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 Nanette Moss, BSO Gary Schweon, Unaffiliated Community Member Adrein Sipos, 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 Jack Lawler; IBC Member; Pathology
Date:	September 3, 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.	

Item Category	*Topic*	*Discussion / Follow-Up*
	Call to Order	Quorum present for meeting.
Meeting Minutes Approval	August 6, 2025 Minutes	No issues or questions regarding these minutes from members. Presiding motioned to approve, motion second, minutes were approved.
Scheduled Business	*Santra*—25-0058-R: Immunopathogenesis and immune responses to human and nonhuman primate immunodeficiency viruses NIH Section: Not Applicable	**Review:** The BSO presented the risk assessment. This is a 5-year renewal/rewrite. This research involves evaluation of the efficacy of experimental HIV/SIV vaccines developed at the Duke Human Vaccine Institute, Durham, NC and tested in nonhuman primates at Bioqual, Rockville, MD. The vaccines are made with a replication incompetent, nonintegrating lentiviral vector expressing HIV-1/SIV proteins (<1/3 of genome) and a reporter gene. At BIDMC there will be no propagation or experimental manipulation/engineering of lentiviral vectors. However, the BIDMC research staff may dilute the vaccine vector and prepare syringes for agent administration at the primate center. After treating the animals, specimens will be sent to BIDMC. Here, the NHP blood and tissue samples from the animals who have received vaccines and challenge agents (SIV or SHIV), will be processed for various assays (e.g. flow cytometry, ELISpot, ELISA, and other immunological/virological assays). Lab safety training compliance is a stipulation for all staff and specialized training for working with NHP specimens. The lab was recently inspected and is in good compliance. **Biosafety Level Approval:** **Biosafety Level-1 (BSL-2)** **Discussion:** No additional questions or concerns from committee members.

		Vote to approve: For: 10 Against: 0 Abstain: 0
Scheduled Business	*Robson*—25-0057-R: Purinergic signaling and CD39 family in inflammation, fibrosis, cardiovascular diseases and cancer NIH Section:	**Review:** The BSO presented the risk assessment. This is a 5-year renewal/rewrite. The lab studies genes such as CD39 in the context of inflammation, fibrosis, cardiovascular disease and cancer. The lab utilizes replication incompetent adenovirus for invitro studies as well as human donor derived cells for animal studies. Lab safety training compliance is a stipulation for all staff. The lab was recently inspected and is in good compliance. The BSO noted the following edits needed on the protocol form: – Clarify if any recombinant vectors are delivered directly into mice. – Clarify inclusion of lentivirus within the adenovirus entry—likely a carry-over from prior work. – Address viral vector use in the risk assessment section on the protocol form. **Biosafety Level Approval:** **Biosafety Level-1 (BSL-1)** for plasmid cloning in non-pathogenic E. coli **Biosafety Level-2 (BSL-2) and Animal Biosafety Level-2 (BSL-2)** for work with human cells and housing animals that are administered human cells. **Biosafety Level-2 (BSL-2)** for laboratory work with replication incompetent adenovirus. **Discussion:** No additional questions or concerns from committee members. **Vote to approve, pending edits/clarifications to the protocol form:** For: 10 Against: 0 Abstain: 0
Scheduled Business	*McDermott*—25-0053: "A prospective, multicenter, open-label, randomized, actively controlled, parallel-group Phase 3 clinical trial to evaluate efficacy, safety, and tolerability of IMA203 versus investigators choice of treatment in patients with previously treated, unresectable or metastatic cutaneous melanoma (ACTengine® IMA203-301) NIH Section: Section III-C	**Review:** The BSO presented the risk assessment. This multi-site clinical trial is to evaluate the efficacy, safety and tolerability of IMA203, an adoptive cellular therapy (ACT) approach based on the use of T cell receptor (TCR)-engineered autologous T cells directed against tumor-specific human leukocyte antigen (HLA)-presented peptides. Risk to staff are considered low given that there is minimal chance of Replication Competent Lentivirus (RCL) and BBP precautions with enhanced PPE are deemed to provide appropriate exposure protection. Specialized safety training for handling/administering chemotherapeutic and biotherapy is a stipulation for clinical staff. **Clinical Review:** The appointed MD reviewer described the details of the study. IMA203 is an autologous T cell product engineered to express a PRAME-specific T Cell Receptor. PRAME, which stands for Preferentially Expressed Antigen in Melanoma, is a protein that is often found in melanoma cells and can be used as a diagnostic marker for melanoma and other cancers. The study product will only need to be thawed at BIDMC. It is then administered as a one-time IV infusion on an inpatient oncology unit by chemotherapy/ biotherapy certified oncology nurses. The research study will last 5 years with additional safety monitoring for 10 additional years. The biosafety risks and control measures are adequately documented. Recommend approval pending clarifications/edits to the protocol that the BSO noted in their review. **Biosafety Level Approval:** **Biosafety Level-1 (BSL-2) with** use of **chemotherapy level PPE**

		Discussion: No additional questions or concerns from committee **Vote to approve, pending requested edits to protocol form:** For: 10 Against: 0 Abstain: 0
Scheduled Business	*Liegel*—25-TBD: "A Phase 1 Study of adoptive T cell therapy with T cells stimulated by dendritic cell (DC)/tumor fusions in combination with decitabine and venetoclax in patients with acute myeloid leukemia (AML)" NIH Section: Not Applicable	**Review/Clinical Review:** This study is a Phase I, first in human trial in which patients with newly diagnosed AML are treated with decitabine/venetoclax in conjunction with DC/AML Primed T-cells (a personalized autologous adoptive T-cell infusion) and then boosted with DC/AML fusion cell vaccination. The primary objective is to assess safety and toxicity of therapy. The study is limited to patients who are not eligible for stem cell transplant, with rationale of adding immunotherapy to standard of care decitabine/venetoclax frontline therapy to improve durability of remission. The team has prior approvals for creation and administration of DC/AML fusion vaccines. This study adds the T-cell adoptive transfer component which is new and not previously presented to the IBC. Lab safety training compliance is a stipulation for all staff. The lab was recently inspected and is in good compliance. Clean rooms meet GMP clean room criteria. Staff that are RNs and other staff not differentiated **Clinical Review:** The appointed MD reviewer described the details of the study. Overall the study design is very traditional and appropriate—dose escalation with 3 different doses, very appropriately staggered, description of visit procedures and evaluations, including related to T-cell infusion. The most detailed description of the hypothetical toxicities, that relates to the T-cell infusion and the DC/AML, is located in the informed consent. Issues that the reviewer would like addressed: (1) Are there any data about the therapeutic product toxicities and (2) clarification regarding T-cell infusion toxicities and if it has been tested in humans or if no toxicities have been observed, (3) inclusion of a summary on potential risk to personnel. Recommend voting to approve, pending these clarifications. BSO advised he can ask the study team for data and will review ancillary study data, as well. **Biosafety Level Approval:** **Biosafety Level-1 (BSL-2)** **Discussion:** No additional questions or concerns from committee members. **Vote to approve, pending receipt and review of requested additional information:** For: 10 Against: 0 Abstain: 0
Reported Incidents		No incidents to report
Adjournment		Meeting adjourned at 1:45 PM.
General	**Next meeting**	The next meeting will be held on October 1st at 1:00 PM on Zoom Meeting