CRC-SPO STAFF SERVICES

PRE-AWARD: REGULATORY

The CRC has two full-time Regulatory Specialists handling IRB and other aspects of study start-up, including:

- Schedules and facilitates pre-study site visits;
- Processes confidentiality disclosure agreements through UCSF Industry Contracts;
- Prepares all regulatory documents for initial and continuing review applications to the IRB and study sponsors, including consent form revisions required by UCSF CHR and CMC IRB;
- Reviews all protocol amendments and submits study modifications to the IRB;
- Ensures that protocols, amendments, ICFs, investigational drug brochures, and other miscellaneous documents are approved by the IRB;
- Works with PI, IRB and sponsors to resolve questions or issues regarding regulatory submissions (e.g. response to IRB contingent approval); documenting regulatory activity and status for all sponsored studies;
- Engages with CRMC departments to review new studies and obtain signed Area Director Agreement forms;
- Enters study details into UCSF's Online Collaborative Research Environment (OnCore) software.

PRE-AWARD: BUDGETS/CONTRACTS

Study budgets and contracts are reviewed and negotiated by the CRC Administrator in coordination with Industry Contract Officers at UCSF. Responsibilities of the CRC Administrator include:

- Performs UC-mandated Medicare Coverage Analysis based on the study schedule of events;
- Prepares and negotiates study budget with sponsor based on study-related procedure costs (e.g. CRMC research rates) and fair market values for industry-sponsored trials;
- Reviews and negotiates payment terms with sponsor;
- Coordinates with UCSF Industry Contracts officer to negotiate Clinical Trial Agreement;
- Facilitates COI clearance with the UCSF Office of Clinical Research and Office of Ethics and Compliance.

POST-AWARD: STUDY COORDINATION

Clinical Research Coordinators are the cornerstone of a successful clinical trial. Responsibilities of the Clinical Research Coordinator include:

- Identifies, screens and enrolls study subjects. Obtains informed consent, reviewing study information with potential subjects, and/or their families, including the eight elements of informed consent required by the FDA (45 CFR part 46);
- Develops recruitment and retention strategies, establishing rapport with subjects and their family or caregiver to ensure effective communication and advocating for their diverse needs;
- Schedules and conducts study visits per protocol requirements. Includes administering questionnaires, collecting medical history, performing various study procedures within your scope of practice (e.g. vitals, EKG, blood collection, etc.);
- Maintains communication with subject's care providers to ensure safety and continuity of care;
- Performs lab processing procedures (centrifuge, aliquot, freeze), ensuring correct labeling and storage of specimens based on the study protocol; maintaining IATA certification for proper shipment of specimens to central labs and storage facilities;
- Coordinates, communicates and networks with other departments and affiliates to ensure proper study procedures are ordered, time windows are met and registration/billing is correct;
- Ensures that all laboratory tests are completed for the research project and are reviewed and signed by the Investigator
- Conducts medical record review to extract data for use in studies; maintains proper source of the data for correct data entry and verification;
- Enters data collected into electronic or paper case report form accurately and resolves any discrepancies or queries in a timely manner;
- Maintains subject tracking logs, including study visit log and billing log to ensure accuracy; keeps receipt of patient time and travel payments to ensure correct balance of study specific petty cash;
- Documents adverse events and submits to appropriate agencies within required timeframes; includes prompt communication with Investigators for proper assessments;
- Helps train study staff and affiliates on the study protocol; attends and actively participates in regular team meetings and sponsor trainings/visits;
- Maintains adherence to the existing policies and procedures by following the most current SOPs for the UCSF Fresno Clinical Research Center and those of the University of California, and any other affiliate institutions;

- Implements and maintains periodic quality control procedures; participates in and cooperates with any internal and external audits or reviews of study protocols; prepares necessary documentation.

PRE/POST-AWARD: PHARMACY

UCSF Fresno employs a full-time research pharmacy technician, housed in the CRMC inpatient pharmacy. The research pharmacy technician is responsible for the following:

- Meets with sponsors for site selection visits; answers pharmacy related questions on feasibility questionnaire;
- Prescreens new study protocol; identifies and addresses any issues pharmacy might have with investigational product (IP) storage or dispensing;
- Discusses pharmacy-related study information with pharmacy director; obtains pharmacy Area Director Agreement signature;
- Completes required IP training for new study protocols; sets up trainings, collects documentation and CV's for additional pharmacy staff;
- Sets up access to IXRS, IVRS, and IWRS randomization and drug accountability software;
- Meets with sponsors for site initiation; receives initial drug shipments and maintains appropriate inventory levels of IP;
- Monitors TempTrak devices for refrigerated, frozen and ambient storage temperatures for all IP; submits temperature logs to sponsors as requested;
- Maintains pharmacy binder for each study, including protocol, IB, pharmacy manual, inventory accountability logs, shipping invoices, patient drug logs and patient consents;
- Works with CRMC's Willow Build Team to pre-build EPIC entries (IP orders) for each inpatient study;
- Works with CRC research coordinators to ensure pre-printed chart orders for inpatient study drug are written correctly and contain all required information;
- Sets up Randomization schedules for investigator-initiated drug studies;
- Compounds IV study drug infusions, including chemotherapy, for both outpatient and inpatient study protocols; dispenses outpatient study drug per protocol;
- Tracks study drug expiration dates, quarantines expired drug, prepares expired drug for return shipping to sponsor;
- Accounts for and document patient returned study medication;
- Meets with sponsors for site monitoring visits and study closeout visits.

POST-AWARD: FINANCE

The CRC Administrator and UCSF Fresno Finance Manager are responsible for managing study budgets. The CRC Research Supervisors and CRC Administrator track study activity and assign staff FTE to studies based on subject enrollment. This often requires modification to a coordinator's fund distribution on a quarterly basis. Other responsibilities include:

- Assigns award to department ID, creates fund tracking/reporting spreadsheet;
- Performs accrual accounting: tracks study activity to determine accounts payable and receivable;
- Tracks deposits and invoices sponsor for payments due;
- Allocates and re-assigns staff FTE based on study activity and reimbursement;
- Reviews and approves study expenses, including all CRMC study-related invoices;
- Prepares annual profit/loss reports for each sponsored project;
- Prepares study closeout reports to insure receipt of all payments due, payment of all outstanding debts and transfer of residual funds to the proper PI account(s).