

SAFETY Meeting Minutes
IBC Committee
WebEx

MEETING TIME RECORDS

Meeting start time: 6/20/2025 12:00 PM

Meeting end time: 6/20/2025 01:41 PM

NOTE: IBC members conflicted with any registration being reviewed or feel that there is a perception of a conflict are removed from the meeting prior to review of the specific registration. IBC staff ensure that there is a quorum at all times.

Name of Regular/Alternate Member	Status (Member or Alternate)	Present by Teleconference?
Kevin Prestia	Member	Yes
Ludovic Desvignes	Member	Yes
Richard Egnor	Non-Affiliate Member	Yes
James Borowiec	Member	Yes
Ramin Herati	Member	Yes
Robert Holzman	Member	Yes
Huma Arshad	Alternate Member	Yes
Benjamin Wu	Member	Yes
Paul Cella	Non-Affiliate Member	Yes
Gabriela Romero-Meza	Member	Yes
Abby Jennis	Non-Affiliate Member	Yes
Shamsul Arfin Qasmi	Member	Yes
Gregory David	Member	Yes
Cameron Meyer	Member	Yes
Magdalena Podkowik	Member	Yes
Takuya Tada	Member	Yes
Melvin Delvillar	Non-voting Member	Yes
Alison Gilchrist	Member	Yes
Fanny Tang	Member	Yes
Mark Olmsted	Member	Yes

QUORUM INFORMATION

Number required for quorum: 13

All members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

GUEST NAMES

Natalie Mays

Sanoma Morrison
Maxine Melchior

Motion to approve **IBC Meeting 05-16-25 12PM** IBC meeting minutes.

First Motion	Robert Holzman
Second Motion	Ramin Herati
Unanimously approved, no objections or abstentions	

Previous Meeting minutes approved: Yes

REVIEW OF SUBMISSIONS

1. Amendment/CR

Review of SAMENDCR202500000091

Name:	Amendment/CR for SPROTO202400000121
PI:	Milan Amin
Submission ID	SAMENDCR202500000091
Summary of Research	This study is intended to characterize the safety profile and dose-limiting toxicities of ascending doses of BB-301 administered locally to the middle pharyngeal constrictor muscles and the inferior pharyngeal constrictor muscles of subjects with Oculopharyngeal Muscular Dystrophy (OPMD) following open surgical dissection of the pharyngeal region under general anesthesia. The objectives are to identify the maximum tolerated dose/recommended phase 2 dose of BB-301, and to determine the impact of BB-301 on swallowing efficiency, swallowing safety, and pharyngeal constrictor muscle function in subjects diagnosed with OPMD with dysphagia via the use of serial clinical and videofluoroscopic assessments.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendation: BL1 for Pharmacy/Laboratory handling of genetically modified type 9 AAV construct. (will be administered intra-operatively) Section III-C, NIH Guidelines. Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation Section III-C-1, NIH Guidelines. Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants Human gene transfer is the deliberate transfer into human research participants of either: 1) Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or

	2) Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria: a) Contain more than 100 nucleotides; or b) Possess biological properties that enable introduction of stable genetic modifications into the genome (e.g., cis elements involved in integration, gene editing); or c) Have the potential to replicate in a cell; or d) Can be translated or transcribed. Appendix B-I, NIH Guidelines. Risk Group 1 (RG1) Agents RG1 agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic <i>Bacillus subtilis</i> or <i>Bacillus licheniformis</i> (see Appendix C-IV-A, <i>Bacillus subtilis</i> or <i>Bacillus licheniformis</i> Host-Vector Systems, Exceptions); adeno- associated virus (AAV – all serotypes); and recombinant or synthetic AAV constructs, in which the transgene does not encode either a potentially tumorigenic gene product or a toxin molecule and are produced in the absence of a helper virus. A strain of <i>Escherichia coli</i> (see Appendix C-II-A, <i>Escherichia coli</i> K-12 Host Vector Systems, Exceptions) is an RG1 agent if it (1) does not possess a complete lipopolysaccharide (i.e., lacks the O antigen); and (2) does not carry any active virulence factor (e.g., toxins) or colonization factors and does not carry any genes encoding these factors.
Motion to approve this registration with suggested biosafety recommendations.	

Determination: Approved

First Motion	Robert Holzman
Second Motion	Ramin Herati
Unanimously approved, no objections or abstentions	

Review Discussion:

This registration was presented to the IBC Committee, no questions or concerns were raised.

2. Initial Protocol

Review of SPROTO202500000097

Name:	S25-00556
PI:	Umamaheswar Duvvuri
Submission ID	SPROTO202500000097
Summary of Research	Xerostomia and salivary gland hypofunction is a serious side effect of cancer therapies. Radiation-Induced Xerostomia (RIX) significantly impairs patients' health and quality-of-life. This is a FIH, Phase I/IIa, multi-center, dose-escalation study evaluating the safety, tolerability and preliminary efficacy of intraductal administration of RXRG001 to parotid gland(s) in adults with RIX and hyposalivation.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: BL-1 given use of recombinant nucleic acid molecules Section III-C-1. Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Ramin Herati
Second Motion	Robert Holzman
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

This registration was presented to the IBC Committee, no questions or concerns were raised.

3. Amendment

Review of SAMEND202500000140

Name:	Amendment for IBC22-000098 NYULH
PI:	Tanya Sippy
Submission ID	SAMEND202500000140
Summary of Research	The Sippy Lab aims to understand the neural mechanisms underlying how sensory stimuli become associated with goal directed behavior. To accomplish this, the lab uses viruses (Adeno-Associated Virus, canine adenovirus, and glycoprotein deficient Pseudotyped Rabies Virus) to express fluorescent proteins in neurons. Viruses are injected in wild-type or transgenic animals, the aim being to more efficiently identify target neuronal populations and the connections between neurons.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1/BL-1N minimum):

	BL-1N For experiments involving the purchase or transfer of transgenic rodents are exempt if they conform to Section III-F-8-C-VII, NIH Guidelines BL-1N: BL-1N for infection of animals with recombinant AAV - NIH Guidelines, Section III-D-4-a. BL-2N: BL-2N for infectious recombinant canine adenovirus and glycoprotein deficient rabies virus in animals - NIH Guidelines Section III-D-1-a. BL-2 for use of tetrodotoxin and botulinum neurotoxins in animals under BMBL Appendix 1
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Alison Gilchrist
Second Motion	Fanny Tang
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

IBC Chair (Ludovic Desvignes) requested update to the biosafety recommendations to include BL-2 for the use of botulinum neurotoxin in animals under BMBL Appendix 1. The biosafety recommendations were updated to reflect the requested change.

4. Initial Protocol
Review of SPROTO202500000070

Name:	A platform for new antibiotic discovery Boeke
PI:	Jef Boeke
Submission ID	SPROTO202500000070
Summary of Research	Our goal is to create a library of brewer's yeast <i>S. cerevisiae</i> strains producing natural anti-bacterial products. We propose to develop a high-throughput synthetic biology platform for the structural diversification of therapeutically interesting products by expression of their biosynthetic gene clusters. After optimizing the production of a key biosynthetic intermediate we will express selected, or random subsets of tailoring enzymes. This will afford large libraries of clones with unique combinations of modifying enzymes that have the potential to produce novel bioactive structural derivatives. A rapid phenotypic screen will serve as an efficient read-out technique to identify colonies that contain bioactive analogs. Mass spectrometry (MS) and NMR spectroscopy will be used to assign the chemical structures of the metabolites produced by those yeast colonies that display the most interesting antibacterial properties. Our ultimate goal is to automate the entire process from colony picking, phenotypic screening to MS-measurements for the most promising candidates.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1/BL-1N minimum) BL-1 For recombinant plasmids in K12 strains of <i>E. coli</i> – Exempt under NIH Guidelines, Section III-F-8-C-II. BL-1 For recombinant plasmids in <i>S. cerevisiae</i> – Exempt under NIH Guidelines, Section III-F-8-C-III. BL-1 For recombinant plasmids in <i>B. subtilis</i> – Exempt under NIH Guidelines, Section III-F-8-C-V. BL-2: BL-2 For handling of <i>Klebsiella pneumoniae</i>, <i>Pseudomonas aeruginosa</i>, and <i>Staphylococcus aureus</i> -- Appendix D of the BMBL
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Alison Gilchrist
Second Motion	James Borowiec
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

This registration was presented to the IBC Committee, no questions or concerns were raised.

5. Amendment/CR

Review of SAMENDCR202500000088

Name:	Amendment/CR for IBC23-000087 NYULH
PI:	Richard Possemato
Submission ID	SAMENDCR202500000088
Summary of Research	Metabolic pathways are essential for maintaining cellular biology, and in dividing cells the demand to accumulate biomass requires substantial pathway alteration. Indeed, altered metabolism is a hallmark of cancer. In contrast to normally proliferating cells, those within a tumor are frequently starved for nutrients due to a combination of increased nutrient consumption and unreliable tumor vasculature. Fluctuations in nutrient availability affect cancer cell metabolism, the response to therapy, and may be part of a selective process that occurs during tumorigenesis. The proposed research will seek to understand both the altered metabolism of cancer cells and their response to nutrient deprivation. The goal of this work is to enable identification of metabolic liabilities that can be exploited for cancer therapy and yield a fuller understanding of normal cellular metabolism. To this end, we will express genes related to cellular metabolism to understand the consequences of pathway activation in mammalian cell systems. We will also suppress or delete genes to understand the consequences of pathway abrogation. These approaches require recombinant DNA technology to create vectors for both transient and stable gene delivery, and these vectors include retroviruses and lentiviruses to transduce a wide variety of cell types. For example, MDM2 and loss-of-function mutants will be expressed in mammalian cells to assess gene function, which may also include deletion of the wild-type MDM2 copy.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1/BL-1N minimum): BL-1 For recombinant plasmids in K12 strains of E. coli – Exempt under NIH Guidelines Section III-F-8-C-II. Experiments involving the purchase or transfer of transgenic rodents are exempt if they conform to Section III-F-8-C-VII, NIH Guidelines. BL-1/BL-1N: BL-1 For recombinant plasmids in cultured cells (murine) – NIH Guidelines Section III-E-1. BL-1 For infectious recombinant ecotropic retrovirus envelope glycoprotein in murine tissue culture cells – NIH Guidelines Section III-D-3-e. BL-1N For xenografts of animal cells (genes altered using a non-infectious lentivirus protocol) into animals – NIH Guidelines Section III-D-4-a BL-2/BL-2N:

	BL-2 For infectious recombinant retrovirus packaged with ecotropic envelope glycoprotein in human tissue culture cells – NIH Guidelines Section III-D-3-e and Occupational Safety and Health Administration's (OSHA) standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." BL-2N for xenografts of human cells (genes altered using a non-infectious lentivirus protocol) into animals – NIH Guidelines Section III-D-4-b, and OSHA Standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens") BL-2+: BL-2+ For infectious recombinant lentivirus expressing/targeting oncogenes in human tissue culture cells – Section III-D-1-a and Section II-A-3, NIH Guidelines, and Occupational Safety and Health Administration's (OSHA) standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Alison Gilchrist
Second Motion	James Borowiec
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

IBC Chair (Ludovic Desvignes) suggests modification of the biosafety recommendations for the infections ecotropic retrovirus envelope glycoprotein in murine tissue culture cells from Section III-E-1 to Section III-D-3-e of the NIH Guidelines. Also, as Section III-D-4-a is for BL-1 only, the BL-2N recommendation for xenografts of human cells (genes altered using a non-infectious lentivirus protocol) into animals should be changed to Section III-D-4-b. The biosafety recommendations were updated to reflect the suggested changes.

6. Amendment

Review of SAMEND202500000125

Name:	Amendment for SPROTO202500000005 - using TTX in animals
PI:	Richard Tsien
Submission ID	SAMEND202500000125
Summary of Research	The Tsien Lab is studying how the location and identity of presynaptic calcium channels is regulated. We use viruses to express certain proteins in animals or in cultured eukaryotic cells (e.g. primary rodent neurons) with high efficiency. Adeno-associated virus or Herpes simplex virus will be used to drive expression of the desired protein, Channelrhodopsin, in interneurons in the hippocampus animals. For expression of proteins in hard to transfect, cultured eukaryotic cells (e.g. primary rodent neurons), we will use replication-deficient lentivirus to deliver transgene expression of desired protein. Replication-deficient lentiviral particles is packaged in HEK293T cells, and the collected lentivirus is then used in infections. For analyzing calcium channel activities using some of these viruses infected materials (both animals and cultured neurons) and other animals or cultured cells without any viral infections, Tetrodotoxin (TTX, a sodium channel blocker) is added in the incubating solutions containing animal brain slices or culture cells at 1 uM final concentration for a duration between 2-48 hours. Subsequently, analysis using electrophysiological recordings or imagining or immunological staining procedures are applied to the brain slices or cultured neurons. For further understanding the homeostatic role of TTX in vivo, and to compare to those data obtained in in vitro experiments using isolated cells, we plan to directly infuse TTX into animal brains and analyze changes in gene expression or study the electrophysiological properties of neuronal cells using brain slices.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1/BL-1N minimum) BL-1N The purchase or transfer of transgenic animals are exempt based upon NIH Guidelines Section III-F-8-C-VII, otherwise BL-1N BL-1N The generation of BL1 transgenic animals via breeding are exempt based upon NIH Guidelines Section III-F-8-C-VIII, otherwise BL-1N Experiments using Adeno-associated virus infections in animals are based upon NIH Guidelines Section III-D-4-a, NIH Guidelines. BL-1 Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus are based upon NIH Guidelines Section III-E-1 BL-2/BL-2N BL-2 Recommended for exposure to primate/human tissue/fluids. Recommendation based on BMBL and OSHA Standard 29 CFR 1910.1030 "Occupational Exposure to Blood borne Pathogens" BL-2 Experiments involving the use of infection DNA or RNA Viruses or Defective DNA or RNA viruses (replication deficient lentivirus) in the

	presence of helper system (VSV-G) are based upon NIH Guidelines Section III-D-3a of the NIH Guidelines BL-2 Appendix I: Guidelines for Work with Toxins of Biological Origin, BMBL PIs possessing any quantity of the tetrodotoxin must maintain required records of transfers of any quantity of these toxins outside of their laboratory (OSHA 42 CFR 73.3(d)(7)(i)). These records must include the name of the recipient, entity name, address, telephone number, email, toxin and quantity transferred, purpose of use.
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Benjamin Wu
Second Motion	Robert Holzman
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

IBC Chair (Ludovic Desvignes) suggests modification of the biosafety recommendations to remove the BL-2 for experiments involving the introduction of recombinant nucleic acid molecules into Risk Group 2 agents (generation of and infection with recombinant lentivirus or retrovirus, in tissue culture cells) – Section III-D-1-a, NIH Guidelines recommendation as it is not relevant. The biosafety recommendations were updated to reflect the suggested change.

7. Amendment
Review of SAMEND202500000137

Name:	Amendment for IBC23-000112_NYULH
PI:	Jonas Schluter
Submission ID	SAMEND202500000137
Summary of Research	Our lab studies how the evolutionary conflict between gut microbes and host manifests has beneficial or detrimental consequences on health. In particular, we are investigating whether the interplay between the viral constituents of the gut microbes and host immune system could impact tumor growth. We will use murine norovirus (MNV) as a model gut virus. We will introduce an expression plasmid containing MNV to cell lines and harvest the virus from lysed cells to be used for animal experiments. The virus will be expanded in the RAW animal macrophage cell line. We will also use commercially available transgenic animals to delineate the molecular pathway via which MNV modulates host immunity. Animals are infected via oral gavage, and to investigate how MNV infection of the gut impacts immune checkpoint inhibitor responsiveness, the animals are initiated on antibody treatment (isotype control vs anti-PD1 immune checkpoint blockade) starting day 7 post cell line injection when palpable tumors have formed. The tumors sizes are measured every 3 days while being cognizant of humane endpoint.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1/BL-1Nminimum): BL-1 For cloning in Escherichia coli K-12 Host-Vector Systems under Section III-F-8 C-II, NIH Guidelines BL-1N For the purchase or transfer of transgenic rodents, BSL1 only, under Section III-F-8-C-VII, NIH Guidelines BL-1N For the generation of BL1 Transgenic Rodents via Breeding under Section III-F-8-C-VIII, NIH Guidelines BL-2/BL-2N: BL-2 For the use of infectious norovirus in tissue culture cells - Section III-D-1-a, NIH Guidelines BL-2 For the cloning and propagation of norovirus in a prokaryotic (E. coli) system - Section III-D-2-a BL-2N For animals infected with norovirus – Section III-D-4-b, NIH Guidelines. BL-2 For the use of primate cells - Occupational Safety and Health Administration's (OSHA) standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." BL-2 For the use of primate cells - Appendix I: Guidelines for Work with

	Toxins of Biological Origin, BMBL
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Determination: Modifications Required

First Motion	Benjamin Wu
Second Motion	James Borowiec
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

IBC Chair (Ludovic Desvignes) suggests modification of the biosafety recommendations for the cloning and propagation of the norovirus in E. coli at BL-2 under Section III-D-4-b of the NIH Guidelines. The biosafety recommendations were updated to reflect the suggested change.

8. Amendment/CR

Review of SAMENDCR202400000115

Name:	Amendment/CR for IBC21-000097 NYULH
PI:	Leopoldo Segal
Submission ID	SAMENDCR202400000115
Summary of Research	The aim of this project is to determine how short chain fatty acids modulate the phagocytic response to Mycobacterium tuberculosis. Human primary alveolar cells will be incubated overnight with short chain fatty acids such as butyrate and propionate. After 24 hours of incubation, cells will be infected with H37Rv, which is the laboratory strain of Mycobacterium tuberculosis. Cells will be lysed with saponin after 4h, 24h, 48h and 72h of infection. Control cells will not be incubated with short chain fatty acids. The lysates will be plated on agar plates to assess Colony Forming Unit counts.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: BL-2/BL-2N BL-2 for primate cells, including human alveolar cells (OSHA Standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens") BL-3/BL-3N BL-3 for infecting tissue culture cells with Risk Group 3 Bacteria Mycobacterium tuberculosis (strain H37RV) not harboring recombinant DNA (BMBL 6th Edition Section VIII-A: Bacterial Agents and NIH, Appendix B-III-A).

Determination: Modifications Required

First Motion	Fanny Tang
Second Motion	Alison Gilchrist
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

This registration was presented to the IBC Committee, no questions or concerns were raised.

9. Initial Protocol

Review of SPROTO202500000092

Name:	Testis aging R21_Bach
PI:	Erika Bach
Submission ID	SPROTO202500000092
Summary of Research	The objectives of this application are to characterize how age-related changes (1) in gene expression in niche cells and (2) in the niche microenvironment impact the process of spermatogenesis. It is known that decreased stem cell function with age is due at least in part to a decline in niche cell function and number. However, niche cell aging is poorly understood in most tissues. This proposal uses the adult <i>Drosophila</i> testis as a model for identifying age-related intrinsic and extrinsic processes in niche cell function. The work will capitalize upon the powerful genetics available in flies, as well as the ability to unequivocally identify all cells in the testis. The fly testis stem cell niche is formed by 12 quiescent niche cells (termed “hub” cells), which supports germline stem cells and somatic cyst stem cells (CySCs). The number of hub cells significantly declines during aging as they lose quiescence and transdifferentiate into fully-functional CySCs. Transcriptomic techniques will be used to identify genes differentially expressed in young and aged hub cells and genes whose expression is dependent on Activin signaling. Validated genes will be used to test the model that the differentially-upregulated genes causes hub cell proliferation, hub-to-CySC conversion, and, ultimately, hub cell loss.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1 minimum) BL-1 for recombinant plasmids in K-12 <i>E. coli</i> strains (NIH Guidelines, Section III-F-8 Appendix C-II) BL-1/BL-1N BL-1 for transfection of <i>Drosophila</i> tissue culture cells with recombinant plasmids (NIH Guidelines, Section III-E-1). BL-1N for recombinant plasmids in <i>Drosophila melanogaster</i> (NIH Guidelines, Section III-D-4-a)
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Fanny Tang
Second Motion	James Borowiec

Unanimously approved, no objections or abstentions, pending modifications

Review Discussion:

IBC Chair (Ludovic Desvignes) requested removal of the BL-1N for Drosophila obtained from commercial vendors (NIH Guidelines, Section III-D-4-a) biosafety recommendation as it was deemed redundant. The biosafety recommendations were updated to reflect the requested change.

10. Initial Protocol

Review of SPROTO202500000064

Name:	De Novo - IBC22-000045-Schneider
PI:	Robert Schneider
Submission ID	SPROTO202500000064
Summary of Research	The Schneider Lab studies translational regulation in human cancer and muscular dystrophy. This project focuses on the role of AUF1/hnRNP, an RNA binding protein, in the process of muscle regeneration. We will deliver through retroorbital injections the gene AUF1/hnRNP using adeno-associated virus mdx animal. mdx animals have a point mutation in the Dystrophin gene, changing the amino acid coding for a glutamine to STOP codon. This causes the muscle cells to produce a small, nonfunctional dystrophin protein. As a result, the animal has a mild form of Duchenne muscular dystrophy (DMD) where there is increased muscle damage and weakness. We expect to promote skeletal muscle cell regeneration by inducing AUF1 expression in mdx animals. Cell studies will investigate the roles of over expression or silencing of translation factors of protein synthesis including eIF4, eIF4A, eIF4G1, 4E-BP1, on tissue culture parameters of transformation, their roles in promoting tumor cell invasion, migration, and other functions. This will be performed by over expressing or silencing the mRNAs of these translation factors in human (MDA-MB-231) and animal (4T1, E0771) breast cancer cell lines using lentivirus vectors. Other studies will introduce these cells into the mammary fat pad or flank of animals to study the effect on tumor development and metastasis, by increasing or decreasing the expression of these translation factors in the same fashion. Experiments with human MDA-MB-231 cell line will be performed using NOD/SCID animals which are commercially purchased. These animals are bred to be immunodeficient by mutations that impair B cell and T cell development and are routinely purchased from commercial sources.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1/BL-1N minimum) BL-1 for recombinant plasmids in K-12 E. coli strains (NIH Guidelines, Section III-F-8-C-II).

	BL-1N For generation of transgenic rodents via breeding is exempt if it conforms to NIH Guidelines Section III-F-8-C-VIII. BL-1/BL-1N BL-1N for recombinant Adeno-Associated Virus Serotype 8 without helper plasmids in animals (NIH Guidelines, Section III-D-4-a and Appendix B-1) BL-2/BL-2N BL-2 for primate cells, including human cells (OSHA Standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens") BL-2N for implantation of human breast cancer cells into animals (OSHA Standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens"). BL-2+ BL-2+ for infectious recombinant lentivirus packaged with helper plasmids and expressing genes in tissue culture cells that will cause a reduction in tumor suppressor activity or overexpression of oncogenes (NIH Guidelines, Section II-A-3 and III-D-3-a)
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Fanny Tang
Second Motion	Ramin Herati
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

This registration was presented to the IBC Committee, no questions or concerns were raised.

11. Initial Protocol

Review of SPROTO202500000103

Name:	De Novo -IBC22-000061_Sigurdsson
PI:	Einar Sigurdsson
Submission ID	SPROTO202500000103
Summary of Research	The Sigurdsson Lab is interested in studying amyloid immunotherapy and diagnosis. The overall objective of this research is to determine how neurodegeneration as found in models of Alzheimer's disease, tauopathies and Parkinson's disease affects neuronal function, and to study the efficacy of potential therapies to slow the progression of these diseases. The rDNA to be used consists mostly of various AAV constructs to allow imaging of neurons (fluorescent label), their function (calcium imaging) and to deliver therapies to target hallmark protein aggregates in these diseases for clearance. Our pioneering findings indicate that tau antibodies are promising as a therapy for Alzheimer's disease. The antibodies can act extra- and intracellularly but very little is known about these pathways in vivo. Antibodies targeting alpha-synuclein will be explored as well.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1/BL-1N minimum) BL-1N For transgenic rodents obtained from commercial vendors are exempt if they conform to NIH Guidelines, Section III-F-8-C-VII. BL-1/BL-1N BL-1N for recombinant Adeno-Associated Virus Serotypes 1, 5, and 9 with adenovirus-free helper plasmids in animals (NIH Guidelines, Section III-D-4-a and Appendix B-1) BL-2/BL-2N BL-2 for primate cells, including human cells (OSHA Standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens") BL-2 for infectious recombinant lentivirus packaged with helper plasmids in tissue culture cells (NIH Guidelines, Section III-D-3-a)
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Fanny Tang
Second Motion	Ramin Herati
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

This registration was presented to the IBC Committee, no questions or concerns were raised.

12. Amendment

Review of SAMEND202500000167

Name:	Amendment for IBC23-000045 NYULH
PI:	Jane Skok
Submission ID	SAMEND202500000167
Summary of Research	The information needed for human cells to grow and function properly is written on a long molecule called DNA, found in the nucleus of each cell in our body. Approximately 6 feet of DNA needs to fit in the nucleus of each cell, which is two hundred times smaller than a pinhead. Thus, DNA needs to be tightly packed in an organized manner into structures called chromosomes. Although the DNA content of every cell is identical, functionally distinct sets of proteins are produced in different cell types, encoded by genes positioned along the DNA molecule. Packaging of DNA occurs in a distinct manner in different cell types to facilitate the production of these different subsets of proteins by the action of cell type specific transcription factors. Disruption in the way chromosomes are organized can affect these processes and result in diseases and cancer. 1. CTCF is an architectural protein that plays a key role in organizing the way DNA is packaged in each cell. Mutations in CTCF are common in cancers, and these mutations can alter the binding specificity of CTCF. We propose to create CTCF mutations by using CRISPR to study their impact in generation of cancers. Additionally, we plan to overexpress a homologue of CTCF, CTCFL, using a lentivirus system to study the impact on melanoma cancer. 2. During the cell cycle chromosomes are organized into active and inactive compartments and interacting subdomains which are important for gene regulation. In mitosis an architectural protein called condensin condenses the chromosomes in preparation to cell division. Such organization play also an important role in regulating gene expression over the cell cycle. However, such gene expression regulatory role of condensin has not been yet investigated. We will specifically target condensin, our protein of interest, for degradation to test how the cell cycle changes. The protein of interest is recognized thanks to a tag, called HaloTag, inserted via CRISPR/Cas12a genome editing strategy. 3. Histones H3, H4, H2A and H2B make up the octamer core of the nucleosome around which approximately 147 bp of DNA is wound. In contrast, linker histone H1 binds to the linker DNA exiting from the nucleosome, holding the entering and exiting DNA strands in place to stabilize chromatin. The histone H1 family of proteins have been implicated in numerous cellular functions including chromatin compaction, heterochromatin formation, transcription, replication, pluripotency and differentiation. We aim to study two histone H1 variants, H1.X and H1.3 by tagging the proteins for acute degradation.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1/BL-1N minimum) BL-1 for recombinant plasmids in K-12 E. coli strains (NIH Guidelines, Section

	III-F-8 Appendix C-II) BL-1N For transgenic rodents obtained from commercial vendors are exempt if they conform to NIH Guideline, Section III-F-8-C-VII BL-1N For generation of transgenic rodents via breeding is exempt if it conforms to NIH Guidelines, Section III-F-8-C-VIII BL-1/BL-1N BL-1 For recombinant plasmids in tissue culture cells (NIH Guidelines, Section III-E-1) BL-2/BL-2N BL-2 For primate cells, including human cells (OSHA Standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens") BL-2 For infectious recombinant lentivirus packaged with helper plasmids in tissue culture cells (NIH Guidelines, Section III-D-3-a)
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Fanny Tang
Second Motion	James Borowiec
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

This registration was presented to the IBC Committee, no questions or concerns were raised.

13. Amendment/CR

Review of SAMENDCR202500000069

Name:	Amendment/CR for SPROTO202400000049
PI:	Dafna Bar-Sagi
Submission ID	SAMENDCR202500000069
Summary of Research	The Bar-Sagi Lab is studying the Ras signal transduction pathway. The experiments in this protocol are designed to elucidate cell signaling pathways and how these signals are generated and maintained inside the cells in vitro, and the effect on tumor initiation, maintenance, and regression by modulating the levels of the protein in vivo. This is achieved by using a construct to either express or knockdown the expression of proteins of interest. A subset of the vectors used for knockdowns will be used for follow up in vivo studies in animals using recombinant adenoviral or lentiviral infected human or animal cells to inject into animals. This is in order to assess initiation, maintenance, or regression of tumors.
Discussion and Applicable NIH	Biosafety Recommendations:

Guidelines:	Exempt (BL-1/BL-1N minimum) BL-1 for experiments that use Escherichia coli K-12 host-vector systems – Section III-F-8-C-II, NIH Guidelines Experiments involving the purchase or transfer of transgenic rodents are exempt if they conform to Section III-F-8-C-VII, NIH Guidelines, otherwise BL-1N BL-1 for experiments involving the formation of recombinant nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus (transfection of tissue culture cells with plasmids) – Section III-F-8-C-I, NIH Guidelines BL-1/BL-1N BL-1N for injection of transgenic animals with animal cells transduced with recombinant lentivirus or adenovirus – Section III-D-4-a, NIH Guidelines BL-2/BL-2N BL-2 for primate cells – Occupational Safety and Health Administration's (OSHA) standard 29CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." BL-2 for experiments involving the introduction of recombinant nucleic acid molecules into Risk Group 2 agents (recombinant adenovirus in tissue culture cells) – Section III-D-1-a NIH Guidelines BL-2 for experiments involving the introduction of recombinant nucleic acid molecules into Risk Group 2 agents involving a helper system (generation of and infection with recombinant lentivirus, in tissue culture cells) – Section III-D-3-a, NIH Guidelines BL-2N for injection of transgenic animals with human cells transduced with recombinant lentivirus or adenovirus – Section III-D-4-b, NIH Guidelines BL-2 for Botulinum Neurotoxin (storage only), Diphtheria toxin, and Cholera toxin in tissue cell culture – Appendix I: Guidelines for Work with Toxins of Biological Origin, BMBL BL-2 for handling and growth of non-recombinant Risk Group 2 bacteria (Klebsiella pneumoniae, Staphylococcus aureus) – Section VIII-A: Bacterial Agents, BMBL BL-2 for Ebola virus-like particles (EBOVL) in tissue culture cells– Section III-E-1, and Section II-A-3: Comprehensive Risk Assessment, NIH Guidelines BL-2+/BL-2N+
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	BL-2+ for experiments involving the introduction of recombinant nucleic acid molecules into Risk Group 2 agents (generation of and infection with recombinant lentivirus expressing known oncogenes, or knocking out known tumor suppressors in tissue culture cells) – Section III-D-3-a, and Section II-A-3: Comprehensive Risk Assessment, NIH Guidelines
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	James Borowiec
Second Motion	Ramin Herati
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

IBC Chair (Ludovic Desvignes) to contact the NIH OSP for guidance regarding the biosafety recommendation for the use of Ebola virus-like particles (EBOVL) in tissue culture and whether a formal request to downgrade is needed.

14. Initial Protocol
Review of SPROTO202500000106

Name:	De Novo -IBC22-000029_Ortigoza
PI:	Mila Ortigoza
Submission ID	SPROTO202500000106
Summary of Research	The Ortigoza lab studies transmission of respiratory pathogens in adult and infant animals. Our projects aim to characterize the role of pathogen and host on various aspects of transmission between hosts using the animal model. We work with orthomyxoviruses (influenza viruses A and B; low-pathogenic strains only), paramyxoviruses (respiratory syncytial virus); gram-positive bacteria (<i>Streptococcus pneumoniae</i>, <i>Staphylococcus aureus</i>); and SARS-CoV-2. Viral titers are determined by infection of mammalian cells. Transmission assays will be assessed in vivo using animals (infants and adults). Daily shedding is performed by gently dipping the nares in viral media or agar, and returning the animal to the cage. Transmission is assessed via quantification of pathogen in the lavage (via plaque assay, PCR, or plating). Host and viral factors identified from in vivo studies will be further characterized in various assays including the use of genetically modified animals, tissue culture models of viral infection, and biochemical assays such as cytokines, antibodies, expressed genes, to uncover the molecular mechanisms by which the host controls viral replication, shedding and transmission. We will also use viral gene DNA (whole viral genomes or subgenomic fragments) to probe for the impact of individual viral nucleic acid moieties on transmission. These viral genomes will also be used to generate recombinant virus from plasmids. Our goal is to evaluate influenza virus' transmission (via respiratory droplets and via breastfeeding) in our murine transmission model and evaluate viral and host factors that contribute to its transmissibility. Pathogenesis of viruses are assessed by rate of weight loss (morbidity) and mortality of animals during the experiment. Furthermore, titer of pathogen in the shedding or lavage fluid is a function of replication.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1/BL-1N minimum) BL-1 for experiments that use <i>Escherichia coli</i> K-12 host-vector systems – Section III-F-8-C-II, NIH Guidelines BL-1 for experiments involving the formation of recombinant nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus (transfection of tissue culture cells with plasmids) – Section III-F-8-C-I, NIH Guidelines Experiments involving the purchase or transfer of transgenic rodents are exempt if they conform to Section III-F-8-C-VII, NIH Guidelines, otherwise BL-1N BL-1N for the breeding of transgenic rodents, BSL1 only – Section III-F-8-C-VIII, NIH Guidelines

	BL-2/BL-2N BL-2 for primate cells – Occupational Safety and Health Administration's (OSHA) standard 29CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." BL-2 for experiments in which DNA from Risk Group 2 agents is transferred into nonpathogenic prokaryotes – Section III-D-2-a, NIH Guidelines. BL-2 for experiments involving Influenza Viruses in vitro (generation of and infection with recombinant influenza A and B virus strains, in tissue culture cells) – Section III-D-1-a, NIH Guidelines BL-2N for experiments involving Influenza Viruses in animals (infection of transgenic rodents with recombinant influenza A and B strains) – Section III-D-1-a, NIH Guidelines BL-2 for handling and growth of non-recombinant Risk Group 2 bacteria (Streptococcus pneumoniae, Staphylococcus aureus) – Section VIII-A: Bacterial Agents, BMBL BL-2N for infection of animals with non-recombinant Risk Group 2 bacteria (Streptococcus pneumoniae, Staphylococcus aureus) – Section VIII-A: Bacterial Agents, BMBL BL-2 for handling and growth of non-recombinant Risk Group 2 viruses (propagation of respiratory syncytial virus in tissue culture cells) – Section VIII-E: Viral Agents, BMBL BL-2N for experiments involving exposure of animals to non-recombinant Risk Group 2 viruses (infection of rodents with respiratory syncytial virus) – Section VIII-E: Viral Agents, BMBL BL-2 for experiments involving recombinant SARS-CoV-2 in tissue culture cells – Section III-D-1-a, NIH Guidelines BL-2+/BL-2N+ BL-2+ for experiments involving recombinant attenuated Influenza A/Vietnam/1203/04 virus (HALo) in tissue culture cells (including viral propagation, characterization and generation of reassortants with Risk Group 2 influenza A viruses) - Section III-D-1-a, Section III-D-7-b, Section II-A-3 (Comprehensive Risk Assessment), NIH Guidelines and NIH-OSP approval of 2/13/2025. BL-2N+ for experiments involving recombinant attenuated Influenza A/Vietnam/1203/04 virus (HALo) in animals (including transmission and
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	passaging experiments with HALo and HALo reassortants) - Section III-D-1-a, Section III-D-7-b, Section II-A-3 (Comprehensive Risk Assessment), NIH Guidelines and NIH-OSP approval of 2/13/2025. BL-3/BL-3N BL-3N for the infection of animals with recombinant SARS CoV-2 – Section III-D-1-b, and Section II-A-3: Comprehensive Risk Assessment, NIH Guidelines
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	James Borowiec
Second Motion	Alison Gilchrist
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

IBC Chair (Ludovic Desvignes) suggested modification of the biosafety recommendations to remove the BL-2N for experiments involving the infection of animals with recombinant SARS-CoV-2 – Section III-D-1-a of the NIH Guidelines recommendation as this should be conducted under BL-3N. Also, updates to the biosafety recommendations for BL-2 for infection of influenza A and B strains in tissue culture and in animals and change to Section III-D-1-a as Section III-D-7 is to be conducted at BL-3 for the use of highly virulent strains.

15. Initial Protocol**Review of SPROTO202500000067**

Name:	Neurodegeneration in Alzheimers_Sadowski
PI:	Martin Sadowski
Submission ID	SPROTO202500000067
Summary of Research	Our research identifies and manipulates genes of interest that contribute to neurodegeneration in disorders like Alzheimer's Disease. We do this by modeling neurodegeneration in transgenic animal strains alongside constitutional or conditional manipulation of genes and examining the consequences of these manipulations. Our findings help to determine viable targets for future Alzheimer's therapies. Using our transgenic animal lines or crosses between them, we can manipulate target genes by knocking in, knocking out, or conditionally expressing/silencing genes that have an impact on Alzheimer's disease progression. Either after or alongside modifying expression of these genes in animals, Alzheimer's pathology is modeled through strain-specific knock-in of mutations that induce aberrant accumulation of amyloid beta or tau protein, or through inoculation with animal brain tissue infected with scrapie prions. This neurodegeneration is closely followed by frequent monitoring of signs of worsening condition, as well as behavior tests that indicate memory or locomotor impairment. At the experimental endpoint for each animal, brain tissue is collected and analyzed for various markers of neurodegeneration and other relevant proteins or cell types to get a better idea of what neural systems, brain regions, and molecular mechanisms were affected by our manipulations. At the end of each experiment, we are able to quantitatively analyze which genetic modification led to the best outcomes and develop more fine-tuned future experiments accordingly. Cell culture models are also used in our lab particularly to observe specific cell types (e.g., neurons, microglia, astrocytes, etc.) and how they behave differently under different treatment conditions or to model neurodegenerative conditions. Alongside transgenic animal lines, cell culture allows us to more closely examine cellular mechanisms or morphological changes involved in the pathophysiology of a neurodegenerative disorder, treatments for these disorders, and/or differential underlying risk for disorders based on genetic background. Recently, human cell lines have been used as part of preliminary work towards a project to develop a potential off-the-shelf Alzheimer's therapy, which will first be developed and tested in cell culture models and then animals.
Discussion and Applicable NIH Guidelines:	Biosafety Recommendations: Exempt (BL-1/BL-1N minimum) BL-1 For the purchase of BL1 transgenic rodents from commercial vendors under Section III-F-8-C-VII, NIH Guidelines. BL-2 BL-2 For handling of animal-adapted scrapie prions in tissue culture cells and

	animals under Section VIII-H: Prion Diseases, BMBL 6th edition. BL-2 For handling of human cells, including microglia cell lines and inducible pluripotent stem cells, under Occupational Safety and Health Administration's (OSHA) standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens". BL-2 For handling of recombinant human cells, including microglia cell lines and inducible pluripotent stem cells, in tissue culture under Section III-E Experiments that Require IBC Notice Simultaneous to Initiation and Section II-A-3 Comprehensive Risk Assessment, NIH Guidelines. BL-2N For injection of recombinant human cells, including inducible pluripotent stem cells, into animals under Section III-D-4-b, NIH Guidelines. For experiments involving recombinant or synthetic nucleic acid molecules and whole animals, including transgenic animals, and not covered by Sections III-D-1 or III-D-4-a, NIH Guidelines.
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Ludovic Desvignes
Second Motion	James Borowiec
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

This registration was presented to the IBC Committee, no questions or concerns were raised.

16. Amendment

Review of SAMEND202500000107

Name:	Amendment for SPROTO202400000165
PI:	Sergei Korolov
Submission ID	SAMEND202500000107
Summary of Research	We are using Cas9-guided gene editing to evaluate the role of various signaling pathways in persistence of plasma cell responses. In addition, our lab uses animal models to study both molecular and cellular mechanisms of pathology in diseases such as cancer and chronic inflammatory diseases. Specifically, we are trying to examine the connection between inflammation caused by activated T cells and the eventual malignant transformation of these cells into cutaneous T cell lymphoma (CTCL) and its leukemic counterpart (Sezary disease). We are currently examining the impact of Staphylococcus aureus colonization on disease progression in our existing CTCL animal model.
Discussion and	Biosafety Recommendations:

Applicable NIH Guidelines:	BL-2/BL-2N BL-2N For the culture of and infection of animal with wild-type Staphylococcus epidermidis under Section II Biological Risk Assessment, Section IV Laboratory Biosafety Criteria and Section V Vertebrate Animal Biosafety Level Criteria for Vivarium Research Facilities, BMBL. BL-2N For the culture of and the infection of animals with recombinant Staphylococcus aureus expressing luciferase under Section III-D-1-a, NIH Guidelines. Experiments involving the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 2 agents.
Motion to approve this registration with suggested biosafety recommendations, pending required modifications.	

Determination: Modifications Required

First Motion	Ludovic Desvignes
Second Motion	Robert Holzman
Unanimously approved, no objections or abstentions, pending modifications	

Review Discussion:

Committee member (Robert Holzman) clarified that Staphylococcus epidermidis is ubiquitous (found everywhere) and that the needle precautions would not necessarily determine BSL1 vs BSL2 containment, but that the blood body fluid precautions would mandate BSL2 containment.

REVIEW OF ADMINISTRATIVE APPROVALS

Submission Type	Submission ID	Name	Approval Date
Amendment	SAMEND202500000148	Amendment for IBC23-000092_NYULH	5/20/2025
Amendment/CR	SAMENDCR20250000082	Amendment/CR for SPROTO202400000086	5/21/2025
Amendment	SAMEND202500000149	Amendment for SPROTO202300000033	5/21/2025
Continuing Review	CR202500000069	Continuing Review for IBC21-000052_NYULH	5/23/2025

Amendment	SAMEND20250000 0097	Amendment for SPROTO202300000022	5/27/2025
Continuing Review	CR202500000071	Continuing Review for SPROTO202400000098	5/28/2025
Amendment/CR	SAMENDCR20250 0000090	Amendment/CR for SPROTO202400000083	5/28/2025
Amendment	SAMEND20250000 0154	Amendment for SPROTO202300000012	6/3/2025
Amendment	SAMEND20250000 0153	Amendment for IBC23- 000045_NYULH	6/4/2025
Continuing Review	CR202500000076	Continuing Review for SPROTO202400000096	6/4/2025
Amendment/CR	SAMENDCR20250 0000089	Amendment/CR for IBC23-000044_NYULH	6/5/2025
Amendment	SAMEND20250000 0151	Amendment for IBC23- 000071_NYULH	6/6/2025
Amendment	SAMEND20250000 0155	Amendment for IBC21- 000039_NYULH	6/9/2025
Amendment/CR	SAMENDCR20250 0000099	Amendment/CR for SPROTO202400000056	6/9/2025

Amendment	SAMEND20250000 0157	Amendment for SPROTO202400000128	6/9/2025
Amendment/CR	SAMENDCR20250 0000073	Amendment/CR for SPROTO202400000101 C5561001 24-00800 CR1	6/9/2025
Amendment/CR	SAMENDCR20250 0000095	Amendment/CR for SPROTO202400000113	6/10/2025
Amendment	SAMEND20250000 0164	Amendment for SPROTO202300000022	6/10/2025
Amendment/CR	SAMENDCR20250 0000102	Amendment/CR for IBC23-000082_NYULH	6/11/2025
Amendment/CR	SAMENDCR20250 0000072	Amendment/CR for SPROTO202400000061	6/11/2025
Continuing Review	CR202500000083	Continuing Review for SPROTO202400000100	6/11/2025
Amendment/CR	SAMENDCR20250 0000104	Amendment/CR for IBC23-000085_NYULH	6/13/2025
Continuing Review	CR202500000084	Continuing Review for IBC23-000071_NYULH	6/17/2025

REVIEW OF OTHER AGENDA ITEMS

17. Introduction of new IBC Committee Members

- a) IBC Chair to organize new member review training for the week of 6/23/2025.

18. Investigations:

- a) BS Lab Incident Report submitted to NIH OSP – Needle stick with recombinant strain of *S. aureus* – closed
- b) Potential Investigation – GE Lab – failure to register recombinant DNA research.
- c) Potential Investigation – EN Lab - failure to list and properly train a protocol team member and the potential lapse in an IRE registration to register a select agent.

19. New NIH notice regarding termination of funding for any Dangerous gain-of-function (GOF) Research in foreign countries and will suspend all other GOF Research funding in the USA. The NIH will allow all US Institutions until 6-30-2025 to review and identify these types of research.

20. Other NIH notice regarding “Maximum Transparency”, effective as of 6-1-2025: The names of all IBC members of registered IBCs in the USA were published on the NIH webpage, along with the names and email addresses of the IBC Chair, BSO, and Director. As of 6-1-2025 an additional requirement is that the minutes for the June 2025 IBC meeting and all other meetings moving forward must be posted on an Institutional IBC public facing page.

Approved 10/15/2025

X 

Ludovic Desvignes, Ph.D.

Chair- Institutional Biosafety Committee (IBC)