

# **Institutional Dual Use Research of Concern Committee (IDURCC) ByLaws**

## **Introduction**

The United States Government (*USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (Policy for Institutional DURC Oversight)*) requirements related to the institutional review of life sciences research that meets the scope of the Policy, requires the establishment of an Institutional Review Entity.

## **Authority of the Institutional Review Entity (IRE)**

University of Louisville (UofL) has established an Institutional Dual Use Research of Concern Committee (IDURCC) to serve as the Institutional Review Entity under this Policy. The IDURCC shall implement and fulfill the requirement for institutional review and oversight requirements of the *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (Policy for Institutional DURC Oversight)* for research for DURC potential.

The committee is qualified through the experience and expertise of its members to ensure compliance and accountability of dual use research at UofL with the September 24, 2014 *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (Policy for Institutional DURC Oversight)*.

All members of the IDURCC are appointed by the President of UofL. The UofL IDURCC meets the compositional requirements set forth in the Policy.

## **Requirements for Institutional Dual Use Research of Concern Committee (IDURCC)**

- Be composed of at least five members;
- Be sufficiently empowered by the University to ensure it can execute the relevant requirements in the section on **Responsibilities of U.S. Government (USG)-Funded Research Institutions**;
- Have sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at the University;
- Include persons with knowledge of relevant USG policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity.
- The review entity may also include, or have available as consultants, at least one person knowledgeable in the institution's commitments, policies, and standard operating procedures;
- On a case-by-case basis, recuse any member of an IDURCC who is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the IDURCC; and
- Engage in an ongoing dialogue with the PI of the research in question when conducting a risk assessment and developing a risk mitigation plan.

## **Institutional Contact for Dual Use Research (ICDUR)**

The Policy requires that an individual serve as the Institutional Contact for Dual Use Research (ICDUR).

The University has named the Administrator for the IDURCC as the ICDUR. The Administrator will be the Biosafety Officer of the University. The function of the ICDUR is to receive information on the use of specified toxins and agents at the University and facilitate the review and communication of this information by the IDURCC to verify compliance with applicable USG policies. In addition, the ICDUR is a resource to the faculty seeking advice on regulatory and dual use research issues. The ICDUR is available to assist investigators in maintaining compliance with federal regulations, granting agency requirements, and institutional policies. See the IDURCC Contacts for a complete listing of contact information.

## **Membership**

### **Introduction**

This topic discusses who appoints members of the IDURCC, their term of service, and duties while on the committee.

### **Appointment**

The **Executive Vice President for Research and Innovation** in conjunction with the ICDUR and the Chair of the IBC will select and appoint members to the IDURCC.

### **Term**

Each appointed member of the IDURCC serves a regular term of one year. Any member's term may be extended for an additional one year term without limitation. At the expiration of an IDURCC member's term of office, the IDURCC Chair recommends re-appointment of the member.

### **Committee composition and qualifications**

- Be composed of at least five voting members;
- Be sufficiently empowered by the University to ensure it can execute the relevant requirements in the section on **Responsibilities of USG-Funded Research Institutions**;
- Have sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at the University;
- Include persons with knowledge of relevant USG policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity; and,

- The IDURCC may also include at least one person knowledgeable in the institution's commitments, policies, and standard operating procedures.

### **Chair and Vice Chair**

A Chair of the committee will be appointed, as well as Vice-Chair(s), if needed.

### **Consultant members**

At its discretion, when the IDURCC does not feel it has the scientific or scholarly expertise required among its members to review a protocol, the IDURCC may recruit (non-voting) consultants and are appointed by the DURC Chair.

### **Duties of members**

Members are expected to meet these requirements:

- Have knowledge of dual use issues and policies and understand risk assessment and risk management;
- Remain impartial and objective in their reviews;
- Vote on research proposals to determine if they meet criteria for dual use research of concern;
- Work with the appropriate government entity to draft and approve a risk mitigation plan when necessary;
- Attend IDURCC meetings on a regular basis;
- Serve as primary reviewers for research as assigned;
- Serve as team reviewers for research as assigned; and,
- Participate in the discussion on all research discussed at fully convened meetings.

## **Meetings**

### **Introduction**

This topic discusses the frequency and conduct of fully convened meetings.

### **Frequency**

The IDURCC meets at least annually. Special meetings may be called with short notice at the discretion of the IDURCC Chair.

## **Quorum**

A meeting quorum consists of greater than fifty percent (>50%) of the regular IDRCC voting members.

## **Conduct of meetings**

IDURCC meetings are led and directed by the IDURCC Chair. The Chair presides over the meeting: directing the agenda, voting, and ensuring adherence to policies and procedures. An IDURCC member designated by the IDURCC Chair presides over meetings on occasions when the IDURCC Chair is unavailable for a meeting or is an investigator on a research project being reviewed or considered by the IDURCC. The designated IDURCC member assumes all duties and responsibilities of the IDURCC Chair in the event of the IDURCC Chair's inability to serve.

## **Conflicts of interest in review**

Any member of the IDURCC who is involved in the research project in question under review or has a direct financial interest should both recuse and absent themselves from discussions and determinations of the IDURCC, except to provide specific information requested by the IDURCC.

IDURCC members with potential conflict(s) of interest related to topics under discussion are excluded from the meeting for the duration of the discussion and vote of such topics.

## **Consultants**

At its discretion, when the IDURCC does not feel it has the scientific or scholarly expertise required among its members to review a protocol, the IDURCC may recruit (non-voting) consultants. The IDURCC may invite these consultants with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available to the committee. Consultants, sometimes referred to as non-voting or *ex officio* members, may be present at the meeting or submit a written report to aid the IDURCC in conducting its duties, however, these individuals may not vote with the IDURCC.

## **Non-IDURCC member attendance**

Attendance of non-IDURCC members, including investigators, requires prior approval by the Chair.

Investigators may not participate in a convened discussion of the IDURCC except by invited attendance by the Chair to provide information to the IDURCC.

## **Subcommittees**

Subcommittees may be formed by the IDURCC when the need arises for the conduct of reviews. However, the fully convened committee shall conduct final reviews and determinations required by the Policy.

## **Minutes**

Meeting minutes serve as IDURCC records of proceedings and application/protocol review. Minutes must be in sufficient detail to show:

- Attendance at the meetings;
- Actions taken by the IDURCC;
- Results of every vote taken on these actions, including members voting for, against, and abstaining;
- Any recusals of members for conflicts of interest;
- Summary of the discussion of issues and their resolution

Minutes of the IDURCC meetings are reviewed and approved by the IDURCC and are then filed with the ICDUR. Minutes are made available for review to the Institutional Official. Minutes are also made available to other authorized University personnel and any federal research oversight agency upon request.

## **Recordkeeping**

### **Responsibility**

The IDURCC through the ICDUR is responsible for maintaining the following records:

- Minutes of IDURCC meetings;
- Documentation of applications/protocols reviewed by the IDURCC
- Risk assessments and risk mitigation plans, as part of the IDURCC application/proposal including research personnel training

### **Availability**

All records of the IDURCC must be available for inspection and copying by authorized representatives of:

- National Institutes of Health (NIH);
- Department of Health and Human Services (DHHS);
- National Science Advisory Board for Biosecurity (NSABB) officials;

- any additional federal research oversight agency; and,
- UofL, such as but not limited to, the responsible institutional official.

### **Retention**

The IDURCC will maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.