

University of Central Florida Board of Trustees (UCF) -IORG0000781
Federalwide Assurance: FWA00000351
IRB Registration: IRB00001138

Florida A&M University Board of Trustees (FAMU) – IORG0003149
Federalwide Assurance#: FWA00005391
IRB Registration #: IRB00003768

Florida Gulf Coast University Board of Trustees (FGCU) – IORG0004349
Federalwide Assurance: FWA00010703
IRB Registration: IRB00005161

University of North Florida Board of Trustees (UNF) - IORG0001057
Federalwide Assurance: FWA00000737
IRB Registration: IRB00001451

University of West Florida Board of Trustees (UWF) - IORG0001310
Federalwide Assurance: FWA00002657
IRB Registration: IRB00001740

New College of Florida Board of Trustees – IORG0003394
Federalwide Assurance: FWA00001440
IRB Registration: IRB00004039

4) Name of other Institutions that may in turn rely on Participating Organizations (Affiliated Institutions):

Institutions affiliated with the Participating Organizations are listed in Appendix 1.1, et. seq.

5) COMPLIANCE WITH OFFICE OF HUMAN RESEARCH PROTECTION'S GUIDANCE

This MOU meets the federal requirements for designation of another institution's IRB as the Reviewing IRB, as set forth in guidance issued by the Office for Human Research Protections' (OHRP), Terms of the Federalwide Assurance, March 20, 2002.

6) AUTHORITY:

- a) 45 CFR Part 46 Subparts A (Common Rule), B, C & D
- b) 21 CFR Parts 50, 56, 312, and 812
- c) 45 CFR Parts 46.160 & 164 (HIPAA Privacy Rule)

7) DEFINITIONS

- a) **Affiliated Institutions** - an institution relying on any of the Participating Organization's IRB and formally agreeing to participate in this MOU, as evidenced by its inclusion in Appendix 1.1, et. seq. Upon written agreement to participate in this MOU, an Affiliated Institution shall become a Participating Organization.
- b) **Human Research Protection Program (HRPP)** - encompasses the entities within the Participating Organization that contribute to the mission to protect the rights and

welfare of participants who take part in human subject research, including but not limited to the institutional officials, IRB, and research staff.

- c) **Human Subject Research** - Activities that meet the United States Department of Health and Human Services (DHHS) definition of research set forth in 45 CFR § 46.102(d) and involve human subjects as set forth in 45 CFR § 46.102(f), or activities that meet the United States Food and Drug Administration (FDA) definitions of research/clinical investigation set forth at 21 CFR § 50.3(c) and § 56.102(c) that involve human subjects as set forth at 21 CFR § 50.3(g), §103(e), §312.3(b) and §812.3(p).
- d) **Institutional Official** - The individual who is the signatory on the FWA filed with OHRP to assure compliance with regulations governing protection of human subjects. OHRP requires the Institutional Official to be a high-level official who has the authority to represent the institution named in the FWA.
- e) **Participating Organizations** - all institutions participating in this reciprocity agreement and that are signatories to this MOU.
- f)

as appropriate,

11) CRITERIA FOR DETERMINING THE REVIEWING IRB

The Reviewing IRB shall be at:

- a) the location that is the prime recipient of the research award; **or**
- b) the organization with which the lead Principal Investigator for the study is primarily affiliated or employed (in studies where the research is not funded by an external award); **or**
- c) the location where the following shall entirely or substantially take place: human

16) TERM AND TERMINATION

This MOU is effective as of the date of last signature, and will automatically renew each year. Subject to the obligations set forth in 9(j), any party may terminate its participation in this MOU, with or without cause, by giving all the other parties at least 60 days advanced written notice of its intention to terminate. Termination shall be without penalty.

17) NOTICES

Any party giving or making any notice, request, demand, or other communication (each, a "notice") pursuant to this MOU must give the notice in writing by one of the following means: personal delivery; registered or certified mail (in each case, return receipt requested); nationally recognized overnight courier; electronic mail; or facsimile. Any party giving notice must address the notice to the appropriate person at the receiving party at the address listed below:

University of Florida

Vice President for Research
Office of Research
Box 100115
Gainesville, FL 32611-5500

Florida Atlantic University

Vice President for Research
Division of Research
777 Glades Road, Bldg. 10 Suite 392
Boca Raton, Florida 33431

Florida International University

Vice President for Research
Office of Research and Economic Development
Modesto Maidique Campus
11200 SW 8 St., MARC 430
Miami, FL 33199

University of South Florida

Assistant Vice President for Research Compliance
USF Research & Innovation
3702 Spectrum Blvd. Ste. 155
Tampa, FL 33612

Florida State University

Associate Counsel
FSU Human Subjects Committee
2010 Levy Ave., Building B, Suite 276

University of Central Florida

Associate Vice President for Research and Commercialization
12201 Research Parkway
Orlando, FL 32826

Florida A&M University

Division of Research
1700 Lee Hall Drive
Tallahassee, FL 32307-3800

Florida Gulf Coast University

Associate Vice President for Research
Office of Research and Graduate Studies
10501 FGCU Boulevard South
Fort Myers, FL 33965

University of North Florida

Associate Vice President for Research
Office of Research and Sponsored Programs
1 UNF Drive, Building 3, Ste 2501
Jacksonville, FL 32224

University of West Florida

Associate Vice President for Research and Economic Opportunity
Office of Research and Sponsored Programs
11000 University Parkway
Pensacola, FL 32514

New College of Florida

Director of Research Programs & Services
5800 Bay Shore Road
Cook Hall 228
Sarasota, FL 34243