

Establishing an Institutional Framework for Governance of Dual Use Research of Concern and an Institutional Review Entity

Texas A&M University



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Background

- DURC was not new to the institution
 - 2007 - NSABB *Proposed Framework for the Oversight of Dual Use Life Sciences Research*
 - 2010 - Video *Dual Use Research: A Dialogue*
 - 2012 - USG *Policy for Oversight of Life Sciences Dual Use Research of Concern*
 - 2014 - USG *Policy for Institutional Oversight of Life Sciences Dual use Research of Concern*



Background

- DURC was not new to the institution
 - Associate Vice President for Research
 - Biological Safety Officer \ Responsible Official
 - Institutional Biosafety Committee



Background

- The *Policy for Institutional DURC Oversight* requires that institutions:
 - Have policies and practices in place that enable PIs to identify and refer to an IRE any life sciences research that requires institutional review.
 - Establish and implement policies and practices in place for institutional review and oversight of research.



Policy Development

- Division of Research
 - Associate Vice President for Research
 - Director Office of Biosafety \ Biological Safety Officer \ Responsible Official
- Period of several months
- As part of scheduled update of university rule for use of biohazards



Policy Development

- Questions to address
 - Who would “own” DURC within Texas A&M University?
 - What about Texas A&M System members using Texas A&M IBC?
 - Institutional Review Entity (IRE)
 - New or
 - Extant committee, such as an institutional biosafety committee (IBC);
 - Scope



Policy Development

- Questions to Address
 - Training - Audience
 - Institutional Review Entity Members
 - Institutional Biosafety Committee
 - Principal Investigator
 - Training - Type
 - Initial
 - Ongoing



Outcome

- Revised Rule included DURC
 - Vice President for Research (VPR) is “owner”
 - ICDUR is VPR or designee
 - IBC shall serve as IRE
 - All System members served by A&M’s IBC also use Texas A&M’s DURC program as applicable



Outcome

- All PIs are made aware of DURC
 - DURC training incorporated into *NIH Guidelines* Training (required of ALL PIs)
 - Seven listed experimental effects are asked of ALL PIs on IBC application



Outcome

- Time and effort to revise rule due to required rule review process
- Time and effort to write procedures
- Time and effort to train IRE (IBC)



Outcome

- Very small actual impact due to use of only one agent at this time. Expect this to grow with time.

