Johns Hopkins University
Institutional IRE/DURC Policy
Implementation

Andrew Pekosz, PhD
Professor of Molecular Microbiology and Immunology
IRE member

Johns Hopkins Bloomberg School of Public Health
JHU IRE composition

• JHU Entities involved in identifying DURC/IRE
  • Institutional Biosafety Committee (IBC)
    • Biosafety protocols
  • Institutional Animal Care and Use Committee (IACUC)
    • Animal experiment protocols
  • Institutional Review Board (IRB)
  • Offices of Research Administration
    • Grants Admin: Biosafety concerns with new grant applications
    • MTA/Tech Transfer Office: Material Transfer Agreements

• IRE expertise is augmented by members from:
  • JHU General Counsel Office
  • Microbiology/Molecular Biology focused faculty
  • University Leadership
JHU IRE current members

- **ICDUR, IBC, IACUC**
  - Stephen Dahl, PhD, Institutional Biosafety Officer

- **JHU Research Administration**
  - Michael Amey – Associate Dean for Research Administration
  - Frank Barker - Import/Export Control Officer

- **JHU General Counsel**
  - Stefanie Gregory, JD – Assistant General Counsel

- **JHU Faculty**
  - Andrew Pekosz, PhD – Professor of Microbiology
  - Alan Scott, PhD – Director of Genomics Resources Center, Associate Professor of Medicine (IBC)

- **JHU Leadership**
  - Denis Wirtz, PhD – Vice Provost for Research
  - Jonathan Links, PhD – Vice Provost/Chief Risk Officer
JHU IRE Review Procedure

• JHU IRE policies are posted in the Health Safety and Environment website
  • http://www.hopkinsmedicine.org/hse/ire/index.html

• The committee meets whenever research is identified that involves one of the 15 agents or toxins listed in the US Government DURC policy and no less than annually
  • Reminder of the committee’s purpose
  • Review of criteria involving DURC/IRE concerns

• PIs are expected to alert the ICDUR of research with DURC potential

• IBC, IRB, IACUC and Office of Research Administration also may refer potential DURC/IRE to ICDUR identified through their review processes

• Meeting procedure:
  • PIs submit assessment of whether research involving one of the 15 agents or toxins produces, aims to produce, or is reasonably anticipated to produce one of the 7 effects identified by the US Government as having dual use potential.
  • DURC/IRE assessment is distributed to the JHU IRE committee
  • JHU IRE committee reviews, discusses, and votes as to whether the research contains
    • No DURC/IRE concerns
    • DURC/IRE concerns (formal, in person meeting is arranged)
    • More information or discussion needed (formal, in person meeting is arranged)
JHU IRE Reviews

• The committee has averaged 1 – 3 cases per year
• All decisions have been unanimous
  • All DURC/IRE cases have involved toxins available from commercial sources
  • No DURC/IRE concerns have been identified
  • No further action has been needed
  • Annual updates from investigators whose research was flagged as potentially DURC/IRE is required
• The committee has not, to date, been challenged with any true DURC/IRE research