Clinical Trials Unit
at Ochsner

The Region’s Only Clinical Trials Unit
The Clinical Trials Unit at Ochsner

The Clinical Trials Unit (CTU) at Ochsner is located on the Ochsner Baptist Medical Center campus in New Orleans, and is the region’s only clinical trials unit. Its central uptown location provides easy access to volunteer research subjects, research investigators, study coordinators, and sponsors. Covered parking is available in the Jena Garage free of cost.

Objectives

- To foster and promote clinical and translational research
- To cultivate spirit of cooperation and partnership with industry sponsors and Clinical Research Organizations (CRO)
- To provide a convenient site for investigators and scientists at Ochsner to conduct research studies
- To serve as an innovative resource for to conduct research studies by investigators and scientists from regional academic and non-academic institutions

The Clinical Trials Unit has capabilities to successfully support all varieties of clinical trials:

<table>
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<tr>
<th>Phases</th>
<th>I, II, III, IV</th>
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| Types | Diagnostic  
Proof of Concept  
Safety  
Nutrition  
Prevention  
Treatment  
End-of-Life |
| Clinical Areas | Cardiology  
Endocrinology  
Oncology/Hematology  
Infectious Diseases  
Neurology  
Pediatrics  
And more... |

The CTU Offers Many Amenities:

Reception Area
A large reception/waiting area welcomes visitors to the CTU. Staffed by courteous and knowledgeable receptionists, it is suitable for handling large volume clinical trials.

Examination Rooms
Five spacious, fully-equipped examination rooms are available in the CTU. These rooms are ideally suited for obtaining informed consents, physical examinations, patient counseling, etc.

Float Offices
The CTU provides the convenience of multiple float offices for visiting investigators, sponsor representatives, study monitors, and research staff. The availability of free wireless internet access adds to the convenience of using this facility.

Conference Room
A multi-purpose conference room with advanced audio-visual teleconferencing and video conferencing capabilities is available in the CTU. The conference room can be used by study teams to discuss the progress of their studies, by monitors to conduct study monitoring activities, or by investigators for meeting with groups of volunteer research subjects.

Access to Biobank
For protocols that require processing and storage of biological specimen such as tissue biopsies, blood, urine, etc., access to an in-house, state-of-the-art biorepository unit is available.
**Infusion Suite**
The eight (8) chair Infusion Suite provides a comfortable environment to volunteer research subjects during infusions. Equipped with flat-screen television sets, this Infusion Suite is located within the CTU and is staffed by experienced infusion nurses.

**Research Pharmacy**
A full line of pharmacy services is available to research teams in the state-of-the-art, 500 square feet research pharmacy. All investigational drugs are handled by experienced and dedicated Research Pharmacists who provide services such as, but not limited to, receiving, storing, dispensing, shipping, compliance, and accountability of investigational drugs.

**Phlebotomy Services**
Volunteer research subjects can have blood drawn in the CTU by an experienced phlebotomist. Blood specimens can also be processed, stored, and shipped according to protocol specifications by the CTU staff.

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**Ochsner Baptist Medical Center Offerings:**

**Inpatient Beds**
The campus consists of 43 all-private medical/surgical beds available for conducting complex inpatient clinical trials. These inpatient clinical trials can be efficiently managed by the CTU staff.

**Sleep Lab**
The CTU boasts access to a newly renovated Sleep Lab that accommodates up to eight (8) sleep studies at any given instance. Sleep clinic services are also available on campus.

**Imaging Center**
The on-site Ochsner Baptist Imaging Center offers a range of state-of-the-art equipment, including a 64-slice CT, MRI, Ultrasound, Radiography, Fluoroscopy, Nuclear Medicine, Radiation Therapy and Echo Cardiology testing. In addition, a Picture Archive and Communication System (PACS) is in place to allow research investigators to view images of volunteer research subjects in their offices and throughout the hospital, including the operating rooms.

**Dietary Services**
Ochsner Baptist Medical Center’s cafeteria, Café De Lis, is located on the first floor of the Clara Wing, and is open for breakfast and lunch. For clinical protocols that have specific dietary requirements, arrangements can be made through the CTU.
Experienced Clinical Trials Team

Experienced and diligent CTU staff ensures that clinical trials meet the highest standards of ethical, legal, and regulatory compliance.

Biostatistical Support

Investigators at the CTU can conveniently avail the biostatistical consulting services provided by the Office of Biostatistical Support at Ochsner.

Local IRB Oversight

All studies involving human research subjects in the CTU require approval and ongoing oversight by Ochsner Institutional Review Board (IRB). The Ochsner IRB is a component of the Ochsner’s Office for the Protection of Research Subjects, which is housed in the Institute for Clinical Research. Research protocols for IRB review can be submitted conveniently using Electronic Research Study Application (ERSA) system and are routed, reviewed and finalized electronically for faster outcomes.

Experienced Budget/Contract Team

The experienced staff of the Office of Grants Management and Development (OGMD) can assist research investigators in ensuring that the budget negotiations and contract execution processes are accomplished efficiently for timely start-up for clinical trials. OGMD can also help with activities such as grant writing, pre-award fiscal planning, and post-award fiscal monitoring.

On-site Guest Accommodations

An overnight stay may occasionally become necessary for the family members of volunteer research subjects involved in inpatient clinical trials. Some out-of-town study monitors may also prefer to stay closer to the CTU when they are visiting for study monitoring activities. The McFarland Inn is a hotel conveniently located on the Ochsner Baptist hospital campus. Reservations can be made by calling 504-894-2400.

Other Support/Ancillary Services:

Protocol Development and Implementation

The CTU offers a range of tools, templates, and consultation services to assist investigators in writing and developing clinical trial protocols that are in compliance with regulatory/GCP requirements.

Design and Monitoring of Pharmacokinetic Studies

The infrastructure at the CTU supports safe and efficient conduct of Phase I clinical trials that require close and careful monitoring of healthy volunteer research subjects including vital signs, blood chemistry, ECG, and other relevant clinical parameters.
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