Rady Children's Hospital-San Diego
Research Handbook

December 2020

Rady Children's Research Administration Mission Statement
Our mission is to provide professional, efficient customer service to the pediatric research community and to facilitate collaboration and coordination of services within the integrated research enterprise while promoting fiscal responsibility and maintaining the highest ethical standards.

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Contents

A. INTRODUCTION

Any research-related activity conducted on the Rady Children's Hospital (RCHSD) campus or involving RCHSD patients, data, or resources, requires RCHSD Research Administration review and approval before the project can start.

This handbook provides information about how to carry out research at RCHSD from study planning and start-up to study close-out.

We encourage you to visit our RCHSD Research Administration intranet page. There you will find the latest announcements, forms, research policies and procedures, and information about upcoming seminars.

For questions about anything in this Handbook, please contact Research Administration at research@rchsd.org.

B. GENERAL INFORMATION

1. Relationship between RCHSD and UCSD

In 2001, RCHSD and UCSD signed the Joint Powers Affiliation agreement. Although the institutions remain separate, we work collaboratively on research. This means that:

- All human-subjects research conducted at RCHSD is reviewed by the UCSD Human Research Protection Program (HRPP), including studies by RCHSD/CSSD investigators who are not employed by UCSD.
- Issues related to protection of RCHSD health information that are not reviewed by UCSD HRPP are reviewed by RCHSD's Privacy Board, under the guidance of the Privacy Rule. This includes Preparatory-to-Research activities, Decedent Research, and Case Reports.
- For investigators who are not UCSD employees, RCHSD Research Administration submits proposals, negotiates and processes awards on their behalf.
- For UCSD-employed investigators, UCSD central offices submit proposals and negotiate and process awards. UCSD then flows down the terms and funding to RCHSD.

This Handbook will provide information explaining the processes in more detail.

2. Responsibilities of a Principal Investigator

Principal Investigator (PI) in this Handbook refers to the RCHSD PI. If a PI at UCSD is not eligible to be a PI at RCHSD, the RCHSD PI is the individual who agrees to assume oversight responsibility for all activities at RCHSD.

The Principal Investigator is responsible for:

- All aspects of their research happening at RCHSD. PIs will be held accountable for any compliance violations.

- Following all RCHSD and Institutional Review Board (IRB) policies and procedures. This includes, but is not limited to, ensuring that IRB consent/assent and HIPAA Use & Authorization forms are completely filled out and are filed in the patients' medical records.
- Notifying Research Administration of any changes in use of resources at RCHSD.
- Conducting the project according to the approved IRB protocol and the statement of work or the terms and special conditions published in the award agreement and the study protocol.
- Notifying the appropriate administrative offices at RCHSD and UCSD of any proposed changes in the scope of the project, change or absence of PI, changes in budget, period of performance, etc.
- Obtaining proper training for him/herself and his/her research team to work effectively within the IRB guidelines and within RCHSD policies and standard operating procedures.
- Supervising expenditures in conformity with the budget approved by the sponsor. Budget shortfalls are the PI's responsibility and must be addressed immediately.
- Writing and submitting progress reports as stipulated by the sponsor in the award agreement.
- Completing the final technical report and submitting it within the time and in the format specified by the sponsor. Failure to submit timely technical reports can penalize the institution as a whole by possibly making RCHSD/UCSD ineligible to receive new awards.

Industry sponsors require that the PI sign the FDA Form 1572. This form has two purposes: 1) To provide the sponsor with information about the investigator's qualifications and the clinical site that will enable the sponsor to establish that the investigator is qualified and the site is an appropriate location at which to conduct the study, and; 2) To inform the investigator of their obligations and obtain the investigator's commitment to follow pertinent FDA regulations.

Investigators should complete the form as accurately as they can. Investigators should be aware that making a willfully false statement is a criminal offense under 18 U.S.C. 1001.

The form can be accessed at http:///www.fda.gov. Below is a copy of the commitments as described in section 9 of the form:

STATEMENT OF INVESTIGATOR (FDA 1572 form)
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312):

Principal Investigator:

- Agrees to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.
- Agrees to personally conduct or supervise the described investigation(s).
- Agrees to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.
- Agrees to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. Has read and understands the information in the investigator's brochure, including the potential risks and side effects of the drug.
- Agrees to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.
- Agrees to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

- Ensures that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation.
- Agrees to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
- Agrees to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

Frequently asked questions, such as, "does a Pharmacist need to be listed on the 1572?" can be found in the FDA guidance document.

3. Principal Investigator Eligibility

a) General Requirements

PIs must meet any one of the following criteria (RCHSD Policy CPM 11-92):

- Physician member of the RCHSD Medical Staff with hospital-active status and clinical privileges consistent with the activities of the research project, or
- Scientific member of the RCHSD Medical Staff, or
- Full-time physician with Rady Children's Specialists of San Diego (RCSSD) who provides services on behalf of the Medical Practice Foundation; or
- RCHSD employee; or
- Investigator in the Child & Adolescent Services Research Center (CASRC) who is conducting a project within the auspices of CASRC

Investigators who do not meet eligibility criteria must identify an RCHSD-eligible investigator. The RCHSD-eligible investigator, who acts and serves as the "on-site" PI of record, assumes full responsibility for the research project and is subject to the roles and responsibilities as defined in this policy.

Note: Trainees, including Fellows and Residents are not eligible to serve as a PI at RCHSD

b) Principal Investigator Eligibility for Drug and Device Studies

The PI for drug and device studies must be an active physician member of the RCHSD Medical Staff. Physician extenders (e.g., nurse practitioners, physician assistants) cannot serve as the Principal Investigator for drug and device studies.

Investigators who do not meet eligibility criteria must:

- Identify an RCHSD-eligible investigator who will assume responsibility for the conduct of the research at RCHSD and will oversee all aspects of the study as it relates to RCHSD.
- Include the identified RCHSD-eligible investigator in the Institutional Review Board research plan.

c) Request for Exceptions

By exception, the Sr. VP/Chief Operating Administrative Officer may approve an exception of PI eligibility status in special circumstances when the individual is highly qualified and when such action is in the best interest of RCHSD. For assistance with and access to the Exception to Policy Request form, please contact Research Administration at research@rchsd.org.

Previous approval of an exception of Principal Investigator status is not a prima facie guarantee of approval of subsequent requests for exceptions.

d) Principal Investigator Eligibility at UCSD

Not all employees of the University are eligible to submit proposal for extramural support. See UCSD PPM 150-10 to learn which employee job titles (appointment titles) are automatically eligible and what the process is for submitting a PI exception requests.

4. Industry-Initiated vs. Investigator-Initiated Clinical Trials

Summary of differences between Industry-initiated and Investigator-initiated clinical trials

Categories	Industry-Initiated Clinical Trial	Investigator-Initiated Clinical Trial
Human subjects	Yes	Yes
FDA regulated	Yes	Yes
FDA phase	Phase I, II, III, and IV	Usually Only I or II
Multi-centers	Usually	Unlikely
IND (FDA 1571)	Submitted to FDA by sponsor	Submitted to FDA by faculty sponsor-Investigator
Drug or Device	Proprietary Drug or Device Provided by sponsor	Not necessarily provided by sponsor
Investigator's brochure	Provided by sponsor	Not required
Protocol and protocol revision(s)	Authorized and issued by sponsor, or contributions made by Investigator	Conceived and designed by Investigator
Clinical Trial Monitor	Assigned by sponsor	None
Case Report Form (CRF)	Must be submitted to sponsor	Generally not submitted to sponsor (not required in Phase I)
Ownership/access to records	Sponsor may own or have access	University or RCHSD owns; sponsor may access to de-identified patient information
Intellectual Property rights	Sponsor owns inventions conceived and reduced to practice in the direct performance of the study	University or RCHSD retains title to inventions; sponsor may be granted first right to negotiate an exclusive license
Financial terms	Usually fixed payment based upon performance (e.g. # enrolled / case report forms / completions)	Except as may be approved by the department: 25% of Year 1 budget upon receipt of a fully-executed agreement, then either quarterly payments or payment due based on participant enrollment
Data	Sponsor owns CRFs	In general, not submitted to sponsor. Sponsor receives report of the results
Informed Consent	UCSD/RCHSD Standard – Sponsor pays for injury	Non Standard – University/RCHSD covers cost of treatment for injury resulting from participation in the study
Indemnification	Sponsor Assumes Liability	University/RCHSD Assumes Liability (sponsor has product liability)

Subject injury	Sponsor must reimburse University/RCHSD for cost of care	University/RCHSD covers cost of care
Direct costs	Sponsor covers all direct and indirect costs of the trial	Sponsor covers all direct and indirect costs of the trial
Indirect costs	30% of total direct cost	Actual UCSD Federally Negotiated rate total modified direct costs
Accounting	RCHSD PeopleSoft # set up by Research Administration UCSD Index set up by OCTA	RCHSD PeopleSoft # set up by Research Administration Index set up by OPAFS
Required Forms	RCHSD Project Initiation Form UCSD Forms: CTA Request Form (replaced by ePD in most departments) Billing Addendum 700U HIPAA Budget	RCHSD Project Initiation Form UCSD Forms: RES Form (replaced by ePD (electronic Proposal Development in most departments) 700U HIPAA Budget Copy of Completed Bulk Application (if cost, such as labs etc. are incurred related to patient visit) Protocol (Statement of Work)
Authorized RCHSD Administrative Office	Research Administration	Research Administration
Authorized UCSD Administrative Office	Industry-Initiated Clinical trials are processed and negotiated by the Office of Clinical Trials Administration (OCTA).	Investigator-Initiated Clinical Trials are processed and negotiated by the Office of Contract & Grant Administration (OCGA).

5. What Do All the Numbers Mean?

Institution	Description	Example
RCHSD		
Research Administration number (aka “RAMP number”)	4-digit number that identifies the study at RCHSD ➔Include this # in the subject headers of all emails to enable Research Admin to identify the study.	1234 (4 digits)
Epic research number	Use this number to: • Link subjects with studies in Epic. • Link research visits, tests, and procedures to the study so visits can be tracked and charges billed to the study.	789 (2, 3, or 4 digits)
PeopleSoft number	This number is used for charging personnel effort and research costs to the study.	RC100 4010 9999 PCINT 1234567 AWD (28 characters)
UCSD		
Index number	Each funded project is assigned an Index #, which allows charges for staff salaries and other research costs to be captured and for sponsor payments to be recorded.	PEDJB10
RES number / UCSD number	8-digit number that identifies each funded project. This number is assigned when the RES (Request for Extramural Support) or CTA (Clinical Trial Agreement) request form or the new ePD (electronic Proposal Development) record is submitted.	20152547
IRB number	A UCSD Institutional Review Board number is assigned when the IRB protocol and supporting documents are uploaded to the UCSD IRB.	209999 (6 digits)

6. Key Contacts at RCHSD and UCSD

Contacts	Description	Contact Info
Central Offices		
RCHSD	Research Administration	Director: Joey Principato Email: research@rchsd.org Phone: 858-966-5934 Intranet:
	Research Compliance	Program Manager: Venise Shazier Email: researchcompliance@rchsd.org Phone: 858-966-5972
	Privacy Board	Chair: Venise Shazier Email: vshazier@rchsd.org Phone 858-966-5972 Vice Chair: Christina Galbo Email: cgalbo@rchsdRady Children's.org
	Research Integrity Officer	Sr. VP/Chief Medical Officer: Irvin Kaufman, MD Email: ikaufman@rchsd.org Phone: 858-966-4001
	Center for Pediatric Clinical Research (CPCR)	Manager: Joan Pancheri, RN Email: jpancheri@rchsd.org Phone: 858-966-6264
	Clinical Research Navigation	Clinical Research Navigator: Cassidy Callahan Email: ccallahan@rchsd.org Phone: 858-966-8841
UCSD	Office of Clinical Trial Administration (OCTA); processes Industry-initiated clinical trials	Assistant Director, Industry Contracts: Lauren Sanfilippo, lsanfilippo@health.ucsd.edu Email: octa@ucsd.edu
	Office of Contract and Grant Administration (OCGA); processes Investigator-initiated and NIH sponsored Clinical Trials	Assistant Vice Chancellor Contracts & Grants / Executive Director Sponsored Research Administration: Ross Dammann Phone: 858-534-0240 Email: rtdammann@ucsd.edu
	Altman Clinical and Translational Research Institute (ACTRI)	Director: Gary Firestein, MD Phone: 858-657-5143 Email: transmed@ucsd.edu
	Human Research Protection Program (HRPP)	Director: Kip Kantelo Phone: 858-246-4777 Email: kkantelo@health.ucsd.edu
	Research Compliance Program (RCP)	Interim Chief Compliance and Privacy Officer: Cheryl Wagonhurst, JD Phone: (858) 657-7487 hscomply@health.ucsd.edu
	Health Sciences Sponsored Project Pre-Award Office (HSSPPO) Reviews and submits proposals to NIH and AHRQ for UCSD Health Sciences Faculty	Erika Wilson, Senior Director Email: eswilson@ucsd.edu HSSPPO email: vchsgrants@ucsd.edu
	Vice Chancellor for Research and Research Integrity Officer	Dr. Sandra A. Brown Email: sandrabrown@ucsd.edu Phone: 858-534-3526

Other Helpful Contacts		
Inter-Institutional Liaison	Assistance with inter-institutional issues and process improvements	Vice Chair of Clinical Research for the Dept. of Pediatrics at UCSD and Rady Children's Hospital.: Christina Chambers, PhD, MPH Email: chchambers@health.ucsd.edu
For Junior investigators	Assistance for junior investigators in navigating through the clinical research pathways	Director of Division of Clinical Research: Michael Ziegler, MD Email: mziegler@health.ucsd.edu
Investigator-initiated trials	Assists with questions regarding Investigator-initiated trials and INDs.	Clinical Research Navigator: Cassidy Callahan Email: ccallahan@rchsd.org Phone: 858-966-8841
UCSD Profiles	A Research Networking and Expertise Mining Tool	

7. Research Resources Summary

a) RCHSD and UCSD collaborate to provide many resources to investigators.

See the summary table below.

Resources	Description	Links and Contact Information
Statistics and Data Bases, Extraction and Management / Subject Recruitment		
Clinical Trial Alerts	RCHSD Research Informatics Analyst can assist with creating Clinical Trial Alerts out of Epic. Note: Your Project must have IRB approval	Submit an Informatics request
	Cogito Slicer Dicer for Cohort Identification. Identified data can be accessed with IRB approval	Submit an Informatics request
	An Informatics Analyst assists with creating EPIC reports, using Clarity and/or Reporting Workbench; study enrollment alerts, templates for research documentation such as Smart Forms. Note: Your project must have IRB approval.	Submit an Informatics request
	UC ReX Cohort identification, allowing users to perform an UC-wide search on a de-identified repository to determine the existence of a set of patients meeting certain inclusion or exclusion criteria	https://myresearch.ucsf.edu/uc-rex
Clinical Record Management	Velos eResearch software system for managing clinical trials	https://medschool.ucsd.edu/research/actri/Informatics/velos/Pages/default.aspx
Research Data Base	REDCap Research Electronic Data Capture is a secure, web-based application for building and managing online surveys and databases.	RCHSD-hosted REDCap: Submit an Informatics request. UCSD-hosted REDCap
PHIS Database	The Pediatric Health Information System (PHIS), a comparative pediatric database managed by the Children's Hospital Association, includes clinical and resource utilization data for inpatient, ambulatory surgery, emergency department and observation unit patient encounters for 45 children's hospitals.	Submit an Informatics request
Statistical support	Basic biostatistical assistance is available at no cost to Rady Children's investigators, including fellows and residents for: Study design and proposal writing; Study implementation and management; Statistical analysis; Publishing	To request biostatistical assistance from the UCSD Altman Clinical & Translational Research Institute (ACTRI), access the service-request form.
Pre-Award Services		
Budget Preparation and/or Negotiation	**RCHSD** Research Administration assists with Rady-based cost in all budgets and negotiates budgets with sponsors for projects by non-UCSD investigators	Email: research@rchsd.org
	UCSD Pediatrics Office assists with preparation of budgets for UCSD Pediatrics investigators	Christine Moran, Department of Pediatrics, Director Sponsored Projects & Clinical Operations Phone: 858-246-0026 |

		Email: clmoran@health.ucsd.edu
	UCSD OCTA assists with preparation of budgets of industry initiated clinical trials for all non-Pediatrics UCSD Faculty	Email: OCTA@health.ucsd.edu
	UCSD Business Offices / Fund Managers assist with budget preparations for all investigator-initiated projects.	Contact your Fund Manager or your Department Business Office for contact information
Proposal preparation and submission	**RCHSD** Research Administration assists with proposal preparation and obtains institutional approval for submission of proposal by RCHSD/CSSD PIs.	Email: research@rchsd.org
	UCSD Departmental Business Office assists with proposal preparation and works with UCSD central office (OCGA or HSSPPO) to obtain institutional approval for submission of proposal	Contact your Fund Manager or your Department Business Office for contact information
	Fund matching for grants or philanthropy is offered as part of the clinical research navigation services	Cassidy Callahan, Clinical Research Navigator Phone: 858-966-8841 Email: ccallahan@rchsd.org
Grant editing / Proposal design assistance	**UCSD** Department of Pediatrics: The Senior Writer assists with editing your NIH grant proposals.	Jouni Vesa, Senior Writer Email: jvesa@ucsd.edu
	UCSD ACTRI provides proposal design assistance.	https://medschool.ucsd.edu/research/actri/clinical/clinical-resources/Pages/Design.aspx
	UCSD RAPIDS provides full-scale assistance for selected, large, interdisciplinary proposals. For other proposals, RAPIDS offers limited help. For all engaged in proposal development, RAPIDS provides proposal preparation advice and example text that can be adapted for use in proposals	Email: researchdevelopment@ucsd.edu https://blink.ucsd.edu/research/finding-funding/rapids.html
Industry-Initiated Clinical Trials	**RCHSD Assistance** responding to Industry-Initiated Clinical Trials Inquiries/Questionnaires	Cassidy Callahan, Clinical Research Navigator Phone: 858-966-8841 Email: ccallahan@rchsd.org
"Facilities Form/Resources " Information for grant proposals	This Facilities Form/Resources page can be used for grant proposals.	Available on the RCHSD Intranet
Contract Negotiations, including Confidentiality Agreements (CDA)	RCHSD Research Administration negotiates agreements for non-UCSD faculty	RCHSD Research Administration email: research@rchsd.org
	UCSD OCTA negotiates all agreements for UCSD industry-initiated clinical trials	Phone: 858-822-2940 Email: OCTA@health.ucsd.edu https://medschool.ucsd.edu/vchs/research-services/octa/Pages/default.aspx
	UCSD OCGA negotiates all agreements for UCSD investigator-initiated projects	See Staff Assignments at: http://blink.ucsd.edu/sponsor/ocga/staff-assignments.html Phone: 858-534-3330 Email: ocgainfo@ucsd.edu https://blink.ucsd.edu/sponsor/ocga/
Human Subjects Protection		
UCSD Human Subjects Protection Program (HRPP or IRB)	UCSD IRB reviews all Human Research Activities that are conducted on the RCHSD campus regardless of Investigator's affiliation with UCSD or RCHSD.	Forms for UCSD-salaried faculty where RCHSD is a performance site: https://irb.ucsd.edu/Forms.shtml
		Forms for RCHSD researchers who have no affiliation with UCSD where RCHSD is the performance site: https://irb.ucsd.edu/RCHSD-only-Forms.shtml
		Guidance and link to Forms for Quality Improvement / Quality Assurance Projects: https://irb.ucsd.edu/EBP_QA_QI_factsheet.pdf
RCHSD Privacy Board	Reviews projects that are not considered Human Subject Research at UCSD HRPP such as:	Instructions and forms

	- Preparatory Research Activity - Case Reports - Decedent Projects	
Study-related services		
Study Coordination	**RCHSD** Research Nurse Coordinators and non-RN Study Coordinators assist with IRB submissions and coordinate all phases of a study. Hourly recharge in 15-minute increments: • Industry Initiated Clinical Trials: $125 (starting negotiated rate) • Investigator Initiated Study: Actual Coordinator salary rate is used.	Joan Pancheri, Research Nurse Manager, Email jpancheri@rchsd.org Emily Ewing, Research Coordinator Supervisor, Email eewing@rchsd.org
	UCSD ACTRI Research Coordinators (non-RNs) and Research Nurses are available through the UCSD Altman Clinical & Translational Research Institute on a re-charge basis.	Requests are submitted through the ACTRI website at https://medschool.ucsd.edu/research/actri/clinical/clinicalservices/Pages/StudyCoordin.aspx
	UCSD ACTRI Red Team provides project management to UCSD faculty projects.	Email: redteam@ucsd.edu
Study Conception	Clinical research navigation services are available to help you conceptualize your next study.	Cassidy Callahan, Clinical Research Navigator Phone: 858-966-8841 Email: ccallahan@rchsd.org
RCHSD Investigational Drug Service	Stores and dispenses investigational product	Email: RxInvestigationalDrugs@rchsd.org
RCHSD Research Intranet	Contains information for moving your project forward at RCHSD, forms, upcoming events, tip sheets, and policies	http://intranet.rchsd.org/categories/departments/research
	Responding to Industry-initiated Clinical Trial Inquiries	Cassidy Callahan, Clinical Research Navigator Phone: 858-966-8841 Email: ccallahan@rchsd.org
	Budget Worksheet template will help you develop your RCHSD study budget.	http://intranet.rchsd.org/categories/departments/research/forms-resources-research
Support with Post Award Services		
Post Award	**RCHSD** Research Administration reviews project-specific RCHSD cost/expenditures and provides monthly expenditure reports on awards issued to RCHSD. RCHSD Accounting invoices the sponsor (UCSD or other) generally on a monthly basis.	Jeanne Barnes, Grants & Contracts Administrator. Phone: 858-966-6742 Email: jbarnes@rchsd.org
	The **UCSD** Fund Manager reviews project specific expenses, invoices and reconciles payments from sponsor and issues payment to RCHSD for services provided.	Contact your Fund Manager or Department Business Office.
Specimen Collection, Processing and Storage		
Collection	**RCHSD** Research Nurses or RCHSD Lab assist with blood draws	Contact Research Administration Email: research@rchsd.org
Processing	Research Nurses have access to refrigerated and unrefrigerated centrifuges in the Research Lab for processing.	
	RCHSD/UCSD Biorepository assists with specialized processing	Contact rcucsd.biobank@ucsd.edu
Storage	Short-term: Ultra-low freezer and refrigerator-freezer with Isensix temperature monitor are available in RCHSD Research Lab for temporary specimen storage until specimens can be shipped out.	Contact: Research Administration Email: research@rchsd.org
Long Term / Biorepository	The Rady Chilldren's Institute for Genomic Medicine Biorepository serves as the centralized biospecimen processing and clinical data acquisition center. The main function of the Biorepository is to collect and store high-quality biospecimens using stringent standard operation	Shareef A. Nahas, PhD, FACMG, CGMB, Senior Director of Clinical Operations Rady Children's Institute for Genomic Medicine Email: snahas@rchsd.org Phone: (858) 966-8391 https://medschool.ucsd.edu/som/pediatrics/research/ucsd-rd-biorepository/Pages/default.aspx

	procedures and to provide researchers biospecimens and related derivatives that best meet their research requirements.	
Education / Training		
RCHSD Research Education Programs	The RCHSD intranet Research home page lists upcoming seminars and symposia.	Cassidy Callahan, Clinical Research Navigator Phone: 858-966-8841 Email: researcheducation@rchsd.org http://intranet.rchsd.org/categories/departments/research/research-admin-announcements
UCSD Research Training Programs	The UCSD ACTRI offers a structured training program in clinical research called "Clinical Research Enhancement through Supplemental Training (CREST Program)."	https://medschool.ucsd.edu/research/actri/education/crest-program/Pages/default.aspx
	UCSD offers a Master of Advanced Studies in Clinical Research.	https://clre.ucsd.edu/
	UCSD offers a variety of online and in-person compliance training opportunities.	http://blink.ucsd.edu/research/policies-compliance-ethics/training.html

b) RCHSD Research Administration Intranet Site

Research Administration makes the following information available to individuals logged onto the RCHSD network.

Information available to users logged onto the RCHSD network	
Research Administration Department intranet page	• Information about compliance, resources, tip sheets, and upcoming seminars. • Forms • Polices and Procedures:
Active studies at RCHSD (Requires RCHSD Intranet access)	• Allows users to search for studies being conducted at RCHSD • Investigators and their coordinators can access the IRB, PeopleSoft and Epic numbers #'s for each of their studies. http://radyspf/sites/research/SitePages/Landing%20Page.aspx

8. RCHSD Research Forms

The following Research Administration forms are available on the Intranet Research Forms page.

- Budget Worksheet Template
- Project Initiation Form
- Research Progress Note–Study Entry–Template
- Research Progress Note–Study Re-Consent–Template
- Research Specimen Submission Form (For inclusion with research specimens sent to Lab/Pathology)

9. UCSD Research Forms

Forms can be found on the websites of each of the UCSD Central Offices (OCGA, OCTA, COI). We suggest you contact your Business Office Fund Manager or the Health Sciences Core for assistance with the appropriate forms required for UCSD.

C. STUDY PLANNING AND START-UP

This section discusses funding opportunities for your studies, proposal development, investigator- and industry-initiated studies, as well as IRB and Privacy Board submissions. In order for your study to commence at RCHSD, Research Administration will review the project and once review is finalized, issue a Ready-to-Accrue Letter (RTA). **Without an RTA, a study cannot start at RCHSD**.

1. Funding Your Investigator-Initiated Project

Below is a list of funding opportunity resources; however, this is not a comprehensive list of all funding opportunities.

a) RCHSD/RCSSD Funding Opportunities

RCSSD Physician Development Fund	Dr. Robin Steinhorn Email: rsteinhorn@rchsd.org
Internal funding opportunities	Cassidy Callahan, RCHSD Clinical Research Navigator Email: ccallahan@rchsd.org

b) UCSD Funding Opportunities

Pediatrics Intramural Clinical Grants	Michael Gottschalk, MD, PhD Email: mgottschalk@rchsd.org
ACTRI funding opportunities such as various Pilot Projects, Academic-Community, External Funding Opportunities, Pfizer collaboration Projects	Murray Stein, MD, Director of ACTRI Pilot Project Funding Email: mstein@ucsd.edu https://medschool.ucsd.edu/research/actri/funding/Pages/default.aspx
UCSD Intramural Genomics Award	Kelly Frazer, PhD Email: kafrazer@ucsd.edu
Moores Cancer Center Grants and Funding: Office of Grant Development	Angela Ballantyne, PhD aballantyne@ucsd.edu
UCSD Academic Senate Funding	http://senate.ucsd.edu/grants-awards/grant-funding/
UCSD Young Investigator Funding Opportunities	https://foundationrelations.ucsd.edu/funding-opportunities/young-investigators.html
UCSD Corporate Foundation Relations	Assists with funding opportunities for Investigator-initiated projects. https://foundationrelations.ucsd.edu/
UCSD Limited Submissions Funding	http://blink.ucsd.edu/research/finding-funding/lim-sub.html lists all sponsors that have a limited submission policy (only a limited number of applications per institution are allowed). Your proposal is reviewed and selected by the Limited Submission Committee and the successful candidates are invited to submit a proposal to the sponsor.
UCSD Office of Research Affairs Website	http://blink.ucsd.edu/research/finding-funding/index.html

c) Federal Funding Information

NIH funding	Search for funding: http://www.grants.gov/web/grants/search-grants.html

d) Non-Profit Foundations

Rady Children's Hospital Foundation	https://www.radyfoundation.org/ Rady Children's Hospital Foundation raises over $34 million in gifts to support research, treatment and education to improve the life of every child we serve. Contact ccallahan@rchsd.org for more information on how research is supported by the Foundation.
Patient Centered Outcomes Research Institute (PCORI)	http://www.pcori.org/funding-opportunities PCORI, Patient-Centered Outcomes Research Institute, an independent nonprofit, non-governmental organization located in Washington, DC Their mandate is to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers to make informed health decisions. Specifically, they fund comparative clinical effectiveness research, as well as support work that will improve the methods used to conduct such studies
Hartwell Foundation	http://www.thehartwellfoundation.com/. The Primary Mission of The Hartwell Foundation is to grant awards to individuals for innovative and cutting-edge biomedical applied research that will potentially benefit children. The general aim is to provide funds for early stage research projects that have not yet qualified for funding from traditional sources. Applications are reviewed by UCSD Limited Submission Committee. Further information can be found at: UCSD Limited Submissions
Autism Speaks	https://www.autismspeaks.org/research Autism Speaks supports global biomedical research into the diagnosis, causes, prevention, and treatment of autism or its disabling symptoms.

	Their mission is to improve the future for all who struggle with autism spectrum disorder.
Robert Wood Johnson Foundation	The Robert Wood Johnson Foundation supports research and programs throughout the nation which are working to build a 'Culture of Health.' Funding Opportunities: http://www.rwjf.org/en/how-we-work/grants/funding-opportunities.html
American Heart Association	The AHA is the largest non-profit funding source for cardiovascular and cerebrovascular disease research next to the federal government. https://professional.heart.org/en/research-programs
Cystic Fibrosis Foundation	The CF Foundation supports a wide range of innovative research programs to discover and develop new and effective CF therapies. https://www.cff.org/Our-Research/For-Researchers/

2. Proposal Development

- For Investigators who are not employed by UCSD ("RCHSD/CSSD-employed investigators"), RCHSD Research Administration submits funding proposals and negotiates budget, contracts, and agreement.
- For UCSD-employed Investigators, UCSD submits funding proposals and negotiates budgets, contracts, and agreements.

a) RCHSD/CSSD-Employed Investigators

RCHSD Research Administration will assist with budget and proposal preparation, and routing for approval and submission of proposal. **Do not submit a proposal to the sponsor without RCHSD Institutional Official review and approval.**

b) UCSD-Employed Investigators

Your Business Office Fund Manager/Health Sciences Core will assist you with the preparation of UCSD forms, sponsor budget and submission to the UCSD Central Office for review and submission to the sponsor. RCHSD Research Administration will supply the budget numbers for any RCHSD-related costs, such as staff, pharmacy, and lab tests.

UCSD HSSPPO or OCGA will review your proposal and submit to the sponsor. Do not submit a proposal to the sponsor without UCSD Institutional Official review and approval.

- UCSD OCGA and HSSPPO Forms: RES, 700 U, PI Exception, NIH Proposal Forms, etc. **Note**: The paper forms have been replaced with ePD. Contact your Department Business Office for more information.
- UCSD OCTA Forms: Clinical Trial Agreement Request Form, 700 U, etc. **Note**: The paper forms have been replaced with ePD. Contact your Department Business Office for more information.

c) Assistance with Protocol Design

Experienced clinical investigators are available to assist with protocol design at the UCSD Altman Clinical and Translational Research Institute. Submit a Request for Services..

d) Assistance with Proposals

Jouni Vesa, Senior Writer at UCSD, assists with editing NIH grant proposals. Email: jvesa@ucsd.edu.

e) Statistical Support

Biostatistical assistance for studies conducted at RCHSD is available through UCSD's ACTRI at no cost for study design and proposal writing, study implementation and management, statistical analysis, and publishing. For more information, submit a service request..

Requests for biostatistics faculty support of larger collaborative projects and grant submissions can be directed to Dr. Karen Messer, Division Chief, at kmesser@ucsd.edu, for triage to biostatistics faculty.

f) Budget Development

- All research costs involving RCHSD services and personnel must be covered by the study budget or by departmental manager approval.
- For RCHSD-employed investigators, Research Administration will assist with budget development.
- UCSD-employed investigators must work with their respective UCSD fund managers to develop the budget. RCHSD's indirect rate of 3.32% is charged only on RCHSD personnel effort (salary and benefits).
- An RCHSD budget worksheet template is available.
- Work with your UCSD fund manager, who will contact RCHSD Research Administration about the RCHSD budget.

Budgets are a crucial part of a project and require diligent scrutiny. A budget that does not correctly reflect the cost of the project is a huge strain on all involved. Investigators are responsible for any financial shortfalls in their projects. Last-minute requests for an RCHSD budget cannot be accommodated.

The cost elements of a budget must be those necessary to accomplish the proposed activity. Cost estimates of individual line items should be carefully calculated so that the requested funds are adequate, but not excessive. As you develop your budget, it is important to keep in mind that sponsored project costs fall into two broad categories: Direct Costs and Facilities and Administration ("F&A") costs ("indirect costs" or "IDC").

g) Direct Costs

Generally, direct costs are those which can be specifically identified and allocated to a single sponsored project, such as:

h) Salaries and Wages / Fringe Benefits

Current salary figures and fringe rates can be obtained from RCHSD Research Administration for RCHSD staff or from the UCSD departmental Business Office for UCSD staff.

i) Equipment

Only items costing $5,000 or more, each with a useful life of one year or more, should be listed here. Cost estimates should include any tax, shipping and installation costs associated. Parts or pieces of equipment to be fabricated (totaling $5,000 or greater) should also be included in this category. Don't include maintenance contracts or estimated cost of repairs.

j) Travel

Think about who will travel and why. Be sure that the travel will tangibly benefit your research program, and think carefully about potential costs for your proposed travel. Remember to include registration

fees, roundtrip airfare and baggage fees, roundtrip ground transportation between the airport and hotel, hotel guestroom costs, including taxes, and meals.

- RCHSD Per diem rates: Policy CPM 7-33
- UCSD Per diem rates: Per Diem Rates

k) Materials and Supplies

This should be the PI's best estimate or the catalog price, plus tax (if applicable), and shipping costs for each item.

l) Pharmacy Costs

For RCHSD/CSSD investigators, Research Administration will obtain RCHSD Pharmacy costs (start-up, dispensing, close-out, etc.).

For UCSD investigators, the fund manager should contact the RCHSD Research Administration pre-award Grants & Contracts Coordinator for prices at research@rchsd.org.

m) Research Procedure Costs

For RCHSD/CSSD investigators, Research Administration will obtain RCHSD procedure costs.

For UCSD investigators, the fund manager should contact the RCHSD Research Administration pre-award Grants & Contracts Coordinator for prices.

The UCSD fund manager can use the form below to request prices.

Request for research price		
RCHSD 4-digit project #		
CPT code if applicable	Test/Procedure Name or other Item	Leave blank (Research Admin will add the research price)

n) Lab Tests

Resources for looking up lab tests:

- RCHSD Lab Test Dictionary at http://labtests.rchsd.org/.
- Department's billing slip (what physicians fill out when they see patients or want to order a test) includes CPT codes and CPT names.
- If you still cannot find the CPT code, please include as much detail as possible under Procedure Name in the table above and ask your fund manager to submit it to the RCHSD pre-award Grants & Contracts Coordinator.

o) Professional Fees

The Research Administration pre-award Grants & Contracts Coordinator can obtain the professional fee for physician services for the following:

- Medical Practice Foundation
- San Diego Imaging
- Sharp-Children's MRI Center
  Anesthesia Service Medical Group Phone

p) IRB fees

The UCSD IRB does not charge a fee for investigator-initiated or NIH-funded projects. For industry-sponsored studies, see the IRB's review fee site..

q) Publications

This should be the Investigator's best estimate of page charges, etc. If there is a journal to which you are likely to submit a paper, check submission fees, publication charges, and if necessary, any fees for figures. This is a good start to a fairly accurate estimate of this expense.

r) Consultant and Contracted Services

This category consists of services rendered by others EXCEPT equipment rentals, repairs, and maintenance. It includes consultant/professional services, honorariums and speaker fees.

s) Subcontracts

For subcontracts with other institutions, follow these steps:

- Have each subcontractor prepare and submit a detailed budget and a scope of work.
- Each subcontract should be listed separately on your budget. Math on budgets submitted by subcontractors should be checked.
- If the subcontractor is requesting facilities and administration (F&A) costs include them as a direct cost to your budget under sub-contract costs.
- Ask the sub-contractor to send a letter of intent signed by their Institutional Official.

t) Communication

This includes telephone costs, postage, FedEx, advertising and associated costs.

u) Repairs and Maintenance

This includes costs of maintaining property (e.g., maintenance for office equipment and repairs of that equipment) and repairs to vehicles).

v) Participant Support Costs

This expense type is generally used on federal awards for the costs of the travel, meals and lodging of project participants; for example, the participants in a conference.

A budget narrative should follow your itemized budget to fully identify and explain unusual items or activities. For example, the need for the use of contracted services, use of sub-contractors or other collaborating organizations, items of equipment having a unit cost of $5,000 or more, or the necessity for foreign travel should be highlighted in the budget narrative.

w) Budget Items to Consider

See Section 4 on Industry-initiated Clinical Trials.

x) Costs for RCHSD Resources, Including Personnel

All RCHSD resources must be paid for by the study budget. Investigators who wish to utilize RCHSD-employed staff to support a project must either include the cost in the budget for personnel effort or have approval from each employee's Manager/Director for their departmental budget to cover employee's effort on the project.

y) Facilities and Administration (F&A) Costs / Indirect Cost (IDC)

Indirect costs, sometimes referred to as over-head or IDC or Facilities and Administrative Costs (F&A Costs) -- are those costs not specifically identifiable for any one project or program, but which are valid expenses of conducting research, instruction, and other sponsored activities. For example: use of the building, equipment depreciation, operation and maintenance of facilities, student services, departmental administration, or administrative support offices.

If payment of F&A costs is not allowed by the sponsor, or the sponsor has an established facilities and administration cost rate that is different from the federally-negotiated rate, a copy of the sponsor's statement to that effect should be attached to the Grant Proposal Submission Form when it is submitted to the RCHSD or UCSD Institutional Official for review and approval. Since the F&A cost rate is negotiated periodically with the U.S. Department of Health and Human Services, contact the pre-award office for the current rate before assembling your proposal budget.

Generally, the full federally-negotiated F&A costs will be applied on all proposals unless the sponsor prohibits these costs, has its own rates, or a different rate has been approved in advance by the pre-award office. In the case of the funding agency prohibiting F&A or having its own rates, please provide the policy guidelines from the agency stipulating this to your institutional contracts and grants office.

As a reminder, all costs in an industry-sponsored clinical trial are subject to the UCSD 30% indirect cost rate, including IRB review fees, invoiced items, and patient stipends.

z) For Questions on Indirect Costs Contact:

- RCHSD/CSSD-Employed Investigators

  RCHSD Research Administration at research@rchsd.org

- UCSD-Employed Investigators

  Information on the various Indirect Cost Rates for UCSD can be found here: https://blink.ucsd.edu/research/preparing-proposals/budgets/indirect.html.

  For additional questions contact:
  - OCGA for Federally-Funded or Investigator-Initiated projects
  - OCTA for Industry-Initiated projects

3. Investigator-Initiated Proposals for External Funding

a) Submitting a Proposal

For all proposals that include activities at the RCHSD campus, the completed RCHSD budget must be submitted to research@rchsd.org prior to proposal submission.

b) RCHSD/CSSD-Employed Investigators

Submit your proposal (draft of narrative final budget, and budget justification) to RCHSD Research Administration at research@rchsd.org at least 14 business days before the proposal submission due date for RCHSD Institutional Official review and approval. Once the proposal has been approved by the RCHSD Institutional Official, the final version of the proposal (including the budget and all supporting documents), will be submitted to the sponsor by the due date from RCHSD Research Administration.

c) UCSD-Employed Investigators

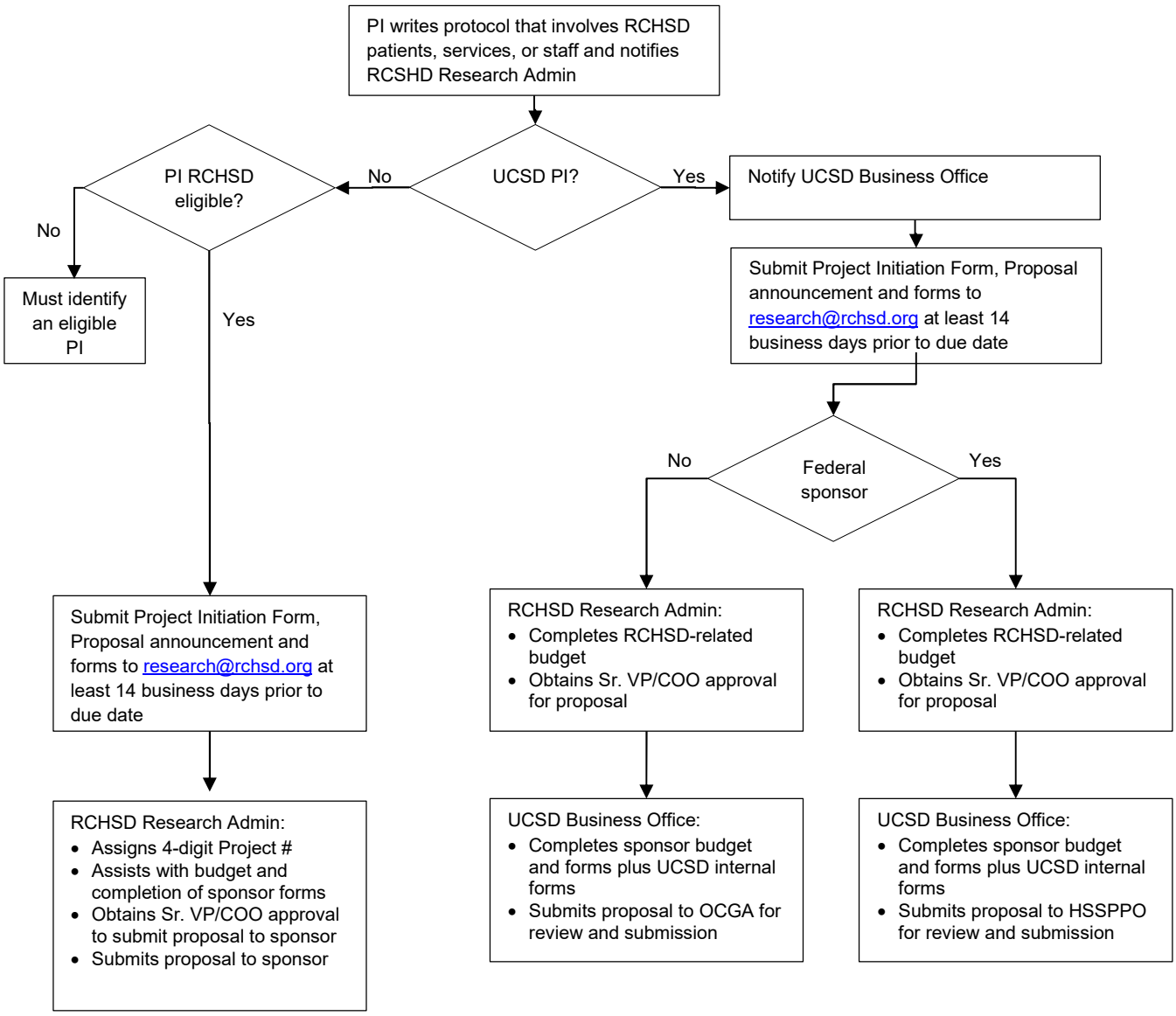
Work with your Business Office Fund Manager to create the proposal documents and budget. The proposal must be submitted to the UCSD Institutional Official (OCGA or HSSPPO) as per their guidelines:

- OCGA Timely Submission of Proposals
- HSSPPO Proposal Submission Policy

Generally, the Institutional Official at OCGA or HSSPPO will submit the proposal to the sponsor.

The flow chart on the next page explaining the process of submitting a proposal:

RCHSD/UCSD Proposal Submission Process



d) Award Announcement and Fund Set-Up

Typically, a funding agency will notify the Institutional Official regarding its decision on a proposal. Occasionally, however, the PI is contacted. Please remember that RCHSD Research Administration (for RCHSD/CSSD-employed Investigators) or UCSD OCGA (for UCSD-employed investigators) administers awards and handles contract negotiations.

If you receive an award announcement or contract (usually by email), forward the original award document to the appropriate office immediately (RCHSD Research Administration for proposals submitted through RCHSD or to the UCSD Fund Manager or UCSD OCGA for proposals submitted through UCSD). All awards must be processed through the appropriate Pre-Award Office before an award can be accepted and a subsequent account is opened.

e) RCHSD/CSSD-Employed Investigators

RCHSD Research Administration will set-up up a PeopleSoft # for your project once the award agreement is signed, the IRB has released the approval letter, and all RCHSD pending issues are resolved. The funds will be managed within RCHSD Research Administration and RCHSD Accounting will invoice the sponsor as per agreement terms.

f) UCSD-Employed Investigators

OCGA will initiate the set-up of a Fund # and Index # once the award agreement is signed. Depending on agreement terms, invoices are sent to the sponsor or the sponsor makes automatic payments. The Business Office Fund Manager will assist with invoicing and reconciliation.

In addition to the UCSD Fund # and Index #, RCHSD will set-up a PeopleSoft # for all RCHSD-related costs. Such costs may include RCHSD staff salaries, lab and pathology tests, and other research-related procedures. RCHSD accounting will invoice UCSD once a month for RCHSD costs.

4. Industry-Initiated Clinical Trials

a) How Does an Industry-initiated Trial Get Started?

A pharmaceutical company may contact the Investigator directly, or you may receive an email from the Clinical Research Navigator in RCHSD Research Administration that a pharmaceutical company is looking for investigators to conduct a clinical trial. The sponsor may ask the Investigator to sign a Confidentiality Agreement prior to reviewing the full protocol. When this occurs, the Clinical Research Navigator can facilitate the signing of the Confidentiality Agreement (CDA) with RCHSD Research Administration (for RCHSD/CSSD investigators) or the UCSD Fund Manager (for UCSD investigators). The CDA must be reviewed and signed by an institutional official at RCHSD or UCSD. Investigators should not sign the CDA themselves.

Industry sponsors will ask for a completion of a preliminary questionnaire to evaluate if the Investigator and site meet the basic requirements and if the patient population is available to conduct the study. After the questionnaire is completed, the sponsor will then arrange what is called the Site Evaluation Visit (SEV), Site Qualification Visit (SQV), or Site Selection Visit (SSV). The purpose of this visit is to determine if the Investigator and clinical site have the capability to conduct the study.

These visits usually last between 2 and 6 hours. During this visit, both the Investigator and a study coordinator must be available. The investigator generally spends 1 – 2 hours with the sponsor's representative to review the protocol and discuss any concerns. The sponsor's representative will usually request a tour of the facility and time to discuss the basic fundamentals of the protocol and how that relates to the feasibility of recruiting potential participants. An appointment with the RCHSD Investigational Drug Service Pharmacist needs to be arranged ahead of time if the study involves an investigational drug. This visit verifies that space, pharmacy, support staff, and the patient population are adequate to conduct the study. The sponsor will then decide if the site qualifies to conduct the study and will issue a formal letter within a couple of weeks approving the site selection.

For RCHSD-employed coordinators, their hours for the SEV, SQV, or SSV should be pre-approved by their Manager or Director.

Once a site is selected, the sponsor will send the contract, initial budget, and regulatory documents. Make sure you forward these documents to your UCSD Fund Manager or to RCHSD Research Administration.

The budget for the start-up and closing costs should be agreed upon before beginning any IRB work. When the start-up budget has been set, the research coordinator starts working on the IRB submission and regulatory documents, and the central office (UCSD or RCHSD) negotiates the contract and per-patient budget concurrently. After the budget has been agreed upon, the contract is signed, and IRB approval is obtained, the sponsor will set up the Site Initiation Visit (SIV). This is the visit where the entire study is reviewed in detail with all members of the study team. A visit with the research pharmacists needs to be scheduled as well.

b) Budget Development

Please review Section 2(f) for budget development and direct costs for proposals. Much of the costs are similar for investigator- and industry-initiated studies.

Be aware that various "hidden" costs can make your budget overrun in an industry-initiated clinical trial. When budgeting, consider including costs such as:

- Research staff time for blood draws on children (who are usually more difficult to draw then adults).
- Research staff time for sponsor monitoring visits;
- Training on the protocol for research staff including pharmacists, nurses, and therapists. (Consider that if someone leaves, the new research staff will have to be trained);
- Research staff time for creation of source documents (if sponsor doesn't provide);
- Research staff time for Investigator Meeting;
- Research staff time for AE (Adverse Events) and SAE (Serious Adverse Events) reports;
- Research staff time for answering queries;
- Research staff time for sponsor-initiated conference calls.

c) OCTA Budget Negotiation Fees

The fee for budgets negotiated by the OCTA budget team is $2,500 for new industry-sponsored clinical trial budgets and $1,000 for budget amendments. The OCTA budget service fee is built into the start-up costs to be paid by sponsors.

d) Pharmacy Fees

For RCHSD Pharmacy costs (start-up, dispensing, close-out, etc.), contact the RCHSD pre-award Grants & Contracts Coordinator at research@rchsd.org.

e) IRB Fees

A flat rate fee of $3,510 for an initial review and $3,510 for each 10-year "resubmission" (treated as a "new" project by the IRB) review and $1,300 for each annual continuing review are applied to Industry-initiated studies. These fees include the Indirect Cost of 30% and are based on the actual cost of services provided and on comparability with equivalent services provided by other UC campuses and commercial IRB organizations. The invoice for IRB review will be sent by the UCSD Office of Clinical Trial Administration to the sponsor, not to the Principal Investigator.

f) Indirect Costs

At UCSD, all costs in an industry-initiated clinical trial are subject to 30% indirect cost rate, including IRB review fees, invoiced items, and patient stipends. [Link]

RCHSD's indirect cost rate of 3.32% is charged only on RCHSD personnel effort (salary & benefits) on study budgets of UCSD-employed investigators. RCHSD charges the full indirect cost rate of 30% on industry-sponsored studies of RCHSD/CSSD-employed investigators.

g) Award and Fund Set-Up

- RCHSD/CSSD-Employed Investigators

RCHSD Research Administration will set-up a PeopleSoft # when the Project Initiation form is submitted in order to track the expenses that will be incurred during the start-up phase of the clinical trial. When the budget has been negotiated, the Clinical Trial Agreement (CTA) has been executed (signed by both parties), and the IRB has approved the study, Research Administration will manage the funds and invoice the sponsor according to the agreement terms.

- UCSD-Employed Investigators

When the budget has been negotiated, the Clinical Trial Agreement (CTA) has been executed (signed by both parties), and the IRB has approved the study, OCTA will initiate the set-up of the Index #. Your Business Office or Health Sciences Core Fund Manager will inform you of the Index #. Funds will be managed by your Business Office Fund Manager or the Health Sciences Service Core (please discuss with your Department Business Officer). Payments are usually made when milestones are reached and sent to OCTA. OCTA will inform your Fund Manager of receipt of funds.

RCHSD will set up a PeopleSoft # for each project (equivalent of the UCSD Index #) to capture the costs that incur at RCHSD (coordinator salaries, lab tests, procedures etc.) at the time when the Project Initiation Form was submitted in order to capture the cost that incurred during the start-up phase. Once the Procurement Service Agreement is signed with UCSD, RCHSD accounting will invoice UCSD on a monthly basis for RCHSD cost.

5. Obtaining Approval to Conduct Research at RCHSD

- ❖ RCHSD Research Administration approval is needed for any project that involves RCHSD patients, access to patient records, resources, personnel, an IRB application (even if the IRB certifies that the study does not involve human subjects research and does not require IRB review).
- ❖ Human subjects research cannot begin at RCHSD until Research Administration has issued a Ready-to-Accrue (RTA) letter.
- ❖ The first step in the RCHSD approval process is to submit a Project Initiation Form.
- ❖ Plan the study logistics in detail and consider all budgetary aspects of the study early on.

a) Industry-Initiated Clinical Trials

- RCHSD/CSSD-Employed Investigators:

What forms/documents are needed and where should they be submitted:

Activity	Submit to
RCHSD Project Initiation Form	RCHSD Research Administration
IRB Proposal	UCSD IRB
Any type of agreement	RCHSD Research Administration negotiates terms and obtains signatures from the Institutional Official

Industry sponsor's budget proposal	RCHSD Research Administration negotiates budget.

The sponsor will require that a Confidentiality Disclosure Agreement (CDA) be signed before the full protocol is made available for review and that a Site Evaluation Visit will occur before the sponsor issues the official site selection letter, and forwards the regulatory documents, contract template and initial budget to Research Administration. The CDA must be reviewed and signed by an institutional official at RCHSD. Do not sign the CDA yourself.

When you receive the Site Selection Letter from the sponsor (after the Site Evaluation Visit), follow these steps to get the project started:

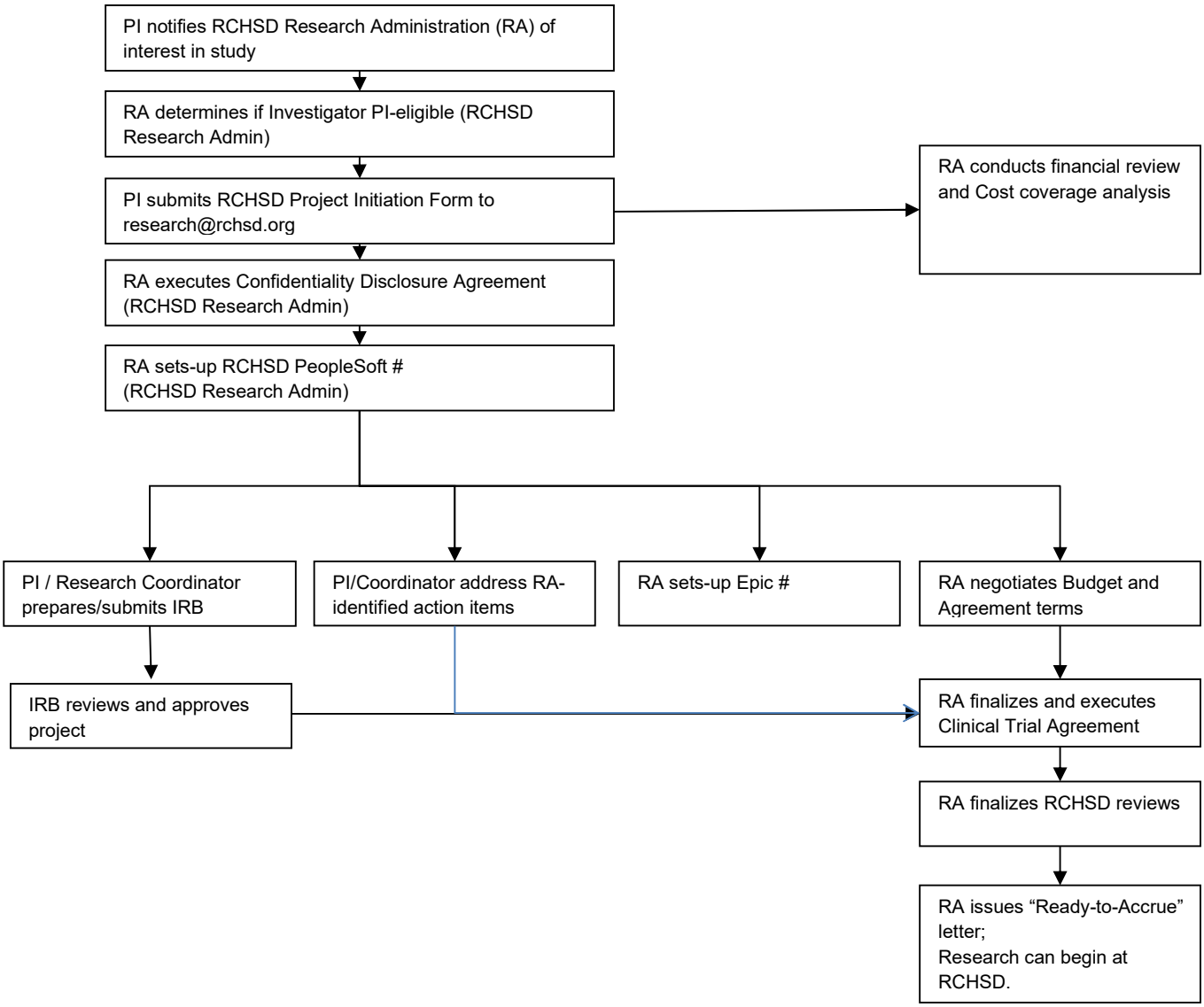
- Complete the RCHSD Project Initiation Form and submit it to research@rchsd.org.
- A 4-digit RCHSD Research Administration # (RAMP #) will be assigned to your project; please use this number in the subject header of communications with Research Administration.
- If RCHSD research coordinator time is needed for the project start-up period (e.g., IRB research plan, IRB application, and consent submission), RCHSD Research Administration will request a PeopleSoft # from RCHSD Accounting and the research nurse coordinator will charge their hours to the PeopleSoft #.
- Forward the protocol, Clinical Trial Agreement, and budget templates to RCHSD Research Administration at research@rchsd.org. Negotiation of the budget and terms of the agreement will be handled by RCHSD Research Administration. Research Administration will discuss the budget negotiations with you throughout the process. The budget will include costs such as research coordinator fees, lab tests, pharmacy cost and all research-related procedures (such as x-rays, ECGs).
- The IRB application must be submitted to UCSD IRB.
- If investigational drugs are used in the clinical trial, contact the RCHSD Investigational Pharmacist. See paragraph d in this Section (below) RCHSD Investigational Drug Services (Investigational Pharmacy) for additional information.

When RCHSD Research Administration has reviewed the IRB research plan, received the executed Clinical Trial Agreement, has conducted a Coverage Analysis review, and determined that all pending issues have been resolved, and when the IRB has released its approval letter, RCHSD will issue a Ready to Accrue Letter approving the start of the clinical trial at RCHSD.

The RCHSD Research Administration Post-Award Office will assist with financial reports throughout the study.

Following is a flowchart for industry-initiated clinical trials for RCHSD/CSSD-employed investigators:

Flowchart for Industry-Initiated Clinical Trials: RCHSD/CSSD-Employed Investigators



- UCSD-Employed Investigators

What forms/documents are needed and where should they be submitted:

Activity	Submit to
RCHSD Project Initiation Form	RCHSD Research Administration
IRB proposal	UCSD IRB
Any type of agreement	UCSD Department Business Office or Health Sciences Service Core will submit to UCSD OCTA to negotiate terms and sign the agreement
Industry sponsor's budget proposal	UCSD Department Business Office or Health Sciences Service Core will either negotiate the budget or forward to OCTA to negotiate the budget (according to Investigator's request).

As mentioned above, the sponsor will require that a Confidentiality Agreement (CDA) be signed before you receive the full protocol for review. A Site Evaluation Visit will occur before you receive the official site selection letter, regulatory documents, contract template, and initial budget. The CDA must be reviewed and signed by an Institutional Official at UCSD. Do not sign the CDA yourself.

When you receive the Site Selection Letter from the sponsor, please follow these steps to get the project started:

- Forms:

- RCHSD Project Initiation Form.

- The UCSD Business Office Fund Manager will assist with UCSD forms (CTA request form or ePD submission, Conflict of Interest Form).

- UCSD forms are available at Office of Clinical Trials Administration (OCTA): Clinical Trials Forms **Note**: Most, if not all UCSD departments, are now submitting their requests via ePD (electronic Proposal Development). This is a campus-wide initiative to implement systems and tools that support improved management by departmental personnel and central offices throughout the sponsored research lifecycle.

Steps:

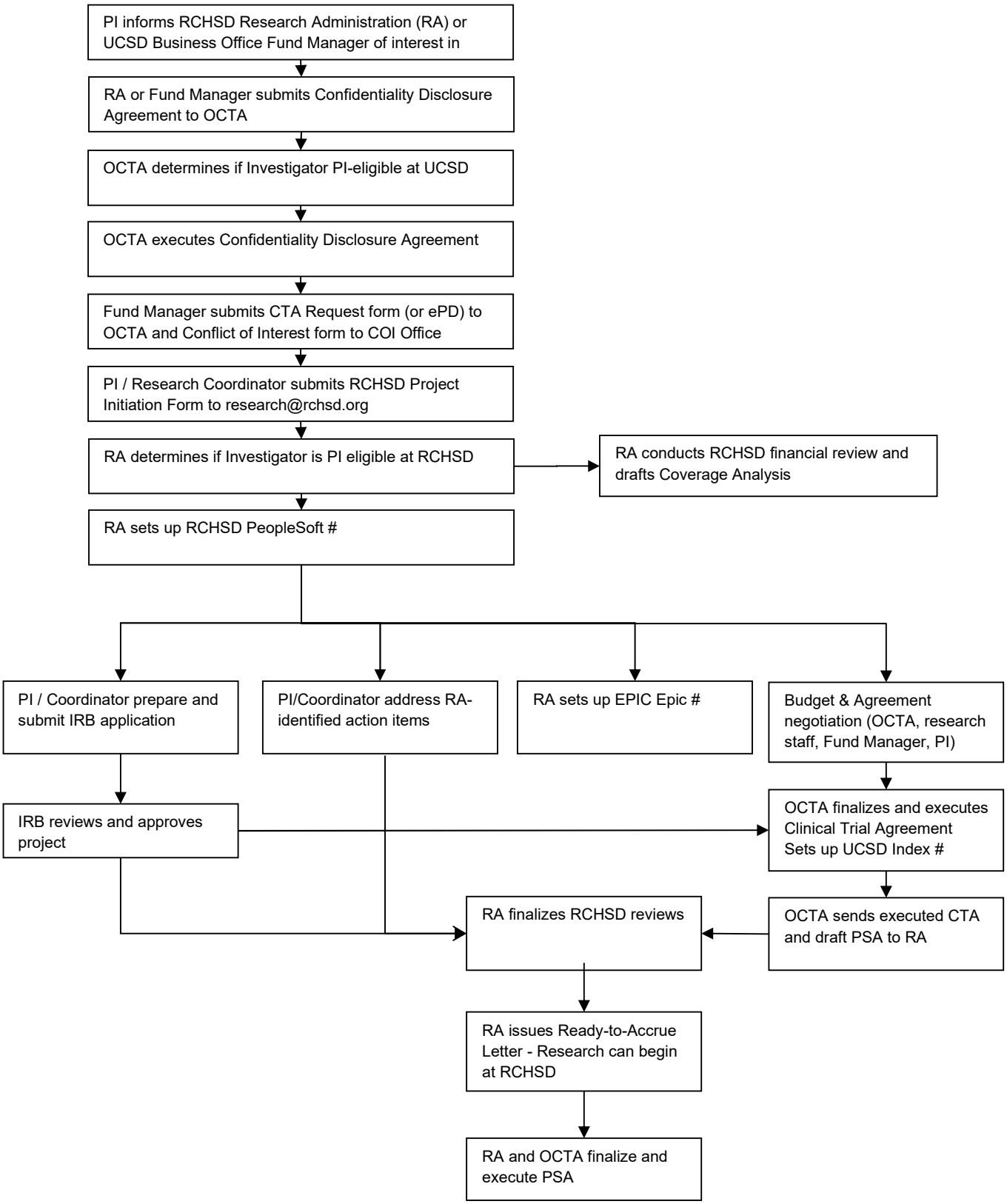
- Complete the RCHSD Project Initiation Form and submit it to research@rchsd.org. A 4-digit RCHSD will be assigned to your project; please use this number in the subject header of future emails with RCHSD Research Administration.
- Forward the protocol, Clinical Trial Agreement, and budget templates to your Business Office Fund Manager. The Clinical Trial Agreement terms will be negotiated by OCTA. The budget can be negotiated by OCTA (a flat fee will be added to the budget for this service), the PI and study team, or Business Office Fund Manager. Make sure you discuss your budget negotiation plans with your Business Office Fund Manager.
- The Business Office Fund Manager will assist with submission through ePD or submission of the CTA Request Form to OCTA; OCTA (or ePD) will assign a UCSD # (example 20155998). The agreement with the sponsor cannot be signed until the CTA Request form has been signed by the PI and the Department Chair or ePD submissions has been approved by Department Chair and PI.
- Complete and submit the Conflict of Interest Form (700 U) to the Conflict of Interest Office. Make sure you add the UCSD # and IRB # on the form.

- RCHSD Research Administration will complete a financial review / cost coverage analysis once the protocol and consents are uploaded to the UCSD IRB.
- If RCHSD research nurse coordinator or research coordinator time is needed for the project initiation period, RCHSD Research Administration will request a PeopleSoft # with RCHSD Accounting. The coordinator will charge hours worked on the project to the PeopleSoft #. Costs on the PeopleSoft # will be invoiced once a month after the Procurement Service Agreement is executed.
- The UCSD Fund Manager or the OCTA budget negotiator must contact research@rchsd.org for RCHSD budget costs such as research coordinator rate, lab tests, and research-related procedures.
- The IRB protocol must be submitted to UCSD IRB as per their Instructions.
- If investigational drugs will be used in the clinical trial, contact the RCHSD Investigational Drug Service at rxinvestigationaldrugs@rchsd.org.

- When UCSD has finalized the budget with the sponsor, the Clinical Trial Agreement is executed (signed by both parties), and the IRB has approved the study, OCTA will release the UCSD Index #.
- When RCHSD Research Administration has reviewed the final IRB research plan, received the executed Clinical Trial Agreement from UCSD OCTA, has determined that any pending or compliance issues have been resolved, and has completed the Coverage Analysis, and when the IRB approval is in place, RCHSD will issue a Ready-to-Accrue Letter approving the start of the clinical trial at RCHSD.
- UCSD OCTA and RCHSD Research Administration will process a Procurement Service Agreement (PSA) for all RCHSD costs.
- RCHSD will send monthly invoices to UCSD for all RCHSD costs related to the study.
- The research coordinator must report to the Fund Manager the details of the number of enrolled patients and other billable tasks completed (such as IRB amendments and renewals and monitoring visits) so that the UCSD Fund Manager can appropriately invoices the sponsor and monitor payments received.
- The UCSD Fund Manager will provide the PI with financial reports throughout the study.

Following is a flowchart for Industry-initiated clinical trials for UCSD-employed investigators:

Flowchart for Industry-Initiated Clinical Trials: UCSD-Employed Investigators



b) Investigator-Initiated Clinical Trials

- What forms/documents are needed and where should they be submitted:

RCHSD and Non-UCSD-Employed Investigators

Activity	Submit to
RCHSD Project Initiation Form	RCHSD Research Administration at research@rchsd.org
Research proposals	RCHSD Research Administration will assist with proposal, obtain Institutional Official approval, and submit to sponsor
IRB proposal	UCSD IRB
Any type of agreement	RCHSD Research Administration will negotiate terms and obtain signatures

UCSD-Employed Investigators

Activity	Submit to
RCHSD Project Initiation Form	RCHSD Research Administration at research@rchsd.org
IRB proposal	UCSD IRB
Research proposals	UCSD Department Business Office or Health Sciences Service Core will assist with the proposal and forward it to the Institutional Official for approval and submission to the sponsor.
Any type of agreement	UCSD Department Business Office or Health Sciences Service Core will forward it to the Institutional Official to negotiate the terms and sign the agreement.

Steps to obtaining approval for Investigator-initiated clinical trials are similar as those for Industry-initiated studies.

For all proposals that include activities involving RCHSD, the completed RCHSD budget must be submitted to research@rchsd.org prior to proposal submission.

- RCHSD/CSSD-Employed Investigators

The sponsor's award letter and/or agreement must be forwarded to RCHSD Research Administration for processing and Institutional Official signature. Please include the 4-digit RCHSD # that was assigned at time of the Project Initiation Form submission on your communications.

If the project requires IRB approval and it hasn't been submitted yet, the IRB research plan consents as well as HIPAA Authorization Form and/or Waiver Request Form (as applicable) must be submitted (see Section 5).

Once the award has been accepted or the agreement signed by the RCHSD Institutional Official, the IRB has released its approval letter, and Research Administration has reviewed the project, Research Administration will request a PeopleSoft # and issue the Ready to Accrue (RTA) Letter, which will allow you to begin your study.

- UCSD-Employed Investigators

The sponsor award letter and/or agreement must be forwarded to the UCSD Business Office Fund Manager for processing with the Institutional Official. Additionally, RCHSD Research Administration should be notified of the award. Please include the 4-digit RCHSD # that was assigned at time of Project Initiation Form submission on your communication.

If the project requires IRB approval and it hasn't been submitted yet, the IRB research plan, consents as well as HIPAA Authorization Form and/or Waiver Request Form (as applicable) must be submitted (see Section 5).

Once the award has been accepted, or the agreement signed by the Institutional Official at OCGA, the IRB has released the approval letter, and RCHSD Research Administration has reviewed the project, UCSD will generate a UCSD Index # for your project and RCHSD Research Administration will request a PeopleSoft # from Accounting and then issue the Ready-to-Accrue (RTA) Letter so you can begin your study.

c) Obtaining Institutional Review Board (IRB) Approval

The UCSD IRB reviews all human-subjects research that is conducted at RCHSD. For any questions regarding IRB review, contact the UCSD Human Research Protections Program at 858-246-4777. RCHSD Research Administration is unable to address IRB-review matters. Follow the Instructions and Standard Operating Procedures on https://irb.ucsd.edu/.

IRB Forms

- Forms for UCSD-salaried faculty are available online. Use the RCHSD-UCSD forms. Forms for RCHSD researchers who have no affiliation with UCSD and who have no UCSD co-investigators are at: https://irb.ucsd.edu/RCHSD-only-Forms.shtml.
- Investigators who are not UCSD-salaried but who have UCSD-salaried co-investigators or UCSD trainees should use the RCHSD-UCSD forms.

Tools and checklists used by the IRB to review projects are located on the UCSD IRB Checklists page:

- Checklists to Determine Whether Proposed Activities are Human Research (Box Diagram) (Flowchart)
- Initial Review Submission Checklist for Biomedical Research Studies
- Initial Review Submission Checklist for Social and Behavioral Sciences Research Studies
- Project Reviewer Checklist for Biomedical Research Studies (includes checklist for both Research Plan and consent)
  Project Reviewer Checklist for Social and Behavioral Sciences Research Studies (includes checklist for both Research Plan and consent)
- Project Reviewer Checklist for Emergency Use of a Test Article

d) HIPAA Authorization

California law requires a separate stand-alone HIPAA authorization form. The UCSD IRB provides a RCHSD-UCSD HIPAA form template. Because of the complexities of both HIPAA and the California Medical Information Act (CMIA), UCSD Investigators cannot use sponsor-offered forms or make modification to the authorized HIPAA stand-alone form. These forms are available on the UCSD IRB website in English and Spanish.
Note: In order to inform the research patient about what information is released, you must complete Section B of the form and check the appropriate boxes. Incomplete HIPAA Authorization forms will delay the release of the RTA letter.

e) Experimental Subject's Bill of Rights

Consents for Parents and Adults must be accompanied by the Experimental Subject's Bill of Rights.

f) Application of Waiver for HIPAA Authorization

The HIPAA Privacy Standard at 45 CFR 164.512(i) requires that certain criteria be met in order to grant a waiver of individual authorization for research uses of Protected Health Information (PHI, i.e., individually identifiable health information held by a health care provider or health plan covered by HIPAA, e.g., Rady Children's Hospital-San Diego). In addition to these criteria, the federal Common Rule (45 CFR 46 section 116(d)) stipulates that "whenever appropriate, the subjects will be provided with additional pertinent information after participation."

Total Waiver

When you request a total waiver of HIPAA Authorization, you are requesting permission to access, use or disclose a research subject's PHI for your research study without seeking the subject's specific authorization for that use or disclosure.

Partial Waiver

When a partial waiver is requested, you may request that certain required elements of the HIPAA authorization be altered or that the HIPAA authorization be waived for a portion of the study. For instance, you may request a waiver for subject identification or recruitment purposes, but not for enrollment purposes. For example, you may request a waiver of the HIPAA authorization requirement so that you may view patient records for eligible patients and obtain verbal permission from the patient/parent so that you can notify the study coordinator of the patient's/parent's interest in the study. Once the study coordinator has discussed the study with the interested patient and parent, they will consent the participant and parent and obtain a full authorization. Since this activity generally occurs in a clinical trial where the study team may look through medical records to identify eligible patients, a partial HIPAA waiver is most likely required to be submitted.

In summary, if patient records (including clinical schedules) will be used to identify potential patients for recruitment, whether patients are consented at RCHSD or UCSD, an IRB partial waiver for individual HIPPA use and disclosure is required.

IRB approval is necessary but not sufficient to begin research at RCHSD. The research can only begin after RCHSD Research Administration issues the Ready-to-Accrual letter after IRB and all RCHSD fiscal and operational approvals are in place, along with any applicable agreements.

Reliance IRBs

See the UCSD IRB's IRB Oversight by Non-UCSD "Centralized" IRBs. If UCSD IRB is being asked to rely on another IRB that is not listed in this document, contact the UCSD IRB for information about establishing a reliance agreement, as well as instructions for providing the necessary documents for review including an appropriate agreement between UCSD and the other entity.

g) IRB Training

UCSD IRB's human subject protection training has expanded to include the Collaborative Institutional Training Initiative (CITI) Program's Human Subject Protection Course. As part of continuing education efforts in the area of Human Research Protection and as a requirement to ensure more consistent and documented training of those involved in human research and/or the review of such research, RCHSD/CSSD employees, UCSD faculty who are conducting research as Principal Investigators, and staff and students (undergraduate and graduate) who are key personnel (those who are listed on an

IRB application to be reviewed by a UCSD IRB or that is found to be exempt from IRB review), must take the research-appropriate course on the CITI website.

The total course time is estimated to be 2 to 3 hours. It is strongly suggested that the entire course not be taken in one sitting; individuals may enter the course at any time. Modules are designed to be taken sequentially.

The CITI Basic Course certification is good for three (3) years at which time the course may be re-taken.

More Information on training and links to the training modules can be found here: UCSD IRB CITI Training.

Investigators and study team members who are not employed by UCSD should select UCSD as their institution.

h) Coverage Analysis

A Coverage Analysis is a systematic review of clinical trial documents, published practice, guidelines, and national and local coverage determinations to determine the billing status of items and services that are documented in the research protocol, contract, protocol, research plan, consent, and negotiated budget.

It is important to complete a Coverage Analysis for each clinical trial to avoid million-dollar settlements by the government due to improper billing and to minimize and if possible eliminate improper billing to patients on a clinical trial.

The four highest-risk areas providers need to tackle and implement safeguards for are:

- Billing for items and services to patient/insurance that are paid for by a contract or grant
- Billing for services to patient/insurance promised free in the informed consent
- Whether a study is deemed a “qualified” clinical trial
- Applying national and local Medicare rules to any items and services in a research study that are “routine costs”

Although RCHSD does not treat many (if any) patients covered by Medicare, RCHSD follows Medicare rules and guidelines as it is considered the golden standard.

Determining a Qualifying Trial

For any items or services required by the protocol to be billed to Insurance/Medi-Cal/Medicare, the research study must first qualify for coverage. If the research study does not qualify for coverage, then even medically necessary items and services will not be covered.

The term “qualifying clinical trial” is used to describe a research study that qualifies for coverage. If the research study as a whole does not qualify for coverage, then no services are billable to Insurance/Medical/Medicare. A qualifying clinical trial is a research study that is one of 4 types of studies that are “deemed” to have 7 “desirable characteristics”:

Must be one of 4 types of trials deemed to meet 7 desirable characteristics + **Must meet all three necessary requirements**

1. Funded by NIH, CDC, AHRQ, CMS, DOD or VA	1. Evaluate an item or service that falls within a Medicare benefit category
OR	**AND**
2. Supported by center or cooperative group funded by NIH, CDC, AHRQ, CMS, DOD or VA	2. Have a therapeutic intent
OR	**AND**
3. Conducted under an investigational new drug application (IND reviewed by the FDA	3. Enroll patients with diagnosed disease
OR	
4. IND exempt under 21 CRF 312.2(b)(1)	

UCSD's Office of Coverage Analysis Administration (OCAA) reviews all clinical trials that incur charges at UCSD. Since most pediatric clinical trials only incur charges at RCHSD, Research Administration assumes the responsibility to complete a Coverage Analysis. The Coverage Analysis will start with the submission of the research plan, Master Protocol and consents to the UCSD IRB. Clinical Trial Agreements and the budget will also be considered when completing the Coverage Analysis. Research Administration will work with the Investigator and research staff to discuss any discrepancies.

i) RCHSD Investigational Drug Service (Investigational Pharmacy)

RCHSD has an Investigational Pharmacy. All studies involving investigational medications must adhere to Policy PM 9-39 (Investigational Medications).

If the study is prospective and involves medications, email the RCHSD Investigational Drug Service (IDS) at rxinvestigationaldrugs@rchsd.org with the items below.

- Names(s) of investigational drug(s)
- Supplier of investigational drugs
- Sponsor protocol
- IRB research plan
- Investigator's brochure
- Pharmacy Manual / Investigational Product Manual (This needs to be done well in advance of the Site Initiation Visit and the issuance of the "Ready-to-Accrue" Letter.)
- Any IVRS/IWRS info if applicable (An IVRS/IWRS envelope containing an access code and an instruction guide/manual are typically supplied.)
- If the RCHSD Investigational Pharmacy needs to order any drug supplies, please provide them with a PeopleSoft #.
- If Investigational Pharmacy Services will be needed after hours (weekends; holidays; or after hours [3pm – 6:30am]), please let them know. Please also let your UCSD fund manager know so that the appropriate fees can be added to the budget.
- Provide the patient care setting (1, 2 or 3 below):
  1) **Outpatient Clinic:**
     a. Will the first dose of investigational medication be administered in Clinic prior to discharge home? If yes, how will the dose be documented (in Epic or on study source document)?
     b. Will investigational medication be only given at home as self-administered?
  2) **Inpatient admission**: Indicate whether patient is admitted with primary reason to receive study drug or patient potentially enrolls to the study while being admitted for a primary diagnosis. May need to submit an Order Set request.

3) **Infusion Center:** Indicate who will be Research RN administering research medication at Infusion Center. May need to submit a request for an Order Set or Therapy Plan.

Let the IDS know the details of upcoming site visits or sponsor in-services. In all emails to the IDS at rxinvestigationaldrugs@rcshd.org, include the 4-digit RCHSD project number in the subject header.

j) Photography, Videotaping, and Image Capture

Cameras used in clinical research studies must be owned and managed by RCHSD. A separate RCHSD Authorization for Use, Disclosure or Publication of Photographs blank-template must be uploaded to the UCSD IRB, even if the IRB-approved consent includes language regarding photography/videotaping/image capture, and even if the IRB requires that participants sign a stand-alone video consent form (Policy CPM 11-79, Photography of Patients and Staff).

Should you need to use non-RCHSD-owned video or still camera for your research project, you must submit an exception-to-policy request. Contact RCHSD Research Administration at research@rchsd.org to get started on this form, which must be reviewed and signed by the Research Administration Director, the Senior Vice President/Chief Medical Officer, and the Chief Administrative Officer. For Industry-Initiated studies in which the sponsor will provide image-capture devices/equipment, the agreement must include the provision of the devices/equipment.

Note: Privately-owned video or still cameras or cell phone, or other electronic devices may not be used for research purposes.

k) Clinical Trial Registration at www.Clinical Trials.gov

Clinical Trials must be registered with ClinicalTrials.gov and results must be posted. Pharmaceutical companies who sponsor clinical trials usually register the studies with ClinicalTrials.gov. However, as the Investigator, you are responsible to assure that this requirement has been fulfilled. It is the Investigator's responsibility to register Investigator-initiated trials with ClinicalTrials.gov. For more information, see the UCSD IRB fact sheet titled Registration of Clinical Trials in a Public Registry for Publication and visit http://www.clinicaltrials.gov.

l) Equipment Used in Research at RCHSD

Should your project involve a piece of equipment or a device, RCHSD Biomedical Engineering will need to test and approve the equipment or device before the project can begin. See Policy SM 8-14 (Incoming Inspection of Medical Equipment) for additional detail. Communicate with RCHSD Research Administration at research@rchsd.org early in the project approval process if your project includes equipment. RCHSD Research Administration will assist with initiating contact with Biomedical Engineering, if needed. Biomed requires a copy of the Ready-to-Accrue Letter and IRB approval before releasing equipment or devices for a study.

- Equipment must be inspected by Biomed at the beginning of the study and at the end of the study.
- To get the equipment inspected: Contact Biomed at 858-966-5806, or go to the Biomed repair shop, and any Biomed Tech can inspect the equipment. Their hours of operation are 6:00 am to 4:30pm.
  - Along with the equipment, provide Biomed with a copy of:
    - The RCHSD Ready-to-Accrue Letter
    - The UCSD IRB approval letter
    - If the equipment is not owned and managed by RCHSD, also include an RCHSD-signed exception-to-policy request form or a copy of the agreement authorizing the equipment to be

used at RCHSD for the research. If the agreement is not executed by RCHSD (i.e., if UCSD executes the agreement with the sponsor), a memo should be submitted explaining the situation along with the agreement.

All medical and other equipment that stores PHI or transfers PHI to a server must comply with RCHSD policies for PHI Security.

If non-RCHSD-owned equipment will be used for a study, one of the following must be on file in RCHSD Research Administration:

- Equipment-loan language for the device is contained in the Clinical Trial Agreement.
- Clinical Trials Agreement references the Master Protocol, which includes reference to using the sponsor-provided piece of equipment.
- Equipment Loan Agreement is used when UCSD is accepting the equipment on behalf of the Investigator and the equipment is being used at RCHSD. Research Administration will assist with this agreement.
- The Product Trial Release Form is used if a company provides equipment to an RCHSD Investigator for a study and the equipment comes here directly. Research Administration will assist with this agreement.

m) Studies Involving Specimens and Non-Fluid Tissues

Specimens delivered to the Lab or Pathology must be accompanied by a copy of the "Research Specimen Submission Form". The form is available on the RCHSD research intranet forms page. Non-fluid tissues must be accessioned by Pathology immediately after removal from patients.

Studies involving the transfer of specimens (fluid and non-fluid) to another institution, including UCSD, require the appropriate agreement or contract prior to transfer (see Section 5 m)

n) Submission of Specimens/Tissues to the RCHSD Lab & Pathology

When dropping off specimens and tissues to the Lab and Pathology, submit a Research Specimen Submission Form with each specimen.

o) Non-Fluid Tissues Used for Research

Per California Title 22 regulations, all prospectively-obtained surgical specimens for research must be accessioned by Pathology. This includes skin biopsies done anywhere at RCHSD, including outpatient clinics. Exceptions are not permitted. Specimens must be taken directly to Pathology following removal from the patient. A copy of the consent must accompany non-fluid tissues and research devices, along with a Research Specimen Submission Form.

- Reference: 22 CCR § 70223(g): "*All anatomical parts, tissues and foreign objects removed by operation shall be delivered to a pathologist designated by the hospital and a report of his findings shall be filed in the patient's medical record.*"

Research Administration will ask investigators whose studies involve surgical specimens to complete a "Research Involving Pathology" table. Research Admin will send the table to the Pathology Medical Director and Administrative Director for review and will copy the PI and Coordinator on the email so they can answer any questions Pathology may have. If the study requires that the specimens be placed in a special medium immediately after removal from the patient, that information should be included in the table.

Pathology will let the PI and Research Administration know which CPT codes will apply, so Research Admin can provide the PI with the research fee(s) for inclusion in the study budget.

p) Specimen and Tissue Transfer to Outside Institutions

- RCHSD/CSSD-Employed Investigators

Research Administration will assist with any agreements that are needed for the transfer of materials from RCHSD to an outside entity. Email research@rchsd.org.

- UCSD-Employed Investigators

Generally, Industry-initiated clinical trials include the material transfer terms in the Clinical Trial Agreement and/or the Master Protocol and therefore, no additional Material Transfer Agreement is needed.

For non-industry-initiated studies, Research Administration will facilitate an RCHSD-UCSD Material Transfer Approval Notification Letter (MTA Letter), which will be issued at the same time as the Ready-to-Accrue Letter is issued and which will allow for the transfer of materials from RCHSD to UCSD. The PI will be listed as both the Providing Scientist (as a physician at RCHD) and the Recipient Scientist (as a UCSD employee). When the MTA Letter is issued, Research Administration will copy the UCSD eMTA Office on the email so that they are aware of the materials that will be transferred. For the additional transfer of materials from UCSD to any Collaborating Institutions, the PI will need to work with the UCSD eMTA office to facilitate an MTA that allows the materials to transfer from UCSD to any collaborating institutions, but this latter activity will not hold up the Ready-to-Accrue Letter. The materials cannot be transferred to any collaborating institutions until UCSD executes a Material Transfer Agreement or other collaboration agreement with the external institution(s).

q) Health Center Badging & System Access for Non-RCHSD-Employed Study Personnel

See RCHSD Center Policy CPM 4-53 on Health Center Badging and System Access. The sponsoring department at RCHSD is generally responsible for initiating the badging and system access process, as well as other onboarding activities.

r) Translation Services for IRB Documents

To inquire about translation services and costs for consents and assents, here are some options:
If the PI is a UCSD employee, check with the PI's UCSD fund manager for that PI to see if the fund manager recommends a particular translation service (especially if there's already an existing payment mechanism established).

You can contact the RCHSD Translation Services to find out if consent-document translation services are available and what the costs are.

Some investigators are bilingual and translate their own consents.

Some investigators use outside translation services, e.g., Burg Translation Services. RCHSD does not endorse any specific company.

Check with the IRB before you start so that they can tell you what documentation you need to provide to show that the translation is accurate.

There is a Spanish-translation of the latest RCHSD/UCSD HIPAA Use & Disclosure Form on the UCSD IRB website.

s) Interpreter Services

See the RCHD intranet page for translation services.

6. RCHSD Privacy Board

RCHSD's Privacy Board was established to act upon requests for waiver of the authorization requirement under the Health Insurance Portability and Accountability Act (Privacy Rule) for uses and disclosures of Personally Identifiable Information (PII) and Protected Health Information (PHI) for activities that are not otherwise reviewed by the Institutional Review Board (IRB).

Under certain circumstances, the Privacy Rule permits the covered entity to use or disclose PHI for research without patient authorization, such as by obtaining proper documentation of a waiver of the authorization requirement by an IRB or a Privacy Board. The Privacy Board or IRB may waive and/or alter all or part of the authorization requirements for a specified research project or protocol.

The functions of the RCHSD Privacy Board include:

Protecting the privacy and security of PII and PHI as they relate to activities that are not otherwise reviewed by the UCSD IRB

a. Patient recruitment activities where UCSD IRB is not the IRB of record;
b. Retrospective data collections that are UCSD IRB exempt as per 45 CFR 46 subpart A and are not certified by the IRB as being exempt from IRB review or that are not otherwise certified as not requiring IRB review.
c. Preparatory-to-research projects
d. Decedent research where IRB approval is not required as per Policy CPM 11-61
e. Case reports where written authorization from patients cannot be obtained
f. Studies involving review or extraction of large data sets

Forms and Instructions can be found on the RCHSD Intranet Privacy Board page. Contact Research Administration at research@rchsd.org if questions.

7. Agreements

Once the study sponsor (federal, state, for-profit or non-profit) decides to fund a project, an agreement or Notice of Award will be sent to the Investigator or the Institutional Official. The Investigator must forward the agreement or Notice of Award to the appropriate Institutional Official for review, execution and processing. The Investigator cannot sign the agreement.

a) RCHSD/CSSD-Employed Investigators

Agreements with all sponsors are negotiated and processed by RCHSD Research Administration.

b) UCSD-Employed Investigators

Agreements with the study sponsor are negotiated and processed by one of the UCSD Central Offices.

- OCGA for awards from federal, state, non-profit agencies, and Investigator-initiated clinical trials with Industry
- OCTA for Industry-initiated clinical trials

t) Confidentiality Agreements

A Confidentiality Agreement (CDA) or a Non-Disclosure Agreement (NDA) is commonly used in Industry-initiated clinical trials. Before the industry sponsor shares the full protocol with the Investigator, the sponsor requests that a CDA or NDA be signed. **Note**: The Investigator cannot sign CDAs and NDAs. These agreements must be signed by the Institutional Official. Forward the CDA or NDA to RCHSD Research Administration or your Business Office or Health Sciences Service Core for processing.

u) Clinical Trials Agreement (CTA)

Clinical Trial Agreements are used for Industry-initiated and for Investigator initiated studies. **Note:** Investigators cannot sign the CTA. The UCSD or RCHSD Institutional Official will negotiate terms and prepare the document for signature.

v) Data sharing outside RCHSD

Patient information that is shared with UCSD and does not leave UCSD does not require a Data Use Agreement. However, patient information, even if de-identified, that will be shared outside RCHSD/UCSD, does require a Data Use Agreement or equivalent.

- RCHSD/CSSD-Employed Investigators

Research Administration will facilitate the Data Use Agreement.

- UCSD-Employed Investigators

If RCHSD gives the data directly to the external recipient, Research Admin will initiate the Data Use Agreement.

If RCHSD gives the data to the PI or if the PI collects the information at RCHSD and then sends it to the recipient, OCGA will initiate the Data Use Agreement. To initiate an agreement, submit a UCSD OCGA eForm . Once you submit your request, the OCGA team will reach out to you with the assignment and the Case #. Here is their email: OCGA Contract Support: ocgacontractsupport@ucsd.edu.UCSD OCGA has advised that only UCSD employees should submit the request.

If the sharing of data with an outside institution is already covered by data-use-agreement terms in a written agreement or contract, a Data Use Agreement may not be necessary.

w) Business Associate Agreements

A Business Associate is a person or organization that provides a service or function on behalf of a covered entity (RCHSD) that involves use of the RCHSD's PHI. RCHSD may disclose PHI to a Business Associate under an agreement that, among other things, defines what the Business Associate may do with the data.

Research collaborators (e.g., researchers at other sites) are not Business Associates because sharing PHI for research purposes does not create a business associate relationship. If PHI is sent to Research collaborators, a Data Use Agreement may be needed.

The Privacy Rule permits RCHSD to hire a third party as a Business Associate to de-identify RCHSD's PHI. A Business Associate may de-identify PHI for use by RCHSD or its own use. Once de-identified, the data are is no longer subject to HIPAA and may be used or shared by the Business Associate.

However, the Business Associate may not disclose the original PHI except as permitted or required by the Privacy Rule.

Research Administration will facilitate the Business Associate Agreement.

x) Agreement between RCHSD and UCSD – Invoicing of RCHSD costs

To pay for the cost and flow-down of the terms from the prime agreement with the sponsor, UCSD and RCHSD process the following agreements for each project:

y) Procurement Service Agreement (PSA) for Industry-Initiated Clinical Trials

The Procurement Service Agreement is initiated when the Clinical Trial Agreement (CTA) between UCSD and the sponsor is executed. The PSA includes a budget for RCHSD costs (e.g., coordinator time, lab tests, procedures, patient stipends, pharmacy fees) and is signed by the Investigator, the UCSD Institutional Official, and the Sr. VP / COO at RCHSD. The PSA terminates at the time of study completion.

z) Purchase Order (PO) for All Other Awards

RCHSD Research Administration will generate a budget for all RCHSD costs (coordinator time, lab tests, procedures, patient stipends, pharmacy fees) and ask the PI/study coordinator for approval of the budget before sending it to UCSD with a request to issue a PO for the agreed-upon project period.

aa) Sub-Award Agreement

Occasionally, RCHSD receives a sub-award agreement that is issued when a defined portion of the RCHSD work statement includes intellectually significant activity that is assigned to an RCHSD/CSSD-employed Investigator. The sub-award agreement flows down the terms from the prime agreement and includes budget for the effort of the RCHSD/CSSD Principal Investigator and other activities led by the RCHSD/CSSD Principal Investigator.

If you have any questions about which agreement is required or which institution will process an agreement, contact Research Administration at research@rchsd.org for assistance.

8. No-Cost/Unfunded Projects

Your project may not be funded, and there are no costs associated with the project. There will be no funding agreement with a sponsor and you will not require any coordinator time to assist with the project.

Here are the steps for approval:

- Complete the RCHSD Project Initiation Form and submit it to research@rchsd.org. A 4-digit RCHSD will be assigned to your project; please use this number in the subject header of future communications with RCHSD.
- Submit the IRB application to the UCSD IRB.
- When RCHSD Research Administration has reviewed the final IRB research plan, has determined that any pending or compliance issues have been resolved, and the IRB approval is in place, RCHSD will issue a Ready-to-Accrue Letter approving the start of the project at RCHSD.

9. Setting up New Project Accounts (UCSD Index # or RCHSD PeopleSoft #)

a) RCHSD/CSSD-Employed Investigators

RCHSD Research Administration will initiate the set-up of a new PeopleSoft # with Accounting.

b) UCSD-Employed Investigators

For Investigator-initiated or NIH-funded projects, OCGA will initiate the set-up of a new Index # when the IRB approval is in place and the award is accepted or the agreement between UCSD and the sponsor is executed. Be aware that if your project incurs costs at RCHSD (pharmacy, labs, procedures, RCHSD staff), it will require an RCHSD PeopleSoft # in addition to the UCSD Index #. RCHSD Research Administration will assist with setting up the RCHSD PeopleSoft #.

For Industry-initiated projects, OCTA will initiate the set-up of a new Index # when the IRB approval is in place and the agreement between UCSD and the sponsor is executed. Be aware that if your project incurs costs at RCHSD (pharmacy, labs, procedures, RCHSD staff), your project also requires a RCHSD PeopleSoft # in addition to the UCSD Index #. RCHSD Research Administration will assist with setting up the RCHSD PeopleSoft #.

See additional information regarding how the funds flow in Section 8 on Post-Award Management.

10. Setting Up the Epic

Research Administration assigns an Epic # from the patient financial services department for each project that involves written consent and an individual HIPAA Use &Disclosure form. Each patient who consents to participate in a research study must be linked to the Epic #. If any per-patient charges occur during the study that will be billed to the study, the research patient's visits must be linked to the Epic # so that research-related charges correctly flow to the research study as determined by the Coverage Analysis. The Epic # will be provided in the Ready-to-Accrue Letter. You must ensure that study participants and research encounters are linked in Epic to the research study Epic #. Information on how to do that is detailed in Section 24.

D. DURING THE STUDY

1. Access to RCHSD Research Lab with Centrifuge and Freezer Space

The Research Lab contains a refrigerated centrifuge, a regular non-refrigerated centrifuge, an ultra-low freezer, and a refrigerator/freezer.

All users need to obtain the door pass code and undergo training on the use of freezer and centrifuges. Contact Joan Pancheri, Clinical Research Nurse Manager, jpancheri@rchsd.org.

Do not take any supplies from the shelves in the Research Lab. They are reserved for specific studies.

RCHSD is not responsible for specimens that become unusable in the event of equipment failure or a rise in freezer or refrigerator temperature.

a) Centrifuges

Contact Joan Pancheri, Research Nurse Manager, at jpancheri@rchsd.org to set up a training session.

Contact research@rchsd.org to obtain maintenance logs for the centrifuges.

b) Short-Term Specimen Storage

An ultra-low freezer (set at -70°C or colder) with Isensix temperature monitor is available for short-term specimen storage (up to six months) until specimens can be shipped. All specimens must be clearly labeled with the PI's name, the RCHSD 4-digit Research Administration project number, collection date, and contact Name/Email/Phone #/Pager #. Inadequately-labeled specimens may be discarded.

PIs and Research Teams should be aware that they run the risk of losing samples if specimens are not forwarded promptly to the sponsor or an outside institution for processing. Although the freezer is plugged into a "red" power outlet and, therefore, on the Hospital's backup generator, there is always the risk of specimen spoilage if there is a motor failure or if a user leaves the door unlocked.

The ultra-low freezer is equipped with an Isensix sensor. Monthly logs are available here.

c) Refrigerator/Freezer

A standard refrigerator/freezer is available for short-term storage of ice packs and supplies for up to six months. They must be clearly labeled with the PI's name, RCHSD 4-digit Research Administration project number, and contact Name/Email/Phone #/Pager #. Inadequately-labeled items may be discarded. The notebook containing the temperature log is in the Research Lab.

Note: RCHSD is not responsible for specimens or supplies that become unusable in the event of equipment failure or a rise in temperature.

2. Rady Children's/UCSD Biorepository (RUB)

The RCHSD-UCSD Biorepository (RUB) located on the RCHSD campus at 7910 Frost Street and is the central repository of specimens collected from RCHSD patients. The Biorepository's mission is to obtain, characterize, maintain and deliver high-quality pediatric specimens and related clinical data to maximize the potential use of the material for current and future research studies and to do so within the National Cancer Institute (NCI) "Best Practices for Biospecimen Resources" guidelines.

All standardized policies and procedures used for collection must be approved by the UCSD IRB and RCHSD Research Administration.

To maximize research productivity, the RUB implements a Standard Operating Procedure (SOP)-focused prospective collection model; specimens that are collected are based upon Investigator requests with specific attention to the requirements of each Investigator.

The Biorepository will help to maximize the potential use of specimens for a wide variety of research projects, including genomics, proteomics, transcriptomics, and metabolomics, which will provide a deeper understanding of the mechanisms controlling pediatric disease states and result in sub-classification of these diseases in an effort to optimize and personalize patient care.

Biorepository services include:

- Prospective collection of specimens
- Retrospective collection of archived frozen specimen
- Sharing of existing specimens from the Biorepository
- Developing collection protocols for IRB-approved projects
- Collecting and transporting specimens to the Investigator's Lab at UCSD
- Collecting and storing Investigator's samples at Biorepository
- Processing, disbursing, and shipping Investigator's samples
- Processing specimens for DNA, RNA, and viable and frozen cells

Requests for Biorepository services should be sent to Shareef A. Nahas, PhD, FACMG, CGMB, snahas@rchsd.org. More information can be found on the UCSD Biorepository site.

Biorepository staff will work with PIs on the Investigator Application Instructions and the agreement package. Individual proposals will be reviewed by the Director of the Biorepository to determine the validity and feasibility of the project. Biorepository personnel will meet with the Investigator (PI) and discuss specimen requirements, special handling, processing and logistics and create a Standard Operating Procedure for collection, storage and distribution.

Rady Children's Institute for Genomic Medicine Biorepository Contacts	
Shareef A. Nahas, PhD, FACMG, CGMB, Senior Director of Clinical Operations Rady Children's Institute for Genomic Medicine Phone: 858-966-8391 Email: snahas@rchsd.org	Kathy Bouic UCSD Staff Research Associate Location: 7910 Frost St, Room 370 Phone (858) 966-1700 Ext. 221025 Email: kbouic@ucsd.edu Linda Luo UCSD Staff Research Associate Location: 7910 Frost St, Room 370 Phone (858) 966-1700 Ext. 221026

3. Linking Study Participants and Encounters to a Study in Epic

To ensure correct processing of billing, it is important that all study visits be linked to the Epic #.

Epic numbers are assigned if a study involves consent and individual HIPAA Use and Disclosure Authorization, or if per-patient items will be charged to the study. If the study requires an Epic #, RCHSD Research Administration will include the number in the "Ready-to-Accrue" Letter.
If your study has been assigned an Epic research registration number, subjects must be linked to the study via the Epic # within 24 hours when:

- Consent is obtained and individual HIPAA Use & Disclosure Authorization is obtained; and
- At each subsequent visit that involves research, even if the visit also involves clinical care

Step-by-step instruction Tip Sheets (requires RCHSD intranet access) are available for:

- Ambulatory Prescription Ordering Screenshot
- Ambulatory Research Order Linkage Process
- Associating a Patient with a Research Study
- Epic Ordering and Linking Research Labs / Procedures for Inpatients
- Ordering research medications

Activity	Who can do this?
Link subjects to the study	Research Nurse Research Coordinator Physician Patient Access Rep
Obtain Medical Record Numbers for subjects who don't have an MRN	Central Scheduling

Physicians are not able to associate patients with Epic research numbers in Epic. If no RCHSD member of your study team has the ability to associate patients to the Epic research number, a Patient Access Rep (PAR) in the care area where you are doing the research can do it. Please check with the care-area supervisor first.

4. Writing Orders for Research Activities

a) Investigational Pharmacy (Investigational Drug Service)

Per Policy RX 8120 (Investigational Medications), available on the RCHSD intranet:

- The Investigational Drug Service (IDS) is responsible for the oversight of Investigational Drug Product use within all RCHSD licensed locations. IDS has the authority, at its discretion, to permit a PI to be responsible for the oversight of the Investigational Drug Products in a licensed location for his/her protocol.
- Investigational Medication must be dispensed only on the order of an authorized prescriber.
- All orders for investigational drugs shall be entered in the patient's permanent medical record by the PI or Co-Investigator, or other individual in a role allowed by RCHSD policy to enter drug orders (e.g., RCHSD RN), which must be later co-signed by the PI or Co-Investigator.
- All initial orders for investigational drugs shall be accompanied by a completed copy of the signature page of the informed consent/assent.
- Pre-printed investigational medication order sheets for each study will be developed (by Pharmacy) to assure proper authority.
- The protocol and/or IRB project number shall be included on all orders for investigational drugs.

b) Laboratory and Pathology

On submission of the Project Initiation Form, Research Administration will provide guidance regarding appropriate approvals and help determine the cost of the required services. To assist with correct handling and billing (if applicable) of the research specimens throughout the project, the intranet Research Specimen Submission Form must be completed and submitted together with the specimens to the Laboratory or Pathology.

c) Other Research-Related Tests and Procedures

Investigators must submit an order (either paper or via Epic) and note that the test/procedure is for a research study. If the order is placed via Epic, a comment can be entered in the comment section that the test/procedure is research-related. Comments must also identify the Epic # and the study name for the study. Research-related tests and procedures must also be linked to the assigned Epic # so that the billing can be routed correctly and charged to the study or insurance as determined during the Coverage Analysis.

5. Medical Record Documentation/Research Progress Notes

If an Epic research # has been assigned to your project, submit the following documents within 24 hours to Health Information (Mail Code 5049) for scanning into ChartMaxx / Epic: RCHSD CPM 11-52

- Consent, Assent, Subject's Bill of Rights, and HIPAA Authorization for Use & Disclosure form (unless waived by the IRB). Health Information will upload these forms into the Media Section of Epic.
  - Based on the barcodes, Consents and Assents will be categorized under [Document Type] = "Consent – Clinical Trials"
  - HIPAA authorization forms will be categorized [Document Type] = "Authorization for PHI for Research."
- A research enrollment note that includes:
  - Name of study and RCHSD PI
  - RCHSD 4-digit project number and IRB #
  - Name of person obtaining consent
  - Statements that:
    - The participant, or the participant's legally-authorized representative, was capable of understanding the consent process
    - The study was explained to the participant
    - The participant was given the opportunity to ask questions
    - The participant was given a copy of the Consent/Assent and Authorization for Use & Disclosure forms
  - A statement to indicate if the study involves the use of any investigational drugs or devices
  - Contact information for a research team member who is available at all times and from whom additional information concerning the study can be obtained.
  - A Research Progress Note–Study Entry–Template is available on the intranet.
- A research note at each subsequent visit (within 24 hours of the visit) during which any research activities are conducted.

6. Study Monitor Visits

Generally, the study sponsor will send monitors on a frequent basis to review the data and source documents, the regulatory binders, and the subject binders. Here are some tips to consider for these visits.

a) Scheduling the Monitoring Visit

Work with the Monitor to schedule a mutually convenient date and time to conduct the monitoring visit.

Arrange for a desk where the Monitor can work during the visit. Visits can be one or more days, depending on the amount of data that needs to be reviewed. Make sure you let others in the office know of the visit and confirm desk availability in the Research Administration office with Tye Barber, ebarber1@rchsd.org.

Confirm the start and stop time for the visit with the monitor. The study coordinator must be available during the entire visit.

Assure that the Monitor is not left alone in an office. If you cannot stay in the office, either ask the Monitor to leave with you or ask a fellow coordinator to assist while you are away.

b) Preparing for the Monitoring Visit

- Ensure that all regulatory documentation and case report forms are complete and available for review.
- Ensure that all data queries received to date have been resolved to the extent possible.
- Ensure that the appropriate patient medical records will be available for review at the time of the monitoring visit.
- Request Monitor Epic access from Health Information by entering the request into Infra (Service Desk). See the intranet tip sheet for Requesting Access to Patient Records for Monitoring Visits
- Obtain the Monitor's signature on the Confidentiality Agreement before their initial visit. If the Monitor changes be sure to obtain a signed Confidentiality Agreement from the new Monitor. Retain copies of signed form(s) in your regulatory binder.
- Inform the RCHSD investigational pharmacist of the scheduled visit so that study drug storage and drug accountability records can be prepared for review.
- Inform the Investigator's fiscal analyst (such as the UCSD Fund Manager) of the visit and request information on outstanding or problematic payments.

c) Managing the Monitoring Visit

- Ensure that the Monitor signs the Visit Monitoring Log.
- Ensure that the Monitor has all documents required to complete the monitoring visit. Provide the Monitor with an update on any study-related issues.
- Ensure that the Monitor doesn't remove any documents from the source document binder or print any information from Epic that includes any Personal Identifiable Patient Information, unless approved through the Patient Consent and HIPAA Authorization for Use & Disclosure form.
- At the conclusion of the visit, meet with the Monitor to discuss any issues related to:
- Adherence to the protocol
- Review of the regulatory files
- Verification of data in the CRFs with the source documentation
- Study drug storage, dispensing and accountability requirements for data storage
- The study coordinator must be available at the conclusion of the visit.
- Discuss any payment issues. If necessary, have the Fiscal Analyst (e.g., Fund Manager) participate at this meeting.
- The Research Coordinator must log the hours spent with the Monitor and request that the UCSD Business Office Fund Manager (for UCSD Investigators) or the RCHSD Grants & Contracts Coordinator (for RCHSD Investigators) create an invoice per the approved clinical trial budget.

d) Follow-Up after the Monitoring Visit

Ensure that all issues identified for resolution or follow-up at the monitoring visit are addressed in a timely manner and document the actions.

7. Adverse Event Reporting

Significant adverse events need to be reported through the RCHSD safety reporting system (Penguin). This includes medications and unanticipated adverse events that are related or possibly related to a research study or considered a new risk.

See the Quality Management Department's live system, the Real Learning for Safety System.

Adverse events also need to be reported to the UCSD IRB. See the IRB's Adverse Biomedical Research Forms page for more information.

For additional information on the reporting of Serious Adverse Events (SAEs) and Adverse Events (AEs), review the SOPs on the Research Administration intranet.

8. Invoicing and Post-Award Management

For UCSD Investigators, the UCSD Business Office Fund Manager manages the project funds over the life of the project. Invoices have to be approved by the Investigator before payment is issued. Monthly reports are provided to keep the Investigator informed of the financial status. Ordering of budgeted supplies or equipment and invoicing to the sponsor as per the agreement terms and budget are processed by the Fund Manager. RCHSD's Accounting department invoices UCSD on a monthly basis for all RCHSD costs accrued at Rady Children's.

For RCHSD Investigators, RCHSD Research Administration manages the project funds during the life of the project. Invoices have to be approved by the Investigator before payment is issued. Monthly reports are provided to keep the Investigator informed of the financial status. Orders for budgeted supplies or equipment are processed by Research Administration and invoicing to the sponsor as per agreement terms and budget are processed by the Accounting Department.

Here are some details on how the various costs are processed at RCHSD:

a) RCHSD Research Nurse Coordinator Time

The coordinator will log the hours spent on a project through API Labor Workx®. The hours will be charged to the PeopleSoft # at the end of each pay-period, every two weeks. The PI should monitor Research Coordinator time by asking for reports on the time spent on the project.

b) Lab Tests and Procedures

Research-related lab tests and procedures must be associated with the Research Epic # when such tests or procedures are ordered in Epic. See the Tip Sheets for detailed information on how to associate research patients with tests and procedures in Epic. Epic will flag the research patient record and research procedure, and Patient Financial Services will post the charges to the PeopleSoft # after the PI or Research Nurse Coordinator has confirmed the charges are to be billed to the research study as per the Coverage Analysis. For inpatients who are admitted for standard of care and are concurrently enrolled in a research study, follow the tip sheet "Associating a Patient with a Research

Study." Do not associate the admission with the research study. Any study-related lab tests and procedures for inpatients must be noted and submitted to Patient Financial Services, Judy Thomas, jmthomas@rchsd.org no later than at time of discharge. Patient Financial Services generates a monthly statement for all patient encounters that were linked to the Epic #. The Research Coordinator or Investigator must review and approve the statements and make any corrections, if necessary. Contact RCHSD Research Administration at research@rchsd.org if you have any questions.

c) Pharmacy Fees

RCHSD Pharmacy generates periodic invoices charging for start-up, annual renewals, and drug dispensing fees. After review and approval from the PI/Research Nurse Coordinator, RCHSD Research Administration will process the charges to post to the Project's PeopleSoft #.

RCHSD Accounting invoices the sponsor once a month or per agreement for all RCHSD-related costs.

d) Physician Fees

Fees for physician services provided by contracted providers that are not billed by RCHSD, (e.g., San Diego Imaging, Sharp MRI, and Anesthesia Service Medical Group) will be include in the RCHSD budget and charged to the PeopleSoft #.

To avoid erroneous billing, a fax needs to be sent in advance of he scheduled procedure to San Diego Imaging or ASMG, alerting them to a research patient order and to not bill patient or patient insurance. Below is an example of the fax cover sheet you can send to San Diego Imaging for patients undergoing radiological imaging.

NOTE: The fax cover sheet is not to arrange for services by the radiologist, but rather to ensure that the radiologist's professional fees are charged to the study rather than to the patient's insurance or to the family.

Rady Children's Hospital San Diego

SDI Research Order Notification

Send Fax to: San Diego Imaging
Attention: Nury Castro, Billing (Email: nury.castro@sandiegoimaging.com)
Fax: **858-256-2981 (Call Nury before faxing to ensure the fax # is correct)**
Phone: 858-836-8212

Patient Name: _____
Date of Birth: _____
Exam Ordered: _____
Ordered by: _____ Date: _____
For questions, please contact: _____

At: _____

RCHSD Study ID / IRB# _____

SDI Billing Instructions:

Please reference RCHSD Study ID (listed above) or IRB # on your invoice.

Mail Invoice to:

Rady Children's Hospital-San Diego
Attn: Research Administration, MC 5074
3020 Children's Way
San Diego, CA 92123
(858) 966-5934

THIS TEST IS FOR RESEARCH
DO NOT BILL PATIENT or INSURANCE

Below is the fax cover sheet you can send to Anesthesia Service Medical Group/Anesthesia Management Professionals for patients needing anesthesia services.

NOTE: This cover sheet is not for arranging services by an anesthesiologist,, but rather to ensure that the anesthesiologist's professional fees are charged to the study rather than to the patient's insurance or to the family.

Rady Children's Hospital San Diego

Anesthesia Service Medical Group
Research Order Notification

Send Fax to: Anesthesia Management Professionals
Attention: Jennifer McHugh
Email: jennifer.mchugh@abeo.com
Fax: **Call Jennifer for the fax # to use**
Phone: (858) 244-3163

Patient Name: _____
Date of Birth: _____
Anesthesia Service Ordered: _____
Ordered by: _____ Date: _____
For questions, please contact: _____
At: _____

RCHSD Study ID / IRB# _____

ASMG Billing Instructions:

Please reference the RCHSD Study ID# (listed above) or IRB # on your invoice.

Mail Invoice to:

Rady Children's Hospital-San Diego
Attn: Research Administration, MC 5074
3020 Childrens Way
San Diego, CA 92123
(858) 966-5934

THIS TEST IS FOR RESEARCH
DO NOT BILL PATIENT or INSURANCE

e) Billing Error Reporting

If you encounter a billing error (e.g., a research patient's family contacts because they received an invoice for activities that have been promised to be free of charge in the consent), please contact Venise Shazier, Research Administration, at vshazier@rchsd.org.

E. THE STUDY IS COMPLETED

1. Closing Out a Study

For an Industry-initiated study, the monitor will schedule a close-out visit.

a) Administrative and Financial Close-Out

You must notify your Business Office Fund Manager, your research coordinator, RCHSD Research Administration, and the Investigational Drug Service when you withdraw or close your project.

All outstanding invoices must be settled before the project can be completely closed by Research Administration.

RCHSD Research Administration and the UCSD Business Office will initiate contractual and fiscal close-out processes.

b) IRB

Study Withdrawal and Closure Policy and Procedure .

How to Submit a Study Withdrawal or Closure

Submitting a Biomedical Research Study Withdrawal or Closurel

2. Research Document Storage

a) While the Project is Active

See Policy CPM 11-63 on Records Retention (Business Records).

b) After the Study Has Closed: Retention of Records

See Policy CPM 11-63 on Records Retention (Business Records).

F. ABBREVIATIONS

AHRQ	Agency for Healthcare Research and Quality
CDA	Confidentiality Agreement (see also NDA)
CDC	Centers for Disease Control
COI	Conflict of Interest
CMS	Centers for Medicare & Medicaid Services
CPCR	Center for Pediatric Clinical Research
CRF	Case Report Form
CRO	Contract Research Organization
CSSD	Children's Specialists of San Diego
CTA	Clinical Trial Agreement
DOD	Department of Defense
DUA	Data Use Agreement
ePD	electronic Proposal Development
eRAP	Electronic Research Administration Program
HIPAA	Health Insurance Portability and Accountability Act
HRPP	Human Research Protections Program
HSSPPO	Health Sciences Sponsored Project Pre-Award Office
IDC	Indirect Cost
IRB	Institutional Review Board
IVRS/IWRS	Interactive Voice Response System / Interactive Web Response System
NDA	Non-Disclosure Agreement (see also CDA)
NIH	National Institutes of Health
OCAA	Office of Coverage Analysis Administration
OCGA	Office of Contract and Grant Administration
OCTA	Office of Clinical Trials Administration
OPAFS	Office of Post-award Financial Services
PHI	Protected Health Information
PI	Principal Investigator
PO	Purchase Order
PSA	Procurement Services Agreement
RAMP	Research Administration Management Portal
RES	Request for Extramural Support
RTA	Ready-to-Accrue Letter
UCSD	University of California, San Diego

G. FREQUENTLY ASKED QUESTIONS

Q: When do I need to obtain RCHSD Research Administration approval to do research?

A: Approval is needed for any project that involves:

- RCHSD patients
- Access to patient records or other RCHSD databases
- RCHSD resources or personnel
- An IRB application (even if the IRB certifies that the study does not involve human subjects research and does not require IRB review).
- Recruitment of subjects at RCHSD, who are not patients, including family members, RCHSD employees, physicians, and trainees
- Flyers

Q. **Who is responsible for developing the budget for RCHSD-related costs?**

A: For RCHSD/CSSD PI's, Research Administration will assist the PI with the budget for RCHSD costs. Contact Research Administration research@rchsd.org for assistance.

For UCSD-employed PIs, the PI's UCSD Fund Manager is responsible for developing the study budget with the PI and will work with RCHSD Research Administration to identify the RCHSD-related costs.

Q: **Who negotiates the budget with the Sponsor?**

A: For RCHSD/CSSD-employed Investigator RCHSD Research Administration (research@rchsd.org) will negotiate budgets with sponsors.

For UCSD-employed investigators the budget with the industry sponsor is negotiated by either OCTA (for a fee) or if you are an Investigator in the Department of Pediatrics, the Pediatrics Business Office will assist with negotiating budgets with the sponsor.

Q: **I am an RCHSD-employed coordinator for a UCSD PI. What are my responsibilities regarding the budget, contract, and invoicing for RCHSD charges?**

A: Budget: The person who negotiates the budget will need your assistance in determining how much time is needed for each of the research activities, including the start-up budget. It is important that you determine any hidden costs that may not be easily gleaned by looking at the study grid. Contract: Should you receive the contract, make sure you send it on to the PI's UCSD Fund Manager so that the contract can be forwarded to the appropriate office (either OCTA or OCGA at UCSD).

If this is a study that is conducted by an Investigator who is not affiliated with UCSD, please forward it to Research Administration at research@rchsd.org. If in doubt on what to do with a specific contract or agreement, don't hesitate to contact Research Administration at research@rchsd.org.

Invoicing of RCHSD charges: During the study, you will have to make sure that all charges (labs, tests, pharmacy, etc.) are charged to your research project. By linking each visit to the Epic #, you will ensure that the billing is not being sent automatically to Insurance or the Payer. For inpatient visits that will incur costs, notify Patient Financial Services (Judy Thomas, jmthomas@rchsd.org). If you find any discrepancies, contact Venise Shazier, Research Administration, at vshazier@rchsd.org. Invoice statements from Hospital Billing, Professional Billing, and Pharmacy will be provided to you and you must review and approve them before they are processed for transfer to the PeopleSoft #. The PeopleSoft # where all RCHSD charges will be posted will be given to you by Research Administration. Please work with Research Administration

research@rchsd.org if you have any questions. It is important that you link the research patient and outpatient visits to the Epic # so that the billing is routed appropriately.

Q: **I am a UCSD-employed coordinator for a UCSD PI. What are my responsibilities regarding the budget, contract, and invoicing for RCHSD charges?**
A: Same as above.

Q: **How does invoicing work for RCHSD costs?**
A: The cost for all research activities, including staff time, as well as labs, tests, procedures, and pharmacy are posted to a PeopleSoft # that is assigned to each project that incurs cost. You will receive frequent statements from Hospital Billing, Professional Billing and Pharmacy for your review and approval. Once approved, Research Administration will assist with posting the correct charges to the study and RCHSD Accounting will invoice the sponsor (including UCSD) for the cost on a monthly basis.

Q: **I am an RCHSD employee and my time is being charged to the study. What do I need to do?**
A: When you complete the Project Initiation Form, RCHSD Research Administration will assign a PeopleSoft # to the study. You must add the name of the study and the PeopleSoft # to your time sheet, add the hours you worked on the study and submit your time card to Tye Barber, ebarber1@rchsd.org. The percent effort you worked on each study is entered into API Labor Workx®.

Q: **When is a Purchase Order needed, and when is a Procurement Services Agreement needed? What is the fundamental difference between the two?**
A: Purchase Orders are created by UCSD to allow payment of RCHSD services during the life of the study (e.g., labs, pharmacy, staff hours). Studies that receive purchase orders are Investigator-initiated studies including NIH grants. In short, all agreements that are negotiated through UCSD OCGA will result into a purchase order to RCHSD.

A Procurement Service Agreement is the document used to allow payment of RCHSD services (labs, pharmacy, staff hours, etc.) during the life of the Industry-initiated study which is negotiated through UCSD OCTA.

Note: Occasionally, RCHSD receives a Subaward Agreement that is issued when a defined portion of the RCHSD work statement includes intellectually significant activity of a RCHSD/CSSD-employed Investigator. The Subaward Agreement flows down the terms from the Prime Agreement and includes budget for the effort of RCHSD PI and other activities led by the RCHSD PI.

Q: **If there are no costs at RCHSD, why does Research Administration need a Procurement Services Agreement for Industry-initiated studies?**
A: In addition to budget terms, the Procurement Service Agreement (PSA) also addresses terms such as period of performance, compliance, termination, insurance, and indemnification. The PSA is a template agreement that is used for each Industry-initiated study regardless of RCHSD costs.

Q: **I am an RCHSD employee—How do I know if I should work with the Principal Investigator's UCSD fund manager, OCTA, or OCGA?**
A: It is best that you contact the UCSD Fund Manager who is responsible for processing the appropriate documents for UCSD central offices (OCTA and OCGA).

Q: If adult subjects who are not RCHSD patients are enrolled in genomics studies, do they need a separate medical record account?

A: Yes

H. FOR QUESTIONS ABOUT ANYTHING IN THIS HANDBOOK

Contact Research Administration at research@rchsd.org.

END