research is conducted in all professional schools and covers a wide array of diseases, interventions, and populations. Yet despite the importance of clinical research, UCSF does not have a coordinated approach to supporting these studies. As a result, UCSF's performance in trials does not meet the standard of excellence the institution is known for in its basic research and UCSF is not the site of choice for industry-sponsored trials.

Over the last several years, there have been a number of efforts by a number of different groups to grapple with this issue and to find a solution that would allow UCSF to become more competitive in clinical research. The most recent examples are the CTSI proposal for the establishment of a UCSF Clinical Trials Institute (2009) and the report of the Research Administration System Assessment and Strategic Planning Clinical Trials Infrastructure Working Group (June, 2009). No direct actions were taken on any of the recommendations of either report.

2) Rationale

UCSF is embarking on a number of initiatives to strengthen our contributions to research and the understanding of human biology. For these initiatives to be successful UCSF investigators need to have the ability to conduct cutting edge clinical research and for that they will need a robust clinical research infrastructure. In order to move UCSF closer to that goal, Susanne Hildebrand-Zanki convened this taskforce with the following goal: to create a conceptual framework for a clinical research infrastructure at UCSF that truly supports the faculty, and allows them to perform effective and efficient clinical research. The task force was charged with reaching a consensus on what resources would make up the clinical research infrastructure at UCSF, to determine what needs to be done to obtain and deploy those resources, to identify the gaps that currently exist, and to make recommendations on how to move this effort forward.

3) Process

The taskforce met three times over a period of 3 months. The first two meetings were used to validate the current state at UCSF for all phases of clinical research, to identify available resources, and to determine gaps. Clinical research was defined as encompassing all studies that require interaction with the Human Resource Protection Program.

Based on the results of the discussions, all steps in the research process were rated on how well UCSF performed those functions: green for activities that we are currently doing well and where little additional effort or support are needed; yellow for activities that are done well by some or that marginally meet the current need and where additional effort and support is needed; and red for those activities that are not done well anywhere at UCSF and will require significant resources to raise them to an acceptable level. The Current State document is attached as Appendix A. Appendix B is a list of currently available services.

A Gap list was developed and organized into several categories: people, services, cores, other resources, and IT systems. Each item on the list was rated on 3 dimensions: importance, difficulty, and cost. The Gap document along with the ratings is attached as Appendix C.

The third document created is a visual depiction of the clinical infrastructure as envisioned by the taskforce. It shows all the elements required to ensure that clinical research can be conducted in an efficient, effective, and competitive manner at UCSF. The document is attached as Appendix D.

4) Findings and Recommendations

a) Taskforce members listed the following principles as critical to the clinical research enterprise at UCSF: Principles

   i) The clinical research enterprise must contribute to making UCSF a leader among academic medical centers and a site of choice for industry, foundations, and NIH to conduct their trials.
   ii) A highly effective clinical research enterprise will support teaching the next generation of clinical investigators and allow for effective mentoring of junior faculty. It will also foster innovation.
   iii) Faculty must be able to conduct their research in a timely, efficient matter that respects their expertise.
   iv) Faculty must have easy access to the research infrastructure.
   v) Studies have to meet compliance standards for patient safety, information security, and fiscal management.
   vi) Research should be conducted in an efficient manner and without duplicating efforts across different administrative units.

As the Current State document shows, UCSF does well in the planning and final stages of a clinical research study where the intellectual input of the investigators is most critical. However, all other areas of conducting clinical research require serious attention.

b) People

The expertise of our staff to support clinical research is not consistently at the level to allow for first-rate research execution across the University. We identified a few critical areas that need to be addressed:

i) Clinical coordinators, who are critical to the conduct of clinical studies and can make the difference between the success and failure of a study, do not have clear career paths and are hired into a variety of job classifications. There is no consistency in what is expected from the incumbents relative to how they are classified or compensated. Investigators struggle to support clinical coordinators and other research staff, especially when they only need part of an FTE but have to hire at 100% effort in order to attract suitable candidates. Also, needs vary over time and hiring new staff can be a major inefficiency particularly given the training required. One initiative underway to address this problem is the Clinical Research Service's (CRS) program to train clinical coordinators and make them available to faculty on a part time basis.

(1) Recommendations:

(a) Develop a job family for Clinical Coordinators with standardized expectations with regard to skills and experience at each level.

(b) Publicize and expand the Clinical Coordinator Service currently being developed in the CRS

(c) Develop and deploy campus-wide training for Clinical Coordinators

ii) There are not a sufficient number of Bioinformaticians available to work with our faculty on structuring data and conducting data analyses. CTSI is providing some support but it is not sufficient to meet the more complex needs of our faculty.

(1) Recommendations:

(a) Expand the pool and breadth of expertise of bioinformaticians available as a resource to faculty.

(b) Foster collaborations with other campuses that have strong programs in this area, such as UC Berkeley and UC Santa Cruz

iii) Pre- and post-award staff supporting our faculty have varying degrees of expertise in how to handle the pre-and post-award function for clinical research. The lack of understanding by many faculty of what can and should be charged to the clinical budget, regardless of sponsor, has the unfortunate consequence of UCSF not recapturing all or even most of the costs of conducting some trials, leaving the investigator, his/her department, or the Medical Center to cover the shortfall. There is no campus training and few resources they can turn to in order to obtain reliable information on how to perform their jobs. Some departments, such as Neurology and Medicine, have formed their own internal central services units to ensure that study budgets are created correctly and that post-award functions are carried out in a consistent and timely manner.

(1) Recommendations:

(a) Take advantage of Operational Excellence which can aid this effort by advocating for the formation of shared service centers for clinical research administration, with trained personnel that can provide high levels of pre-and post-award services to the faculty.

c) Services

i) The CTSI provides a number of services for faculty throughout the lifecycle of a clinical study. Individual units with large volumes of clinical research, such as the Cancer Center, Radiology, Neurology, the Department of Medicine, and the Immune Tolerance Network, also provide their investigators with support services. The problem is that these services are not well publicized, are often not available to all investigators who might need them, are not consistent across units, and are currently not staffed at a level to provide a comprehensive service to all. To a large degree, investigators are left to their own devices to navigate the clinical research landscape and the taskforce members felt strongly that we need more consistent expertise across units and greater awareness that these services exist. Taskforce members identified the following services as those of highest importance: Patient Recruitment and Retention, Regulatory and Compliance Oversight, Medicare Coverage Analysis, IND/IDE Preparation and Filing, and Regulatory and Compliance Training for the research teams. There is a difference between the needs of investigator-initiated versus industry-sponsored research. Investigator-initiated research requires a greater investment in regulatory expertise, which needs to go beyond making sure the rules are followed to include strategic and scientific considerations about appropriate and possible research. This requires a level of expertise currently found in pockets on campus, but not widely available.

(1) Recommendations:

(a) Strengthen and expand the IND/IDE Preparation and Filing service currently provided by CTSI

(b) Provide strategic support for clinical studies involving IND/IDE filing

(c) Continue the development of the Patient Recruitment and Retention currently ongoing in the CTSI

(d) Provide clinical trial project management, with a goal-oriented view of the entire arc of the project

(e) Hire and train staff to carry out Medicare Coverage Analysis of all relevant studies

(f) Develop a regulatory and compliance oversight program of clinical studies

(g) Develop and deploy a regulatory and compliance training program for the research teams

ii) Another service that needs to be strengthened is the Research Pharmacy Service (RPS). UCSF currently has 2 research pharmacists and 1 pharmacy technician who support 307 studies; the University Health Service Consortium identifies workload as 50 studies/pharmacist and 100 studies/pharmacy technician. Of additional concern is the fact the space allocated to the RPS is inadequate to handle the volume of study drugs, leading to study drug dispensing errors.

(1) Recommendations:

(a) Develop a business plan for the Research Pharmacy Service that addresses the needs and will provide a path to a sustainable model

(b) Develop appropriate recharge rates and ensure that these rates are consistently included in study budgets

(c) Identify additional space to meet the needs of the RPS

iii) Also of concern was the fact that UCSF does not have a consistent way to construct or analyze study budgets. Consequently, faculty are mostly on their own when developing their study budgets or evaluating study budgets provided by pharmaceutical companies or NIH collaborators. The lack of guidance leads to inconsistent pricing for services, omission of legitimate costs from the budget, and the risk of incorrectly charging third party payers, especially Medicare.

(1) Recommendations:

(a) Develop and deploy the Charge Master for laboratory and medical assessments

(b) Develop a standard template for clinical research budgets that includes all items that can be charged as a direct cost to the study

(c) **Implement a mandatory budget review process prior to submission to the sponsor**.

d) Cores

In order to make optimal use of the specimens collected from clinical studies, we will need to develop core specimen and tissue repositories.

(1) Recommendations:

(a) Develop well curated specimen and tissue banks

(b) Develop an inventory of all existing repositories and their contents

e) IT Systems

Information Technology promises to have the highest impact on improving the quality and timeliness of clinical research. Ultimately, the available IT infrastructure will separate institutions that do it well from those that do not. UCSF needs systems that support the entire lifecycle of clinical research and assist with study management, patient tracking, compliance, billing, and managing study data. While no vendor is offering one system that can perform all of these functions, members agreed that we need to be able to connect the various modules and that this is key to making things consistent and to integrating the vast variety of data generated in clinical research. The members emphasized the importance of working with the Medical Center now on optimizing APEX's research functionality while there is the ability to build from the ground up. It is critical that we take advantage of the capabilities of the system to aid in the conduct of clinical studies, especially with regards to sending de-identified data to the IDR, identifying and tracking research patients, and accurate billing.

i) Highest on the list of necessary IT resources are a Clinical Research Management System (CRMS), an Integrated Data Repository (IDR), and a Research Database Management System (RDMS). While UCSF has made initial investments in these areas, these systems need to be scaled so that they are available to all faculty. Efforts are currently underway to broaden the use of Oncore and evaluate its potential as the CRMS of choice for UCSF, to strengthen the IDR infrastructure, and to increase the utility of MyResearch. Additionally, UCSF is looking at the feasibility of implementing a patient relationship management system to aid investigators in identifying and contacting potential study participants.

ii) There was consensus that we need to develop a sophisticated and well thought out technology road-map in order to achieve these goals.

(1) Recommendations:

(a) Develop a strategy for clinical research data management
(b) Implement a CRMS
(c) Optimize the use of APEX
(d) Link APEX and the CRMS
(e) Strengthen and expand the IDR
(f) Strengthen and expand the RDMS
(g) Implement a biospecimen tracking system

5) Next Steps

This report, in conjunction with the work of the Decade of Human Biology Clinical Research Taskforce, will serve as the foundation to develop more detailed project plans, to prioritize projects, and to develop the roadmap for implementation of the recommendations. In the meantime, ongoing efforts, such as the evaluation of Oncore, will continue and the Office of Research will ensure that any decisions will be in support of the recommendations laid out in this report.

Among the issues to be decided moving forward is how to deploy any new and/or existing services. One option is to create a Clinical Trials Office to carry out all of the functions that benefit from a more coordinated approach, including Medicare Coverage Analysis, budget review, activities that relate to risk and compliance, or are otherwise identified as benefitting from standardization. Other pre-and post-award activities during the implementation of the trial should be handled in a Shared Service Center. These discussions should take place in the early part of 2011 and will involve the Taskforce Members who have contributed to this effort to date as well as other stakeholders, such as the new Associate Vice Chancellor for Ethics and Compliance.

The goal is to finalize the implementation plan by the end of March, 2011.

APPENDIX A

Phase 1: Conceptual Phase/Design

Activities	Who is responsible for the activity?	What Resources are available?	What is needed?	Revised Status
1.1 Identify Research Opportunity	Research Team	C&G, COS	Greater awareness that these tools exist	
1.2 Identify Funding Source	Research Team	C&G, COS, CTSI	See above	
1.3 Develop Concept	Research Team	CTSI Cons.Serv.		
1.31 Peer Review of Concept				
1.4 Risk Assessment/Feasibility	Research Team	CTSI Cons.Serv., Internet, MyResearch	Robust analysis of research participant availability/suitability; build on Cancer Center expertise	*
1.5 Develop Cost Estimate	Research Team	Cancer Center, DOM, Neurology	Charge Master; charge sponsor for feasibility analysis; better IT to help with the task	
1.6 Study Drug Supply	Research Team, Departmental Staff, Central Campus Staff	Res. Pharmacy	space	
1.61 GMP				
1.7 Submission to Funder	Research Team, Departmental Staff, Central Campus Staff	Proposal Express, Cayuse, RAS		

Phase 2: Planning and Development

Activities	Who is responsible for the activity?	What Resources are available?	What is needed?		Revised Status
2.1 Finalize Study Design	Research Team	CTSI Cons. Serv., CC, ITN	Study Management System for clinical trials for all operations aspects of the protocol	Clinical Research Management System	
2.2 Plan statistics	Research Team	CTSI Cons. Serv., CC, ITN			
2.3 Determine Randomization	Research Team	CTSI Cons. Serv., CC, ITN			
2.4 Finalize Protocol	Research Team	CTSI Cons. Serv., CC, ITN	Greater awareness that resources exist		
2.5 Create Schedule of Events	Research Team	CTSI Cons. Serv., CC, ITN	Need more consistency of expertise across units, CTSI is developing expertise, could serve as model		
2.6 Develop Consent Form(s)	Research Team	CTSI Cons. Serv., CC, ITN			
2.7 Develop CRF's	Research Team	CTSI Cons. Serv., CC, ITN			
2.8 Create Sample Collection Plan	Research Team	CTSI Cons. Serv., CC, ITN			
2.9 Create Assay Plan	Research Team	CTSI Cons. Serv., CC, ITN			
2.10 Develop risk-based monitoring plan	Research Team	CTSI Cons. Serv., CC, ITN			
2.11 Develop Patient Recruitment Plan	Research Team	CTSI Cons. Serv., CC, ITN			
2.12 Develop Promotional Materials	Research Team	CTSI Cons. Serv., CC, ITN			
2.13 Complete Operations Manual	Research Team	CTSI Cons. Serv.			
2.14 Finalize arrangements with Research Pharmacy	Research Team, Res. Pharmacist	CTSI Cons. Serv.			
2.15 Finalize site selection	Research Team	CTSI Cons. Serv.			
2.16 Build database	Research Team	MyResearch			
2.17 Finalize study drug packaging/labeling	Research Team, Res. Pharmacist				
2.18 Perform Medicare Coverage Analysis	Research Team		Consolidated expertise to conduct the analysis		
2.19 Finalize budget	Research Team	Some departments provide excel templates for the PI(s)			
2.20 Finalize contracts with third party vendors	Research Team. Departmental Staff, Central Campus Staff	P2P			
2.21 Establish subcontracts and payment schedules for sites	Departmental Staff, OSR Staff	Proposal Express, RAS, ICD database			

Phase 3: Approvals and Set Up

Activities	Who is responsible for the activity?	What Resources are available?	What is needed?		Revised Status
3.0 Scientific review and approval of protocol	Review committee	Cancer Center has formal process, not sure how handled in other departments; often default is CHR	Consistent approach for scientific review	Clinical Research Management System	
3.1 CHR submission and approval	Research Team, HRPP Staff	iMedris			
3.2 Other safety committee approvals as needed	Research Team, Central Campus Staff	RIOS	Be aware of need for EHS involvement		
3.3 IND/IDE submission and approval	Research Team	CTSI Cons. Serv.	Greater awareness of availability of services		
3.4 Set up DSMB	Research Team				
3.5 Database Management	Research Team	MyResearch, CTSI, Radiology Imaging Database	Ensuring that MyResearch is robust and can support the needs of the faculty; awareness of availability; assess future needs to ensure that demand can be met both in terms of infrastructure and tools; address security issues		
3.6 Research Pharmacy Support	Research Team, Res. Pharmacist	2 research pharmacists handling over 300 trials	More research pharmacists to handle the workload, better facilities, a business plan for the research pharmacy		*
3.7 GCP, SOP, and pharmacovigilance training	Research Team		Need for centralized services; speciment banking, etc.		
3.8 Patient Recruitment and Retention Strategies	Research Team		Under development in the CTSI, need to pay aprticular attention to underserved populations		
3.9 Clinical Trial Billing	Research Team, Med Ctr		Need a robust system to manage; take advantage of EPIC as much as possible; link EPIC with CTMS to achieve seamless process; establish coordinated service for MCA and budget analysis		
3.10 Register Trial on Clinicaltrials.gov	Research Team, HRPP	NIH website	Training on how to enter data; possibly centralizing the effort		

Phase 4: Implementation

Activities	Who is responsible for the activity?	What Resources are available?	What is needed?		Status
4.1 Recruitment	Research Team		Patient recruitment service	Clinical Research Management System	
4.2 Enroll subjects	Research Team	CTSI Clinical Research Services for location to conduct clinical research and to access services for the life of the trial			*
4.3 Drug accountability, pharmacy checks, distribution	Research Team, Research Pharmacy Service	Resource constrained RPS	Adequately sourced and housed RPS		
4.4 Scheduling Visits	Research Team				
4.41 Subject Treatment	Research Team	CTSI Clinical Research Services for location to conduct clinical research and to access services for the life of the trial, Hospital, Outpatient Clinics	Ability to track patients as research subjects, dedicated clinical research space		
4.5 Completion of CRF's	Research Team				
4.6 Data Management	Research Team				
4.7 Specimen Management	Research Team	Core banking facilities			
4.8 Clinicaltrial.gov updates	Research Team				
4.9 Patient retention	Research Team		need to pay aprticular attention to underserved populations		
4.10 Post Award Management	Research Team, Med Ctr Staff, Dept Staff		Better trained staff; integratio with MedCtr staff; should be provided as a core service		
4.11 Invoicing sponsor	Research Team, Departmental Staff		Feedback from Controller's office re billing of sponsors and payments received; access for post award staff to see billing and payments in the system		
4.12 Regulatory Oversight	Research Team, DSMC, CHR	iMedris, Oncore for CC	A consolidated approach to make sure that these activities happen; systems to assist the Research Team to meet reporting requirements		
4.12 Data Safety and Oversight	Research Team, IT	MyResearch, IDR	A consolidated approach to make sure that data is stored securely and that acess is granted with appropriated safeguards		

Phase 5: Analysis and Publication

Activities	Who is responsible for the activity?	What Resources are available?	What is needed?	Revised Status
5.1 Perform primary and secondary data analyses	Research Team	Statistical software packages, My Research, Imagine Analysis		
5.2 Write primary publication	Research Team			
5.3 Post results on clinicaltrials.gov	Research Team	NIH website		
5.4 Post-hoc analysis	Research Team	Statistical software packages, My Research		*
5.5 Data Dissemination	Research Team, Campus staff	Statistical software packages, My Research	Broader dissemination of research results; involve PR office	
5.6 Open Access to Data	Faculty, Cores, IT	Statistical software packages, My Research	make exisiting data accessible; ability to link clinical data with assay data;	

*** indicates that the activity is leaning towards red or yellow, respectively**

Appendix B

Current Clinical Research Resources 12/30/10

- CTSI
  - Training and education
  - Consulting
    - Biostatistical
    - Regulatory
    - Data Management
    - Study Design and Implementation
    - Ethics
    - Bioinformatics Data Analysis
    - Patient Recruitment (under development)
  - CRS
    - Trial Implementation
    - Nursing Services
    - Bionutrition
    - Clinical Coordinator Training
    - Clinical Coordinator Pool
  - BC&E Labs
    - Sample Processing

- Cancer Center
  - Clinical Trial Management Unit (ITI)
    - Study management assistance throughout the lifecycle of a study

- Department of Neurology
  - Budget, Budget Negotiations, Billing, Invoicing

- Department of Medicine
  - Clinical Coordinator Training
  - Clinical Trial Budget Template

- Department of Radiology
  - Transcribe paper CRFs into web-applications for ease of data entry
  - Begun investigating FDA part 11 compliance requirements for electronic CRF data management and signatures for clinical trials currently underway in Radiology
  - Imaging Database

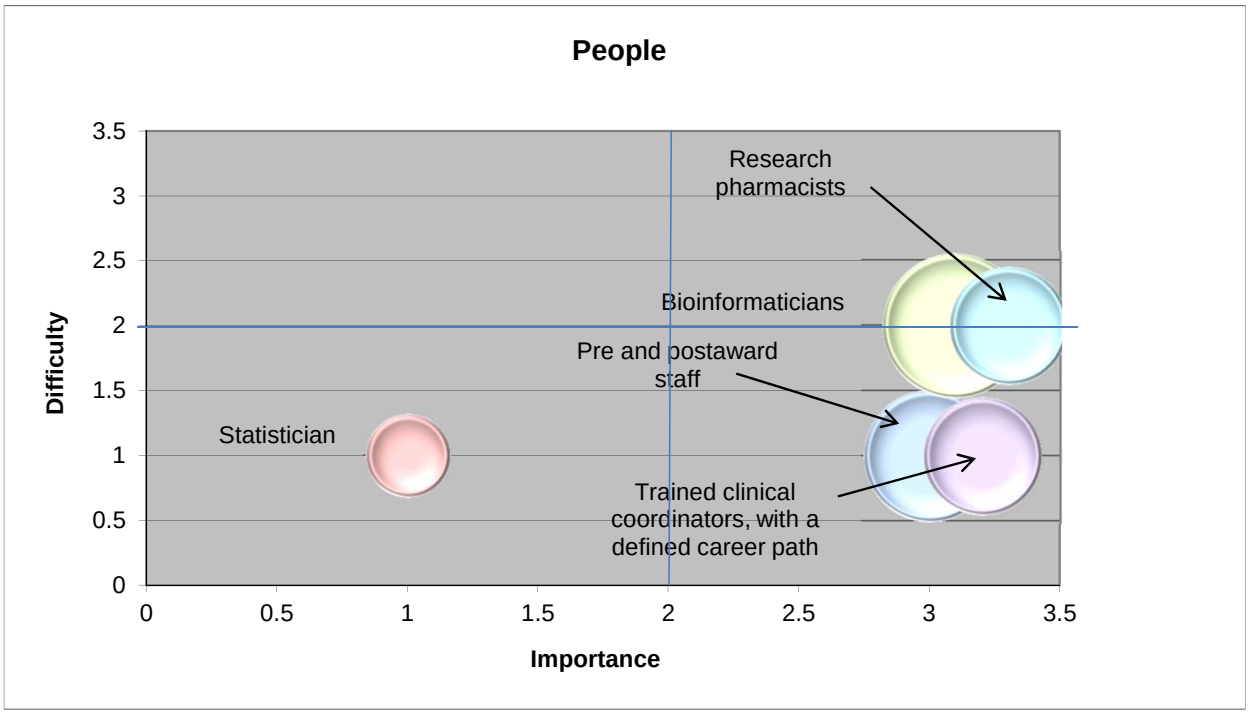
APPENDIX C

Gaps in the Clinical Research Infrastructure

	Importance H=high M=medium L=low	Difficulty H=high M=medium L=low	Costs H=high M=medium L=low
People			
Trained clinical coordinators, with a defined career path	H	L	M/H
Statistician	L	L	L
Bioinformaticians	H	M	H
Pre and postaward staff	H	L	M
Research pharmacists	H	M	M
Services			
Statistical support for study design	L	L	L
Bioinformatics support for data analysis	H	M	H
Scientific review of protocol	L	L	L
Patient Recruitment/Retention Service	H	H	H
Research Pharmacy Service	M	M	M
IND/IDE preparation and filing	H	L	L
Medicare Coverage Analysis	H	H	L
Clinical research budget preparation	M	L	L
Clinical research post award	M	L	L
Clinicaltrials.gov account maintenance	M	L	L
Clinicaltrials.gov account updates and posting of results	M	L	L
Regulatory and Compliance Training for research team	H	L	L
Regulatory and Compliance oversight	H	H	M
Data dissemination	M	L	L
Cores			
Specimen banks	M	H	H
Tissuebanks	M	H	H
Data Repository	H	H	H
Other Resources			
Budget templates	L	L	L
Protocol templates	L	L	L
CRF templates	L	L	L
Consent Form templates	L	L	L
Dedicated clinical research space	L	H	H
Space for research pharmacy	M	H	H
Processes			
Research Patient Tracking	H	L	L

Gaps in the Clinical Research Infrastructure (continued)

	Importance H=high M=medium L=low	Difficulty H=high M=medium L=low	Costs H=high M=medium L=low
IT Systems			
Data Respository (IDR)	H	H	H
Database Management System (MyResearch)	H	H	H
Specimen tracking system	H	M	L
Clinical Research Management System (CRMS)	H	H	H
EPIC, linked to CRMS	H	L	L
Research Patient Tracking	H	L	L
Charge Master	H	L	L


People
Difficulty
Importance
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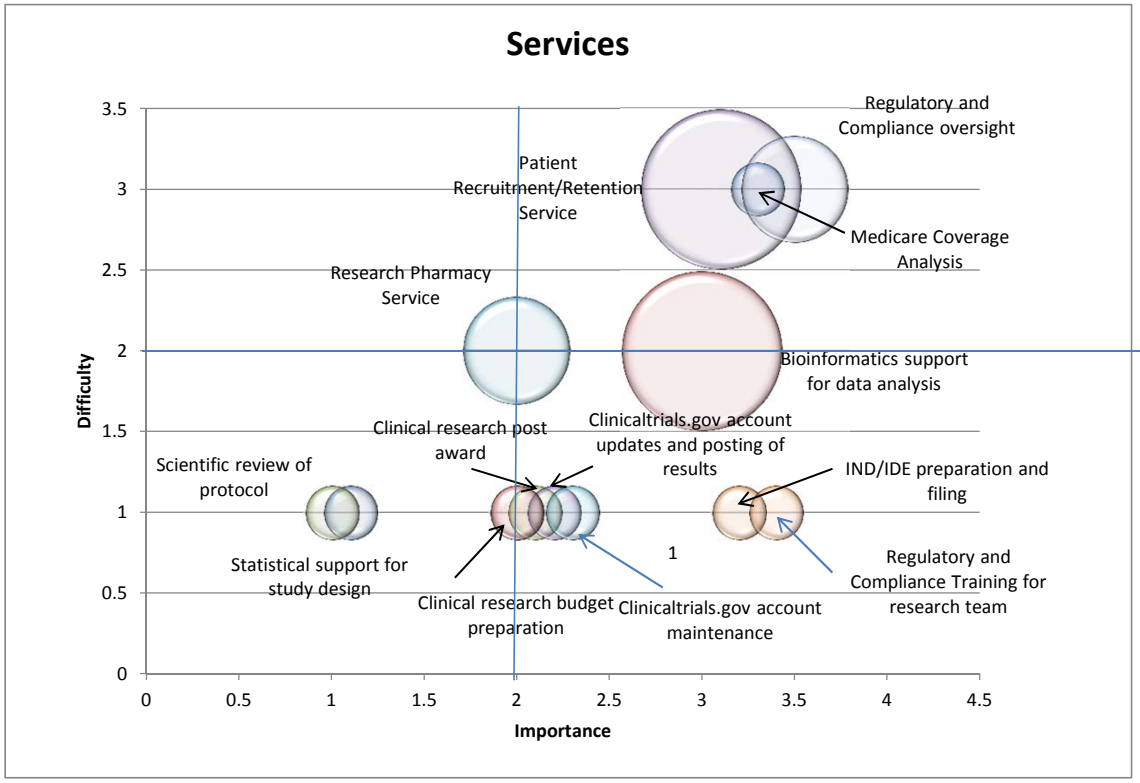
Research pharmacists
Bioinformaticians
Pre and postaward staff
Statistician
Trained clinical coordinators, with a defined career path


Services
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Research Pharmacy Service
Bioinformatics support for data analysis
Clinical research post award
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Scientific review of protocol
IND/IDE preparation and filing
Statistical support for study design
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Regulatory and Compliance Training for research team
Clinical research budget preparation
Clinicaltrials.gov account maintenance
Difficulty
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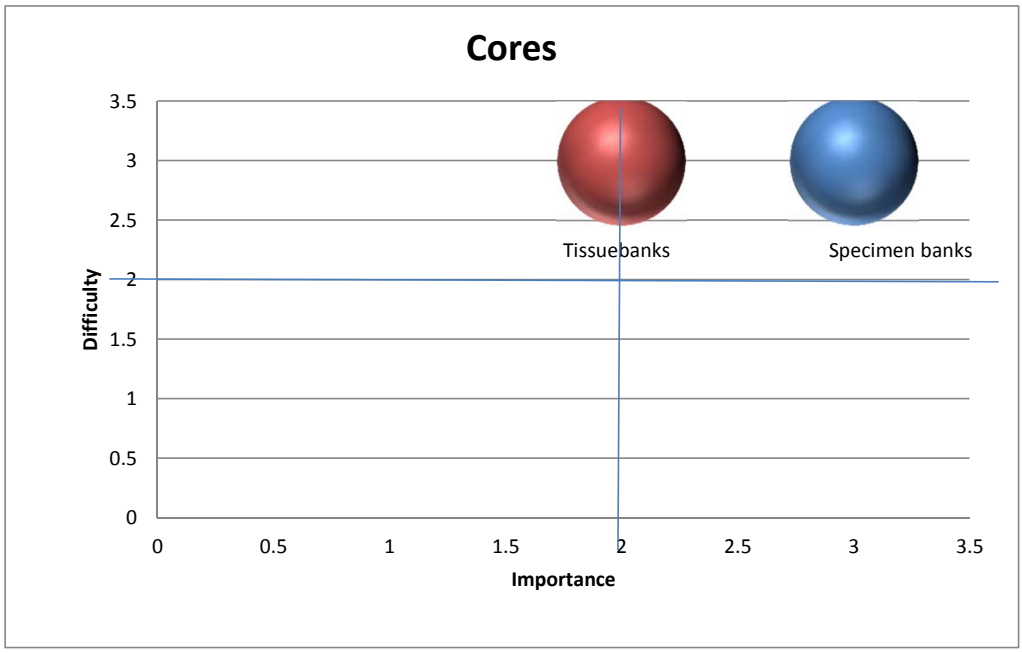
Cores
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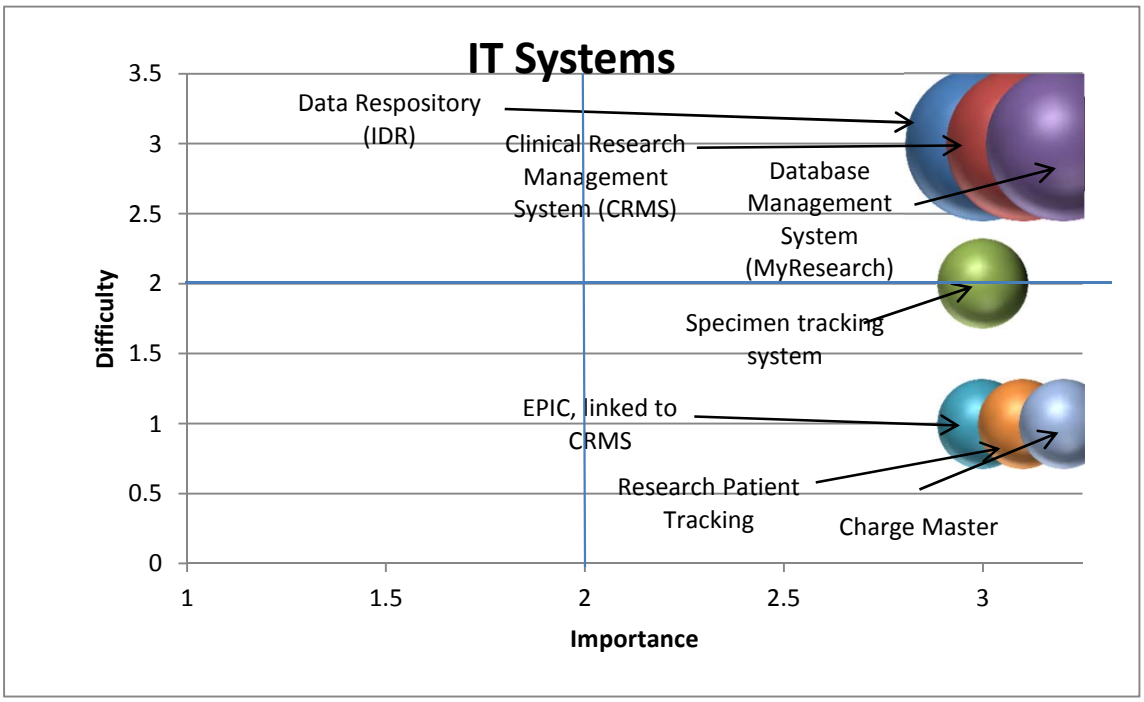
Importance


IT Systems
Data Respository (IDR)
Clinical Research Management System (CRMS)
Database Management System (MyResearch)
Specimen tracking system
EPIC, linked to CRMS
Research Patient Tracking
Charge Master
Difficulty
Importance
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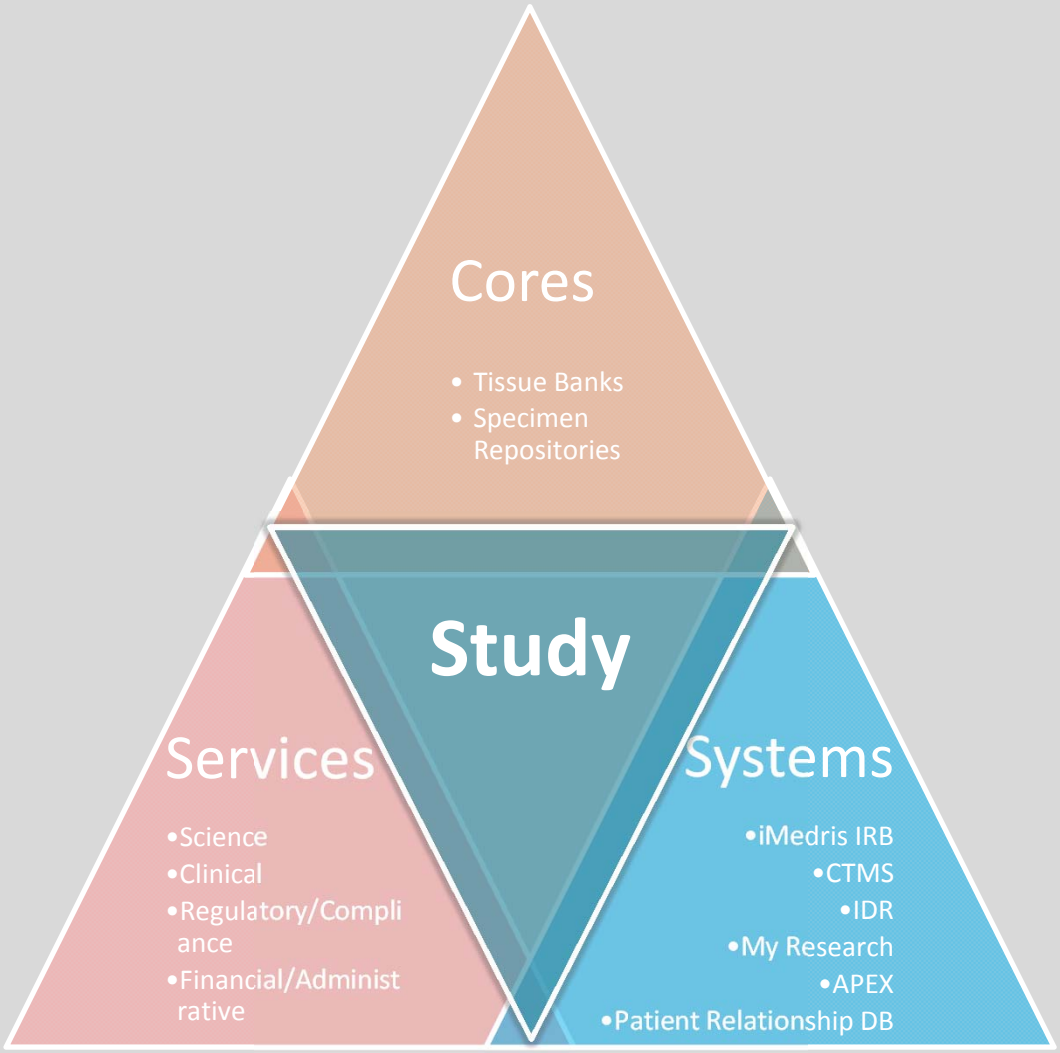
Appendix D

Clinical Research Infrastructure



Framework for Clinical Research At UCSF