

UC Davis Clinical and Translational Science Center: Adopting an “Investigator-centered” Approach to Best Practices in Clinical Research



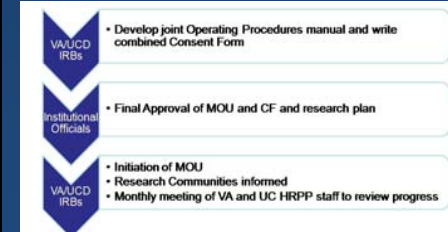
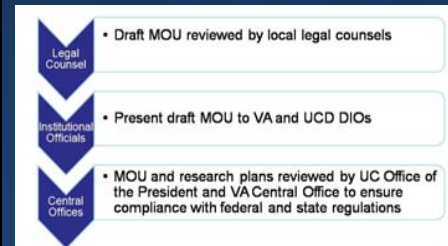
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Methods cont.

CCRC: SWOG 0533: A Pilot Trial Of Cisplatin/Etoposide/Radiotherapy Followed By Consolidation Docetaxel And The Addition Of Bevacizumab (NSC-704865) In Three Cohorts Of Patients With Inoperable Locally Advanced Stage III Non-Small Cell Lung Cancer

	Reviewer	Date	Status	Comments
Administration	Debbie Schilling	12/4/2007	Approved	Please review on or before 12/18/07. Respectfully, Debbie
RKS Director	N/A	N/A	N/A	N/A
CCRC Director	Ted Wun	12/13/2007	Approved	N/A
CCRC RSA	Nicholas Kenyon	12/9/2007	Approved	Approved. Pilot study in Stage III Non-small cell lung cancer. Complicated study design testing early vs late Bevacizumab with other chemo regimens. There is significant data in humans with this agent.
CCRC Pediatrics	Alexander Kon	12/12/2007	Approved	Please note that study includes children aged 18-21 years. Approve.
CCRC Manager	Nicole Mullen	12/12/2007	Approved	Nursing support is being requested at the CTSU and CCRC to administer chemo, collect VS and specimens.
CCRC: Nursing Support	Nicole Mullen	12/12/2007	Approved	Cisplatin to be given day 1, 8, 29, and 36. Etoposide to be given on Day 1-5 and 29-33. Radiation to be daily x7weeks. Possible that some study visits may take place at the CCRC.
CCRC: Dietary Assessment	N/A	N/A	N/A	N/A
CCRC: Imaging* Radiology	Nicole Mullen	12/13/2007	Approved	VA patients will use VA radiology resources.
CCRC: Body Composition Laboratory	N/A	N/A	N/A	N/A
CCRC: Analytical Laboratory	Sridevi Devaraj	12/4/2007	Approved	N/A
Biostatistics	N/A	N/A	N/A	N/A
Informatics Director	N/A	N/A	N/A	N/A



Background

The UC Davis Clinical and Translational Science Center (CTSC) was awarded in 2006. The CTSA program allowed greater flexibility in protocol management and this was an area targeted for process improvement. In the GCR model, protocols underwent both administrative and scientific review similar to a study section or protocol review committee. It was determined that this pathway was duplicative and slow. The new UC Davis CTSC Clinical Research Center (CCRC) is physically housed in the Sacramento VA Medical Center (VANCHCS) in Mather, CA. However, separate IRB approval was required for CTSC studies seeking to enroll VA patients. This addition hurdle resulted in very few studies being activated at the VA. Therefore, initiatives were launched to change these two processes to decrease investigator administrative burden and approval time, increase the number of studies and investigators utilizing CTSC resources, and make studies accessible to VA patients.

Hypothesis

Interventions targeted towards streamlining the scientific and administrative review for clinical research protocols will decrease processing time, enhance resource utilization, and increase available studies for patients at the University of California, Davis Health System (UCDHS) and VA Northern California Health Care System (VANCHCS)

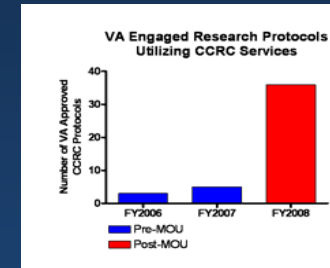
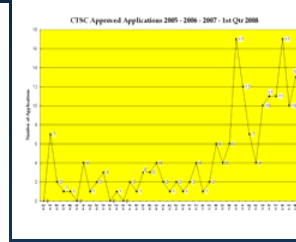
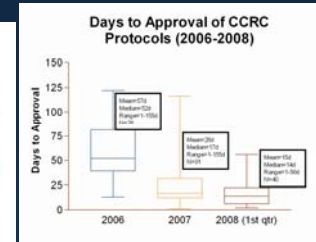
Objectives

- To move the new CCRC committee away from a scientific review and approval body to a board with oversight and advisory roles.
- To develop a joint UCD/VA IRB for CTSC studies to facilitate clinical protocol activation and management.

Methods

- GCR Advisory Committee (GAC) → CCRC
 - Move to corporate governance oversight model for CCRC
 - Define a core group of scientific reviewers (Core directors-RKS, PCIR, RSA, Ethics, Peds, staff)
 - On-line submission and approval process
 - Benchmark 2 wk review and approval process
- VA/UCD IRB Memorandum of Understanding (MOU)
 - Outline agreement by DIOs
 - Emphasize common practices in research
 - Decrease regulatory burden for Pls

Results



Limitations/Lessons Learned

- The flexibility afforded by the CTSA in redesigning the GCRs should be emphasized. Flexibility breeds partnership and engagement.
- Innovation with informatics is necessary.
- Success requires dedicated core group of Co-Directors.
- Time needs to be protected and compensated.
- Effort needs to be recognized in academic environment.
- Focus upon engaging interested parties; it is too difficult to include all.
- “Value-added” customer service approach is helpful.

Conclusion

We redesigned our GAC to fit the more flexible CTSA clinical research model and promoted common research practices with a new UCD/VA IRB agreement. These two actions improved our clinical research protocol management. Adopting an “investigator-centered” customer service model is essential in fostering new partnerships with Pls.

