Icahn School of Medicine at Mount Sinai

CHARTER

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

1. The Icahn School of Medicine at Mount Sinai (ISMMS) will maintain an Institutional Biosafety Committee (IBC) consistent with the National Institutes of Health (NIH) Guidelines published in the Federal Register, July 5, 1994 (59 FR 34496) and its most recently published amendment. In compliance with the *NIH Guidelines*, the IBC was established specifically to review research involving recombinant or synthetic nucleic acid molecules for conformity with the *NIH Guidelines*.

2. Membership of the committee will consist of no fewer than five individuals with experience and expertise in recombinant DNA (rDNA) technology, pathogens, and other biosafety concerns. At least one member shall not be affiliated with the ISMMS. At least one member shall have expertise in animal containment principles and one member shall be a Biological Safety Officer.

3. Meetings of the IBC will be held at a minimum on a quarterly basis per calendar year. Additional meetings may be called at the discretion of the Chairperson. A quorum of five IBC Members including at least one Non-institutional member will be required to review activities and approve protocols.

4. The responsibilities of the IBC include, but are not limited to the following:

    a. Review research conducted at ISMMS involving rDNA, blood borne pathogens, oncogene, xenotransplantation, stem cell, select agents and toxins, nanotechnology, and toxic chemicals; or “Dual Use” research conducted at ISMMS. These reviews shall include:

        i. Independent assessment of containment levels.

        ii. Review of adequacy of facilities, Standard Operating Procedures (SOPs), and training of PI and lab personnel for research involving significant biohazards.

        iii. Verification and assignment of the classification of the rDNA research in accordance with the *NIH Guidelines*.

    b. Notify the Principal Investigator of the results of the IBC review and approval/non-approval.

    c. Set appropriate containment levels for experiments as specified in the most recent edition of the *NIH Guidelines.*

d. Provide for the adjustment of containment levels for certain experiments as specified in the *NIH Guidelines* and CDC/NIH Biosafety in Microbiological and Medical Laboratories (*BMBL*, latest edition).

e. Conduct periodic reviews of rDNA, pathogen, oncogene, toxin and toxic chemical research conducted at the ISMMS for compliance with the *NIH Guidelines* and CDC/NIH *BMBL.*

f. Review and approve emergency plans covering spills and personnel contamination from containment laboratories.

g. Report any significant problems with or violations of the *NIH Guidelines* and any significant research-related incidents or illnesses to the appropriate institutional official and the NIH within 30 days (*NIH OBA Incident Reporting Template*).

h. Provide an open forum for the discussion of biosafety concerns and assist in the resolution of any biosafety issues brought before the committee.

i. Provide training for members of the committee.

5. Subcommittees may be established by the Chairperson in order to review and resolve a variety of biosafety issues. Examples of these subcommittees are the Recombinant DNA Technical Review Subcommittee, the Pathogen Technical Review Subcommittee, and the Dual Use Research of Concern (DURC) Subcommittee. Meetings of the subcommittees can be arranged at the discretion of the members. The Chair of the committee will update the committee regularly on relevant issues.

6. Investigators must notify the IBC Chair and the Grants and Contracts Office in writing of any adverse event within 24 hours of the event and document the event in an annual report.

7. Any research-related accident (i.e. exposure /needlestick/illness that is related to rDNA activity) must be reported in writing to the Biosafety Officer.

8. The Committee will review and assist in the development of training materials, including on-line exercises, for investigators. The Committee will review and assist in the development of more extensive training material for those who must access the BSL-3+ facility.

9. References:

    a. NIH Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*; current edition).

    b. CDC-NIH Biosafety in Microbiological and Biomedical Laboratories (*BMBL*; current edition).

    c. NIH Institutional Biosafety Committees; Template for Reporting Incidents Related to Research Subject to the *NIH Guidelines* for Research Involving Recombinant or Synthetic Nucleic Acids to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) (*NIH OBA Incident Reporting Template*)

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Approved: