

December 15, 2011

GABRIEL HADDAD, M.D.  
Chair  
Department of Pediatrics  
0984

KATHLEEN NAUGHTON  
Chief Compliance and Privacy Officer  
0836

**Subject: *Rady Children's Hospital, San Diego Research Compliance Review  
Audit Project 2011-26***

The final audit report for Rady Children's Hospital, San Diego Research Compliance Review, Project #2011-26, is attached. We would like to thank all Rady and UCSD personnel for their cooperation and assistance during the audit.

Because we were able to reach agreement regarding corrective actions to be taken in response to the audit recommendations, a formal response to the report is not requested.

The findings included in this report will be added to our follow-up system. While management corrective actions have been included in the audit report, we may determine that additional audit procedures to validate the actions agreed to or implemented are warranted. We will contact you to schedule a review of the corrective actions, and will advise you when the findings are closed.

UC wide policy requires that all draft audit reports, both printed and electronic, be destroyed after the final report is issued. Because draft reports can contain sensitive information, please either return these documents to AMAS personnel, or destroy them.

Stephanie Burke  
Assistant Vice Chancellor  
Audit & Management Advisory Services

Attachment

cc: D. Brenner  
J. Brokowski  
L. Giddings  
I. Kaufmann  
A. McMahill  
C. Moon  
G. Matthews  
M. Norton  
T. Perez  
E. Quigley  
R. Siwabessy  
S. Vacca  
E. Wilson

**AUDIT & MANAGEMENT ADVISORY SERVICES**



University of California  
**San Diego**

**Rady Children's Hospital, San Diego  
Research Compliance Review  
December 2011**

**Performed By:**

Aparna Handa, Auditor  
Terri Buchanan, Manager

**Approved By:**

Stephanie Burke, Assistant Vice Chancellor

Project Number: 2011-26

***Rady Children’s Hospital, San Diego Research Compliance Review  
Audit & Management Advisory Services Project #2011-26***

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*Rady Children's Hospital, San Diego Research Compliance Review  
Audit & Management Advisory Services Project #2011-26*

**Executive Summary**

UCSD Audit & Management Advisory Services (AMAS) has completed a review of Rady Children's Hospital, San Diego (RCHSD) research compliance activities and related research administration processes as part of the approved audit plan for Fiscal Year 2010-11.

The objectives of our review were to evaluate the effectiveness of the RCHSD research administration infrastructure and associated business process controls; and to determine whether research compliance activities conducted at RCHSD met the seven elements of an effective research compliance program as provided in the Federal Sentencing Guidelines.

After September 2009, RCHSD research administration processes and related compliance activities were modified significantly to reflect the shift in responsibility for administering research projects from RCHSD to UCSD. The majority of research projects are now submitted through the UCSD Institutional Review Board (IRB), and pre-award research administration is shared between the UCSD Office of Clinical Trial Administration (OCTA) or the Office of Contract and Grant Administration (OCGA), Department Business Offices, and the RCHSD Joint Pediatric Clinical Research (JPCR) office. Charge capture and billing for ancillary clinical services provided to research subjects continue to be processed and billed through RCHSD systems.

RCHSD has implemented a number of improvements to research administration and patient care systems that facilitate research coordination and information sharing within RCHSD and with UCSD, and reduce overall compliance risk. However, the infrastructure for managing research and ensuring regulatory compliance remains divided between RCHSD and UCSD personnel. Re-organization of the research support infrastructure; increased coordination between UCSD and RCHSD; and greater use of existing UCSD policies, processes and systems when practical; would likely result in improved organizational accountability, regulatory compliance, and efficiency.

In addition, we noted that improvements to the research compliance training program and processes for auditing/monitoring charges for research services were needed to further reduce compliance risk. Joint research monitoring of key compliance risk areas such as research billing, was not being performed, pending UCSD Research Compliance Program (RCP) access to related RCHSD computer systems and records.

Audit recommendations focused on re-organization of the research support infrastructure, increased coordination between UCSD and RCHSD; and greater use of existing UCSD policies, processes and systems when practical to improve regulatory compliance and efficiency.

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**I. Background**

UCSD Audit & Management Advisory Services (AMAS) has completed a review of Rady Children's Hospital, San Diego (RCHSD) research compliance activities and related research administration processes as part of the approved audit plan for Fiscal Year 2010-11. This report summarizes the results of our review.

*Affiliation Summary*

In August 2001, the Joint Powers Affiliation Agreement between the Regents of the University of California (UC) and Children's Hospital and Health Center of San Diego, now referred to as RCHSD became effective. The primary intent of the agreement was to combine UCSD Health System (UCSDHS) and RCHSD physicians, staff, hospitals and clinics into one virtual healthcare program to provide services to children in the greater San Diego area. When all components of the agreement were implemented, RCHSD became the primary service location for the majority of children's healthcare services formerly provided in UCSDHS facilities.

At that time, UC also entered into a related affiliation agreement with the Children's Specialists of San Diego, a Medical Group, Inc. (CSSD) to coordinate professional medical services, and the billing for those services, on behalf of UCSD Department of Pediatrics specialists, and RCHSD physicians.

In September 2009, UCSD entered into five new Agreements with RCHSD and CSSD which created the Rady Children's Specialists Medical Foundation (Foundation), to build upon the 2001 affiliation of Pediatric programs. In accordance with the new Agreements, faculty appointments were offered to, and accepted by approximately 120 CSSD physicians. As a result, the UCSD School of Medicine (SOM) recognized the need for joint clinical research<sup>1</sup> administrative function to facilitate research projects conducted at RCHSD.

The following five Agreements became effective on September 1, 2009:

- ***Professional Services Agreement (PSA)***: This agreement was executed between RCHSD and CSSD, and contains terms related to the governance and structure of the Foundation, the responsibilities of the Foundation and CSSD, and physician compensation.
- ***Administrative and Third Party Services Agreement (ASA)***: This agreement was executed between RCHSD and CSSD, and contains terms regarding CSSD performing certain physician administrative services, such as Hospitalist services, Medical Director services, and on-call coverage at RCHSD.

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<sup>1</sup> Research conducted by a UCSD Principal Investigator (PI) at RCHSD pursuant to the September 2009 agreements.

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- ***Staffing Agreement between CSSD and UCSD:*** This agreement describes the expected delivery of physician related services, and the related terms of compensation and employment of CSSD physicians by UCSD. Selected Agreement terms are similar to those included in the PSA.
- ***Agreement between RCHSD and UCSD:*** This agreement describes the financial support RCHSD is providing to UCSD through Dean’s Office and Department taxation and funds flow; the physician recruitment process; and UCSD employment, faculty performance obligations, and research integration.
- ***The Joint Compliance, Risk Management and Common Interest Defense Agreement (JCRM):*** This Agreement, executed between RCHSD, CSSD and UCSD, requires that the following oversight Committees be formed:
  - ✓ Joint Compliance Committee (JCC): This Committee is given investigatory and disciplinary authority related to compliance policies and procedures; and is responsible for developing an annual Compliance Work Plan.
  - ✓ Joint Risk Management Committee (JRMC): This Committee has representatives from each entity that jointly monitor, identify and analyze compliance risk and how it will be addressed. Risk related to patient injury, clinical services and research activities is included in this Committee’s purview.

***Research Projects at RCHSD***

The table below provides a summary of active research projects conducted at RCHSD as of October 2011. About 336 or 83% of the total 407 active projects were joint research studies conducted by UCSD PIs. As a result, close coordination of research compliance initiatives between the two entities is critical to reduce compliance risk.

<b><i>Type of Research</i></b>	<b><i>Number of Joint Research Projects</i></b>	<b><i>% of Total</i></b>	<b><i>Number of RCHSD-Specific Research Projects<sup>2</sup></i></b>	<b><i>% of Total</i></b>	<b><i>Total</i></b>
Commercially Sponsored Clinical Trials	72	99%	1	1%	73
Principal Investigator (PI) Initiated Studies	264	79%	70	21%	334
Total	336	83%	71	17%	407

<sup>2</sup> This category of projects includes research administered by RCHSD and conducted by non-UCSD PIs.

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*Research Administration Practices – Joint Research*

Joint research projects conducted at RCHSD are evaluated by units or departments at RCHSD and UCSD prior to final approval. Initial review and ongoing oversight of the ethical conduct and risks associated with protocols involving human subjects is provided by UCSD's Institutional Review Board (IRB).

During the period when clinical research projects were being transitioned from RCHSD to UCSD, the Joint Pediatric Clinical Research office (JPCR) was created. JPCR personnel were familiar with UCSD and RCHSD requirements, had access to RCHSD support systems, and were able to assist PIs with facilitating the completion of research approval, and post award study coordination and financial management processes. The JPCR Research Administration Officer (RAO) was a RCHSD employee who reported to the RCHSD Chief Medical Officer (CMO), and the Director of Clinical Research (DCR) (vacant). When filled, the DCR position will report to the Chief Scientific Officer; and have a dotted line reporting relationship to the RCHSD Chief Operating Officer. In the interim, the RAO reported directly to the Chief Scientific Officer.

When the JPCR was established, both UCSD and RCHSD staff participated in developing more effective business results. The UCSD personnel who worked in the JPCR reported to Department of Pediatrics Business Office management, but provided pre and post award support to PIs with commercially sponsored projects through the JPCR. By summer 2011, the UCSD staff positions were eliminated, leaving only RCHSD staff in the JPCR.

After the study budget is prepared and reviewed by the JPCR, all required documentation is forwarded either to the UCSD Office of Clinical Trials Administration (OCTA) for commercially sponsored trials or the Office of Clinical Grant Administration (OCGA) for federally funded and PI initiated awards. Post award clinical services are processed primarily through RCHSD systems. Study visits are scheduled and linked to the research cost center by use of a study-specific Epic<sup>3</sup> research indicator. All visits with the study Epic indicator are queued to an RCHSD patient account specialist who then routes charges at the applicable research rate to the study cost center. Total cost center charges are then billed to UCSD for reimbursement on a monthly basis.

In April 2011, UCSD management approved a multi-phase project to improve clinical research charge capture, and billing systems and processes to reduce compliance risk associated with research billing errors. In conjunction with this project, UCSD has

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<sup>3</sup> The EpicCare (Epic) electronic health record (EHR) application is a product of Epic Systems Corporation of Verona, Wisconsin. Epic offers an integrated suite of health care software centered on a hierarchical object-oriented database system. All Epic applications leverage the same central database, and Epic data can be queried using built-in reporting tools for research and other analyses. UCSDHS has selected Epic as its primary clinical information system.

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purchased the Velos<sup>4</sup> application to provide a tool for managing research subject visits and associated tasks. When fully implemented, Velos will be the system used to create a Coverage Analysis (CA), and manage patient study visits for each approved clinical research project. The CA process will improve research billing compliance by identifying each study related test or procedure as “standard of care” (SOC) or “research-only.” To create a centralized approach to managing research related services, UCSD plans to create the Office of Coverage Analysis and Application (OCAA). When established, the OCAA will be responsible for reviewing and approving CAs in coordination with the research unit. Pre-billing charge reviews and post billing monitoring will also be conducted. As UCSD administered awards, joint research projects conducted at RCHSD will be managed using these systems and processes.

*RCHSD Research Compliance Program*

The RCHSD Chief Compliance Officer resigned his position in November 2010, and a new Chief Compliance Officer was hired in June 2011. The Compliance Officer is responsible for evaluating research compliance issues and prioritizing areas of compliance focus. Currently, the Compliance Officer is focusing on developing and revising RCHSD research compliance policies.

*RCHSD/CSSD/UCSD Joint Compliance Committee (JCC)*

The JCC has been established as required by the *Joint Compliance, Risk Management and Common Interest Defense Agreement*. The Committee includes representation from RCHSD, CSSD, the Foundation, and UCSD; and meets on a quarterly basis. The JCC provides oversight and guidance on appropriate compliance issues pertaining to the affiliated parties’ common interests. A risk assessment was completed for calendar years 2010 and 2011. Areas of focus identified during the risk assessment included privacy and security of data, research billing, conflict of interest and physician billing.

**II. Audit Objectives, Scope, and Procedures**

The objectives of our review were to evaluate the effectiveness of the RCHSD research administration infrastructure and associated business process controls; and to determine whether research compliance activities conducted at RCHSD met the following seven elements of an effective research compliance program as provided by the Federal Sentencing Guidelines:

- Compliance Standards and Procedures
- Oversight Responsibility
- Due Care in Delegation of Authority
- Effective Employee Training & Education

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<sup>4</sup> Velos eResearch supports patient recruitment, patient scheduling, IRB and study monitoring, project planning, study design, protocol compliance, budget, invoicing, and milestone management; data safety monitoring, adverse event reporting, system integration and study execution.

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- Monitoring, Auditing & Communication
- Enforcement & Discipline
- Response & Prevention

We completed the following audit procedures to achieve the project objectives:

- Reviewed the September 2009 Agreements, and associated Memoranda of Understanding and Amendments;
- Met with RCHSD and UCSD managements to determine areas of concern;
- Discussed the role of the Children's Specialist Foundation (CSF) in RCHSD research compliance with the CSSD Legal Counsel and the Foundation Administrator;
- Reviewed current and draft RCHSD research administration policies and procedures;
- Interviewed the RCP Director and former RCHSD Corporate Compliance Officer to discuss research compliance activities;
- Met with the former RCHSD internal auditor to obtain information about a research billing audit in process;
- Interviewed RCHSD, UCSD and outside billing group staff to obtain an understanding of the research charge capture and monitoring processes. Personnel interviewed included:
  - ✓ JPCR Research Administrative Officer
  - ✓ JPCR Contract and Grants officer
  - ✓ JPCR Clinical Research Operations officer
  - ✓ RCHSD Hospital Billing Department staff
  - ✓ RCHSD accounting staff
  - ✓ Selected UCSD, CSSD and RCHSD Research Coordinators
  - ✓ UCSD and RCHSD Institutional Review Board (IRB) Directors
  - ✓ RCHSD Revenue Cycle Applications Manager
  - ✓ Personnel in the Physicians Medical Group (PMG) and Physician Management System (PMS) professional fee billing groups
- Discussed Investigational Drug Pharmacy management with the Investigational Drug Pharmacist;
- Discussed Health Insurance Portability and Accountability Act (HIPAA) data security communications and practices with the UCSD Corporate Compliance Officer and RCHSD Corporate Compliance Officer;
- Compiled a process flowchart for UCSD research projects conducted at RCHSD (***Attachment A***);
- Evaluated RCHSD research administration infrastructure and communication processes with UCSD and CSSD (***Attachment B***), and identified additional areas of coordination for RCHSD and UCSD management consideration (***Attachment C***);
- Compared RCHSD research compliance activities with Federal Sentencing Guidelines;
- Judgmentally selected eight studies and evaluated how pre-award processes were completed, including IRB and Finance project reviews and approvals; and,

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- Reviewed wording of the IRB approval letters for a judgmental sample of 15 studies for which a HIPAA or informed consent (IC) waiver had been granted to determine whether the approval letters clarified that both HIPAA and IC waivers had been granted when appropriate.

### **III. Conclusions**

After September 2009, RCHSD research administration processes and related compliance activities were modified significantly to reflect the shift in responsibility for administering research projects from RCHSD to UCSD. The majority of research projects are now submitted through the UCSD IRB, and pre-award research administration is shared between the UCSD OCTA or OCGA offices, UCSD Departments, and the RCHSD JPCR. Charge capture and billing continue to be processed through RCHSD systems.

RCHSD has implemented a number of improvements to research administration and patient care systems that facilitate research coordination and information sharing within RCHSD and with UCSD, and reduce overall compliance risk. Several examples include the creation of the JPCR, and implementation of the Epic EHR. However, the infrastructure for managing research and ensuring regulatory compliance remains divided between RCHSD and UCSD personnel (*Attachment B*). Re-organization of the research support infrastructure (*Attachment C*), increased coordination between UCSD and RCHSD; and greater use of existing UCSD policies, processes and systems when practical; would likely result in improved organizational accountability, regulatory compliance, and efficiency.

Overall research compliance risk could be reduced through collaborative compliance efforts and focused joint research billing reviews.

### **IV. Observations, Management Corrective Actions, and Recommendations**

#### **A. Joint Research Administration, Processes and Systems**

**The joint research administration infrastructure and processes lacked clarity and were in some cases inefficient.**

##### *Joint Research Administration*

The *Agreement between RCHSD and UCSD, Section 10.2.4*, makes reference to UCSD development of a “consolidated clinical grants management and support structure for all research conducted at RCHSD and Medical Foundation.” The Agreement also provided that pre award activities would be managed by the consolidated clinical group and post award processes and monitoring would be managed by the PI’s UCSD department.

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RCHSD maintained a research administration unit prior to the 2009 Agreements. When that unit was given the new title of JPCR, UCSD Pediatric research support staff joined the JPCR, which provided the foundation for the consolidated grants management structure referred to in the 2009 Agreement. The inclusion of staff employed by both UCSD and RCHSD was important during the transition period to ensure continuity of operations, and an increased focus on compliance with UCSD research policies, processes and systems. When the staff positions of the UCSD personnel who worked in the JPCR were eliminated; pre- and post-award project support were decentralized to Fund Managers in UCSD Departments. UCSD Fund Managers are knowledgeable about UCSD research policies, requirements, and support offices, but may not have in-depth knowledge of RCHSD policies and requirements, or access to RCHSD financial and billing systems. The RCHSD staffed JPCR is relied upon to provide RCHSD process expertise and system access. However, the advantages of a well coordinated research support system may not be realized if all key personnel do not have a reporting relationship to UCSD.

RCHSD also employs research nurses and/or Study Coordinators that may be assigned to UCSD research projects. However, similar to JPCR staff, they are not UCSD employees, and are not typically granted access to UCSD systems<sup>5</sup>. UCSD and RCHSD will need to reach an agreement that would allow UCSD or RCHSD employed research personnel (administrators, nurses and/or Study Coordinators) the access required to support a study, regardless of which institution employs them.

We believe that the JPCR staff should continue to be located at RCHSD where the research is being performed. However, the current organizational structure depicted in ***Attachment B*** does not facilitate consistency in goals and priorities. Transition of the majority of RCHSD employees to UCSD employment would remediate most of the concerns discussed above. As new UCSD staff members, those staff members would become increasingly familiar with UCSD guidelines and use of UCSD systems to manage joint research, while maintaining expertise in RCHSD research policies and requirements as well.

Because RCHSD also requires staff to support research projects that are not joint research conducted by UCSD faculty, it may also be preferable and more efficient for RCHSD to request that UCSD provide administrative services for non-joint projects on a reimbursement basis via a service agreement. Staff who transition to UCSD employment could continue to be located at the JPCR offices under a space agreement. A proposed organization structure is presented in ***Attachment C***.

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<sup>5</sup> Health Insurance Portability and Accountability Act (HIPAA) privacy and security regulations require that institutions actively manager access to patient records, and have authority to direct staff and take corrective action in the event that inappropriate access occurs.

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In addition, given that the number and complexity of RCHSD IRB reviews has decreased, outsourcing the RCHSD IRB function would likely be more cost effective. A RCHSD funded Quality Assurance Coordinator (QAC) could provide oversight and serve as the liaison between RCHSD and the outsourced IRB. In addition, the QAC could verify that all study pre-award requirements had been met before an RTA letter was issued to reduce compliance risks. This proposed QAC position has also been incorporated into ***Attachment C***.

***Attachment C*** also references the proposed UCSD OCAA, which will assist in CA development and billing quality assurance on research related charges. When the OCAA has been fully staffed, research charge capture and quality assurance processes associated with joint research projects should be coordinated between RCHSD Hospital Billing staff and the OCAA.

**Management Corrective Actions:**

1. RCHSD and UCSD managements are in the process of drafting an MOU related to research staff employment to address the issues noted above.
2. RCHSD management is considering outsourcing the RCHSD IRB function to UCSD.

**B. Joint Research Compliance Activities**

**Selected Research Compliance Program elements including procedures, and post-award auditing and monitoring require improvement to reduce compliance risk.**

Research compliance risk at RCHSD is primarily associated with joint research projects. To provide an overall assessment of status of research risk mitigation processes, AMAS utilized information about the current status of key research compliance activities obtained through document review and management and staff interviews, and compared that information to the Federal Sentencing Guidelines. This analysis helped to identify improvements needed to ensure that research compliance risk was being addressed and mitigated to the fullest extent possible.

AMAS used the following four status indicators to assess of status of research compliance activities:



*Procedures are in place to address the compliance area, and there is appropriate validation or monitoring performed.*

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*Some procedures to address the compliance area are in place, however process weakness may be present, or process improvement may currently be underway. There also may be inconsistent validation/monitoring of the process.*



*Significant weaknesses in procedures and/or monitoring and validation of activities exist.*



*Procedures are not in place to address the compliance area, or they are not sufficient. There may be no monitoring or validation of the activity.*

*Compliance Program Oversight* ●

The JCC establishes RCHSD compliance management priorities, which include research issues. The Fiscal Year 2010-11 Joint Compliance Plan developed by the JCC identified research billing as a key concern, in addition to Compliance Program activities not associated with research including physician billing, security of protected health information (PHI), and adequate disclosure of conflict of interest.

The RCHSD Corporate Compliance Officer resigned in November 2010, and a new Compliance Officer was hired in June 2011. This position provides consistent management of compliance issues specific to RCHSD and CSSD personnel, facilities and systems, and a designated point of liaison for the RCP.

*Delegation of Authority* ●

The JCC Charter authorized the JCC to set RCHSD and CSSD Compliance Program priorities with management approval. The RCHSD Corporate Compliance Officer works closely with the JCC and has the authority to evaluate research compliance issues and implement procedural changes or new systems as needed to achieve compliance goals and objectives.

*Standards and Procedures* ▲

The JCC has focused on ensuring that UCSD and RCHSD/CSSD research policies contain the same or similar requirements. In addition, selected research compliance policies were drafted by the former RCHSD Research Compliance Officer. Although good progress has been made, policies have not been finalized and distributed or posted to a website for easy access by PIs and research personnel.

*PI and Staff Training* ●

The RCP maintains a robust intranet site that provided valuable links to research policies, standards, and guidelines which is available to UCSD and RCHSD research staff. The monthly RCP Research Coordinator and Administrator Training notices, and bi-monthly Newsletters and Hot Topics are sent to the RCHSD coordinators and research staff. In March 2011, UCSD affiliated physicians were also added to the RCP contact list and receive the education as well as other announcements.

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When JPCR research staff discussed post award processes with AMAS, it was clear that many were not fully informed about how clinical research management processes and billing systems operated. The development of guidelines and training sessions that focus on the RCHSD and CSSD research infrastructure would provide staff with the information needed to improve the consistency of joint research study management, and reduce research compliance risk.

**Auditing and Monitoring** 

The *Agreement between RCHSD and UCSD* stated “UCSD shall be responsible for compliance of Sponsored Projects with all applicable legal and other requirements.” However, joint research monitoring of key compliance risk areas such as research billing, was not being performed. In March 2011, RCHSD and the RCP were still in the process of granting RCP access to related RCHSD computer systems and records to allow joint research monitoring of key compliance risk areas. When RCHSD and RCP managements have reached an agreement, research monitoring reviews should be implemented as soon as possible.

**Enforcement and Discipline and Response and Remediation** 

Enforcement and disciplinary processes were consistently described in UCSD compliance policies, and RCHSD draft compliance policies. AMAS was advised that there were no pending disciplinary actions and/or remediation issues, which was likely due to the absence of a monitoring program for research billing activities.

Although selected elements of the joint Research Compliance Program were not fully developed at the time of our review, an infrastructure has been established for joint compliance oversight, training and enforcement. The RCP provides the primary resources for the periodic monitoring of joint research activities. Affiliation agreements did not specifically describe RCP responsibilities and associated support of joint research projects. Therefore, it would be reasonable to address those issues in a separate memorandum of understanding, which would allow the RCP to plan activities and assign an appropriate level of resources to meet service expectations.

**Management Corrective Actions:**

1. RCP was granted access to RCHSD systems and records in August 2011, which will allow RCP to complete the auditing and monitoring activities identified in the 2011 JCC Risk Assessment.

RCHSD and UCSD managements will also:

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2. Encourage the JCC to prioritize the revision of research compliance policies, and adopt UCSD research policies, processes and systems when reasonable to avoid disparate practices.
3. Establish a UCSD/RCHSD/CSSD memorandum of understanding to establish RCP joint research compliance monitoring responsibilities, and to provide for RCP resource support.

**C. Research Billing – Operational Issues**

Several opportunities for research billing system and process improvements were identified.

1. RCHSD Epic System

**The Epic EMR did not capture research specific data or facilitate research billing.**

RCHSD staff stated that a second patient visit could not be entered into Epic during an inpatient stay. This functionality would be useful in cases when research related procedures need to be performed after a subject has been admitted to the hospital. Because a new visit could not be created in this circumstance, all charges, including research related services, were charged to the subject's inpatient account. When this occurred, the Study Coordinator was required to work with the RCHSD Hospital Billing Department to separate research and hospital charges, and route research charges to the study cost center.

The Epic clinical system did not capture research visit information. As a result, research records were maintained on paper or in an alternative application to ensure that regulatory requirements were met.

AMAS also noted that Study Coordinators had the option to make changes to a subject's visit information (including the Epic research indicator) after charges had been billed. Unless the RCHSD Hospital Billing Department is informed of any changes made to a visit, associated charges may be incorrectly routed to a third party payer, rather than the study cost center.

2. RCHSD Research Rate Application Process

**Research rates were not built into the hospital chargemaster.**

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The RCHSD Hospital Billing Department created monthly billing statements for clinical research projects and forwarded them to Study Coordinators for review. After the Study Coordinator verified that all hospital charges were associated with a particular study, the hospital charges were manually adjusted to the research rate. This manual process was time-consuming, and could potentially result in inconsistent rates being charged for the same service/procedure. Incorporating a research rate table into the RCHSD hospital chargemaster, similar to the chargemaster structure UCSD, would assure greater research rate consistency and accuracy.

3. Research Billing – Tracking Billing Errors

**The system used to track research billing errors was not consistently updated.**

The Safety Reporting System (SRS), which was designed primarily to report research safety issues or incidents, was also used to record and track billing errors for research conducted at RCHSD. Study Coordinators stated that entering billing error data in SRS was a time consuming process. As a result, the SRS was not consistently updated. Furthermore, it did not appear that a SRS billing error report was forwarded to the RCHSD Compliance Officer to identify high risk issues, or to periodically monitor charge activity.

4. Research Invoice Process

**A manual process was used to invoice research projects for hospital services provided to the study.**

The RCHSD Hospital Billing Department manually prepared monthly statements for research related services provided to each study, and sent them to the JPCR Clinical Trials Coordinator (CTC), Clinical Grants Officer (if applicable), and related Study Coordinators for review. The CTC discussed and verified charges with Study Coordinators and prepared charge corrections, adjusted charges to research rates, and returned the statements to the RCHSD Hospital Billing Department to be posted to the study cost center. This process was manual and time consuming and caused delays in research charge posting.

**Management Corrective Actions:**

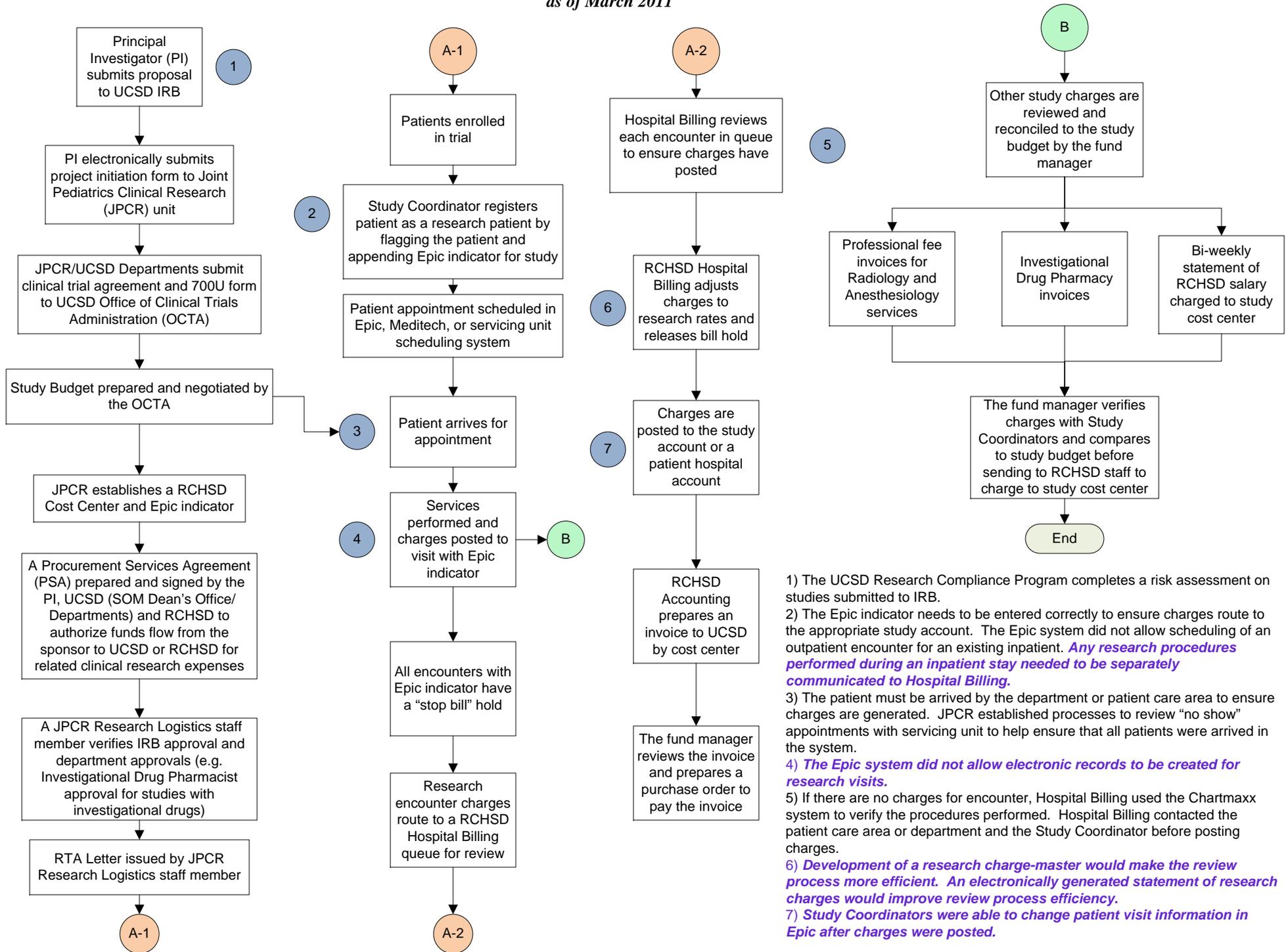
1. A RCHSD Task Force has been formed to identify research process and communication protocol improvements. The Task Force includes representation from Research Administration,

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RCHSD Hospital Billing, RCHSD/CSSD Professional Fee Billing, Patient Financial Services, Information Technology, Quality Management, Central Registration/Scheduling, and Education. This Task Force will consider automating billing for research procedures during inpatient stays, development of a research chargemaster, and improvements to the research invoice preparation and approval processes.

2. The Epic Research Module was implemented in September 2011 to facilitate the capture of research data in the EMR and support related research processes including scheduling/registration, participant recruitment and enrollment, and charge capture and billing.

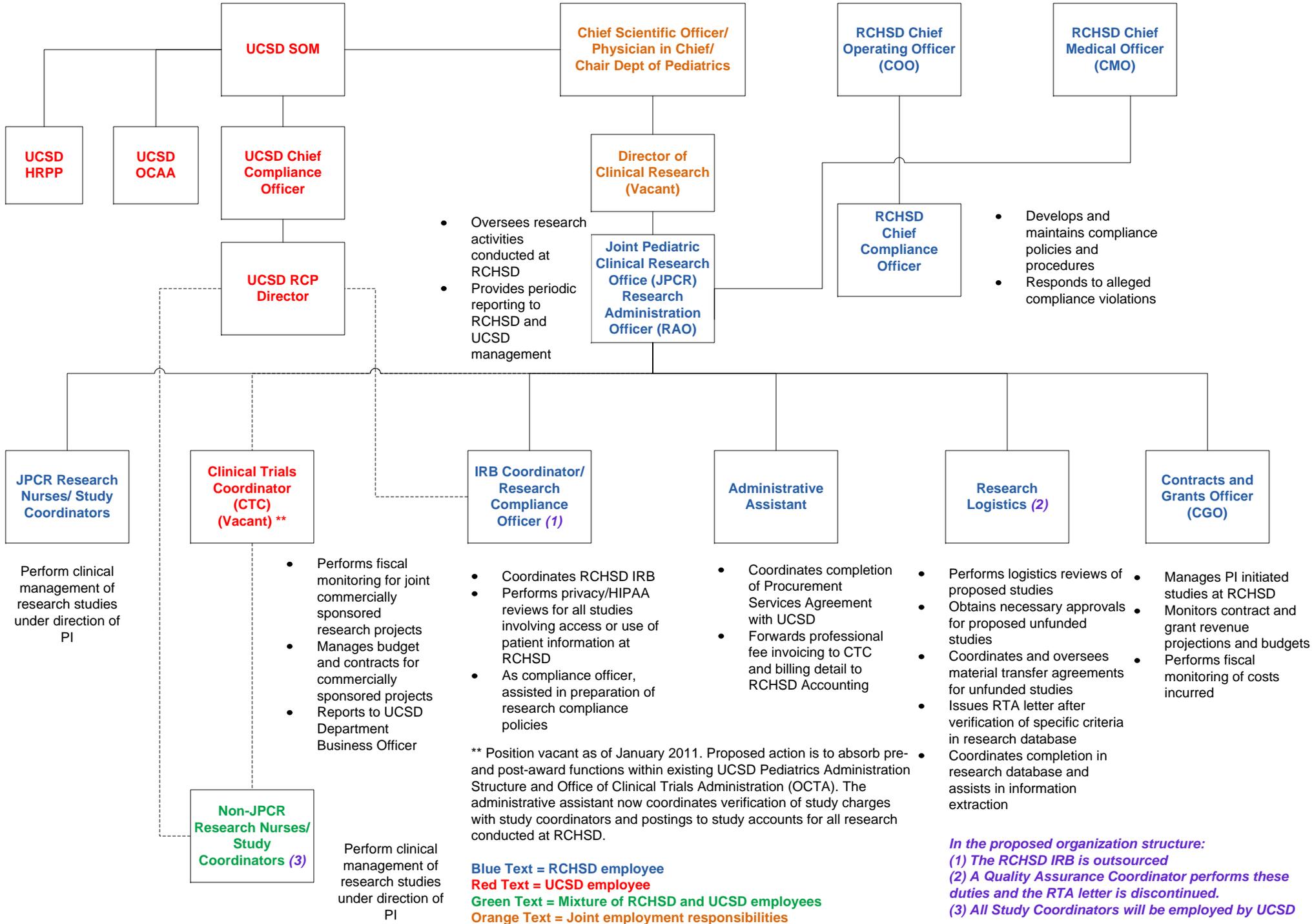
**RCCHSD Research Compliance Review, UCSD Audit and Management Advisory Services Project #2011-26  
ATTACHMENT A - Joint Clinical Trials Research Process Flowchart for Commercially Sponsored Projects  
as of March 2011**



- 1) The UCSD Research Compliance Program completes a risk assessment on studies submitted to IRB.
- 2) The Epic indicator needs to be entered correctly to ensure charges route to the appropriate study account. The Epic system did not allow scheduling of an outpatient encounter for an existing inpatient. **Any research procedures performed during an inpatient stay needed to be separately communicated to Hospital Billing.**
- 3) The patient must be arrived by the department or patient care area to ensure charges are generated. JPCR established processes to review "no show" appointments with servicing unit to help ensure that all patients were arrived in the system.
- 4) **The Epic system did not allow electronic records to be created for research visits.**
- 5) If there are no charges for encounter, Hospital Billing used the Chartmaxx system to verify the procedures performed. Hospital Billing contacted the patient care area or department and the Study Coordinator before posting charges.
- 6) **Development of a research charge-master would make the review process more efficient. An electronically generated statement of research charges would improve review process efficiency.**
- 7) **Study Coordinators were able to change patient visit information in Epic after charges were posted.**

**Note: Potential process improvements are highlighted in purple bold.**

**RGHS Research Compliance Review, Audit and Management Advisory Services #2011-26  
ATTACHMENT B - Current RGHS Research Administration Structure**





*Rady Children's Hospital, San Diego Research Compliance Review  
Audit & Management Advisory Services Project #2011-26  
Report Acronyms  
Attachment D*

**Acronyms**

<b>AMAS</b>	Audit and Management Advisory Services
<b>ASA</b>	Administrative and Third Party Services Agreement
<b>CA</b>	Coverage Analysis
<b>CMO</b>	Chief Medical Officer
<b>CSF</b>	Children's Specialist Foundation
<b>CSSD</b>	Children's Specialists of San Diego, a Medical Group, Inc
<b>CTC</b>	Clinical Trials Coordinator
<b>EHR</b>	Electronic Health Record
<b>Epic</b>	EpicCare
<b>HIPPA</b>	Health Insurance Portability and Accountability Act
<b>IC</b>	Informed Consent
<b>IRB</b>	Institutional Review Board
<b>JCC</b>	Joint Compliance Committee
<b>JCC</b>	Joint Compliance Committee
<b>JCRM</b>	Joint Compliance, Risk Management and Common Defense Interest Agreement
<b>JPCR</b>	Joint Pediatric Clinical Research office
<b>JRMC</b>	Joint Risk Management Committee
<b>OCAA</b>	Office of Coverage Analysis and Application
<b>OCGA</b>	Office of Clinical Grant Administration
<b>OCTA</b>	Office of Clinical Trials Administration
<b>OIG</b>	Office of Inspector General
<b>PCIS</b>	Patient Care Information System
<b>PHI</b>	Protected Health Information
<b>PI</b>	Principal Investigator
<b>PMG</b>	Physician's Medical Group
<b>PMS</b>	Physician Management System
<b>PSA</b>	Professional Services Agreement
<b>QAC</b>	Quality Assurance Coordinator
<b>RAO</b>	Research Administration Officer
<b>RCHSD</b>	Rady Children's Hospital, San Diego
<b>RTA</b>	Ready to Accrue letter
<b>SOC</b>	Standard of Care
<b>SOM</b>	University of California, San Diego, School of Medicine
<b>SRS</b>	Safety Reporting System
<b>UC</b>	University Of California
<b>UCSD</b>	University of California, San Diego
<b>UCSDHS</b>	University of California, San Diego Health System