University of Colorado
Denver | Anschutz Medical Campus

University of Colorado Denver | Anschutz Medical Campus
Institutional Biosafety Committee (IBC)

Title: Institutional Biosafety Committee Policy and Procedures

Approval Date: June 1, 2019 **Revision Date:** August 25, 2025

General:

The purpose of this policy is to set the guidelines, requirements, and procedures regarding the Institutional Biosafety Committee at University of Colorado Denver | Anschutz Medical Campus ("CU-Denver").

Introduction:

The University of Colorado Denver | Anschutz Medical Campus Institutional Biosafety Committee (IBC) maintains oversight review for federally mandated regulations and guidelines with regard to potentially biohazardous research involving recombinant or synthetic nucleic acid molecules, infectious or potentially infectious agents, and occupational health risks associated with such research for the University of Colorado Denver | Anschutz Medical Campus. The IBC also provides oversight for NIH-covered clinical trials at affiliates based on institutional agreements, including Children's Hospital Colorado (CHCO). Researchers who maintain dual appointments with the University of Colorado and other institutions (i.e., CHCO) also fall under the purview of the CU-Denver IBC.

Overview:

The CU-Denver IBC is organized under the Institutional Official (IO). The IO for the university is the Associate Vice Chancellor for Research Compliance (or designated interim Responsible Official). The IBC reports to the Associate Vice Chancellor for Regulatory Compliance for the University on matters related to the use of recombinant and synthetic nucleic acid (rDNA) technology, and/or the use of infectious or potentially infectious agents in research, clinical, and educational activities at the University.

The IBC is responsible for compliance oversight regarding *NIH Guidelines*, Biosafety in Microbiological and Biomedical Laboratories (BMBL), other applicable federal, state, and local regulations and guidelines, and best research safety practices in the biomedical research arena. This applies to any activity (i.e., research, manufacturing, etc.) conducted at or sponsored by the university (and its associated affiliates) involving recombinant or synthetic nucleic acid molecules, or infectious or potentially biohazardous materials, regardless of the funding source or the location of the activity. Program oversight is exercised by both the IBC (program, protocol approval, policies) and the Biological

Safety division of the Environmental Health and Safety department (input on policy, biosafety pre-review).

Responsibilities of the IBC:

The IBC is an institutional-level committee, and as such is the direct representative of the chancellor. The IBC's specific charges include:

- To assess the safety of rDNA research experiments, including review of Human Gene Transfer clinical protocols, and recommend policies and procedures to ensure the health and safety of all faculty, staff, students, patients, and visitors within the University.
- To review protocols provided by principal investigators, clinical researchers, or laboratory core managers relating to the use of biological hazards and/or rDNA and to review and verify the appropriate biosafety containment level of those laboratories, clinics, and/or practices. Activities requiring BSL-2 and greater may not be initiated without written approval from the IBC. The IBC may not authorize initiation of experiments involving rDNA molecules which are not explicitly covered or exempted from the *NIH Guidelines* until the NIH with the advice of the NIH Director (as needed) establishes the containment requirement, per Section IV-B-2-b of the *NIH Guidelines*.
- Determining the risk hazard level of the research, the appropriate biosafety level, and containment conditions for the work.
- Approving Principal Investigators (PIs), their laboratories, and/or practices for work at graded biosafety levels, as appropriate, in accordance with the *NIH Guidelines*.
- Identifying the tasks that carry a risk of exposure to rDNA and/or infectious agents, what the risk of exposure entails, and notifying the research personnel and the Occupational Health Program of the occupational risk groups involved, and any Occupational Health intervention measures that can be implemented.
- Ensuring compliance with all surveillance, data reporting, significant incidents, problems, violations, or adverse event reporting requirements of the NIH, and other appropriate guidelines.
- Overseeing the follow-up and monitoring of those persons with occupational exposure to rDNA and/or infectious agents.
- Identifying activities which may require additional scrutiny by other university compliance offices for such issues as export control, Dual Use Research of Concern (DURC), and Pathogens with Enhanced Pandemic Potential (PEPP) or Select Agents and Toxins.
- Establishing and implementing policies providing for the safe conduct of activities involving recombinant or synthetic nucleic acid molecules or other potentially biohazardous materials and ensuring compliance with *NIH Guidelines* and other appropriate regulations, guidelines, and policies.
- Overseeing the development and maintenance of written biological safety plans that specify practices for minimizing occupational exposures to infectious biological agents and/or rDNA

(including exposures to organisms and viruses containing rDNA, and products of rDNA) for all affected populations through the use of proper engineering controls and work practices; making the plan available to the institutional community; recommending updates to the plan as necessary; and overseeing the development and implementation of educational programs related to infectious biological agents, rDNA and biological safety.

- To ensure that when the institution participates in, or sponsors recombinant/synthetic nucleic acid molecule or other potentially biohazardous activities involving human subjects:
    - The IBC has adequate expertise and training (using ad hoc consultants as deemed necessary).
    - All aspects of the *NIH Guidelines* have been appropriately addressed by the Principal Investigator (including relevant appendices).
    - Ensuring that final IBC approval is granted, and that no research participant is enrolled in a Human Gene Transfer clinical trial until:
        - The NIH and FDA protocol registration process has been completed.
        - IBC approval (from the clinical trial site) has been obtained.
        - Institutional Review Board approval has been obtained.
        - All applicable regulatory authorizations have been obtained.
    - IBC approval must be obtained from the clinical trial site for all human gene transfer and attenuated or live vaccine trials.
    - Certain clinical trials that require IBC review may on occasion be sent to an external IBC, managed by the WIRB-Copernicus Group (WCG/WIRB IBC). The determination of clinical trials that should be sent to the WCG/WIRB IBC will be made by CU Denver's upper administration, in coordination with the clinical PI. The Biosafety Officer (BSO) serves as a reviewing and voting member of the WIRB IBC. The IBC Administrator acts as a point of contact should the WCG/WIRB IBC have questions or concerns regarding our campus. After a clinical trial is reviewed and approved by the WCG/WIRB IBC, a copy of the approval document is maintained by the CU Denver IBC for records only. All other documents are maintained by the WCG/WIRB IBC team but can be requested at any point should they be needed by the CU Denver IBC.
- Lowering containment levels for certain experiments or activities, as specified in Section III-D-2-a of the *NIH Guidelines*, Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host Vector Systems.
- Setting containment levels as specified in Section III-D-4-b of the *NIH Guidelines*, Experiments Involving Whole Animals, and Section III-D-5, Experiments Involving Whole Plants.

- Reviewing, every three years, recombinant or synthetic nucleic acid molecule research or activities involving potentially biohazardous materials that are conducted at the university to ensure compliance with *NIH Guidelines*.
- Adopting emergency plans to cover accidental spills and personnel contamination during the conduct of research involving recombinant or synthetic nucleic acid molecules or activities involving potentially biohazardous materials.
- Notifying the PI of the results of IBC review (approval, modifications required, or deferral).
- Reporting any significant violations of *NIH Guidelines*, and any significant research-related accidents or illnesses to the appropriate institutional official and the NIH Office of Science Policy (OSP) within 30 days, unless a report was filed by the PI.
    - Reports shall be submitted by email to NIH OSP. (Additional contact information is available on the OSP website).
- The IBC may perform such other functions as may be delegated to it under Section IV-B-2 of the *NIH Guidelines*, and by the university.
- The IBC may suspend any activity which it previously approved if it determines that the activity is not being conducted as described by the PI or is not in compliance with NIH Guidelines or other federal, state, or local regulations or guidelines, or university policy.

The University Environmental Health and Safety (EHS) is designated as the monitoring and effector arm of the IBC to ensure that details specified in protocols are feasible and appropriate.

To facilitate efficient and comprehensive regulatory compliance across campus, the IBC will communicate regularly with other regulatory committees, including the Institutional Animal Care and Use Committee (IACUC), the Radiation Safety Committees, the Institutional Review Board (IRB), and the Institutional Review Entity (IRE). Coordination with each of these different committees will be maintained throughout the review process via in-person, email, Teams and online database communications between the IBC administrative team and representatives of the other committees.

Composition of the IBC:

The IBC consists of a minimum of five voting members, so selected that they collectively have experience and expertise in:

- Recombinant or synthetic nucleic acid molecule technology and/or infectious agents.
- Biological safety.
- Physical containment.

- Assessment of the safety of recombinant or synthetic nucleic acid molecule and/or infectious agent research, and identification of any potential risk to the health of workers or the public, or to the environment.
- Human clinical research activities, including clinical trials and routine medical care.

At least two members shall be unaffiliated with CU Denver | Anschutz Medical Campus (except as members of the IBC), and shall represent the interest of the surrounding community with respect to health and protection of the environment (e.g., representatives of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). At least one member will be a researcher or veterinarian with expertise in animal containment principles for studies involving animal work, requiring approval by the IBC. At this time, there is no recombinant plant research being conducted at CU Denver; however, if this research is proposed to the committee in the future, then at least one member will be sought out with expertise in plant, plant pathogens, or plant pest containment principles for review of those studies.

The current CU Denver | AMC IBC committee is comprised of the following voting members:

- Three or more faculty members with experience in infectious disease research, infection prevention, rDNA technology, and/or biological safety and containment. *
- One or more faculty members with experience in Human Gene Transfer or clinical studies. *
- Two or more non-affiliated community members. *
- One or more CU-Denver Office of Laboratory Animal Resources (OLAR) veterinarians with expertise in animal containment (for protocols with animal work). *
- Biological Safety Officer. *

*Required members by the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules*

<u>*Ex-Officio Members*</u>:

- The following are designated as members without a vote, and do not count toward a quorum:
    - The Director of the Office of Research Committee Support (ORCS)
    - The IBC Coordinator
    - Representative(s) from EHS Occupational Health
    - Representative from COMIRB

<u>Additional non-voting members for the IBC:</u>

Administrators or other members of the university community may participate in IBC deliberations as non-voting members, as deemed desirable or necessary by the IBC or the University leadership.

Chair and Co-Chair:
The IBC Chair and Co-Chair will be appointed by the Institutional Official. The IBC Chair and Co-Chair should be a qualified scientist or clinician scientist, preferably holding academic tenure. Members will be informed of the names of those being considered as IBC chair or co-chair, allowing the opportunity to provide pre-selection input. The IBC Chair and Co-Chair will retain full signing authority during both service terms.

Alternate members for the IBC:
Former IBC members may serve as alternate members, with full voting privileges, and substitute for a current member with similar expertise. These are the only substitute representatives permitted.

Community observers of the IBC:
When possible and consistent with the protection of privacy and proprietary interests, the university encourages that IBC meetings be open to the public. In the event of the exchange of proprietary or personnel information, community observers may be asked to leave the room. IBC meeting minutes are available to the public upon request.

Ad hoc membership for the IBC:
The IBC may invite consultants to assist in the review of complex issues arising from proposed activities. The consultants may not approve or withhold approval of an activity and may not vote (unless they are also IBC members).

- When the university participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects, the IBC must appoint or consult a researcher (ad hoc is acceptable) with adequate expertise and training.
- People who are knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment may also serve as consultants to assist in the review of issues as the need arises.

Ad hoc committees for the IBC:
To ensure the IBC has adequate expertise and training, it may designate an ad hoc committee, subject to the following provisions:

- With consent of the committee, the chair shall appoint the members of all ad hoc committees and shall designate the ad hoc committee chair. All members need not be members of the IBC.
- Ad hoc committees shall have no separate substantive powers or authority for action or decisions not ultimately subject to the approval of the IBC.

- A quorum for the transaction of ad hoc committee business shall consist of a simple majority of its members, unless otherwise directed by the IBC.
- The ad hoc committee may also call upon ad hoc consultants as deemed necessary.

Conflict of interest for IBC members:

No member may participate in the IBC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IBC. No member who has a conflicting interest may contribute to the constitution of a quorum. The IBC views conflict of interest in a broad sense. Other possible examples of conflict of interest include cases where a member is involved in a potentially competing research program, has access to funding or intellectual information that may provide an unfair competitive advantage, or has personal biases that may interfere with his or her impartial judgement.

All individuals who participate in any way with the administration, processing, or review of IBC protocols must complete annual Conflict of Interest (COI) disclosures, as required by the institution. This includes all members, administrators, etc.

Appointment of Members:

- The Institutional Official will appoint members to the IBC.
- A faculty member is appointed by the Institutional Official to be the Chair, Co-Chair, or vice-chair.
- Any committee member may nominate candidate members to the institutional official, either directly or through the IBC Chair or Co-chair, or the Director of ORCS.
- The Director of ORCS, the BSO, or the EHS Director, may also make membership recommendations in order to ensure adequate and appropriate distribution of membership on the committee. This will aid in fulfilling regulatory requirements, ensure that no more than three members are from the same administrative unit (defined as the lowest academic unit recognized by the university administration, e.g., department or division), and include needed expertise, such as might be needed with an increase in protocols involving a specific specialty.
- The Institutional Official may solicit IBC member candidates from the department chairs, division heads, affiliate institution directors, and the general university community. The Institutional Official will request in writing the names of the nominated individuals. The letter will contain information regarding the term of appointment, qualifications, and duties of IBC members.
- Once candidates have been identified, the IBC coordinator will obtain a brief biographical sketch of each, to include faculty association, research interests, previous IBC experience, and other pertinent information. Members will be informed of the names of the candidates, allowing the opportunity to provide input.

- The nominated member's name and biographical sketch will be sent to the institutional official for consideration for appointment to the IBC.
- The preferred timing of the appointment process will be:
    - Recommendations to the Institutional Official.
    - Once the Institutional Official has accepted a nominee provisionally, the nominee will receive an IBC orientation seminar, prior to the next IBC meeting.
    - Subsequent to the orientation seminar, the nominee will attend two IBC meetings as an observer.
    - The IBC Coordinator will initiate the NIH-Registration Management System (NIH-RMS) for the new member
    - Once the orientation and meeting attendance have been completed, the institutional official will appoint the nominee, in writing, as an IBC member.
    - The new IBC member may review & vote on protocols once the NIH-RMS update has been accepted & approved by the NIH.

Qualifications/training of IBC members:

It is the responsibility of the University to ensure that all IBC members are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction.

- Available training and instruction include:
    - Orientation of potential new members, which will occur prior to their appointment to the committee.
    - Continuing education, which will be provided for members at regularly scheduled meetings, by email and other means.
- The provision of continuing education/training will be facilitated by the IBC administrator, the ORCS Director, the IBC Coordinator, the BSO, the EHS director, the university attending veterinarian, or their designee. Any IBC member may provide relevant training material or suggest pertinent continuing education topics for continuing education.
- Training will include topics such as:
    - The requirements of the *NIH Guidelines*, IBC policies, OSHA regulations as they relate to research, and guidelines such as the BMBL.
    - Mechanisms for reviewing applications for use of recombinant and synthetic nucleic acid molecules, infectious and potentially infectious materials.

Resignation of IBC members:

A member may resign at any time upon written notice to the institutional official (with a copy to the IBC chair), submitted at least 15 days prior to the effective date. Upon resignation, the IBC administrator shall recommend a replacement, pending approval by the IBC chair and the institutional official.

Professional Conduct and Termination of Service of IBC members:

- IBC members' responsibilities include, but are not limited to:
  - Attending regularly scheduled meetings.
  - Providing timely reviews and evaluations of assigned protocols.
  - Upholding the standards of professional conduct.
- IBC members may be removed from the committee "for cause" if they regularly fail to fulfill the requirements detailed in the policy. "Cause" for termination may include, but is not limited to:
  - Consistent failure to attend scheduled meetings.
  - Consistent failure to provide timely reviews of assigned protocols.
  - Failure to uphold the standards of professional conduct.
  - Change in eligibility status.

Professional conduct of IBC members:

Professional conduct required of IBC members requires dealing with committee business and protocols in an unbiased manner. If a member feels they have a conflict of interest for any reason, they have the responsibility to not review the protocol and not participate in the committee discussion. Unprofessional conduct includes, but is not limited to, abuse of conflict of interest, or inappropriate behavior and/or inappropriate language.

Procedure for IBC member removal for cause:

- If a member is not fulfilling the responsibilities outlined above, the member will meet with the chair(s) and ORCS Director for discussion of the problems. If the issue is resolved at this point, no further action will be required.
- If a member is fulfilling the responsibilities outlined above, and a satisfactory resolution is not achieved, the member will be notified in writing.
- The IBC chair (or co-chair) and the Director of ORCS will meet with the Institutional Official to indicate that a problem exists and to provide a review of the situation.
- Following notification of the members' unsatisfactory service, a discussion will be held between the member and the Institutional Official.

- The Institutional Official (or designee) and the committee will meet to provide information to committee members and to gather feedback from members.
- The Institutional Official will make the final decisions regarding termination of service.
- Committee members removed in this manner will be informed in writing of their termination of service, and their right to appeal. The appeal process will be provided.

Appeal process:

- An appeal of a termination for cause from the IBC may be submitted to the Associate Vice Chancellor for Regulatory Compliance (ACVRC). An appeal must specify why the termination should not be imposed.
- The AVCRC will evaluate the merits of the appeal with consultation with the terminated member, the IBC chairs, and other personnel deemed necessary.
- The decision of the AVCRC is final and binding.
- The whole appeal process must be conducted in a timely manner, but no longer than three months.

Attendance Requirements:

Each member of the IBC is expected to attend meetings of the IBC on a regular basis. Failure to attend regularly may result in removal from the IBC.

Special Provisions:

- No member may appoint a designee to participate in the deliberations of the committee in the absence of another member, with the exception of designating a former IBC member.
- No member may be involved in the review or approval of a project in which he/she has or expects to be engaged, or has a direct financial interest, except to provide information requested by the IBC.
- Each member shall agree to and sign a CU Denver | Anschutz Conflict of Interest form (administered in InfoEd), to be in effect during the entire term of IBC membership, plus two years.
- If a member's job duties change such that the majority of his/her time is spent in administrative oversight of other faculty, the IBC member may either:
    - Change to non-voting status within the committee, continuing to review and participate in the discussion of protocols, or
    - Resign from IBC membership.

Expectations of Voting Members:

- All voting members will review assigned protocols in advance of the monthly meetings.
- If unable to attend a meeting, the member will send comments to the administrator or coordinator for inclusion in the meeting.

- Members may be exempted from providing reviews up to three times within a calendar year, e.g., if traveling or clinical duties interfere.

Roles and Responsibilities:

Committee Chair and Co-Chair:

The Chair and Co-Chair:

- Serve as the convening authority for the IBC (or designate convening authority in the event that neither chair nor co-chair can attend).
- Sign, on behalf of the committee:
    - All correspondence related to approval or disapproval of IBC protocols.
    - All reports to the institutional official of committee reviews, evaluations, and recommendations.
- Appoint sub-committees and ad hoc committees, and their chairs, as needed.
- Assigning such additional duties to other members as deemed necessary to assist in the conduct of work, and which are not inconsistent or in conflict with the duties prescribed for those officers.
- Will review protocols submitted to the IBC and document his/her comments & recommendations.

Biological Safety Officer (BSO):

The BSO will:

- Participate in committee business as a full voting member of the IBC.
- Review protocols for compliance with the *NIH Guidelines*, BMBL, environmental and occupational health and safety aspects, and biosafety.
- Perform periodic inspection to ensure that laboratory standards are rigorously followed.
- Report to the IBC and the university any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the BSO becomes aware.
- Develop emergency plans for handling accidental spills and personnel contamination and investigate laboratory accidents involving recombinant or synthetic nucleic acid molecule research.
- Provide advice on laboratory security and biosecurity.
- Provide technical advice to PIs and the IBC on research safety procedures.

Veterinarian(s):

The Veterinarian(s) will:

- Participate in committee business as full voting members of the IBC.
- Provide guidance for the committee, the committee leadership, and the Institutional Official on matters of federal law and policy, accreditation, established guidelines and best practices

regarding use of animal in research being reviewed by the IBC to assure adequacy of animal care and use, and will collaborate in protecting workers from related hazards.

Researcher/Scientist Member:

The Researcher/Scientist member will:

- Participate in committee business as a full voting member of the IBC.
- Review protocols for acceptability of procedures and risk assessment/mitigation regarding research involving recombinant or synthetic nucleic acid molecules, or infectious of potentially infectious materials.
- Review reports of occupational exposures and/or illnesses associated with the research reviewed and approved by the IBC.

Non-Affiliated Members:

Non-Affiliated and members will:

- Participate in committee business as full voting members of the IBC.
- Review protocols for acceptability regarding public accountability and the non-academic sector.
- Consider biological safety and regulatory compliance pertaining to the application.

IBC Administrator:

The IBC Administrator is the senior-level professional responsible for the overall administrative functions of the IBC. The IBC Administrator will:

- Assure regulatory compliance regarding potential biohazards involving recombinant or synthetic nucleic acid molecules, infectious or potentially infectious agents, and regarding occupational health risks associated with such research.
- Prepare reports, policies and procedures for efficient IBC function.
- Prepare documents and correspondence and act as liaison for the IBC with internal administrators and external regulatory agencies.
- Oversee the financial and operational aspects of the IBC.

IBC Coordinator:

The IBC Coordinator will:

- Organize and manage support for the IBC.
- Review, update and compile information on potential biohazards involving recombinant or synthetic nucleic acid molecules, or infectious or potentially infectious agents used in research, to ensure that the university remains in compliance with set guidelines.

- Review and report on the status of researchers regarding required training and enrollment in the Occupational Health Program.
- Assist the committee with the preparation for convened meetings.
- Assist the chair and administrator with preparation of reports, letters, correspondence and requests for information.
- Support functions of the IBC office including protocol updates & system changes.

Consultant:

The IBC may invite consultants to assist in the review of complex issues arising from its review of proposed activities. Consultants may not approve or withhold approval of an activity and may not vote with the IBC unless they are also members of the IBC.

Institutional Biosafety Committee Meetings:

- The IBC meets at least once per month to review project descriptions (protocols) prepared by investigators or instructors prior to beginning research or teaching which involves biohazardous materials. Review and approval of protocols shall be conducted only at a convened meeting with a quorum present.
- The IBC Office shall advise the members of the time and place of the meeting. If pending business requires resolution, a meeting may be called by the chair or the BSO.
- Rules of Order: All business meetings shall be conducted in accordance with Robert's Rules of Order (current revision), unless inconsistent with specific provisions of this policy or of university policy.
- Quorum: A majority (>50%) of voting members present shall constitute a quorum for transaction of business at any IBC meeting, as long as relevant expertise is adequately represented to review the protocols involving recombinant or synthetic nucleic acid molecules or infectious agents. No action shall be taken at any meeting at which a quorum is not present; the only motion which the chair shall entertain will be the motion to adjourn to a stated time and place. This shall not preclude the committee from discussing issues of business in the absence of a quorum, provided no action is taken on such items. Adequate notice of the time and place of such adjourned meetings shall be made to the membership in accordance with these bylaws.
- Schedule: The regular date, time and place of meetings shall be posted on the IBC webpage or other suitable site accessible to the public.

IBC Review Process:

- In order to approve proposed activities or significant changes in ongoing activities, the committee will review aspects related to research involving recombinant or synthetic nucleic acid molecules, and infectious or potentially infectious agents, to ensure the proposals are in accordance with all laws,

policies, and guidelines noted above, unless acceptable justification for a variance is presented in writing.

- All proposals will be submitted to the committee using the Cayuse database (for bench/laboratory protocols) or the most current & appropriate non-Cayuse application version (clinical trials, manufacturing protocols, etc.). The current version is defined as the version provided to the PI and research team by the IBC Coordinator following their inquiry.
- All protocols will be available to all IBC members, upon request. At least five business days prior to a scheduled meeting, each member will be provided with a list via email of protocols and clinical trials to be reviewed. The list will include, at minimum, the title of the protocol and the name of the Principal Investigator. The 5-day rule may be set aside by the chair for issues determined by the chair or BSO to be of an urgent or emergency nature.
- The IBC will determine whether proposed activities or significant changes to ongoing activities meet the following requirements:
    - Procedures involving biohazardous materials follow the appropriate federal, state, or university regulations, guidelines, or best practices.
    - Personnel conducting procedures with biohazardous materials will be appropriately qualified and trained in those procedures (e.g., personnel qualifications forms, classes, individual training) and are enrolled in the university Occupational Health Program.
    - Approval is granted only when appropriate containment levels, facilities, procedures, practices, training, and personnel expertise are presented in protocol registration documents.
- Procedures for full-committee review of **new, renewal, and amendment** protocols:
    - Each bench top/animal-based research protocol shall be reviewed by a scientific/research member, a veterinary member (if animal work is included), a community member and an EHS member. Their findings will be presented before the full committee, either in-person, via Zoom or in writing to the IBC administrator, the ORCS Director, or the IBC Coordinator.
    - Clinical trials shall be reviewed by one to two clinical/MD members, a community member, and an EHS member.
    - A majority of the quorum is required for approval. The committee may require modifications to the protocol, and PI responses can be reviewed by the full committee at a subsequent convened meeting, or by designated member review.
    - Any member can request to review answers to IBC requests.
    - A written minority report is requested by the chair from dissenting voters.
    - Experimentation is prohibited before committee approval is granted. The IBC has full authority to approve, require modifications to protocols pending approval, defer, or deny.
- Except as specifically authorized by law or these regulations, nothing in this policy shall be deemed to permit the IBC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility. The IBC does not review the science of the proposal

but can consider the scientific methods as they relate to appropriate use of recombinant or synthetic nucleic acid molecules, infectious or potentially infectious agents, or other biohazardous materials.

- Proposed activities and proposed significant changes in ongoing activities that have been approved by the IBC may be subject to further appropriate review and approval by officials of the research facility. However, those officials may not approve an activity involving recombinant or synthetic nucleic acid molecules, infectious or potentially infectious agents that has not been reviewed and approved by the IBC.

Voting of IBC Members:

- Each voting member shall have one vote. Alternate members shall vote in place of the individual for whom they sit as a substitute.
- If provisional approval (requiring modifications) has been voted on, pending completion of relevant documentation of other requirements, final approval may be granted by the EHS reviewer unless otherwise indicated at the meeting.
- Members shall change to non-voting status upon transfer to an administrative position within the university.

Notification of PIs:

The IBC will notify the PI in writing of a decision to approve or withhold approval of activities related to the use of biohazardous materials, or of requirement of modifications for approval. If approval is withheld, notification will include reasons for the decision, giving the PI an opportunity to respond in-person or in writing.

Appeal of IBC Decision:

A PI may appeal an IBC decision in writing to the IBC Office, including specific reasoning. The appeal must be received by the IBC at least eight days before the next scheduled meeting, for review of the appeal to be entertained at that meeting.

Open/Closed IBC Meetings:

- All meetings will be open to the public (per NIH Guideline Section IV-B-2-a-(6)), except:
    - When personnel matters are considered, or
    - When protection of privacy and proprietary interest is required, or
    - When matters relating to Select Agents are considered.
- When any of these exceptions apply, the IBC may meet in closed session.

Recordkeeping Requirements:

IBC Meeting Minutes – At each meeting, minutes will be recorded in accordance with guidance from the NIH *Guidelines* and NIH OSP regarding its contents. These minutes will be reviewed and approved by all members during the next convened IBC meeting.

For each meeting, the following information will be included in the minutes:

- Date and place of meeting
- Whether the minutes of the previous meeting were approved
- IBC members in attendance.
- Voting and Deliberation activities
- Time of meeting adjournment

For each protocol, the following minimum information must be included in the minutes:

- IBC protocol number, PI name and title of protocol
- Applicable section of the NIH Guidelines
- Whether the protocol was reviewed or not
- What significant questions were asked (if any)
- The decision made about the protocol
- The total number and types of votes

Approved minutes shall be posted on the IBC Website in keeping with the NIH Office of Science Policy Implementation guidelines. Portions of the minutes dealing with proprietary issues, sensitive materials, or Select Agents and Select Agent Toxins may be redacted, in compliance with the *NIH Guidelines,* 42 CFR 73, 9 CFR 121, and 7 CFR 331 (Section IV-D-5-a).

If public comments are made on IBC actions, the university will forward both the comments and the IBC's response, by email, to the NIH Office of Science Policy, nihguidelines@od.nih.gov.

Record Requirements:

All records and reports of the IBC meetings and protocol approvals will be retained for three years. These records shall include:

- Protocol records, copies of all research proposals, reports of serious adverse events or incidents associated with the research studies, and any scientific evaluations and/or progress reports submitted by researchers.
- Records of continuing review activities
- Minutes of IBC meetings showing attendance and actions taken

Records related directly to approved activities and proposed significant changes in ongoing activities will be retained for the duration of the activity, plus three years. Records related to proposed activities which were not approved, due to lack of documentation, will be retained for one year, and then purged for the files.

Release of any such materials, including reports, summaries, photographs containing trade secrets, or commercial or financial information that is privileged or confidential, will be governed by applicable sections of the Colorado Open Records and US Freedom of Information acts.

Reporting Requirements of the IBC:

In an annual report to the NIH/OSP, (which are subject to FOIA requests), the IBC administrator will submit an updated roster of all IBC members that clearly indicate the IBC Chair, contact person, Biological Safety Officer, plant expert (if applicable), animal expert, rDNA technology experts, and human gene therapy expert or ad hoc consultant (if applicable). Biographical sketches of all IBC members, including community members, with personal contact information redacted for privacy will also be submitted.

The IBC shall prepare regulatory reports as required by federal and state agencies. Such reports will be reviewed by the chair, approved by the committee, and signed by the institutional official.

The IBC shall report any significant issues or violations of *NIH Guidelines*, as well as significant research-related accidents or illnesses involving recombinant or synthetic nucleic acid molecules to the appropriate institutional official and the NIH OSP within 30 days of occurrence, unless the IBC determines that a report has already been filed by the PI. Examples include needlesticks containing rDNA, the escape or improper disposal of a transgenic animal, or spills of high-risk recombinant materials outside of a biological safety cabinet.

Spills and accidents which result in overt exposures to risk group 2 (RG2) agents or overt or potential exposures to risk group 3 (RG3) agents containing rDNA molecules must be immediately reported to EHS for investigation and reporting of the incident to NIH/OSP and the IBC. Reports will be emailed to nihguidelines@od.nih.gov.

IBC Authority and Operations:

The IBC has the authority to assess the risks associated with undertaking rDNA research and/or infectious agent research and based on their findings, to exempt, approve, require modifications to, or disapprove all research activities under its jurisdiction. The IBC also has the authority to suspend or terminate a study approval for failure to meet the requirements set forth herein or as a result of a serious adverse event. Any notification of suspension or termination of a study shall be given in writing to the principal investigator of a study and shall include a statement giving the reasons for the suspension or termination. The IBC may

also notify the appropriate university officials and funding source (if the project is funded by an external source) and as appropriate the NIH OSP. The IBC may also place restrictions on studies as it may deem appropriate and necessary, and may supersede the BMBL, *NIH Guidelines* or the Institutional Biosafety Manual when deemed necessary.

Amendment of Procedural Policy:

This policy may be amended at a regularly scheduled IBC meeting by the affirmative vote of a majority of the full voting membership, in accordance with applicable federal and state regulations and university policies.

Approved by a majority vote of the University of Colorado Anschutz Medical Campus Institutional Biosafety Committee on:

_____8/25/2025_____
Date

Thomas Morrison

Tem Morrison, PhD
Chair, Institutional Biosafety Committee

Bruce McCollister, MD
Co-Chair, Institutional Biosafety Committee

Brett M Haltiwanger

Brett Haltiwanger, PhD, CBSP
Biological Safety Officer

Appendix 1

References:

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. Biosafety in Microbiological and Biomedical laboratories (BMBL), (current edition):
- CFR 1910.1030, OSHA Bloodborne Pathogen Standard.Needlestick Safety and Prevention Act, April 18, 2001:
- 29 CFR 1910.1450, OSHA Laboratory Safety Standard
- 29 CFR 1910.1200, OSHA Hazardous Communication:
- 49 CFR Subtitle B Department of Transportation (DOT)
- International Air Transport Association (IATA), Dangerous Goods Regulations (DGR)
- 7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73: Select Agent Regulations
- NSF/ANSI 49 Biosafety Cabinetry: Design, Construction, Performance, and Field Certification, (current edition)
- Export control, US Department of Commerce. Dual Use Research of Concern:
- NIH Grant Policy: The policy requirements that serve as the terms and conditions of NIH grant awards. By accepting an award, grantees agree to comply with the requirements in the NIH Grants Policy Statement, (current edition)
- NIH Design Policy and Guidelines, (current edition)

Appendix 2

Definitions:

1. Biohazard:
    1. Material which may pose a risk to human health of the environment arising from biological work, especially with microorganisms.
    2. Potential source of harm from biological agents; includes infectious agents, potentially infectious materials, and recombinant and synthetic nucleic acid molecules.
    3. Any microorganism (including but not limited to bacteria, viruses, fungi, rickettsiae, prions or protozoa) or infectious substance, or any naturally occurring, bioengineered, or synthesized component or any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, animal, plant, or other living organism; deterioration of food, water, equipment, supplies, or materials of any kind; or deleterious alteration of the environment.
2. Biohazardous materials – materials containing or contaminated with recombinant or synthetic nucleic acid molecules, infectious or potentially infectious agents.
3. Biological agent – any microorganism, including those which have been genetically modified, cell cultures and human endoparasites, which can cause harm to human health, usually due to infection (some are toxic or allergenic). This may include agents with low pathogenicity, but which could still cause illness or issue for immune-compromised individuals (such as lab strains of E. coli).
4. Biological Safety Cabinet (BSC) – ventilated enclosure intended to offer protection to the user and the environment from the aerosols arising from handling of potentially hazardous and hazardous microorganisms, with means for filtering air discharged to the atmosphere.
5. Biosafety/Biological Safety – The application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards. Biosafety defines the containment of conditions under which infectious agents can be safely manipulated. The objective of containment is to confine biohazards and to reduce the potential exposure of the laboratory worker, persons outside of the laboratory, and the environment to potentially infectious agents
6. Biosafety in Microbiological and Biomedical Laboratories (BMBL) – The CDC/NIH publication that is both a code of practice and an authoritative reference for laboratory safety practices, equipment, and facility safeguards.
7. Biological Safety Officer (BSO) – An individual appointed by an institution who has expertise in the biohazards encountered in the organization and is competent to advise top management and staff on biorisk management issues. The *NIH Guidelines* require that a BSO be appointed when the institution is engaged in large-scale research or production activities, or in research requiring containment at a BSL3 or BSL4. The duties of the BSO are described in Section IV-B-3 of the *NIH Guidelines*.

8. Biorisk – The combination of the likelihood of the occurrence of an adverse event involving exposure to biological agents and toxins, and the consequence (in terms of accidental infection, toxicity or allergy, or unauthorized access, loss, theft, misuse, diversion or release of biological agents or valuable biological materials) of such an exposure.
9. Biosafety level – Guidelines for the safe use of infectious organisms, based on the risk group of the organisms being handled, laboratory practices, techniques and procedures, engineering controls, and building containment features.
10. Biosecurity – Refers to measures taken to stop the spread or introduction of harmful organisms to human, animal and plant life.
11. Centers for Disease Control and Prevention (CDC) – The leading national public health institute of the United States; a federal agency under the US Department of Health and Human Services.
12. Committee – Institutional Biosafety Committee (IBC) established by the institution to comply with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.
13. Decontamination – The procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects.
14. Environmental Health & Safety (EHS) – University department charged with the responsibility to protect employees, the public, and the environment, to comply with applicable laws, and to protect the institution's reputation. The division of Biological Safety is within EHS and responsible for overseeing the University's compliance with *NIH Guidelines* for Research Involving Recombinant and/or Synthetic Nucleic Acids and CDC guidelines for the conduct of research involving potential biohazardous agents.
15. Hazard – A potential source of harm.
16. Infection – The invasion and multiplication of microorganisms such as bacteria, viruses, and parasites that are not normally present within the human body, animal, plant or insect. An infection may cause no symptoms and be subclinical, or it may cause symptoms and be clinically apparent (pathogenic).
17. Infectious agent – A microorganism capable of producing infection.
18. Institution – The University of Colorado Denver | Anschutz Medical Campus
19. Institutional Official – An individual at the research facility who is authorized to legally commit on behalf of the research facility to the requirements of the *NIH Guidelines*, NIH Grant Policy, Select Agent and Toxin regulations, and Material Transfer Agreements.
20. Non-affiliated community member – An Individual who is not affiliated with the institution in any way other than as a member of the IBC and is not a member of the immediate family of a person who is affiliated with the institution.
21. National Institutes of Health (NIH) –The preeminent federal funder of medical research in the US. The NIH, comprised of 27 separate institutes and centers, is one of eight health agencies within the US Public Health Service, which is an agency within the US Department of Health and Human Services. The goal of the NIH is to acquire knowledge to help prevent, detect, diagnose, and treat disease and disability. The NIH mission is to uncover knowledge that will lead to better health for everyone.

22. Nucleic acids – In the context of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), recombinant and synthetic nucleic acids are defined as:
    1. Molecules that a) are constructed by joining nucleic acid molecules, and b) that can replicate in a living cell, i.e., recombinant nucleic acids.
    2. Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
    3. Molecules that result from the replication of those described in item 1 or 2 above.
23. Principal investigator (PI) –
    1. An individual who is designated by the University of Colorado Denver to direct a project or program, and who is responsible to the entity for the scientific and technical direction of that project or program.
    2. An employee of a research facility, or another person associated with a research facility, responsible for a proposal to conduct research, and for the design and implementation of research involving potentially biohazardous materials. A PI at CU Denver | Anschutz Medical Campus must hold a faculty appointment at the Instructor level or above at the University.
24. Quorum – Minimum number appointed voting members of the committee present for an official meeting. A quorum (>50% of voting membership) is required for the conduct of official committee business. A simple majority vote of the quorum is required to conclude any action or activity on behalf of the committee.
25. Researcher – A practicing scientist who possesses a terminal degree and who is experienced in research involving animal, biological agents or toxins, or recombinant or synthetic nucleic acid molecules.
26. Risk – A combination of the probability of occurrence of harm and the severity of that harm.
27. Risk assessment – A systematic process of evaluating the potential risks that may be involved in a projected activity or undertaking. This includes identifying potential hazards an organization may face and analyzing methods of response if exposure occurs.
28. Risk group – One of four designations for a microbe or biological agent based on its capacity to infect and cause disease in a susceptible human or animal host, its virulence as measured by the severity of disease, mode of transmission and host range, and the availability of preventive measures and effective treatments for the disease.
29. Risk mitigation – Steps taken to reduce adverse effects; efforts taken to reduce the probability or consequences of a threat, accident or incident.
30. Select Agents and Toxins – Biological agents and toxins deemed by the US Secretary of Health and Human Services to have the potential to pose a severe threat to public health and safety. Select Agents and Toxins are listed in 42 CFR 73.3 and 73.4.
31. Standard Operating Procedures (SOP) – A set of fixed instructions or steps for carrying out usually routine operations.

32. Standard microbiological practices – Basic safe laboratory protocols for working with non-pathogenic biological materials in which all research staff are trained, including hygiene and housekeeping, personal protective equipment, and security and access.
33. Toxin – The toxic materials or product of plants, animals, microorganisms (e.g., bacteria, viruses, fungi, rickettsiae, protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever its origin or method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology or produced by a living organism, or any poisonous isomer or biological product, homolog, or derivative of such a substance.
34. University – The University of Colorado Denver | Anschutz Medical Campus, including the South Campus.
35. Veterinarian – A Doctor of Veterinary Medicine, with training or experience in laboratory animal science and containment.