CHRISTUS Health

OUR MISSION "To Extend the Healing Ministry of Jesus Christ"

MEMORANDUM

To: CHRISTUS Research Community

From: Pukar Ratti, MSChE, MSHCM, CIM, CCRP, FACMPE

Date: April 11, 2018

RE: Utilization of the CHRISTUS Health IRB

Driven by the mission '*to extend the healing ministry of Jesus Christ*', CHRISTUS Health's Office of Human Subjects Research Protection Program (OHSRPP) under our Federalwide Assurance (FWA) is responsible and accountable for promoting high-quality clinical care to our research subjects, ensuring safety and welfare of research subjects, upholding optimal ethical standards, and maintaining high-levels of regulatory compliance. To fulfill these responsibilities in the best manner, we must require all clinical trials and research projects to undergo review by our local CHRISTUS Health IRB or by the local IRBs at one of the pre-approved academic partners as the IRB of record, whereby eliminating utilization of commercial IRBs. This also relieves our study teams of required double-work for ensuring simultaneous regulatory compliance at commercial IRBs and via 'facilitated review' process at CHRISTUS Health IRB. Therefore, effective May 1, 2018, all new clinical trials and research projects must be submitted either to CHRISTUS Health IRB or to the IRBs at one of the pre-approved academic partners for review and approval as the IRB of record.

However, we recognize that there may be rare and unusual circumstances that warrant use of a commercial or central IRB as the IRB of record. In such cases, the study teams should request the applicable study sponsor to complete the 'Request to waive use of the CHRISTUS Health IRB' form (attached). This form will be reviewed by the CHRISTUS Health Institutional Official for approval or disapproval.

Finally, we are confident that this new process will further allow responsible conduct of research at CHRISTUS Health. Additionally, our research teams will highly benefit from hands-on support available at a local level during their conduct of clinical trials and research projects. We kindly request your cooperation and support in this important endeavor towards research excellence at CHRISTUS Health.

Sincerely,

Pukar Ratti, MSChE, MSHCM, CIM, CCRP, FACMPE
System Director of Research, and Institutional Official
Institute for Innovation & Advanced Clinical Care
CHRISTUS Health

CHRISTUS Health

REQUEST TO WAIVE USE OF THE CHRISTUS HEALTH IRB

SUBMIT completed form to christus.irb@christushealth.org

Protocol Title	
Principal Investigator	
Research Facility	
Sponsor	
Sponsor Representative	
Phone	
Email Address	
Commercial/Central IRB requested	
Waiver justification # 1	
Waiver justification # 2	
Waiver justification # 3	

Authorized Sponsor Signature & Title _____ Date _____

System Director of Research, and Institutional Official
CHRISTUS Institute for Innovation & Advanced Clinical Care

Date _____

☐ Approved ☐ Denied

Note: For any questions, contact christus.irb@christushealth.org

(Version 1.0; April 11, 2018)