



STATEMENT OF COMPLIANCE WITH INTERNATIONAL CONFERENCE ON HARMONIZATION GUIDELINES FOR GOOD CLINICAL PRACTICE

The Institutional Review Boards of University of Miami assures the following:

1. The responsibilities of the University of Miami Institutional Review Boards are in accordance with ICH-GCP section 3.1.
2. The composition, function and operations of the University of Miami Institutional Review Boards are in accordance with ICH-GCP section 3.2.
3. The policies and procedures of the University of Miami and its Institutional Review Boards are documented in writing and are in accordance with ICH-GCP section 3.3
4. The records of submissions to and deliberations and determinations of the University of Miami Institutional Review Boards are maintained in accordance with ICH-GCP section 3.4
5. For studies that are conducted in the United States, the University of Miami Institutional Review Boards are established and constituted in accordance with the Federal Food, Drug and Cosmetic Act 21 CFR 50 and 56.