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

Texas A&M University

Bruce Whitney, Ph.D.
Chief Research Compliance Officer
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
• 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.