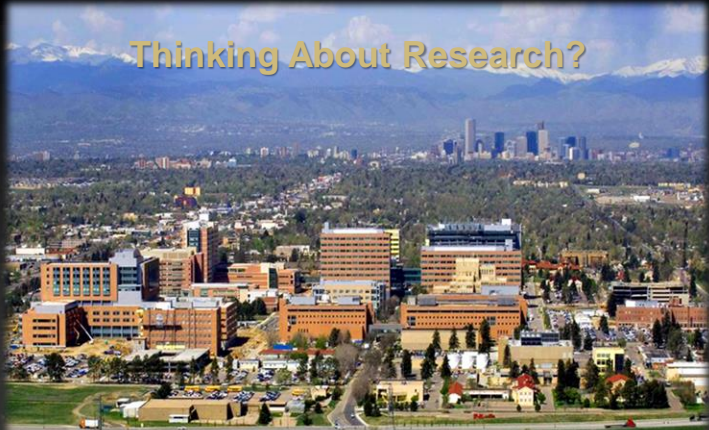



# Thinking About Research?




Alison Lakin RN, LLB, LLM, PhD  
Associate Vice Chancellor for Regulatory Compliance


 University of Colorado Denver | Anschutz Medical Campus

1

## 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?



 University of Colorado Denver | Anschutz Medical Campus

2

# The Research Environment at the University of Denver | Anschutz Medical Campus:

## A Spectrum of Research:

- Clinical Trials
- Physiology
- Social and Behavioral
- Community
- Device and Product Development
- Translational
- Multi-site



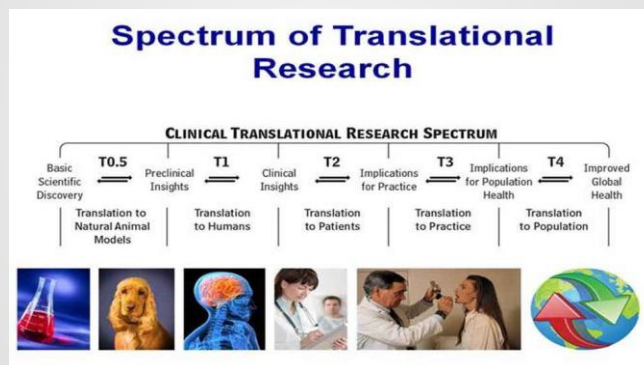
Annual Research Grant Awards 2018 = \$516 million

1,300 Principal Investigators

3

## Why Do Research?

### To Improve Health Care:



4

## 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



5

## 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

6

## 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

7

## Why Does the Mission Matter?

- Scope
- Timeline
- Expectations
- Leadership Commitment



8

## 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

11

## Build on the Culture of the Organization:



12

## How Do You Get Started?

- Establish a plan
  - Business
  - Regulatory
  - Operations
- Do a Risk Assessment



13

## 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)

14

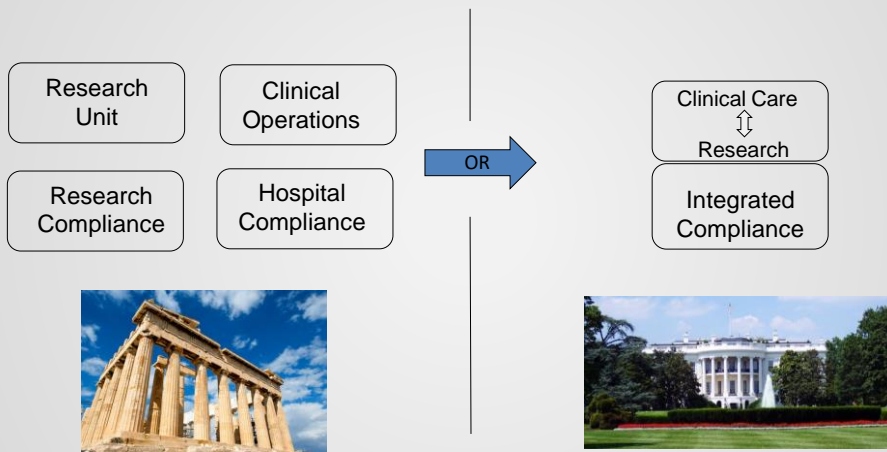
## Planning: Regulatory Compliance




 University of Colorado Denver | Anschutz Medical Campus

15

## Operational Strategies



 University of Colorado Denver | Anschutz Medical Campus

16



# Do a Research Risk Assessment Periodically

Campus-wide Risk Assessment			
Category	Current State	Next Steps	Timeline/Action
Compliance Officer & Compliance Committee	<ul style="list-style-type: none"> <li>1) IRB policies and procedures are revised in the process of updating procedures from policies.</li> <li>2) IRB identified opportunities for improvement during past audit.</li> </ul>	<ul style="list-style-type: none"> <li>1) Compare/contrast IRBAs with other policies on the same topic, determine where we can align.</li> <li>2) Additional evaluation/updates regarding department's policies during past audit.</li> </ul>	<ul style="list-style-type: none"> <li>1) OBE - LUM - Research compliance priorities</li> <li>2) OBE - IRBAs, Team Security &amp; Protect, Research compliance priorities</li> </ul>
Quality of administration	<ul style="list-style-type: none"> <li>1) Training, campus-wide IRBAs (staff) has been formed and has not been in the process of documenting current state of roles within existing process.</li> <li>2) Academic staff quality, mostly IT administration, and printing/computer system. New IT administration hold at university.</li> </ul>	<ul style="list-style-type: none"> <li>1) Training, IRBA documentation of current state, determine if all institutions agree on definition of "backbone". This is a dependency for further action.</li> <li>2) Academic research and future thought on additional topics for compliance (campus, social media), measure value of current IRBAs to academic efforts.</li> </ul>	<ul style="list-style-type: none"> <li>1) IRBA/IRB C/Chairing/IRB, update potential need for LIP IRB reporting IRB</li> <li>2) IRBA/IRB for compliance IRB</li> </ul>
Monitoring and Auditing	<ul style="list-style-type: none"> <li>1) Strong network monitoring and intrusion analysis, monitoring and reporting plans in place for computer research system.</li> <li>2) Critical IRBAs maintain IRBAs.</li> <li>3) All IRBA training systems require that are monitoring for compliance with the IRBAs. Or primary involved in monitoring and follow through.</li> <li>4) Ongoing effort to align with efforts on IRBA/IRBAs of IRBAs to this for IRBA/IRBAs (authorizations, authorizations).</li> <li>5) No current audit process in place to evaluate and track compliance efforts.</li> </ul>	<ul style="list-style-type: none"> <li>1) Maintain working up with ever changing industry standards.</li> <li>2) Continue to improve and align (strong IRBA/IRBAs efforts).</li> <li>3) IRBA/IRBAs potential need for additional effort with investigation, incident response, and security as a result of IRBAs.</li> <li>4) IRBA/IRBAs: the IRBA/IRBAs of implementing IRBA/IRBAs during IRBAs of IRBAs.</li> <li>5) Ongoing efforts to understand on IRBA/IRBAs of IRBAs (authorizations, authorizations) related to IRBA/IRBAs (authorizations, authorizations) on IRBA/IRBAs.</li> <li>6) Determine what resources are needed and what IRBAs needs, develop a plan to move forward.</li> </ul>	<ul style="list-style-type: none"> <li>1) IRBA/IRBAs based on IRBA/IRBAs.</li> <li>2) IRBA/IRBAs based on IRBA/IRBAs.</li> <li>3) IRBA/IRBAs based on IRBA/IRBAs.</li> <li>4) IRBA/IRBAs based on IRBA/IRBAs.</li> <li>5) IRBA/IRBAs based on IRBA/IRBAs.</li> <li>6) IRBA/IRBAs based on IRBA/IRBAs.</li> </ul>
Response to IRBAs	<ul style="list-style-type: none"> <li>1) IRBA/IRBAs and IRBA/IRBAs are well documented, but compliance on IRBA/IRBAs.</li> </ul>	<ul style="list-style-type: none"> <li>1) IRBA/IRBAs of continuing current state, consider potential alignment with IRBA/IRBAs.</li> <li>2) IRBA/IRBAs: response to IRBA/IRBAs.</li> <li>3) IRBA/IRBAs of current approach with IRBA/IRBAs on IRBA/IRBAs.</li> </ul>	<ul style="list-style-type: none"> <li>1) IRBA/IRBAs based on IRBA/IRBAs.</li> <li>2) IRBA/IRBAs based on IRBA/IRBAs.</li> <li>3) IRBA/IRBAs based on IRBA/IRBAs.</li> </ul>
Risk Assessment/Response	<ul style="list-style-type: none"> <li>1) IRBA/IRBAs assessment.</li> </ul>	<ul style="list-style-type: none"> <li>1) IRBA/IRBAs assessment.</li> <li>2) IRBA/IRBAs assessment.</li> </ul>	<ul style="list-style-type: none"> <li>1) IRBA/IRBAs based on IRBA/IRBAs.</li> <li>2) IRBA/IRBAs based on IRBA/IRBAs.</li> </ul>

17

# Research Compliance Program-Not "One-Size-Fits All"

	Innovative Care	QI, QA, PE Project	Data Health Outcomes
Oversight Committee	X	X	
Billing Compliance	X		
Audit	X	X	
Budget Development	X	X	
• Tracking			
• Training			
IRB			X
Privacy Board			X
Data Storage	X	X	X

18

# Research Compliance Program Gets Complicated:

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

19



20

## Integrate with Existing Clinical

## Infrastructure:



21

## 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

22

## 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!

**Alison Lakin RN, LLB, LLM, PhD**

Associate Vice Chancellor for Regulatory Compliance

(303)724-1010

**Research website:**

<http://www.ucdenver.edu/research>

