May 8, 2025

COLUMBIA UNIVERSITY
INSTITUTIONAL BIOSAFETY COMMITTEE

CHARGE, BY LAWS AND PROCEDURES

I. Charge

The Columbia University (**Columbia** or the **University)** Institutional Biosafety Committee **(IBC** or the **Committee)** is charged with the responsibilities described in Section III below in connection with:

- Compliance with 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);**
- Oversight of research involving human gene transfer (**HGT)**;
- Compliance with the May 5th 2025 Executive Order on Dangerous Gain of Function research
- Oversight of certain gene editing research.

Oversight of the University's research using infectious materials and other potentially dangerous biological agents that are exempt from the NIH guidelines is provided by the Institutional Biological Research Activities Committee (**IBRAC**).

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

II. Definitions

Appendix A: Columbia University Hazardous Materials Appendix A.

Appendix M: Columbia University Hazardous Materials Appendix M.

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..

DURC Policy: as defined in Section I.

EVPR: as defined in Section III(C).

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.

HGT: as defined in Section I.

HGT Expert: as defined in Section V(B).

IBC Governing Document: this Charge, By Laws and Procedures

IBRAC: Institutional Biological Research Activities Committee

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(C).

NIH: as defined in Section I.

NIH Guidelines: 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, Appendix M and any supplementary materials relating to such study.

rDNA: as defined in Section 1.

USG: United States Government

III. IBC Responsibilities

A. Research involving rDNA

The IBC shall be responsible for the following in connection with research involving rDNA:

- Reviewing Protocols for such research, including those with respect to experiments listed in Section III-A, B, C, D, E and F of the NIH Guidelines;
- Notifying the applicable PI of any IBC determination;
- Assessing containment levels required by the NIH Guidelines for the proposed research;

- Setting containment levels and modifying such levels for ongoing experiments as warranted;
- Assessing the facilities, procedures, practices and the training and expertise of personnel involved in rDNA research;
- For rDNA research involving human research participants, assessing the biosafety aspects of such research;
- Periodically reviewing rDNA research at the University to ensure compliance with the NIH Guidelines and other relevant regulations;
- Adopting emergency plans covering accidental spills and personnel contamination resulting from rDNA research;
- Reporting to the appropriate institutional official and the OSP any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses unless the IBC determines that a report has already been filed by the applicable PI; and
- Performing such other functions that are delegated to the IBC by the University.

B. HGT Research

The IBC shall be responsible for the following in connection with research involving HGT:

- Assessing the biosafety issues relating to such research (e.g., route and dose of administration, shedding);
- Reviewing Protocols for HGT research;
- Notifying the applicable PI of any IBC determination; and
- Generally overseeing such research until the last research subject has been administered the final dose of the product or such other end point determined by the IBC has been reached.

C. Dangerous Gain of Function (GOF) Research that is subject to the NIH Guidelines

At Columbia, the institutional review of Dangerous GOF Research is performed by three committee components: (1) the **IBC**, or (2) the **IBRAC** and (3) the Institutional Review Entity (**IRE**), an "ad hoc Committee" established by the Columbia Executive Vice President for Research ("**EVPR**"), which is responsible for any risk-benefit analysis, risk mitigation and communication plans associated with Dual Use Research of Concern (**DURC**).

The IBC shall be responsible for the following in connection with Dangerous GOF Research that is also 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 IBC 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 IBC 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). If the IBC 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.

D. Research Involving Gene Editing

In connection with research involving gene editing, the IBC shall be responsible for:

- Reviewing and approving, disapproving, or requiring modifications of any gene editing constructs introduced by Risk Group 2 (as defined in Section III-D and E of the NIH Guidelines) viral vectors such as lentiviral vectors whether *in vitro* or *in vivo,* including gene editing experiments in plant or invertebrate animals that are vectors of disease and gene editing in vertebrate animals and human subjects; and
- Reviewing and approving, disapproving, or requiring modifications of any experiments involving gene drives in any sexually reproducing organism, including animals (vertebrates and invertebrates), plants and fungi.

Note that IBC review is not required for any gene editing experiment that is exempt from the NIH Guidelines, including *in vitro* experiments in Risk Group 1 prokaryotes, eukaryotic cell lines or embryonic stem cells or embryos that are not implanted and experiments in invertebrates such as *D. melanogaster* or *C. elegans* (but excluding gene-drive experiments).

IV. Biosafety Officer Responsibilities

A. Review of Research Studies

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

- Reviewing Protocols of all research studies described in Section III above prior to submission of the Protocol to the IBC:
- Reviewing Protocols involving rDNA for compliance with the NIH Guidelines. Research that is subject the NIH Guidelines will be referred to the IBC. Research that is not subject to the NIH Guidelines will be referred to the IBRAC.
- Determining whether the research employs any of the DURC or PPP agents.
- Supporting and enhancing systems that allow for the submission of Protocols to the IBC.
- 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 IBC members to ensure that the necessary expertise is maintained;
- Periodically reviewing the NIH Guidelines and other relevant regulations to ensure that updates are incorporated into IBC practices and recommendations; and
- If necessary, on a quarterly basis, reserving time at an IBC meeting to provide in-house training to IBC members.

C. Reporting

The BSOs shall be responsible for:

- Providing the NIH on an annual basis a roster of the IBC members, together with their biographical sketches;
- Reporting to the OSP the following:

    - Any significant problem in any rDNA research study, any violation of the NIH Guidelines or any significant accident or illness relating to a rDNA study;
    - If rDNA research is conducted in a BSL-2 laboratory, any spill or accident resulting in an overt exposure to organisms containing rDNA molecules immediately upon notification from the applicable PI;
    - Any public comment received regarding rDNA activities or IBC affairs, and the IBC's response to such comments; and
    - With respect to HGT research, any serious adverse event that is unexpected and associated with the gene transfer product within 15 days or the if event is fatal or life threatening, within 7 days of notification from the applicable PI.

- Ensuring that all rDNA research involving human subjects is performed in compliance with Section III-C of the NIH Guidelines and that such research is not initiated until IBC and IRB approval have been granted; and
- Reviewing this IBC Governing Document for adjustments or amendments no less than annually or upon request by any voting member of the IBC.

V. Bylaws

A. IBC Membership

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

B. Member Qualifications

The membership of the IBC shall consist of faculty members and administrative officials of the University with relevant knowledge of, and interest in, molecular biology, epidemiology, infection control, regulatory compliance and research facility design. The membership must include the following individuals as provided in Section IV-B-2-a of the NIH Guidelines:

1. At least five individuals who collectively have experience and expertise in rDNA technology and the capability to assess the safety of rDNA 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. At least one scientist with expertise and training in HGT research (an **HGT Expert)**;
5. The EH&S Director for Biosafety; and
6. At least one BSO.

Although not required by Section IV-B-2-a of the NIH Guidelines, in order to ensure the competence necessary to review and approve rDNA activities, the NIH Guidelines recommend that the IBC (a) include persons with expertise in rDNA technology, biological safety and physical containment, (b) include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes and the environment, and (c) include at least one member representing the laboratory technical staff.

The NIH Office of Science Policy (OSP) will publicly post the rosters of all active IBCs registered with OSP via the IBC-Registration Management System (RMS). These rosters will include all members identified by name and role on the committee. In addition, NIH will be posting the contact information for the IBC Chair, Biological Safety Officer, and IBC Contact.

C. Alternate Members

Any member of the IBC may request that an alternate be appointed to take his/her place at meetings to permit more consistent participation and representation on the IBC. 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 IBC;
2. If the alternate member is serving as such for an IBC 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 IBC shall be appointed by the EVPR or the EVPR Designee.

E. Chair

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

F. Recording Secretary

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

G. Term

Each member of the IBC shall be appointed for a term of three years from the date of appointment, provided that the Chair of the IBC 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 IBC 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.

When possible and consistent with the protection of privacy and proprietary interests, the IBC meetings will be open to the public and any person may contact a BSO for information on meeting attendance.

J. Quorum

A quorum consisting of at least 50% of the members shall be present at all IBC 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 IBC 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.

Approved meeting minutes from all IBC meetings occurring on, or after 06/01/2025 will be posted publicly on an institutional website https://research.columbia.edu/ibc-meeting-minutes. Minutes will be posted immediately after approval and once all appropriate and allowable redactions have been made.

Section IV-B-2-a-(7) of the NIH Guidelines requires that IBC minutes and documents be made available to the public upon request. Minutes from meetings before 06/01/2025 do not need to be posted but still must be provided to members of the public upon request.

In reviewing all requests for IBC minutes or other documents, the University reserves the right to redact predefined information from the minutes or other documents due to privacy, security or proprietary concerns.
Information that will not be redacted includes:

- The IBC roster and biographical sketches of the members;
- The names of the PIs;
- The vectors, inserts, hosts and animal species employed;
- Details of any significant problems with, or violations of the NIH Guidelines; and
- Any significant rDNA accidents or illnesses.

Information that will be redacted includes:

- Private information, such as names of research staff other than the PIs, addresses, telephone numbers, email addresses, etc.);
- Proprietary information, information that could affect the conduct or outcome of research or the ability to patent or copyright the research or any related trade secrets or sponsor information;

- The location of biohazardous agents or toxins, or research animals, numbers of research animals employed, or any other information that might compromise the University or local or national security; and
- Any information relating to non-rDNA-related studies.

The IBC shall refer to or coordinate with the University's Office of the General Counsel and the Office of Communications and Public Affairs any requests that it receives from the public for IBC minutes or documents. The IBC will be notified of all such requests. The IBC members expertise in animal containment principles will be consulted concerning redactions of information on animals research. Before a public request is fulfilled, PIs identified in the minutes will be notified that a public request has been made and will be offered copies of the redacted minutes. All such requests shall be handled expeditiously.

VI. Procedures

A. IBC Approvals

The IBC must review (1) all newly submitted Protocols relating to research required by this IBC 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 IBC must also review each Protocol (4) involving *in vitro* research, animals or human subjects triannually (except HGT studies).

Protocols are approved by action of the IBC 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 IBC 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 IBC (**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 IBC or IBC Chair review.

B. BSO Approvals

1. Research Involving rDNA

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

are no changes to the Protocol involving the use of rDNA or Infectious Materials. A BSO will provide a summary of such approvals at the next subsequent meeting of the IBC.

2. HGT Research

For time sensitive proposals, an *ad hoc* meeting of the IBC can be convened to consider a Protocol involving HGT research so long as a HGT Expert is present at the meeting at which the Protocol is discussed or a BSO receives feedback from such Expert in advance of the meeting and such information is provided at the meeting.

A PI requesting approval of a HGT research study (a **HGT Study)** must submit to the IBC at least one week prior to the IBC meeting:

- The relevant IRB Protocol with an Appendix M attached;
- The relevant scientific abstract, which may be from the grant proposal or may be included in the Investigator's Brochure;
- A copy of the Investigator's Brochure; and
- The informed consent document that is or will be reviewed by the IRB.

A member of the IBC will present each HGT Study at the meeting, which presentation will include:

- The clinical trial phase of the project;
- The condition or disease being addressed;
- A description of the vector, the gene product(s) to be expressed and how this might have a positive impact on the study subjects;
- Whether viral replication is expected if a viral vector is being used;
- Any relevant information on adverse events from prior clinical or pre-clinical activities; and
- The means to ensure that rDNA or its products are not spread to personal contacts of the subjects or the community.

The minutes of the discussion at the IBC meeting considering a HGT Study will include:

- Any questions or issues raised during the discussion and how they were addressed;
- Whether the Protocol was approved during the meeting or made contingent on the provision of addition information;
- Whether the Recording Secretary was permitted to grant approval on behalf of the IBC or if the discussion was to be continued at a subsequent meeting; and
- Any minority viewpoints presented, if the approval is not unanimous.

Following approval of the HGT Study, the PI shall notify the IBC of the following, as applicable:

- Significant changes in the Investigator Brochure of Protocol;

- A safety report, if any serious adverse event that is unexpected and there is a reasonable possibility that the event is due to the use of the gene transfer product; and
- Any occurrences at other study sites that might affect the relevant Columbia study.

A HGT Expert will review any reports relating to human subject safety. If there are technical or environmental issues, additional IBC expertise will be solicited. The IBC will be briefed upon completion of the review.

IBC approvals for HGT studies are granted for the duration of the study. IBC oversight of a HGT Study may conclude only after the last subject has been administered the final dose of the product.