June 5, 2025

COLUMBIA UNIVERSITY
INSTITUTIONAL BIOLOGICAL RESEARCH ACTIVITIES COMMITTEE

CHARGE, BY LAWS AND PROCEDURES

I. Charge

The Columbia University (**Columbia** or the **University)** Institutional Biological Research Activities Committee **(IBRAC** or the **Committee)** is charged with the responsibilities described in Section III below in connection with:

- Oversight of the University's policies and procedures with respect to research using infectious materials and other potentially dangerous biological agents;
- Compliance with the May 5th 2025 Executive Order on Dangerous Gain of Function research

The Institutional Biosafety Committee (**IBC**) shall be responsible for review of research that is subject to the National Institute of Health (**NIH**) Office of Science Policy (**OSP**) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (**rDNA**).

Certain capitalized terms used in the IBRAC Governing Document are defined in Section II below.

II. Definitions

Appendix A: Columbia University Hazardous Materials Appendix A.

BMBL: Biosafety in Microbiological and Biomedical Laboratories 6th ed. CDC advisory document recommending best practices for the safe conduct of work in biomedical and clinical laboratories.

DURC: Dual Use Research of Concern; Dual Use Research of Concern ("DURC") is a subset of Dual Use Research and is defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be misapplied to do harm with no, or only minor, modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

EVPR: as defined in Section III(B).

EVPR Designee: as defined in Section V(C).

GOF: Gain-of-Function research genetically alters an organism in a way that may enhance the biological functions of gene products.

IBC: Institutional Biosafety Committee

IBRAC Governing Document: this Charge, By Laws and Procedures

Infectious Materials: Substances that contain or are reasonably suspected to contain microorganisms, such as bacteria, viruses, or parasites, which can cause disease in humans or animals.

IRE: as defined in Section III(B).

NIH: as defined in Section I.

OSP: as defined in Section I.

PI: Principal Investigator

Protocol: any research project, as applicable, including: the Columbia University Human Subjects Protocol Data Sheet, the Columbia University Animal Care Protocol Data Sheet, Appendix A, and any supplementary materials relating to such study.

rDNA: as defined in Section 1.

USG: United States Government

III. IBRAC Responsibilities

A. Infectious Materials

The IBRAC shall be responsible for the following in connection with research involving infectious agents and other potentially infectious biological agents such as clinical specimens and research animals (**Infectious Materials)**:

- Reviewing such research, including studies using cultured agents required to be handled at Biosafety Level 2 (**BSL-2)** and above, or agents of public health concern, such as SARS-CoV-2; Reviewing research with biological materials, if a risk assessment by the biosafety office identifies the potential for infectious agents of concern or their biologically active products to be produced during culture of the material.
- Reviewing Protocols for such research;
- Notifying the applicable PI of any IBRAC determination;
- Reviewing and advising on policies and procedures proposed by Environmental Health & Safety (**EH&S)** or other University departments directed to mitigating exposure to Infectious Materials; and
- Maintaining biosecurity and adhering to applicable regulations and standards, including Biosafety in Microbiology and Biomedical Laboratories (**BMBL**) of the Centers for Disease Control and Prevention (**CDC**), the Federal Select Agent Program regulations., and the OSHA Bloodborne Pathogen Standard.

B. Dangerous Gain of Function (GOF) Research that is not subject to the NIH Guidelines

At Columbia, the institutional review of Dangerous GOF Research is performed by three committee components: (1) the **IBRAC**, or (2) the **IBC** and (3) the Institutional Review Entity (**IRE**), an "ad hoc Committee" established by the Columbia Executive Vice President for Research ("**EVPR**").

The IBRAC shall be responsible for the following in connection with Dangerous GOF Research that is not subject to the National Institute of Health (NIH) Office of Science Policy (OSP) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (rDNA) (the NIH Guidelines):

The IBRAC will review research utilizing the definitions of Dangerous GOF in Sec. 8 of the May 5th 2025 Executive Order:

- https://www.whitehouse.gov/fact-sheets/2025/05/fact-sheet-president-donald-j-trump-achieves-improved-safety-and-security-of-biological-research/
- https://www.whitehouse.gov/presidential-actions/2025/05/improving-the-safety-and-security-of-biological-research/

If the IBRAC concludes that the research does meet the definition of Dangerous GOF, the committee will refer the review to the **EVPR** for higher level review by the **IRE** (and notify the **PI** that it has done so). The IRE is responsible for any risk-benefit analysis, risk mitigation and communication plans associated with Dual Use Research of Concern (**DURC**). If the IBRAC concludes that the research does not meet the definition of dangerous GOF and is not subject to additional IRE oversight, it will so notify the PI in writing.

IV. Biosafety Officer Responsibilities

A. Review of Research Studies

The Biosafety Officers (each, a **BSO)** shall be responsible for:

- Reviewing Protocols of all research studies described in Section III above prior to submission of the Protocol to the IBRAC:
- Supporting and enhancing systems that allow for the submission of Protocols to the IBRAC.
- Reviewing containment levels for any proposed research activity as required by the NIH, CDC, USDA, or the U.S. Occupational Safety and Health Administration.
- Assessing personnel training, practices, procedures and laboratory facilities for the proposed research.

B. Training

The BSOs shall be responsible for:

- Training IBRAC members to ensure that the necessary expertise is maintained;

- Periodically reviewing the Biosafety in Microbiology and Biomedical Laboratories (**BMBL**) of the Centers for Disease Control and Prevention (**CDC**), the Federal Select Agent Program regulations., and the OSHA Bloodborne Pathogen Standard, and other relevant regulations to ensure that updates are incorporated into IBRAC practices and recommendations

C. Reporting

The BSOs shall be responsible for:

- Reviewing this IBRAC Governing Document for adjustments or amendments no less than annually or upon request by any voting member of the IBRAC.

V. Bylaws

A. IBRAC Membership

All members shall meet the qualifications set forth in Section B below.

B. Member Qualifications

The membership of the IBRAC shall consist of faculty members and administrative officials of the University with relevant knowledge of, and interest in, microbiology, epidemiology, infection control, regulatory compliance and research facility design. The membership must include the following individuals:

1. At least three individuals who collectively have experience and expertise in microbiology or infection control and the capability to assess the safety of infectious agent research and to identify any potential risk to public health or the environment;
2. At least two individuals who are not affiliated with the institution and who represent the interest of the surrounding community with respect to health and protection of the environment;
3. At least one scientist with expertise in animal containment principles;
4. The EH&S Director for Biosafety; and
5. At least one BSO.

C. Alternate Members

Any member of the IBRAC may request that an alternate be appointed to take his/her place at meetings to permit more consistent participation and representation on the IBRAC. Such appointment must meet the following conditions:

1. The alternate member shall be appointed by the EVPR or his/her duly qualified designee (**EVPR Designee),** formally added to the Committee roster and receive training as to his/her role and responsibilities as a member of the IBRAC;
2. If the alternate member is serving as such for an IBRAC member with special expertise, he/she must have sufficient expertise to fill that role, and the authority to speak and vote on behalf of the regular member;

3. The alternate may attend those meetings when the member for whom he/she is an alternate is present, but will not count towards a quorum or be able to vote; and
4. The alternate member must attend at least two meetings annually.

D. Appointment of Members

The members of the IBRAC shall be appointed by the EVPR or the EVPR Designee.

E. Chair

The Chair of the IBRAC shall be appointed by the EVPR or the EVPR Designee.

F. Recording Secretary

The Chair of the IBRAC shall appoint one of the BSOs as the Recording Secretary of the IBRAC.

G. Term

Each member of the IBRAC shall be appointed for a term of three years from the date of appointment, provided that the Chair of the IBRAC may recommend to the EVPR that the term of any member be extended for an additional three-year term. Subject to Section G below, a member may serve for successive three-year terms.

H. Resignation or Removal of Members

Any member may resign from the IBRAC by delivering a written notice of resignation to the EVPR or the EVPR Designee. The EVPR or the EVPR Designee may remove any member at any time and for any reason.

I. Meetings

Meetings of the Committee shall be held at least once a month. *Ad hoc* meetings may be held on at least three days' prior notice for urgent or time-sensitive issues.

Meetings may be held in person or by videoconference (e.g., Zoom, Ring Central). If any member is unable to be present at an in-person meeting, attendance may be accomplished by videoconference or teleconference.

J. Quorum

A quorum consisting of at least 50% of the members shall be present at all IBRAC meetings, including, whenever possible, the Chair. In the absence of the Chair, the Director for Biosafety shall chair the meeting.

K. Actions

Any action of the Committee may be taken if it is approved by a majority of the members at a duly convened meeting at which a quorum is present at the time of the vote.

L. Conflicts of Interest

Each member of the IBRAC must execute a Conflict of Interest and Confidentiality Statement in a form approved by the Committee that provides that a member must recuse him/herself from any meeting should any issue arise where his/her presence might pose a real or perceived conflict of interest,

M. Minutes

Minutes of each meeting of the Committee will be recorded by the Recording Secretary. The minutes will include:

1. The date and time of the meeting;
2. The members present and absent;
3. Whether the minutes of the previous meeting were approved;
4. A summary of deliberations and discussions;
5. Recommended actions and the numerical results of each vote; and
6. If an action is not taken by unanimous vote, any minority views.

VI. Procedures

A. IBRAC Approvals

The IBRAC must review (1) all newly submitted Protocols relating to research required by this IBRAC Governing Document, (2) all renewals of any such Protocol, and (3) any modification of any such Protocol that includes significant changes or additions to the Hazardous Materials Appendices, before approval is granted by a BSO in Rascal. The IBRAC must also review each Protocol (4) involving animals or human subjects triannually and (5) involving *in vitro* research triannually.

Protocols are approved by action of the IBRAC in accordance with Section V above. If a protocol does not receive approval, the Recording Secretary will direct any comments or requests for additional information to the PI. The IBRAC will determine if the Protocol must be resubmitted at the next meeting (**tabled)** for a re-vote, after the PI addresses any issues of concern or if the Recording Secretary may approve the Protocol on behalf of the IBRAC (**conditional approval).** If conditional approval of a Protocol is granted, the Recording Secretary or another BSO designated by the Recording Secretary may grant final approval once the conditions to approval are met by the PI, without further IBRAC or IBRAC Chair review.

B. BSO Approvals

1. Research Involving Infectious Materials

A BSO may grant preliminary administrative approval for Protocols in advance of an IBRAC meeting, provided that the PI agrees in writing that he/she will not begin work associated with Infectious Materials-related activities until final approval is given by the IBRAC.

Administrative approval is intended solely to permit administrative work relating to the research to begin (e.g., ordering of animals, animal breeding, grant writing, etc.)

A BSO may grant final approval for annual renewals or modifications of a Protocol submitted in advance of an IRB meeting, if the Protocol has previously been approved by the IBRAC and there are no changes to the Protocol involving the use of Infectious Materials. A BSO will provide a summary of such approvals at the next subsequent meeting of the IBRAC.

2. SARS-CoV-2 Research

In 2020, the University required institutional review of all research involving SARS-CoV-2 because of public health concerns. The IBRAC reviews all work where infectious SARS-CoV-2 is being handled in a laboratory (e.g., viral culture, processing of specimens from patients).

In his/her discretion, a BSO may approve research employing only inactivated viral material using an inactivation method approved by the IBRAC. Submission of an Appendix A is not required for this type of research; a written description of the inactivation method submitted to the BSO via email is adequate. If an Appendix A is submitted, it may be approved by a BSO without IBRAC review, provided that a summary report is presented to the IBRAC.

A BSO may review and approve procurement requests and Material Transfer Agreements for infectious SARS-Co-V-2 and full-length viral genomes that have the potential to recreate an infectious virus, provided that a summary report is presented to the IBRAC. The BSO may request that the PI submit an Appendix A describing the proposed research prior to approving the procurement request. Alternatively, the PI may attest that he/she will receive and store infectious SARS-CoV-2, but may not commence any active work until the IBRAC has reviewed and approved the research.

3. Emerging agents of public health concern

In the event of any future infectious disease outbreak, epidemic or pandemic, in order to protect the health and safety of the University and wider community, the IBRAC may review any associated research, including in vitro, in vivo or clinical studies. Such reviews may include, in addition to reviews of research studies to be conducted with such agent, reviews of requests for procurement of infectious materials, establishment of biocontainment levels, and evaluation of inactivation methods.