



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

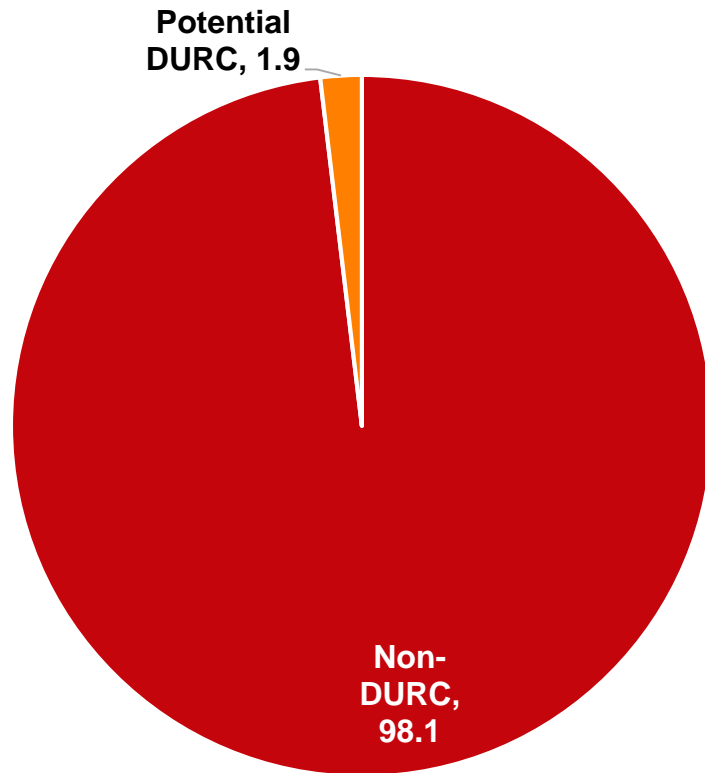
- Permanent Subcommittee of IBC
 - Chair- ICDUR (Biosafety, biosecurity, and regulatory)
 - Bacteriology
 - Virology
 - Immunology
 - Infectious Disease
 - Public Health
 - Consultants as needed

- Additional Review of DURC Reports
 - IBC
 - Biosecurity Task Force

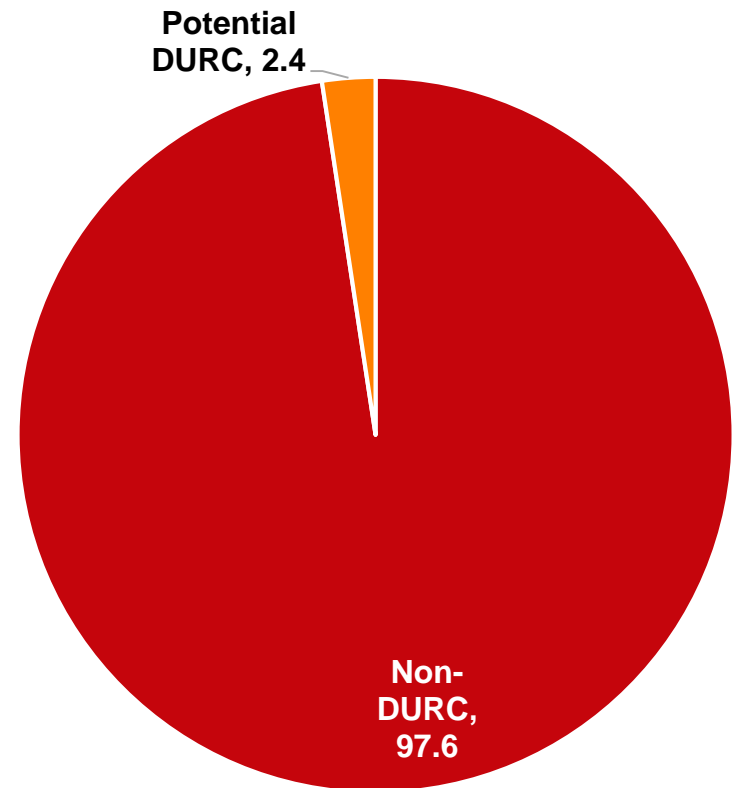


Percentage of Life Sciences Research

Percent of PIs



Percent of Research Portfolio



How Much Effort for 2.4%?

| Material | Not DURC | DUR | DURC | Total |
|------------------------|----------|-----|------|-------|
| Grants | 1 | 3 | 8 | 12 |
| Manuscripts | 7 | 3 | 12 | 22 |
| Experiments/Assessment | 9 | 1 | 2 | 12 |
| Risk mitigation plans | N/A | N/A | N/A | 6 |

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

