# Always a Work in Progress

Research Compliance Programs



HCCA Research Compliance Conference, Baltimore, June 2017

# Disclaimer, thanks

- We have no financial conflicts of interest
- The opinions presented here are our own
- $\, \bullet \,$  We love building compliance programs

Dwight Claustre Karen Mottola 7 June 2017

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# **Objectives**

#### Fruitful reflection upon and discussion of:

- $\, \bullet \,$  current state and "opportunities for improvement"
- $\, \bullet \,$  desirable enhancements and potential obstacles
  - $\ldots$  in order to re-engineer the existing  $% \left( \mathbf{r}\right) =\mathbf{r}$  and  $\mathbf{launch}$  the new

### Who are we?

- Academic?
   Community hospitals, large health systems?
   Clinical Research Organizations?
   Sponsors?
   Other?

- Dwight: compliance consultant
   Karen: large health-system research compliance
- Building a research compliance program from scratch?
   Updating one?
   Part of a general/corporate compliance program?
   Other?

- Loves compliance? Loves building?



### First, imagine the perfect world

The dream research compliance program



#### If you could rule your universe...

#### What would your research compliance program be?

- Free associate; don't overthink it: what comes to mind?
  - $\, \bullet \,$  Let it be idealistic, a mere sketch, a pipe dream
  - $\, \bullet \,$  A single improvement, a few touch-ups, a radical redesign
  - One you got it, don't abandon it − refine as needed
  - $_{\odot}$  Let it be a guiding start to where you're headed
  - And then get practical
  - (Repeat as needed)



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# Assessment 1: Mapping the territory

Institution, research operations, research compliance



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# Measuring the universe

#### Identify the character of your organization

- What are its **structure** and **mission**?
- What is its level of risk tolerance?
- How **prominent** is research?
- How much do its leaders know about research?
- What departments (should) care abut research?

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### Locating the country

#### Take a fresh look at your research program(s)

- What kind(s) of research is/are conducted?
- How much?
- $\bullet$  Is it **programmatic** (say, as opposed to haphazard)?
- To what degree is it centralized?
- Is its structure shifting?
- What are its larger cultural risks?



# Defining the borders

#### Outline the intersection of organization, research, research compliance

- To whom does research operations report?
- How **independent** is it from the larger institution?
- $\, \bullet \,$  To whom does research compliance report?
- Does it collaborate closely with research?
- With "corporate" compliance?
- With the larger institution?



### **Assessment 2:** Finding yourself in your world

The research compliance program and staff



## Scoping the layout

- 1. Is the program centralized or scattered across multiple offices? If scattered, the divisions may be telling...
- 2. Is it structured by:
- risk area?
- the 7 elements of an effective compliance program?
- historical accretion, perhaps haphazardly?
  some combination?
- other?



3. Is it recognized by the institution, by research operations as a program?

### Sizing up the locals

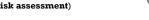
- Who comprises the research compliance staff?
- Is its leader (you?) strategic or tactical?
- What are the relations among team members?



- Is the team **prominent** among researchers, research administrators? Staff? Compliance leaders? Non-research
- What is the team's degree of specialization(s)?
- Are you trusted? Does research see you as an ally?
- Do you have a research compliance champion?

#### Taking direction from the risks...

- ... and focusing specifically on mitigations
- (Conduct classic risk assessment)



- Classic risks, top risks, hot-topic risks, your unique risks
- But also assess from a different perspective: mitigations  ${\bf assessment} \ {\bf to} \ {\bf challenge} \ {\bf your} \ {\bf current} \ {\bf program}$
- $\odot$  A prime focus: **policy and processes** review
- Consider the other elements: what's still in infancy or could use a little boost or refashioning?

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#### Risk assessment areas

- Grants and contracts accounting
- Physician disclosure Conflict of Interest

- Coding, billing
   Research medical records
- Laboratory practices
   Physician contracting
- Stark, anti-kickback compliance Good Clinical Practices
- Financial reporting
- Investigational Drug Services Investigator-initiated trials
- Bio-safety and -security
  HIPAA, HITECH
- Patient safety
   Patient care/quality

- Gaps in policies and procedures
- Budget development
- Managed care contracts Human subjects protection
- · Medicare cost report
- · Effort reporting
- Registration & patient accounts Healthcare quality and outcomes
- Clinical trials billing
- · Fair market value Consenting process
- · Scientific Misconduct
- · Animal Ethics
- · Research accounting

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1. Standards & Procedures	Implement written policies and procedures and standards of conduct
2. Oversight	Designate a compliance officer and committee
3. Training & Education	Provide regular and relevant training and education
4. Reporting	Develop lines of communication for reporting of complaints/incidents that protect anonymity, prevent retaliation
5. Enforcement & Discipline	Enforce standards through well-publicized and utilized disciplinary guidelines
6. Auditing & Monitoring	Conduct internal monitoring and auditing
7. Investigation & Remediation	Respond promptly to detected offenses and undertaking corrective action

#### Places to go, people to meet

Identifying enhancements and potential obstacles





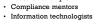
# After surveying the land...

# Identify structural and personnel enhancements (and prepare for potential obstacles)

- Change in organization/org charts
  - Is RCP reporting structure adequate? Optimal?
     Are there redundancies across offices?

  - · Is there room for research centralization/standardization?
  - · Is the RCP overstaffed or understaffed?
- Development of relationshipsTo researchers

  - · To research administrators
  - To non-research offices Research champion

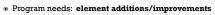




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### And draft the bucket list

- Potential general tools toward enhancement
  - · Could you develop buy-in for an external effectiveness review?
  - · Do you need specific audits?
  - Does RCP staff need specialized training?
  - ${\boldsymbol \cdot}$  Is there sufficient value in general program benchmarking?
- Program needs: process improvements by area
  - E.g. Need to rework Conflict of Interest process







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#### Finalizing the itinerary

To launch the new program



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#### Commit to a schedule

# And prepare for unplanned obstacles – or benefits – and unexpected

- Timeline structure--
  - Scope it to the planned enhancements
  - Plan for wiggle room but not too much give
  - Could it be tied to a larger compliance or research initiative?
- Timeline content
  - Depends upon your planned changes but some one or combination of  $% \left( 1\right) =\left( 1\right) \left( 1\right)$
  - $\bullet \ \ Reorganization, large \ or \ small$
  - · Personnel development
  - · Risk area
  - · Elements



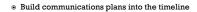
# Mind your travel companions

#### Who needs to stay apprised and when?

- Track your contacts on the timeline-
  - By time e.g. quarterly, monthly
    By role

  - · General operations
  - · General compliance

  - Research operations
     Special committees



- $\ensuremath{\mathfrak{G}}$  Do you need a committee, a work plan item, some other larger support?
- $\, \odot \,$  Balance your working with leadership and with staff

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### **Group sessions**



# Questions



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