Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

Department / Committee:	**IBC Committee**
Institution:	BIDMC, Boston Campus
Membership Present:	Alex Toker, Chair Nanette Moss, BSO 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 Peter Tsvetkov; IBC Member; Pathology
Date:	February 4, 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.	

Item Category	*Topic*	*Discussion / Follow-Up*
	Call to Order	Quorum present for meeting.
Meeting Minutes Approval	January 7, 2026 Minutes	No issues or questions regarding these minutes from members. Presiding motioned to approve, motion second, minutes were approved.
Scheduled Business	*Lee* — 25-0076: Intracranial AAV injections in mice and rats NIH Section: III-D	**Review/Clinical Review:** The BSO presented the risk assessment for this new protocol. The lab studies neural activity related to memory processing using a mouse and rat model. AAV vectors containing optogenetic actuators for stimulating or suppressing neural activity and/or calcium sensors will be injected into brains of wild type or transgenic mice or wild type rats to study memory processing. The AAV vectors are of different serotypes of AAV (AAV1, AAV5, AAV8, AAV9) to control the number of neurons that are affected. AAV is Risk Group 1. Vectors are purchased ready to use and are replication incompetent (cap genes are deleted). The lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval. **Biosafety Level Approval:** **Biosafety Level-1 (BSL-1)** **Animal Biosafety Level Approval:** **Biosafety Level-1-N (BSL-1-N)** **Discussion:** No additional questions or concerns from committee members. **Vote to Approve:** For: 10 Against: 0 Abstain: 0

Scheduled Business	*Scammell* — 25-0035-R: Monosynaptic Tracing of Neural Circuits that Regulate Arousal and Sleep NIH Section: III-D	**Review/Clinical Review:** The BSO presented the risk assessment for this 5-year rewrite of an approved protocol. This lab studies the neural circuitry that regulates sleep/wake. To this end, the lab utilizes a number of recombinant viral vectors, all of which are administered intracranially. Most vectors are AAV-based. For retrograde tracing, a modified rabies SAD-B19 vaccine strain that lacks the G glycoprotein needed for infection and is replication incompetent is used. The G glycoprotein is provided in trans by an AAV vector. This vector system is in use by several other BIDMC labs as well. The lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval. **Biosafety Level Approval:** **Biosafety Level-1 (BSL-1)** for AAV **Biosafety Level-2 (BSL-2)** for G-deleted rabies **Discussion:** No additional questions or concerns from committee members. **Vote to Approve:** For: 10 Against: 0 Abstain: 0
Scheduled Business	*Stephenson* — 25-0002: HVTN 322: A phase 1 clinical trial to evaluate the safety and immunogenicity of the V2 apex-directed immunogens DV201P-RNA and DV202B1-RNA in adult participants without HIV NIH Section: III-C	**Review/Clinical Review:** The BSO presented the risk assessment for this multicenter, open-label trial. It is a first-in-human (FIH) trial for DV201P-RNA and DV202B1-RNA. This first-in-human Phase 1 clinical trial will evaluate two immunogens designed to induce HIV-1 envelope (Env) V2 apex-specific broadly neutralizing antibodies (V2 apex bnAbs). Both vaccines consist of a modified messenger ribonucleic acid (mRNA) encapsulated in lipid nanoparticles (LNP) that when translated in cells produces HIV-1 Env gp 150 transmembrane trimers. There will be forty volunteers without HIV and in overall good health, aged 18 to 55 years. Study duration is 22 months. It is manufactured under GMP at the Duke Human Vaccine Institute, Durham, NC. Risk to staff is unknown but considered to be minimal as there is no live agent or vector and allergic reaction or immune response is possible but unlikely. Solid waste materials must be disposed of in biohazardous waste containers and universal precautions will be followed. The lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval. The appointed MD reviewer described the details of the study and had no biosafety concerns with the study design or execution. Recommended approval. One member had a question about the vaccine schedules for the four groups in the study. The appointed MD reviewer provided a detailed rationale and explanation based on the study design and methodology. **Biosafety Level Approval:** **Biosafety Level-2 (BSL-2)** **Discussion:** No additional questions or concerns from committee members. **Vote to approve:** For: 10 Against: 0 Abstain: 0
Scheduled Business	*Rosenblatt* — 25-0075: A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel Versus	**Review/Clinical Review:** The BSO presented the risk assessment. This trial is designed to evaluate Anitocabtagene AutoLeucel (Anito-cel) vs. standard of care in RRMM patients. Anito-cel is a CAR-T cell product. Similar to other CAR-T cell products, Anito-cel is an autologous activated T cell preparation that has been transduced by 3rd generation lentivirus encoding anti-BCMA binding domain. Cells are then expanded, washed, and cryopreserved. The protocol does not list the spaces that may be used for administration,

	Standard of Care Therapy in Participants With Relapsed/ Refractory Multiple Myeloma NIH Section: III-C	however, assuming the spaces are the usual Gryzmish and Feldberg units for Car-T studies, they are suitable for the risks. Will ask the PI to confirm the rooms that will be used before final approval. The Dana 9 facilities have been inspected and are in good compliance. Staff training must be confirmed prior to final approval. The appointed MD reviewer described the details of the study. The only concerns were related to how the protocol form was filled out: 1. The section requesting a description of the structure and composition of recombinant or synthetic nucleic acid materials is incomplete. It is currently marked as "N/A," which is not appropriate. This section is not limited to materials produced at BIDMC, so it requires a description of the study product itself. 2. The section about testing for replication-incompetence also incorrectly marked "N/A". Testing for replication competence is performed at the study central lab, so "yes" should be marked. 3. The section about the vector being replication competent should be marked "No". Recommended approval, following completion of the above changes to the registration from as well as the confirmation of study drug administration rooms. **Biosafety Level Approval:** **Biosafety Level-2 (BSL-2)** **Discussion:** No additional questions or concerns from committee members. **Vote to Approve, pending edits/clarification to protocol form:** For: 10 Against: 0 Abstain: 0
Reported Incidents		No incidents to report
Adjournment		Meeting adjourned at 1:20 PM.
General	**Next meeting**	The next meeting will be held on March 4 at 1:00 PM on Zoom Meeting