



STATE
UNIVERSITY
SYSTEM
of FLORIDA
Board of Governors

INSTITUTIONAL REVIEW BOARD (“IRB”) RECIPROCITY AGREEMENT AND MEMORANDUM OF UNDERSTANDING

1) PURPOSE:

This IRB Reciprocity Agreement and Memorandum of Understanding ("MOU") sets forth the agreement among participating State University System of Florida Institutions concerning the reciprocal use of each other's IRB for research that will be conducted by investigators at those institutions. The Participating Organizations are listed in Section 3 of this document and defined below. Additional institutions may participate by executing the MOU and appending information on an Affiliated Institution, as defined below, as an additional Appendix.

2) SCOPE:

The signatory officials agree that the parties to this MOU may rely on each other's IRBs for review, approval and continuing oversight of human subject research as defined by federal regulations.

3) Names of Participating Organizations, Organization Number, Federalwide Assurance Number (FWA) and IRB Registration Number(s)

University of Florida Board of Trustees (UF) –IORG0000203

Federalwide Assurance: FWA00005790

IRB Registration: IRB00000335; IRB00000336; IRB00000337; IRB00009720

Florida Atlantic University Board of Trustees (FAU) -IORG0000684

Federalwide Assurance: FWA00000157

IRB Registration: IRB00001030; IRB00009484; IRB00009485

The Florida International University Board of Trustees (FIU) – IORG0000573

Federalwide Assurance: FWA00000060

IRB Registration: IRB00008168; IRB00008169

University of South Florida Board of Trustees (USF) –IORG0000217

Federalwide Assurance: FWA00001669

IRB Registration: IRB00000362; IRB00000363; IRB00001786; IRB00001787

Florida State University Board of Trustees (FSU) – IORG0000263

Federalwide Assurance: FWA00000168

IRB Registration: IRB00000446

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) **Relying Institution** - a Participating Organization that agrees to rely on another Participating Organization's IRB for a specific study.
- g) **Reviewing IRB** - a Participating Organization that agrees to serve as the IRB of record for a specific study for one or more of the other Participating Organizations.

8) BACKGROUND:

Each Participating Organization shall maintain a separate, active FWA with OHRP. Each Participating Organization recognizes OHRP's current policy guidance on defining when an institution is engaged in research covered by the Common Rule and each institution's FWA. The review and continuing oversight performed by the Reviewing IRB will meet the human subject protection requirements of each Relying Institution's OHRP-approved FWA. Relevant minutes of the Reviewing IRB meetings will be made available to the Relying Institutions upon request. This document must be kept on file at all Relying Institutions and provided to OHRP upon request.

9) RIGHTS, DUTIES, AND RESPONSIBILITIES OF THE REVIEWING IRB:

- a) Establish and follow its written policies and procedures as required, to comply with federal and state laws pertaining to the protection of human participants in research.
- b) Ensure that the Relying Institution has agreed in writing to rely on the Reviewing IRB for each study.
- c) Receive documentation of the disclosure of financial conflicts of interest pursuant to the policies of the Relying Institution and a list of management controls from the Relying Institution. The Reviewing IRB can implement additional management controls yet cannot take away from controls implemented by the Relying Institution.
- d) Notify the Relying Institution of any unanticipated problems involving risks to subjects or others, serious or continuing non-compliance with the regulations or the requirements or determinations of the Reviewing IRB, and termination or suspension of Reviewing IRB approval of research.
- e) Make its records, including any relevant communications with investigators, available upon request to appropriate officials at the Relying Institution and to regulatory and accrediting entities.
- f) In cooperation with the Relying Institution, develop a mutually agreeable process to ensure that the Reviewing IRB communicates to the Relying Institution all initial approvals, disapprovals, addendums, modifications, and/or closures of the proposed research.
- g) Conduct a monitoring visit and/or observe the consent process at the Relying Institution,

as appropriate, at a mutually agreed upon date and time.

- h) Cooperate with the Relying Institution on the investigation, management, and reporting to regulatory agencies and appropriate Institutional Officials of serious or continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions and terminations of IRB approval.
- i) A Reviewing IRB may decline, on a case-by case basis, to be the Reviewing IRB (or IRB of record).
- j) After initial approval of a study, the Reviewing IRB may terminate serving as the IRB of record for a study with at least six (6) months advance written notice to the Principal Investigator (PI) and the Relying Institution, in order to provide time for the protocol to be transferred to another IRB.

10) RIGHTS, DUTIES, AND RESPONSIBILITIES OF THE RELYING INSTITUTION:

- a) Establish and follow its written policies and procedures as required, to comply with federal and state laws pertaining to the protection of human participants in research.
- b) Bear responsibility for the conduct of all human subject research in which it is engaged.
- c) Grants the Reviewing IRB the authority to:
 - i. Approve, require modifications to secure approval, and disapprove the research. The Relying Institution shall not knowingly approve specifically related research that was reviewed and not approved (i.e., disapproved) by the Reviewing IRB.
 - ii. Suspend or terminate approval of the research when not being conducted in accordance with the Reviewing IRB's requirements or that has been associated with unexpected serious harm to subjects.
 - iii. Observe, or have a third party observe, or require the Relying Institution to observe, the consent process and the conduct of the research at the Relying Institution, as appropriate, at a mutually agreed upon date and time.
- d) Ensure that each submission to the Reviewing IRB complies with any applicable local policies and procedures of the Relying Institution, prior to site activation.
- e) Promptly comply with the notification requirements of the Reviewing IRB.
- f) Cooperate with the Reviewing IRB on the investigation, management, and reporting to regulatory agencies and appropriate Institutional Officials of serious or continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions and terminations of IRB approval.
- g) The Relying Institution may accept or decline, on a case by case basis, in its sole discretion, to rely on the Reviewing IRB. The Relying Institution shall notify the Reviewing IRB of its decision in writing.
- h) The Relying Institution may suspend or terminate the conduct of research at its local organization. If this occurs, the Relying Institution shall promptly notify the Reviewing IRB in writing.
- i) The Relying Institution may terminate, on a case by case basis, its reliance on the Reviewing IRB. If this occurs, the Relying Institution will notify in writing both the site Principal Investigator and the Reviewing IRB and ensure that the research has been reviewed and approved by another IRB prior to termination of reliance on the Reviewing IRB.
- j) The Relying Organization remains responsible for ensuring compliance with the Reviewing IRB's determinations as relates to matters within the purview of the Relying Organization and with the terms of its OHRP-approved FWA.

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 subject contact, interactions or interventions with the human subjects, or private, identifiable information is obtained **or**
- d) upon mutual agreement of the Participating Organizations based on other factors.

12) MODIFICATIONS

No amendment to this MOU shall be valid unless it is reduced to writing and signed by authorized representatives of all parties.

13) CONFIDENTIALITY

Each party shall hold in confidence any confidential information obtained from the other party within the scope of this MOU. The recipient party's obligation shall not apply to information that:

- a) is already in the receiving party's possession at the time of disclosure; or
- b) is or later becomes publicly available through no fault of the receiving party; or
- c) is received from a third party with no obligation of confidentiality to the disclosing party; or
- d) is independently developed by the receiving party; or
- e) is ethically required to be disclosed to participants because of any unforeseen risk identified by either party during or after completion of the study; or
- f) is required by applicable law or regulation or valid court order to be disclosed.

In the event that information is required to be disclosed pursuant to subsection (f), the party required to make disclosure shall notify the disclosing party(ies) to allow that/those party(ies) to assert whatever exclusions or exemptions may be available to it/them under such law or regulation.

14) INDEPENDENT CONTRACTOR

It is mutually understood and agreed that in the performance of this MOU, the parties are at all times acting as independent contractors. None of the parties nor any of its employees shall for any purpose be deemed to be employees, agents, ostensible or apparent agents, servants, partners, or joint ventures of any other party.

15) ASSIGNMENT

None of the parties shall voluntarily or by operation of law, assign or otherwise transfer its rights or obligations under the terms of this MOU to any other entity without the prior written consent of all the other parties. Any attempted assignment or transfer by any party of its rights or obligations without such consent shall be void.

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