

Policy Number	CIIACC 002
Title	Compliance with Policies and Procedures Mandate
Department/Division	Research/IRB — General Administration
Owner	System Director of Research
Approvers	Dr. Bagchi, Pukar Ratti, Phyllis Everage, Francis Kanayo
Review Frequency	Every 3 years
Effective Date	April 14, 2015
Last Review Date	July 2018

Purpose

To ensure compliance with the Policies and Procedures of the CHRISTUS Health Institutional Review Board (IRB) (SOPS).

Definitions

- A. Human Subjects Protection Office (HSP) — Human Subjects Protection office at CHRISTUS Health, which supports the CHRISTUS Health IRB administratively.
- B. Institutional Review Board (IRB) — means any board, committee or other group formally designated by an institution's Institutional Official to review, to approve the initiation of and to conduct periodic review of biomedical research involving human subjects. The IRB must meet all Federal requirements. The primary purpose of such review is to assure the protection of the rights, safety and welfare of the human subjects.
- C. CHRISTUS Health — includes all legal entities and partnerships of CHRISTUS Health.

Statement of Policy

- A. These policies are binding on the IRB members, IRB staff, investigators, research staff and any other individuals involved in the conduct of research under the jurisdiction of the CHRISTUS Health IRB. Further, compliance with all applicable laws and regulations is required.
- B. It is the personal responsibility of each individual directly or indirectly involved in the conduct of research under the jurisdiction of the CHRISTUS Health IRB to know, understand, and implement the policies and the underlying laws, regulations and ethical and scientific principles applicable to human subject research. Lack of knowledge does not justify failure to comply.
- C. Each IRB member, IRB staff person, investigator, research staff or others involved in research under the jurisdiction of the CHRISTUS Health IRB must complete training in accordance with the Training and Education Policy. In addition, review all applicable policies prior to undertaking any research responsibilities. Evidence of training must be documented and file with the Office of the IRB.
- D. Failure to comply with the requirements of this policy may be grounds for disciplinary action or immediate termination of research privileges and/or Human Resources sanctions.

References

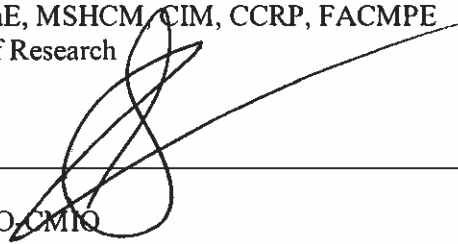
- 45 CFR 46 and CHRISTUS Health IRB Policies

Approved By



Pukar Ratti, MSChE, MSHCM, CIM, CCRP, FACMPE
System Director of Research

30 JULY 2018
Date



Sam Bagchi, MD
SVP, Clinical CMO, CMIO

8/14/2018
Date