Thinking About Getting Involved in Research…

- Why is research important?
- How do you develop a strategic approach?
- How do you operationalize the mandate?
- How do you manage the risk?
- What are some lessons I have learned along the way?
The Research Environment at the University of Denver I Anschutz Medical Campus:

A Spectrum of Research:
- Clinical Trials
- Physiology
- Social and Behavioral
- Community
- Device and Product Development
- Translational
- Multi-site

Annual Research Grant Awards 2018 = $516 million
1,300 Principal Investigators

Why Do Research?

To Improve Health Care:

Spectrum of Translational Research

[Diagram showing the spectrum of translational research]

[Image of ice cream cones]

[Image of medical staff]

[Image of research equipment]
There are Good Business Reasons:

- Develop Innovative Care
- Access to Investigational Product
- Workforce Satisfaction
- Market Differentiator
- Improve Health Outcomes
- Expand Patient Care Options
- Personalized Medicine

Where Should You Start?

Be Strategic:

- Translational Science / Lead site on a multi-site study
- Federally Funded
- Industry Clinical Trials
- Access to Investigational Product
- Health Outcomes
- Innovative Care
Why Does Your Institution Want to do Research?

- Understand the mission
- Understand the priority within the organization
- Know any resource limitations
- Build on the culture of the organization

Why Does the Mission Matter?

- Scope
- Timeline
- Expectations
- Leadership Commitment
Understand the Priority:

- Where does it fit in the current risk assessment matrix?
- Know the risk tolerance
- Metrics of success
- Impact on other priorities

Know the Resource Limitations:

- Do an inventory of expertise
- Understand available technology resources/ technology gap analysis
- Expand offices and integrate existing resources
- Develop tracking and reporting system
- Understand budget limitations
Beware of:

The One Person Shop

- High compliance risk
- No business continuity
- It takes a village

Build on the Culture of the Organization:

Centralize Control

Decentralize Innovation / Adaptation

Mind the Culture Gap
How Do You Get Started?

- Establish a plan
  - Business
  - Regulatory
  - Operations

- Do a Risk Assessment

Business Plan

- Any research requires infrastructure support
- Broader opportunity to outsource
  - Central IRB regulatory requirements
  - Other also outsource other regulatory services:
    - CTA negotiation
    - Budget development
    - Coverage Analysis

Note: Every research dollar costs the institution money (F&A)
Planning: Regulatory Compliance

Strategic Planning

- Regulatory and industry approvals
- Operations
- Regulatory monitoring and auditing
- Fiscal compliance

Operational Strategies

- Research Unit
- Clinical Operations
- Research Compliance
- Hospital Compliance

OR

- Clinical Care
- Integrated Compliance
- Research
Do a Research Risk Assessment Periodically

Research Compliance Program-Not “One-Size-Fits All”

<table>
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<tr>
<th>Innovative Care</th>
<th>QI, QA, PE Project</th>
<th>Data Health Outcomes</th>
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<tbody>
<tr>
<td>Oversight Committee</td>
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<td>Data Storage</td>
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Research Compliance Program Gets Complicated:

<table>
<thead>
<tr>
<th>Access to Investigational Product</th>
<th>Industry CT Drug Device</th>
<th>Federal</th>
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</thead>
<tbody>
<tr>
<td>Billing Compliance</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
  • Research                        |                         |         |
  • 3rd Party                       |                         |         |
| IRB                               | X                       | X       |         |
  • 21 CFR 50, 56                   |                         |         |
  • 42 CFR 45                       |                         |         |
| Contracting / sub contracts       | X                       | X       |         |
| Budget                            | X                       | X       |         |
| FDA Reporting                      | X                       | X       |         |
| Pharmacy/Device Storage/Administration | X               | X       |         |
| Record Retention                   | X                       | X       |         |
| Coverage Analysis                  | X                       | X       |         |
| Responsible Conduct of Research (RCR) |                     |         |
| COI Research                       | X                       | X       |         |
| Authorization                       | X                       | X       |         |
| Effort Reporting                    | X                       |         |         |
| CT.gov                             | X                       | X       |         |
| Data Sharing                       |                         |         |
| OMB Uniform Guidance               |                         |         | X       |

Adding More Complexities:

- Human
- Animal
- Basic/Lab
- Auditing
- Monitoring
- Multi-site
Integrate with Existing Clinical Infrastructure:

Pillars of Clinical Operations

Foundation of QUALITY CLINICAL CARE

Translating Clinical to Research:

HIPAA Privacy

- Clinical Care
  - Notice of Privacy Practices
  - Consent to Treat
- Research
  - Privacy Board
  - Research Consent
  - Waiver of Authorization
  - Data Sharing Agreements
Lessons Learned:

- All research costs and adds risk
- Regulations require similar infrastructure regardless of volume
- Try to stay focused on the mission
- Use external resources – consulting companies to help move clinical structure to support research
- Strategically outsource until have internal capacity
- Partner with academic institutions when appropriate

Thank You!

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(303)724-1010

Research website:
http://www.ucdenver.edu/research