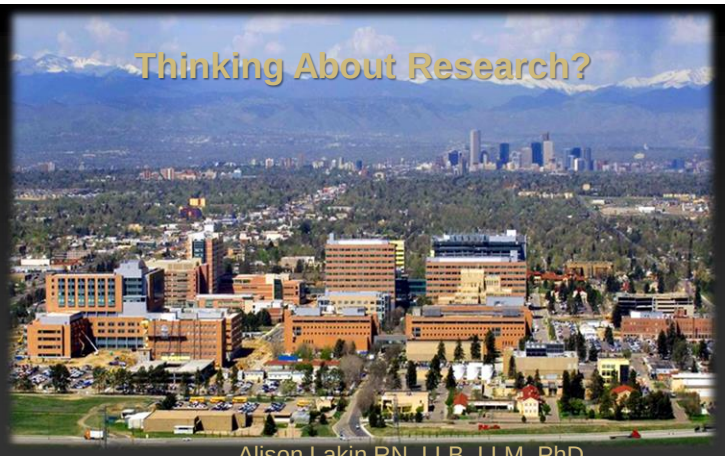

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Associate Vice Chancellor for Regulatory Compliance

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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?

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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

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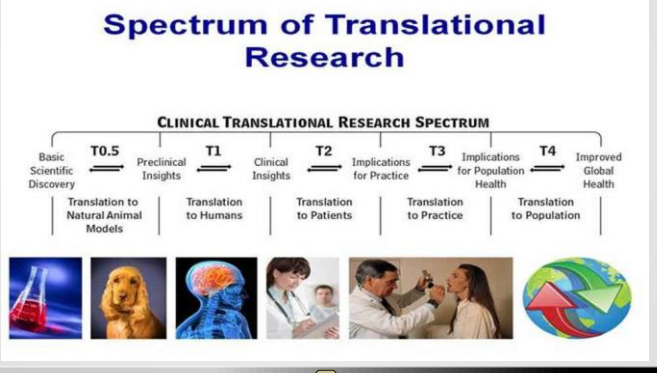
Why Do Research?

To Improve Health Care:



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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

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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

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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

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Understand the Priority:

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

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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

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Beware of:

The One Person Shop

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

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Build on the Culture of the Organization:

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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

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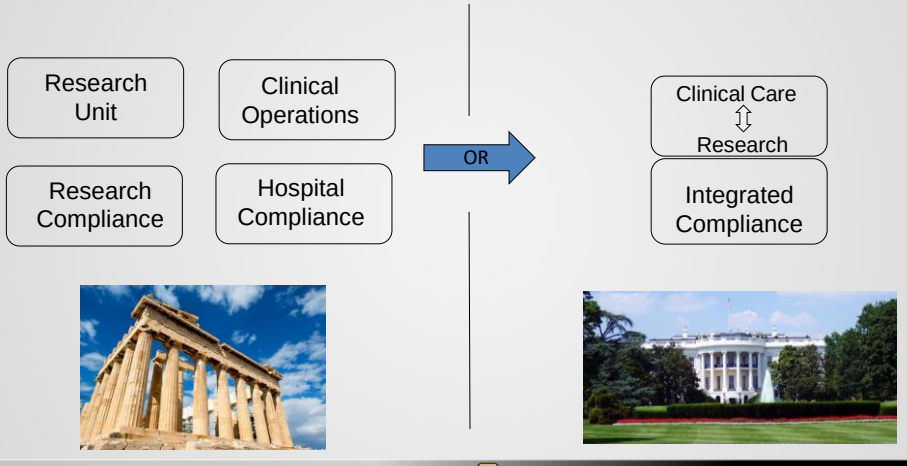
Operational Strategies



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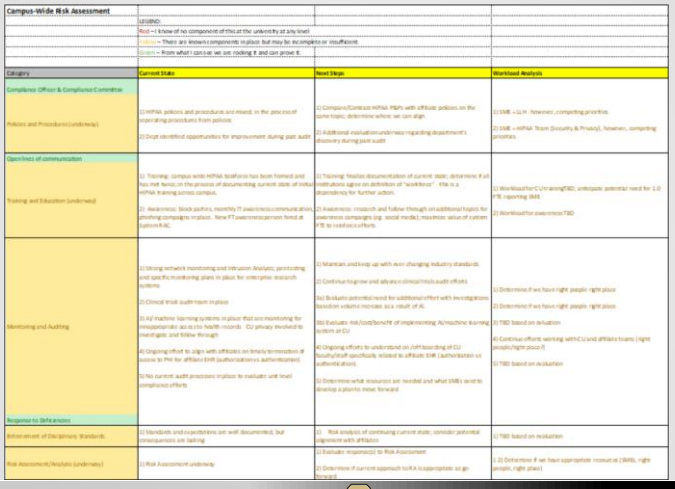
Do a Research Risk Assessment Periodically



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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 • Tracking • Training	X	X	
IRB			X
Privacy Board			X
Data Storage	X	X	X

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Research Compliance Program Gets Complicated:

	Access to Investigational Product	Industry CT Drug Device	Federal
Billing Compliance • Research • 3rd 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

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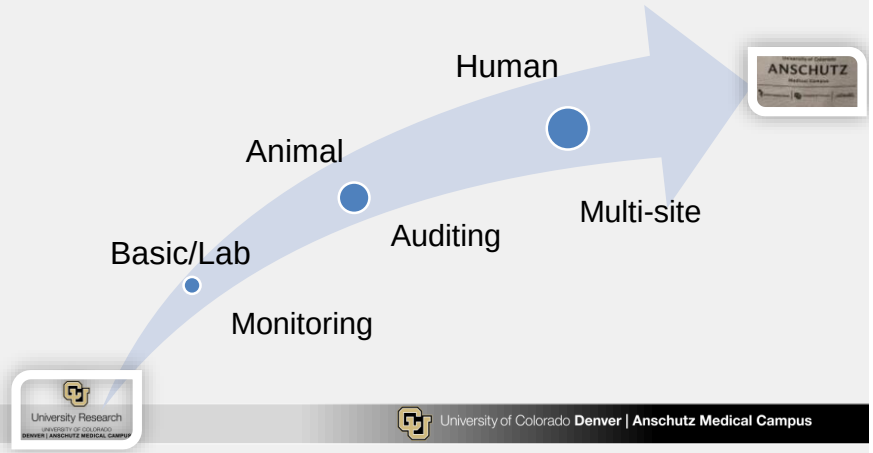
Adding More Complexities:



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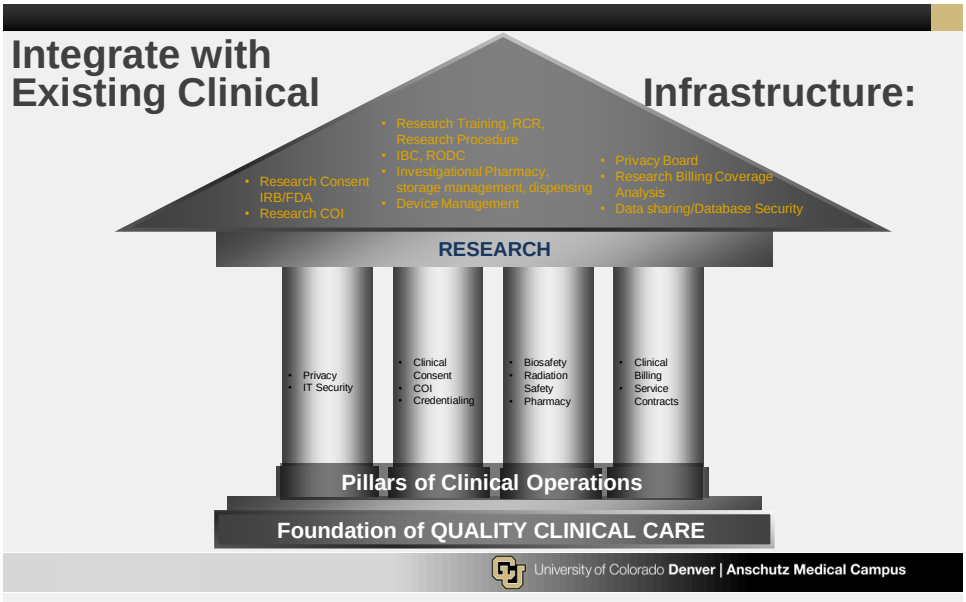
Integrate with Existing Clinical Infrastructure:
Research Training, RCR, Research Procedure
IBC, RODC
Investigational Pharmacy, storage management, dispensing
Device Management
Research Consent IRB/FDA
Research COI
Privacy Board
Research Billing Coverage Analysis
Data sharing/Database Security
RESEARCH
Privacy
IT Security
Clinical Consent
COI
Credentialing
Biosafety
Radiation Safety
Pharmacy
Clinical Billing
Service Contracts
Pillars of Clinical Operations
Foundation of QUALITY CLINICAL CARE
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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
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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

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Thank You!

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

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