

Institutional Biosafety Committee Minutes

Lahey Hospital and Medical Center

April 1, 2025

9:00am- 10:30am

Committee Name: Institutional Biosafety Committee

Committee Chair: Alexander Pyden, MD

Recorder: Patricia Bruff, Biosafety Coordinator

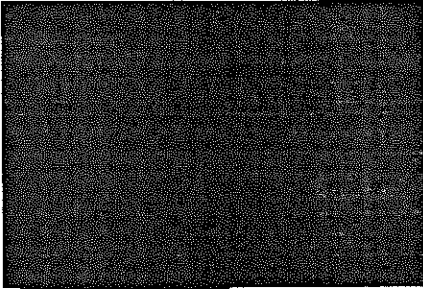
Members Present: Robert Belanger (remote), Patricia Bruff (Administrative), Nancy Campbell, RN, Bin Chen, MD, PhD, Kimberly Rieger-Christ PhD (invited guest), Christine Mathis, Alexander Pyden, MD, Nicholas Repucci (invited guest), Travis Sullivan, Juliana Torres (Administrative)

Members Excused: Robert Jurgen

Topic	Discussion	Action	Follow-Up
Committee Membership	<p>Membership was reviewed by the committee.</p> <p>Since the last meeting in April 2024, Juliana Torres joined Research Administration. After this meeting, Patricia Bruff will be stepping down from her role as IBC Coordinator and Juliana will be taking over the position. In preparation Juliana has been helping with IBC correspondence and meeting preparation.</p>	<p>Juliana was welcomed by the Committee.</p> <p>Membership contact information reviewed and approved.</p>	<p>IBC Coordinator will update Coordinator contact information.</p> <p>Review at next meeting.</p>

Emergency Coordinator Roster	Emergency contacts were reviewed by the Committee.	Emergency Coordinator Roster and contact information reviewed and approved.	IBC Coordinator will update Coordinator contact information. Review at next meeting.
Review of IBC Functions and Standards	Functions and Standards were reviewed by the Committee, no changes or questions.	Accepted by the Committee.	Review at next meeting.
Review of minutes from April 5, 2024	The Committee reviewed the meeting minutes from April 5, 2024	The minutes from the April 5, 2024 meeting were approved and accepted by the Committee.	None.
Review of Laboratory Inspection April 5, 2024	<p>The inspection reports from April 5th were reviewed by the Committee.</p> <p>Ian C. Summerhayes, PhD, Cell and Molecular Biology Laboratory – there were no major deficiencies identified. The committee recommended to replace a liquid hazardous waste secondary container with a larger container able to hold 110% of the volume.</p> <p>Laboratory of Tissue Regeneration, Plastic Surgery- no major or minor deficiencies identified, and no recommendations were made.</p>	<p>Reports were noted by the Committee.</p> <p>All items had been addressed since the last meeting.</p>	None.

Adverse Events	No adverse events, spills, or personal exposure reported during 2024.	None.	None.
Review of Town of Burlington rDNA Permits	The 2025 permit was reviewed.	Noted by the Committee.	Permit posted in laboratories. Renew permit by February 28, 2026.
Review of NIH Annual Report	Registration active and current until July 24, 2025. Lahey Clinic's IBC Registration was found to be compliant with Sections IV-B-2-a(3) of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.	Noted and reviewed by the Committee.	Next report will be due by July 24, 2025.
Review of Biosafety Manual	No changes at this time.	None.	None.
Review of Select Agents List	The list of HHS and USDA Select Agents and Toxins was updated on January 14, 2025. The committee reviewed the Select Agent Lists submitted to the Committee by investigators Rieger-Christ & Guo.	No changes. The investigators do not use or store any of the Select Agents or Toxins listed.	None.

New Protocol Review	<p>Oleg Yerstein, MD (IBC) #25-001:</p>  <p>The purpose of this Neurology study is evaluating the safety and effect of [REDACTED] administration on progranulin protein levels in patients with frontotemporal dementia with progranulin mutations (FD-GRN).</p> <p>[REDACTED] is the investigational biological agent, adenoassociated virus serotype 9 (rAAV9.CBA.GRN), a non-replicating recombinant adeno-associated virus of serotype 9 (rAAV9) utilizing an AAV9 vector to deliver a functional GRN gene.</p> <p>The IBC Coordinator gave a brief overview of the protocol to the</p>	<p>The Committee was in favor of the clinical trial being conducted at Lahey.</p> <p>The Committee unanimously voted to categorize it as BSL-2, RG-2.</p> <p>The Committee requested that protocol pages be prepared with the following information: a summary of appropriate training, agent preparation and transportation conditions, spill response, PPE requirements, and proper disposal practices.</p>	<p>Biosafety Coordinator to connect with Safety Officer and Study Team to prepare protocol page addressing the Committee's concerns and send to Committee for review and determination via Email once available.</p>
---------------------	---	---	--

	<p>Committee members. The Committee reviewed the safety and precaution recommendations in the pharmacy manual provided by the sponsor.</p> <p>The sponsor suggested assigning BSL-1 status.</p> <p>The Committee discussed applicable training for study personnel. They recommended general precaution and bloodborne pathogen trainings in addition to Biosafety and study specific training.</p> <p>The Safety Officer made recommendations for spill response and transportation precautions in a secondary container.</p> <p>The Committee recommended to have the agent prepared in a BioSafety Cabinet.</p> <p>The Committee also discussed the proper disposal of the agent.</p>		
New Protocol Review	Matthew Clements, MD (IBC) #25-002:	The Committee was in favor of the clinical trial being conducted at Lahey.	Biosafety Coordinator to connect with Safety Officer and Study Team

	<p>[REDACTED]</p> <p>The purpose of this study is to learn about how effective and well tolerated the study drug, [REDACTED], is alone or in combination with other study drugs in patients with high-grade non-muscle invasive bladder cancer.</p> <p>[REDACTED] is a replication-deficient recombinant type 5 adenovirus vector containing the human interferon-α2b (IFN-α2b) gene and the excipient Syn3NODA.</p> <p>The IBC Coordinator gave a brief overview of the protocol.</p>	<p>The Committee unanimously voted to categorize it as BSL-2, RG-2.</p> <p>The Committee requested that protocol pages be prepared with the following information: a summary of appropriate training, agent preparation and transportation conditions, spill response, PPE requirements, and proper disposal practices.</p>	<p>to prepare protocol page addressing the Committee's concerns and send to Committee for review and determination via Email once available.</p>
--	--	---	--

	<p>The sponsor suggested assigning BSL-1 status.</p> <p>The Director of Safety will work with Environmental Health & Engineering to suggest proper PPE and disposal methods for the study team for [REDACTED]</p>		
New Protocol Review	<p>Matthew Clements, MD (IBC) #25-003:</p> <p>[REDACTED]</p> <p>The purpose of this research study is to evaluate how effective and well tolerated the study drug [REDACTED] is in patients with intermediate risk non-muscle invasive bladder cancer.</p> <p>The IBC Coordinator gave a brief summary of the protocol.</p>	<p>The Committee was in favor of the clinical trial being conducted at Lahey.</p> <p>The Committee unanimously voted to categorize it as BSL-2, RG-2.</p> <p>The Committee requested that protocol pages be prepared with the following information: a summary of appropriate training, agent preparation and transportation conditions, spill response, PPE requirements, and proper disposal practices.</p>	<p>Biosafety Coordinator to connect with Safety Officer and Study Team to prepare protocol page addressing the Committee's concerns and send to Committee for review and determination via Email once available.</p>

	<p>The sponsor suggested assigning BSL-1 status.</p> <p>The Committee reviewed the spill protocol suggested by the Sponsor.</p>		
Review of Annual Report	<p>Kimberly Rieger-Christ, PhD</p> <p>LCID# 97-00: "Oncogenesis of Epithelial and Mesenchymal Cells"</p>	<p>The Committee reviewed the annual report from Dr. Rieger-Christ and Travis Sullivan gave a brief description of the projects and materials used.</p> <p>Travis Sullivan abstained from voting.</p> <p>The Committee voted unanimously to approve for continuation.</p>	Continuation approval letter will be sent to the PI.
Review of Annual Report	<p>Lifei Guo, MD, PhD, FACS</p> <p>(IBC) 13-001: "Wound Healing and Tissue Regeneration"</p>	<p>The Committee reviewed the annual report from Dr. Guo and Bin Chen gave a brief update of the projects and materials used.</p> <p>Bin Chen abstained from voting.</p> <p>The Committee voted unanimously to approve for continuation.</p>	Continuation approval letter will be sent to the PI.
Inspection of Laboratories			

<p>Ian C. Summerhayes, PhD, Cell and Molecular Biology Laboratory</p> <p>Kim Rieger-Christ, PhD 31 Mall Road, Second Floor [REDACTED]</p>		<p>No major or minor deficiencies were identified. No recommendations were made.</p> <p>Some clutter under the biological hood was noted.</p>	None.
<p>Laboratory of Tissue Regeneration, Plastic Surgery</p> <p>Lifei Guo, MD, PhD 31 Mall Road, Second Floor [REDACTED]</p>		<p>No major or minor deficiencies were identified. No recommendations were made.</p>	None.
Topic	Discussion	Action	Follow-Up
Open Forum	<p>According to a Memo sent by the NIH on March 27, 2025-</p> <p>To maximally meet the transparency aims of the NIH Guidelines, on June 1, 2025:</p> <ul style="list-style-type: none"> • The NIH Office of Science Policy (OSP) will publicly post the rosters of all active IBCs registered with OSP via the IBC-Registration Management System (RMS). These rosters will include all members identified by name and role on the committee. In addition, NIH will be posting the contact information for the IBC Chair, Biological Safety Officer, and IBC Contact. 	<p>Kim Rieger-Christ, PhD notified Marketing & Communications of this new policy.</p> <p>Committee supported the posting of the IBC Roster and Minutes.</p>	<p>IBC Coordinator to coordinate with Marketing & Communications to have signed Meeting Minutes posted on Institution's website.</p>

	<ul style="list-style-type: none"> • NIH expects that approved meeting minutes from all IBC meetings occurring on, or after this date will be posted publicly on an institutional website. It is NIH's expectation that minutes will be posted immediately after approval and once all appropriate and allowable redactions have been made. Provisions of this memo only apply to meetings taking place on, or after June 1, 2025. Minutes from meetings before that date do not need to be posted but still must be provided to members of the public upon request. However, institutions may opt to voluntarily post this information in the spirit of transparency. 		
Adjournment	All agenda items were reviewed and discussed.	None at this time.	None.

Respectfully Submitted,

Patricia Bruff
Patricia Bruff (04/23/2025 09:35 EDT)

Patricia Bruff, Biosafety Coordinator

Alexander Pyden, MD
Alexander Pyden, MD (04/23/2025 15:31 EDT)

Alexander Pyden, MD

Chair, Biosafety Committee

Date: 04/23/2025