

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 Adrien Sipos, Unaffiliated Community Member Lauren Peter, IBC Member; Research Compliance Barbara Garibaldi, IBC Member; Vet Simon Dillon, IBC Member; Genomics Jack Lawler; IBC Member; Pathology Peter Tsvetkov, IBC Member; Pathology
Date:	November 5, 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.
	Committee Member Changes	The committee welcomed Peter Tsvetkov and expressed appreciation to departing member, Jack Lawler, for his contributions to the IBC.
Meeting Minutes Approval	October 1, 2025 Minutes	No issues or questions regarding these minutes from members. Presiding motioned to approve, motion second, minutes were approved.
Scheduled Business	<i>Perelman</i> —25-0065-R: “LSS detection and identification of bacteria in human biologic fluids” NIH Section: NA	<p>Review/Clinical Review: The BSO presented the risk assessment. This is a 5-year rewrite of a previously approved protocol. The lab has developed an optical system for identification of clinically relevant bacteria related to sepsis in humans and they are creating a spectral library for the bacterial organisms that are Risk Group 2 pathogens, none of which bear antibiotic resistance and are all acquired from ATCC. To build the optical-signature library they will spike blood samples with bacteria and conduct measurements using their optical system and compare to standard hospital laboratory diagnostic tests. The lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval.</p> <p>Stipulations in approval letter will include consult with Employee Health regarding 1) reproductive risks and exposure to <i>L. monocytogenes</i> and 2) availability of vaccination for <i>N. meningitidis</i>.</p> <p>Biosafety Level Approval: Biosafety Level-2 (BSL-2) for work with the bacteria and human blood samples.</p> <p>Discussion:</p>

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		<p>A member inquired about which serogroup is used for Neisseria meningitidis work. The BSO clarified that the previous restriction limiting lab work to vaccine-covered strains is no longer in effect, as all strains are now considered covered. Employee Health noted that both the quadrivalent and serogroup B vaccines are available, though availability of the pentavalent vaccine is uncertain. A request was made to include a reminder in the approval letter that staff may contact Employee Health to receive these vaccines.</p> <p>Vote to approve: For: 11 Against: 0 Abstain: 0</p>
<p>Scheduled Business</p>	<p><i>Jiang</i>—23-0030-R- Amendment: “Center for Virology and Vaccine Research Cell Sorting Facility” NIH Section: NA</p>	<p>Review/Clinical Review: The BSO presented the risk assessment. This is an amendment to a previously approved protocol. The lab is proposing to add two new agents to the registration: Human cytomegalovirus (HCM) and herpes simplex virus (HSV) including cells which may contain these pathogens. This applies to work at the core cell sorting facility in CLS-10 which processes samples including fixed and unfixed samples of human or non-human primate (NHP) cells or cultured cells or cell lines which may contain these viral agents. They are obtained from Dr. Coen of Harvard Medical School and are both classified as Risk Group 2. Sorter is enclosed in a biosafety cabinet as well. The lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval.</p> <p>Biosafety Level Approval: Biosafety Level-2+ (BSL-2+)</p> <p>Discussion: No additional questions or comments from committee members.</p> <p>Vote to approve: For: 11 Against: 0 Abstain: 0</p>
<p>Scheduled Business</p>	<p><i>Verstegen</i>—25-0062-R: “Bladder fullness signaling and the neural control of continence” NIH Section: III-D</p>	<p>Review/Clinical Review: The BSO presented the risk assessment. This is a 5-year rewrite of a previously approved protocol. The lab proposes to use Adeno-Associated Viral vectors (AAVs) from approved Viral Vector Cores to introduce genes into distinct groups of neurons in the central nervous system of transgenic mice. Modified Rabies-virus will also be used (glycoprotein-deleted Rabies viral vector EnvA-SAD-deltaG-GFP) for transneuronal, monosynaptic retrograde tracing to reconstruct the neuronal circuitries. It lacks the rabies glycoprotein essential for viral spread and expresses the fluorescent protein GFP instead. The transgenes are not considered hazardous. The lab is on the schedule to be inspected and compliance will be confirmed prior to final approval, along with confirmation of staff training.</p> <p>Biosafety Level Approval: Biosafety Level-1 (BSL-1) for lab work with AAV Biosafety Level-2 (BSL-2) for lab work with EnvA-SAD-deltaG-GFP</p> <p>Animal Biosafety Level Approval: Biosafety Level-1-N (BSL-1-N) for housing AAV only treated mice Biosafety Level-2-N (BSL-2-N) for housing Mod Rabies G-deleted injected mice</p> <p>Discussion: No additional questions or comments from committee members.</p> <p>Vote to approve For: 11 Against: 0 Abstain: 0</p>
<p>Scheduled Business</p>	<p><i>Santra</i>—25-0070-R:</p>	<p>Review/Clinical Review: The BSO presented the risk assessment. This is a</p>

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	<p>“Design and Development of a Panbetacoronavirus Vaccine” NIH Section: NA</p>	<p>5-year rewrite for a previously approved protocol. The lab is working to develop vaccine candidates that will be effective against a spectrum of Coronavirus strains. To this end, all vaccine manipulations as well as vaccine administration and challenge will be performed at an external BSL-3 animal facility. The lab will receive animal specimens (non-human primates) after vaccine administration and/or subsequent challenge. Non-human primate materials training slides are sent to PI to ensure staff training. The lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval.</p> <p>Biosafety Level Approval: Biosafety Level-1 (BSL-2+), but for most unfixed work the lab will handle at BSL-2+</p> <p>Discussion: The BSO noted that there is a non-human primate tissue handling training that Dr. Santra uses for staff that handle the primate tissues.</p> <p>Vote to Approve: For: 11 Against: 0 Abstain: 0</p>
<p>Scheduled Business</p>	<p><i>Karnoub—25-0069-R:</i> “Molecular Mechanisms of Tumor Progression” NIH Section: III-D and III-E</p>	<p>Review/Clinical Review: The BSO presented the risk assessment. This is a 5-year rewrite of a previously approved protocol and no new materials are proposed. The lab uses retroviral and 3rd generation lentiviral vectors to modify human and mouse cell lines. Cell lines will subsequently be injected into mice for in vivo tumor studies. The lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval.</p> <p>Biosafety Level Approval: Biosafety Level-2+ (BSL-2+)</p> <p>Discussion: One member asked to clarify if the lab had recently moved to a new location and another member indicated that are in the process of moving location. The BSO indicated that they will re-inspect the lab once they have fully moved.</p> <p>Employee Health advised that there is updated guidance that has come out for post-exposure prophylaxis for lentiviral vectors exposures, as well as for retroviral vector exposures. The protocol indicates they are working with second generation lentivirus but want to confirm if there are any safety features in the retroviral vectors they are using so to help determine exposure response and treatment. The committee discussed and agreed that this will be applicable to many other protocols and it would be appropriate to create guidance, broken up by the different retroviruses and lentiviruses, that can be distributed with the approval letters.</p> <p>Vote to Approve: For: 11 Against: 0 Abstain: 0</p>
<p>Scheduled Business</p>	<p><i>Hochbaum—25-0008</i> Amendment: Understanding molecular pathways that shape cognition and behavior NIH Section: III-D</p>	<p>Review/Clinical Review: The BSO presented the risk assessment. This is an amendment to a previously approved protocol that requests to add lentiviral constructs for in vitro studies. The vectors will be created in house using 3rd generation packaging system in HEK293 cells. The genes of interest are either fluorphoes or bioactive genes involved in thyroid regulation pathways. The lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval.</p> <p>Biosafety Level Approval: Biosafety Level-2 (BSL-2)</p> <p>Discussion: No additional questions or comments from committee members.</p> <p>Vote to Approve:</p>

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		<p>For: 11 Against: 0 Abstain: 0</p>
Scheduled Business	<p><i>Penaloza</i>—25-0032-Amendment: Evaluation of immune responses following immunization with novel vaccine platforms NIH Section: III-D</p>	<p>Review/Clinical Review: The BSO presented the risk assessment. This is an amendment to a previously approved protocol. The lab is studying vaccine development and subsequent immune responses as applied for pathogens of interest as well as cross reactivity with closely related pathogens. The lab wishes to add several additional vaccines, including Attenuated Junin Virus Candid#1, Attenuated Pichinde Virus, and SARS-CoV-2 vaccine candidates (mRNA; E1/E3-deleted Adenovirus 5/26; VSV). Additionally, for the SARS-CoV-2 portion, mice will be challenged with either human coronavirus OC43 or mouse coronavirus MHV-A59 mouse hepatitis virus. OC43 causes mild cold symptoms in humans. MHV-A59 can cause severe respiratory disease in mice and is used as a safer surrogate to study severe respiratory disease in mouse models. The lab has been inspected and is in good compliance. Staff training must be confirmed prior to final approval.</p> <p>Biosafety Level Approval: Biosafety Level-2 (BSL-2) for all vaccine candidates as well as the coronaviruses proposed</p> <p>Discussion: No additional questions or comments from committee members.</p> <p>Vote to Approve: For: 11 Against: 0 Abstain: 0</p>
Scheduled Business	<p><i>Stephenson</i>—24-0022-Amendment: A Phase 1 clinical trial to evaluate the safety and immunogenicity of CH505M5 N197D mRNA-gp160 followed by CH505 TF mRNA-gp160 in adults in overall good health without HIV NIH Section: III-C</p>	<p>Review/Clinical Review: The BSO presented the risk assessment. This is an amendment to an approved clinical trial evaluating mRNA vaccine candidates for developing immune response to HIV in participants that do not have HIV. One added boosting vaccine option is added with a modified gp160 antigen.</p> <p>Appointed Review: The appointed MD reviewer described the details of the study amendment and noted so far the vaccine has been well tolerated, and no significant adverse events have been reported. The Summary of Changes document suggests that this third vaccine (Boost 2) is an optional vaccine for study participants. It is not clear if it is only an optional vaccine for those already enrolled in the study, but part of the study going forward for newly enrolled participants. Recommended approval once this is clarified.</p> <p>Discussion: The BSO indicated that typically when something is added they have study participants sign a re-consent.</p> <p>Vote to Approve, pending requested clarification: For: 11 Against: 0 Abstain: 0</p>
Old Business	<p>Review of proposed approval letter statement regarding Employee Health consultation</p>	<p>The committee reviewed proposed language for inclusion in approval letters to remind staff they may contact Employee Health with any questions or concerns related to personal safety or additional support needs. The committee agreed on “Consultation with Employee Health is available for any unique risks or concerns regarding your personal health status and this research work and the availability of vaccines, if applicable.” The committee agreed that a link to Employee Health’s web address on the portal will be included in the letter as well.</p> <p>The BSO clarified that this language does not replace language that is included for work with specific agents that have unique hazards, such as listeria or HSV.</p>

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Scheduled Business	NIH Guidelines Review for Committee Members	An overview was given to committee members related to the basics of the NIH guidelines as they apply to IBC members. This included a brief history of the NIH guidelines, IBC committee requirements under the NIH guidelines, protocol review responsibilities, NIH classifications of research, meeting minute requirements, IBC review and conflicts of interest, and potential NIH guideline revisions coming in the future.
Reported Incidents		No incidents to report
Adjournment		Meeting adjourned at 2:00 PM.
General	Next meeting	The next meeting will be held on December 3 at 1:00 PM on Zoom Meeting