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 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:	December 10, 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	November 5, 2025 Minutes	No issues or questions regarding these minutes from members. Presiding motioned to approve, motion second, minutes were approved.
Scheduled Business	*Kahn* – 25-0061-R: "Quantification of gene expression (mRNA), protein amount and metabolites associated with insulin resistance in human serum, tissue biopsies (liver, fat and muscle) and primary cells" NIH Section: NA; OSHA BBP: Yes	***Administrative Approval: Informational only,*** *no vote required.*
Scheduled Business	*Popov* – 25-0068-R: "Mechanisms of liver fibrogenesis and animal models of liver fibrosis and cancer" NIH Section: III-D, III-E	**Review/Clinical Review:** The BSO presented the risk assessment. This is a 5-year rewrite of a previously approved protocol. The lab studies hepatic fibrosis using in vitro and mouse models and testing compounds that potentially inhibit fibrosis. Lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval. **Biosafety Level Approval:** **Biosafety Level-2 (BSL-2)** for AAV, plasmids, human cells and transfected mouse cells **Biosafety Level-1 (BSL-1)** for non-transfected mouse cells **Discussion:** No additional questions or concerns from committee members.

		Vote to Approve: For: 9 Against: 0 Abstain: 0
Scheduled Business	*Bonder* – 25-0072: "A Phase 2 Randomized, Double-blind, Placebo-controlled, Parallel Study Evaluating the Safety and Efficacy of LB-P8 in Patients with Primary Sclerosing Cholangitis (PSC)" NIH Section: NA	**Review/Clinical Review:** The BSO presented the risk assessment. This is a clinical trial evaluating LB-P8 for the treatment of Primary Sclerosing Cholangitis (PSC). LB-P8 is an oral, once-daily live biotherapeutic product comprised of the Sponsor's proprietary L. citreum G511—a gram-positive, non-motile, non-spore-forming and facultative anaerobic single bacterium. Because gut microbiota can influence bile acid metabolism, LB-P8 is being tested as a treatment for PSC by normalizing bile acid homeostasis. Lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval and staff also undergo a study specific training. **Clinical Review:** The appointed MD reviewer described the details of the study. The study product, LB-P8 is a single-strain live biotherapeutic product (LBP) containing *Leuconostoc citreum* strain *G511*, a probiotic strain that has been isolated from vegetable-fermented food, delivered as a gastric-resistant oral capsule. The most common risk associated with taking LB-P8 is flatulence; less common risks include abdominal distension, abdominal pain, nausea and vomiting. Rare risks include severe nausea, severe abdominal pain, severe abdominal distension, severe vomiting, severe diarrhea, severe infection, biliary tract infection. These risks are adequately described in the Informed Consent Forms for both Part 1 and Part 2. LB-P8 is manufactured according to current Good Manufacturing Practice at BIOSE INDUSTRIE in Pompidou, France. Capsules arrive prepackaged in blister pouches. There is no preparation or manipulation of the study product at BIDMC, so risk to staff is not greater than routine patient care. Standard precautions are indicated. Recommend approval. **Discussion:** No additional questions or concerns from committee members. **Vote to Approve:** For: 9 Against: 0 Abstain: 0
Reported Incidents		No incidents to report
Adjournment		Meeting adjourned at 1:15 PM.
General	**Next meeting**	The next meeting will be held on January 7 at 1:00 PM on Zoom Meeting