



MARY E. DICKINSON, PH.D.
SENIOR VICE PRESIDENT AND DEAN OF RESEARCH
PROFESSOR AND KYLE AND JOSEPHINE MORROW ENDOWED CHAIR
DEPARTMENT OF MOLECULAR PHYSIOLOGY AND BIOPHYSICS
DEPARTMENT OF MOLECULAR AND HUMAN GENETICS

April 20, 2022

Lowell Marshall
Electronic Submissions Gateway
U.S. Food and Drug Administration
3WFN, Room 7C34
12225 Wilkins Avenue
Rockville, MD 20852

RE: Letter of Non-Repudiation Agreement regarding Electronic Signatures at Baylor College of Medicine

Dear Mr. Marshall,

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations this is to certify that the Baylor College of Medicine (BCM) intends that all electronic signatures executed for the purposes of conducting Baylor College of Medicine business by our officers, directors, employees, students or contractors, agents or representatives located anywhere in the world, are the legally binding equivalent of traditional hand-written signatures.

These electronic signatures are subject to applicable BCM policies and procedures when utilizing one of the systems/software validated by BCM Information Technology.

This certification also applies to electronic signatures executed for records subject to the requirements set forth in FDA regulations, the Federal Food, Drug and Cosmetic Act - 21 U.S.C. §§ 301-392 Suppl. 5, and the Public Health Service Act - 42 U.S.C. §§ 201-291n.

BCM Information Technology will maintain a list of electronic systems/software for which 21 CFR 11 compliance has been validated.

Sincerely,

Mary E. Dickinson, Ph.D.
Senior Vice President and Dean of Research
Professor and Kyle and Josephine Morrow Endowed Chair
Baylor College of Medicine

Lee Leiber, MBA
Chief Information Officer
Information Technology
Baylor College of Medicine