

# AGENDA Audit, Risk Management, Compliance, and Ethics Committee April 11, 2024

- I. Approval of Minutes February 15, 2024
- II. Review of Operational Metrics
- III. Action Items (Mr. Wayne Poole)
  - A. FY 2025 Annual Audit Plan
  - B. Changes to Internal Audit Charter and Audit Committee Charter
- IV. Informational Items
  - A. Enterprise Risk Management Update (Ms. Stephanie Coleman)
  - B. Research Administration and Compliance Update (Ms. Becky Welch)
  - C. REDE Compliance Monitoring Update (Mr. Kenneth Briley)
  - D. Recent Internal Audits (Mr. Wayne Poole)
- V. Closed Session
- VI. Other Business



Meeting of the Board of Trustees Audit, Risk Management, Compliance & Ethics Committee April 11, 2024

# **AGENDA ITEM**

I.	Approval of Minu	tesVince Smith, Committee Chair
Situa	tion:	Approval of the minutes from the most recent committee meeting.
Back	ground:	N/A
Asses	ssment:	N/A
Actio	n:	This item requires a vote by the committee.



### Minutes from the Audit, Risk Management, Compliance, and Ethics Committee February 15, 2024 – Main Campus Student Center and Online Meeting

The Audit, Risk Management, Compliance, and Ethics Committee of the ECU Board of Trustees met in person on February 15, 2024.

Committee members present: Vince Smith (Chair), Vanessa Workman, Jeff Roberts, and Javier Limon.

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Trustee Vince Smith, Chair of the Committee, convened the meeting at 2:10 PM. Mr. Smith read the conflict-ofinterest provisions as required by the State Government Ethics Act. Mr. Smith asked if anyone would like to declare or report an actual or perceived conflict. None were reported.

Mr. Smith asked for the approval of the minutes of the November 30, 2023 committee meeting minutes.

Action Item: The minutes of the most recent committee meeting were approved with no changes.

#### **Operational Metrics Review**

The committee reviewed the operational metrics related to Internal Audit and Compliance, which were presented by Chief Audit Officer Wayne Poole. For fiscal year 2024, all metrics are in the green for the year to date through the end of January, except for auditor productivity. Mr. Poole told the committee that KPI should be back in the green by the end of this month.

#### Action Item

The committee had no action items.

#### Informational Items

#### Enterprise Risk Management – Ms. Stephanie Coleman

Vice Chancellor Coleman shared the matrix of top risks and briefed the committee on the recent activities of the ERM Committee. Ms. Coleman briefly discussed risks and mitigation efforts related to campus safety, the federal government FAFSA (financial aid) changes, and the Course Program of Study (CPOS) requirements. Ms. Coleman advised that a new emerging risk related to the collegiate athletics landscape has been added to the enterprise risk register. She also told the committee that the ERM Committee will begin the bi-annual risk assessment and ranking process next month. The updated risk register will be presented to the Audit Committee in September.

### Office of Institutional Integrity – Ms. Michelle DeVille

Ms. DeVille briefed the committee on the roles and responsibilities of the Office of Institutional Integrity. Among other things, the office plays a major role in compliance efforts related to healthcare, HIPAA, and various privacy laws and regulations. Ms. DeVille told the committee that the Office recently created and implemented the University's privacy incident response plan as directed by the Chancellor and has established a compliance committee with Student Health Services and the student Counseling Center.

### Athletics Compliance – Ms. Alex Keddie

Ms. Keddie provided an update on sports wagering rules that have been enacted by the NCAA and the State of North Carolina. She advised the committee that the American Athletic Conference has entered into an agreement with US Integrity to provide analytical monitoring services to detect sports gambling activity related to student athletes or athletics staff. Ms. Keddie also provided an update on the constantly changing rules related to student athletes' Name, Image, and Likeness, or "NIL". Ms. Keddie reminded the committee that this is an evolving area of compliance risk, and the University will need to remain vigilant in monitoring changes.



### Minutes from the Audit, Risk Management, Compliance, and Ethics Committee February 15, 2024 – Main Campus Student Center and Online Meeting

### University Policy Process Update - Mr. Wayne Poole

Mr. Poole updated the committee on the previous recommendations to streamline the University's policy development process. Mr. Poole told the committee that the open comment period for the new regulation closed on January 31, and very few comments were received. The new policy process and the governing regulation have been revised, approved by the Chancellor, and are in place. Committee Chair Vince Smith told Mr. Poole that as a next step in addressing the original recommendations, the Board would like the University to move forward with moving all policies and regulations to the University Policy Manual and expects all Board-approved policies to be incorporated into the Manual.

#### Recent Internal Audits - Mr. Wayne Poole

Mr. Poole briefed the committee on two recent internal audit engagements, related to Succession Planning and Athletics Safety.

### Closed Session

At 2:48 pm, Trustee Limon made a motion that the committee go into closed session to discuss items that are not public record and are protected by applicable state law. The motion was seconded and unanimously approved.

The committee returned to open session at 2:53 pm.

#### Other Business

There was no other business to discuss, and the committee meeting was adjourned at 2:53 PM.

Respectfully submitted, Wayne Poole ECU Office of Internal Audit and Management Advisory Services



# **AGENDA ITEM**

II.	Operational Metr	ics Wayne Poole, Chief Audit Officer
Situa	tion:	Presentation of the metrics that are monitored by this committee.
Back	ground:	Each committee of the Board receives regular updates on metrics pertaining to their area of oversight. This committee receives metrics related to audit and compliance activities.
Asses	ssment:	Metrics for FY 2024 year to date are generally on track.
Actio	n:	This item is for information only.



#### CEO Tracking Sheet Fiscal Year - 2024

Fiscal Year - 2024 Audit, Risk Management, Compliance & Ethics Committee

KPI	Measurement	Prior Year	Target	Variance	July	August	September	October	November	December	January	February	March	April	May	June	Total
	Percent of			Plan	6.6%	6.6%	6.6%	6.6%	6.7%	6.7%	6.7%	6.7%	6.7%	6.7%	6.7%	6.7%	80.0%
Audit Plan Completion	projects on annual	87.3%	80%	Actual	7.0%	7.1%	5.7%	9.1%	7.3%	9.1%	4.3%	7.1%	7.0%				63.79
(Internal Audit)	plan that are			+/-	0.4%	0.5%	-0.9%	2.5%	0.6%	2.4%	-2.4%	0.4%	0.3%				
	completed			YTD +/-	0.4%	0.9%	-0.2%	2.5%	3.1%	5.5%	3.1%	3.5%	3.8%				
				Plan	75.0%	75.0%	75.0%	75.0%	75.0%	69.0%	76.0%	76.0%	76.0%	76.0%	76.0%	76.0%	75.0%
Auditor Productivity	Direct Audit &	76.7%	75%	Actual	71.0%	79.1%	80.5%	79.8%	72.2%	58.4%	76.5%	86.6%	70.070	70.070	70.070	70.070	75.6%
(Internal Audit)	Consult hrs vs.		, 5, 6	+/-	-4.0%	4.1%	5.5%	4.8%	-2.8%	-10.6%	0.5%	10.6%					/ 510/
(	Total hours			YTD +/-	-4.0%	0.1%	1.9%	2.6%	1.6%	-1.6%	-0.8%	0.6%					
	Total nours				11070	0.170	1.570	2.070	21070	2.070	0.070	0.070					
	Percent of			Plan	95.00%	95.00%	95.00%	95.00%	95.00%	95.00%	95.00%	95.00%	95.00%	95.00%	95.00%	95.00%	95.00%
Management Corrective Actions Completion	recommendations	98.8%	95%	Actual	100.00%	100.00%	100.00%	100.00%	100.00%	78.60%	100.00%	100.00%	75.00%				95.90%
Rate	resolved when			+/-	5.00%	5.00%	5.00%	5.00%	5.00%	-16.40%	5.00%	5.00%	-20.00%				
(Internal Audit)	IA follows up			YTD %	5.00%	5.00%	5.00%	5.00%	5.00%	1.10%	1.40%	1.80%	0.90%				
	Number of			Plan	25	25		25	25	25	25	25	25	25	25	25	30
lumber of Rules Education Sessions (Athletics	sessions spent	359	300	Actual	18	36	29	41	29	26	29	35					24
Compliance)	educating athletes,			+/-	-7	11	4	16	4	1	4	10					
	staff & others			YTD +/-	-7	4	8	24	28	29	33	43					
	1													r	r		
Number of NIL Education and Consultation	Sessions spent			Plan	4	4	4	4	4	4	4	4	4	4	4	4	4
Sessions	educating athletes,	78	48	Actual	3	9	4	10	4	9	11	17					6
(Athletics Compliance)	staff & others			+/-	-1	5	-	6	-	5	7	13					
( · · · · · · · · ,	(NIL-specific)			YTD +/-	-1	4	4	10	10	15	22	35					
	Number of sessions			Plan	63	63	63	63	62	63	63	63	63	63	63	63	756
Number of Education Sessions	Number of sessions	1070	756	Actual	64	66		66	63 62	66	63	63	63	63	63	63	/50
(Healthcare Compliance)	spent educating providers and	1070	/30	+/-	04	00	00	00	02	00	05	04					51:
(nearlicare compliance)	staff			+/- YTD +/-	1	3 4	ر ۵	12	11	14	14	15					
	Starr				-					÷.,	÷.	10					
	Number of			Plan	23	23	23	23	23	23	23	23	23	23	23	23	276
Number of Proactive Provider Documentation	providers whose	587	276	Actual	23	27	24	24	25	24	26	25					198
Reviews	doc. accuracy			+/-	0	4	1	1	2	1	3	2					
(Healthcare Compliance)	was reviewed			YTD +/-	0	4	5	6	8	9	12	14					
Pass Rate Results of Healthcare Provider	Percent of			Plan	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%
Documentation Reviews	reviewed providers	92.3%	90%	Actual	100.0%	95.0%	100.0%	100.0%	90.0%	100.0%	100.0%	100.0%					98.1%
(Healthcare Compliance)	receiving a			+/-	10.0%	5.0%	10.0%	10.0%	0.0%	10.0%	10.0%	10.0%					
()	passing score			YTD +/-	10.0%	7.3%	8.2%	8.7%	6.9%	7.4%	7.8%	8.1%					
			1											-	-		
	Number of sessions			Plan	2	2	2	2	2	2	2	2	2	2	2	2	24
Number of Group Education Sessions	spent educating	Not tracked	24	Actual	3	6	4	4	3	3	4	3					30
(Human Subjects Research/IRB)	groups of			+/-	1	4	2	2	1	1	2	1					
	researchers			YTD +/-	1	5	/	9	10	11	13	14					
	Number of human			Plan	3	2	2	2	3	2	2	2	2	2	2	2	30
Number of Compliance Monitoring Reviews	Number of human	Not tracked	26		3	3	3	3	3	3	3	3	3	3	3	3	30
Human Subjects Research/REDE Compliance	subjects studies reviewed for	Not tracked	36	Actual +/-	3	3	3	3	0	2	2	3					25
Monitoring Office)	compliance			+ / - YTD +/-	0	0	0	0	2	-1	-1	1					
	compliance	1		110+/-	0	0	0			Z	1	1					
	Percent of			Plan										90.0%	5.0%	5.0%	100.0%
Employee COI Disclosure Rate	employees who	99.85%	100%	Actual										50.076	5.076	5.0%	100.07
(Research Compliance)	submitted	55.0570	100/0	+/-													
(·····································	req'd disclosure			YTD +/-													
		I	l														



# **AGENDA ITEM**

III.A FY 2025 Ann	nual Audit Plan Wayne Poole Chief Audit Officer
Situation:	The University's annual audit plan, and any significant changes to it, must be approved by this committee.
Background:	Internal Audit has completed the annual audit plan for FY 2025. The process involves, among many steps, assessing risks, reviewing ECU's strategic priorities, and discussing risks and plans with compliance officers and management of the University.
Assessment:	Chancellor Rogers has endorsed the plan and it is presented to this committee for final approval before being submitted to the UNC System and the NC Council of Internal Audit (which oversees the audit functions at all state agencies).

Action: This item requires a vote by the committee.

# FY 2025 Annual Audit Plan

# Office of Internal Audit and Management Advisory Services



**Protecting the Pirate Treasure** 

# **Annual Audit Planning Process – Why?**

- Required to comply with IIA Standards
- Required to submit to UNC System Office/BOG and NC Council of Internal Audit
- Determine the priorities of the IA team based on assessment of risks and strategic priorities
- Coordinate with all compliance and risk units and senior leaders to avoid duplication and ensure key risks are covered



# **Annual Audit Planning Process – How?**

Continuously Assess and Monitor Risk / Update Audit Universe and Plan

Define/Update Audit Universe	Conduct Bottom-Up Risk Assessment	Conduct Top- Down Risk Assessment	Other Items Assessed	Develop Audit Plan	Finalize Plan
<ul> <li>Ensures completeness of risk coverage</li> <li>Vision, mission, and strategic plan</li> <li>Latest financial statement</li> <li>Financial balances</li> <li>Organization charts, chart of accounts</li> <li>Recent internal and external audits completed and results</li> </ul>	<ul> <li>Each unit and business process</li> <li>Criticality</li> <li>Strategic impact</li> <li>Internal Control</li> <li>Public or political sensitivity</li> <li>Legal and regulatory requirements</li> <li>Changes in management</li> <li>Financial Impact</li> <li>Fraud and Abuse</li> </ul>	<ul> <li>Facilitated by ERM</li> <li>Issues impacting University at an enterprise level</li> <li>Links to strategic objectives</li> <li>Identifies most critical risks (strategic, operational, compliance, reputational, financial)</li> </ul>	<ul> <li>Other ECU compliance and assurance providers' plans &amp; programs</li> <li>Review latest findings from State Audit reports</li> <li>Review UNC KPIs and Internal Control Assessments</li> <li>Discuss with VCs and key management personnel</li> <li>Review industry literature for emerging risks and hot topics</li> </ul>	<ul> <li>Based on prioritized audit universe</li> <li>Include management requests</li> <li>Determine if pending audits from previous plan need to be brought forward</li> <li>Determine follow- up reviews</li> <li>Determine available auditor hours</li> </ul>	<ul> <li>Share with Vice Chancellors and AD</li> <li>Approval by Chancellor</li> <li>Approval by ECU BOT Audit Committee</li> <li>Submit to UNC SO</li> <li>Submit to NC Council of Internal Auditing</li> </ul>



# **Annual Audit Planning Process – Result**

- A work plan/list of priorities for the IA team
- Includes hours for unplanned consultations and investigative audits – based on historical trends
- Flexible; can and will change as new priorities emerge
- Changes will be brought to the Chancellor and BOT/Audit Committee for approval



# **Annual Audit Plan – Next Steps**

- Chancellor approved in March 2024
- BOT/Audit Committee approval sought
- Submit to required external agencies
- CAO will keep Chancellor and BOT/Audit Committee apprised of progress and desired changes throughout the year



### East Carolina University Office of Internal Audit Annual Engagement Plan By Type FY 2025

Project Description		Budgeted Hours	% of Total	Key Risk	Strategy/ Mission	Division
Integrated/Internal Controls/Operational/Performance Audits:		nours	UT TULAI	NISK	WISSION	DIVISION
HR Benefits Processes and Accounting	WIP	100	0.6%	Х		AF
Cashier's Office	WIP	100	0.6%			AF
Research Systems	WIP	200	1.2%			AA
Data and User Access - Financial Aid	OP	200	1.2%			AA
Data and User Access - Finance	OP	300	1.8%			AF
Office Space Utilization	OP	300	1.8%			ALL
Lab Safety	OP	300	1.8%		х	AF, AA
Public Consulting Services	OP	300	1.8%		×	AI, AA AA
Travel Expense Analytics Review	OP		1.8%		X X	ALL
	_	300			^	
Emeritus Staff and Faculty Access to Resources	OP	300	1.8%			ALL
Athletics Facility Security	OP	300	1.8%			AT
Aquatics Center	OP	300	1.8%			AT
Student Emergency Response Process	OP	300	1.8%		Х	SA
Central Reservations and Ticketing Operations	OP	300	1.8%	х		SA
		3600	21.6%			
Compliance Audits: Research Security	00	000	4.00/	х	V	A A
	OP	300	1.8%	X	X	AA
Expense Review for External Sponsor - Climate Initiative Grant	OP	200	1.2%	Ň	X	AA
Admissions Process Compliance (selected programs only)	OP	300	1.8%	Х	Х	AA
		800	4.8%			
Information Technology Audits:						
IT Disaster Recovery	OP	260	1.6%	Х	Х	AF
Teams, OneDrive, Sharepoint Configuation and Processes	OP	300	1.8%			AF
Enterprise Apps and Storage Activity Logging	OP	300	1.8%			AF
		960	E 20/			
Investigative Reviews:		860	5.2%			
Triage of Allegations, Complaints, Concerns	OP	300	1.8%			ALL
Investigative Reviews - Details not included	OP	1500	9.0%			ALL
	0.	1000	0.070			,
		1800	10.8%			
Follow-Up Reviews:	0.0	000	0.00/			
Action Plan Tracking and Follow-Up	OP	600	3.6%			ALL
2nd Follow Up - Campus Safety Systems	OP	100	0.6%	Х		AF
			0.0%			
		700	4.2%			
Consultations/Advisory Services						
Routine and Unplanned Consultations	OP	600	3.6%			ALL
Continuous Auditing and Monitoring Analytics	OP	300	1.8%			ALL
University Committees, Workgroups, Education, and Client Relations	OP	400	2.4%			ALL
ERM and Regulatory Compliance Committee Support	OP	200	1.2%			ALL
Student Athlete Course Clustering	OP	40	0.2%			AA
ECU Health Rev Cycle Integration	OP	200	1.2%			ECUH
Generative Al Policies and Practices	OP	100	0.6%			ALL
		100	0.070			
		1840	11.1%			

#### East Carolina University Office of Internal Audit Annual Engagement Plan By Type FY 2025

		Budgeted	%	Key	Strategy/	
Project Description		Hours	of Total	Risk	Mission	Division
Other/Special Projects:						
External Audits, SBI Reports, Routine Mtgs, BOT Comm	OP	1600	9.6%			ALL
Audit Software Admin and Maintenance	OP	100	0.6%			CH
Student Intern Program	OP	120	0.7%			CH
Annual Self-Assessment and QAIP Activities	OP	160	1.0%			СН
Risk Assessment/Audit Planning 2025-2026	OP	160	1.0%			ALL
		2140	12.9%			
Total Direct/Chargeable Hours		11740	71%			
Administration		1800	10.8%			NA
Leave/Holiday		2300	13.8%			NA
Professional Development		800	4.8%			NA
Total Indirect Hours:		4900	<b>29%</b>			
Grand Total Hours		16640	100%			

Original Plan Approved by Chancellor Rogers on 03/20/2024

Original Plan Approved by ECU Board of Trustees Audit, Risk Management, Compliance, and Ethics Committee on xx/xx/2024



Meeting of the Board of Trustees Audit, Risk Management, Compliance & Ethics Committee April 11, 2024

# **AGENDA ITEM**

III.B Approval of changes to Audit Committee and Internal Audit charters.......Wayne Poole Chief Audit Officer

Situation:	The University's charters/mandates related to the Internal Audit function must be approved by the BOT Audit Committee.
Background:	Recent changes to the <i>Global Internal Audit Standards</i> (" <i>Standards</i> ") necessitated some wording changes to the charter for this committee and the charter for ECU's Office of Internal Audit. ECU is required by state law to comply with the <i>Standards</i> .
Assessment:	Nothing materially has changed in how Internal Audit is required to conduct its business, or the committee's responsibilities for oversight of the Internal Audit function. However, there are some wording differences in how the requirements are conveyed and the charters have been updated to reflect this.
Action:	This item requires a vote by the committee.



# Purpose

The purpose of the Audit, Enterprise Risk Management, Compliance, and Ethics Committee (hereafter referred to as Committee) is to assist the East Carolina University Board of Trustees in fulfilling its oversight responsibilities for (1) the integrity of the University's financial statements, (2) the University's compliance with legal, regulatory, and ethical requirements, (3) the performance of the University's internal audit function, (4) the University's compliance with audit and compliance guidelines adopted by the UNC Board of Governors, the UNC System Office, and the North Carolina Council of Internal Audit, and (5) the University's Information and IT Security programs. The Committee has jurisdiction over internal audit, enterprise risk management, compliance, information security, conflicts of interest, and ethics.

# Organization

The Committee shall be a standing committee of the ECU Board of Trustees. Each Committee member must be independent of management and free of any relationship that would impair such independence.

If practicable, at least one member of the Committee should be a financial expert. A financial expert is someone who understands generally accepted accounting principles and financial statements; experience in applying such principles; experience in preparing, auditing, analyzing, or evaluating financial information; experience with internal controls and procedures for financial reporting; and an understanding of the audit committee function. If feasible, the role of financial expert will be rotated on an annual basis.

## Meetings

The Committee shall meet at least four times a year and hold additional meetings as circumstances require. The Committee will invite representatives of management, auditors, legal counsel, and others to attend meetings and provide pertinent information as necessary. The Committee will receive reports regarding internal audit, enterprise risk management, compliance, conflicts of interest, and ethics. It will also hold private meetings with the Chief Audit Officer if deemed necessary. Meeting agendas will be prepared and provided in



advance to members, along with appropriate briefing materials. Minutes of the meetings will be prepared.

# **Duties and Responsibilities**

The following shall be the principal duties and responsibilities of the Committee as prescribed by applicable state and UNC System Guidelines and the *Global Internal Audit Standards* published by the Institute of Internal Auditors:

- Meet at least four times during the year.
- Review the results of the annual financial audit with the North Carolina State Auditor or his/her designated representative.
- Discuss the results of any other audit performed and report/management letter (i.e., information system audits, investigative audits, etc.) issued by the North Carolina State Auditor with either the State Auditor or his/her staff, the Chief Audit Officer, or appropriate campus official.
- For any audit finding contained within a report or management letter issued by the State Auditor, review the institution's corrective action plan and receive a report once corrective action has taken place.
- Discuss the results of any audit performed by independent auditors and, if there were audit findings, review the institution's corrective action plan and receive a report once corrective action has taken place.
- Review all audits and management letters of University Associated Entities as defined in the UNC Policy Manual.
- Receive regular reports from the Chief Audit Officer that, at a minimum, include material (significant) reportable conditions, the corrective action plan for these conditions and a report once these conditions have been corrected.
- Ensure that the Chief Audit Officer reports to the Chancellor with a clear, recognized reporting relationship to the chair of the Committee.
- Receive, review, and approve the annual audit plan for the Office of Internal Audit.
- Ensure that all internal audits were conducted in accordance with professional standards and that the internal audit function operates in conformance with the applicable professional standards.
- Ensure the Chief Audit Officer forwards copies of both the approved audit plan, summary of internal audit results, and any other required reports and data to UNC System Office and any other agencies required by state and UNC System guidance in the prescribed format.



- Review and concur in the appointment, replacement, or dismissal of the Chief Audit Officer and the compensation package.
- Understand the necessary qualifications for the Chief Audit Officer position when it is being filled.
- Review and ensure the internal audit function has appropriate budget and staff resources.
- Review and accept internal audit reports when issued.
- Periodically review and revise the internal audit charter and the committee's charter as needed.
- Resolve disagreements between internal audit and management concerning audit findings and recommendations or audit scope.

This version approved by the Committee by formal vote on April 11, 2024.



### Purpose

The purpose of the Audit, Enterprise Risk Management, Compliance, and Ethics Committee (hereafter referred to as Committee) is to assist the East Carolina University Board of Trustees in fulfilling its oversight responsibilities for (1) the integrity of the University's financial statements, (2) the University's compliance with legal, regulatory, and ethical requirements, (3) the performance of the University's internal audit function, (4) the University's compliance with the Best Financial Practices Guidelinesaudit and compliance guidelines adopted by the UNC Board of Governors in November of 2005, the UNC System Office, and the North Carolina Council of Internal Audit, and (5) the University's Information and IT Security programs. The Committee has jurisdiction over internal audit, enterprise risk management, compliance, information security, conflicts of interest, and ethics.

### Organization

The Committee shall be a standing committee of the ECU Board of Trustees. Each Committee member must be independent of management and free of any relationship that would impair such independence.

If practicable, at least one member of the Committee should be a financial expert. A financial expert is someone who has an understanding of<u>understands</u> generally accepted accounting principles and financial statements; experience in applying such principles; experience in preparing, auditing, analyzing, or evaluating financial information; experience with internal controls and procedures for financial reporting; and an understanding of the audit committee function. If feasible, the role of financial expert will be rotated on an annual basis.

## Meetings

The Committee shall meet at least four times a year and hold additional meetings as circumstances require. The Committee will invite representatives of management, auditors, legal counsel, and others to attend meetings and provide pertinent information as necessary. The Committee will receive reports regarding internal audit, enterprise risk management, compliance, conflicts of interest, and ethics. It will also hold private meetings with the Chief Audit Officer



if deemed necessary. Meeting agendas will be prepared and provided in advance to members, along with appropriate briefing materials. Minutes of the meetings will be prepared.

## **Duties and Responsibilities**

The following shall be the principal duties and responsibilities of the Committee as prescribed by the UNC BOG Best Financial Practices applicable state and UNC System Guidelines and the *Global Internal Audit Standards* published by the Institute of Internal Auditors:

- Meet at least quarterly four times during the year.
- Review the results of the annual financial audit with the North Carolina State Auditor or his/her designated representative.
- Discuss the results of any other audit performed and report/management letter (i.e.i.e., information system audits, investigative audits, etc.) issued by the North Carolina State Auditor with either the State Auditor or his/her staff, the Chief Audit Officer, or appropriate campus official.
- For any audit finding contained within a report or management letter issued by the State Auditor, review the institution's corrective action plan and receive a report once corrective action has taken place.
- Discuss the results of any audit performed by independent auditors and, if there were audit findings, review the institution's corrective action plan and receive a report once corrective action has taken place.
- Review all audits and management letters of University Associated Entities as defined in section 600.2.5.2[R] of the UNC Policy Manual.
- Receive regular reports from the Chief Audit Officer that, at a minimum, reports-include material (significant) reportable conditions, the corrective action plan for these conditions and a report once these conditions have been corrected.
- Ensure that the Chief Audit Officer reports to the Chancellor with a clear, recognized reporting relationship to the chair of the Committee.
- Receive, review, and approve the annual audit plan for the internal audit department Office of Internal Audit.
- Ensure that all internal audits were conducted in accordance with professional standards and that the internal audit function operates in conformance with the applicable professional standards.



- Receive and review an annual summary of audits performed by the internal audit department.
- Ensure the Chief Audit Officer forwards copies of both the approved audit plan, and summary of internal audit results, and any other required reports and data to UNC System Office and any other agencies required by state and UNC System guidance in the prescribed format.

## **Other Committee Responsibilities**

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- •\_\_\_Review and concur in the appointment, replacement, or dismissal of the Chief Audit Officer and the compensation package.
- <u>Understand the necessary qualifications for the Chief Audit Officer position</u> when it is being filled.
- Review and <u>asen</u>sure the internal audit function has appropriate budget and staff resources.
- Review and accept internal audit reports when issued.
- Periodically review and revise the internal audit charter and the committee's charter as needed.
- Resolve disagreements between internal audit and management concerning audit findings and recommendations or audit scope.

This version approved by the Committee by formal vote on September April 9,11, 2021<u>4</u>.

Most recent review by Audit Committee September 28, 2023

# Purpose

The purpose of the Office of Internal Audit and Management Advisory Services (OIAMAS) is to strengthen the University's ability to create, protect, and sustain value by providing the board and management with independent, risk-based and objective assurance, advice, insight, and foresight.

## **Professional Standards**

The internal audit activities for state agencies in North Carolina are governed by state law and are expected to operate in conformance with the *Global Internal Audit Standards*, published by The Institute of Internal Auditors.

## Scope and Services

The scope of work of the OIAMAS is to determine whether the organization's network of risk management, control, and governance processes, as designed and represented by management, is adequate and functioning in a manner to ensure:

- Risks are appropriately identified and managed.
- Interaction with the various governance groups occurs as needed.
- Significant financial, managerial, and operating information is accurate, reliable, and timely.
- Employees' actions are in compliance with policies, standards, procedures, and applicable laws and regulations.
- Resources are acquired economically, used efficiently, and adequately protected.
- Programs, plans, and objectives are achieved.
- Quality and continuous improvement are fostered in the organization's control process.
- Significant legislative or regulatory issues impacting the organization are recognized and addressed appropriately.

Opportunities for improving management control and the organization's image may be identified during audits. They will be communicated to the appropriate level of management, and to senior University leadership and the Board of Trustees.

## Accountability

The Chief Audit Officer, in the discharge of his/her duties, shall be accountable to the East Carolina University Board of Trustees through the Audit, Enterprise Risk

Management, Compliance, and Ethics Committee (hereafter referred to as "Committee") and the Chancellor to:

- Provide assessments on the adequacy and effectiveness of the organization's processes for controlling its activities and managing its risks.
- Report significant issues related to the processes for controlling the activities of the organization and its affiliates, including potential improvements to those processes, and provide information concerning such issues through resolution.
- Periodically provide information on the status and results of the annual audit plan and the sufficiency of internal audit resources.
- Coordinate assurance and monitoring activities with other functions such as risk management, compliance, IT and information security, legal, ethics, environmental, and external auditors.

# Independence and Objectivity

The internal audit activity shall be free from interference in determining the scope of internal auditing, performing work, and communicating results. To provide for the independence of the OIAMAS, its personnel report to the Chief Audit Officer, who reports administratively to the Chancellor and functionally to the Committee. The Chief Audit Officer shall have full and independent access to the Chancellor and the Committee. Actual or perceived impairments to independence and objectivity will be communicated to the Chancellor and the Committee.

Functional oversight by the Committee includes:

- Approve the annual internal audit plan and significant changes, and monitor progress throughout the year.
- Review and accept internal audit reports when issued.
- Periodically review and revise the internal audit charter as needed.
- Confirm and ensure the independence of the internal audit function.
- Review and concur in the appointment, replacement, or dismissal of the Chief Audit Officer and the compensation package.
- Review and ensure the internal audit function has appropriate budget and staff resources.
- Meet privately with the Chief Audit Officer as necessary.
- Review the effectiveness of the internal audit function, including compliance with the *Global Internal Audit Standards* (hereafter referred to as the "*Standards*".).
- Resolve disagreements between internal audit and management concerning audit findings and recommendations, audit scope, or other aspects of the internal audit activity.

Administrative oversight by the Chancellor includes:

- Day-to-day oversight such as approval of Chief Audit Officer leave and travel.
- Regular communications with the Chief Audit Officer and completion of any attestations or other documents required by the North Carolina Council of Internal Audit or the UNC System.

# Responsibility

The Chief Audit Officer and staff of OIAMAS have responsibility to:

- Develop a flexible annual audit plan using an appropriate risk-based methodology, including consideration of any strategy, opportunities, risks or control concerns identified by management, and submit that plan and any significant updates during the year to the Chancellor and the Committee for review and approval.
- Implement the annual audit plan, as approved, including as appropriate any special tasks or projects requested by management, the Chancellor, the UNC System, external auditors, and the Committee – so long as such special requests do not cause the OIAMAS to be out of conformance with the Standards.
- Maintain a professional audit staff with sufficient knowledge, skills, experience, and professional certifications to meet the requirements of the Internal Audit Charter.
- Inform the Chancellor and the Committee if changes to the budget or staffing have a significant detrimental impact on the ability to meet the requirements of the Internal Audit Charter.
- Evaluate and assess significant functions and new or changing services, processes, operations, and control processes coincident with their development, implementation, and/or expansion.
- Issue periodic reports to management, the Chancellor and the Committee summarizing results of audit activities.
- Keep the Chancellor and the Committee informed of emerging trends and successful practices in internal auditing.
- Provide a list of significant measurement goals and results to the Chancellor and the Committee.
- Conduct investigations of alleged misuse of University resources and other matters submitted to the office's hotline and perform or assist with other investigations as requested by the Chancellor, University Counsel, and/or others as appropriate.
- Consider the scope of work of the external auditors and regulators and other internal compliance offices, as appropriate, for the purpose of providing optimal assurance and monitoring coverage to the organization.
- Serve as a liaison between University management and external auditors.

- Provide assurance services for management, the Chancellor, and the Committee (Assurance services involve an objective assessment of evidence to provide an independent opinion or conclusions regarding an entity, operation, function, process, system, or other subject matter. The nature and scope of the assurance services are determined by the internal auditor.)
- As appropriate, provide consulting and advisory services to management that add value and improve the governance, risk management, and control processes without the internal auditor assuming management responsibility. (Consulting and advisory services are generally performed at the specific request of an engagement client. The nature and scope of advisory services are subject to agreement with the engagement client.)
- Establish a quality assurance program consistent with the *Standards*, by which the Chief Audit Officer monitors and continually improves the operation of internal audit activities and communicates the results of the program with the Chancellor and the Committee.
- Ensure the requirements are met regarding internal audit activities as set forth by UNC Board of Governors, UNC System Office, North Carolina General Statutes, and the North Carolina Council of Internal Auditing.

# Authority

The Chief Audit Officer and the staff of OIAMAS are authorized to:

- Have unrestricted access to all functions, records, property, and personnel of the University and its affiliated entities in accordance with North Carolina General Statutes and UNC System policies.
- Allocate resources, set frequencies, select subjects, determine scope of work, and apply the techniques required to accomplish audit objectives.
- Provide consulting and advisory services to management as deemed appropriate.

The Chief Audit Officer and the staff of OIAMAS are not authorized to:

- Perform any operational duties for the organization or its affiliates.
- Initiate or approve accounting transactions external to OIAMAS.
- Direct the activities of any organization employee not employed by OIAMAS, except to the extent such employees have been appropriately assigned to auditing teams or to otherwise assist the internal auditors.

Revised Version Approved by the BoT Audit, Risk Management, Compliance, and Ethics Committee on April 11, 2024.

# Mission Purpose and Scope of Work

The <u>mission purpose</u> of the Office of Internal Audit and Management Advisory Services (OIAMAS) is to <u>enhance strengthen the University's ability to create</u>, <u>protect</u>, and <u>sustain valueand protect organizational value</u> by providing <u>the board</u> <u>and management with independent</u>, risk-based and objective assurance, advice, <u>insight</u>, and <u>infore</u>sight.

## **Professional Standards**

The internal audit activities for state agencies in North Carolina are governed by state law and are expected to operate in conformance with the *Global Internal Audit Standards*, published by The Institute of Internal Auditors.

### **Scope and Services**

The scope of work of the OIAMAS is to determine whether the organization's network of risk management, control, and governance processes, as designed and represented by management, is adequate and functioning in a manner to ensure:

- Risks are appropriately identified and managed.
- Interaction with the various governance groups occurs as needed.
- Significant financial, managerial, and operating information is accurate, reliable, and timely.
- Employees' actions are in compliance with policies, standards, procedures, and applicable laws and regulations.
- Resources are acquired economically, used efficiently, and adequately protected.
- Programs, plans, and objectives are achieved.
- Quality and continuous improvement are fostered in the organization's control process.
- Significant legislative or regulatory issues impacting the organization are recognized and addressed appropriately.

Opportunities for improving management control and the organization's image may be identified during audits. They will be communicated to the appropriate level of management, and to senior University leadership and the Board of <u>Trustees</u>.

## Accountability

Last Review by CAO and Audit Committee September 28, 2023

The Chief Audit Officer, in the discharge of his/her duties, shall be accountable to the East Carolina University Board of Trustees through the Audit, Enterprise Risk Management, Compliance, and Ethics Committee (hereafter referred to as <u>"Committee"</u>) and the Chancellor to:

- Provide assessments on the adequacy and effectiveness of the organization's processes for controlling its activities and managing its risks in the areas set forth under the mission and scope of work.
- Report significant issues related to the processes for controlling the activities of the organization and its affiliates, including potential improvements to those processes, and provide information concerning such issues through resolution.
- Periodically provide information on the status and results of the annual audit plan and the sufficiency of the internal audit department resources.
- Coordinate internal assurance and monitoring activities with other monitoring functions such as risk management, compliance, IT and information security, legal, ethics, environmental, and external auditors.

# Independence and Objectivity

The internal audit activity should shall be free from interference in determining the scope of internal auditing, performing work, and communicating results. To provide for the independence of the OIAMAS, its personnel report to the Chief Audit Officer, who reports administratively to the Chancellor and functionally to the Committee. The Chief Audit Officer shall have full and independent access to the Chancellor and the Committee. Actual or perceived impairments to independence and objectivity will be communicated to the Chancellor and the Committee.

Functional oversight by the Committee includes:

- Approve the annual internal audit plan <u>and significant changes</u>, and monitor progress <u>quarterlythroughout the year</u>.
- Review and accept internal audit reports when issued.
- Periodically review and revise the internal audit charter as needed.
- Confirm and <u>asen</u>sure the independence of the internal audit function.
- Review and concur in the appointment, replacement, or dismissal of the Chief Audit Officer and the compensation package.
- Review and <u>asen</u>sure the internal audit function has appropriate budget and staff resources.
- Meet privately with the Chief Audit Officer as deemed necessary.
- Review the effectiveness of the internal audit function, including compliance with The Institute of Internal Auditors' *Standards for the Professional*

Last Review by CAO and Audit Committee September 28, 2023

Practice of Internal Auditingthe Global Internal Audit Standards (hereafter referred to as the "Standards".)

 Resolve disagreements between internal audit and management concerning audit findings and recommendations, <u>audit scope</u>, or other aspects of the <u>internal audit activity</u>.

Administrative oversight by the Chancellor includes:

- <u>dD</u>ay-to-day oversight such as approval of Chief Audit Officer annual leave and travel.
- <u>Regular communications with the Chief Audit Officer and completion of</u> any attestations or other documents required by the North Carolina Council of Internal Audit or the UNC System.

# Responsibility

The Chief Audit Officer and staff of OIAMAS have responsibility to:

- Develop a flexible annual audit plan using an appropriate risk-based methodology, including <u>consideration of</u> any <u>strategy</u>, <u>opportunities</u>, risks or control concerns identified by management, and submit that plan <u>and any</u> <u>significant updates during the year</u> to the Chancellor and the Committee for review and approval as well as periodic updates.
- Implement the annual audit plan, as approved, including as appropriate any special tasks or projects requested by management, the Chancellor, the Vice President of Compliance and Audit Services of the UNC System, external auditors, and the Committee – so long as such special requests do not cause the OIAMAS to be out of conformance with the Standards.
- Maintain a professional audit staff with sufficient knowledge, skills, experience, and professional certifications to meet the requirements of the Internal Audit Charter.
- Inform the Chancellor and the Committee if changes to the budget or staffing have a significant detrimental impact on the ability to meet the requirements of the Internal Audit Charter.
- Evaluate and assess significant functions and new or changing services, processes, operations, and control processes coincident with their development, implementation, and/or expansion.
- Issue periodic reports to management, the Chancellor and the Committee summarizing results of audit activities.
- Keep the Chancellor and the Committee informed of emerging trends and successful practices in internal auditing.
- Provide a list of significant measurement goals and results to the Chancellor and the Committee.

Last Review by CAO and Audit Committee September 28, 2023

- Conduct investigations of alleged misuse of University resources <u>and other</u> <u>matters submitted to the office's hotline</u> and <u>perform or</u> assist with other investigations as requested by the Chancellor, University Counsel, and/or others as appropriate.
- Consider the scope of work of the external auditors and regulators <u>and other</u> <u>internal compliance offices</u>, as appropriate, for the purpose of providing optimal <u>audit assurance and monitoring</u> coverage to the organization.
- Serve as a liaison between University management and external auditors.
- Provide assurance services to for management, the Chancellor, and the Committee (Assurance services involve an objective assessment of evidence to provide an independent opinion or conclusions regarding an entity, operation, function, process, system, or other subject matter. The nature and scope of the assurance services are determined by the internal auditor.)
- As appropriate, provide consulting and advisory services to management that add value and improve the governance, risk management, and control processes without the internal auditor assuming management responsibility. (Consulting and advisory services are generally performed at the specific request of an engagement client. The nature and scope of advisory services are subject to agreement with the engagement client.)
- Establish a quality assurance program <u>consistent with the Standards</u>, by which the Chief Audit Officer monitors and continually improves the operation of internal audit activities <u>and communicates the results of the program with the Chancellor and the Committee</u>.
- Ensure the requirements are met with regard to regarding internal audit activities as set forth by UNC Board of Governors, UNC System Office, North Carolina General Statutes, and the North Carolina Council of Internal Auditing.

# Authority

The Chief Audit Officer and the staff of OIAMAS are authorized to:

- Have unrestricted access to all functions, records, property, and personnel of the University and its affiliated entities in accordance with North Carolina General Statutes and UNC System policies.
- Allocate resources, set frequencies, select subjects, determine scope of work, and apply the techniques required to accomplish audit objectives.
- Provide consulting and advisory services to management as deemed appropriate.

The Chief Audit Officer and the staff of OIAMAS are not authorized to:

• Perform any operational duties for the organization or its affiliates.

Last Review by CAO and Audit Committee September 28, 2023

- Initiate or approve accounting transactions external to OIAMAS.
- Direct the activities of any organization employee not employed by OIAMAS, except to the extent such employees have been appropriately assigned to auditing teams or to otherwise assist the internal auditors.

### **Standards of Internal Auditing**

The internal audit profession is covered by the International Professional Practice Framework of The Institute of Internal Auditors. This framework includes mandatory elements consisting of Core Principles, the Definition of Internal Auditing, the Code of Ethics, and the *International Standards for the Professional Practice of Internal Auditing*. The OIAMAS will meet or exceed these mandatory requirements of the profession.

Revised Version Approved by the BoT Audit, <u>Risk Management</u>, <u>Compliance, and Ethics</u> Committee on September <u>April 911</u>, 2021<u>4</u>.



Meeting of the Board of Trustees Audit, Risk Management, Compliance & Ethics Committee April 11, 2024

# **AGENDA ITEM**

Situation:	Regular update to the committee on the University's top enterprise risks and emerging risks.
Background:	This committee oversees ERM. The ERM function is owned by University senior management and is tightly integrated with Internal Audit, which develops and executes the annual risk-based audit plan.
Assessment:	Ms. Coleman will update the committee on the current risk matrix, any recent events and changes that impact the risk landscape, and/or activities and updates from the University's ERM Committee.
Action:	This item is for information only.

# East Carolina University Enterprise Risk Management 2022-2024 Cycle Top Risks (as of April 2024)

Risk	Advisory Team(s)	Sponsor(s)
University workforce challenges: Recruiting and retaining qualified and diverse faculty and staff, including healthcare professionals; Retaining institutional knowledge for long-term success and sustainability; Competitive compensation; Faculty and staff wellness, stress, and burnout concerns; Morale and effectiveness of the workforce. Employee flexibility and remote work are key ways to mitigate these challenges, but these opportunities present risks related to cybersecurity, tax, export controls, compliance, and accountability of University assets.	Cabinet, Human Resources	VCAF
University financial sustainability: The ability to maintain sustainable revenues from all sources (enrollment, auxiliaries, appropriations), understanding the impacts of the new funding model, and the impact of economic conditions during the period covered by this risk assessment	Cabinet, Finance	VCAF
Student crisis management, including basic necessities, mental and physical health, and other urgent needs (revised Nov 2023)	Cabinet, Student Affairs	VCSA
Student recruitment and retention in an increasingly competitive market, magnified by reputation/perception challenges outside eastern NC	Strategic Enrollment Planning Team	Provost and All VC's
Cyber threats (from external and internal sources) to the confidentiality, integrity, and availability of data and information systems	CIO, CISO	VCAF
Significant changing regulatory compliance requirements, including healthcare, HIPAA, research, foreign influence/research security, DoD cybersecurity requirements, athletics, Title IX, personnel, pandemic relief funding, equal opportunity, and privacy	Legal Affairs, Internal Audit, Compliance Offices	Chancellor, VC Legal Affairs
Clinical Healthcare: financial sustainability, dependence on external relationships for healthcare delivery, and risks related to the ECU Health integration	BSOM Dean	Chancellor, BSOM Dean
Position vacancies in key areas resulting in weakening of internal controls	Cabinet, Internal Audit	All VCs
Maintaining campus infrastructure, including routine and deferred maintenance, and hiring of external contractors/service providers	Campus Operations	VCAF
Continuing senior leadership transitions and reorganization, consistency and stability at the top, and impact on university's reputation, culture, strategy, goals, and sharing of information across divisions and units	Cabinet	Chancellor

# East Carolina University Enterprise Risk Management 2022-2024 Cycle Secondary Risks

(These were considered by the ERM Committee but are not presently considered "top risks")

- ECU's reputation and visibility in large urban areas/competitive markets and with financial supporters (donors, legislators)
- Governance relationships and the impact on ECU's reputation, budget, and support (in the top 10 during our previous risk cycle)
- Sustainability of academic and student support programming and services and ability to meet student needs and parent and societal expectations, especially in the current environment (*in the top 10 during our previous risk cycle*)
- Technology backup, recovery, and continuity and coordination of priorities between IT and functional management
- Increased risk in academic integrity issues with the number of remote students and exams
- Legal liability issues specifically related to or resulting from COVID-19, including health and safety, student access, long-term accommodations, and employment matters (EEOC, ADA, etc.)
- Inability to sustain innovation and economic development due to resource constraints, impacting the engagement with and positive outcomes for eastern NC
- Business continuity planning that could be insufficient to prevent an operational failure from a disaster or other significant event(s)
- Lack of dedicated identification and monitoring of sponsored program expenditures and tracking of institutional metrics for externally funded research amplified by inadequate interfaces between the information systems used for research
- Conflicts of interest in research and patient care, which could result in loss of external funding and reputational damage
- Affiliated Entities' risk of noncompliance with operating agreements, misalignment with the university's mission, and potential for reputational damage
- Social unrest that could result in unsafe conditions, property damage, or reputational damage (could be related to students, employees, or the general public)

# East Carolina University Enterprise Risk Management Emerging Risks

- Inability to sustain extramural research and sponsored programs due to resource constraints, impacting faculty scholarship, discoveries and advances, faculty recruitment and retention, and student engagement.
- Responding to the changing demographics of our students. Adult learners' needs will be different than traditional college-aged students. Adult learners will not be as interested in student affairs services such as clubs, organizations, activities, etc., or perhaps athletics. The University will need to right-size these and other services to meet the needs of our different student populations.
- Artificial intelligence the rising availability and use of which presents opportunities in higher education, but also increases risks related to academic integrity, research, data privacy and security, and student educational outcomes. *(Added Nov 2023.)*
- The collegiate athletics landscape NIL, employer status, amateurism model, revenue model, etc. (Added Feb 2024)



Meeting of the Board of Trustees Audit, Risk Management, Compliance & Ethics Committee April 11, 2024

# AGENDA ITEM

IV.B. Research Administration and Compliance Update .....Becky Welch Assistant VC for Research Admin and Compliance

- Situation:This committee is responsible for oversight of regulatory compliance at the University<br/>and periodically receives updates from the various compliance officers.
- Background:The Office of Research Administration and Compliance is responsible for many of the<br/>University's research compliance efforts. Its purview includes oversight of sponsored<br/>programs financial management, managing the conflicts of interest disclosure<br/>processes, import and export controls, and other duties.
- Assessment: Ms. Becky Welch will update the committee on the office's current purview and priorities.
- Action: This item is for information only.

Office of Research Administration and Compliance (ORAC) Bevelop Proposal GRANT LIFE CYCLE Submit Proposal Award Setup

# **ORA Pre-Award**

Pre-Award Services efforts begin with pre-submission proposal development/review through award negotiation and acceptance, with relevant follow-on effort provided during the life of the project.

# **Compliance Roles**

- Application compliant with ECU, agency, federal regs
- Agreement negotiation for acceptable ECU terms/ conditions
- Mitigation efforts for less optimal terms/conditions
- Award setup: confirm research subject protocols in place
- Subawards crafted to reflect risk assessment

# **Compliance Priorities**

- Establish pre-award processes for projects containing export control, disclosure of information
- ECU meets new federal certs
- Update ECU agreement template with updated/ expanded terms/conditions
- Provide additional negotiation training
- Create resources, workflow for subaward lifecycle

# **Notable Risks**

- New federal certifications (e.g. Other Support, Malign Foreign Talent Program)
- DOD funding: export control, disclosure, and NIST requirements

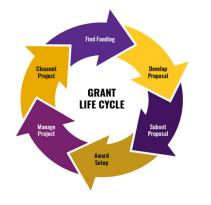
# **Outcomes of Noncompliance**

- Applications returned without review
- Termination of sponsored projects
- Possible debarment and suspension

## **ORA Post-Award**

#### Grants and Contracts Administration Team

- \$85.6M sponsored projects awarded in FY23
- 825+ active sponsored projects and clinical trials
- Monitors sponsored projects
  - effort reporting
  - cost allowability
  - subrecipient invoicing
  - residual balances
  - financial reporting
  - project closeout
- Monthly reports identify potential red flags
- Repercussions of noncompliance can include
  - work suspension on project
  - termination of sponsored project
  - withholding of support
  - loss of future projects
- Future priorities are to continue to create tools and training to help support departments with compliance management and onboarding of new departmental grant administrators



Billing and Revenue Team

- Processes over 900 invoices
- Manages ~785 Federal Cash Draws
- Processes an average of 2,100 deposits quarterly
- Consequences of noncompliance include a delay in payments from sponsor or could result in nonpayment of invoice

#### Award Setup Team

- Created 362 new funds in FY23
- Processes over 300 eTRACS actions quarterly and fields numerous requests daily
- Requests approval from Financial Services to create new fund in Banner to ensure compliance with University policies and procedures
- Monitors funds using monthly reports to ensure complete data is maintained on fund
- Noncompliance can result in incorrect fund creation and incorrect reporting of sponsored project information

# University & Medical Center Institutional Review Board (UMCIRB)

- The primary function of the UMCIRB is to protect the rights and welfare of human research participants in accordance with federal regulatory requirements. This mission is accomplished by an institutional commitment to education and establishment of a collaborative relationship with researchers and key support staff.
- Electronic submission
- ePIRATE Login
- Two IRB committees
- SMART IRB member since 2017 SMART IRB
- Three Certified IRB Professionals (CIP) and one Certified HIPAA Professional (CHP) on staff
- UMCIRB office provides education/presentations across campus and to external partners
- UMCIRB provides support for non-research activities (Humanitarian Use Device (HUD), expanded access, emergency use)
- UMCIRB office manages IRB reliance agreements for ECU and maintains Master Agreements for ECU to rely on federal and major for-profit IRBs:



# UMCIRB: Compliance Priorities and Opportunities

- Develop and understand the human research administration and oversight relationship with ECU Health
  - ECU Health is engaged in greater than minimal risk clinical trials under their own master agreements with external IRBs—if ECU is asked to administratively manage and provide oversight and monitoring for these research studies, an assessment of added risks and additional resources would be required
- Without appropriate administrative management and oversight of human research activities, there is a potential for noncompliance with human research regulations and repercussions could include:
  - research participant injury
  - $\circ$  data breach
  - federal/FDA suspension (which could lead to an inability to accept federal funding for research or expenditure of industry funds for FDA regulated research)
  - $\circ~$  bad press and diminished public perception

## OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE OPERATIONAL AREAS

#### **Conflicts of Interest**

- Annual COI disclosures
- Project specific COI disclosures
- Administrative support to the COIC
- Guidance to faculty, staff and students regarding COI and NOI issues
- Provide and monitor required COI training
- Review and make COI determinations
- Draft and implement COI management plans
   ORIC

#### **Responsible Conduct of Research**

- Coordinate and monitor training of Postdoctoral Scholars
- Provide training to undergraduate students involved in research experience
- Monitor and adjust to federal regulatory requirements related to RCR training

#### **Export Controls**

- EC disclosures (embedded within COI)
- Guidance to faculty, staff and students regarding export and import compliance
- Review, assess and resolve export/import compliance concerns
- Draft, submit and manage U.S. license applications for sanctions and export controls

#### Research Misconduct

- Assess research misconduct allegations
- Maintain confidentiality of proceedings
- Sequester and inventory research records
- Administrative support to inquiry panels and investigation committees
- Submit inquiry and investigation reports to DO and sponsors as required
- Submit annual research misconduct report to ORI



# Institutional Animal Care and Use Committee (IACUC)

- Vertebrate animals and cephalopods
- Full AAALAC accreditation
- PHS assurance with Office of Laboratory Animal Welfare (OLAW) through 1/31/28
- The IACUC is authorized to suspend an animal care and use activity that fails to comply with federal regulation or an IACUC approved protocol.
- At least once every six months
  - inspect all ECU animal housing facilities and animal use areas (laboratories), using specified standards as the basis for evaluation and reporting
  - review ECU's program for the care and use of animals, using specified standards as the basis for evaluation and reporting.

# Any questions?



Meeting of the Board of Trustees Audit, Risk Management, Compliance & Ethics Committee April 11, 2024

#### **AGENDA ITEM**

IV.C.	REDE Compliance Monitoring Update	Kenneth Briley
		Director, REDE Compliance Monitoring Office

Situation:	This committee oversees the University's regulatory compliance efforts and periodically receives updates from the various compliance offices.
Background:	The Compliance Monitoring Office oversees human subjects research compliance, adherence to conflict-of-interest management plans, review of certain aspects of sponsored programs effort reporting, and performs other duties.
Assessment:	Mr. Briley will update the committee on the current purview and priorities of his team.
Action:	This item is for information only.

# **REDE Compliance Monitoring Update**

Kenneth Briley, MSW, CIP Interim Director Office of Compliance Monitoring



April 11, 2024



# Compliance Monitoring: Sponsored Projects

### **Applicable Federal Regulations**

**2 CFR Part 200** - also known as the Uniform Guidance (UG); the federal government's framework for managing grants, providing rules and requirements for federal awards

### **Failure to Comply**

- Withhold funding pending correction of deficiency
- Deny use of all or part of funds for the cost of the action/activity not in compliance
- Suspend/terminate in part or whole the federal award
- Initiate suspension/debarment proceedings
- Withhold further Federal funds for the project or program
- Reputational harm

# Compliance Monitoring: <u>Human Research</u>

### **Applicable Federal Regulations**

**45 CFR Part 46** – also known as the Common Rule, a set of federal regulations which aim to protect human subjects taking part in federally funded research

**21 CFR Parts 50 & 51** – FDA rules & regulations pertaining to the protection of the rights, safety & welfare of human subjects who take part in clinical trials

### Failure to Comply

- Possible harm to participant
- Compromise the integrity of the data
- IRB may sanction, suspend or terminate approval
- Serious non-compliance is reportable to OHRP/FDA
- Result in a Federal audit
- Financial penalties
- Reputational harm

# Compliance Monitoring: COI Management Plans

### **Applicable Federal Regulations**

### 42 CFR Part 50, Subpart F -

establishes standards that provide a reasonable expectation that the design, conduct, or reporting of NIHfunded research (grants and cooperative agreements) will be free from bias resulting from any Investigator's conflicting financial interest

### Failure to Comply

- Institutional retrospective review of activities and reporting to PHS if bias, related to COI, discovered during time of non-compliance
- Issuance of awards may be delayed
- Specific award terms/conditions may be imposed
- Enforcement actions taken to remedy non-compliance

# Compliance Monitoring: Data Management & Sharing

### **Applicable Federal Policy**

### **Failure to Comply**

NIH Policy for Data Management & Sharing (January 25, 2023) – establishes requirements for management and sharing of scientific data generated from NIH-funded or conducted research, as well as the requirements of submission of Data Management and Sharing Plans and compliance with NIH Institute, Center, or Office (ICO)-approved Plans

- May result in the addition of special terms and conditions
- Termination of the award
- Affect future funding decisions for the institution

RESEARCH ADMINISTRATION AND COMPLIANCE

# Questions?



### AGENDA ITEM

IV.D. Recent Internal Audits	е
Chief Audit Office	؛r

Situation:	The committee receives a briefing at each meeting on selected internal audit engagements that have been closed.
Background:	Committee Chair Smith and Vice Chair Workman selected the engagements to be discussed at this meeting.
Assessment:	Mr. Poole will present background and results of the selected engagements. Members of University management will also be present to answer questions about the status of resolving any audit recommendations.
Action:	This item is for information only.



### AGENDA ITEM

V.	Closed Session	Wayne Poole
		Chief Audit Officer

	The committee will need to discuss certain ongoing or completed audit issues or other issues under the committee's purview that are not a matter of public record due to their content.
Background:	This committee is responsible for receiving reports of all internal and external audits.
Assessment:	The committee will receive a briefing on the relevant issues.

Action: The closed session business is for information only.



Meeting of the Board of Trustees Audit, Risk Management, Compliance & Ethics Committee April 11, 2024

### AGENDA ITEM

VI.	Other Business	
		Chief Audit Officer

Situation:	Other items to be brought to the committee if applicable.
Background:	N/A
Assessment:	Other items to be brought to the committee if applicable.
Action:	This item is for information only.

Other items to be brought to the committee if applicable.