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 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

Administrative Process Coordinator is responsible for the initial technical and administrative review of all IBC submissions. This initial review is used to determine iooo

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 who1.ere.6 (re ∋DCy)-4.5L-0.00 (a 8 -1

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

5. Inspections:
I) Lab Inspections:
i) The IBC strongly encourages PI's to self-inspect their labs at least monthly with the