Icahn School of Medicine at Mount Sinai

Institutional Dual Use Compliance Committee

Committee Description

1. Composition

The committee will consist of a Chair, the Biosafety Officer, and at least three additional faculty members of diverse backgrounds who have the professional competence to assess Dual Use Research of Concern ("DURC") conducted at Mount Sinai Health System facilities. Additional members may be identified at the discretion of the Committee Chair.

2. Appointments

The chairperson and four faculty members of this committee will be appointed by the Dean of Basic Sciences. Both the Chair and members will be appointed to a renewable term of three years.

3. Charge to Institutional Dual Use Compliance Committee (IDUCC):

This committee is mandated by US Government ("USG") Policy ("the Policy") to ensure that regulation-relevant research is identified at the institutional level and risk mitigation measures are implemented as necessary.

Committee responsibilities under this Policy are to:

a. Establish and implement institutional policies and practices for the identification and effective oversight of research that falls under the Policy.
b. Review research that may qualify for oversight under the Policy and notify USG agencies as required.
c. Develop risk mitigation plans for projects that qualify for USG oversight under the Policy and submit to USG agencies as required.
d. Oversee compliance with risk mitigation plans.
e. Report instances of noncompliance with the Policy, as well as mitigation measures undertaken by Mount Sinai Health System to prevent recurrences of similar noncompliance, within 30 calendar days to federal agencies as required.
f. Provide oversight of education and training for individuals conducting DURC.
g. Certify that Mount Sinai Health System is in compliance with all aspects of the Policy when applying for or accepting US Government funds for DURC.
h. Designate an Institutional Contact to respond to questions regarding compliance and oversight.
i. Maintain records of committee reviews and finalized risk mitigation plans, for the term of the research grant or contract plus three years after its completion, but no fewer than eight years, unless a shorter period is required by law or regulation.
j. To the extent provided in the Policy, make information about the review process available upon request as consistent with applicable law.

Responsibilities of Investigators

In accordance with Policy, a Principal Investigator ("PI") seeking/approved to conduct DURC for a project ("the Project") must:

a. Notify the Institutional Dual Use Compliance Committee ("the Committee") if he or she believes that:
    i. The research involves any of the following agents or toxins:
        1. Avian influenza virus (highly pathogenic)
        2. *Bacillus anthracis*
        3. Botulinum neurotoxin (any quantity)
        4. *Burkholderia mallei*
        5. *Burkholderia pseudomallei*
        6. Ebola virus
        7. Foot-and-mouth disease virus
        8. *Francisella tularensis*
        9. Marburg virus
        10. Reconstructed 1918 Influenza virus
        11. Rinderpest virus
        12. Toxin-producing strains of *Clostridium botulinum*
        13. Variola major virus
        14. Variola minor virus
        15. Yersinia pestis
    ii. And/or the research will produce, aims to produce, or can be reasonably anticipated to produce one or more of the following effects:
        1. Enhances the harmful consequences of the agent or toxin
        2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
        3. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
        4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
        5. Alters the host range or tropism of the agent or toxin
        6. Enhances the susceptibility of a host population to the agent or toxin
        7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above
b. Provide the Committee with the required documentation and other information requested for review of the Project.
c. For projects determined by the Committee to qualify for oversight under the Policy:
    i. Conduct Project in accordance with the approved risk mitigation plan
    ii. Comply with all institutional and USG policies and requirements for oversight of DURC.
    iii. Ensure that lab personnel have received education and training on DURC.
    iv. Communicate research and findings in a responsible manner in compliance with the approved risk mitigation plan.

Responsibilities of the Committee

In accordance with Policy, the Institutional Dual Use Compliance Committee ("the Committee") must:

a. Verify whether a research Project ("the Project") identified by a Principal Investigator ("PI") utilizes one or more of the agents listed below:
    a. Avian influenza virus (highly pathogenic)
    b. *Bacillus anthracis*
    c. Botulinum neurotoxin (any quantity)
    d. *Burkholderia mallei*
    e. *Burkholderia pseudomallei*
    f. Ebola virus
    g. Foot-and-mouth disease virus
    h. *Francisella tularensis*
    i. Marburg virus
    j. Reconstructed 1918 Influenza virus
    k. Rinderpest virus
    l. Toxin-producing strains of *Clostridium botulinum*
    m. Variola major virus
    n. Variola minor virus
    o. Yersinia pestis
b. Review the PI's assessment of whether the Project produces, aims to produce, or is reasonably anticipated produce one of the below effects:
    a. Enhances the harmful consequences of the agent or toxin
    b. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
    c. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
    d. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
    e. Alters the host range or tropism of the agent or toxin
    f. Enhances the susceptibility of a host population to the agent or toxin
    g. Generates or reconstitutes an eradicated or extinct agent or toxin listed above
c. Determine, based on the above, whether the research meets the definition of DURC in accordance with the Policy.
d. Notify within 30 calendar days the appropriate USG agency/agencies of whether the proposed research is determined to meet the definition of DURC.
e. Identify the anticipated benefits and risks of the Project.
f. Develop a draft risk mitigation plan and submit it to USG agencies within 30 calendar days of the committee's determination that the research meets the definition of DURC. In accordance with the Policy, the USG will provide an initial response within 30 calendar days of receipt of the draft plan, and final approval will be given within 60 calendar days.
g. Collaborate with the appropriate USG agency to complete the draft within 90 calendar days of the Committee's determination.
h. Implement approved risk mitigation plans
i. Provide ongoing oversight of approved DURC projects.
j. Perform an annual review of all active risk mitigation plans and modify as necessary. Notify USG agencies of any changes either to risk mitigation plans or to the status of approved projects.