



Protecting Agriculture.
Preserving Public Health.



Self-Audit of Biosafety Practices

Keeping Your Ducks in a Row



High Containment Research Oversight

- High risk, greater consequences – requires enhanced oversight
 - » Personnel illness/injury
 - » Environmental consequences (agriculture)
 - » Regulatory violations
- Integration of research goals
 - » Goal is to support and facilitate research, not impede or hinder



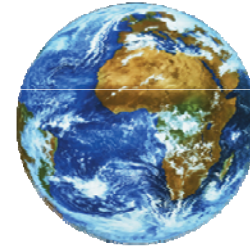
Needed Research Oversight Programs

- Occupational Medicine
- Training
- Emergency Response
- Regulatory Compliance
 - » Select Agents - USDA and CDC
 - » USDA APHIS transport permits
 - Veterinary Services (VS)
 - Plant Protection and Quarantine (PPQ)
 - Biotechnology
 - » Institutional Biosafety Committee (IBC)
 - » Institutional Animal Care and Use Committee (IACUC)



Needed Research Oversight Programs

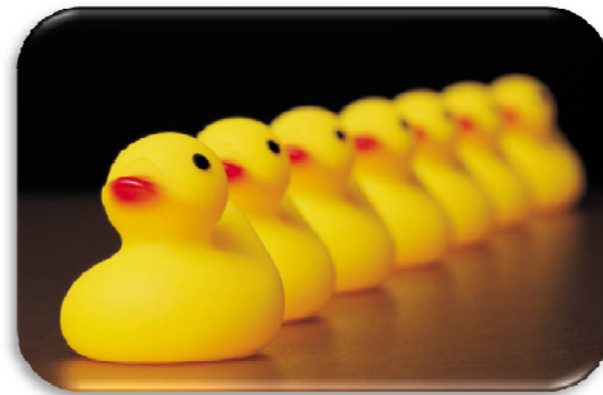
- Occupational Medicine
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- Others



Needed Research Oversight Programs

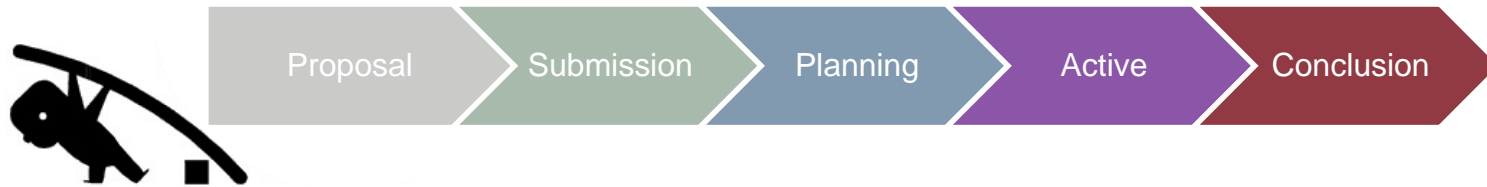
- Occupational Medicine
 - Training
 - Emergency Response
 - Regulatory Compliance
 - Others

HOW TO KEEP TRACK OF IT ALL?...HERDING THE DUCKS



How to Juggle it All? ...Leverage

- Leverage all necessary resources and commitments from appropriate stakeholders from the very start:
 - » Ensures safe operating conditions
 - » Strong indicator of a successful research program



{A magic wand doesn't hurt either}





Let's Start at the Very Beginning, a Very Good Place to Start...



- New Research Project Initiation Checklist
 - » Early introduction
 - » Comprehensive requirements summary
 - » Flexibility to include research and support staff needs
 - » Ensures requirements are met before research begins



New Research Project Initiation Checklist

- Forces interaction with all support groups
 - » Builds relationships from the start
 - » Fosters creativity



Leverage

APHS
DOC
Cost Structure
Billing
Purchasing
Parking
EPA
Workplace
Medical Assessment
Wallet Cards
Hazard Inventory
Assessment
IRB
Chemical Inventory
Biological Inventory
Hazard Comm Signage
Electrical & Facility
PPE
Waste Disposal & Decon



Background Check
SRA
Access Badge
Orientation
Animal Care & Use
Biosafety
Security
Cybersecurity
Drills
Biosafety
Manual
Protocols
Risk
Assessment
Caging and Penning
Health Monitoring
Metrology
Animal Acquisition
Scheduling Care

New Research Project Initiation Checklist

NEW RESEARCH PROJECT INITIATION CHECKLIST [BRI-0001-F1]

Items on this checklist must be completed prior to beginning a project in the BRI. PIs are responsible for accurately completing the checklist and getting any necessary institutional approvals.

PI name

College Department

PIs approved designate

(Approved designate is a person designated by the PI to be responsible for activities in Pat Roberts Hall laboratories in his/her absence)

Project Title

Authorized Project Personnel (list all persons who will be conducting work on this project in Pat Roberts Hall, including the PI and approved designate)

Name	Title	Phone	Email	Office Address
------	-------	-------	-------	----------------

<input type="text"/>				
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Administration

Administration (contact BRI Office Manager at 532-1333 for assistance)
Office Manager initials

- | Yes | NA | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Accounting and billing process established with Office Manager? |
| <input type="checkbox"/> | <input type="checkbox"/> | Purchasing needs reviewed and coordinated as needed with Office Manager? |
| <input type="checkbox"/> | <input type="checkbox"/> | Parking policies and needs reviewed with Office Manager? |
| <input type="checkbox"/> | <input type="checkbox"/> | Copy of Kansas State University Transmittal Sheet (SP001) submitted to Office Manager? |

Security

Security (contact BRI Facility Security Manager at 532-1333 for assistance)
Facility Security Manager initials

- | Yes | NA | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Background checks completed for all personnel involved in the project? |
| <input type="checkbox"/> | <input type="checkbox"/> | Access requests processed and ID/access badges received for all personnel involved in the project? |
| <input type="checkbox"/> | <input type="checkbox"/> | Security Awareness training completed for all personnel involved in the project? |

Information Technology

Information Technology (contact BRI IT Officer at 532-1333 for assistance)
IT Officer initials

- | Yes | NA | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Information Technology and telecommunications accounts set up as needed? |
| <input type="checkbox"/> | <input type="checkbox"/> | Information Technology accounts set up as needed? |
| <input type="checkbox"/> | <input type="checkbox"/> | Cybersecurity training completed? |
| <input type="checkbox"/> | <input type="checkbox"/> | Research Project Information System (RPIIS) account set up? |
| <input type="checkbox"/> | <input type="checkbox"/> | BRI Information Technology account set up? |

Biosafety

Approvals and Permits (contact BRI Biosafety Officer at 532-1333 for assistance)
Biosafety Officer initials

- | Yes | NA | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | All required permits, such as USDA transport and/or import permits, obtained? [copy of application and approved permit must be attached] |
| <input type="checkbox"/> | <input type="checkbox"/> | Registration for use of Select Agents submitted and approved? (contact Responsible Official Julie Johnson) [copy of application and approval must be on file] |
| <input type="checkbox"/> | <input type="checkbox"/> | Laboratory/project specific Biosafety Manual completed and approved by BRI Biosafety Officer? |
| <input type="checkbox"/> | <input type="checkbox"/> | Approval for controlled substance use received? (DEA and KS Pharmacy Association) [copy of license must be attached] |

Approvals and Permits (contact BRI Biosafety Staff at 532-1333 for assistance)
Biosafety Officer initials

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Research Compliance

Research Compliance (contact UNL Compliance Officer at 402-475-2222 for assistance)
Office Manager initials

- | Yes | NA | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Institutional Biosafety Committee application submitted and approved? (http://www.k-state.edu/research/comply/ibc/) [copy of application and approval must be attached] |
| <input type="checkbox"/> | <input type="checkbox"/> | Institutional Animal Care and Use Committee application submitted and approved? (http://www.k-state.edu/research/comply/iacuc/) [copy of application and approval must be attached] |

New Research Project Initiation Checklist

Medical Surveillance

Training

Laboratory Setup

Animal Use

- Institutional Review Board application specific to the BRI project submitted and approved? (<http://www.k-state.edu/research/comply/ibc/>) [copy of application and approval must be attached]
- Application for Radioisotope Authorization submitted and approved? (<http://www.k-state.edu/safety/Documents/RSM2006.doc>, Section 4.1) [copy of application and approval must be attached]
- University Export Control training completed by all research personnel?

Medical Surveillance (contact BRI Biosafety Staff at 532-1333 for assistance)

Biosafety Officer initials

Yes NA

- Workplace Hazard Inventory Form completed by all personnel involved in the project and submitted to BRI Biosafety Officer?
- Initial Medical Assessment questionnaire and exam completed by all personnel involved in the project?
- Wallet cards issued to all personnel involved in the project?

Safety Training (contact BRI Biosafety Staff at 532-1333 for assistance)

Biosafety Officer initials

Yes NA

- BRI Safety Training completed by all personnel?
- Training records maintained?
- Safety training records reviewed by BRI Biosafety Officer?

Lab

Laboratory Set Up (contact BRI Laboratory Coordinators at 532-1333 for assistance) *designated Lab Coordinator initials*

Yes NA

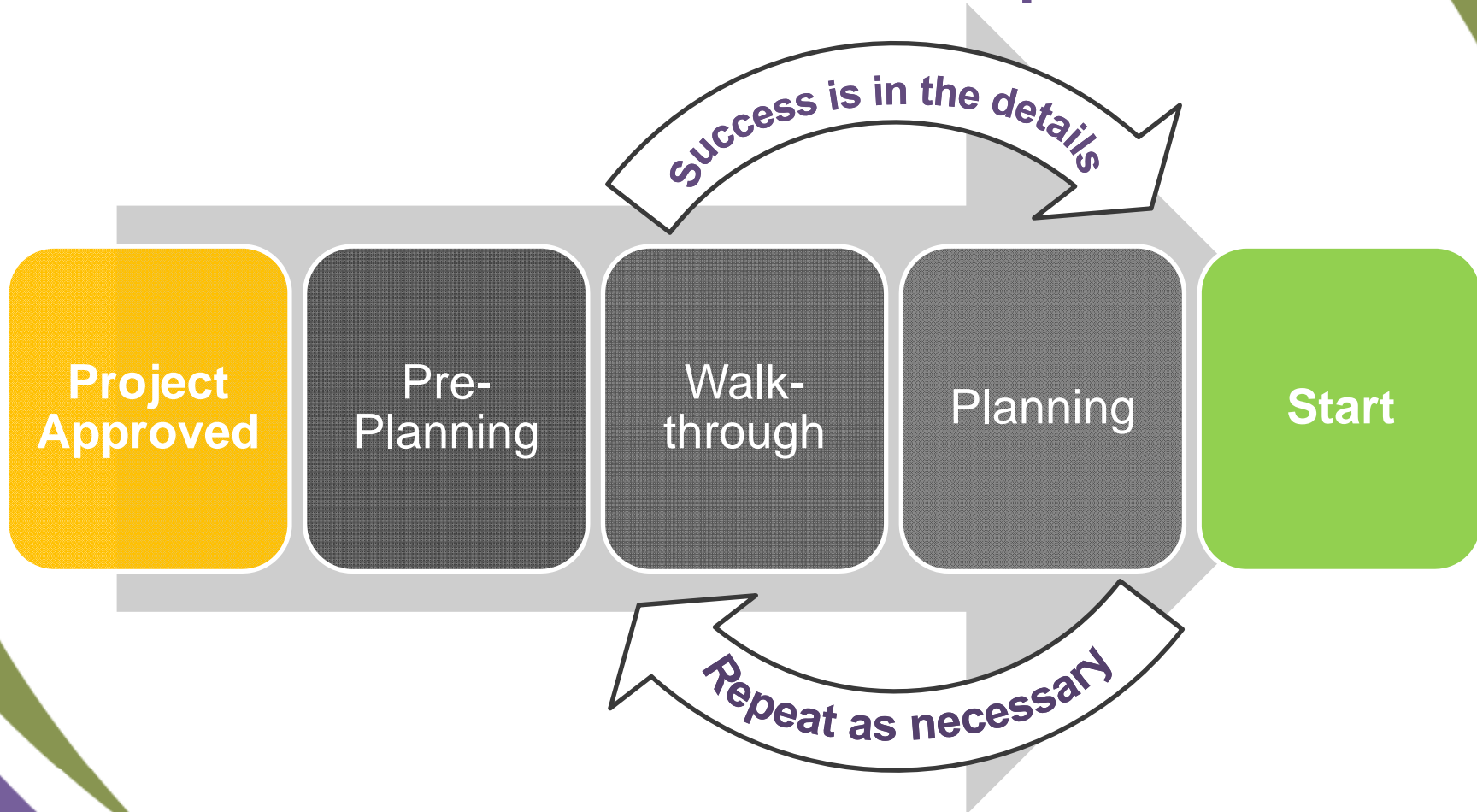
- Chemical Materials Inventory Form completed and submitted to BRI Laboratory Coordinators?
- Biological Materials Inventory Form completed and submitted to BRI Laboratory Coordinators?
- Hazard and contact information signage posted?
- Electrical and other facility needs reviewed with BRI Facility Engineer?
- Lab clothing, shoes and any other required personal protective equipment on hand?
- Appropriate waste containers and labels on hand?

Yes NA

- Caging, space and handling procedures reviewed with Comparative Medicine?
- ARF 90 form completed and approved?

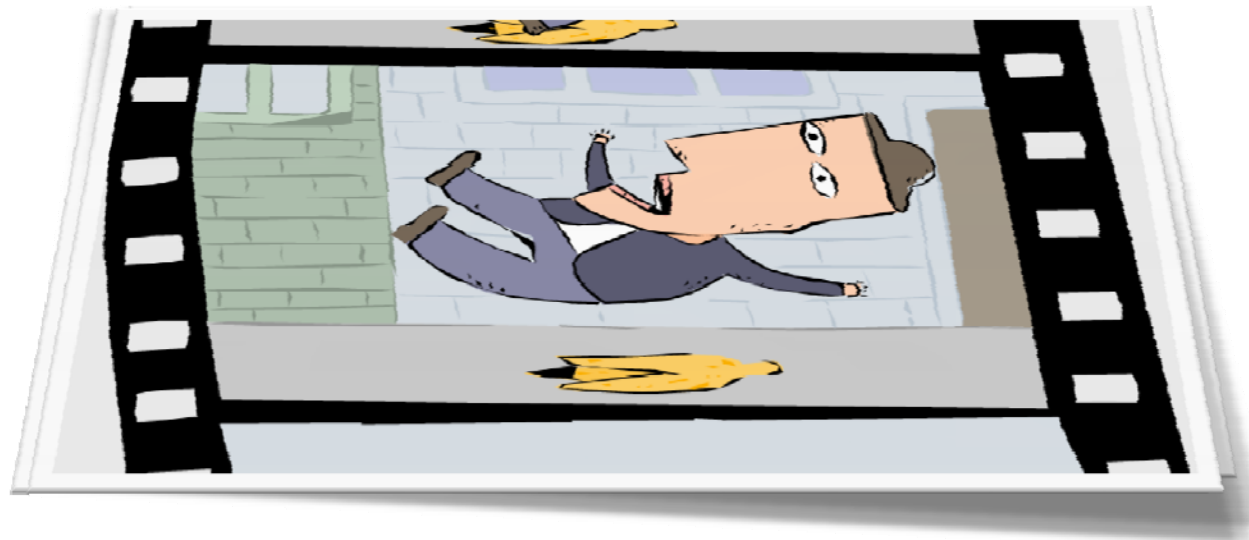
New Research Project Initiation Checklist

Continuous Process: Preparation



Active Research Monitoring (Audits)

- Single Annual Assessment (Snapshot)
- Continuous Assessment (Profile)



Audit Approaches

Single Annual Snapshot

vs.

Continuous Process

Surprises
(Reactive)

No Surprises
(Proactive)



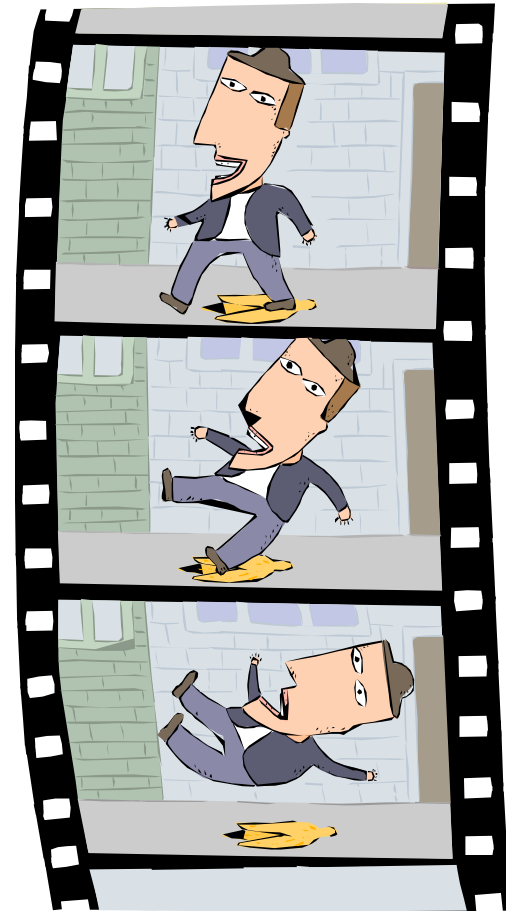
Single Annual Assessment (Snapshot)

- Annual comprehensive inspection
- May coincide with annual whole facility shut down for validation
- Expectations are clarified during annual trainings and orientation
- Incorporated into trainings and daily activities



Continual Assessment (Profile)

- Weekly eyewash log
- Daily BSC operations log
- Daily respirator evaluation
- Daily autoclave verification
- Weekly, monthly, and annual housekeeping
- Scheduled inventory audits
- Quarterly self audits by researchers
- Others



Eating the Whole Elephant at Once

- Not very palatable



Eating the Elephant One Bite at a Time

- Much more palatable



Continuous Assessment: One Bite at a Time

- Continuous process gives researchers shared responsibility for safety culture
 - » Prioritizing
 - » Continuous Sampling
 - » Deputizing



Continuous Assessment: Prioritizing

- Focus on a few most critical safety issues
 - » Top Ten List
 - » High risk vs. low risk activities



Continuous Assessment: Sampling

- Spot checks by safety staff
 - » Early detection
 - » Early prevention and mitigation
 - » Minimal intrusion and interruption
 - » Increased dialogue and opportunity to develop relations

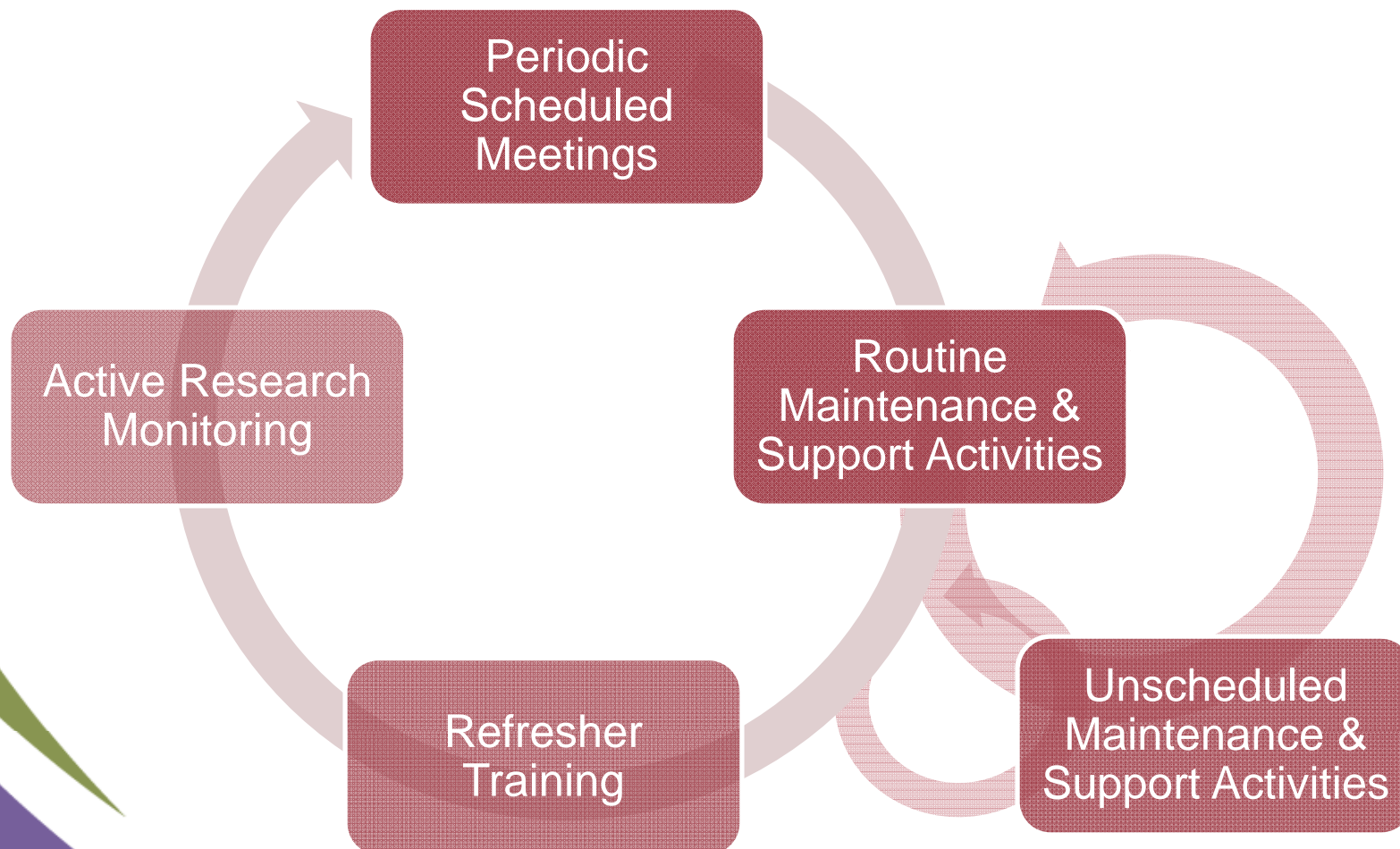


Continuous Assessment: Deputizing

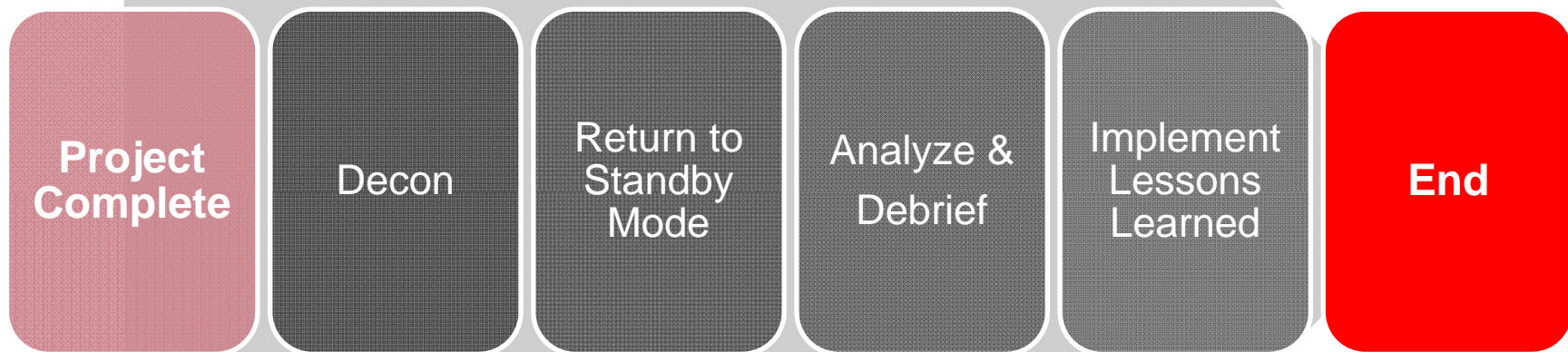
- Continuous process gives researchers shared responsibility for safety culture
 - » Laboratory user groups – sharing of best practices
 - » Local safety committees – sharing of oversight responsibilities



Continuous Assessment: Simplicity and Moderation



Continuous Assessment: After Action Review



External Audits

- Eating the elephant one bite at a time works the same for external audits.
- Self audit using same checklists inspectors will use
 - » Ensures fixes done ahead of time
 - » Tab documents to show where requirements are addressed
 - » Research & support staff more at ease
 - » Makes inspectors' jobs easier
 - » No surprises in inspection report



Value Added Audits

- True value of audits is how you use the collected data.
 - » Does it increase awareness and accountability?
 - » Does it increase healthy communication?
 - » Does it promote change?
 - » Is the targeted change sustainable?
 - » Does it make you safer?

