

302: SCCE Higher Education Compliance Conference

# **New Perspectives in Compliance Awareness and Training**

**INDIANA UNIVERSITY** 

#### **Today's Presentation**

- Traditional views on compliance training requirements and sources of authority
- 2. Awareness vs. Training- a risk based approach: addressing the challenges of attendance, engagement, and relevance
- 3. The benefits of a tailored and matrixed approach



#### Importance of Training

- 83% of compliance professionals surveyed reported that their program had prevented one or more incidents in the last two years. Compliance officers from larger organizations were more likely to indicate awareness that an incident had been avoided.
- Compliance training drives inquiries or reports of wrongdoing over time.
- Overall 82% of compliance professionals surveyed said that training led to some increase in inquiries and reports about the topic. In addition, 76% report that training has resulted in an employee report that led to action that prevented or stopped wrongdoing.
- Especially true of larger organization (30,001+ employees), where 89% of respondents said there had been a report of wrongdoing as a result of training.



SCCE and HCCA 2016 Compliance Effectiveness Survey

**302: SCCE Higher Education Compliance Conference** 

# I. Traditional Views of Training

#### **Traditional Training**

#### **Types**

- 1. Instruction Based
- 2. Information Based
- 3. Rules Based

#### **Attributes**

- Classroom/lecture
- Often lengthy in duration



NDIANA UNIVERSITY

#### **Sources of Authority**

- Regulations or other guidance (e.g. Dear Colleague Letters, circulars, etc.)
- Resolution agreements
- Typically outline:
  - Who must be trained
  - When and how frequently training is required
  - What topics or risk areas should be covered



#### **Examples**

- OIG Compliance Program Guidance for Pharmaceutical Manufacturers
- Resolution Agreement Fresenius Medical Care North America



INDIANA UNIVERSITY

# OIG Compliance Program Guidance for Pharmaceutical Manufacturers

C. Designation of a Compliance Officer

The compliance officer's primary responsibilities should include:

- Developing, coordinating, and participating in a multifaceted educational and training program
  that focuses on the elements of the compliance program, and seeking to ensure that all
  affected employees and management understand and comply with pertinent federal and state
  standards;
- D. Conducting effective training and education

The proper education and training of officers, directors, employees, contractors, and agents, and periodic retraining of personnel at all levels are critical elements of an effective compliance program.



NDIANA LINIVEDSITY

#### OIG Compliance Program Guidance for Pharmaceutical Manufacturers

- All employees and, where feasible and appropriate, contractors should receive the general training.
- More specific training on issues, such as (i) the anti-kickback statute and how it applies to
  pharmaceutical sales and marketing practices and (ii) the calculation and reporting of pricing
  information and payment of rebates in connection with federal health care programs, should be
  targeted at those employees and contractors whose job requirements make the information
  relevant.
- The specific training should be tailored to make it as meaningful as possible for each group of participants.



INDIANA UNIVERSITY

# Fresenius Medical Care North America Resolution Agreement

- G. Develop an Enhanced Privacy and Security Awareness Training Program
- The FMCNA Covered Entities shall augment their existing mandatory Health Information Privacy and Security Awareness Training Program ("Training Program") for all the FMCNA Covered Entities' workforce members who have access to PHI, including ePHI.
- The Training Program shall include general instruction on workforce members' obligation to comply with the FMCNA Covered Entities' policies and procedures related to the HIPAA Rules.
- The Training Program shall also include training on the new or revised Evaluation Process and all of the new or revised Device and Media Controls Policies and Procedures and Physical Access Policies and Procedures (collectively, the "Policies and Procedures"), to the extent such new or revised Policies and Procedures are developed and existing policies and procedures are revised.
- The FMCNA Covered Entities shall provide training on the policies and procedures related to the HIPAA Rules
  to active workforce members of the FMCNA Covered Entities, as necessary and appropriate for such
  workforce members to carry out their functions, annually.



302: SCCE Higher Education Compliance Conference

## II. Awareness vs. Training

SECTION TITLE GOES HERE IF NECESSARY

#### **General Definitions**

- I. Training: organized activity aiming at imparting instructions and information that will improve the recipient's performance or to reach a level of skill or knowledge Black's Law Dictionary
- 2. Awareness: knowledge that something exists, or understanding of a situation or subject at the present time based on information or experience Cambridge Dictionary



INDIANA LINIVEDSITY

SECTION TITLE GOES HERE IF NECESSARY

#### **NIST Security**

- 1. Awareness: to focus attention on security
- 2. Training: to produce relevant needed security skills and competency
- **3. Education**: to integrate all security skills and competencies into a common body of knowledge, adding a multidisciplinary study of concepts, issues, and principles

https://csrc.nist.gov/Projects/Awareness-Training-Education



INDIANA UNIVERSITY

SECTION TITLE GOES HERE IF NECESSARY

#### **Key Challenges**

- Attendance
- Engagement
- Relevance



INDIANA LINIVEDSIT

# You Now Have a Shorter Attention Span Than a Goldfish

- The Goldfish Myth?
- People now generally lose concentration after eight seconds
- Our ability to multitask has drastically improved in the mobile age
- Those who use social media heavily had more "intermittent bursts of high attention"

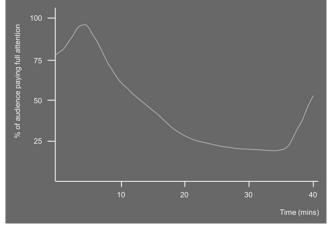
Note: study was done by Microsoft Corporation related to advertising data

Time Magazine (2015) http://time.com/3858309/attention-spans-goldfish/



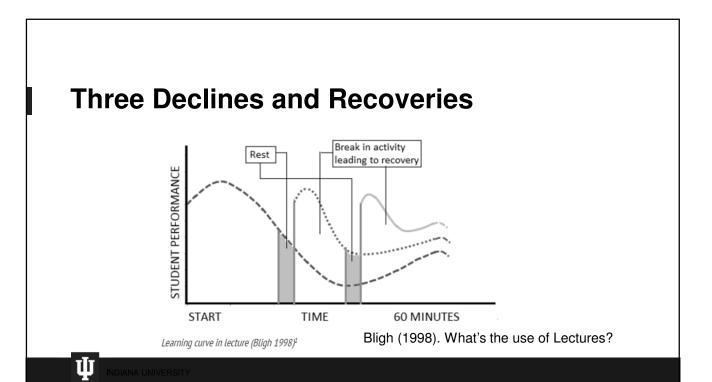
NDIANA UNIVERSITY

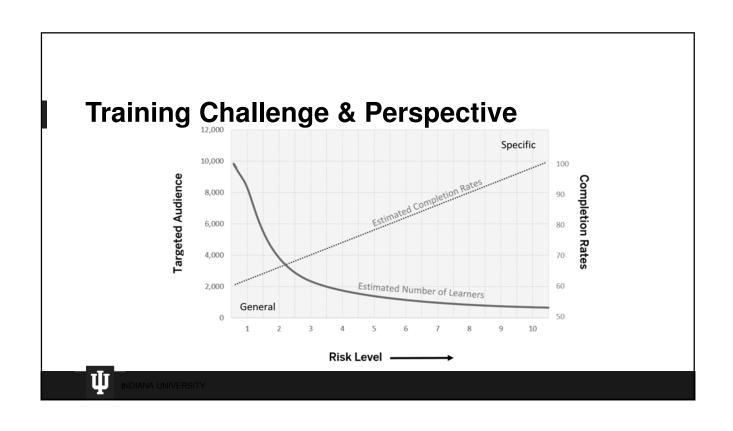
#### **Attention Span**



Mills, H.R. (1977) Techniques of Technical Training, 3rd Ed. Macmillan, London







302: SCCE Higher Education Compliance Conference

# III. The Benefits of a Tailored and Matrixed Approach

#### **Learning Capacity**

"Grabbing attention to drive performance is one significant way to advance learning and make lectures effective."

- Engage in some activities before the start of the session (e.g. an "ice-breaking" activity or a quick game lasting for few seconds)
- Speak for 20 minutes, then interact regarding that section
- Every few minutes or seconds throw some attention captivating stimulus
- Use of breakout rooms to form small groups and to discuss on the specific topic
- Change the style of presentation

AYRUZ Data Marketing- How the learning capacity of human beings vary listening to long lectures https://ayruz.com/functions/data-consulting/how-the-learning-capacity-of-human-beings-vary-listening-to-long-lectures/



#### **Attendance**

- Determine who must receive training
- Provide in-person training at existing staff or faculty meetings
- Allow requirements to be met during existing required training sessions where possible (e.g. orientation)
- Use convenience to eliminate excuses



INDIANA UNIVERSITY

#### **Engagement**

- Mix up learning methods and media- don't assume everyone learns best in the same way
- Avoid information overload- focus on key takeaways
- Make it mobile-friendly
- Break it up and consider timing



#### Relevance

- Provide a wide range of examples
  - Simple every day occurrences with less risk
  - More exciting examples with greater impact
- Know your audience and tailor the presentation accordingly



INDIANA UNIVERSITY

#### **Blended Learning**

- 1. Blending learning: a way of learning that *combines traditional classroom* lessons *with lessons that use computer technology* and may be given over the internet cambridge Dictionary
- 2. Blended learning is any formal education program in which a student learns at least in part through online learning, with some element of student control over time, place, path, and/or pace Blended Learning Universe
- 3. Providing high-value content in both settings the *classroom* (rich, yet high cost) and *online* (efficient, yet low cost), **enhances learner performance**

Journal of Behaviour & Information Technology "Playing 'catch up' with blended learning: performance impacts of augmenting classroom instruction with online learning." Timothy Hill, Laku Chidambaram, & Jana D. Summers. 02 Jun 2016



INDIANA LINIVEDOIT

#### **Blended Learning Framework and Strategies**

 The framework is concerned with the assumption that science learning activities should be applicable and relevant to contemporary life and transferable to 'real-world' situations. The design framework aims at integrating learning in formal and informal contexts through blended learning scenarios by using today's flexible, interactive and immersive technologies (e.g. mobile, augmented reality, virtual reality).

The Journal of Open, Distance and e-Learning "Towards a pedagogical model for science education: bridging educational contexts through a blended learning approach" Jose Bidarra and Filen Rusman 21 Dec 2016

Several instructional strategies are deemed effective to promote more application of learning during blended or online instructions: (1) *making learning content applicable*, (2) utilizing *reflective activities* that assist learners to apply their learning to personal situations during instructions, and (3) embedding a *structured learning process*: instruction, guided practice, individual practice

Journal of Asynchronous Learning Networks "Online vs. Blended Learning: Differences in Instructional Outcomes and Learner Satisfaction." Doo Hun Lim, Michael L. Morris, Virginia W. Kupritz. July 2007



INDIANA UNIVERSITY

#### **Burst Learning**

The ideal burst training can be defined as "ten minutes of training, within five minutes of its need, to an audience of one."

Learning Solutions Magazine

Navex Global (2014) cited the following 11 benefits:

- Address different learning styles
- Cover more risk topics
- Address secondary risks
- Raise awareness
- Reinforce foundational training with reminders
- Reduce seat time

- Emphasize key risk areas
- Respond quickly to incidents or emerging trends
- Train third parties and other nontraditional audiences
- Training on the go
- Train the rarely trained



### **Training Inventory**

- Course
- Defined audience or role
- Forum
- Registration details if applicable
- When and how often
  - Upon employment
  - Every 1/2/3/5 years
  - · Refresher as needed
  - When new systems or processes are implemented



NDIANA UNIVERSITY

### **Training Inventory**

|                                       | Course Title or Description   | Audience   | Forum                      | Registration   | Upon<br>Employment | Refresher as<br>Needed | Prior to/<br>Upon Access | Annually | Every 2<br>years | Every 3<br>years | Every 5<br>years |
|---------------------------------------|---|--|----------------------------|--|--------------------|------------------------|--------------------------|----------|------------------|------------------|------------------|
|                                       | Nev Employee Compliance Orientation (NECO) for Health<br>Sciences                                     | All new employees of Health Science Schools of Control (currently comprised of the Schools of Centrally, Health and Philabitis ston Sciences, Medicine, Narsing, Opnomery, Publish Health (Bloomington and Indianagols) and Social Viola)  | In person or video stream* | https://expand.ku.edu/hrowsele-training/courses/health-sciences-neco   | х                  |                        |                          |          |                  |                  |                  |
|                                       | RIPUI New Employee Genreral Safety Orientation  | IJPUI new employees  | In-person                  | https://eupand.ku.edubcovsete.traininglehatsousesfupui.neo   | ×                  |                        |                          |          |                  |                  |                  |
|                                       | IJD New Employee General Safety Orientation   | I/O nev employees  | In-person                  | https://expandiu.edubrovserle-traininglehalrousses/lub-new-employee-general-safety-<br>orientation-classroom |                    |                        |                          |          |                  |                  |                  |
|                                       | HIPAA Privacy and Security for Nev Employees  | Nev Employees in a HEPAA Affected Area   | Online                     | https://expandiu.edu/brousele-training/courses/hipaa-new-employees   | ×                  |                        |                          |          |                  |                  |                  |
|                                       | HIPAA Privacy and Security for Faculty & Stalf  | Faculty and Stall in a HIPAA Allected Area   | Online                     | https://expand.iu.edu/browsele.training/courses/hipaa  |                    |                        |                          | ×        |                  |                  |                  |
| Core Courses                          | Mobile Device Security  | Angone using mobile devices to access thiversity accounts or data;<br>"Certification for Use of Personally Owned Devices" also required (trigor/lines is eduhasik/lu/verification-<br>for-use-of-personally-owned-devices)   | Online                     | https://expandiu.edu/brovsele-trabing/rouses/mobile-device-security  | ×                  |                        | ×                        |          |                  |                  |                  |
|                                       | FERPA (before access to student data is granted)  | Plequired for angone accessing shadent data, new requirement, for all faculty and stalf  | Online                     | https://ferpaluseduhssponsibilitiesihstoolal.html  |                    |                        | ×                        |          | ×                |                  |                  |
|                                       | HFIMS Data Use Tutorial   | Anyone with access to employee human resources and/or payroll related data   | Online                     | https://oceiu.edukask/luforms.data.use.tutorial  |                    |                        | ×                        |          | ×                |                  |                  |
|                                       | DHS Courses (vuoruniambulau)  | See EHS section below or browse EHS E Training Cutalog or browse their website at<br>https://ehs.kpui.edu/training/index.ktml  | Online Fits-<br>person     | https://expand.iu.edu/brovselv-training/ehs  |                    |                        |                          |          |                  |                  |                  |
|                                       | Data Protection and Privacy   | Recommended for all employees; some units may require  | Online                     | https://expand.iu.edu/browsele-training/courses/data-protection-and-privacy-tutorial                         |                    |                        |                          |          |                  |                  |                  |
|                                       | An hirroduction to Compliance at IU   | Available to and recommended for all nev employees, Required for all nev employees at the regional<br>computer,  For the Health Science Schools only, this server as the native alternative to NECCO completion for<br>employees that work less than 29 hoursheet or otherwise went table to attend the in-pressor or video<br>streament session. These ordensings amonths MECCO periods complete that course. | Online                     | https://teip.ord.iu.edu/ticovsele.training/courses/fetro.no.compliance                                       | ×                  |                        |                          |          |                  |                  |                  |
| Financial                             | Payment Card Industry Data Security Standards (PCIDSS)<br>Security Awareness Education (SAE) Training | Employees involved in processing, transmitting, or handling cardholder data, as well as angone that manages<br>people or systems that process cardholder data, including listal officers, managers, and IT technical experts<br>that configure velocities.   | Online                     | https://heasurer.ku.edu/heasury-operations/heasuroes/huibing.html  |                    |                        | ×                        | ×        |                  |                  |                  |
|                                       | Online Revenue Processing Tutorial (offered through Revenue<br>Processing/Office of Treasurer)        | Flequired for any employee processing revenue. Full time stall must complete online tutorial before revenue processing, attend next face to face session offered (then once every two years)   | Online filt-<br>person     | https://brasurer.luedu/brasury.operations/hesources/haining.html   |                    |                        | ×                        |          | ×                |                  |                  |
|                                       | Face to Face Revenue Processing Training  | Required for any employee processing revenue. Full time stall must complete Face to Face Revenue<br>Processing Training every two years.   | In-person                  | https://treasurer.lu.edu/treasury.operations/hesources/haining.html  |                    |                        | ×                        |          | ×                |                  |                  |
|                                       | Disbursement Voucher (DV) Certification Training  | Angone respecible for processing Disbursement Youshers   | Online Fin-<br>person      | https://fims.iu.edu/training/de.certification/   |                    |                        | ×                        |          |                  |                  |                  |
| Public Safety<br>& Student<br>Welfare | Clery/Campus Security Authority (CSA)   | Campus Security Authorities, defined as "someone who has significant responsibility for student and campus activities"—See Protect. Liedu for more info  | Online                     | https://expand.iu.edu/trousele.training/coursesissa-2015.  | ×                  |                        |                          | ×        |                  |                  |                  |
|                                       | Sexual Misconduct   | Available for all employees, required for Plesponsible Employees as defined by Sevual Misconduct Policy,<br>officed to all new employees and available to all employees  | Online                     | https://expand.ku.edu/browserle-training/courses/sexual-misconduct-2016.                                     | ×                  |                        |                          | ×        |                  |                  |                  |



UDIANA LINIVEDSITY

## **Training Inventory**

| Course Title or Description Audience |  | Forum  | Registration                        | Upon<br>Employment  | Refresher as<br>Needed | Prior to/<br>Upon Access | Annually | Every 2<br>years | Every 3<br>years | Every 5<br>years | New Systems<br>or Process<br>Implemented | When<br>Offered | School/<br>Dept.<br>Specific |  |
|--------------------------------------|--|--|-------------------------------------|---|------------------------|--------------------------|----------|------------------|------------------|------------------|--|-----------------|------------------------------|--|
|                                      | CITS Responsible Conduct of Research Course  | Flequired for undergraduate, graduate or post doors supported by NSF funds, available to all, NOT required for<br>IFID submission  | Online                              | http://esseschoonglienos/usedulen/eq_olicitetal   |                        |                          | ×        |                  |                  |                  |  |                 |                              |  |
|                                      | CIT- IACUC module  | Required if you plan to use lab animals in research/submission to IACUC  | Online                              | htp://tesearchcompliance/u.edu/ec/ec_cit/itml   |                        |                          | ×        |                  |                  | ×                |  |                 |                              |  |
|                                      | CITs Good Clinical Practice Course   | The GCP educational course is a condition of PIB approval for Principal Investigators and Co-Principal<br>Investigators conducting interventional clinical studies. It is optional for all others.   | Online                              | http://esseschootsplience.iu.edu/eo/eq_citi.html  |                        |                          | ×        |                  |                  |                  |  |                 |                              |  |
|                                      | Pladiation Salety Orientation  | Required for all nev radioactive material users on the LRFUs campus and a associated facilities (e.g., various IV.)<br>He alth Facilities/departments), Depending on year training and/or reperience, registrants may also need to attend<br>the Padaston Salety Course.   | in-person.                          | http://tesseushcompilance.ku.edukadsseinyhapsikadssein_education.html   |                        |                          | ×        |                  |                  |                  |  |                 |                              |  |
| Research                             | Radiation Salety Course  | Pleguized for all nev radioactive material users with inadequate or no previous training or experience with<br>radioactive material.   | in-person                           | http://tesearchcompilance.iu.edu/tadsralety/hpuit/adsrale_education.html  |                        |                          | ×        |                  |                  |                  |  |                 |                              |  |
|                                      | Pladiation Safety Châte Education  | On fire training programs are available and provided for specific applications. Please reliet to your department of<br>supervisor to determine what if any, additionally along you might need (a.g. to along the senting personnel, non-<br>horance set induced by the provided provided and to recommend to the provided and to the operators).                           | Online                              | http://meneschcomplience.lueduhadoulntylupuihadouln_croline_training.html   |                        |                          | ×        |                  |                  |                  |  |                 |                              |  |
|                                      | Radiation Salety Retrester Training  | Penahing required annually for all radiation vorkers. The Radiation Salety Office (RSO) distributes training topics<br>pena annually to all-Penni Holders to be circulated among stat. The Penni Holder must continued the RSO<br>that all radioution terraining lasers vorking under histiline penial have been provided that training in                                 | Yales                               | NA.   |                        |                          |          | ж                |                  |                  |  |                 |                              |  |
|                                      | Diological Saleng Training   | Peopled for personnel associated with work in biologic all aboratories, either for research or teaching purposes.<br>The tailing encurse that personnel vorking in certain before tokes have been hained in basis biologic all adeq principals before conducting work in before one at bidness before size of the personnel below.   | Oráne                               | https://expandis.edu/brossels.tuininglehuls.ourseafilicsalety   |                        |                          | ×        |                  |                  |                  |  |                 |                              |  |
|                                      | NM Fit Test and Training   | Pleasanth personnell required to use respiratory protection in the course of their research programs must receive<br>appropriate medical screening and surveillance. In tenting, and saiming to ensure proper use of the respiratory<br>protection as required to CPM. See also DEP replacement before<br>protections are required to CPM. See also DEP replacement before | In-person                           | Conract Biosaley Office or EHS  |                        |                          | ×        | ж                |                  |                  |  |                 |                              |  |
|                                      | Blootborne Parhogen Training   | Pregaind for any personnel who have a potential for compational reposure to blood or blood products, unlead fissus, other potentially infectious materials, or oil ordinars of human or non-human-primate origin. See also DHS requirement below.  | Online or<br>In-person<br>available | https://expand.ix.edultrovasle.trankingkhalkoursealbloodbome.pakhopena<br>https://expandix.edultrovasle.trankingkhalkoursealblo |                        |                          | ×        | ж                |                  |                  |  |                 |                              |  |
|                                      | NH Training Guidelines   | Pequired for all personnel/co-investigators in order to be officially added to an EIC protocol   | Online                              | https://equalsis.edu/brousele-trabing/souseshib   |                        |                          | ×        |                  |                  |                  | ×  |                 |                              |  |
|                                      | COI in Piesearch   | Angone involved in the design, conduct or reporting of research. Training component currently provided at beginning of disclosure process.   | Online                              | http://eseasch.compliance.iu.edu/colicol_doclosuse.html   |                        |                          |          | ж                |                  |                  |  |                 |                              |  |
|                                      | Legal Compliance Training (IUB only) for supervisors<br>• AOA • EEO • PLSA • FMLA • Seaud Harassment | Supervisors on Bloomington campus  | In person or Otline                 | http://fite.iu.edu/tr.uining/blocomingron/index.html<br>https://imp.and.iu.edu/trovosele-tr.uining/br/programs/fir-ics          |                        |                          | ×        |                  |                  |                  |  |                 |                              |  |



NDIANA UNIVERSITY

### **Training Topics**

| TOPICS  |  | NECO | NEO | TOPICS  | Online | NECO | NEC |
|---|--|------|-----|---|--------|------|-----|
| Welcome Message from President McRobbie                   |  | х    |     | Documentation   | Х      | Х    |     |
| University Resources                                      |  | х    |     | Fraud & Abuse   |        | Х    |     |
| Introduction to Ethics and Compliance                     |  | х    | х   | Conflicts of Interest   |        | Х    |     |
| The University Compliance Program                         |  | х    | х   | Research Ethics   |        | Х    |     |
| The Principles of Ethical Conduct                         |  | х    | х   | Signature Authority   | Х      | Х    |     |
| Individual Responsibilities for Compliance                |  | х    | х   | What to do if Contacted by a Government Official, Auditor, or Regulator |        | Х    |     |
| Reporting Concerns  |  | х    | х   | Requests for Public Records   | Х      | Х    |     |
| ntroduction to University Policies                        |  |      |     | Use of University Resources & Political Activity                        | Х      |      |     |
| - Non-Discrimination/Equal Opportunity/Affirmative Action |  | *    |     | Documentation   | Х      | Х    |     |
| - Firearms and Weapons                                    |  | *    |     | Privacy & Security Reminders  |        |      |     |
| - Tobacco Free and Substance-Free Workplace Policies      |  | *    |     | Privacy & Security (more in-depth)                                      |        | Х    |     |
| - Sexual Misconduct                                       |  | *    |     | Export Controls & Travel Restrictions                                   |        | Х    |     |
| - Policy on Programs Involving Children (PIC)             |  | х    |     | Emergency Procedures  | Х      |      |     |



| KEY    |   |  |  |  |  |  |
|--------|---|--|--|--|--|--|
| Online | An Introduction to Compliance at IU                         |  |  |  |  |  |
| NECO   | New Employee Compliance Orientation for the Health Sciences |  |  |  |  |  |
| NEO    | New Employee Orientation                                    |  |  |  |  |  |
| Х      | covered in presentation                                     |  |  |  |  |  |
| *      | mentioned in presentation, covered in handout               |  |  |  |  |  |
|        |   |  |  |  |  |  |

#### **Increase Awareness**

- Posters
- Notification cards
- Brief animated videos
- Infographics
- Reinforce with regular communications (e.g. Risky Academy, distribution lists to liaisons, campus news, etc.)



INDIANA UNIVERSITY

#### **University of Illinois Animated Video Series**

- 1. Videos are less than five minutes
- 2. Intended to promote awareness so that someone will know when to seek additional guidance
- 3. Each video also includes a printable resource page that:
  - Reiterates key points from the video
  - Links to important info
  - Provides points of contact for questions

Looking Out for Fraud





### **Ongoing Considerations**

- Changes in roles and responsibilities
- Tracking
- · Measuring effectiveness
- Refreshing content
- · Changes in regulations and enforcement



INDIANA UNIVERSITY

#### **QUESTIONS?**

#### **Marcia Gonzales**

Senior Associate General Counsel Indiana University marcgonz@iu.edu

#### Jennifer Weddle

Compliance Consultant Indiana University jnspurge@iu.edu

