Build It to Comply!

A Research Compliance Program

Disclaimer, thanks

- We have no financial conflicts of interest
- The opinions presented here are our own
- We love building compliance programs
- Thanks to national research compliance expert Lisa Murtha, JD – and to the natural eloquence of babies

Dwight Claustre
Karen Mottola
8 June 2016
Objectives

Awareness – or increased awareness of – the:

- relation between research operations and compliance program
- seven elements of an effective compliance program
- the basics of risk assessment

Reflection on and practice in designing a research compliance program suited to your organization

Why compliance?

In five words: to protect participants, taxpayers, us
## Laws, regs, rules, and *relata*

<table>
<thead>
<tr>
<th>False Claims Act</th>
<th>Export Controls</th>
<th>Scientific Misconduct</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRS non-profit status</td>
<td>FDA approval process</td>
<td>HIPAA, HITECH</td>
</tr>
<tr>
<td>Effort Reporting</td>
<td>Federalwide Assurance</td>
<td>“Common Rule”</td>
</tr>
<tr>
<td>Stark; Anti kickback</td>
<td>Animal Welfare Act</td>
<td>Allowable Costs</td>
</tr>
<tr>
<td>Document Consistency</td>
<td>Investigational Device Exemption billing</td>
<td>Coverage Analysis</td>
</tr>
<tr>
<td>Conflict of Interest (COI)</td>
<td>Clinical Trials Agreement</td>
<td>Good Clinical Practices</td>
</tr>
<tr>
<td>Social Security Act (Medicare)</td>
<td>FDA Amendment Act (clinicaltrials.gov)</td>
<td>Investigational Drug Services</td>
</tr>
<tr>
<td>Open Payments (aka “Sunshine Act”)</td>
<td>Medicare claims processing rules</td>
<td>Coverage with Evidence Development</td>
</tr>
</tbody>
</table>

From the mouths of babes:

[https://www.youtube.com/watch?v=znUAYLqyEgQ](https://www.youtube.com/watch?v=znUAYLqyEgQ)
Oversight offices

Research operations is beholden to:
- Food and Drug Administration
- National Institutes of Health
- Centers for Medicare and Medicaid Services (CMS, “Medicare”)
- Office of Human Research Protection (OHRP)
- Office of Research Integrity (ORI)
- Agency for Healthcare Research and Quality (AHRQ)
- Office of Management and Budget (OMB)
- National Science Foundation
- United States Department of Agriculture
- And many others

Why now?

Building a strong research compliance program:
- Protects our patients and animal subjects
  - Safety, autonomy, fairness, privacy, protection against inadvertent misbilling
- Protects taxpayers
  - Federal use of funds
- Protects our institution, employees, colleagues
  - From negative publicity and fines
- Is the right thing to do
  - Federal regulation is the minimum
  - Compliance meets those regs, but goes beyond to ethics
How now?

Analysis, planning, stakeholder gathering, buy-in

- What is your present set-up?
  - Consider research operations and compliance
- Are there burning needs?
  - Often, the top concerns are obvious; others may be hidden
- Who needs to be consulted? persuaded?
- Who will analyze needs? Internal or external?
- Does buy-in require audit?
- Ultimately, scale determines timing, robustness

Who are we?

- Academic?
- Community hospitals, large health systems?
- Clinical Research Organizations?
- Sponsors?
- Other?
- Dwight: compliance consultant and …
- Karen: large health-system research compliance and …
- Building a research compliance program from scratch?
- Updating one?
- Part of a general/corporate compliance program?
- Other?
- Loves compliance? Loves building?
The seven elements
Of an effective compliance program

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

*From Office of the Inspector General; see Federal Register, v63, n35 (1998)*
**Does type of organization matter to compliance plan? Academy**

Academic sites tend to have, among other things:

- lots of, **varied** research
- majority of providers **required to conduct research**
- **leaders who “get” research**, a mission that emphasizes it
- their **own** Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Conflict of Interest process
- significant **experience with federal grants** and contracts
- dedicated, extensive **research accounting** staff
- relatively more protection, some say

**Does type of organization matter for compliance plan? Hospital**

Community hospitals, systems tend to have

- Relative to universities, **fewer studies**
- **No requirement** to conduct research
  - Providers may not be trained as scientists, may have fewer peers
- **Less specialized** research staff
- Leadership, mission that are **less research-focussed**
- Little to middling experience with **federal grants**
- Compliance office with little to modest **research** experience
- No dedicated **Investigational Drug Services**
- **Varying resources** for IRB, FCOI; **varying awareness** of research billing and other esoteric research compliance reqs
Does org type matter to compliance plan? CRO, sponsors

- Clinical research organizations are more focused
  - dedicated to research alone
  - more likely to be specialized, allowing tighter focus, may
    - conduct clinical trials only
    - have specialties within clinical trials
    - provide a non-clinical specialty (e.g., MMSEA §111 compliance)

- Sponsors are also focused, however differently
  - giant, but many separate divisions, or small and specialized
  - managing global compliance
  - required to have regular monitoring
  - closely working with the FDA
  - cushioned from some big risks (e.g., research billing); exposed to others (e.g., liability)

The seven for research?

Depending upon institution type, more or less similar

- The seven are basic, virtually intuitive
- But each element must fit institutional needs
  - More focus, more specialty: less division of attention
    - No animal research? No IACUC, no USDA visits, no animal research policies, training, enforcement, …
    - Diabetes drug research only? Similar protocols, highly trained staff
  - More volume, potentially more or less risk
    - Lots of NIH studies, probably significant compliance resources
    - Greater the number on immunosuppressant drugs with incomplete safety profiles, the greater the patient safety risks
    - More knowledgeable leadership, more research attention

HCCA Research Compliance Conference, Baltimore, June 2016
The seven for research?

Simultaneously: like and unlike general compliance

- **Variety, volume**, knowledge of **leaders** shape a program
- Must understand **organizational mix** to build a program
- Some **risk areas** are (more or less) **closely associated**
  - Conflict of interest; research conflict of interest
  - Pharmacy; investigational drug services, some FDA research compliance
  - Federal service grant reqs; federal research grant reqs
- Yet, even when similar, research is often **more complicated**
  - Health care billing rules *plus* research specificities
- Or **differently complicated**
  - New employee orientation; non-monetary compensation training

*Bottom line: need to attend to all seven, however uniquely, and add the eighth...*

---

Risk assessment

Analyzing relative needs
Are your top three covered?

https://www.youtube.com/watch?v=L8xUl0hBdOI

Are your top 3* covered?

**Human subjects protection**
- subject to major update, changing rules
- crucial to participant rights
- basic to admirable ethics
- no matter how strong your base, needs your attention

**Financial conflict of interest**
- new rules, 2012, stressed existing processes; posed stricter limits
- increasing culture of compliance questions definitions
- in public eye
- new CMS system: challenging and potentially misleading
- all need vigilance and readiness for update

**Research billing**
- as frequent as study visits and related ancillary services
- confusing to revenue cycle
- changing, increasing rules (latest: July 2015)

* Not to mention federal grants, records management, investigational drug services, and many more...

HCCA Research Compliance Conference, Baltimore, June 2016
Risk assessment: what?

Risk assessment...

...is the identification, measurement, and prioritization of likely relevant events or risks that may have a material consequence on an organization’s ability to achieve its business and ethics objectives

Risk assessment template

Administration

Management

Operations Staff
Risk assessment: who?

The more, the merrier

- Research compliance officer
- General compliance officer (if different)
- IRB
  - Chair
  - Member
  - Manager/coordinator
- Risk manager
- Legal counsel

Risk assessment: who?

The more, the merrier (cont’d)

- Research nurses (or nursing representatives)
- Research coordinators
- Regulatory specialists (IRB coordinators on admin side)
- Research pharmacists
- Research investigators
- Research financial analysts
- Billing specialist
- Registration specialist
- Etc, dependent upon organizational structure
Risk assessment areas

- Effort reporting
- Research accounting
- Physician disclosure
- Conflict of Interest
- Coding, billing
- Research medical records
- Laboratory practices
- Physician contracting
- Stark, anti-kickback compliance
- GCP
- Financial reporting
- Investigational Drug Services
- Investigator-initiated trials
- HIPAA, HITECH
- Patient safety
- Gaps in policies and procedures
- Budget development
- Managed care contracts
- Institutional Review Board
- Residual funds
- Medicare cost report
- Research administration
- Patient care/quality
- Registration & patient accounts
- Healthcare quality and outcomes
- Clinical trials billing
- Fair market value
- Consenting process
- Scientific Misconduct
- Animal Ethics

Are you centralized or not?
Structuring the compliance program to fit operations
Non-central/Central

Un-Centralized Ops
- Staff multi-tasks, supports general knowledge
- Duplicates management
- Protects freedom of PI and PI-led staff
- Avoids pain of change to centralized ops
- Challenges enterprise consistency
- Stymies compliance oversight

Centralized Ops
- Staff specializes, supports pinpoint knowledge
- Streamlines management
- Requires compromise of PI independence and teams
- Is painful in transition from un-centralized ops
- Supports enterprise consistency
- Is more amenable to compliance oversight

Change the words?

Whatever the rhetoric, no institution seeks to establish a research compliance program without seeking centralization of some sort

Compliance is about standardization, if only through compliance to federal standards

“Centralization” may not be politically correct at your institution. But you seek compliance assurance under any vocabulary. Switch to “compliance assurance,” “adherence to federal regulation,” and connect the dots between those and standardization.

And then “centralization” is not so critical.
When ops is central – or headed there

Tilt toward central eases compliance program launch
- One set of ops leaders; defined, specialized staff roles
- Standardized processes are in place
- Build plan with reference to elements – the building blocks
- Prioritize risk areas and compliance needs
  - Do you need to:
    - develop policies and written procedures?
    - establish a compliance committee? A training platform?
  - Or are the first three elements relatively mature?
    - can you focus on reporting, enforcing, auditing, investigating?
  - Or, more likely, you need to toggle back and forth?

When ops is not central – but could be

Is leadership open to centralization?
- Many institutions are centralizing if they have not already
- Point out: those fined for non-compliance tend to centralize
- Research compliance may be situated to support centralization
  - Become acquainted with the non-central teams; assess their compliance-assurance and aptitude toward increased measures
  - Identify obvious risks or conduct risk assessment
  - Seek centralization champions
  - Work from “top” (leaders) and “bottom” (interested staff)
  - An institution that seeks a research compliance program is likely to want system-wide policies
  - Begin with policies, compliance committee, initial training (FCOI, federally required, if federal grant applying or funding)
When ops is decidedly non-central

**But institution seeks research compliance program?**
- A program implies a **standardizing attitude**
- Our code of conduct requires **adherence to federal regulation** and an **ethical stance**
  - Seek unambiguous scaffolding (e.g. FCOI disclosure requirements)
  - Identify non-varying system-level processes: IRB, billing system
  - Rally around common cause of patient safety
- Even if **centralization is taboo**
  - Find your own structure in the elements; in risk assessment
  - Share research regulations with non-research leaders
  - Get to know leaders, staff; seek **champions at all levels**
  - Consider monitoring/auditing to jumpstart awareness

Love the (long) process

No matter the level of openness to centralization
- Compliance requires standardization
- Centralization is its most obvious but not its only form
- Sometimes the **fastest way is the long way around**
  - Standardize to the extent possible
  - Love the process
- And note: under **all three scenarios**, we recommend:
  - Champions
  - Elements
  - Obvious risks or formal risk assessments
  - Collaboration
The trickiest thing
Where does research ops end and compliance begin?

Ops/compliance relations

Unless ops’ compliance assurance is mature, comprehensive:
- New and/or improved processes are needed
- Ops is likely be fully engaged in present tasks
  - No time for improvements
  - Potentially insufficient knowledge of requirements
  - Perhaps some resistance
- Before compliance officer can act as such, may need to collaborate for process improvement
  - Influence ops to improve processes that you identify?
  - Become a process builder yourself?
One for all, all for one in compliance

- Compliance starts with operations: **first line** of assurance
  - Principal investigator: responsible for everything
  - Research staff, administrators: PI's delegates to assist in meeting all requirements
- Compliance department, program: **second line** of assurance
  - Compliance officer charged with:
    - Ensuring that rules are upheld and needed processes, followed
    - Providing advice on federal, state, institutional requirements
    - Supporting or instituting the seven elements
    - Writing policy, perhaps developing processes, best practices

But: a balancing act to maintain distance

Is compliance officer developing ops processes?

- May be most knowledgeable, especially if experienced in research ops, talented in process/systems design
- But: assess for **coverage and distancing** needs
  - Who will audit, investigate, enforce?
    - Use of external auditors and/or internal support staff?
    - Find methods to ensure sufficient perspective and measure
  - Who will train and provide educational materials?
  - Who will conduct **risk assessments**?
- And: plan for **limited engagement**
  - When, how can blending be phased out?
Structural analysis

To whom does research compliance report?
- Research administration?
- University/hospital/corporate administration?
- General/corporate compliance?
- Other?
- Not applicable: it doesn’t exist yet?

- Reporting structures may need analysis and/or determination
  - What are the benefits of an embedded program? of a separate one?
  - If research compliance is not part of general compliance, is there a point – of maturity, of complexity, of recognized risk – when it should be?
  - Does organizational type, leadership, mix of research make a difference?

Putting it all together

Steps involved in designing a program
**Brainstorming the build**

1. Divide by **institutional similarity**, groups of 6-8
   - Large academic
   - Small academic
   - Large health system
   - Small health system
   - Sponsors (include Clinical Research Organizations)

2. Elect a **spokesperson**

3. Collaborate: **order steps**, adding as needed

4. **Tape order** of steps to giant post-it

5. Share business cards

6. Spokesperson presents plan

---

**Contact**

**Dwight Claustre**
Director
Aegis Compliance and Ethics Center, LLC
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
415-385-5916