FIU | Office of Internal Audit

FLORIDA INTERNATIONAL UNIVERSITY

**Audit of the Office of Research and
Economic Development –
Research Training and Policy Compliance**

**Report No. 22-23/04
November 9, 2022**

Date: November 9, 2022

To: Andres Gil, Vice President for Research

From: Trevor L. Williams, Chief Audit Executive

Subject: **Audit of the Office of Research and Economic Development - Research Training and Policy Compliance Report No. 22/23-04**

We have completed an audit of the Office of Research and Economic Development (ORED) - Research Training and Policy Compliance for the period of July 1, 2021, through June 30, 2022, and have assessed the current practices through October 2022.

ORED supports the endeavors of the University's research community and ensures the stewardship of research activities. During the audit, we reviewed ORED's research-related policies and training. We ensured its policies were developed following University policy development and adoption protocol, and along with ORED's trainings, were adequate and compliant with applicable federal and state regulations.

In summary, we concluded that ORED's processes related to research-related policies and procedures and research-related training were adequate and adhered to pertinent state and federal regulations.

We want to take this opportunity to express our appreciation to you and your staff for the cooperation and courtesies extended to us during the audit.

Attachment

C: FIU Board of Trustees
   Kenneth A. Jessell, University President
   Elizabeth M. Bejar, Interim Provost, Executive Vice President, and Chief Operating Officer
   Aime Martinez, Interim Chief Financial Officer and Senior Vice President of Finance and Administration
   Javier I. Marques, Vice President for Operations & Safety and Chief of Staff, Office of the President

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EXECUTIVE SUMMARY

Introduction

The Office of Research and Economic Development (ORED) assists the University research community by stewarding research activities. ORED provides guidance in research administration and supports the University's research community. ORED accomplishes its mission by minimizing the impediments to research activity and promoting research conduct that meets the standards of ethical integrity.

What We Did

We performed this audit to determine if ORED's research-related policies were enacted according to University Policy and whether they, along with research-related trainings, are adequate and adhere to applicable federal and state regulations.

What We Concluded

In summary, we concluded that ORED has effective process controls for creating and maintaining research-related policies and ensuring research-related training is adequate and completed timely.

- We performed a comparison of research-related policies among FIU and other selected SUS institutions and found ORED's policies to be comparable to its peers.

- We reviewed ORED's process for monitoring policy violations, including how violations are received and documented. We found ORED's process to be adequate.

- We reviewed ORED's research-related policies and they were enacted in accordance with University policy development and adoption protocol. The policies were reviewed timely and communicated adequately.

- We found that ORED's research-related policies and research-related trainings addressed key risks and adhered to pertinent federal and state regulations.

- We found that required research trainings were completed prior to researchers working on their projects. We confirmed this via the Collaborative Institutional Training Initiative (CITI) Program online training platform.

- We performed a comparison of research-related trainings among FIU and other selected SUS institutions and found ORED's training to be comparable to its peers.

We found no adverse reportable conditions. The areas tested and the results obtained are detailed in the Observations section beginning on page 6 of this report.

OBJECTIVES, SCOPE, AND METHODOLOGY

Pursuant to the Office of Internal Audit (OIA) approved annual plan for the 2022-2023 fiscal year, we completed an audit of ORED research training and policy compliance. The primary objective of our audit was to evaluate the effectiveness of the University's efforts to comply with University policy and federal regulation as it relates to:

- Research-related policies
- Research-related training

Our audit period was July 1, 2021, through June 30, 2022. Additionally, we assessed current practices through October 2022.

The audit was conducted in conformance with the *International Standards for the Professional Practice of Internal Auditing*, promulgated by The Institute of Internal Audit. The audit included tests of the supporting records and such other auditing procedures, as we considered necessary under the circumstances. We performed audit planning and fieldwork from June 2022 to October 2022.

During the audit, we:

- reviewed University policies and procedures, and applicable laws, rules, and regulations (federal and state, accordingly);
- interviewed responsible University personnel;
- obtained an understanding of management's processes pertaining to research-related policies and research-related training;
- evaluated documentary evidence; and
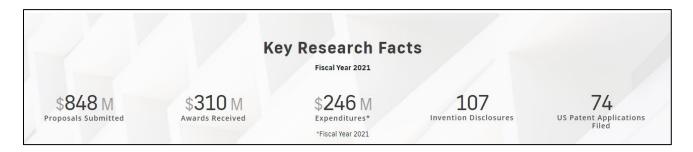- reviewed and evaluated in-scope controls.

Sample sizes selected for testing were determined on a judgmental basis applying a nonstatistical sampling methodology.

We reviewed all internal and external audit reports issued during the last three years and found no reports with any applicable recommendation related to the scope and objectives of this audit, which otherwise would have required follow-up.

BACKGROUND

ORED's mission is to provide leadership in research administration, support the endeavors of the University's research community, and ensure the responsible stewardship of research activities. ORED accomplishes its mission by minimizing impediments to research activity, promoting research conduct that meets the highest standards of ethical integrity, and ensuring that research activity is compliant with all local, state, and federal regulations.

ORED contributes to FIU's building of research infrastructure to support the goals of research breakthroughs and discoveries. The follow information are key facts related to research for fiscal year 2021.

Key Research Facts

Fiscal Year 2021

$848 M	$310 M	$246 M	107	74
Proposals Submitted	Awards Received	Expenditures*	Invention Disclosures	US Patent Applications Filed
		*Fiscal Year 2021		

Research Policies and Procedures

ORED's policies are owned by the responsible officials charged with developing, updating, administering, communicating, training, monitoring, and ensuring compliance with the policy. University policy requires that if a new policy or change in policy is needed, the Vice President over ORED will provide the Office of University Compliance and Integrity with a draft of the new or updated policy. Appropriate input from affected University units will be obtained prior to submitting the policy or change in policy. The Office of University Compliance and Integrity will review the policy or policy change for consistency with other University regulations, policies, and procedures and obtain feedback from the Office of the General Counsel regarding any legal considerations if that feedback has not already been obtained. Procedures implementing University policies or regulations require approval only by ORED's Vice President and those of any other areas directly and significantly impacted by the procedures. Such procedures will be provided to the Office of University Compliance and Integrity for review and posting in the University Policies and Procedures Library. Currently, ORED has 57 research-related policies, all of which have gone through their required three-year review to ensure they are current and relevant. The method used for the communication of policies and procedures is

dependent on the significance of the policy, the audience impacted, and the associated risk. Policies can be found on ORED's website. At other times, ORED will send out information during critical touchpoints to specific audiences or when there are new or updated changes to policies. Additionally, ORED conducts monthly meetings that cover certain topics and the applicable policy. Presentations are also made for special interest groups based on topics and need for compliance.

Research Training

To receive approval for research, all researchers need to complete the required training. There are three committees that approve research applications depending on research topics:

- The *Institutional Review Board* (IRB) is a committee established under federal regulation 45 CFR 46 that regulates the protection of human subjects in research.

- The *Institutional Animal Care & Use Committee* (IACUC) reviews all protocols involving animals to ensure that they are justified by their benefits and minimize any distress.

- The *Institutional Biosafety Committee* (IBC) approves research involving Recombinant, Synthetic Nucleic Acid molecules or Deoxyribonucleic Acid (DNA) or Ribonucleic Acid (RNA) derived from Synthetic Nucleic Acid Molecules.

Pursuant to FIU policies 2370.001 *Research, Teaching and Training with Animals or Animal Biospecimens*, 2370.015 *Human Subjects Research Approval and Registration/Publication of Clinical Trial Results*, and 2370.021 *Research and Teaching with Recombinant and Synthetic Nucleic Acid Molecules*, research personnel are required to go to through the required training for the committee to approve the research project. FIU uses an online, web-based training service called Collaborative Institutional Training Initiative (CITI) Program. The researcher is required to create an account and select the training that correlates to their research. For the human subject research courses, researchers select either "Biomedical Human Research Investigators Course" or "*Social & Behavioral Human Research Investigators Course.*" For animal testing, the researcher selects either "*Working with the FIU IACUC-Field Course-For Field/Wildlife Studies*" or "*Working with FIU IACUC-Field Course For Laboratory Studies.*" For biosafety research, the researcher must complete the "Biosafety & Biosecurity Basic Course." Additionally, FIU promotes Responsible Conduct of Research (RCR) by practicing high standards of ethics and accountability as it relates to research planning, implementation, behavior, and information dissemination. RCR training is required for National Science Foundation (NSF), National Institute of Health (NIH), and U.S. Department of Agriculture (USDA) funded grants.

OVERALL ASSESSMENT OF INTERNAL CONTROLS

Our overall assessment of internal controls is presented in the table below.

INTERNAL CONTROLS ASSESSMENT			
CRITERIA	SATISFACTORY	OPPORTUNITIES TO IMPROVE	INADEQUATE
Process Controls	X		
Policy & Procedures Compliance	X		
Effect	X		
Information Risk	X		
External Risk	X		
INTERNAL CONTROLS LEGEND			
CRITERIA	SATISFACTORY	OPPORTUNITIES TO IMPROVE	INADEQUATE
Process Controls: Activities established mainly through policies and procedures to ensure that risks are mitigated, and objectives are achieved.	Effective	Opportunities exist to improve effectiveness	Do not exist or are not reliable
Policy & Procedures Compliance: The degree of compliance with process controls – policies and procedures.	Non-compliance issues are minor	Non-compliance issues may be systematic	Non-compliance issues are pervasive, significant, or have severe consequences
Effect: The potential negative impact to the operations- financial, reputational, social, etc.	Not likely to impact operations or program outcomes	Impact on outcomes contained	Negative impact on outcomes
Information Risk: The risk that information upon which a business decision is made is inaccurate.	Information systems are reliable	Data systems are mostly accurate but need to be improved	Systems produce incomplete or inaccurate data which may cause inappropriate financial and operational decisions
External Risk: Risks arising from events outside of the organization's control; e.g., political, legal, social, cybersecurity, economic, environment, etc.	None or low	Potential for damage	Severe risk of damage

OBSERVATIONS

State University System (SUS) Policy and Procedure Comparison

We reviewed all ORED research-related policies and procedures and compared them against other selected SUS institutions (*UCF, USF, and FSU)* and evaluated whether FIU had policies and procedures in place to address similar risks and adhered to pertinent legislation, regulations, and procedures for research-related items. ORED's policies and procedures were found comparable with the other SUS institutions reviewed.

Monitoring of Research Violations

We conducted an evaluation of ORED's monitoring of policy violations. We requested all ORED policy violations and reviewed each violation and the respective final report to understand the full outcome of the investigation. We also reviewed each violation to ensure that violations were timely communicated to appropriate parties and that the violations were properly addressed. Additionally, we reviewed the mechanisms for receiving and documenting allegations. We found ORED's procedures for monitoring violations to be reasonable.

Review of Research Policy and Procedures

To ensure that research-related policies and procedures were being enacted in accordance with University Policy 150.205 *Developing University Wide Policies,* we judgmentally sampled 20 research-related policies and procedures and reviewed whether they were properly approved, had effectively addressed the underlying process, were current and relevant, had the desired effect, and were being communicated to the applicable employees. We found ORED's policies were enacted following the protocol set out in University Policy 150.205. Further, ORED is reviewing its policies and procedures every three years to ensure that they stay relevant. New or updated policies and procedures are communicated in a variety of ways depending on the significance of the policy and the audience impacted. Communication of new or updated policies varies from being posted on ORED's website to being communicated via emails, monthly meetings, or forums.

Research Policy and Training Development Process

We met with ORED to evaluate the process for managing and creating research-related policies along with how they conduct and document research-related training. Most of ORED's policies are driven by federal or state regulations, but the responsibility for the structuring of the policy and procedures falls on the policy owner. ORED offers a variety of trainings, and most of the required training is completed on the CITI Program online training platform. ORED tailors the courses to their specific needs. Proof of training completion must be attached to any research proposal submission prior to receiving approval.

ORED Training Evaluation

Federal regulations along with University policies, require that when research involves human subjects, animals, or recombinant or synthetic nucleic acid, training must be completed prior to the researcher participating in such research. We identified ORED's required training for research involving human subjects, animals, and recombinant or synthetic nucleic acid and evaluated the courses below on the CITI Program online training platform to ensure the content of the training addressed relevant regulations and pertinent University policies.

CITI Program Online Training Courses:

- Biomedical Human Subjects Research Investigators Course
- Social & Behavioral Human Research Investigators Course
- Working with the FIU IACUC-Field Course for Field/Wildlife Studies
- Working with the FIU IACUC-Lab Course for Laboratory Studies
- CITI Biosafety & Biosecurity Training Course

Our review found the training material to be adequate and to have addressed areas impacted by ORED policy and applicable regulations.

Researcher Training

To ensure that all researchers completed their required trainings before they commenced working on a research project, from a list of researchers provided by ORED, we judgmentally sampled 30 researchers, as follows:

- 10 who worked on projects that contained payments to human participants,
- 10 researchers participating in projects involving animal research, and
- 10 researchers working on Institutional Biosafety Committee (IBC) approved research projects.

We validated that all 30 researchers completed their required research training prior to when they were first paid by the project.

SUS Training Comparison

Finally, we completed a review of other selected SUS institutions' (*UCF, USF, and FSU)* research-related trainings to ensure that FIU had trainings in place to address similar research processes. The other SUS institutions also used the CITI Program online training platform and required that their researchers complete the trainings prior to conducting their research. The training modules offered by ORED were found to be comparable to those of the other SUS institutions examined.

APPENDIX I – OIA CONTACT AND STAFF ACKNOWLEDGMENT:

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Definition of Internal Auditing

Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.