Always a Work in Progress
Research Compliance Programs

Disclaimer, thanks

- 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 disclosures
- 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)

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**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
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

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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