**IBC Meeting Minutes**
May 22, 2025 (Thursday) at 11:00 A.M.
via Zoom Conference Bridge

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**IBC members present:**

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| Tom Greenough (Chair) | X | Shaoguang Li | | Carol Schrader | X | Edward Jaskolski (alt) | X |
| Lisa Cavacini | X | Philip Tai | X | Mohan Somasundaran | | Timothy Kowalik (alt) | |
| Colleen Driskill | X | Robert Klugman | | Richard Ellison III (alt) | | Regino Mercado-Lubo (alt) | X |
| Kris Giaya | | Amelia Houghton | X | Sharone Green (alt) | | Casey Moran (alt) | X |
| Hardy Kornfeld | | Eric Rouse | X | Jennifer Wang (alt) | | | |

**Non-members present:** Patrice Rando (IACUC/IBC Office)

## I. Introductory Remarks

1) The Chair brought to the attention of the Committee the action items completed since the previous meeting and those submissions still under review by IBC.
2) The Chair brought to the attention of the Committee the meeting minutes from the previous IBC meeting. **Meeting Decision: Vote to approve April 17, 2025 Meeting Minutes**
3) DURC/PEPP policy go-live 05/06/2025; Executive order 05/05/2025 indicating upcoming revisions
4) IBC Minutes public posting go-live 06/01/2025

## II. Report on incidents/accidents from Employee Health Services (EHS)

1) Past incidents: all closed
2) Recent incidents: 04/20205 ferret bite without infectious agent or rsNA involvement). 05/2025 PAPR malfunction in BSL-3. Details pending

## III. Protocols Reviewed Administratively

1) Investigator: Punzo, C
Title: Photoreceptor metabolism in ocular diseases
**IBC Registration: 453-20, Amendment**
Training Verification: Acceptable
Brief Summary: Adding following routes of administration: Intraocular

2) Investigator: Reboldi, A
Title: B cell response at the mucosal interface
**IBC Registration: 666-21, Amendment**
Training Verification: Acceptable
Brief Summary: Adding following routes of administration: Pertussis toxin: IV, Diphtheria toxin: IV, Salmonella Particle: IP, Salmonella: IP

3) Investigator: Wu, M
Title: Novel mechanism tumorigenesis and immune evasion
**IBC Registration: 903-24, Amendment**

Training Verification: Acceptable
Brief Summary: To add: human peripheral blood mononuclear cells (PBMCs) or leukopacks purchased from the UMass Chan Human Peripheral Blood Leukocyte Procurement Core. These human-derived samples will be used in new in vitro experiments designed to study the epigenetic and metabolic regulation of human immune cell function. No infectious agents will be introduced. All manipulations will be conducted under BSL-2 containment. No new recombinant or synthetic nucleic acid molecules are introduced into the human cells at this stage.

4) Investigator: Zhou, W
Title: Immune Regulation in Intestinal Physiology, Inflammation, and Diseases
**IBC Registration: 918-25, New**
Training Verification: Acceptable pending completion of PI training / Acceptable
Brief Summary: The gastrointestinal (GI) tract plays an essential role in our overall health and well-being. It contains one of the largest immune systems which promotes tolerance to the nonharmful microbiota and protects against infection. However, dysregulated immune response drives numerous diseases. The goal of this project is to dissect, at the cellular and molecular level, 1) how immune homeostasis is achieved in the gut; 2) how dysregulation of these pathways impacts health and disease, and 3) how we can harness approaches to reinstate gut homeostasis, treat human diseases, and advance healthy life span.

## IV. Protocols to Discuss

1) Investigator: Adair, J
Title: Genetic engineering of cell lines and primary hematopoietic cells ex vivo and in vivo
**IBC Registration: 919-25, New**
Training Verification: Acceptable pending completion of PI training
Brief Summary: This research will develop scalable and cost-effective gene therapy to elicit directed immunity against human respiratory or immunodeficiency virus infections which impact tens of millions of patients worldwide, and for which traditional vaccination development has failed. We are proposing to use CRISPR to deliver precise genetic insertion of broadly neutralizing antibody transgenes against these viruses in immune cells and repopulating hematopoietic stem and progenitor cells both outside and inside the body. Our goals are:

- Genetic engineering of repopulating hematopoietic stem and progenitor cells (HSPC) to introduce broadly neutralizing engineered antibody transgenes
- Genetic engineering of various B cell types (i.e. the cells which naturally produce antibodies) to introduce broadly neutralizing engineered antibody transgenes

Evaluation of success by determining the extent to which genetically engineered HSPC or B cells fight off the relevant infection.

**Brief Summary and Review by Primary Reviewer**

**Overview and Objectives:** To develop scalable and cost-effective gene therapy to elicit directed immunity against human respiratory or immunodeficiency virus infections. To use CRISPR to deliver precise genetic insertion of broadly neutralizing antibody transgenes against these viruses in immune cells and repopulating hematopoietic stem and progenitor cells both outside and inside the body.

**Experimental Approach:** Genetic engineering of hematopoietic stem and progenitor cells (HSPC) and various B cell types to introduce broadly neutralizing engineered antibody transgenes. Evaluation of success by determining the extent to which genetically engineered HSPC or B cells fight off the relevant infection.

Engineering of murine, human and nonhuman primate cells ex vivo and in vivo in mice that result in directed immunity against specific viral pathogens including HIV, influenza and respiratory syncytial virus (RSV).

Electroporation, viral vectors and synthetic gold nanoparticles will be used for delivery of genetic engineering cargo. Genetic engineering cargo can include CRISPR as ribonucleoprotein complexes (protein + guide RNA), with or without a DNA template in the form of single stranded DNA, double stranded linear DNA, plasmid DNA, double stranded DNA genome adeno-associated virus (AAV), or RNA genome lentivirus vector (LVV). Genetic loci targeted for CRISPR gene editing include: β-2-microglobulin (B2M), immunoglobulin heavy chain (IgH), kappa light chain (Ig$\kappa$), c-c chemokine receptor 5 (CCR5). B2M is targeted to compare the activity of different nanoparticle formulations head-to-head. IgH, Ig$\kappa$, and CCR5 are clinically relevant loci for the addition of antibody transgenes.

Cell lines will be used to develop optimal genetic editing approaches, which will then be validated in primary cells. Optimized approaches will then be administered in vivo using synthetic nanoparticles or engineered viruses.

Species include human (healthy donors), nonhuman primate (rhesus and pigtailed macaque), and mouse (both immune deficient and wild-type strains). Nonhuman primate blood cells will be obtained from the Washington National Primate Research Center, animals are screened by IDEXX Bioanalytics testing for Corynebacterium bovis, Corynebacterium sp. (HAC2), EBV, HAdV, Hantaan, HCMV, Hepatitis A, Hepatitis B, Hepatitis C, HHV 6, HHV 8, HIV1, HIV2, HPV16, HPV18, HSV 1, HSV 2, HTLV 1, HTLV 2, LCMV, Mycoplasma sp., Seoul, Sin Nombre, Treponema pallidum, and VZV.

Cell lines include K-562, Jurkat, 293T, LCL 8664, MC38, and HeLa. Primary cells and tissues from all three species include blood and bone marrow. Mice will be purchased from Charles River Labs, Dr. Anthony Rongvaux of the Fred Hutchinson Cancer Center, or Jackson Laboratories. In some experiments, humanized or primatized mice will be treated with nanoparticles or viral vectors in vivo and genetic engineering of blood cells and other tissues will be assessed by flow cytometry over time and at necropsy.

Cells or animals may be challenged with antigens to which directed immunity has been engineered. Antigens can include viral proteins such as gp120 (HIV). Cell or animals may be challenged with infectious virus to determine protection from infection conferred by directed immunity. Infectious viruses can include HIV-1 or simian-human immunodeficiency virus (SHIV).

This project is a collaboration with the laboratory of Dr. Justin Taylor at the University of Virginia (UVA). While studies involving pathogens (HIV, SHIV, influenza and RSV) are included in this project, influenza and RSV infectious agents will be tested in Dr. Taylor's laboratory, while HIV and SHIV will be tested in the Adair laboratory at UMass Chan. Dr. Adair's laboratory is responsible for producing nanoparticles for both laboratories. Thus this application includes some synthetic nucleotides for engineered humoral immunity against RSV and influenza, but does not include infectious influenza or RSV strains. No production of viral vectors or infectious virus will occur in the Adair lab. All are obtained as ready to transduce or infect viral stocks from the suppliers noted.

Electron microscopy and Cryo-EM Cores: to confirm loading of cargo and to validate nanometer sizes of synthetic particles to ensure biocompatibility. The synthetic nanoparticles consist of a gold core nanoparticle (AuNP), CRISPR ribonucleoprotein complexes (RNP; composed of a synthetic guide RNA molecule and a Cas nuclease protein (Cas9, Cas12a or MG29-1)) and cationic polymers, with or without synthetic DNA (single or double-stranded). These nanoparticles are termed. CRISPR-AuNP. Cell lines or primary blood cells treated with nanoparticles in vitro will be examined to visualize subcellular delivery.

Light Microscopy core: Confocal microscopy to visualize nanoparticle uptake in cell lines and primary blood cells, both living and fixed. Nanoparticles are the same as noted above, with the exception that synthetic guide RNA, Cas nuclease protein and/or synthetic DNA cargo are modified to include fluorescent tags to visualize intracellular trafficking and cargo unloading.

Flow core: Flow cytometry is used to establish cell identity and assess genetic engineering in living cells through changes in cellular protein expression.

**IBC Discussion and Vote**

**Discussion:** Reviewer discussed that NHP samples, primarily cells, are coming from Washinton National Primate Research Institute. This project is in collaboration with Dr. Justin Taylor at the University of Virginia where the infectious agents will be administered. Discussion raised about ensuring the approved work area is capable of BSL-2+ work.
**Meeting Decision:** Vote to approve upon completion of action items.
**BSL/ABSL:** **BSL-2+; BSL-2 Enhanced Flow Sorting; ABSL-2**
**NIH Guidelines:** III-D, III-E, III-F

2) Investigator: Cecchini, S
Title: Recombinant Adeno-Associated Viral Vector Large Scale Production
**IBC Registration:** **751-25, Renewal**
Training Verification: Acceptable pending completion of PI training
Brief Summary: We continue to produce rAAV at large scale at UMMS to help researchers to determine the best clinical candidate, we produce rAAV in suspension cell culture using max of 2 x 200L bioreactor scale. We can achieve production of 10e14 vg to 10e16 vg per run depending on the volume of the bioreactor used.

- Using two suspension systems: HEK293 cells and insect cells Sf9
- Producing rAAV of high quality and purity

Clinical material from non-GMP environment

**Brief Summary and Review by Primary Reviewer**

**Overview and Objectives:** Large scale prep of rAAV (10^13 viral genomes/ml) in suspension cultures for internal PIs and external customers.

**Experimental Approach:** Using the standard triple transient transfection method as outlined here: https://www.nature.com/articles/d42473-018-00017-z for HEK293 system. HEK cells will be transfected with a plasmid expressing the Gene Of Interest (GOI) as well as a standard helper plasmid which expresses the viral proteins rep and cap, and one adenovirus-derived helper plasmid such as pAdDeltaF6. The BAC to Bac Sf9 insect cell system will alternatively be used. Final product volume will be 1L, while cell culture volumes in both systems will be 2 x 200L. rAAVs produced, which do not replicate, will be tested for infectivity in mammalian cells during quality control testing

**IBC Discussion and Vote**

**Discussion:** Reviewer discussed that the protocol mentions submitting an amendment for each additional oncogene added in the future. After thorough discussion, it was decided that an amendment would only be necessary if the lab checks “yes” to oncogenes, immunomodulators and toxins.
**Meeting Decision:** Vote to approve upon completion of action items.
**BSL/ABSL:** **BSL-2; BSL-2 Large Scale**
**NIH Guidelines:** III-D, III-E, III-F

3) Investigator: Fitzgerald, K

Title: Innate Immunity to Bacteria, Viruses, and Fungi

**IBC Registration:** **284-20, Amendment**

Training Verification: Acceptable

Brief Summary: We would like to add human Coronavirus Sars-Cov2 variant strains to our current Covid related studies. For both In-vivo and invitro experiments.

1. SARS-CoV-2 Parental
2. SARS-CoV-2 GFP-ORF8del

Addition of additional dose routes for In-vivo studies, for already approved viruses:

1. Alphavirus VEEV TC-83. Route: intracranial, footpad
2. Alphavirus Sindbis virus (SINV): Route: intracranial, footpad
3. Alphavirus Mayaro virus (MAYV), Route: intracranial, footpad
4. siRNA- small interfering RNA, Route: intracranial, footpad or intranasal
5. ASOs (antisense oligos), Route: intracranial, footpad or intranasal
6. Adeno-associated virus (AAV), Route: intracranial
7. HSV: Route: intracranial

## Brief Summary and Review by Primary Reviewer

**Overview and Objectives:** This amendment encompass the addition of globally-circulating variants of SARS-CoV-2 virus into an stablished registration to study the host immune response to these strains as well as exploring the preventive vaccine/treatment against them.

For their in vivo studies, the group is planning to use additional routes of administration for strains of alpha virus (already approved for in vitro use), siRNAs and ASO's. This agents will be included to perform a series of experiments to identify host RNA binding proteins (RBP) that interact with the genomic RNA of the viruses. Once identified, these RBPs will be tested for pro or antiviral functionality throughout viral infection. They will also be studied as potential target for therapeutic intervention. Multiple species of these RNA viruses will be used to see if these RBPS are shared across the genus or if they are unique to the individual species.

HSV virus will be utilized in conjunction with AAV's to investigate the innate immune signaling pathways in response to HSV and whether AAV active suppression of pathogen recognition receptors (PRRs) changes HSV disease progression in mice.

**Experimental Approach:** SARS-CoV-2 (new variants)

1. In vitro experiment: infect human cell lines with viral stock and measure the viral titer at specific time points to determine the infection and growth efficiency, as well as measure cellular response (cytokine mRNA, protein etc.) to the virus.

2. In vivo experiment: HuACE2 transgenic mice will be infected with SARs-Cov2 virus and their health will be monitored. Samples from mice will be harvested by the end of the experiment to study the host immune response, including flow analysis with fixed samples from infected mice. Additionally, recombinant monoclonal anti-human SARS-CoV-2 antibodies will be tested for protectivity against the new variant strains.

Alphaviruses (in vivo experiments)

NLRP1 transgenic mice and C57 WT control mice will infected with:

Sindbis (SINV) AR86: Intracraneal and foodpad

Sindbis (SINV) Toto1101: Intracraneal and foodpad

Sindbis (SINV) 389: Intracraneal and foodpad

Sindbis (SINV) P398.P726G: Intracraneal and foodpad

Venezuelan Equine Encephalitis Virus (VEEV) TC-83: Intracraneal and foodpad

Venezuelan Equine Encephalitis Virus (VEEV) TC-83-GFP: Intracraneal and foodpad

Mayaro Virus IQT 4235 virus: Intracraneal and foodpad
siRNA and ASOs: Intracraneal, foodpad and intranasal
Adeno-associated virus (AAV): Intracranea
Mice health will be monitored during the infectin. Samples from mice will be harvested by the end of the experiment to study the role of inflammation from NLRP1 inflammasomes. Samples will be harvested at distinct timepoints (1, 3, 5, and 7 days post the injection), in addition to survival experiments, where the mice will be closely monitored for signs and symptoms of disease. Measuring viral load in tissues of interest including ankle, quadricep, blood, lymph nodes, spleen and brain for plaque assay and qPCR. Immune response in tissues via qPCR, ELISA, histology and Western blotting.
HSV (in vivo experiment)
To investigate the critical components in innate immune signaling pathways in response to microbial infection including Herpes Simplex Virus (HSV). Mice will be infected intracraneally and their health will be monitored. Samples from mice will be harvested by the end of the experiment to study the role of immune response to the Sting agonist pre-treatment will be used to induce

**IBC Discussion and Vote**

**Discussion:** Reviewer discussed that the lab should name the specific variant of SARS CoV2 that is going to be used. Action items were discussed.
**Meeting Decision:** Vote to approve upon completion of action items.
**BSL/ABSL:** **BSL-3; ABSL-3**
**NIH Guidelines:** III-D

4) Investigator: Gruntman, A
Title: Adeno-associated virus mediated gene delivery for gene therapy of inherited Disorders
**IBC Registration:** **345-22, Amendment**
Training Verification: Acceptable
Brief Summary: Looking to create classical compliment activation by AAV antigen-antibody complexes as well as evaluating the effects on inhibition of the classical and alternative pathways while trying to understand toxicity due to complement activation.

**Brief Summary and Review by Primary Reviewer**

**Overview and Objectives:** Create classical compliment activation by AAV antigen-antibody complexes as well as evaluating the effects on inhibition of the classical and alternative pathways while trying to understand toxicity due to complement activation.

**Experimental Approach:** To study classical compliment activation, look at combined effects of compliment activation by administering anti-AAV9 mAB (monoclonal antibodies) at different concentrations. To study inhibition of classical and compliment pathways administer various pharmaceutical inhibitors such as Sutimlimab, Eculizumab, Pegcetacoplan, Novartis B and D factors and Ravilizumab in various strains of mice and ferrets.

**IBC Discussion and Vote**

**Discussion:** Discussion on action items and adding administration to animals using BSL-2 Precautions/ Sharps Safety
**Meeting Decision:** Vote to approve upon completion of action items.
**BSL/ABSL:** **BSL-2; ABSL-1 with Special Precautions; Administration to animals using BSL-2 Precautions / Sharps Safety**

**NIH Guidelines:** III-D, III-E, III-F

5) Investigator: Harris, J
Title: Determining the Factors that Contribute to Autoimmune Skin Disease
**IBC Registration:** **465-21, Amendment**
Training Verification: Acceptable
Brief Summary: We are proposing to add Adeno-Associated Virus (AAV) to the IBC protocol. This addition involves injections of AAVs to animals.
Biosafety Considerations:

- AAV is a replication-deficient viral vector with a low risk of pathogenicity.
- The proposed work will adhere to BSL-1/BSL-2 containment as appropriate for the specific serotype and use.
- Proper PPE, engineering controls, and decontamination protocols will be followed to mitigate any potential risks.

Added New Agents:

- Adeno-Associated Virus (AAV)

## Brief Summary and Review by Primary Reviewer

**Overview and Objectives:** The goal of the study is to recruit regulatory T cells and CAR Tregs to the skin following AAV vector transduction to treat vitiligo. In addition, the group will utilize AAV vectors to treat skin genetic disorders.
The amendment seeks to add adeno-associated virus (AAV) vectors to the IBC protocol. This addition involves injections of AAV vectors to animals.
The investigators propose that the work will use BSL-1/BSL-2 containment as appropriate for the specific serotype and use.

**Experimental Approach:** In vivo therapies: For AAV-mediated gene therapy approaches, AAV vectors will be packaged by the UMass Viral Vector Core. AAV vectors will be directly injected into animals.
Ex vivo therapies: Human and mouse T cells will be generated ex vivo using lentiviruses or gamma retroviruses (CAR and CAR T-regulatory cells) in Dr. Keeler's lab at UMassMed school and will be injected into animals.

## IBC Discussion and Vote

**Discussion:** The reviewer discussed that the amendment was not very clear in the way it was written. The protocol states that this was in collaboration with the Keeler lab to generate CAR T and CAR T reg cells. However, it was unclear if the Harris Lab is doing the experiments or the Keeler lab. The risk group would also depend on the usage of the CAR T reg cells but according to the amendment only AAV is being used so it was unclear. The reviewer discussed the lengthy action items list.
**Meeting Decision:** Tabled until next meeting
**BSL/ABSL:** **N/A**
**NIH Guidelines:** N/A

6) Investigator: Mercurio, A
Title: Mechanism of Tumor Progression
**IBC Registration:** **222-25, Renewal**
Training Verification: Acceptable pending completion of PI training

Brief Summary: Mechanisms that underlie the genesis of invasive carcinoma and the progression to metastatic disease are the major interests of the Mercurio laboratory with specific focus on breast, colon, and prostate carcinoma. Given that all the carcinomas arise from epithelia, our approach is rooted in the cell biology of the mammary gland and colonic or prostate epithelia and it emphasizes understanding those changes in epithelial organization and function that contribute to invasive carcinoma.

## Brief Summary and Review by Primary Reviewer

**Overview and Objectives:** Mechanisms that underlie the genesis of invasive carcinoma and the progression to metastatic disease are the major interests. Specific focus on breast, colon, and prostate carcinoma. Given that all the carcinomas arise from epithelia, the approach is rooted in the cell biology of the mammary gland and colonic or prostate epithelia and it emphasizes understanding those changes in epithelial organization and function that contribute to invasive carcinoma.

**Experimental Approach:** The experiment approach involves the use of human and murine cell lines as well as freshly procured cells or tissues from human cancer patients, Patient Derived Tumors (PDX) and Patient Derived Organoids (PDO), as well as transgenic mouse models for studying mechanism involved in epithelial morphogenesis and cancer progression. The cell lines and tissues requested for approval will be used for in-vivo as well as injections in mice, with the potential for added chemotherapy treatments.
Flow Cytometry will be utilized to examine changes in surface expression of different glycoproteins. Analysis will be done to quantitatively examine stem cell markers and determination of positive cells for a given stem cell marker.
Mammary Sphere Formation Assays (in vitro) will be done to examine the role of genes in regulating and maintaining Cancer Stem Cells. We will examine whether knockout of the genes affects Mammary Sphere Formation
The reagents requested for approval will be used to modulate the expression of specific genes and proteins in these cells by transfection or transduction and to assess the impact of altered expression on cell morphology and function.
Recombinant nucleic acids will be transfected in cells. These transfected cells will be used to decipher the function of the proteins translated from these rNAs. These rNAs will be expressed in viral vectors.
Platelets will be utilized to study the interactions between platelets and the cell lines requested for approval, via platelet adhesion assays.
Flow core sorting of unfixed, untested human cancer cell lines to stem-like cells using integrin antibodies; sorting at BSL-2 enhanced.
RNAi core will be used to procure pLKO.1 constructs expressing shRNAs targeting various proteins mentioned in section B1.
Animal imaging core will be used for live imaging of mice bearing tumors to estimate the tumor size and monitor metastasis.
EM imaging core will be used as well

## IBC Discussion and Vote

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|---|---|
| **Discussion:** | Reviewer discussed that the lab did a great job filling out the new form. Reviewer also discussed a few minor action items. |
| **Meeting Decision:** | Vote to approve upon completion of action items. |
| **BSL/ABSL:** | **BSL-2, BSL-2 enhanced flow sorting, ABSL-1+BBP with special precautions; administration to animals using BSL-2 precuations/sharps safety** |
| **NIH Guidelines:** | III-D, III-F |

7) Investigator: Reusch, D
Title: Krystal Biotech, Inc. / "A Double-blind, Randomized, Placebo-controlled Study of Ophthalmic Beremagene Geperpavec (B-VEC), for the Treatment and Prevention of Corneal Abrasions in Dystrophic Epidermolysis Bullosa"

**IBC Registration:** **920-25, New**
Training Verification: Acceptable
Brief Summary: DEB is a rare genetic blistering disease caused by mutations in the COL7A1 gene, which leads to a complete lack or dysfunction of its encoded type VII collagen (COL7). COL7 protein is the major component of anchoring fibrils responsible for the binding of the epidermis and dermis. In DEB, this attachment is disrupted leading to skin fragility and wounds involving the entire body surface area, as well as extracutaneous manifestations including oral, ocular, gastrointestinal, and genitourinary symptoms. It can be inherited in an autosomal dominant or recessive manner. In the eye, the corneal epithelial basement membrane is similar to that in the skin, where COL7 anchors the epithelium of the eye to the underlying layers. Therefore, patients with DEB may also suffer from various ocular findings, such as corneal abrasions (also referred to as corneal erosions or corneal lesions), scarring, blepharitis, and impaired vision. If left untreated, blistering and abrasions may give way to chronic scarring and progressive vision loss.

- To evaluate the safety and tolerability of ophthalmic B-VEC
- To evaluate the effect of ophthalmic B-VEC on the frequency of corneal abrasion symptoms in patients with Dystrophic Epidermolysis Bullosa (DEB)
  To evaluate the effect of ophthalmic B-VEC on eye pain

**Brief Summary and Review by Primary Reviewer**

**Overview and Objectives:** A Double-blind, Randomized, Placebo-controlled Study of Opthalmic Beremagene Geperpavec (B-VEC), for the Treatment and Prevention of Corneal Abrasions in Dystrophic Epidermolysis Bullosa

**Experimental Approach:** A decentralized, randomized, double-blind, placebo-controlled trial in patients with DEB will be conducted in which subjects will receive weekly topical doses of either vehicle or B-VEC to both eyes for a period of 12 weeks. All IP will be stored, handled, and dispensed using a central pharmacy and IP administration will occur in the patients' homes via home nursing. No UMASS staff will come in contact with IP throughout the trial.

**IBC Discussion and Vote**

**Discussion:** The Gene and Cell Therapy Committee had already reviewed this protocol.
**Meeting Decision:** Vote to approve upon completion of action items.
**BSL/ABSL:** **BSL-1**
**NIH Guidelines:** III-C

## V. Report on incidents/accidents/issues involving BSL-3 & ABSL-3 Facilities

1) Upgrade on the Lenel system (access control system) planned for June 3. Early am with on-site security in place.

## VI. Information from the field (Senior Biosafety Officer)

1) Select Agent inspection response was submitted to CDC and waiting for their response.

**VII. Other Business**

1) BSC certification is ongoing in the NERB and should be completed May 30

Acknowledgement Items:

1) Simin 443-19 Update *CorMedix* Principal Investigator: Mary Co
Update_Co_Simin 443-19 4.27.25 CorMedix_ PI Co.M/CorMedix DefenCath Protocol 24Oct2024.pdf

**Adjourned at 1:30pm**