

# 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  
7 June 2017*

HCCA Research Compliance Conference, Baltimore, June 2017

## 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

HCCA Research Compliance Conference, Baltimore, June 2017

## 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?



HCCA Research Compliance Conference, Baltimore, June 2017

## First, imagine the perfect world

The dream research compliance program

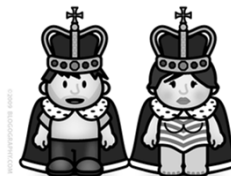


HCCA Research Compliance Conference, Baltimore, June 2017

## 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)**



HCCA Research Compliance Conference, Baltimore, June 2017

## Assessment 1: Mapping the territory

Institution, research operations, research compliance



HCCA Research Compliance Conference, Baltimore, June 2017

## 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?



HCCA Research Compliance Conference, Baltimore, June 2017

## 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**?



HCCA Research Compliance Conference, Baltimore, June 2017

## 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?



HCCA Research Compliance Conference, Baltimore, June 2017

## Assessment 2: Finding yourself in your world

The research compliance program and staff



HCCA Research Compliance Conference, Baltimore, June 2017

## 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*?



HCCA Research Compliance Conference, Baltimore, June 2017

## 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**?



HCCA Research Compliance Conference, Baltimore, June 2017

## 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**?



HCCA Research Compliance Conference, Baltimore, June 2017

## 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**
- 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

HCCA Research Compliance Conference, Baltimore, June 2017

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



HCCA Research Compliance Conference, Baltimore, June 2017

## 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



HCCA Research Compliance Conference, Baltimore, June 2017

## 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



HCCA Research Compliance Conference, Baltimore, June 2017

## Finalizing the itinerary

To launch the new program



HCCA Research Compliance Conference, Baltimore, June 2017

## 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**



HCCA Research Compliance Conference, Baltimore, June 2017

## 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



HCCA Research Compliance Conference, Baltimore, June 2017

## Group sessions

---



HCCA Research Compliance Conference,  
Baltimore, June 2017

## Questions

---



HCCA Research Compliance Conference, Baltimore, June 2017

## Contact

### **Dwight Claustre**

Director

Aegis Compliance and Ethics Center, LLC

[dclaustre@aegis-compliance.com](mailto:dclaustre@aegis-compliance.com)

623-866-9106

### **Karen Mottola, MA, CHRC, CPC, CRCC**

Research Compliance Officer

Ethics and Compliance Services

Sutter Health

[mottolk@sutterhealth.org](mailto:mottolk@sutterhealth.org)

415-385-5916

HCCA Research Compliance Conference, Baltimore, June 2017