

# LA-UR-25-32006

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**Title:** LANL IBC Meeting Minutes, September 4, 2025

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LANL IBC Meeting Minutes, September 4, 2025		
Element		Notes
Institution	Los Alamos National Laboratory	
Meeting Date	Thursday, September 4, 2025	
Meeting Time	8:33 AM – 11:04 AM	
Meeting Type	In person meeting and Virtual via Webex	
IBC Members	1. Kumkum Ganguly (IBC Chair/ Biology) 2. Georga Ali (BSO/ Industrial Hygiene/Biology) 3. Carla Jo Logan Young (BSO Back-up/ Industrial Hygiene/Biology) 4. Sara Pasqualoni, MD (SOMD) 5. Armand Dichosa (IBC Member/ Biology) 6. Sofiya N. Micheva-Viteva (IBC Member/ Biology) 7. Jessica Kubicek-Sutherland (IBC member/Biology) 8. Maureen Dolan (Non-voting member/Observer -LANL- Office of General Counsel) 9. Wesley David Boose, MD (IBC Member/ Occupational Health) 10. Kent Allen Candee (IBC Member/ Industrial Hygiene) 11. Richard Honsinger, MD (Local Non-affiliated Community Member) 12. Joyce Richins, RN (Local Non-affiliated Community Member) 13. Tamas Torok (Other DOE Member; LBNL)	
Quorum	The IBC has 12 voting members, and 1 non-voting member. For a quorum, 7 members are required to conduct business. Late arrivals and early departures to be noted here.	Quorum present. Kumkum Ganguly, Joyce Richins, and Sara Pasqualoni were absent. Kent Candee arrived late to the meeting at 9:25AM and Sofiya Micheva-Viteva arrived slightly late to the meeting. Carla Jo Logan Young left meeting at 9:30AM due to a glovebox event.
Other Individuals in Attendance	None	
Call to Order		IBC Action: Call to order 8:33 AM
Review and approval of previous meeting minutes		IBC Action: June 5th, 2025 meeting minutes approval Votes: 7 members -For - For/Against/Abstain: (7 For/0 Against/0 Abstain)
Review of Prior Business		- Discussion of previous IBC applications. Open discussion and vote per the NIH Guide Notice-NOT-OD-25-082 IBC Meeting Minutes public webpage post and LANL IBC Meeting Minutes from June 5, 2025. LANL IBC Members approved and the vote was passed.
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PI Name(s)	Name (s) Julian Chen	
Registration Number/Title	New Registration 2025: IBC-199 Efficacy assays of ion channel recovery from TTX and STX exposure by designed peptides	Design of peptidomimetics targeting marine toxins
Project Overview	<ul style="list-style-type: none"> <li>• <b>Agent name:</b> HEK 293 cells ; Rhabdomyosarcoma RD CCL-136 cells; Tetrodotoxin (TTX); Saxitoxin (STX).</li> <li>• <b>Agent Characteristics:</b> BT-474 cells are immortalized human cell line derived from human embryonic kidney cells that were transformed with human adenovirus type 5 DNA in the 1970s. Rhabdomyosarcoma (RD CCL-136) cells are large, multinucleated, spindle-shaped cells isolated from muscle tissue. Use this cell line for your research and for the detection of viruses. Tetrodotoxin and Saxitoxin- Select Toxins.</li> <li>• <b>Sources and nature of the nucleic acid sequences (e.g., species, structural transgene, oncogene, toxin):</b> ATCC for BT-474 and RD CCL-136, 12-16 amino acids.</li> <li>• <b>Host(s), vector(s), and Donor Genes if used:</b> None</li> <li>• <b>Modifications (e.g., deletions, insertions, mutations to attenuate, or render replication incompetent) and note of any supporting documentation (published or unpublished data):</b> Designed peptides to block toxin binding.</li> <li>• <b>Types of experimental manipulations that will be employed:</b> cell culturing and toxin challenging of competent cells.</li> <li>• <b>Proposed biosafety containment levels at which each operation will occur:</b> BSL-2</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Additional pertinent information:</b> <ul style="list-style-type: none"> <li>- The PI is proposing to analyze two cell lines, HEK293, and rhabdomyosarcoma (RD) cells, being assayed for the efficacy of designed peptides in blocking the binding of the select toxins- tetrodotoxin (TTX), and saxitoxin (STX).</li> <li>- All cell line work will be manipulated under the BSL-2 conditions inside a Class II Biosafety Cabinet with use of appropriate PPE and methods. This should protect any personnel who are working with these cell lines. This work which is proposed to be conducted at BSL-2.</li> <li>- Section III-D-1-a -the protocol uses commercial cell lines have been tested for well-known bloodborne pathogens, including HIV-1, HCV and HBV. Human cell lines could be potential carriers of poorly identified cancer-inducing viral pathogens. Therefore, these cells shall be handled as containing potentially infectious agents using universal precautions. All human cell lines are considered BSL-2 at LANL and are subject to the provisions of the BBP Standard.</li> </ul> </li> </ul>
NIH Guidelines Section	III-D-1-a: Experiments involving the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 2 agents will usually be conducted at Biosafety Level (BL) 2 containment.	Two cell types — HEK 293 cells and rhabdomyosarcoma RD CCL-136 cells are human cells with epithelial morphology — will be used following standardized protocols. Permissible Toxin Amounts: The following toxins are not regulated if the amount under the control of the principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor does not exceed, at any time, the aggregate toxin limit specified in the HHS select agent and toxin regulations [42 CFR 73.3(d)(7)], or the amounts indicated in the table below. (Tetrodotoxin - 500 mg; Saxitoxin - 500 mg)
Risk Assessment and Discussion	<ul style="list-style-type: none"> <li>• Individuals will wear Standard PPE for BSL-2 labs: a disposable long-sleeved lab coat, safety glasses, and nitrile gloves. Two pairs of gloves (typically one layer of nitrile/neoprene and one layer of vinyl) are worn and disposable sleeves. Hand washing is required before leaving the BSL-2 lab. Staff will be trained in laboratory safety practices, including sharps safety.</li> <li>• No sharps will be used in the BSL-2 labs for any of the activities.</li> <li>• PPE and controls for toxins: The outer/second layer of gloves, typically made of PVC, will be disposed of in specific chemical waste after use. When entering the biosafety cabinet, disposable Tyvek sleeve will be used. TTX and STX will only be used in a chemical hood with proper ventilation. This will follow the approved Chemical Hygiene Plan.</li> <li>• Cells will be cultured in disposable sterile flasks using disposable filtered pipettes for all manipulations to protect against aerosols.</li> </ul>	Pathogenicity: All commercial human cell lines have been tested for well-known bloodborne pathogens, including HIV-1, HCV and HBV. Though, human cell lines could be potential carriers of blood borne pathogens. All human cell lines are considered BSL-2 at LANL and are subject to the provisions of the BBP Standard. TTX and STX are Acute Toxicity, oral - Category 1, Acute Toxicity, dermal - Category 1 Acute Toxicity, inhalation - Category 2 Route of transmission: Direct contact of skin or mucous membranes, ingestion, and accidental parenteral inoculation are the primary laboratory hazards associated with cell cultures of immortalized cell lines. For TTX and STX, the most likely route for personnel handling cell culture samples is dermal exposure. Use in a chemical fume hood, with air supplied by an independent system. Avoid inhalation, contact with eyes, skin and clothing. Avoid the formation of dust and aerosols. Use in a well-ventilated area. Keep away from sources of ignition. Avoid prolonged or repeated exposure. The most like route of transmission of TTX and STX is through direct contact with samples. Environmental stability: Cells are stable for a few hours at 4C. Select toxins, TTX and STX, will not be poured down sinks/ drains. Infectious dose: Concentration/Total volume: To be purchased. Frozen stocks will be stored at 1 x 10 <sup>6</sup> cells/ml. Availability of effective medical preventative or treatment options: Exposure shall be reported immediately to Occupational Medicine and therapeutics will be determined by physician.
Training	Document completion of required institutional level training as well as detailed laboratory or protocol specific training.	<ul style="list-style-type: none"> <li>- Current in LANL Biosafety Training</li> <li>- Current LANL BSL2 Proficiency checklist on file</li> <li>- Current in LANL Chemical Worker Training</li> <li>- Safe sharps handling Training</li> </ul>
Occupational Health Representative review (if applicable):	Note any: • Vaccination requirements • Respiratory protection • Periodic review of any medical surveillance • Post-exposure response procedures	Bloodborne Pathogen Medical Surveillance enrollment in Biohazard Program and Human Pathogen Program. Exposure shall be reported immediately to Occupational Medicine and prophylaxis will be determined by physician.
Biosafety Level Assignment	<ul style="list-style-type: none"> <li>• BSL2 labs for all cell line work will be manipulated inside a Class II Biosafety Cabinet with use of appropriate PPE and methods.</li> <li>• Mixed Waste Requirements</li> </ul>	<ul style="list-style-type: none"> <li>- Individuals will wear Standard PPE for BSL-2 labs: a disposable long-sleeved lab coat, safety glasses, gloves (specific for handling select toxins/chemicals per SDS). Two pairs of gloves (typical example- one layer of nitrile/neoprene and one layer of vinyl) are worn and disposable sleeves.</li> <li>- All waste materials removed from the biosafety cabinet will be reacted to completion with 10% bleach solution and solidified with waste. These include used laboratory plasticware and gloves contaminated with mammalian cells, and culture media, including select toxin specific waste.</li> </ul>
IBC Vote	Note: If the IBC grants approvals based on specific conditions being met, there should be a formal mechanism for verifying the conditions are fulfilled (e.g., the BSO will conduct an inspection to verify all Biological Safety Cabinets are up to date on certification before work may commence, all training must be completed before lab staff may begin work etc.).	IBC Action: Votes: 7 members -For - For/Against/Abstain: (7 For/0 Against/0 Abstain) - Conflict(s) of Interest: None. - A vote to defer with major conditions the IBC Application pending the major changes and/or conditions to be met was made and was seconded, including scheduling a special IBC meeting for the application discussion before 12/1/2025.
New Business/ Additional Topics		The approved IBC Meeting Minutes from June 5, 2025 is currently being reviewed by the LANL Classification Office.
Review of Incidents	The NIH Guidelines require that significant incidents, violations and research-related accidents and illnesses be reported to NIH OSP. For information regarding incident reporting requirements please refer to the Incident Reporting FAQs.	No Incidents were reported.
Inspections/ Ongoing Oversight	For IBC -145 and IBC-198 met inspections for the labs granted approval.	
Public Comments	There were no public comments.	
Adjournment		IBC Action: Adjournment 11:04 AM Votes: 7 members -For - For/Against/Abstain: (7 For/0 Against/0 Abstain) - The next meeting scheduled is for December 4th, 2025 from 8:30 am to 11:30 am in person and via Teams/WebEx.