

C. RESEARCH ETHICS CITI TRAINING

All researchers must complete CITI training at the onset of their research. The initial CITI training requirement will expire 3 years after the initial year the course was completed. During the 3 year period (prior to the expiration date), researchers can remain certified through completion of one of the following:

- Retake the full initial CITI course
- Take the CITI refresher course
- Take 12 hours of GCP credits approved by the CHRISTUS Health IRB*

**There are at least 6 credit hours offered annually. At least 4 credit hours/year for 3 consecutive years need to be earned to qualify.*

D. ANNUAL IRB CONFERENCE

This annual 2-day on-site event offers a unique learning opportunity to all members on IRB's panel and office staff. The major highlights of this educational event are:

- Conduct of monthly IRB meeting in a face-to-face setting
- Educational sessions on emerging and hot topics
- Interactive mock role plays
- Guest speaker session(s)
- Social networking events

E. CTBC TRAINING

This online training covers topics on clinical research billing compliance and best practices to enhance accuracy and compliance in billing, coding, claims processing, and research revenue cycle management.

F. DANGEROUS GOODS TRAINING

This online training provides educational opportunities to learners engaged in hands-on bio-specimen research or bio-banking activities such as handling and shipping of Category A & B medical specimens for research studies. This training covers the regulations imposed on most laboratories and the importance of following them, classification of infectious substances for transport, procedures for legally and safely shipping various infectious specimens, etc.



MISSION:

To extend the healing ministry of Jesus Christ.

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Highlights from FY2019 Program

- ✓ 184 Number of attendees
- ✓ 115 CME, CNE, and contact hours awarded
- ✓ > 99% attendees/lecture agreed to the speaker's subject matter expertise and their content delivery effectiveness
- ✓ > 99% attendees/lecture agreed to the relevance of the lecture contents to the learning outcomes
- ✓ > 99% attendees/lecture agreed to the effectiveness of the teaching methods and learner engagement strategies



Institute for Innovation and
Advanced Clinical Care

FY 2020 RESEARCH EDUCATION PROGRAM

GOOD CLINICAL PRACTICE (GCP)

“A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that rights, integrity and confidentiality of trial subjects are protected.”
-ICH Ed 1.24



PURPOSE

The CHRISTUS Health Office of Human Subjects Research Protection Program is excited to offer ongoing education to support safe, and high quality care to CHRISTUS research subjects, fulfill our obligations under the CHRISTUS Federal Wide Assurance, and other federal regulatory guidance, and to assist members of the CHRISTUS research community in honing their GCP skills.

STATEMENT OF COMMITMENT

“In order to fulfill our unwavering commitment for ensuring high quality standards towards human research subject protections at CHRISTUS Health, it is vital for us to offer a comprehensive, ongoing, in-house Research Education Program. The components of our Research Education Program provides training in Good Clinical Practice (GCP), consistent with the principles of the International Conference on Harmonization (ICH) E6 (R2). This program is required and available to all investigators and research personnel involved in the design, conduct, oversight, and/or management of research studies approved by CHRISTUS Health IRB, and other approved external IRBs.”

-Pukar Ratti, MSChE, MSHCM, CIM, CCRP, FACMPE
System Director of Research & Institutional Official



AVAILABLE RESEARCH EDUCATION OPPORTUNITIES

		Investigators & all Research Staff	Medical Residents & Fellows	IRB Members & Staff
A	CRM Course		✓	
B	GCP Lecture Series	✓	✓	✓
C	Research Ethics CITI Training	✓	✓	✓
D	Annual IRB Conference			✓
E	Clinical Trial Billing Compliance (CTBC) Training	✓		
F	Dangerous Goods Training	✓		

A. CLINICAL RESEARCH METHODOLOGY (CRM) COURSE

OBJECTIVES:

- Provide structured introduction to the concepts in clinical research
- Expand knowledge for development of comprehensive research protocols
- Familiarize with the ethical principles and IRB approval process
- Promote best practices in research data collection, compilation, and analysis
- Develop effective plan for research data dissemination

LECTURES:

The Importance of Research in Medicine	Michael Mitakidis, MD
Principles of Clinical Research Ethics	Phyllis Everage, CIM
Understanding the Building Blocks of a Clinical Research Protocol	Mike Brunet, PhD
Basic Statistics in Clinical Research	Annaliese Cothron, MS
Role of IRB in Clinical Research	James Tyler, PharmD
Clinical Research Data: Collection, Analysis, and Dissemination	Polly Mock, RN, CCRC, CHRC

B. GCP LECTURE SERIES

Conference #: (877) 853-5247
Meeting ID: 572268477

Back To Basics – Reviewing Fundamental Principles in Clinical Research Methods
Stergios (Michael) Mitakidis, MD
Director, Clinical Education and Development
August 8, 2019 (12 Noon - 1 PM)

“Getting your Clinical Trial Started”
Michael Brunet, PhD
Regional Research Director for LA and SETX
October 10, 2019 (12 Noon - 1 PM)

“Creating a Culture for Compliance”
Polly Mock, RN, CCRC, CHRC
Regional Research Manager-Spohn
December 12, 2019 (12 Noon - 1 PM)

“Pediatric Research vs. Standard of Care Treatment”
Mark Gilger, MD
Pediatric Gastroenterologist Physician
February 13, 2020 (12 Noon - 1 PM)

“What’s Law Got to do with it? Understanding the Impact of the new “Hot 3” in CTAs: Record Retention, Privacy, and Inspection by Foreign Regulators”
Melissa Markey, JD, CISSP
April 16, 2020 (12 Noon - 1 PM)

“Investigational Drug Service Best Practices and Real World Applications”
James Tyler, PharmD
CHRISTUS Health IRB Vice-Chair
June 11, 2020 (12 Noon - 1 PM)

Each lecture offers:

- 1.0 CME for Physicians
- 1.0 CNE for RN, LPN, LVN, etc.
- 1.0 contact hour for CRC, Regulatory Specialist, Data Coordinator, etc.

CHRISTUS Trinity Mother Frances Health System is an approved provider of continuing nursing education by the Texas Nurses Association-Approver, an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation.