



STATEMENT OF COMPLIANCE

FWA 00003114 – Expires 7/25/2024

The TriHealth Institutional Review Board is organized and operates in compliance with FDA regulations as described in 21 CFR Parts 50 and 56, and guidelines resulting from the International Conference on Harmonization (ICH) E-6 Good Clinical Practice guidelines as appropriate. As described in the regulations above, this allows only those IRB members who are independent of the investigator and the sponsor of the trial to vote/provide comment on the trial, to assure written procedures for initial and continuing review of clinical trials, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process.

In addition, the TriHealth Institutional Review Board operates in compliance with portions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA Privacy Rule) that apply to research, as described in 45 CFR Parts 160 and 164 as appropriate.

If you have any questions and/or concerns, please contact the TriHealth Institutional Review Board Office at 513-865-5248 or via e-mail at irb_hrpp@trihealth.com.