


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**
- We love building compliance programs

*Dwight Claustre
Karen Mottola
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Objectives

Fruitful reflection upon and discussion of:

- current state and “opportunities for improvement”
- desirable enhancements and potential obstacles

... in order to re-engineer the existing and **launch** the new


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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?



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First, imagine the perfect world

The dream research compliance program




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If you could rule your universe...


What would your research compliance program be?

- Free associate; don't overthink it: what comes to mind?
 - Let it be idealistic, a mere sketch, a pipe dream
 - A single improvement, a few touch-ups, a radical redesign
 - One you got it, don't abandon it – refine as needed
 - 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 about 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?
- Is it **programmatic** (say, as opposed to haphazard)?
- To what degree is it **centralized**?
- Is its structure shifting?
- What are its larger **cultural risks**?



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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?
- To whom does research compliance report?
- Does it collaborate closely with research?
- With “**corporate**” compliance?
- With the larger institution?



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Assessment 2: Finding yourself in your world

The research compliance program and staff



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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*?

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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 departments?
- 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**?

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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 assessment** to challenge your current program
- 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

- | | |
|--|--|
| <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • Gaps in policies and procedures • Budget development • Managed care contracts • Human subjects protection • Residual funds • Medicare cost report • Research administration • 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

*From Office of the Inspector General; see Federal Register, v63, n35 (1998)

Places to go, people to meet

Identifying enhancements and potential obstacles





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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 relationships
 - To researchers
 - To research administrators
 - To **non-research** offices
 - Research champion
 - Compliance mentors
 - Information technologists



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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?
 - Is there sufficient value in general program benchmarking?
- Program needs: **process improvements by area**
 - E.g. Need to rework Conflict of Interest process
- Program needs: **element additions/improvements**
 - E.g. Need to review policies for gaps, required updates



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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
 - **Reorganization**, large or small
 - Personnel development
 - **Risk area**
 - **Elements**



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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



● Build communications plans into the timeline

● Do you need a committee, a work plan item, some other larger support?

● Balance your working with leadership and with staff

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Group sessions



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Questions



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