

Johns Hopkins University
Institutional IRE/DURC Policy
Implementation

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IRE member

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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

