Building an Office of Clinical Research and Trials:  
The UC Irvine Experience 

By Jill Y. Kay, Barrie Pitts, and Randall F. Holcombe

Abstract

The University of California, Irvine School of Medicine (SOM) established an Office of Clinical Research and Trials (OCRT) to assist investigators with clinical research regulatory, budgetary and compliance functions, help junior investigators navigate through University bureaucracy, and facilitate the conduct of clinical trials. The OCRT assists investigators in preparing materials for submission to the Institutional Review Board (IRB), developing study budgets, and negotiating budgets and payment terms with external sponsors. It also provides clinical trial educational programs for faculty and staff. In this article, we describe the successful first year of the OCRT, identifying essential operational components and describing activities and services. This information can serve as a model for development of similar enterprises at other academic health centers.

Objectives

Conducting clinical research studies is an increasingly complex activity, especially at academic institutions. In 2005, clinical research activities at the SOM were less robust and faced greater challenges than nonclinical research activities, as at many other academic institutions.1 Facilitating clinical research would also enhance opportunities for translational research at the University.2 The SOM thus decided to create an Office of Clinical Research and Trials (OCRT). The University chartered OCRT to assist faculty investigators with clinical trial regulatory, budgetary, contracting and compliance functions; help junior investigators navigate through University bureaucracy; provide educational programs; and ultimately facilitate expansion of clinical research at the SOM. In this article, we describe the successful first year of the SOM OCRT, identifying essential operational components and describing activities and services. This information can serve as a model for development of similar enterprises at other academic health centers.

Planning Phase

In the fall of 2006, the SOM Dean’s Office recruited the OCRT Director from the School’s faculty, agreeing to support the initiative for a period of five years. By April 2007, the Director hired an Associate Director of Regulatory Affairs, an Associate Director of Research Initiatives, along with staff to fill one position focused on preparing submissions to the Institutional Review Board (IRB), one position focused on conducting budget and contract negotiations, and one administrative assistant position. Figure 1 shows the initial organization structure.

Early in the planning phase, the OCRT defined its mission within the context of the larger UC Irvine mission, a step sometimes neglected or taken for granted within academic institutions. The OCRT mission statement is “to provide investigators with resources, information and expertise in clinical research in order to foster and facilitate the clinical research enterprise within the School of Medicine and the broader University community.” In essence, the role of OCRT is to facilitate the clinical research activities of its constituency: clinical investigators. The OCRT was established to provide services, not additional supervision. Use of OCRT services by investigators would be completely voluntary.
Figure 1. Initial OCRT Organizational Chart

The OCRT established its operations on a business model rather than an academic department model, defining measurable benchmarks and emphasizing transparency and cost efficiency. We developed a business plan that projected activity volumes and funding requirements for the first fiscal year. We submitted the plan to the Vice Chancellor for Health Affairs, the Vice Chancellor for Research, and the Chair of the Council of Clinical Chairs. We also posted the plan on the OCRT website for faculty comment.

To identify the greatest perceived needs and fine tune the services to be offered, the OCRT Director met with every SOM Department Chair and invited all SOM faculty and staff to participate in an online survey. Forty-four responses to this survey were received. Additional input was gathered from similar offices at other institutions via Internet research, telephone calls, and emails. Based on this input, the OCRT developed its initial offerings of support services and educational programs.

OCRT created a marketing plan to inform faculty and staff of its services. The plan included a website (www.healthaffairs.uci.edu/ocrt), promotional emails, an informational brochure, and an OCRT logo. The marketing plan also included telephone calls and presentations to departments and units involved in clinical research, and a booth at the SOM’s shared resources fair and research poster forums.

Consistent with the spirit of its mission, the OCRT operates with maximum transparency, with frequent status reports on study progress and the Office’s timelines and capabilities. Since all services are voluntary, “customer” satisfaction is paramount. We monitor it by soliciting feedback from users and department chairs on an ongoing basis and via annual SOM-wide satisfaction surveys.

Initial Services

The OCRT’s initial core support services focused on helping investigators take their clinical protocols through the required pre-award SOM approvals and setup steps. These setup steps include helping investigators obtain Institutional Review Board (IRB) approvals; negotiating study budgets and payment terms with sponsors; and coordinating with the University Contracts and Grants Office, which negotiates other contract terms, such as those related to intellectual property concerns and liability. These services are geared toward industry-sponsored clinical trials and assume that protocols are fairly well developed at the time of service request.
IRB preparatory services include assembling regulatory document packets required by industry sponsors, preparing consent forms and protocol summaries for Institutional Review Board (IRB) review, and coordinating and preparing investigator responses to IRB queries. In addition, OCRT personnel process and submit protocol amendments and IRB modifications.

Contracting and budgeting services include assisting investigators in preparing internal budgets, classifying study activities as standard-of-care (SOC) or non-SOC, obtaining approval of proposed charges and reimbursements through the SOM Clinical Research Finance (CRF) office, negotiating budgets with sponsors, obtaining required institutional approvals, and acting as liaison to Sponsored Projects Administration (SPA), which has final signature authority for all University contracts.

In addition to its core support services, OCRT established a series of clinical research educational programs (Table 1), assisted some department and unit heads in developing strategic plans for expanding clinical research, coordinated multidisciplinary writing projects, and provided "educational" audits prior to site visits by outside monitors.

### Table 1. OCRT Educational Programs
(see www.healthaffairs.uci.edu/ocrt for additional information)

<table>
<thead>
<tr>
<th>Program</th>
<th>Description</th>
<th>Audience</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the Trenches</td>
<td>Series of five 90-minute courses, once per week. Limit of 15 participants per course. Covers all aspects of clinical trial conduct.</td>
<td>Clinical research coordinators, research nurses, administrative personnel working with clinical research.</td>
</tr>
<tr>
<td>Protocol Writing Conference Series</td>
<td>Series of six 60-minute sessions. Lecture plus question-and-answer section. Focuses on the essential elements needed to write a clinical trial protocol.</td>
<td>New and junior clinical faculty interested in investigator-initiated studies, staff involved in the writing process.</td>
</tr>
<tr>
<td>Mentorship Program</td>
<td>Matching service to connect junior and new clinical faculty with more senior, experienced clinical researchers. Four or more “contacts” throughout the year.</td>
<td>New and junior clinical faculty.</td>
</tr>
<tr>
<td>Ad hoc lectures and audioconferences</td>
<td>Needed, current and requested topics.</td>
<td>All clinical research personnel.</td>
</tr>
</tbody>
</table>

Educational activities included a year-long, six-lecture protocol writing series for junior investigators; a mentorship program; a five-lecture, five-week series for clinical research staff; and assorted audioconferences, lectures and webinars on topics such as clinicaltrials.gov registration and clinical trial billing and reimbursement. Three junior investigators took advantage of the mentorship program, for which 24 senior investigators volunteered. Each junior investigator was assigned a senior clinical research mentor with expectations that they would meet at least 3-4 times per year. An additional service, OCRTips, involved very brief weekly email messages to all SOM faculty and staff explaining an important piece of information about conducting clinical research. OCRTips are archived on the OCRT website.

OCRT also serves as a convenient source of information about clinical research for faculty and staff, serves as a liaison to the IRB and the University Contracts and Grants office, and serves as a referral guide to other clinical research resources available across the campus.
The OCRT does not offer data management, study coordination, or research nursing services. Investigators use resources in their departments or the General Clinical Research Center (GCRC) for these services. (However, OCRT assists investigators in completing GCRC applications.) In addition, OCRT does not provide biostatistics and informatics services, although we will refer investigators to appropriate entities on campus. Departments, and not OCRT, handle post-award financial management, which, especially for industry sponsored trials, is complicated and requires ongoing interaction between the fiscal administrator and the research coordinator/data manager. The SOM’s NCI-designated comprehensive cancer center provides pre- and post-award services for cancer trials, so OCRT does not support this research. Study personnel are responsible for unanticipated problem/adverse event reporting.

First Year Results

In the business plan, we projected that 12 new protocols would be submitted for IRB preparatory services in the first year, an average of one per month. In actuality, investigators submitted 67 new protocols (about one-third of the total) for IRB preparation during the year (5.6/month, Figure 2A), with an additional 50 modifications and two IRB closures, for a total transaction volume of 119. Despite the unexpected high volume, turnaround time in OCRT for industry-sponsored trials, from receipt of protocol and related documents to submission to the IRB, averaged 31 working days. Average time from submission to IRB to IRB approval for these protocols averaged 37 working days. Therefore, total calendar time (working and non-working days) from OCRT receipt to IRB approval was approximately 3.0 months, a significant improvement over the historical average of 5-6 months at our institution.

In the business plan, we projected that 12 new protocols would be submitted for contracting and budgeting services in the first year. In actuality, we received 56 requests for budgeting and contracting services (4.6/month, Figure 2B). Most requests involved budget negotiation with sponsors and contract research organizations (CROs) for industry-sponsored clinical trials. OCRT turnaround time for contracts executed in the first year, from receipt to submission to the University Contracts and Grants Office, was 41 working days. Turnaround time from receipt at that office to final execution was 59 working days. Therefore, total time from receipt by OCRT to final contract execution (working and non-working days) was approximately 4.8 months, with the majority of that time attributable to the University Contracts and Grants office. This timeline was approximately two months faster than the historical average.
Educational activities were extremely well attended (Table 2) and, according to user satisfaction surveys, extremely well received. OCRTips have also been very well received by the faculty and staff.

**Table 2. OCRT Educational Activity Attendance in Year 1**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>Attendance</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the Trenches</td>
<td>5 part series</td>
<td>288</td>
</tr>
<tr>
<td>Protocol writing conference</td>
<td>6 lectures and practical assistance</td>
<td>122</td>
</tr>
<tr>
<td>Conference series</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trials billing</td>
<td>Single session, given on two separate occasions</td>
<td>39</td>
</tr>
<tr>
<td>Practicum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trials billing</td>
<td>FDA audioconference</td>
<td>50</td>
</tr>
<tr>
<td>Under Medicare</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thompson interactive</td>
<td>&quot;How to prevent inaccurate study site records&quot;</td>
<td>16</td>
</tr>
<tr>
<td>Webinar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinicaltrials.gov education</td>
<td>3 training sessions and issuance of ID/passwords</td>
<td>73</td>
</tr>
</tbody>
</table>
During the first year, it became apparent that OCRT is most useful to faculty investigators by focusing on assistance for industry-sponsored, rather than investigator-initiated trials. While not excluding assistance in IRB and budget preparation for investigator-initiated trials, many of these investigators were referred to the GCRC (renamed the Institute for Clinical Translational Science, ICTS).

Initially, the Dean's Office did not charge departments for OCRT services. However, a cost-recovery program was initiated when it became apparent that activity levels far exceeding projections might require hiring additional personnel. Prior to implementation, we vetted cost recovery proposals with the department chairs and posted them on our website for comment. Cost recovery was implemented from two sources: for-profit sponsors and SOM departments. OCRT charges for-profit sponsors for contract/budget services and IRB preparation, annual renewal, and modification preparation. It charges departments for sponsor audit preparation and one-on-one training sessions for new coordinators because of the extensive amount earned $33,430 in fees from study sponsors. In the first year, OCRT processed clinical trial contracts with budgets of over $2.3 million dollars, including over $600,000 in University overhead. This compares to the approximately $300,000 OCRT total annual operating budget.

Table 3. OCRT Cost Recovery

<table>
<thead>
<tr>
<th>Contract /Grant Status*</th>
<th>#</th>
<th>Direct Cost</th>
<th>F&amp;A</th>
<th>Total Negotiated Budget</th>
<th>Budgeted</th>
<th>Collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executed</td>
<td>1</td>
<td>$1,185,446</td>
<td>$315,595</td>
<td>$1,501,041</td>
<td>$19,780</td>
<td>$13,030</td>
</tr>
<tr>
<td>Pending**</td>
<td>2</td>
<td>$1,166,035</td>
<td>$303,238</td>
<td>$1,469,044</td>
<td>$20,400</td>
<td>N/A</td>
</tr>
<tr>
<td>TOTAL</td>
<td>3</td>
<td>$2,351,481</td>
<td>$618,833</td>
<td>$2,970,085</td>
<td>$40,180</td>
<td>$13,030</td>
</tr>
</tbody>
</table>

*As of 4/1/08, the end of the last reporting period.
**Final budget has been negotiated; contract has been submitted to SPA for language negotiation and execution.

Moving Forward

OCRT distributes annual online user satisfaction surveys and also surveys all SOM faculty and staff. The initial user satisfaction survey received a 30% response rate, with a 75% increase in respondents for the second survey. Respondents were asked to rate their satisfaction with OCRT and other University and SOM clinical-research-related offices. OCRT services have been well utilized and appreciated by the clinical research community, as indicated by overall satisfaction ratings of “satisfied” or better (94%). All comments were positive, for example, “Job well done…the most encouraging and positive program at UCI in the past 6 years.”

Based on our first user satisfaction survey, the main focus of the OCRT remains providing pre-award assistance for, and generally facilitating, industry-sponsored clinical trials. Based on year-one volumes, all activity projections have been increased for year two, with a minimal increase in staffing. We hope to improve both IRB and contracting timelines further.
We may offer post-award financial management. Educational offerings will expand to include advanced topics in clinical trial management for research coordinators and billing regulations. The only program that failed to meet expectations was the mentorship program, so it may be modified, moved to the ICTS, or terminated.

Summary and Recommendations

The first year of the OCRT was, by all accounts, very successful. Activity far outpaced projections, pre-award timelines significantly accelerated, and faculty and staff are very satisfied. The OCRT continues to function on a business model, with a clear mission, defined business plan, maximal transparency, and the flexibility to adapt to changing requirements. Table 4 sets forth recommendations for other academic health centers that may be considering a similar program.

<table>
<thead>
<tr>
<th>Table 4. Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Start with a well-formulated business plan</td>
</tr>
<tr>
<td>• Remember your mission</td>
</tr>
<tr>
<td>• Provide exceptional service and remember your “customer” base</td>
</tr>
<tr>
<td>• If you follow recommendations 1 through 3, expect to be busy</td>
</tr>
<tr>
<td>• Plan for flexibility in staffing and services</td>
</tr>
<tr>
<td>• Adapt services based on feedback</td>
</tr>
</tbody>
</table>

References


Acknowledgements

The authors wish to thank Dean Thomas Cesario and Vice Chancellor and Dean David N. Bailey for their support of the Office of Clinical Research and Trials. There are no financial conflicts to disclose.

Authors

Jill Y. Kay, MS is Associate Director for Research Initiatives, OCRT, at the University of California, Irvine.

Barrie Pitts is Associate Director of Regulatory Affairs, OCRT, at the University of California, Irvine.

Randall F. Holcombe, MD is Professor of Medicine and Director, Office of Clinical Research and Trials at the University of California, Irvine. Contact him at 1.714.456.8708 or rholcomb@uci.edu.