

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 Simon Dillon, IBC Member; Genomics Peter Tsvetkov; IBC Member; Pathology
Date:	January 7, 2026
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	December 10, 2025 Minutes	No issues or questions regarding these minutes from members. Presiding motioned to approve, motion second, minutes were approved.
Scheduled Business	<i>Rosenblatt</i> — 25-0074 “Phase I study of vaccination with DC/MM fusion cells in combination with BCMA directed CAR-T cell therapy in relapsed/refractory multiple myeloma (MM)” NIH Section: Not Applicable	<p>Clinical Review: This is a new phase I clinical trial to evaluate the safety and efficacy of dendritic cell (DC)/myeloma fusion cell vaccination in patients receiving standard of care B-cell maturation antigen (BCMA) directed Chimeric Antigen Receptor (CAR) T-cell Therapy for relapsed/refractory multiple myeloma (MM).</p> <p>A DC/tumor fusion vaccine has been developed in which patient-derived tumor cells are fused with autologous dendritic cells (DCs) allowing a broad array of myeloma antigens to be presented to T cells in the presence of DC-mediated co-stimulation. It is anticipated that a combinatorial strategy will improve the duration of response to CAR-T therapy and minimize chance of relapse.</p> <ul style="list-style-type: none"> Autologous tumor cells will be harvested from bone marrow aspirate and cryopreserved. Patients undergo apheresis for T cell isolation for CAR T-cell generation. Peripheral blood mononuclear cells (PBMCs) will also be collected for DC/MM fusion vaccine generation. Patients undergo lymphodepletion chemotherapy then CAR T-cell therapy (ide-cel or cilta-cel) infusion. Monitoring and supportive care regimen will be implemented as per standard institutional practice. <p>On day 30-60 following CAR T-cell infusion, eligible patients will be evaluated by physical exam and if eligible, will be treated with the DC/MM fusion cell vaccination - 2 doses as a subcutaneous injection in the thigh in</p>

Meeting Minutes

		<p>conjunction with (Granulocyte-Macrophage Colony-Stimulating Factor) GM-CSF every 4 weeks.</p> <p>BSO Risk Assessment: Exposure risk to staff is consistent with those posed by standard patient care tasks (e.g. bloodborne pathogen (BBP) exposure from human body fluids). Standard precautions provide appropriate mitigation for this. Risk is further minimized due to serology screening of patients for: Syphilis (Treponema Pallidum Antibody), Hepatitis B (HBV) Surface Antigen, HBV Surface Antibody, HBV Core Antibody, HBC Antibody, Hepatitis A Antibody, HIV 1&2 Antibody and Antigen, CMV IgG Antibody, Toxoplasmosis, Antibodies for Varicella zoster virus (IgG), TB T-spot, Measles IgG, Mumps IgG, Rubella IgG. The laboratory, manufacturing area and clinics are equipped with PPE, biohazard/medical waste containers and sharps containers for disposal of contaminated materials. The lab is equipped with biosafety cabinets and staff are trained in exposure response procedures. The lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval.</p> <p>No concerns related to biosafety issues, recommend approval.</p> <p>Discussion: One member noted that risks related to other therapies is not included. Committee members concluded that, because those other therapies are being administered as standard of care, description of the risks is not required.</p> <p>Vote to Approve: For: 7 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 February 7 at 1:00 PM on Zoom Meeting