

Beth Israel Lahey Health 
 Beth Israel Deaconess Medical Center

Department / Committee:	IBC Committee
Institution:	BIDMC, Boston Campus
Membership Present:	Alex Toker, Chair Robert Griffin, BSO Gary Schweon, Unaffiliated Community Member Peter Weller, IBC Member; Infectious Disease Deborah Barbeau, IBC Member; Employee Health Lauren Peter, IBC Member; Research Compliance Barbara Garibaldi, IBC Member; Vet Adrein Sipos, Unaffiliated Community Member Simon Dillon, IBC Member; Genomics Jack Lawler; IBC Member; Pathology
Date:	June 4, 2025
Meeting Place:	Zoom Meeting
Meeting Convened At:	1:00 PM
Meeting Type:	Closed
Quorum: Quorum was met (at least one half plus one of roster present) and no committee members left the meeting early.	

<i>Item Category</i>	<i>Topic</i>	<i>Discussion / Follow-Up</i>
	Call to Order	Quorum present for meeting.
Meeting Minutes Approval	May 15, 2025 Minutes	No issues or questions regarding these minutes from members. Presiding motioned to approve, motion second, minutes were approved.
Scheduled Business 5 Year protocol rewrite	<i>Seaman</i> – 25-0041R: “Propagation of primary SIV and HIV-1 isolates and generation of infectious molecular clones and pseudoviruses” NIH Section: III-D and F	<p>Review/Clinical Review: The BSO presented the risk assessment. This is a rewrite/renewal of ongoing work under a previously approved protocol. The experiments will propagate primary isolates of Simian Immunodeficiency Virus (SIV) and Human Immunodeficiency Virus (HIV-1) and generate full-length genomic clones and singly or multiply gene-deleted subgenomic clones for measuring antibody responses in infected individuals or vaccine recipients (ELISA and antibody neutralization assays). PBMCs from human (known to be infected with HIV-1) and NHP will be handled. Staff training and lab inspection compliance was verified by the BSO.</p> <p>Biosafety Level Approval: Biosafety Level 1 (BL1) for plasmid cloning work in non-pathogenic E. coli. Biosafety Level 2 (BL2) for laboratory work with:</p> <ul style="list-style-type: none"> • Non-human primate blood, plasma and peripheral blood mononuclear cells (PBMC) • Human blood, plasma, PBMC and cell lines (e.g. HEK-293, HeLa, Jurkat etc.) <p>Biosafety Level 2 + (BL2+): BL2 containment with BL3 practices and procedures for:</p> <ul style="list-style-type: none"> • Production of SIV or HIV clones with pBR and pUC-based plasmids, SIV or HIV genomic DNA either unaltered or with point mutations, deletions, or insertions and reporter genes (e.g. GFP). • Production of full-length infectious clones of HIV-1 or SIV.

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		<ul style="list-style-type: none"> • Production and handling of HIV or SIV viral stock solutions. • Production of replication defective pseudoviruses with the SG3deltaEnv plasmid vector and site directed mutations for resistance to integrase, protease, or reverse transcriptase inhibitors. <p>Instructions for BL2+ safety procedures were provided to the PI.</p> <p>No comments, questions, or concerns from committee members.</p> <p>Vote to Approve: For: 10 Against: 0 Abstain: 0</p>
<p>Scheduled Business 5 Year protocol rewrite</p>	<p><i>Seaman</i> – 25-0044R: “Humoral Immunity to Coronavirus” NIH Section: III-F and III-E</p>	<p>Review/Clinical Review: The BSO presented the risk assessment. This is a rewrite/renewal of ongoing work under a previously approved protocol. The lab conducts high-throughput in vitro assays that utilize a pseudotyped retrovirus expressing the Coronavirus S protein for measuring neutralizing activity mediated by antibodies or small molecule inhibitors. Serum samples may be obtained from vaccinated mice, non-human primates, convalescent patients or vaccinated human volunteers.</p> <p>Risk to staff include potential exposure to infectious agents in human or animal samples and retrovirus vector. This is mitigated through assignment of BL-2 containment and work practices. OSHA BBP Standard applies. The PI chooses to perform the work with human and NHP source material at BSL2+. Staff training and lab inspection compliance was verified by the BSO.</p> <p>Biosafety Level Approval: Biosafety Level 1 (BL1) for laboratory work with: <ul style="list-style-type: none"> • Non-pathogenic E. coli for plasmid cloning. • Serum from vaccinated mice. Biosafety Level 2 (BL2) for laboratory work with: <ul style="list-style-type: none"> • Non-human primate blood, plasma and peripheral blood mononuclear cells (PBMC). • Primary samples of human blood, plasma, PBMC and other human source materials. • Established human cell lines (e.g. HEK-293/17 cells). • Replication incompetent retroviral vectors expressing the Coronavirus S. protein. The following stipulations apply: <ul style="list-style-type: none"> • An annually certified biosafety cabinet (BSC) must be used for BSL-2 assigned material handling. • Aerosol-proof rotors or centrifuge buckets with safety caps must be used during centrifugation of BSL2 assigned materials. • Follow sharps precautions when there are no alternatives to the use of sharps. Contaminated sharps must be discarded into sharps containers immediately after use. • Liquid potentially infectious cultures and recombinant waste must be treated with an appropriate disinfectant, such as bleach, prior to sink disposal. • Personnel exposure related to the project must be reported to the Biosafety Officer as soon as possible. Discussion: No comments, questions, or concerns from committee members.</p> <p>Vote to Approve: For: 10 Against: 0 Abstain: 0</p>
<p>Scheduled Business 5 Year protocol rewrite</p>	<p><i>Nucera</i> - 25-0045-R: Translational Research in Thyroid Cancer NIH Section: III-D</p>	<p>Review/Clinical Review: The BSO presented the risk assessment. This is a rewrite/renewal of ongoing work under a previously approved protocol and additional in vivo work proposed that is new to the protocol. The lab studies rare mutation Papillary</p>

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		<p>thyroid cancers (PTC) for which prognosis are normal poor and new work will is to evaluate the mechanism of long non-coding intergenic RNA for Xloc13 in PTC cells. Staff training and lab inspection compliance was verified by the BSO. All viral vectors used are replication incompetent.</p> <p>Biosafety Level Approval: BL1 for work with adeno associated virus (AAV) BL2 for all human cell lines as well as lentiral and retroviral vectors. BL2+ for any work where lenti and/or retrovirus vectors encode genes known or suspected to be oncogenic.</p> <p>Animal Biosafety Level Approval: Animal BL1 for implantation of AAV transfected mouse organoids Animal BL2 for implantation of human (transfected and non-transfected) cells.</p> <p>Discussion: One member noted that the IACUC protocol has not been approved yet and is up for review in the next meeting.</p> <p>One member noted that there were formatting issues and missing information in the protocol form, specifically check boxes not selected that should be. The BSO indicated they will review and complete the form in detail with the PI.</p> <p>Non-Biosafety Discussion and Recommendations: One member noted that the protocol does not indicate how donors were tested regarding source of human cells.</p> <p>Vote to Approve, pending corrections/modifications to protocol form. For: 10 Against: 0 Abstain: 0</p>
Reported Incidents		No incidents to report
Adjournment		Meeting adjourned at 1:15 PM.
General	Next meeting	The next meeting will be held on July 2 at 1:00 PM on Zoom Meeting