Preparing for Regulatory Inspections. It isn’t a question of if, but when.
Office of Research Compliance

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The opinions expressed are those of the presenters and may not necessarily reflect Montana State University.
Regulatory Oversight and Inspections

Examples of Regulatory Oversight:

2021 MSU Inspections:

- 2 CDC Inspections for Select Agent Program
- 1 CDC Inspection for imported material work
- 1 NRC Inspection for Radiation program
- 1 USDA inspections for Animal Care & Use Program
Office of Research Compliance Areas

- Biosafety
- Radiation Safety
- Animal Care and Use
- Human Subject Research
Overall Inspection and Program Philosophy

- Inspection
- Preparing for Inspections
- Building Relationships
- Building Programs
Inspection Ready – Building Programs

- Know the Regs
- Trust your Subject Matter Expert and Team
- Be Two Deep
Create a Rhythm
User Friendly Policies
Does it Add Value?
Listen to Your Stakeholders
Building Relationships

- Build staff, laboratorian, PI relationships
- If possible, develop a relationship with inspectors/agencies
- Attend the agency webinars and training
- Ask for guidance
- If required, self-report
Preparing for Inspections

- Conduct self inspections
- Ask inspectors for a pre-inspection meeting
- Appoint a point person and secondary personnel to assist during the inspection
- Communicate inspection with upper administration
During the Inspection

- Have records easily available for inspectors
- Provide requested documents in a timely manner
- Only answer the question
During the Inspection

- If you don’t know, just say you don’t know
- Be available for communication
- Provide information
Post Inspection Wrap Up

- If you need to, push back on a finding interpretation
- Respond to findings
- Conduct self-analysis
- Communicate
Thank You!

Questions?

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