ECU | BOARD OF TRUSTEES

AGENDA
Audit, Risk Management, Compliance, and Ethics Committee
April 25, 2025

I.   Approval of Minutes – February 6, 2025

II.   Review of Operational Metrics

III.   Action Items – Approval of FY 2026 Audit Plan (Mr. Wayne Poole)

IV.   Informational Items
   A. Enterprise Risk Management Update (Mr. Chris Rowland)
   B. Research Compliance update (Ms. Becky Welch)
   C. Academic Advising Update (Dr. Allen Guidry)

V.   Closed Session

VI.   Other Business

AGENDA ITEM

I.   Approval of Minutes..Vince Smith, Committee Chair

Situation: Approval of the minutes from the most recent committee meeting.

Background: N/A

Assessment: N/A

Action: This item requires a vote by the committee.

Minutes from the Audit, Risk Management, Compliance, and Ethics Committee
February 6, 2025 – 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 6, 2025.

Committee members present: Vince Smith (Chair), Vanessa Workman, and Anderson Ward.

Trustee Vince Smith, Chair of the Committee, convened the meeting at 1:35 PM. Mr. Smith read the conflict-of-interest provisions as required by the State Government Ethics Act. Mr. Smith asked if anyone would like to report an actual or perceived conflict. None were reported.

Mr. Smith asked for the approval of the minutes of the November 21, 2024 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, for the 2025 fiscal year to date through December 2024. Wayne Poole briefed the committee on recent Student Health billing and coding audits that were completed by the Office of Institutional Integrity, which are not reflected in the KPI numbers.

Action Items

Audit Plan Change – Mr. Wayne Poole presented one proposed change to the University's annual audit plan. Trustee Ward moved to approve the change as presented in the Board materials. Trustee Workman seconded the motion, and it was approved unanimously. This item does not require any action by the full Board.

Informational Items

Enterprise Risk Management – Ms. Stephanie Coleman
Vice Chancellor Coleman advised that the ERM committee will be evaluating any necessary adjustments to the University's register of top risks and emerging risks and will share any updates with us at our April meeting. Ms. Coleman also advised that the University is closely monitoring federal legislative actions and executive orders to determine any impacts on the University.

Academic Advising Update – Dr. Allen Guidry
Dr. Guidry updated the committee on the steps taken to address previous audit recommendations related to Academic Advising. The University's response has included the establishment of an Advising Standardization Commission and sub-committees to address specific areas of opportunity. Dr. Guidry shared the timeline for the work that has already been done and the future steps that will be taken. The goal is to strengthen advising practices and standardize the student experience across the various colleges and schools, as a key part of the University's Student Success agenda.

Recent Internal Audits – Mr. Wayne Poole
Mr. Poole advised that since the Audit Committee's last meeting, Internal Audit has closed 8 engagements. He briefed the committee on two of the audits – the University Purchasing Card Program, and the Student Emergency Response Process.

Closed Session

At 2:10 PM Trustee Ward made a motion to go into closed session to discuss items that are not a matter of public record according to applicable North Carolina statutes. The motion was seconded by Trustee Workman and approved unanimously.

Minutes from the Audit, Risk Management, Compliance, and Ethics Committee
February 6, 2025 – Main Campus Student Center and Online Meeting

At 2:26 PM the committee returned to open session.

Other Business

There was no other business to discuss, and the committee meeting was adjourned at 2:26 PM.

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

AGENDA ITEM

II. Operational Metrics .... Wayne Poole, Chief Audit Officer

Situation: Presentation of the metrics that are monitored by this committee.

Background: 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.

Assessment: Metrics for FY 2025 to date are generally on track.

Action: This item is for information only.

CEO Tracking Sheet

<mark>Fiscal Year - 2025</mark>

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
Audit Plan Completion (Internal Audit)	Percent of projects on annual plan that are completed	92.0%	80%	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%
				Actual	7.2%	7.4%	9.0%	9.0%	9.1%	1.8%	9.1%	9.2%	9.0%				70.8%
				+/-	0.6%	0.8%	2.4%	2.4%	2.4%	-4.9%	2.4%	2.5%	2.3%				
				YTD +/-	0.6%	1.4%	3.8%	6.2%	8.6%	3.7%	6.1%	8.6%	10.9%				
Auditor Productivity (Internal Audit)	Direct Audit & Consult hrs vs. Total hours	76.3%	75%	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%
				Actual	72.6%	77.4%	79.7%	74.5%	75.1%	55.8%	78.4%	80.6%	83.2%				75.2%
				+/-	-2.4%	2.4%	4.7%	-0.5%	0.1%	-13.2%	2.4%	4.6%	7.2%				
				YTD +/-	-2.4%	-0.1%	1.5%	1.0%	0.8%	-3.0%	-1.6%	-0.7%	0.2%				
Management Corrective Actions Completion Rate (Internal Audit)	Percent of recommendations resolved when IA follows up	96.6%	95%	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%
				Actual	100.00%	100.00%	83.30%	100.00%	83.30%	100.00%	100.00%	100.00%	100.00%				94.70%
				+/-	5.00%	5.00%	-6.70%	5.00%	-11.70%	5.00%	5.00%	5.00%	5.00%				
				YTD %	5.00%	5.00%	-2.70%	-0.90%	-5.30%	-2.70%	-2.00%	-0.80%	-0.30%				
Number of Rules Education Sessions (Athletics Compliance)	Number of sessions spent educating athletes, staff & others	343	300	Plan	25	25	25	25	25	25	25	25	25	25	25	25	300
				Actual	16	34	30	25	20	24	25	28	30				232
				+/-	-9	9	5	-	-5	-1	-	3	5				
				YTD +/-	-9	0	5	5	0	-1	-1	2	7				
Number of NIL Education and Consultation Sessions (Athletics Compliance)	Sessions spent educating athletes, staff & others (NIL-specific)	86	48	Plan	4	4	4	4	4	4	4	4	4	4	4	4	48
				Actual	8	10	10	8	4	5	5	7	12				69
				+/-	4	6	6	4	-	1	1	3	8				
				YTD +/-	4	10	16	20	20	21	22	25	33				
Number of Education Sessions (Healthcare Compliance)	Number of sessions spent educating providers and staff	776	756	Plan	63	63	63	63	63	63	63	63	63	63	63	63	756
				Actual	62	65	71	65	65	69	61	63	63				584
				+/-	-1	2	8	2	2	6	-2	0	0				
				YTD +/-	-1	1	9	11	13	19	17	17	17				
Number of Proactive Provider Documentation Reviews (Healthcare Compliance)	Number of providers whose doc. accuracy was reviewed	298	276	Plan	23	23	23	23	23	23	23	23	23	23	23	23	276
				Actual	25	25	25	25	25	25	23	25	25				223
				+/-	2	2	2	2	2	2	0	2	2				
				YTD +/-	2	4	6	8	10	12	12	14	16				
Pass Rate Results of Healthcare Provider Documentation Reviews (Healthcare Compliance)	Percent of reviewed providers receiving a passing score	98.3%	90%	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%
				Actual	100.0%	95.0%	100.0%	100.0%	100.0%	95.0%	100.0%	100.0%	100.0%				98.9%
				+/-	10.0%	5.0%	10.0%	10.0%	10.0%	5.0%	10.0%	10.0%	10.0%				
				YTD +/-	10.0%	7.5%	8.3%	8.8%	9.0%	8.3%	8.6%	8.7%	8.9%				
Number of Operational Billing Compliance Reviews (Healthcare Compliance)	Number of audits of clinic accuracy for copays, ABN doc, place of service	0 New	50	Plan	0	0	5	5	5	5	5	5	5	5	5	5	50
				Actual	0	0	5	5	5	5	5	5	5				35
				+/-			0	0	0	0	0	0	0				
				YTD +/-			0	0	0	0	0	0	0				
Number of Group Education Sessions (Human Subjects Research/IRB)	Number of sessions spent educating groups of researchers	41	24	Plan	2	2	2	2	2	2	2	2	2	2	2	2	24
				Actual	1	4	6	4	5	3	3	5	6				37
				+/-	-1	2	4	2	3	1	1	3	4				
				YTD +/-	-1	1	5	7	10	11	12	15	19				
Number of Compliance Monitoring Reviews (Human Subjects Research/REDE Compliance Monitoring Office)	Number of human subjects studies reviewed for compliance	40	36	Plan	3	3	3	3	3	3	3	3	3	3	3	3	36
				Actual	2	3	0	8	3	2	3	2	2				25
				+/-	-1	0	-3	5	0	-1	0	-1	-1				
				YTD +/-	-1	-1	-4	1	1	0	0	-1	-2				
Employee COI Disclosure Rate (Research Compliance)	Percent of employees who submitted req'd disclosure	99.87%	100%	Plan										90.0%	95.0%	100.0%	100.0%
				Actual													0.00%
				+/-													
				YTD +/-													

AGENDA ITEM

III   Action Items ....Wayne Poole
Chief Audit Officer

Situation: The University's annual audit plan and internal audit charter, and any significant changes to them, must be approved by this committee.

Background: The committee initially approves the annual audit plan and subsequently hears proposed added or removed assurance engagements for approval. New investigative audits and small-scope consultative/advisory engagements are generally not presented to the committee.

Assessment: The Chief Audit Officer will present the fiscal year 2026 annual audit plan for the committee's approval at this meeting.

The proposed audit plan includes two compliance engagements (*Research Security*, and *Expense Review for External Sponsor – Climate Grant*) that are being proposed for postponement from the 2025 audit plan. The committee's approval, if granted, will apply to the new 2026 audit plan and the amended 2025 audit plan.

Action: This item requires a vote by the committee.

FY 2026 Annual Audit Plan

Office of Internal Audit and Management Advisory Services

ECU

Annual Audit Planning Process – Why?

- Required to comply with *Global Audit Standards*

- Required to submit to NC Council of Internal Audit (also reviewed by UNC BOG)

- 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

ECU

Annual Audit Planning Process – How?

Continuously Assess and Monitor Risk / Update Audit Universe and Plan

Define/Update Audit Universe	Unit and Process Risk Scoring	Conduct Top-Down Risk Assessment	Other Items Assessed	Develop Audit Plan	Finalize Plan
• Ensures completeness of risk coverage • Vision, mission, and strategic plan • Latest financial statement • Financial balances • Organization charts, chart of accounts • Recent internal and external audits completed and results	• Each unit and business process • Criticality • Strategic impact • Internal Control • Public or political sensitivity • Legal and regulatory requirements • Changes in management • Financial Impact • Fraud and Abuse • Recency of last audit engagement	• Facilitated by ERM • Issues impacting University at an enterprise level • Links to strategic objectives • Identifies most critical risks (strategic, operational, compliance, reputational, financial)	• Other compliance and assurance providers' plans & programs (Governance, Risk, Control) • Latest State Audit reports • UNC System KPIs and Control Assessments • Input of senior leaders, Board, and key management personnel • Industry's emerging risks and hot topics	• Based on prioritized audit universe • Include management requests • Determine if pending audits from previous plan need to be brought forward • Determine follow-up reviews • Determine available auditor hours	• Share with Vice Chancellors and AD • Approval by Chancellor • Approval by ECU BOT Audit Committee • Submit to NC Council of Internal Auditing • Update plan as changes in risks and opportunities occur

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Annual Audit Planning Process – Result

- A work plan/list of priorities for the IA team

- Includes hours for unplanned consultations and investigative audits

- Flexible; can and will change as new priorities emerge

- Significant changes will be brought to the Chancellor and BOT Audit Committee for approval

Annual Audit Plan – Next Steps

- Chancellor approved in April 2025

- 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

Project Description		Budgeted Hours	% of Total	Key Risk	Strategy/ Mission	Division
Integrated / Internal Controls / Operational / Performance Audits:						
Travel Expense Analytics Review	WIP	200	1.2%	X		ALL
Web Accessibility Controls	OP	300	1.8%	X		AF, CH
Athletics Team Policies	OP	200	1.2%	X		AT
Accounts Payable	OP	400	2.4%	X		AF
Gift Card Purchases and Controls	OP	300	1.8%	X		ALL
Personnel Records Practices	OP	300	1.8%	X		ALL
Aramark Contract Monitoring	OP	200	1.2%	X		SA
Club Sports	OP	300	1.8%	X	X	SA
Employee Separation Process	OP	300	1.8%	X		AF
SGA Funds Allocation Process	OP	120	0.7%		X	SA
		2620	**15.8%**			
Compliance Audits:						
Admissions Process Compliance	WIP	40	0.2%	X	X	AA
ProCard Program Compliance (UNC Regulation 1300.7.2)	OP	160	1.0%	X		AF
Emergency Communications (UNC Regulation 1300.7.3)	OP	300	1.8%	X	X	AF, CH
Expense Review for External Sponsor - Climate Grant	OP	300	1.8%	X		AA
Research Security	OP	300	1.8%	X	X	AA
		1100	**6.6%**			
Information Technology / Data Protection Audits:						
Finance Data and User Access	WIP	200	1.2%	X		AF
Copier and Scanner Controls and Contract	OP	300	1.8%	X		AF
Sponsored Programs Data Management Plans	OP	300	1.8%	X	X	AA
End User Data Collection and Signature Applications	OP	300	1.8%	X		ALL
		1100	**6.6%**			
Investigative Reviews:						
Triage of Allegations, Complaints, Concerns	OP	200	1.2%			ALL
Investigative Reviews - Details not included	OP	1500	9.0%			ALL
		1700	**10.2%**			
Follow-Up Reviews:						
Action Plan Tracking and Follow-Up	OP	600	3.6%			ALL
Follow-Up on Office Space Utilization	OP	120	0.7%	X		AA
		720	**4.3%**			
Consultations / Advisory Services						
Routine and Unplanned Consultations	OP	600	3.6%			ALL
Routine Analytics - Accounts Payable Transactions	OP	160	1.0%			ALL
Routine Analytics - ProCard Transactions	OP	160	1.0%			ALL
Routine Analytics - Other	OP	80	0.5%			ALL
University Committees, Workgroups, Education, and Client Relations	OP	400	2.4%			ALL
Regulatory Compliance Committee Support	OP	160	1.0%			ALL
Student Athlete Course Clustering	OP	40	0.2%			AA, AT
Minors on Campus	OP	100	0.6%			AF
Employee Eligibility Processes	OP	100	0.6%			AF
Research Hub Operations	OP	200	1.2%			AA
		2000	**12.0%**			
Special Projects / Risk Assessments / Other:						
External Audits, SBI Reports, Routine Mtgs, BOT Comm	OP	1600	9.6%			ALL
Audit Software Admin and Maintenance	OP	100	0.6%			CH

OP=Original Plan
WIP=Work in Progress from prior year
ADD=Added since July 1
CX=Cancelled
PPD=Postponed

Project Description		Budgeted Hours	% of Total	Key Risk	Strategy/ Mission	Division
Annual QAIP Activities	OP	100	0.6%			CH
Risk Assessment/Audit Planning 2026-2027	OP	160	1.0%			ALL
Required IIA External Quality Review (due Mar 2026)	OP	300	1.8%			CH
Fraud Risk Assessment	OP	300	1.8%			ALL
		2560	15.4%			
Total Direct/Chargeable Hours		**11800**	**71%**			
Administration		1600	9.6%			NA
Leave/Holiday		2400	14.5%			NA
Professional Development		800	4.8%			NA
Total Indirect Hours:		**4800**	**29%**			
Grand Total Hours		**16600**	**100%**			

Original Plan Approved by Chancellor Rogers on 04/03/2025

Original Plan Approved by ECU Board of Trustees Audit, Risk Management, Compliance, and Ethics Committee on 04/XX/2025

OP=Original Plan
WIP=Work in Progress from prior year
ADD=Added since July 1
CX=Cancelled
PPD=Postponed

AGENDA ITEM

IV.A. Enterprise Risk Management (ERM) Update .... Chris Rowland
Associate Vice Chancellor for Administration and Finance

Situation: Presentation of the newly updated enterprise risk register for the University, for the 2025-2027 ERM cycle.

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.   The University's ERM Committee completes a formal review and revision of the ERM risk register every other year (or more frequently if appropriate based on the risk landscape). This year's exercise resulted in an updated risk register which has been endorsed by the Chancellor and his Executive Council. The top five risks from each campus are also submitted annually to the UNC System Office.

Assessment: Mr. Rowland will brief the committee on the newly updated risk matrix, any recent events and changes that impact the risk landscape, and/or other activities and updates from the University's ERM Committee.

Action: This item is for information only.

East Carolina University Enterprise Risk Management
2025-2027 Cycle Top Risks (as of April 2025)

Risk	Advisory Team(s)	Sponsor(s)
Financial stability: Declining traditional student enrollment—students coming to campus—resulting in decreasing student fees and reduced state appropriations creates an unstable financial environment. Rising operational costs, deferred maintenance, and limited new revenue sources create ongoing financial challenges. External economic factors such as inflation, high interest rates, increased labor costs, and unpredictable government payments challenge financial resources.	Cabinet	VCAF
Workforce challenges: Workforce challenges continue due to difficulties in recruiting and retaining qualified faculty and staff. Competitive salaries and market demand for specialized roles continue to hinder talent acquisition. Additionally, burnout and stress contribute to turnover.	Cabinet, POSO	All VCs
Student recruitment, retention, and graduation: Challenges in traditional student recruitment continue, aligning with national and regional trends. Barriers to retention and graduation pose risks to student success outcomes. The evolving perception of the value of a degree, increased competition from online programs and alternative education pathways, and shifting workforce demands further complicate recruitment efforts.	Cabinet	Provost
Changing regulatory & policy compliance requirements: As regulatory and policy requirements from the federal government, state government, and UNC System Office rapidly evolve, ECU must navigate complex compliance risks across multiple domains, including healthcare, cybersecurity, privacy, research security, NIL/NCAA policies, Title VI, Title IX, equal opportunity, and digital accessibility.	VC Legal Affairs, Internal Audit, Compliance Offices	Chancellor
Cyber threats: Universities face increasingly sophisticated cyber threats, including social engineering, ransomware attacks, and potential data breaches, which can jeopardize the confidentiality, availability, or integrity of institutional IT systems or data. Protecting the university's expanding digital infrastructure—relied upon by students, faculty, researchers, and administrators for learning, collaboration, and operational efficiency—is critical to ensuring regulatory compliance, maintaining cyber resilience, and safeguarding the university's education, research, and innovation mission.	CISO	CIO
Student crisis management: Student mental and physical health remain critical areas of concern, particularly in the context of increasing campus, regional, and national trends related to stress, anxiety, loneliness, depression, and other crisis-related issues. Additionally, students face significant challenges related to basic needs (e.g., housing, food, clothing, course materials, etc.), which impact student retention, persistence, and the ability to graduate.	Division of Student Affairs	VCSA
R1 Status: As a newly designated R1 institution, ECU faces increased regulatory expectations related to research oversight, foreign influence protections, and federal funding compliance. Possible declining F&A rates further strain research sustainability. Additionally, uncertainty surrounding federal funding under new executive orders and policy changes may impact long-term financial planning.	Cabinet	Provost
Clinical Healthcare: Clinical healthcare operations face financial sustainability challenges due to rising operational costs, reimbursement constraints, and reliance on external funding sources. Dependence on external partnerships for healthcare delivery—including affiliations with ECU Health and other providers—introduces contract stability, service continuity, and strategic alignment risks. Additionally, the ongoing ECU Health integration presents potential financial, operational, and compliance risks, including challenges in governance, resource allocation, and regulatory adherence.	BSOM Dean and Executive Dean	Chancellor
Maintaining campus infrastructure: Budget constraints and limited funding sources for repairs and capital improvements increase challenges in maintaining campus infrastructure. Deferred maintenance continues to grow, increasing the risk of unexpected system failures, operational disruptions, and safety hazards. Aging facilities, outdated systems (HVAC, electrical, plumbing), and compliance requirements (ADA, fire codes, sustainability standards) add complexity to long-term maintenance planning.	Campus Operations	VCAF

Protecting reputation and visibility: Reputation and visibility within the higher education landscape and key constituencies face risks due to increasing competition, evolving public perception, and the rapid spread of information in the digital era.	Cabinet	Chancellor

East Carolina University Enterprise Risk Management
2025-2027 Cycle Secondary Risks
(These were considered by the ERM Committee but are not presently considered "top risks")

- Social unrest, such as protests, demonstrations, or riots, due to various factors, including political tensions, social injustice issues, or campus-specific grievances. These events can potentially create unsafe conditions for individuals on campus, disrupt academic activities, and result in property damage or loss.
- The increasing availability and use of Artificial Intelligence (AI) introduces new risks related to academic integrity, research ethics, data security, and student learning outcomes. As AI-powered tools become more sophisticated, they challenge traditional assessment methods, authorship verification, and knowledge mastery, particularly in remote and online learning environments. Additionally, using AI in research and administrative functions raises concerns about intellectual property protection, bias in AI-generated content, and compliance with privacy and security regulations.
- Increasing risks related to business continuity planning and operational resilience, particularly in the event of technology failures, natural disasters, cyber incidents, or other disruptions. Risks include gaps in backup and disaster recovery processes, supply chain disruptions, and critical infrastructure failures.
- Inability to sustain innovation and economic development due to resource constraints, impacting the engagement with and positive outcomes for eastern NC.
- Inadequate interfaces between the information systems used for research.
- Conflicts of interest in research and patient care 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.

East Carolina University Enterprise Risk Management
Emerging Risks

AGENDA ITEM

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

Situation: The committee receives periodic briefings from the University's various compliance functions.

Background: Recent organizational changes, the University's achievement of R1 status, and recent events at the federal level make this a dynamic time for research at ECU (and nationwide).

Assessment: Ms. Welch will present information on the University's core research compliance responsibilities, recent changes, and future areas of emphasis.

Action: This item is for information only.

Research Compliance Update

Compliance Monitoring: <u>Sponsored Projects</u>

<u>Applicable Federal Regulations</u>

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

<u>Failure to Comply</u>

- 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

ECU RESEARCH ADMINISTRATION AND COMPLIANCE

Compliance Monitoring: Sponsored Projects

Details for FY25FYTD

Completed 26 Risk Assessments

Reviewed 69 Subrecipient Audits

Completed 16 Desk Reviews

Modified Subrecipient Risk Assessments to continually review if Subrecipient is Debarred

Continually adjusting quarterly monitoring reporting to include latest Uniform Guidance changes

Routine Compliance Monitoring

Subrecipient Monitoring

Debarment Monitoring

Financial Compliance Indicator Monitoring

ECU RESEARCH ADMINISTRATION AND COMPLIANCE

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

<u>Applicable Federal Regulations</u>

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

<u>Failure to Comply</u>

- 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

ECU RESEARCH ADMINISTRATION AND COMPLIANCE

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

Routine Compliance Monitoring

FY25FYTD – 27 studies

<u>For Cause</u> Compliance Monitoring

FY25FYTD – None

Details

Biomedical – 19

Behavioral / Social Science – 8

- Federally funded
- Investigator initiated
- Requested – (in preparation for federal audit)
- Follow-up of previous monitoring outcomes

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.

- UMCIRB oversight covers any research involving interactions with living individuals or access to their private identifiable information; "Chart Reviews to Clinical Trials"

- Two IRB committees; one focused on biomedical research and one on social/behavioral research

- Two Certified IRB Professionals (CIP) and one Certified HIPAA Professional (CHP) on staff

- UMCIRB office delivers education/presentations across campus and to external partners

- The UMCIRB provides support for non-research activities such as Humanitarian Use Devices (HUD), expanded access and emergency use that benefit patients within the ECU and ECU Health patient populations

- 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 administrative 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, additional resources and assessment of how to manage added risks would be required

- Without proper 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 or 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)

  - bad press and diminished public perception

UMCIRB: R1 Status and Changes in the Regulatory Environment

- As ECU's research enterprise grows and diversifies, the risks associated with our human research studies will expand

- This may be due to areas of research that are simply new for the university or, may represent new advances in science and technology completely

- New technologies may have limited data we can use to quantify risks

- There may also be a lack of clarity from federal agencies on how those advances fit within the existing regulatory framework

- Regulations for human research already move slowly and changes/reductions to federal agencies may increase the lag time between research advancements and the framework with which they are regulated

- Changes in federal agencies may also result in reduction of federal guidance on interpretation and implementation of existing regulations

- In turn, reduction in federal guidance will put more burden on institutions to make their own interpretations, potentially increasing institutional risk

ECU RESEARCH ADMINISTRATION AND COMPLIANCE

Office of Research Integrity and Compliance (ORIC)

- Foreign Interference

- Research Security

- Controlled Unclassified Information (CUI)

Foreign Interference
Disclosure and Transparency

Revisions for ECU's *Regulation on Conflicts of Interest, Commitment, and External Professional Activities* (REG01.15.03) – currently awaiting formal vetting process

External Professional Activities (EPAs)

EPAs, which include the following, require screening by ORIC and prior approval by the Covered Individual's Supervisor:

- Any formal title, appointment, affiliation, career advancement opportunity, position or other recognition or status outside of ECU with a foreign government or non-U.S. entity, whether paid, unpaid, or honorary.
- Participation with any Foreign Talent Recruitment Program whether paid, unpaid, or honorary.

Externally Sponsored Research

- All Senior/Key Personnel must disclose participation in any Foreign Talent Recruitment Program in the Project Specific COI Disclosure.
- In accordance with the CHIPS and Science Act of 2022, all Senior/Key Personnel involved in research or development awards funded by the U.S. federal government are prohibited from participating in any Malign Foreign Talent Recruitment Program.

Research Security

Defined as: "Safeguarding the research enterprise against the misappropriation of research and development to the detriment of national or economic security, related violations of research integrity, and foreign government interference."

*[**Source**: NSPM-33, January 14, 2021]*

- The Department of Energy (DOE) has a requirement starting on May 1, 2025, that Covered Individuals applying to **DOE Research and Development** applications/projects must have completed Research Security Training prior to proposal submission.

- The DOE is the first of the federal agencies to implement the Research Security Training requirement.

- The National Science Foundation (NSF) is revising their Proposal & Award Policies & Procedures Guide (PAPPG), which will require Research Security training. It is anticipated that the NSF revision will be published this fall.

- ECU is requiring all Covered Individuals on DOE projects to complete Research Security training.

- ECU will expand the Research Security training requirement to include Covered Individuals on all federally funded projects this summer/fall.

ECU RESEARCH ADMINISTRATION AND COMPLIANCE

Controlled Unclassified Information (CUI)

- CUI is government-created or owned information that requires safeguarding or dissemination controls consistent with applicable laws, regulations and government-wide policies.

- CUI is not classified information. It is not intellectual property unless created for or included in requirements related to a government contract.

- When an ECU research project involves CUI, the NIST [Special Publication (NIST SP 800-171) , Safeguarding Controlled Unclassified Information in Non-Federal Systems](#) is followed to safeguard the data.

- For ECU research projects funded by the Department of Defense (DoD) involving CUI, ECU follows [DoD Instruction 5200.48, Controlled Unclassified Information](#) and [DFARS 252.204-7012, Safeguarding Covered Defense Information and Cyber Incident Reporting](#).

References/Supplemental Materials

Foreign government talent recruitment program

…is an **effort organized, managed, or funded by a foreign government**, or a foreign government instrumentality or entity, **to recruit science and technology professionals or students** (regardless of full-/part-time status, citizenship, or national origin), or as may be defined by applicable government or funding agency.

[**Source**: UNC Policy Manual 300.2.2, amended 1/25/2024]

ECU RESEARCH ADMINISTRATION AND COMPLIANCE

Malign Foreign Talent Recruitment Programs (MFTRPs)

An MFTRP is any program, position, or activity sponsored by either:

- *A foreign country of concern or an entity in a foreign country of concern (currently "the People's Republic of **China**, the Democratic People's Republic of **Korea**, the **Russian Federation**, the Islamic Republic of **Iran**"), OR*
- *An academic institution or foreign talent program that appears on this **list**.*

Note that Congress identified in the CHIPS & Science Act of 2022 which countries are considered a "foreign country of concern," and the Secretary of State may update the list at any time; the list of institutions and programs is to be updated annually.

And for which you are offered any of the types of compensation listed for performing any one or more of the problematic obligations or activities listed:

Problematic obligations or activities:

- *Unauthorized transfer of intellectual property, materials, data, or other nonpublic information.*
- *Recruitment of trainees or researchers to enroll in such program, position, or activity.*
- *Establishing a lab or forming a company in a foreign country in violation of terms and conditions of a federal research award.*
- *Accepting a faculty position or undertaking any other employment or appointment in violation of the terms and conditions of a federal research award.*
- *Signing a contract or agreement which you are unable to terminate except in extraordinary circumstances.*
- *Committing a specified amount of time to work for the foreign institution.*
- *Engaging in work that overlaps or duplicates a federal research award.*
- *Applying for or receiving research funding from the foreign government that would be awarded to the foreign institution.*
- *Requirement to omit acknowledgement of the foreign institution, or any U.S. federal research sponsors.*
- *Requirement to not disclose participation in the program, position, or activity to ECU or the U.S. federal government.*
- *Having a conflict of interest or commitment contrary to a federal research award.*

Compensation type(s):

- *Cash*
- *In-kind compensation, including research funding*
- *Promise of future compensation*
- *Complimentary foreign travel*
- *Things of non de minimis value*
- *Honorific titles*
- *Career advancement opportunities*
- *Other types of remuneration or consideration*

ECU RESEARCH ADMINISTRATION AND COMPLIANCE

Decision Matrices

Agency	Risk Factor 1	Risk Factor 2	Risk Factor 3	Risk Factor 4	Co-authorship considered in risk assessment?	How far back?
NIH	Foreign Talent Recruitment Program participation	Undisclosed foreign funding, particularly from foreign country of concern (FCOC)	Undisclosed affiliations with foreign institutions or entities, particularly with FCOC	N/A	No, if not directly related to NIH-funded work	5 years
NSF (Quantum proposals only)	Active appointments and positions with or research support from US proscribed parties and party to MFTRP	Nondisclosures of appointments, activities, and sources of research support	Potential foreseeable national security applications of the research	N/A	No	Undisclosed information will be examined from January 2022 (NSPM-33 implementation guidance issued)
DoD (including DARPA)	Foreign Talent Recruitment Program participation	Funding from FCOC	Patent applications or patents filed outside the US, particularly in FCOC	Association or affiliation with entities on entity lists	Yes	Some factors from October 10, 2019 (Griffin Letter) others from August 9, 2022 (signing of CHIPS)
US Army	Foreign Talent Recruitment Program participation	Funding from strategic competitors	Affiliation with denied entities	Affiliation, association, or collaboration with strategic competitors	Yes	Not specified
DOE	Ties to Malign Foreign Talent Recruitment Program (MFTRP)	Certain foreign funding sources and concerning behaviors associated with patenting	Ties to entities on specified lists	Critical technology, access to critical infrastructure, and proximity to a military installation	Yes, but not explicitly stated in the policy	Not specified, but likely not earlier than 2019

https://www.vanderbilt.edu/researchintegrityandcompliance/research-security/how-sponsors-categorize-risk/

ECU RESEARCH ADMINISTRATION AND COMPLIANCE

AGENDA ITEM

IV.C. Academic Advising Update...Dr. Allen Guidry
Associate Provost, Learner Operations

Situation: This committee receives updates on the status of efforts to remediate previous audit recommendations. An internal audit of Academic Advising resulted in several recommendations which University leadership is addressing.

Background: Academic Advising is crucial to the University's Student Success goals and a concerted effort is being placed on standardizing students' experiences and level of service across colleges, schools, and departments. Dr. Guidry is leading this effort, which includes a commission with participants from the various colleges and schools.

Assessment: Dr. Guidry will update the committee on the efforts that have occurred to date and the goals/timeline for completing the work towards addressing the audit recommendations and optimizing the student advising experience and expectations.

Action: This item is for information only.

The recommendations of the audit...

- Consider establishing a centralized office or person to oversee academic advising and/or establish standard procedures and expectations.

- Develop a clear role and document responsibilities for academic advisors. These expectations should be consistent among all advisors within each of the colleges and communicated with administrators, faculty, advisors, and students.

- Determine the feasibility of moving towards the use of common systems, tools, and communication methods by advising centers. This could potentially result in cost savings and a more consistent experience for students in the various colleges and schools.

- Work with college deans and advising directors to evaluate advising loads and the roles and responsibilities of academic advisors to determine whether their advising loads are reasonable to provide adequate advising and attention to their students. This includes revisiting appropriate mix of telework.

- Determine the criteria for identifying "at-risk" student behaviors and what data is available to identify them in a timely manner. Determine who is responsible for identifying and communicating with these students to determine how the University can support them and encourage their success.
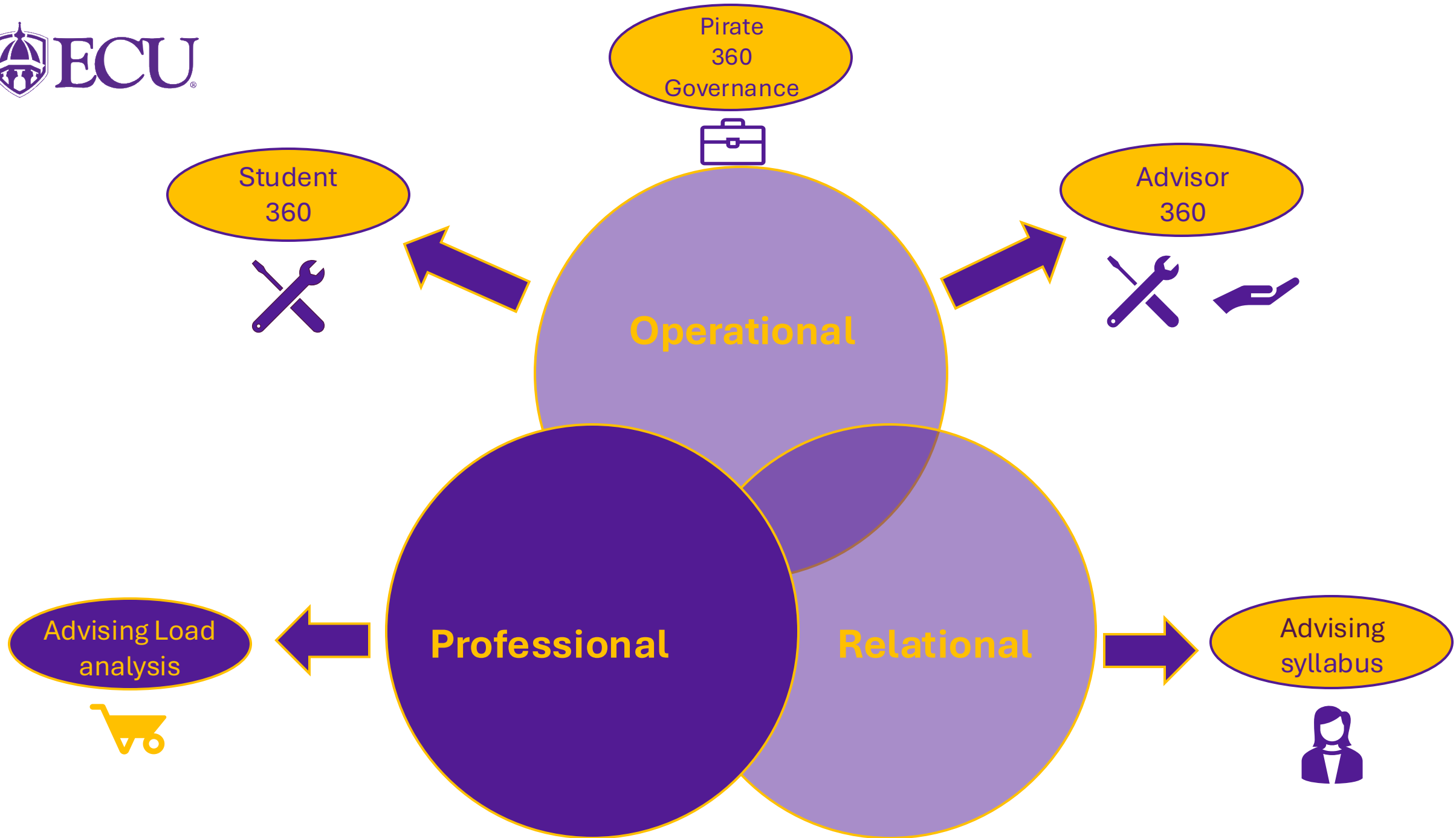
Accomplishments in 2024-2025...

- Change Management via development of SOPs

- SOPs have driven the build of needed functionalities in Pirate 360

- Generation of a standard "advising syllabus" to be deployed in Fall 2025

- Improved reporting to improve efficiency:
  - New "Missing pre-requisite" report
  - Expanded ecuBIC repository for Academic Advisors to access (in a central location)

ECU

ECU

Division of Academic Affairs

Advising Syllabus

	Advisor Commitments	**Student Commitments**
Advising Meetings	Your advisor will be available for meeting with you, their advisee. Appointment will be available by appointment, including in-person, virtual, or telephone.	Initiate a relationship with your advisor by connecting each semester through email, scheduling meetings, and attending them on time. Come prepared, having looked at your Degree Works plan and with an idea for what courses you may need.
Communication	Your advisor will maintain regular communication via Pirate 360 and email sharing key advising information throughout the semester.	Maintain clear and honest communication with your advisor about any challenges you face, so that your advisor can provide resources and referrals as needed.
Engaged in Your Academic Success	Your advisor will be knowledgeable about your educational journey and your progress and will be prepared for your advising meetings, striving to maintain an open and supportive advising relationship.	You should begin to take responsibility for your educational journey at ECU. This means coming prepared for advisor meetings, being open to advice and support, and exploring available opportunities on your academic path.

Areas covered in the advising syllabus:

- Advising meetings
- Communication
- Engaged in Your Academic Success
- Course Selection and Major Program of Study
- Important Academic Dates
- Academic Progress
- Respect and Understanding

Tips for student success in the advisor/advisee relationship

Project Summary: Academic Advising

Complete/In Progress

Stage: Discovery

Completed:

1. 2/13 - Advisor Interface
2. 2/20 - Advising Models
3. 2/24 - Advisor Interface
4. 2/26 - Appointment Scheduling/Topics
5. 3/3 - Notes/Interaction Summaries
6. 3/6 - Case Management
7. 3/14 - Care Plans/Action Plans
8. 3/18 - Learner Portal
9. 3/20 - Learner Wellness
10. 3/25 - Learner Portal #2
11. 3/27 - Appointment Scheduling/Topics #2
12. 4/3 - Communications
13. 3/28 - Alerts preview with Elizabeth and Dylan

Upcoming

Stage: Build (Sprints start April 9, 2025)

In Progress:

- Discovery documentation (epics, user stories)
- Integration / Data Migration discovery sessions (2x week)

Next up:

- Discovery Sessions:
  - Case Management (4/11)
  - 2 more for follow-up
- Sprints start: 4/9
- End of Discovery scope alignment: 4/30

Key Learner Success Features

ECU | salesforce

COMMS & ENGAGEMENT

HOLISTIC ADVISING & COLLABORATIVE SUPPORT

DATA, ANALYTICS & INTELLIGENCE

LEARNER PORTAL
Give learners one place to manage their journeys

LEARNER ACTION CENTER
Help learners stay engaged with a consolidated view of relevant and timely action items

LEARNER 360 VIEW
Understand learners holistically with a 360° view

DATA-DRIVEN ALERTS
Create, automate, and aggregate alerts to take action individually or at scale

APPOINTMENT SCHEDULING
Connect learners to the right staff with streamlined appt scheduling

CARE PLANS
Build personalized care plans that address learners' biggest challenges and work toward specific milestones
Future Phase

INTEGRATIONS
Connect data from CRM, cases, and other campus systems into a single view of every learner

UNIFIED DATA
Harmonize and activate trapped data to power AI in the flow of work
Future Phase

CAMPAIGNS
Build targeted outreach campaigns to specific learner populations who need additional support

PERSONALIZED COMMS
Personalize messages using targeted journeys enriched with learner data

ACTION PLANS
Learners create action plans that define the actions needed to stay on track

SUCCESS TEAMS
Align staff to learner goals and easily collaborate across departments

NOTES
Capture and share structured advising notes, content, and meeting outcomes

SUPPORT PROGRAM MANAGEMENT
Track learners support programs and the services they provide

ADVISOR & DIRECTOR CONSOLES
Gain critical insights into learner success metrics to support retention and graduation goals

IN-APP GUIDANCE
Help users quickly absorb and acknowledge information and then continue with their flow of work

AI-READY CHATBOTS
Automate answers to learners' most common questions

KNOWLEDGE ARTICLES
Generate relevant knowledge articles to help learners self-serve

Future Phase
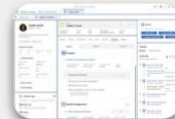
ROBUST CASE MANAGEMENT
Use AI to summarize case resolutions automatically and securely share with staff
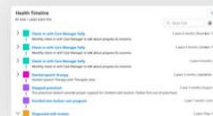
LEARNER TIMELINE
Give advisors a timeline of important learner engagement events

PULSE CHECKS
Easy & quick check-ins to capture learner's well being and sentiment over time
Future Phase

WATCHLISTS
Advisors can add learners to watchlists in order to monitor them over time.

Key Learner Success Features

✓ **360-Degree Learner View:** Provides a comprehensive view of each learner, including academic records and personal information, enabling personalized support.

✓ **Advising:** Tools for academic advisors to track learner progress, schedule meetings, and provide guidance.

✓ **Learner Engagement:** Features to enhance communication and engagement with learners through personalized, and, when relevant, automated emails.

✓ **Case Management:** Helps manage learner issues and support requests efficiently, ensuring timely resolution and follow-up.

✓ **Learner Portal:** Help learners stay engaged with a consolidated view of appointments and relevant and timely action items.

✓ **Mobile Access:** Mobile-friendly interfaces and apps to ensure learners can access important information and services on the go.

✓ **Analytics and Reporting:** Advanced analytics to track learner performance, identify at-risk learners, and measure the effectiveness of engagement and interventions.

✓ **Integration Capabilities:** Seamless integration with other systems such as learner information systems (Banner).

Discovery Sessions

We are actively working with a pool of advisors from across the university to design the capabilities that allow advisors and learners to efficiently engage.

15 Discovery and design sessions with advisors from 11 advising centers:

- Athletics
- CAHS
- COB
- COE
- CET
- CFAC
- CON
- HHP
- Honors
- THCAS
- MAP

Topics of those sessions:

- Learner 360 / Advisor Interface (2/13)
- Advising Models (2/20)
- Learner 360 / Advisor Interface #2 (2/24)
- Appointment Scheduling/Topics #2 (2/26)
- Notes (3/3)
- Case Management (3/6)
- Care Plan/ Action Plan Session (3/14)
- Learner Portal (3/18)
- Learner Wellness (3/20)
- Learner Portal #2 (3/25)
- Appointment Scheduling/Topics #2 (3/27)
- Alerts demo (3/28)
- Communications (4/3)
- Upcoming: Case Management #2 (4/11)
- Upcoming: Alerts (3/14)

Types of Decisions

Data to be integrated from Banner and other systems to reduce swivel chairing.

✓ Approximately 70 bio/demo data points will be integrated from Banner into Salesforce.
Examples:
- Name
- Banner ID and Pirate ID
- Contact information
- First Generation
- Honors
- Military affiliation
- Athletics
- Academic Standing

✓ Other data includes:
- Learner and employee photos
- Programs
- Courses
- Grades
- FERPA Waivers
- Holds

Example: Learner 360
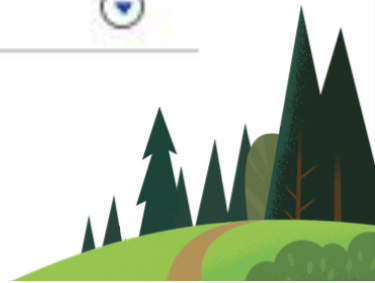
Example: Watchlists

Advisors add learners to watchlists in order to monitor them over time.

- Added from the Learner360
- List of watchlisted learners on Advisor home screen
- Learners are not notified that they are on a watchlist.

	Watchlisted Learne... ↑ ⌄	Case ⌄	Reason ⌄	Start Date ⌄	End Date ⌄	
1	Sofia Sanders	00001271	Low Term GPA	10/11/2024, 5:00 PM		⌄
2	Sofia Student	00001270	Failed Course	1/31/2025, 4:00 PM		⌄

Watchlisted Learners
All Watchlisted Learners
3 items · Sorted by Watchlisted Learner Name · Filtered by All watchlisted learners · Updated a few seconds ago

Questions?

AGENDA ITEM

V.   Closed Session .... Vince Smith
Committee Chair

Situation: This committee receives updates on specific audits, compliance, and other related topics that are not a matter of public record in accordance with applicable North Carolina General Statutes.

Background: The committee does need to receive updates on some non-public matters at this meeting.

Assessment: The committee will receive updates on the relevant issues from University administrators.

Action: This item is for discussion only.

AGENDA ITEM

VI. Other Business .... Vince Smith
Committee Chair

Situation: This agenda item is for any other business deemed necessary by the committee.

Background: This committee members will suggest any other items needing discussion.

Assessment: The committee will discuss the relevant issues.

Action: This item is for discussion only.