

Effective Compliance Responses to Covid-19 and Financial Disruption

A Facilitated Discussion



June 2020

Gates Garrity-Rokous
Office of University Compliance and Integrity
The Ohio State University

OSU © 2020

1

1

Session Objectives

This session will:

- Analyze major Covid-19 related regulatory changes, and expected impact
- Provide a mid-cycle assessment to compliance priorities, due to operational and fiscal pressures; and
- Outline possible approaches to maintain compliance relevance and effectiveness during a protracted crisis

OSU © 2020

2

2

Risk Management in a Crisis: The current challenge

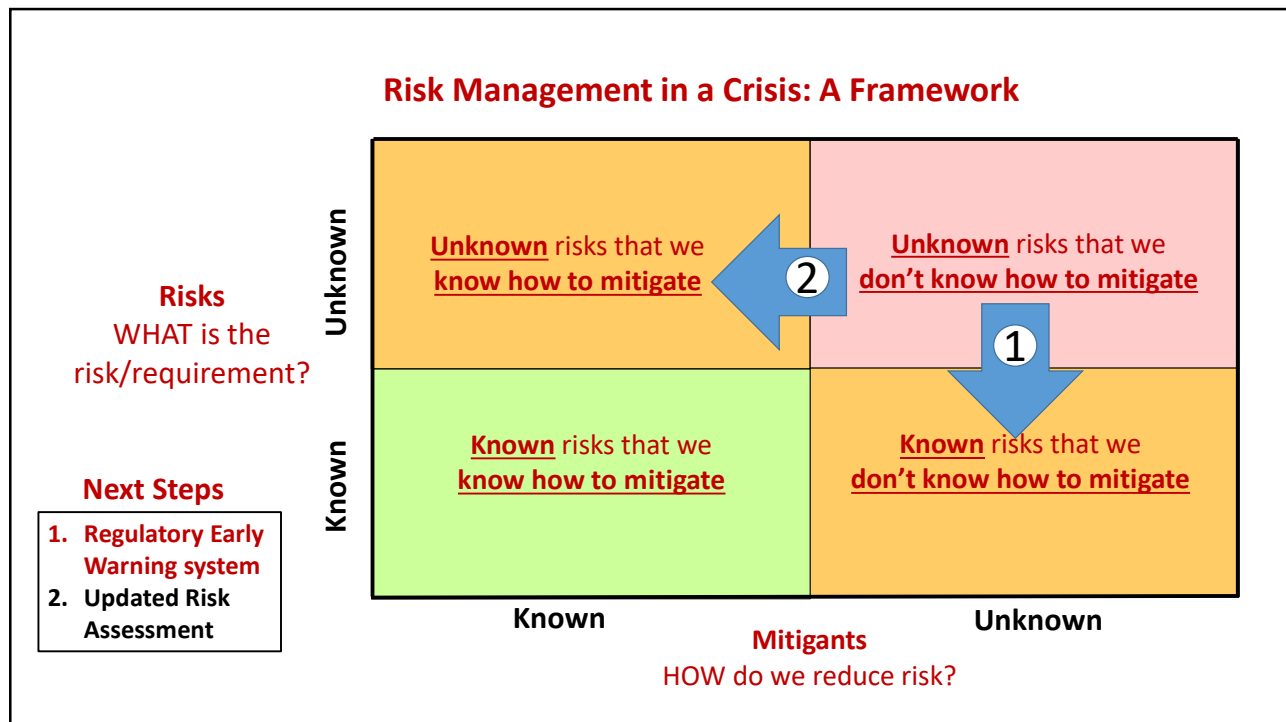
Risks WHAT is the risk/requirement?	Unknown	<u>Unknown</u> risks that we <u>know how to mitigate</u>	<u>Unknown</u> risks that we <u>don't know how to mitigate</u>
	Known	<u>Known</u> risks that we <u>know how to mitigate</u>	<u>Known</u> risks that we <u>don't know how to mitigate</u>
		Known	Unknown
		Mitigants HOW do we reduce risk?	

3

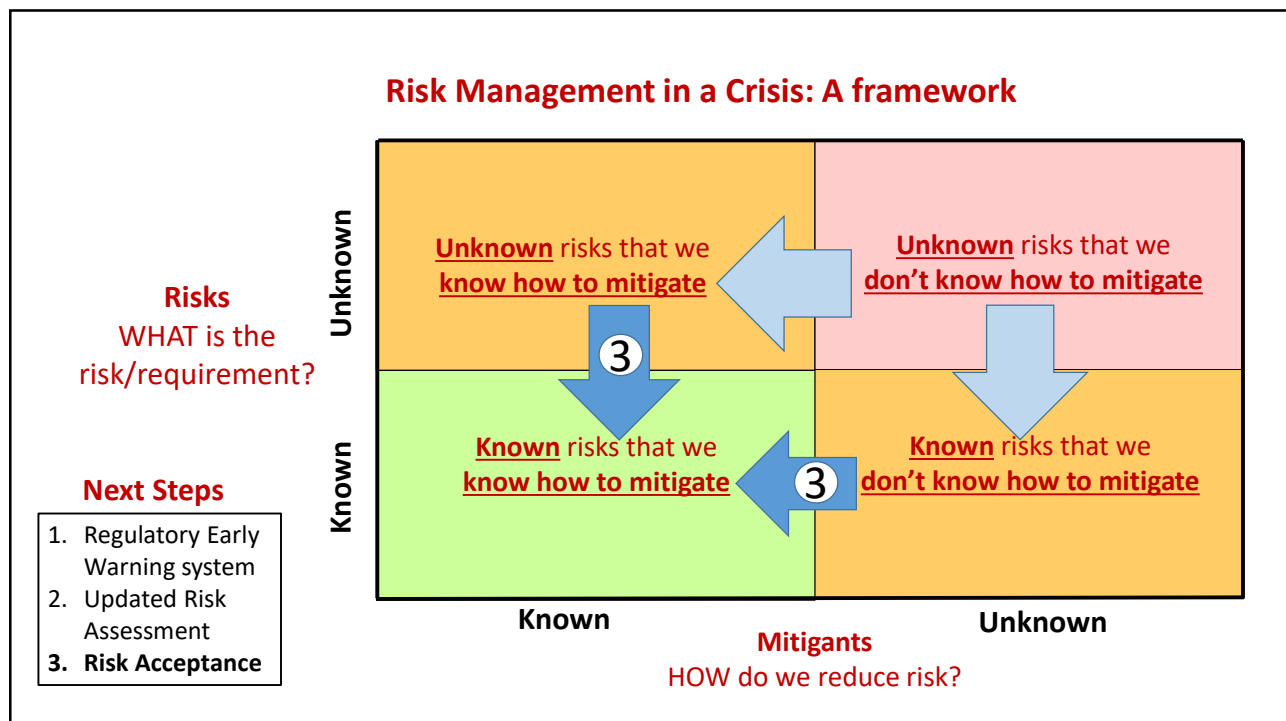
Risk Management in a Crisis: A framework

Risks WHAT is the risk/requirement?	Unknown	<u>Unknown</u> risks that we <u>know how to mitigate</u> <u>Example:</u> investigations under new Title IX regulations	<u>Unknown</u> risks that we <u>don't know how to mitigate</u> <u>Example:</u> on-campus dorm living with possible coronavirus exposures
	Known	<u>Known</u> risks that we <u>know how to mitigate</u> <u>Example:</u> meeting our Clery Act requirements	<u>Known</u> risks that we <u>don't know how to mitigate</u> <u>Example:</u> coronavirus exposure in lab environment under OSHA regulations
		Known	Unknown
		Mitigants HOW do we reduce risk?	

4



5



6

1. Convert “Unknown” Risks to “Known” Risks: Regulatory Early Warning

Process Overview

- Analyzed 18 national law firms’ websites
 - Alerts provided for free as promotional material and client advisories; used Law Student Externs
- Best seven firms selected based on quality of alerts.
- Process electronically links alerts to lawyers, compliance officers, and other subject matter experts (SME)
- Immediate access to alerts assists SMEs in advising university clients
- Inventory of changes provides broad overview of overall pace and extent of regulatory change
- 303 significant regulatory changes in a six-week period (3/15/2020 to 5/1/2020); pace continuing
- Enforcement actions will likewise increase significantly

Ratings

		Potential Impact		
		High	Medium	Low
Trend	Risk Increasing	↑	↑	↑
	Risk Stable	↔	↔	↔
	Risk Decreasing	↓	↓	↓

OSU © 2020

7

7

Regulatory Changes: 1 of 3

Area	Regulatory Topic	Summary of Regulatory Changes	# Alerts	Impact & Trend
Construction Contracts & Insurance	Construction & Contracts	• Ohio asks landlords to suspend rent & evictions • Force majeure provisions arising in contracts	22	↑
	Government Contracting	• CISA guidance issued on essential workers • Defense Production Act invoked, CARES Act extended	3	↔
	Insurance	• Insurance provisions and coverages will be tested	5	↑
Litigation	General	• Significant increase expected in all litigation	10	↑
	Consumer	• Surge in tuition refund class actions	24	↑
	Product Liability	• Limited immunity for healthcare & manufacturers	9	↑
Environmental Health & Safety	EPA	• Reporting and enforcement provisions relaxed	12	↓
	OSHA	• OSHA/CDC guidance on PPE standards, COVID-19 exposures, testing of employees	14	↑
International Issues	Export Controls & Nat. Security	• Travel bans and Entity List additions continue • Restrictions placed on PPE-related exports	25	↔
	Immigration	• Restrictions on foreign entries; work visas extended • Continuing focus on China & intel. property theft	9	↑
Business & Finance, Fed. Funding	Lending and Debt Relief	• CARES Act/DOL guidance expands protections • Temporary protections under Fair Debt Collection Act	26	↔
	Tax-exempt Orgs	• Tax requirements affected by CARES Act	11	↔
	Funding	• CARES Act Emergency Grant; student pass-throughs	5	↑

OSU © 2020

8

8

Regulatory Changes: 2 of 3

Area	Regulatory Topic	Summary of Regulatory Changes	# Alerts	Impact & Trend
Healthcare	Healthcare Services	<ul style="list-style-type: none"> CARES Act expansion of health services CMS expands telehealth; HHS prohibits hoarding 	14	↑
	Medicaid/ Medicare/Stark	<ul style="list-style-type: none"> HHS waivers of Medicare requirements; relief funding CMS waivers on Stark, guidance on patient surges 	10	↑
	Healthcare Professionals	<ul style="list-style-type: none"> Waiver of licensing renewals for healthcare workers Expansion of scope of practice & temporary licensures 	3	↔
Athletics	NCAA Rules	<ul style="list-style-type: none"> NCAA guidance on SA funding/eligibility/transfers Potential rule on name/image/likeness (NIL) comp. 	1	↑
Research	Funding	<ul style="list-style-type: none"> Agencies prioritizing PPE/drug/device shortages 	4	↑
	Medical Equip.	<ul style="list-style-type: none"> Expediting approval of drugs and medical necessities 	10	↑
	Clinical Research	<ul style="list-style-type: none"> Agencies prioritizing Covid-19 research 	10	↑
	Intellect. Prop.	<ul style="list-style-type: none"> USPTO waiving fees & deadlines; patents enforced 	6	↓

OSU © 2020

9

9

Regulatory Changes: 3 of 3

Area	Regulatory Topic	Summary of Regulatory Changes	# Alerts	Impact & Trend
Information Security & Privacy	Cybersecurity Risks	<ul style="list-style-type: none"> Increased risks, including scams and threats Guidance on teleworking security/trade secrets 	15	↑
	HIPAA, FERPA, & Others	<ul style="list-style-type: none"> HHS protocol on HIPAA privacy and release of PHI DOE Guidelines for FERPA 	10	↑
Title IX	Title IX Regs	<ul style="list-style-type: none"> DoE requirements on investigations and adjudications 	2	↑
Labor & Employment	Operations	<ul style="list-style-type: none"> OMB orders agencies to adjust business operations 	8	↓
	Reduced Hours, Layoffs	<ul style="list-style-type: none"> Layoffs trigger WARN Act and ERISA CARES Act funding for short-time compensation 	8	↑
	Benefits	<ul style="list-style-type: none"> Workers comp. requirements regarding COVID-19 CARES Act expands access to health/retirement plans 	9	↑
	Federal Law: Wages and Paid Sick Leave	<ul style="list-style-type: none"> FSLA requirements still apply to employers FFCRA expands FMLA requirements/paid sick leave FMLA/FLSA: student workers may be employees 	7	↑
	Fin. Assist. to Employees	<ul style="list-style-type: none"> Stafford Act enables employers to provide tax-free financial assistance to employees impacted by virus 	2	↔
	Ethics	<ul style="list-style-type: none"> Restrictions on gifts, conflicts, and ethics rules continue 	1	↔
	Discrimination Provisions	<ul style="list-style-type: none"> CARES Act/EEOC guidance on discrimination re COVID-19 status and health care 	10	↔

10

10

Poll Question 1

Which area of regulatory change gives you the most uncertainty?

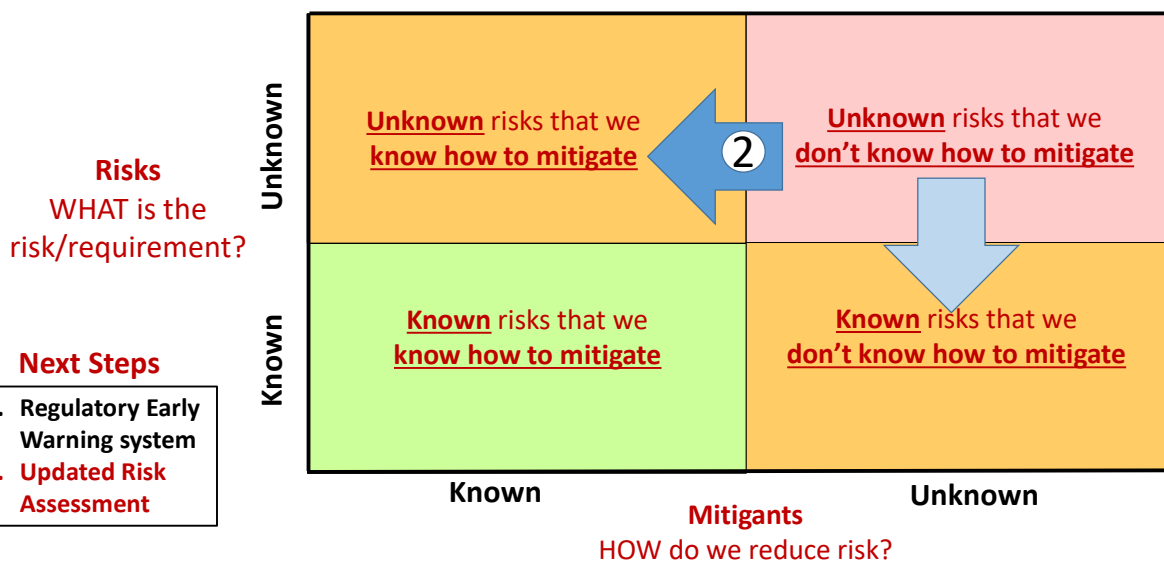
- a. Construction Contracts & Insurance
- b. Litigation
- c. Environmental Health & Safety
- d. International Issues
- e. Business & Finance, Federal Funding
- f. Healthcare
- g. Athletics
- h. Research
- i. Information Security & Privacy
- j. Labor & Employment

OSU © 2020

11

11

2. Convert “Unknown” Risks to “Known” Mitigation Challenges: Mid-Cycle Risk Assessments



12

2. Convert “Unknown” Risks to “Known” Mitigation Challenges: Mid-Cycle Risk Assessments

Analyzing Emerging Compliance Risks

- **Need for mid-cycle revision**, due to extraordinary organizational conditions
- **Regulatory changes**, including changes to regulatory enforcement priorities, constitute a new risk
- **Operational uncertainty** makes risk mitigation uncertain, as ability to mitigate remains unclear
- **Concern reporting** will likely increase as fiscal impacts occur

OSU © 2020

13

13

Rank	Risk	Key Risk Drivers	Impact & Trend	Possible Mitigation Strategies
1	Regulatory Change	Pace/breadth of regulatory change creates add'l risk; enforcement will increase significantly	↑	<ul style="list-style-type: none"> • Relying on subject matter experts to mitigate • See previous chart
2	Research Security	Reviews/enforcement activity ongoing; federal focus on China; physical security/access risks	↔	<ul style="list-style-type: none"> • Addressing investigations • Responding to FBI on COVID-19 research
3	CARES Act	Stimulus package and associated requirements; timing & audit requirements for refunds	↑	<ul style="list-style-type: none"> • Addressing changes through scenario analyses
4	Labor & Employment	Dept. of Labor regulatory changes plus financial challenges increase risk	↑	<ul style="list-style-type: none"> • OHR actively managing risks to meet requirements
5	Medical/clinical Research	Efforts to conduct COVID-19 related research and trials significantly increasing	↑	<ul style="list-style-type: none"> • College of Medicine and Office of Research addressing
6	Information Security	Remote work increases risk as physical security of IT beyond campus control; increase in phishing and ransomware attacks	↔	<ul style="list-style-type: none"> • Attacks contained; education ongoing • ISSA 2020 revision delayed to 7/1/21 • Email multifactor authentication to 8/1/20
7	Athletics Culture	Ongoing NCAA investigations continue to be addressed; enforcement process not delayed	↑	<ul style="list-style-type: none"> • Addressing eligibility & NIL legislation • Resolving ongoing NCAA investigation
8	HIPAA (health info. privacy)	Telemedicine and possible/existing Covid-19 diagnoses reporting increases risk	↔	<ul style="list-style-type: none"> • CMS waivers obtained (section 1135) • Compliance Committee and audits deferred
9	Title IX/OIE	Changes to investigation processes due to remote learning are significant	↓	<ul style="list-style-type: none"> • OIE team continues to address changes • Expectations on new office remain high
10	Medical Billing	Expanded telehealth and novel operational process increase risk	↔	<ul style="list-style-type: none"> • CMS waivers obtained (section 1135) • Existing SOPs providing ongoing mitigation

OSU © 2020

14

14

Rank	Risk	Key Risk Drivers	Impact & Trend	Possible Mitigation Strategies
11	Financial Aid	Borrower defense rules increasing required reporting, disclosures, and potentially loan cancellations; increased threat of litigation nationally; managing CARES Act emergency grant	↑	<ul style="list-style-type: none"> • Prioritizing pass-through of grants to students • Addressing section 117 changes (incl. expanded foreign gift reporting requirements) • Initial CARES report occurred on 5/13
12	Concern Reporting	Increased organizational uncertainty may lead to increase in allegations and concerns	↑	<ul style="list-style-type: none"> • Allegations increase during financial stress • Will further stretch investigation resources
13	Privacy (incl. FERPA)	On-line courses increase FERPA risks; "Zoom bombing," contact tracing increase public att'n	↑	<ul style="list-style-type: none"> • Guidance provided on privacy protections • Privacy projects being re-prioritized
14	EHS: Lab Safety & Biosafety	Biosafety work (esp. coronavirus research) increasing significantly	↑	<ul style="list-style-type: none"> • Postponed safety survey, address urgent needs • Assisting in reducing research security risks
15	Stark/Anti-Kickback (WMC)	CMS issued waiver of sanctions under Stark law	↓	<ul style="list-style-type: none"> • Waiver facilitates urgent contracting; return to controls may be challenging in long term
16	Immigration	Visa process delays creates risk in foreign student admissions; DHS addressing Form I-9 requirement	↑	<ul style="list-style-type: none"> • Working to expedite all applications • I-9 process being mitigated internally
17	EHS: OSHA	Coronavirus exposure increases liability risk; OSHA provided flexibility re: PPE due to shortages	↑	<ul style="list-style-type: none"> • Addressing on ongoing basis and in WMC
18	Crime Reporting (Clery)	Annual Safety Report (ASR) process ongoing; DOE audit due to Strauss case remains ongoing risk	↑	<ul style="list-style-type: none"> • Clery Coordinator leaving position; addressing loss of expertise
19	Research Integrity	Remote work/deadline pressures increase risk	↔	<ul style="list-style-type: none"> • Investigations & prevention efforts ongoing
20	Conflicts of Interest	Enforcement actions increasingly focusing on appropriate disclosure of foreign affiliations	↔	<ul style="list-style-type: none"> • Annual disclosure process underway • Delayed COI to ~6800 WMC non-researchers

OSU © 2020

15

15

Poll Question 2

Which risk presents the most challenge to determine how to mitigate?

- Regulatory uncertainty
- Research Security
- CARES Act
- Labor & Employment
- Medical/clinical research
- Information Security
- Athletics
- HIPAA
- Title IX
- Other (use group chat)**

OSU © 2020

16

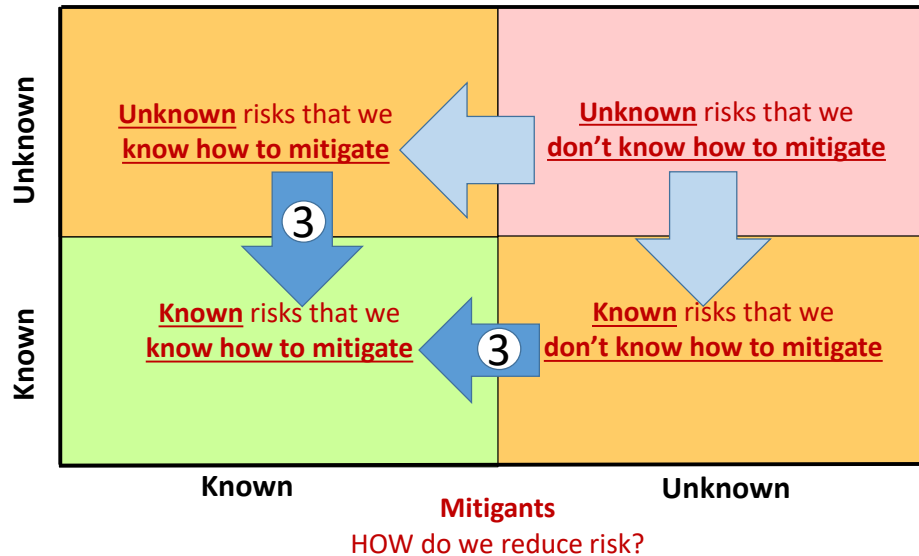
16

3. Converting Unknown Risks and Unknown Mitigation Challenges: Risk Acceptance Decisions

Risks
WHAT is the
risk/requirement?

Next Steps

1. Regulatory Early Warning system
2. Updated Risk Assessment
3. **Risk Acceptance**



17

3. Converting Unknown Risks and Unknown Mitigation Challenges: Risk Acceptance Decisions

Performing Risk Acceptance

- **Balancing the new and the existing**, where there are demands to do both
- **Deciding whether prior planned activities should be deferred**, in light of new risks, and who makes that decision
- **Ensuring that stabilized risks stay that way**, when priorities, leadership attention, and resources go elsewhere
- **Elevating decisions appropriately**, ensuring lower-level decisions are tracked, and ensuring accountability

OSU © 2020

18

18

Risk Acceptance Decisions in Transition: A Methodology

Regulatory Area	Increased Risk <i>Receiving or needing immediate attention</i>	Deferred Risk <i>Reduced priority due to crisis and/or resource constraints</i>	Stable Risk <i>No significant impact due to crisis: mitigation efforts ongoing</i>	Owner	Comments <i>[Financial/regulatory/reputational impact and current mitigation status]</i>
Risks Directly Related to Covid-19 Regulatory and Operational Changes					
Regulatory Change	<ul style="list-style-type: none"> Pace of change across all domains a separate risk 				<ul style="list-style-type: none"> Relying on extensive subject matter expertise to determine ongoing operational impacts
CARES Act	<ul style="list-style-type: none"> Direct and indirect impact of stimulus package is ongoing 				<ul style="list-style-type: none"> Assessment of impact is ongoing
Labor & Employment	<ul style="list-style-type: none"> Diverse range of regulatory and financial challenges 				<ul style="list-style-type: none"> OHR actively managing risks to meet requirements
Medical Billing	<ul style="list-style-type: none"> Expanded telehealth and novel operational processes 	<ul style="list-style-type: none"> Compliance oversight & billing audits deferred 	<ul style="list-style-type: none"> Existing SOPs providing ongoing mitigation 		<ul style="list-style-type: none"> CMS section 1135 waiver authority; obtaining such exemptions as appropriate
HIPAA	<ul style="list-style-type: none"> Telemedicine Reporting of Covid-19 diagnoses increases risk 	<ul style="list-style-type: none"> Compliance Committee oversight and HIPAA audits are being deferred 	<ul style="list-style-type: none"> Reviewing requirements with other Covered Components 		<ul style="list-style-type: none"> HIPAA waivers included in section 1135
Financial Aid	<ul style="list-style-type: none"> Risk under borrower defense rule and other requirements increasing due to fee reimbursements 		<ul style="list-style-type: none"> Improvement of processes for foreign gift reporting continues 		<ul style="list-style-type: none"> Ensuring pass-through of grants to students will be priority Changes to section 117
Information Security	<ul style="list-style-type: none"> Remote work increases risk; physical security of IT beyond campus control 	<ul style="list-style-type: none"> ISSA revision delayed Multifactor authentication delayed 	<ul style="list-style-type: none"> Considering efficiencies Focus on security education 		<ul style="list-style-type: none"> 3 Ohio universities hit by ransomware Remote work expected to be long-term
Privacy (incl. FERPA)	<ul style="list-style-type: none"> Move to on-line courses increased FERPA risks Zoom bombing increased perception of privacy loss 	<ul style="list-style-type: none"> Privacy projects will be delayed and re-prioritized 			<ul style="list-style-type: none"> Significant guidance on privacy protections has been provided through OAA and colleges

OSU © 2020

19

19

Poll Question 3

Which risk acceptance area presents the most challenge?

- a. Balancing the new and the existing**, where there are demands to do both
- b. Deciding whether prior planned activities should be deferred**, in light of new risks, and who makes that decision
- c. Ensuring that stabilized risks stay that way**, when priorities, leadership attention, and resources go elsewhere
- d. Elevating decisions appropriately**, ensuring lower-level decisions are tracked, and ensuring accountability
- e. Other (use group chat)**

OSU © 2020

20

20

Questions?

OSU © 2019

21