

## USG POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DURC:

### POINTS TO CONSIDER WHEN USING AN IBC AS AN IRE

On September 24, 2014, the United States Government (USG) issued its [Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern \(DURC\)](#). The Policy addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. Institutional oversight of DURC is a critical component of a comprehensive oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication of DURC.

One of the primary responsibilities of an institution under the Policy is to establish an Institutional Review Entity (IRE) responsible for reviewing research subject to the scope of the Policy. Since many of the institutions that will be subject to the Policy already have an established Institutional Biosafety Committee (IBC), there is a possibility that some institutions will use their IBC to also act as their IRE. While it is acceptable to have an IBC assume IRE responsibilities, institutions should consider the following points when using this oversight model.

- While the IBC might act in the capacity of an IRE, the committee performing DURC review should be referenced as the IRE, since each committee has a different charge and a unique set of responsibilities.
- The IBC and IRE, as separate review bodies, should be governed by separate policies and procedures. Many requirements for an IBC (e.g. inclusion of unaffiliated members, encouraging open meetings, release of meeting minutes) will not be applicable to an IRE. Institutions should develop policies and procedures specific to the IRE's operation.
- While the IBC must provide certain documentation to the public upon request, such as the minutes from its meetings and any documents submitted to or received from funding agencies, the IRE is required to only publicly provide information pertaining to the review process for research subject to the Policy.
- In many cases, IBC members will have the scientific and technical expertise required to serve on an IRE. However, the composition of the IRE may have to be augmented with additional *ad hoc* members to ensure that the IRE has sufficient breadth of expertise to assess the dual use potential of the research being contemplated.
- An IRE meeting should be held separately from an IBC meeting. While IRE and IBC meetings may be held sequentially, the two committees should be treated as distinct entities.

- Minutes from IRE meetings should remain separate from minutes of IBC meetings to eliminate the need to redact IRE specific information from IBC minutes if the latter are requested by a member of the public.

Additional information about the Policy, and DURC in general, can be found on the Department of Health and Human Services' [S3: Science, Safety, and Security](#) webpage. Another valuable resource that institutions may find helpful as they constitute their IREs is the [Companion Guide](#) to the Policy, which provides guidance on identifying and assessing potential DURC, developing risk mitigation plans, and responsibly communicating DURC. Questions about the Policy, or suggestions for additional resources that the USG might develop, may be sent to [DURC@ostp.gov](mailto:DURC@ostp.gov).