

## 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 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 Division of Biomedical Research or 2) occur as part of a research proposal in which any of the following are used.
- 1) recombinant or synthetically derived nucleic acids – including chemically or otherwise modified analogs of nucleotides (<http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>)
  - 2) known or suspected human, animal, or plant pathogens or infectious agents (<http://www.cdc.gov/biosafety/publications/bmb15/>)
  - 3) potentially infectious materials – including human tissue, blood, body fluids, cells, or cell strains (<http://www.cdc.gov/biosafety/publications/bmb15/>)
  - 4) compounds or materials that are
    - a) Select agents or toxins (<http://www.selectagents.gov/SelectAgentsandToxinsList.html>)
    - b) Included in the current *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*: (<http://www.cdc.gov/niosh/topics/hazdrug/>)
    - c) Classifiable as Category 1 Health Hazards under the *Globally Harmonized System of Classification and Labeling of Chemicals* (<https://www.osha.gov/dsg/hazcom/ghsguideoct05.pdf>)
    - 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 Operational Vice President for Research
- B. Decisions and findings of the IBC are final and may only be overturned or remedied by subsequent action of the committee.

### II. Committee Membership:

- A. **Chair:** The IBC Chair is designated annually by the Operational VP of Research for the Nemours Foundation. The Chair may be removed at any time in the interim by the Operational VP of Research for the Nemours Foundation if more than 2/3 of the committee membership expresses a vote of "no confidence".
- B. **Associate Chair:** The Associate Chair is designated annually by the Operational VP of Research for the Nemours Foundation. The Associate Chair may act as Chair when the Chair is absent and during meetings where the Chair has a submittal in review.
- C. **Biosafety Coordinator:** The Biosafety Coordinator supports the general business operations of Nemours, the Department of Biomedical Research, and the NIH-registered Institutional Biosafety Committees at Nemours. The Biosafety Coordinator files annual reports to NIH/OBA per Section IV-B-2-a-(3) of the *NIH Guidelines*.
- D. **Membership:** Members are nominated by the Chair and must be approved by the Operational

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VP of Research for the Nemours Foundation. Members may be removed by the Operational VP of Research for the Nemours Foundation at any time with the consent of the IBC chair.

### **III. Special Member Responsibilities:**

#### **A. 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 Operational VP of Research of the Nemours Foundation, may temporarily shut down research operations pending an emergency meeting of the IBC.
8. Report IBC proceedings to the office of the Operational VP of Research of the Nemours Foundation and meet with administrative staff 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 Operational Vice President of the Nemours Foundation 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/OBA regarding significant problems or violations per Section IV-B-2-b-(7) of the *NIH Guidelines*.
4. Inform IBC members of OBA and RAC 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 Operational VP of the Nemours Foundation 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. Outside member(s):**

1. Represents the interest of each surrounding community with respect to health and protection of the environment.
2. With the unanimous agreement of the entire geographically distinct outside membership, may terminate, temporarily shut down, or disapprove any submittal considered by the IBC based on community or environmental concerns.

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### **E. All members:**

1. All members must declare any conflict of interests at the onset of meetings.
2. Must review and consider all submittal 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 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.

### **F. Non-committee members:**

IBC meetings are open to the 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 Operational VP of Research of the Nemours Foundation 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 among the IBC members.

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### IV. General IBC Function:

#### A. Meetings

1. Per Nemours Foundation policy, 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 financial interest. Each member is expected to notify the IBC chair in these circumstances and recuse themselves when discussing such submittal and are up for a vote. In addition, if the IBC chair is principal investigator on a submittal, the Associate Chair or another IBC committee member present at the meeting will sign the approval documentation, if approved.

#### 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, Centers for Disease Control and Prevention, or Occupational Safety and Health Administration biosafety and bloodborne pathogen standards.
  - b. Research carried out in CLIA-Approved or 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 JCAHO 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 PI by the IBC Administrative 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 IBC Administrative Coordinator (x536779) or by sending a request to [www.biosafety@nemours.com](mailto:www.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

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Operational VP of Research for the Nemours Foundation.

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 Operational VP of Research for the Nemours Foundation 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.

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### 6. IBC Charter Review:

- D) 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 Guidelines: <https://osp.od.nih.gov/biotechnology/institutional-biosafety-committees/>

Federal Select Agent Program: <https://www.selectagents.gov/index.html>

NFPA: <https://www.nfpa.org/>

OSHA: <https://www.osha.gov>

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December 5, 2018

March 5, 2019

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