C. 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 courses
- 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

2017 GCP Lecture Series Highlights

- ***114*** CNE and contact hours awarded
- ***100%*** of highly experienced speakers with at least a doctoral degree
- > ***95%*** attendees/lecture agreed to the speaker's subject matter expertise and their content delivery effectiveness
- > ***95%*** attendees/lecture agreed to the relevance of the lecture contents to the learning outcomes
- > ***90%*** attendees/lecture agreed to the effectiveness of the teaching methods and learner engagement strategies

CHRISTUS Health

MISSION:
To extend the healing ministry of Jesus Christ.

CHRISTUS Health
919 Hidden Ridge
Irving, Texas 75038
Phone: 469-282-2686
Fax: 469-282-2942

christus.irb@christushealth.org

www.christushealth.org/research

CHRISTUS Health

Institute for Innovation and Advanced Clinical Care

FY 2019 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 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

	A. CRM Course	B. GCP Lecture Series	C. CITI Training	D. Annual IRB Conference
Investigators & all Research Staff		✓	✓	
Medical Residents & Fellows	✓	✓	✓	
IRB Members & Staff		✓	✓	✓

A. CLINICAL RESEARCH METHODOLOGY (CRM) COURSE

TARGET AUDIENCE:
Medical Residents & Fellows

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	Vivienne Marshall, PhD

B. GCP LECTURE SERIES

Conference #: (877) 848-5150
Conference ID: 5008122#

"Preparing for Clinical Trials"
Jennifer Powell RN, BSN, CCRC
Clinical Research Nurse, CHRISTUS Health
August 9, 2018 (12 Noon - 1 PM)

"Essential Questions to Consider when Evaluating a Research Article"
Michael Mitakidis, MD
Clinical Education and Development Director
CHRISTUS Health
October 11, 2018 (12 Noon - 1 PM)

"Incorporating Investigational Pharmacy Services in your Clinical Trial Program"
James Tyler, PharmD
CHRISTUS Health IRB Vice-Chair
December 13, 2018 (12 Noon - 1 PM)

"ERD's in the Workplace"
Becket Gremmels, PhD
System Director of Ethics
CHRISTUS Health
February 14, 2019 (12 Noon - 1 PM)

"Integrating the Recent Changes in the Common Rule"
Brian Gladue, PhD, CIP
CHRISTUS Health IRB Chair
April 11, 2019 (12 Noon - 1 PM)

"Research Compliance Trends"
Polly Mock, RN, CCRC, CHRC
Regional Research Manager-Spohn
CHRISTUS Health
June 13, 2019 (12 Noon - 1 PM)

Each lecture offers:

- 1.0 CNE for RN, LPN, etc.
- 1.0 contact hour for CRC, Regulatory Specialist, Investigator, 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.