

Facility

- Spacious 22 bed inpatient facility dedicated to clinical research (private bathroom in each room, privacy curtains, patient lounge & full working kitchen)
- 4 Rooms equipped with monitoring capability (cardiac, arterial pressure, etc.)
- Rooms equipped with isolated electronic monitoring and one-way observation windows
- 4 outpatient examination and treatment rooms
- Large basic science research lab
- Investigational drug pharmacy
- Conference room
- FDA-compliant file storage area

Description of Facility, Equipment and/or Services

- **Nursing Coordination and Services:** BLS & ONS certified professional nurses. Research coordination by a professional nursing team with thorough understanding of GCP guidelines and providing oversight of all aspects of protocol development and implementation. This includes creation and customization of source documents, developing the research schedule, monitoring and conducting all subject study visits and facilitating accurate and timely data entry. Nursing staff 24/7, on-call service by request. Nursing Practice privileges for research on hospital in-patients. Nurses are trained and certified to conduct study specific procedures such as phlebotomy, IV infusion, QTC studies and monitoring.
- **Research Pharmacy:** Protocol review and development of pharmacy budget for sponsor protocols. Protocol development and review for investigator-initiated protocols. Drug, shipment, storage and dispensing of study drugs. Drug return and destruction. Development and maintenance of all regulatory paperwork, including IDDS, study protocols, drug inventories and dispensing records.
- **Lab Services:** Biological specimen collection. Pharmacokinetic and phar-mo-dynamic studies. Capabilities in ELISAs, flow cytometry, tissue and cell culture, Western blotting, DNA sequencing and immunohistochemistry. Setting up lab kits. Storage/banking capabilities. Coordination with other research core facilities.
- **Budget Development:** Preparation of preliminary budget based upon study synopsis or draft protocol. Assistance in preparation and negotiation of budgets for study sponsors. Assistance in budget preparation for investigator-initiated studies.
- **Logistical Assistance:** Assistance to investigators in acquiring and launching new studies and obtaining Clinical Trial Agreements. Facilitate interactions between industry in need of assistance in clinical trials and faculty interested in clinical research.
- **Data Management:** Assist in patient recruitment, data and clinical report form completion, adverse event reporting, data collection, data entry and storage.
- **Regulatory Assistance:** Assist investigators in completing all required regulatory documentation, IRB submission, oversight and management of regulatory requirements.
- **Services and Pricing:** Costs based on individual protocol needs. Contact CRC for specific pricing information.

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