Charter of the Nemours Institutional Biosafety Committee

The Nemours Institutional Biosafety Committee (IBC) is established and maintained in accordance with NIH Guidelines (59FR34496 and all amendments) and the Nemours Foundation policy. The IBC exists to ensure the safety of patients, staff, visitors, and the community by over-seeing the proper storage, handling, and disposal of all recombinant DNA molecules, infectious agents, and toxic compounds used or developed during the course of research activities.

I. Purview of the IBC:

A. The IBC oversees all activities that 1) occur within all the facilities of the Biomedical Research Department (BRD) or 2) occur as part of a research proposal in which any of the following are used.

1) recombinant nucleic acid molecules or synthetic nucleic acids – including those that are chemically or otherwise modified (analogs of nucleotides) but can base pair with naturally occurring nucleic acid molecules, and cells, organisms, and viruses containing such molecules.
   Recombinant or Synthetically Derived Nucleic Acids
2) known or suspected human, animal, or plant pathogens or infectious agents
   Biosafety in Microbiological and Biomedical Laboratories—6th Edition (cdc.gov)
3) potentially infectious materials – including human tissue, blood, body fluids, cells, or cell strains
   Biosafety in Microbiological and Biomedical Laboratories—6th Edition (cdc.gov)
4) compounds or materials that are
   a) Included in the Select Agents or Toxins List Select Agents or Toxins List
   b) Included in the current version of *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016* NIOSH List of Antineoplastic and Other Hazardous Drugs
   Hazardous Drugs: Draft NIOSH List of Hazardous Drugs in Healthcare Settings, 2020: Procedures; and Risk Management Information
   Drugs Proposed for Placement on the NIOSH List of Hazardous Drugs in Healthcare Settings, 2020
   Controlling Occupational Exposure to Hazardous Drugs
   Controlling Occupational Exposure to Hazardous Drugs
   c) Classifiable as Category 1 Health Hazards under the Globally Harmonized System of Classification and Labeling of Chemicals
   Appendix A 1910.1200 – Health Hazard Criteria (Mandatory)
   d) Study compounds or materials introduced into research animals (note that this does not include those used for veterinary care)
5) other significant biohazards as defined by the Executive Director, Research.

B. Decisions and findings of the IBC are final and may only be overturned or remedied by subsequent action of the IBC.

II. Committee Membership:

A. **Chair**: The IBC Chair is designated by the Executive Director.
The Chair may be removed at any time in the interim by the Executive Director, if more than 2/3 of the committee membership expresses a vote of "no confidence".

B. **Associate Chair**: The Associate Chair is designated by the Executive Director. The Associate Chair will act as Chair when the Chair is absent and during meetings where the Chair has a submittal in review.

C. **Institutional Biosafety Coordinator**: The Institutional Biosafety Coordinator supports the general business operations of Nemours, the BRD, and the NIH-registered Institutional Biosafety Committees at Nemours. The Institutional Biosafety Coordinator files annual reports to NIH Office of Science Policy per Section IV-B-2-a-(3) of the NIH Guidelines.

D. **Administrative Process Coordinator**: The Administrative Process Coordinator is nominated by the IBC Chair and approved by committee membership and shall be a non-voting member of the committee. The

Administrative Process Coordinator is responsible for the initial technical and administrative review of all IBC submissions. This initial review is used to determine if IBC review and approval is required or can be waived, based on whether the submission involves, but is not limited to, recombinant DNA, RNAi, pathogens, human and other potentially infectious material, transgenic animals and biological agents or toxins.
E. **Membership**: Members are nominated by the Chair and must be approved by the Executive Director. Members may be removed by the Executive Director at any time with the consent of the IBC Chair.

III. Special Member Responsibilities:

A. IBC Chair:

1. Calls and presides over meetings.
2. Brings submittals before the committee for review, discussion, and approval/disapproval votes.
3. Informs the committee of research waivers and expedited reviews.
4. Informs investigators of any findings or determinations made by the IBC.
5. Provides scientific and safety opinions but does not vote on approval/disapproval unless:
    a. The number of voting members present does not reach a quorum unless the Chair votes, or
    b. There is a "tie" vote among the members
6. May table consideration of submittals by the committee for administrative reasons, but may not table consideration of submittals by the committee because of scientific or safety concerns.
7. With the consent of the Executive Director may temporarily shut down research operations pending an emergency meeting of the IBC.
8. Report IBC proceedings to the Executive Director and meet with the local administrative leader as needed or requested to assure implementation of IBC decisions.

B. Administrative Liaison:

1. May call and preside over emergency meetings of the IBC absent the Chair.
2. With the consent of the Executive Director and one voting member of the IBC, may temporarily shut down research operations, pending an emergency meeting of the IBC.
3. Files IBC reports with NIH/OTA (Office of Technology Activities) regarding significant problems or violations per Section IV-B- 2-b-(7) of the NIH Guidelines.
4. Inform IBC members of OTA and RAC (Recombinant Advisory Committee) findings pertaining to Nemours Biomedical Research submittals.

C. Animal Containment Expert:

1. Must be present for all IBC functions (e.g., questions to investigators, deliberations, votes, etc.) in which submittals involving the use of animals are considered.
2. Advises the IBC regarding animal containment principles and procedures.
3. With the consent of the Executive Director and the Institutional Animal Care and Use Committee (IACUC) Chair, may temporarily shut down animal research operations pending an emergency meeting of the IBC.

D. Nonaffiliated Members:

1. Nonaffiliated members (not employed by or otherwise affiliated with The Nemours Foundation) represent the interests of each surrounding community or local area with respect to health and protection of the environment.
2. If there is unanimous agreement between the two nonaffiliated members from their local community, they may terminate, temporarily shut down, or disapprove any submittal from their area, considered by the IBC, based on community or environmental concerns. Local areas include Delaware Valley, Orlando, FL and Jacksonville, FL.

E. All Members:

1. All members must declare any actual, potential or perceived conflict of interests, as defined in Nemours Policy 5.9.6, Financial Conflicts of Interest in Research, at the onset of meetings.
2. Must review and consider all submittals and policies of the IBC on an individual basis.

3. May add agenda items for committee meetings at any time to address issues, concerns, or questions relating to biological safety policy and procedures.
4. Exclusive of the IBC Chair, members may not bring a submittal before the committee for consideration, discussion, or a vote during meetings.
5. May petition the Chair or Administrative Liaison to call an emergency meeting or to temporarily shut down a research facility or research activity.

F. Non-committee members:
IBC meetings are open to the PI, public, and any member of the staff, the patient population, the community, or any visitor may attend and participate in order to:
1. Participate in discussions, provide information, or request clarification from the IBC.
2. Petition the IBC for reconsideration and a revote regarding a specific submittal.
3. File a grievance with the IBC. Grievances will be addressed to the Executive Director who may take one of four actions
    1) reject the grievance,
    2) request that the IBC reconsider the specific submittal,
    3) remove IBC members, or
    4) call for a no confidence in the Chair vote by the IBC members.

IV. General IBC Function:
A. Meetings
1. Per Policy 11.1.1, Institutional Biosafety Committees meetings will be held at least quarterly. In cases where the purpose of the meeting is strictly informational, meetings may be held electronically or via email. Votes concerning the acceptance of minutes or other administrative functions may be taken electronically. Discussion of submittals and votes regarding submittals or policies must be carried out in open committee meetings that are accessible to the public.
2. Individuals with submittal(s) appearing before the committee will be invited to that IBC meeting and will be notified in advance of the time and place of that IBC meeting. The schedule of IBC meetings will be posted on the Biomedical Research external web site (Nemours.org), so that other interested parties or members of the public may attend.

B. Conflict of Interest:
It is the policy of this committee that no member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a submittal in which he/she has been or expects to be engaged or has a direct professional or financial conflict of interest. Each member is required to notify the IBC Chair in these circumstances and recuse themselves when discussing and voting on such submittal. If the IBC Chair is Principal Investigator on a submittal, the Chair will recuse themselves from discussion and voting on the submittal. If the submittal is approved, the Associate Chair or another IBC committee member present at the meeting will sign the approval documentation.

C. Registered Submittals:
1. Submission:
I) Types of submissions: In terms of the IBC, there are three types of research activities:
i) **Waived review** – The IBC Process Coordinator can waive a submittal if
    a. Research that is explicitly defined as exempt from IBC review by National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), or Occupational Safety and Health Administration (OSHA) biosafety and bloodborne pathogen standards.
    b. Research carried out in Clinical Laboratory Improvement Amendments (CLIA)-Approved or College of American Pathologists (CAP)-Certified Diagnostic Laboratories using CLIA- or CAP-approved operating procedures.

c. Non rDNA research carried out by trained clinical staff performing routine clinical procedures in a Joint Commission accredited clinical facility.

ii) **Expedited review** – An administrative review will be carried out by the IBC Chair (or delegate), and an approval memo will be issued to the Principal Investigator (PI) by the Institutional Biosafety Coordinator pending final consideration by the IBC at its next meeting. Examples of submittals eligible for expedited review include:
a. Research that requires that the PI only notify the IBC prior to or concomitant with the onset of research activities per NIH, CDC, OSHA, or other pertinent regulatory guidelines.
b. Research that is completely covered by submittals that have been reviewed and approved the IBC within the past three years. Submittals that have been approved reviewed and approved by the IBC are available from the Institutional Biosafety Coordinator (x536779) or by sending a request to biosafety@nemours.com.
iii) **Full IBC Review** – The research will be referred to the IBC for full review at their next quarterly meeting. To be considered at an IBC meeting, the registration survey submittals must be available to the IBC at least 2 weeks prior to the upcoming meeting.

II) Routing of information: A Biosafety Questionnaire must be filed with the IBC for all research activities in which any research activity take place. This process will be coordinated by Research Administration using the methods approved by the Executive Director.
2. Review of Submissions to the IBC:
I) The review process is open.
II) Applicants will be invited to attend IBC meetings at which their submittals appear on the agenda. Applicants have two general options: 1) appear before the committee to answer questions or provide explanatory information; 2) reply to committee inquiries in writing or by email.
III) All questioning and review will be carried out through the committee; all questions and responses must be available to the entire committee for review (i.e., verbal exchanges must take place before the committee and written exchanges must be distributed to the entire committee).
IV) All members are responsible for review and should vote when called upon to vote.
V) Unless otherwise requested or required by federal guidelines or institutional policies, all questions, answers, information provided by the applicant, and committee deliberations, will be summarized in committee minutes which will be considered public knowledge. Minutes will be made accessible to the public upon request. The applicant, the Chair, any IBC member, or the Executive Director may request that certain information be publicly disclosed. Any/all material for which there is a request for confidentiality must be marked clearly as such at the top of each page of each document containing such information. A majority vote of the IBC (a quorum being present) is required to approve the withholding of material from public review.

3. Voting:
I) Voting requires a quorum to be present and must include 2 members from the appropriate outside community.
II) Unless otherwise requested by any member, votes to accept minutes (or perform other administrative functions) may be taken by acclamation.
III) A vote to accept minutes affirms that the content of the minutes is accurate and constitutes a vote to release the minutes to members of the public if requested.
IV) Votes on (accepting) or (rejecting) submittals will be taken during open IBC meetings.
Each member's vote will be recorded; however, the voting record of members will be kept confidential. Members who disagree with the findings of the committee may submit explanatory material for inclusion in the minutes.
V) Members who are investigators on a particular submittal or who otherwise have a conflict of interest regarding a particular submittal may not vote and may not be present during the voting process.

4. Approval Memoranda:
I) Approval memoranda are signed by the IBC Chair or Associate Chair. IBC approvals are issued for time periods no longer than 3 years.

5. Inspections:
I) Lab Inspections:
i) The IBC strongly encourages PI's to self-inspect their labs at least monthly with the understanding that standing members of the IBC may request that a research facility or laboratory be inspected for adherence to NIH Guidelines and safe laboratory practices.
ii) Biosafety inspections or audits will be carried out by a subcommittee of the IBC designated by the IBC Chair.

6. IBC Charter Review:
I) IBC members will review and approve IBC Charter and any proposed amendments to the charter during fully convened IBC meetings and vote on acceptance of such.

References:
NIH Institutional Biosafety Committees: https://osp.od.nih.gov/biotechnology/institutional-biosafety-committees/
Federal Select Agent Program: https://www.selectagents.gov/
National Fire Protection Association (NFPA): https://www.nfpa.org/
Occupational Safety and Health Administration (OSHA): https://www.osha.gov

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