Framework for Institutional Review of Potential DURC

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Creation of Current UW IRE

• Collaboration
  • Office of the Vice Chancellor for Research and Graduate Education
  • IBC Chair
  • Select Agent Program

• Key Questions
  • Who is the best fit for ICDUR?
  • What is the appropriate composition for the IRE?
  • Are checks and balances warranted?
  • Which policies need to be developed?
  • Who will be affected by the policy?
  • Should UW-Madison limit the review to the 15 agents?
  • What type of training should be developed? Frequency?
UW-Madison IRE

- Permanent Subcommittee of IBC
  - Chair- ICDUR (Biosafety, biosecurity, and regulatory)
  - Bacteriology
  - Virology
  - Immunology
  - Infectious Disease
  - Public Health
  - Consultants as needed

- Additional Review of DURC Reports
  - IBC
  - Biosecurity Task Force
Percentage of Life Sciences Research

Percent of PIs
- Potential DURC, 1.9
- Non-DURC, 98.1

Percent of Research Portfolio
- Potential DURC, 2.4
- Non-DURC, 97.6
### How Much Effort for 2.4%?

<table>
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<th>Material</th>
<th>Not DURC</th>
<th>DUR</th>
<th>DURC</th>
<th>Total</th>
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<tr>
<td>Grants</td>
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<td>Manuscripts</td>
<td>7</td>
<td>3</td>
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<td>Experiments/Assessment</td>
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<td>Risk mitigation plans</td>
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</table>
Ensuring Compliance

• Good rapport with PIs
• Biosafety protocols
• Animal protocols
• Grant administrators

• Challenges
  • Exempt quantities of botulinum toxin
  • Trusting PIs to report any research changes
Effects of DURC Policies

• Administrative
  • Another unfunded research mandate
  • Time and effort of ICDUR and IRE
  • Create and maintain training

• Research Progress
  • Less research with exempt quantities of botulinum neurotoxin
  • Other research not being performed
  • Delays
Lessons Learned

• IRE
  • Composition
  • Meeting style
  • Evolution of thought process
  • Willingness to ask for information to be included or moved

• Flexibility is key
  • Unplanned reviews
  • Progress report reviews
  • Contract expectations for subcontractors

• DUR designation is very useful
• Not all PIs want to deal with research being scrutinized