CHRISTUS Health Highlights

Legacy:
In 1999, two historic Catholic charities became one, forming CHRISTUS Health and creating a unique purpose in the modern health care market—to take better care of people.
To extend the healing ministry of Jesus Christ, the mission that the Sisters of Charity Health Care System and Incarnate Word Health System shared for more than a century, is now the mission of CHRISTUS Health. The heart of CHRISTUS Health, the people and facilities dedicated to the service of healing, impact a history of perseverance and faith. The joining of the following three congregations now compose CHRISTUS Health:

- Sisters of the Holy Family of Nazareth
- Sisters of Charity of the Incarnate Word of San Antonio
- Sisters of Charity of the Incarnate Word of Houston

Highlights:
- An international Catholic, faith-based, not-for-profit health system
- Ranked among the top 10 Catholic Health Systems in the United States
- Headquartered in Dallas, Texas
- Comprised of more than 600 services and facilities, including more than 60 hospitals and long-term facilities, 350 clinics and outpatient centers, and dozens of other health ministries and ventures
- CHRISTUS services can be found in 60 cities in the United States, Mexico, Chile, and Colombia

Mission:
To extend the healing ministry of Jesus Christ

Core Values:
Dignity, Integrity, Excellence, Compassion, Stewardship

CHRISTUS Institute for Innovation & Advanced Clinical Care (CIIACC) Highlights

Purpose:
To continue to improve the quality of care provided to our patients and communities through innovative research and advanced clinical care options, conducted in a financially responsible and ethical manner.

Capabilities:

<table>
<thead>
<tr>
<th>Types</th>
<th>Phases</th>
<th>Major clinical areas of focus</th>
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<tbody>
<tr>
<td>Prevention</td>
<td>Phase II</td>
<td>Cardiology</td>
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<tr>
<td>Diagnostic</td>
<td>Phase III</td>
<td>Hematology</td>
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<td>Effectiveness</td>
<td>Phase IV</td>
<td>Neurology</td>
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<td>Safety</td>
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<td>Oncology</td>
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<td>Treatment</td>
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<td>Pediatrics</td>
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<tr>
<td>Pragmatic</td>
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<td>Orthopedics</td>
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<td>Nutrition</td>
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<td>Women’s Health</td>
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<tr>
<td>End-of-Life</td>
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<td>Wound Care</td>
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Organization:

Office of Research & Academics (ORA)

CHRISTUS Institute For Academic Advancement (CIAA)

CHRISTUS Institute For Innovation & Advanced Clinical Care (CIIACC)

Office of Human Subjects Research Protection Program (OHSRPP)

Office of Sponsored Programs & Research Finance (OSPRF)

Office of Investigator Support (OIS)

CHRISTUS Virtual BioBank
CHRISTUS Health is committed to ensuring an institutional culture where research is conducted in an ethically and scientifically sound manner, where the rights, safety, integrity, and welfare of human subjects are held to the highest standard. The Office of Human Subjects Research Protection Program (OHSRPP) at CHRISTUS Health is systematically structured to provide oversight for all human subject research which involves patients, employees, students, funds, assets, or otherwise. The main components of OHSRPP are:

**Institutional Review Board (IRB)**

The CHRISTUS Health IRB is the umbrella IRB that reviews all research protocols at CHRISTUS Health. It conducts ethical review of all research protocols to protect the rights and welfare of humans participating as subjects in research studies. The CHRISTUS Health IRB abides by the CHRISTUS Health policies and procedures, Ethical and Religious Directives for Catholic Health Care Services, The Belmont Report, as well as the regulations set forth by the Food and Drug Administration (21 CFR Part 56), and the Office of Human Research Protections (45 CFR 46).

**Compliance**

The CIACC fosters a rigorous culture of research compliance pursuant to ICH Guidelines for Good Clinical Practice (E6). These responsibilities include, but not limited to: training and informing research stakeholders about the hazards of research misconduct or non-compliance, conducting audits, monitoring research activities, correcting violations, investigating incidents and complaints by employees and subjects, providing regulatory support to all researchers, enforcing policies, reporting to institutional and federal agencies, and appropriately documenting compliance activities and processes.

**Education**

The CIACC offers an ongoing robust research education program for IRB members, researchers, medical residents, fellows, and students to support safe and high-quality care to research subjects, to fulfill the obligations under the CHRISTUS Federal Wide Assurance, and to assist members of the CHRISTUS research community in continually honing their GCP knowledge and skills.

The Office of Sponsored Programs and Research Finance supports the advancement of clinical research by providing leadership and necessary expertise in research administration while ensuring compliance with relevant regulations. This Office is also responsible for the governance and management of the Clinical Research Revenue Cycle. The experienced staff of the Office of Sponsored Programs and Research Finance strives for consistently achieving optimization of financial performance and compliance, reduction in legal consequences stemming from potential research non-compliance events, and protection of CHRISTUS Health assets. For timely launch of clinical trials, this Office is charged with developing relevant processes and internal controls.

**Pre-Award**

The Pre-Award team provides support and assistance to investigators interested in sponsored research as they prepare proposals for submission to sponsors. This team is also responsible for developing, negotiating and executing contracts and budgets for sponsored clinical research. The services offered are:

- Budget Development, Review, and Negotiations
- Contract Development, Review, and Negotiations
- Research Coverage Analysis
- Grant Writing, Review, and Submission
- Management of Research Administrative Charge Master/Feef Schedule
- Fair Market Value Assessments

**Post-Award**

The Post-Award team serves as the liaison between investigators and sponsors upon receipt of research grants and awards. This team manages financial activity through internal controls and review of all research-related transactions. The services offered are:

- Billing and Invoicing
- Cost Sharing/Matching
- Collections and Posting
- Research Expenditure Control
- Trial Coding
- Award Closeout
- Cost Transfers

**Research Finance**

The Research Finance team provides overall management of research finance for accurate reporting. The services offered are:

- Management of Clinical Trial Management System
- Government Financial Reporting
- Time and Effort Reporting
- Internal Financial Reporting
- Account/General Ledger Reporting
Research Facility Locations

Map for general reference only. Not to scale.
Office of Investigator Support

The Office of Investigator Support provides all necessary guidance and support services to physician investigators who are committed to providing innovative and advanced clinical care options to their patients closer to their homes and families. Through multiple regional research offices, the Office of Investigator Support makes available core and ancillary services needed for overall successful conduct of clinical research as follows:

Protocol Development
A range of tools, templates, and consultation services are offered to assist investigators in writing and developing clinical trial protocols that comply with applicable regulatory and GCP requirements.

Protocol Implementation Support
Led by proven regional leaders, the local research facilities come staffed with experienced and diligent research nurses, research coordinators, and regulatory specialists to assist physician investigators. These research teams assist with protocol feasibility analysis, as well as conduct of clinical trials while meeting the highest standards of ethical, legal, and regulatory compliance.

Biostatistics Consultation
Investigators at CHRISTUS Health can conveniently avail the biostatistics consulting services during various stages of their research such as protocol design, grant application preparation, data collection, data analysis, and manuscript preparation.

Research Technology
To ensure efficient conduct and optimal management of clinical research, a variety of solution-oriented e-platforms are offered to research teams. These include: iRIS for IRB application management, eProposal for research contract and budget management, CREDIT® for research finance and research portfolio management, ClinCard for subject payment management, and RedCap for research database management.

Strategic Partnerships
To allow meaningful collaborations, business partnerships, and reliable access to newest clinical trials in market, strategic relationships are built and maintained with academic institutions, clinical research organizations, biospecimen research companies, and pharmaceutical companies at local, regional, national, and global levels.

International Research

Highlights:
• International expansion began in 2001
• International presence currently in Mexico, Chile, and Colombia
• Over 15,000 associates employed in international operations
• Third largest private health care provider in Mexico
• Second largest private health care provider in Santiago de Chile
CHRISTUS Virtual BioBank

CHRISTUS Virtual BioBank is a unique service offering to help advance meaningful biomedical research for improved patient care.

**Purpose**
- To provide high-quality biospecimens from consented human donors, annotated with detailed and de-identified clinical and pathological datasets
- To promote opportunities for research collaboration between CHRISTUS and non-CHRISTUS scientists
- To become a ‘resource of choice’ for local, national, and global research institutions, industry, and academic centers

**Salient Features**
- Access to biospecimens with diverse genetic and epidemiological background
- Strict adherence to local and international ethical regulations and standards
- Guaranteed quality and collection standard compliance
- Same day shipment services (global coverage)
- Shipment compliance management system by IATA-trained personnel
- Cold chain management of biospecimen as follows:
  - Controlled ambient: +15°C to +25°C
  - Refrigerated: +2°C to +8°C
  - Frozen and deep frozen: -20°C to -70°C
  - Liquid nitrogen vapor phase: -180°C
- Flexibility and adaptability to client needs
- Dedicated and professional project life-cycle management

**Scope**

<table>
<thead>
<tr>
<th>Tumor &amp; Normal Tissues</th>
<th>Blood Samples</th>
<th>Other Sample Bio Fluids</th>
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<tbody>
<tr>
<td>Fresh Tissue</td>
<td>Whole Blood</td>
<td>Urine</td>
</tr>
<tr>
<td>Frozen Tissue</td>
<td>Plasma</td>
<td>Synovial</td>
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<tr>
<td>Tissue Blocks (FFPE)</td>
<td>Serum</td>
<td>Sputum</td>
</tr>
<tr>
<td>Tissue H&amp;E Slides</td>
<td>PBMC</td>
<td>Saliva</td>
</tr>
</tbody>
</table>

**Service Lines**

ARCHIVAL BANK
This service line offers access to high-quality, clinically-excess, annotated formalin-fixed paraffin-embedded (FFPE) tissues and H&E slides from Pathology archives.

4U BANK
This service line allows targeted development of a temporary BioBank that strictly meets the specifications of an IRB-approved collection protocol for sole utilization by pre-identified scientists for end-use.

Max and Minnie Tomerlin Voelcker Clinical Research Center

The Max and Minnie Tomerlin Voelcker Clinical Research Center is located at the The Children’s Hospital of San Antonio in downtown San Antonio, Texas. It is an all-inclusive outpatient research facility. With patient-centered design, it spans over 11,200 square feet of space.

**Objectives:**
- Foster and promote clinical and translational research
- Serve as a convenient site for CHRISTUS and non-CHRISTUS scientists to conduct research
- Enhance research-related cross-collaborations locally and regionally
- Support investigators in conduct and management of clinical research

**Facility Highlights:**
- 4 patient exam/treatment rooms
- 2 patient consultation rooms
- Conference Room
- Float Offices
- Multi-purpose patient triage room
- 3 laboratories with biobanking capabilities
- Patient reception/waiting area
- Free parking

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