Always a Work in Progress
Research Compliance Programs

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

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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

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?
  - 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)
Assessment 1: Mapping the territory
Institution, research operations, research compliance

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?
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?

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?
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 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?

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?
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

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

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
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
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

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
Group sessions

Questions
**Contact**

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