## Beth Israel Deaconess Medical Center

Department / Committee:	Institutional Biosafety Committee (IBC)		
Institution:	BIDMC, Boston Campus		
Membership Present:	Alex Toker, Chair		
	Robert Griffin, Biosafety Officer (BSO)		
	Nanette Moss, Biosafety Officer (BSO)		
	Gary Schweon, Unaffiliated Community Member		
	Deborah Barbeau, IBC Member; Employee Health		
	Barbara Garibaldi, IBC Member; Vet		
	Adrien Sipos, Unaffiliated Community Member		
	Simon Dillon, IBC Member; Genomics		
	Jack Lawler; IBC Member; Pathology		
Date:	August 6, 2025		
Meeting Place:	Zoom Meeting		
Meeting Convened At:	1:00 PM		
Meeting Type:	Closed		

**Quorum**: Quorum was met (at least half plus one of the roster members were present). One committee member recused themselves and left the meeting when their protocol was up for approval.

Item Category	Topic	Discussion / Follow-Up
	Call to Order	Quorum present for meeting.
Meeting Minutes Approval	June 4, 2025 Minutes	No issues or questions regarding these minutes from members. Presiding motioned to approve, motion second, minutes were approved.
Scheduled Business	Schulman—25-0018R: "Human endothelial cells and monocytes in blood coagulation" NIH Section: Section III-F, III-D	Review/Clinical Review: The BSO presented the risk assessment. This is a 5-year renewal/rewrite. This lab studies the role that endothelial cells and monocytes play in blood clotting at the genetic and molecular level with a focus on cell surface expression and procoagulant activity of tissue factor. Genes of interest include tissue factor (F3), tissue factor pathway inhibitor (TFPI), and other genes identified as involved in regulation of tissue factor and the blood coagulation cascade. The gene inserts are not considered high risk. No live animal work will be conducted. No sharps are used. Cell lines and vector details are provided in the Protocol Form. Potential staff risk from handling human source material and viral vectors is mitigated through use of BSL-2 containment and work practices. Lab safety training compliance is a stipulation for all staff. The lab was recently inspected and is in good compliance.  Biosafety Level Approval: Biosafety Level-1 (BSL-1) for work with E. coli Biosafety Level-2 (BSL-2) for work with human cells and lentiviral vectors.  Discussion: No additional questions or concerns from committee members.  Vote to Approve: For: 9 Against: 0

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		Abstain: 0
Scheduled Business	Toker—23-0031R: "PI3K and AKT Signaling in Cancer" NIH Section: III-D, III-E	Review/Clinical Review: The BSO presented the risk assessment. This is a 5-year renewal/rewrite. Dr. Toker's lab investigates the role of the AKT gene – (serine/threonine protein kinase) in breast cancer progression. AKT is thought to regulate specific transcription factors involved in cancer cell invasion and proliferation. They will alter the expression or function of these proteins and then examine how the modified tumor cells behave. All experiments are performed in vitro. Risk of exposure to viral vectors or human source material will be mitigated through use of BSL-2 containment and work practices including aerosol and sharps precautions and use of a BSC for all vector work. Lab safety training compliance is a stipulation for all staff. The lab was recently inspected and is in good compliance.
		Biosafety Level 2 (BSL-2)
		<b>Discussion:</b> No additional questions or concerns from committee members.
		Vote to Approve: For: 8 Against: 0 Abstain: 0
Scheduled Business	Clohessey—25-0025R: "PMPF Core COMS" NIH Section: III-D	Review/Clinical Review: The BSO presented the risk assessment. This is a 5-year renewal/rewrite. This lab aims to evaluate new therapies for the treatment of human disease, including cancer. Genetically engineered mouse models (GEMM models) will be acquired from investigators or from commercial sources (e.g., The Jackson Laboratory). Core experiments include: (1) The use of GEMMs to study the initiation and progression of cancer, and study how genetic manipulation influences response to treatment and (2) the use of immunocompromised mouse models for xenograft and transplant studies to evaluate how manipulation of cell lines impacts tumor growth and response to treatment.
		Risks to staff are potential exposure to lentivirus and retrovirus to overexpress or knockdown expression of the genes of interest which include oncogenes and tumor suppressors and the use of human tumor tissue samples for in vivo and in vitro studies. Risks are mitigated through use of BSL-2 and BSL-2+ containment and work practices including appropriate training. Lab safety training compliance is a stipulation for all staff. The lab was recently inspected and is in good compliance.
		Biosafety Level Approval: Biosafety Level 2 (BSL-2) for culturing human cells, work with viral vectors expressing low hazard genes Biosafety Level 2+ (BSL-2+) for LV expression of oncogenes and KO of tumor suppressor genes.
		Animal Biosafety Level Approval: Animal BL-2-N for housing mice with human xenografts
		<b>Discussion:</b> One member noted that a description of a PDX model is in the protocol; however, discussions between the BSO and the PI about this work suggest this may be an error. The committee requests that the PI verify the accuracy of this reference and, if necessary, revise the protocol and submit an amendment accordingly.
		Vote to approve, pending clarification on use of PDX model in the protocol: For: 9 Against: 0
		Abstain: 0

Scheduled Business	Barouch—25-0048: "Analysis of Immune Reponses During Measles Infection" NIH Section: N/A	Review/Clinical Review: The BSO presented the risk assessment. The lab proposes to receive and process measles challenged non-human primate and human clinical samples. Live virus may also be isolated, and stocks generated. All animal work will be carried out at collaborating labs outside of BIDMC. Public Health Agency of Canada and US Centers for Disease Control both recommend a minimum of BSL-2 precautions. Propose to approve at BSL-2+ with inclusion of any relevant medical surveillance as agreed by Employee Health and the committee. The lab has been inspected and has no biosafety deficiencies and staff receive annual institutional as well as division-specific (agent-specific) training.  "Yes" was selected for use in animals in the protocol form; however, this is inaccurate. The PI will be asked to revise the form accordingly.  Biosafety Level Approval: Biosafety Level 2+ (BSL-2+)  Discussion:  The committee agreed that although measles vaccination is a condition of employment, it should also be explicitly stated as a condition in the approval letter.  Vote to approve, pending correction to protocol form:  For: 9  Against: 0  Abstain: 0
Scheduled Business	Wegiel—25-0051: "Use of AAV-8 vectors to deliver gRNA" NIH Section: III-F, III-D	Review/Clinical Review: The BSO presented the risk assessment. The lab will use AAV-8 viral vectors to deliver gRNA to knock down the ZNF469 gene in vitro in cell culture and in live mice. The vectors are replication deficient, and they are purchased from Obio Tech. ready to use. They work with mouse cells and do not use human cells for in vitro work. The in vivo work consists of one-time injections into anesthetized WT mice. The viral vectors will be transported to the BIDMC ARF in special container to prevent leakage. The lab has been inspected and is in good compliance.  Biosafety Level Approval: Biosafety Level Approval: Biosafety Level Approval: Animal Biosafety Level Approval: Animal Biosafety Level Approval: Animal Bu-1-N  Recombinant waste must be treated with an appropriate disinfectant, such as bleach, prior to sink disposal. Contaminated sharps must be discarded into sharps containers immediately after use.  Discussion: No additional questions or concerns from committee members.  Vote to Approve: For: 9 Against: 0 Abstain: 0
Scheduled Business	Hong—25-0054: "Molecular, Cellular, Genetic, and Animal- based Studies of Lymphatic Pathophysiology" NIH Section: III-D, III-E and III-F	Review/Clinical Review: The BSO presented the risk assessment. The Hong lab studies how the body maintains fluid balance by the blood and lymphatic systems with a focus to the eye, where poor fluid drainage can lead to glaucoma. They aim to improve treatments by understanding how the eye's drainage system works, especially after surgery using various in vitro and in vivo approaches. This PI recently joined BIDMC and lab will be inspected prior to commencing work.  Biosafety Level Approval: Biosafety Level 2 (BSL-2) work with human source materials (e.g. cells, tissue), KSHV/HHV8 and adenoviral vectors.  Biosafety Level 2+ (BSL-2+) for work with Lentiviral vectors expressing vGPCR (oncogene) and Sendai virus vectors expressing oncogenes.  Biosafety Level 1 (BSL-1) for work with E. coli.

		Animal Biosafety Level Approval: Animal BSL-2 for injecting recombinant fluorescent-tagged KSHV into mice and housing. Animal BSL-1 (BL-1-N) for housing mice undergoing treatments that do not include human cells, virus or rDNA.  Discussion: Members discussed where the animal work may potentially take place depending on space and initiation of work. No additional questions or comments from committee members.  Vote to approve, pending passing laboratory inspection: For: 9 Against: 0
		Abstain: 0
Scheduled Business	Barouch—25-0056: "Development and Evaluation of Vaccines and Therapeutics against SARS-CoV-2" NIH Section: N/A	Review/Clinical Review: The BSO presented the risk assessment. The lab currently has approval to conduct work with a wide range of SARS-CoV-2 infected samples. Early in the COVID-19 pandemic, propagating, titrating, and other work with purified live virus was only permitted at BSL-3 (NIH/CDC). Within the past year guidance has shifted as the population is no longer naive and vaccination within lab worker populations is high. New guidance now permits the propagation and use of SARS-CoV-2 at BSL2. The lab would like to expand operations to include growing and handling purified virus. Agent-specific training is delivered to all lab staff by the division manager. The division has several trained shippers for 6.2 and class 9 (dry ice) shipping. Three staff members need to provide confirmation that they are up-to-date with the consolidated research safety training refresher before final approval is granted.  Biosafety Level Approval: Biosafety Level Approval: Biosafety Level Approval: Animal Biosafety Level Approval:
		Vote to approve, pending confirmation that staff are up-to-date with
		the consolidated research safety training refresher.
		For: 9
		Against: 0 Abstain: 0
Scheduled Business	Barouch—25-0055: "Propagation and Study of BSL2/BSL2+ Live Virus Isolates of Existing and Emerging Pathogens" NIH Section: N/A	Review/Clinical Review: The BSO presented the risk assessment. This new protocol is to expand the laboratories operations to include new viruses of interest for emerging pathogens. At this time none of the pathogens are known to cause serious or life-threatening disease in immune-competent individuals. The lab will perform several types of experiments, including live virus stock production, live virus titration, RNA extraction, live virus neutralization/inhibition assays, and generating cell lysates from infected cells. No animal experiments are proposed at BIDMC. The lab may receive samples of infectious animal tissues (non-human primates and mice) from experiments carried out at collaborating labs. Lab may also receive human clinical samples.
		Agent-specific training is delivered to all lab staff by the division manager. The division has several trained shippers for 6.2 and class 9 (dry ice) shipping. Three staff members need to provide confirmation that they are upto-date with the consolidated research safety training refresher before final approval is granted. All viruses have recommended containment level of BSL-2 however work will be carried out in the divisions BSL-2+ suites. The BSL2+ was recently inspected and is in good compliance.
		Biosafety Level Approval: Biosafety Level 2+ (BSL-2+) based on the location of where the work will take place.

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		Discussion: No additional questions or concerns from committee members.  Vote to approve, pending confirmation that staff are up-to-date with the consolidated research safety training refresher.  For: 9 Against: 0 Abstain: 0
Scheduled Business	Porter—25-0049: "Study of Single Doses of SBT777101 in Subjects With Hidradenitis Suppurativa (Regulate-HS)" NIH Section: III-C	Review/Clinical Review: The BSO presented the risk assessment. This is a study evaluating SBT777101 as a treatment for Hidradenitis Suppurativa, a chronic skin condition marked with localized inflammation and the presence of skin lesion. The treatment is an autologous T cell formulated by expanding and isolating Treg cell population and transducing with a replication-incompetent lentiviral vector encoding CAR for citrullinated proteins (found within lesions). The cell expansion, selection, and transduction will be carried out in a GMP facility and shipped to BIDMC as a frozen product to the CMSF.  PPE in these units consist of disposable gowns as well as enhanced nitrile gloves designed for handling chemotherapeutics. Waste streams for sharps and other contaminated materials are present. Transport will be in biohazard labelled cooler. Nurses are provided training, per study team, on cell therapy. Clarification on the content of the training is recommended.  The clinical reviewer noted that the protocol for is lacking details about SBT777101 including regarding dosing, transduction of autologous cells, how participants will be monitored, and anticipated risks of thromboembolic events occurring. Clinical reviewer recommends approval following corrections to the form.  Biosafety Level Approval: Biosafety Level Approval: Biosafety Level 2 (BSL-2)  Discussion:  Members agreed that the protocol form was lacking in detail in the areas the clinical reviewer mentioned and that the PI should update the form to include more detail.  One member requested that the PI provide a more recent version of the Investigator's Brochure (IB), as the one provided was more than a year old.  Vote to approve, pending clarification on the content of the training, updates to the protocol, and receipt and review of a more recent IB.  For: 9  Against: 0  Abstain: 0
Reported Incidents		No incidents to report
New Business		A training presentation will be given during the next meeting.
Adjournment		Meeting adjourned at 1:50 PM.
General	Next meeting	The next meeting will be held on September 3rd at 1:00 PM on Zoom.
Contral	Heat meeting	The hort meeting will be held on deptember old at 1.00 1 W on 2001.