Rutgers University
Institutional Biosafety Committee (IBC) – North Campus
Meeting for NIH Guidelines Materials
Minutes of November 11, 2025

1. ATTENDEES

☒ Preeti Bharaj	☒ Shaun Shahani	☒ Brian Eggert - REHS
☐ Theresa (LiYun) Chang	☐ Lanbo Shi	☒ Sivarchana Boada - REHS
☒ Nancy Connell	☒ Jason Weinstein	☒ Marija Borjan - REHS
☐ Roberto Colangeli	☒ Lai-Hua Xie	☒ Blas Peixoto - REHS
☒ Carla Cugini	☒ Amanda Hueting – Local Non-Affiliated	☒ Robert Adcock - REHS
☐ Dominic Del Re	☒ Michael Ricker – Local Non-Affiliated	☐ Jacquelyn Vidal - REHS
☒ Jean-Pierre Etchegaray	☐ Sonia Solano – Local Non-Affiliated	☒ Sophia Cheng - REHS
☒ Roseann Kehoe	☐ Jeetendra Eswaraka – Ex Officio	☒ Elizabeth Minott - Guest
☒ Yosuke Kumamoto	☐ Alejandro Ruiz – Ex Officio	☐
☐ Deborah Lazzarino	☐ Bryan Bocco – Ex Officio	☐
☒ Latisha Moody	☐	☐
☒ Dane Parker	☐	☐

2. MEETING LOGISTICS

CURRENT MEETING		
Called to Order: 10:02 AM	**Adjourned:** 11:01 AM	**Location:** WebEx
PREVIOUS MEETING		
Minutes from September 9, 2025		Approved **(15:0:0)**[1,2]
NEXT MEETING		
Date: January 13, 2026	**Time:** 10:00am	**Location:** WebEx

CONFLICT OF INTEREST STATEMENT
Committee members with a conflict of interest related to the review of a specific registration may not be involved in the review or approval of a project in which he or she has been or expects to be engaged or has a direct financial interest.

3. PRE-AGENDA

TOPIC	SUMMARY
Old Business: **Presidential Executive Order: Improving the Safety and Security of Biological Research**	Dual Use Research of Concern • No updates as of November 11, 2025 • Updates will be provided at future IBC meetings when a new Executive Order becomes available Framework for Nucleic Acid Synthesis Screening • No updates as of November 11, 2025 • Updates will be provided at future IBC meetings when a new Executive Order becomes available Website: https://www.whitehouse.gov/presidential-actions/2025/05/improving-the-safety-and-security-of-biological-research/
New Business: **New NIH Initiative: Modernizing and Strengthening Oversight of Biosafety**	• On 9/9/25, the NIH launched a new initiative for comprehensive changes to modernize and strengthen biosafety policies, practices, and oversight. The effort aims to revamp biosafety oversight to address biosafety risks in a climate of rapidly advancing science and technology. A secondary aim is to empower Institutional Biosafety Committees (IBCs) and reinforce their positions as a front line for biosafety oversight and ensure that IBCs receive comparable support to committees for human subjects and research animals. • Main website: https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/ • To submit a comment: https://osp.od.nih.gov/help-modernize-and-strengthen-the-oversight-of-biosafety/
New Business: **REHS Staff Updates**	• Marija Borjan has joined REHS as senior biosafety officer. • University Biosafety Officer position posted – active as of October

New Business: **IBC Membership Updates**	Departures: • Lidiya Sanchez Additions: • Sivarchana Boada • Marija Borjan In Progress: • Search for new IBC-N Co-chair
New Business: **Meeting Schedule for 2026**	The IBC-North meetings will likely continue to be held within the first or second week of the month but the weekday and time will depend on the new co-chair's availability. If you have days/times that will not work, please notify REHS. A poll may be sent out to select the best day and time.

PROTOCOL REVIEWS

The following protocols were reviewed according to the risk assessment guidelines published in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*. The risk assessment is documented in the REHS Biosafety Protocol Management System and includes a review of the engineering controls, work practices, safety training, and medical surveillance of project personnel. Individual protocols are evaluated on the following matters as appropriate: the proposed biosafety level and safety practices, agent characteristics, source and nature of agents or recombinant/synthetic nucleic acid sequences and resulting effects of expressed proteins, host animals/ cells, and cloning vectors to be used, and the type of manipulations planned.

Note: Protocols were not necessarily reviewed in the order they appear below.

1. ADMINISTRATIVE APPROVALS

PROTOCOL	PI	MATERIAL(S) OF INTEREST	BSL
12-248	Singson, Andrew	Renewal without changes	1
19-067	Petrou, Vasileios	Renewal without changes	2
13-299	Howell, Roger	Renewal with minor changes	2
13-309	Kadouri, Daniel	Renewal without changes	2
22-038	Tambini, Marc	Renewal without changes	2
20-079	Devanshi, Jain	Renewal without changes	1
19-076	Alland, David	Renewal without changes	3
18-052	Barker, David	Renewal without changes	2

13-548	Sadoshima, Junichi	Amendment – integration of #20-064 into this IBC #13-548	2
19-078	Wong, Ching On	Renewal with minor changes	2
15-101	Arnold, Edward	Renewal with minor changes	1
22-041	Herrera, Bobby Brooke	Renewal without changes	2e
15-095	Zhang, Haoran	Renewal with minor changes	1
14-095	Woychik, Nancy	Renewal with minor changes	2
13-342	Rogers, Melissa	Renewal without changes	2
22-033	Patel, Smita	Renewal without changes	2
13-393	Chen, Don	Renewal without changes	2
13-506	Rodriguez, Gloria	Renewal without changes	3
13-591	Gebril, Hoda	Renewal with PI change	2

2. ADMINISTRATIVE TERMINATIONS			
PROTOCOL	**PI**	**TITLE OF PROTOCOL**	**EXPIRY DATE**
None			

3. BIOSAFETY OFFICER REPORT (BSO) Approved (15:0:0) [1]			
PROTOCOL	**PI**	**TITLE & MATERIAL(S) OF INTEREST**	**BSL / GUIDELINES**
15-089	Guo, Yanxiang	**Title:** The role of autophagy in lung tumorigensis **Materials:** rDNA, Lentiviral vector, human cells, mice **Submission Summary:** This amendment adds studies examining the impact of a ketogenic diet on lung tumor progression using luciferase-expressing H358 human lung carcinoma cells. The H358 cell line (ATCC) will be transduced with a third-generation lentiviral vector, Lenti-LucOS-Cre (Addgene; previously approved under the June 2024 amendment), to generate stable luciferase-expressing cells (H358-	2 / III-D-1, III-D-4

		LucOS). Cells will be injected into nude mice either subcutaneously or via tail vein for tumor growth and metastasis assays. Tumor burden and survival will be assessed by weekly IVIS imaging, with treatment groups receiving anti-PD-1 therapy, ketogenic diet, or both. All biomaterial handling procedures will be performed under BSL-2 containment within a biosafety cabinet using established tumor injection and animal handling methods already approved for this group. The viral vector is replication-incompetent, and no new biosafety risks beyond those of existing approved lentiviral and human cell line work are introduced. Waste and carcasses will be decontaminated by chemical disinfection or autoclaving prior to regulated medical waste disposal. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable	
22-026	Yao, Justin	**Title:** AAV Gerbil Optogenetics, Chemogenetics, and Viral tract Tracing **Materials:** rDNA, AAV, gerbil **Submission Summary:** The goal of this research is to examine how sensory cortices (auditory and visual) interact with the parietal cortex during perceptual decision-making and to determine whether perturbing these cortical inputs disrupts task performance. This protocol involves stereotaxic injections of recombinant AAVs into the central nervous system of Mongolian gerbils, followed by behavioral training, neural recordings, and histological analysis. The AAVs will be used to express (1) light-activated opsins (ChR2, ChETA) for optogenetic manipulation, (2) chemo-activated receptors (hM3D(Gq), hM4D(Gi)) for chemogenetic modulation, (3) fluorescent proteins (eGFP, mCherry, eYFP, tdTomato) for anatomical tracing, and (4) genetically encoded	1 / III-D-1, III-D-4

		calcium indicators (AAVrg-syn-jGCaMP8m-WPRE) for fiber photometry recordings. Vectors use cell-type-specific (CaMKII, mDlx) or general (hSyn, CAG) promoters and recombinase-dependent systems (Cre-lox, FLEX). All AAVs are purchased ready-to-use, stored at -80 °C in a dedicated BSL-1 freezer, and handled exclusively in a certified biosafety cabinet per approved SOPs (Yao_AAV_REHS_2019). Viral injections are performed under aseptic conditions using a cannula and syringe pump; for optogenetics, an optrode is implanted for light delivery during behavioral or recording sessions, and for chemogenetics, a cannula allows ligand infusion. Tracing studies involve reporter expression, perfusion after 2–3 weeks, and fluorescence microscopy under a fume hood with PPE. Behavioral testing uses a two-alternative forced-choice (2AFC) paradigm assessing auditory, visual, and audiovisual cue discrimination. No infectious, pathogenic, or replication-competent materials are used. Risk to personnel is minimal and contained within BSL-1 practices; all contaminated waste is autoclaved in Nelson Room A134. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable	
17-062	Nakamura, Tetsuya	**Title:** Genetic recombination in fish **Materials:** rDNA, zebrafish **Submission Summary:** The main aim of this project is to determine the genetic and molecular mechanisms of appendage development using ray-finned fish and cartilaginous fish as model species. The protocol was previously approved for conducting genetic manipulations, live-imaging of fluorescent transgenic fish, and other relevant experiments. We request to amend this protocol to observe cell shape of osteoblasts using new transgenic fish that label	1 / III-D-4

		cell membrane by blue fluorescent protein. We will use the membrane-BFP2 transgenic fish, that express blue fluorescent protein with the membrane-localization signal domain. These transgenic fish are biosafety level-1 organisms that will be obtained from Dr. Natasha O'Brown (Rutgers University) and were previously approved in her IBC protocol. At 10 hours after fertilization, the embryos from these transgenic fish will be collected from mating tanks, anesthetized by tricaine, embedded into 1% agarose gel, and imaged under a confocal microscope. Upon the end of the experiment, biological waste materials including embryonic bodies will be autoclaved and disposed in a biohazard material bag. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable	
14-131	Polack, Pierre-Olivier	**Title:** Expression of optogenetic tools, calcium sensors and voltage indicators to investigate the cerebral cortex physiology **Materials:** rDNA, AAV, mice **Submission Summary:** This amendment adds three adeno-associated viral (AAV) constructs—AAV-CaMKII(0.4)-DIO-TdTomato, AAV1-CaMKII-DIO-ChRmine-eYFP, and AAV-CaMKIIa-jGCaMP8s-WPRE—to the existing protocol for neuronal labeling, monitoring, and manipulation in mice. These vectors are replication-incompetent, non-pathogenic, and classically classified as BSL-1. Each uses the CaMKIIa promoter for excitatory neuron specificity, with DIO configurations providing Cre-dependent expression. The transgenes (TdTomato, ChRmine, and jGCaMP8s) encode non-toxic fluorescent, optogenetic, and calcium-sensing proteins, respectively. Viral injections will be performed stereotaxically in mice, and all work will follow standard BSL-2 containment procedures, including aseptic technique, use of biological safety cabinets, and autoclaving of	2 / III-D-1, III-D-4

		waste. These constructs represent improved versions of previously approved tools for neuronal imaging and manipulation and do not introduce new biosafety risks. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable	

4. AD HOC MEETING APPROVALS			
PROTOCOL	**PI**	**TITLE & MATERIAL(S) OF INTEREST**	**BSL**
None			

5. NEW PROTOCOLS			
PROTOCOL	**PI**	**TITLE & MATERIAL(S) OF INTEREST**	**BSL / GUIDELINES**
25-029	Markowitz, Geoffrey	**Title:** Understanding T cells for anti-tumor immunity **Materials:** rDNA, Lentivirus vector, Retrovirus vector, E. coli, Listeria monocytogenes, mice **Submission Summary:** This is a new protocol that will investigate T cell responses to cancer and infections, with a focus on how these responses impact T cell differentiation and function. The Lab proposes to use in-vitro and in-vivo systems to examine T cell responses. For in vivo, they will use Listeria Monocytogenes infections and orthotopic or subcutaneous implantation of tumor cell lines. For in vitro experiments, they will use PBMCs and immunocompetent patient-derived tumor organoids as well as tumor cell lines from mice. They will also use third-generation lentivirus or gamma-retrovirus to induce genetic modifications in T cells. To genetically modify cell populations, they will use multiple established plasmids (pCMV-VSV-G, psPAX2,	3 / III-D-1, III-D-2, III-D-3, III-D-4

		and pCL-Eco) and cell lines (such as HEK293T, Plat-E, and Phoenix-ECO). They have identified specific metabolic and genetic targets in the description that will be inhibited in their cell populations. To analyze their experiments, they will utilize techniques such as flow cytometry, Seahorse analysis, isotope labeling, and gene expression analysis. All the information in the addendums has been completed correctly. All necessary safety precautions have been implemented for these studies, and the necessary files have been uploaded to the file cabinet. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Required before commencing work **IBC Vote: Approved (15:0:0)[1]**	
25-021	Durham, Benjamin	**Title:** Molecular Pathogenesis and Functional Genomics of Hematological Neoplasms **Materials:** rDNA, E. coli, Lentivirus, Retrovirus, human cells, mice **Submission Summary:** This protocol investigates how related kinases ROSA26, BRAF, MAP2K1, ARAF, CSF1R, PIK3CA, NRAS, KRAS, and NF1 alterations influence histiocytosis, neoplastic hematopoiesis, the tumor microenvironment, and therapeutic response. The work employs murine knock-in models, human xenograft models, murine and human hematopoietic cell lines, and human oncologic biospecimens (fresh, viably frozen, and archival FFPE). Recombinant DNA constructs are commercially obtained (e.g., Addgene, GenScript) and introduced using replication-incompetent gamma-retroviral and third-generation lentiviral vectors to deliver Cas9, sgRNAs, or protein-coding sequences for gene expression and pathway modulation. In vitro procedures include transduction of cell lines and primary cells, protein and nucleic acid	2 / III-D-1, III-D-2, III-D-4

		isolation, flow cytometry, and light and fluorescence microscopy. The primary biosafety considerations relate to the use of replication-incompetent viral vectors and human-derived tissues, all of which will be handled at BSL-2 using Class II biosafety cabinets, sealed centrifuge rotors/safety cups, and chemical disinfection with fresh 10% bleach followed by 70% ethanol. Third-generation lentiviral systems used here incorporate split packaging and gene deletions to minimize risk of generating replication-competent virus; no agents with airborne transmission potential are used. In vivo work will occur in ABSL-2 facilities and involve transplantation of modified murine or human cells into mice, followed by therapeutic intervention and tissue analysis. Endpoint assessments include flow cytometry and histopathology, and infectious waste will be decontaminated according to standard BSL-2 waste management practices. **Occupational Health:** Required before commencing work **Training:** In Place **BioAudit:** Required before commencing work **IBC Vote: Conditionally Approved (14:0:0)[1,3]** Conditions: 1. Address the Occupational Health comments.	

6. AMENDMENTS			
PROTOCOL	**PI**	**TITLE & MATERIAL(S) OF INTEREST**	**BSL / GUIDELINES**
23-026	Kara, Eleanna	**Title:** Understanding the pathways participating in the formation of Lewy Bodies and the role of selective vulnerability in the pathogenesis of a-synucleinopathies and other neurodegenerative diseases **Materials:** rDNA, E. coli, alpha-synuclein, sea lamprey	2 / III-D-2

		Submission Summary: The main goal of this project is to study how alpha-synuclein dysregulation is involved in the pathogenesis of Parkinson's disease. The previously approved protocol included experiments using recombinant alpha-synuclein protein that is aggregated in vitro prior to being added to cultured cells to induce seeding of the endogenous protein for the formation of pathological inclusions. This material will either be purchased commercially or acquired through a collaboration with Prof Jean Baum's lab at Rutgers. In addition, it included lentiviral transfections of cell lines and iPSc-neurons with several genes including TAX1BP1, ADAMTS19, ITGA8, which we previously found to be involved in the pathogenesis of Parkinson's disease. Other experiments include usage of fresh frozen brain tissue from postmortem materials from humans and axolotl. These procedures are classified as BSL2/2+. In the current amendment of this protocol, we will dissect the spinal cord out of sea lamprey and keep it in petri dishes in a tissue culture incubator. We will then microinject recombinant alpha-synuclein into it. Risks include, in addition to the usage of recombinant alpha-synuclein, pathogens commonly found in marine animals such as Aeromonas, Vibrio, Pseudomonas, Mycobacterium marinum, and Salmonella. Therefore, identical precautions as the ones described above will be taken. Endpoints for the newly proposed experiments are at up to two weeks when we will fix and stain the injected spinal cord and prepare it for imaging. Alpha-synuclein is a prionoid. Therefore, its handling in vitro and in cultured cells could be dangerous to lab workers as it could form aerosols and be aspirated accidentally. Human materials carry the risk for blood borne pathogens. To prevent adverse effects for lab workers, we will wear double gloves, plastic sleeves, protective goggles, lab coats and plastic aprons and handle the materials in a Class II A2 biosafety cabinet. Surfaces will be	

		decontaminated through 1%SDS followed by 70% ethanol. All trash produced will be autoclaved prior to being disposed in the regulated medical waste. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable **IBC Vote: Approved (14:0:0)[1]**	
13-385	White, Eileen	**Title:** The role of autophagy in lung tumorigenesis **Materials:** rDNA, retrovirus, human cell lines, mice **Submission Summary:** The main goal of the project is to investigate the metabolic requirements for effective E7-TCR T cell therapy for human papilloma virus (HPV+) cancers. Genetically engineered TCR T cell therapy has been shown to induce regression in metastatic HPV+ epithelial cancers. The preclinical murine model has been published by Hinrichs lab where T cell therapy has shown to effectively induce tumor regression. This amendment adds Target HPV+ cancer cell lines e.g. 4050, CaSki, reagents required for producing E7 TCR gene expressing retrovirus e.g. 293 GP cells, RD114 envelope plasmid, E7 TCR expressing vector plasmid. The 293 GP cells will be transfected with these plasmids to produce E7 TCR expressing retrovirus that is replication-incompetent. The retrovirus will be used to transduce T cells expanded from human PBMCs. The NSG mice will be subcutaneously injected with either 4050 or Caski cancer cells and allowed to form tumors. Once the tumors form 12 days post injection, the mice will be treated with transduced T cells. As shown previously, the tumors respond to the therapy and begin to regress. At 10 days post T cell injection, the mice will be sacked, and spleens will be harvested to extract the T cells.	2 / III-D-1, III-D-4

		Active cytotoxic and exhausted T cells will be sorted and used for metabolomics analysis to determine the metabolic requirements for the persistence of active T cells. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable **IBC Vote: Approved (14:0:0)[1]**	
18-068	Pan, Pingyue	**Title:** synaptic mechanisms of parkinson's disease **Materials:** rDNA, AAV, mice **Submission Summary:**The main goal of the project is to understand how the Parkinson's disease associated gene, SYNJ1, dysregulates the dopamine synapse in early pathogenesis. We employ a combination of cellular and in vivo mouse models to address mechanisms at the synapse. We are currently investigating a transgenic mouse with dopamine neuron specific deletion of Synj1, which exhibit locomotor deficits and striatal pathology. Our goal is to figure out the signaling mechanism underlying these deficits by using gene rescue studies. Our previously approved protocol allowed us to deliver AAV reporters (such as AAV-DAT-pHluorin) in cultured neurons to assess rescue of cellular function and to deliver LV transgene (LV-SYNJ1 WT) in vivo to assess motor recovery. This amendment adds new AAV vectors that carrying different test genes (VPS35 and PKCb shRNA) to be tested for cultured neurons and for in vivo motor recovery. VPS35 is a retromer protein known to be deficient in several neurodegenerative disorders. PKCb is kinase important for cell signaling. There's no known hazards for overexpressing VPS35 or suppressing PKCb, but these genetic manipulations could lead to moderate changes in animal behavior, which is the goal of the study. AAV2/5 vectors are	2 / III-D-1, III-D-4

		commonly used for neuroscience research for intracranial delivery of transgenes. These viral vectors will be packaged in high titer (1e13 gc/ml) by commercial services (OBIO tech) and stored in secondary containers in a -80C freezer in the research lab (RT331). For culture work, 1 uL will be added to culture media for 3 days. Media will be disinfected with 10% bleach after 3 days. Viral injection will be performed in Dr. David Crockett's lab where the stereotaxic injection equipment is located. 0.5-2uL of AAV will be injected into the SNpc of the mouse brain and animal studies will be carried out 1-2 months following injection. We will follow the existing virus transfer and handling procedures for the experiment. All waste materials will be decontaminated using 10% bleach for 30 minutes. Personnel will use PPE and additional administrative measures to minimize exposure. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable **IBC Vote: Approved (14:0:0)[1]**	
12-016	Tran, Tracy	**Title:** Analysis of dendritic morphology and synaptogenesis using in vitro and in vivo approaches **Materials:** rDNA, AAV, mice **Submission Summary:** This protocol investigates the molecular and cellular mechanisms governing the assembly and disassembly of neural circuits during development and how these neuronal connections are refined and maintained in the adult animal using mouse models. For this amendment, we will be investigating the interactions between gene-environment in affecting the behavioral outcomes in mice with a gene mutation susceptible to increase the risk for autism spectrum disorder (ASD). The specific gene we are study is Neuropilin-2	2 / III-D-1, III-D-4

		(Nrp2), a cell surface receptor which we and others have demonstrated to control neuronal morphogenesis and synaptic transmission. The Nrp2 receptor is expressed by spiny projection neurons in the brain region called the striatum, which is associated with ASD when impaired. Our experimental design involves injection of non-pathogenic adeno-associated virus (AAV) vectors for gene expression/inhibition and/or labeling of spiny projection neurons in the striatum during early postnatal ages and histological and immunocytochemical procedures on mouse cells/tissue to assess their neuronal morphologies. These experiments will help to determine if the influence of environmental conditions (e.g. social isolation) could exacerbate the genetically compromised animals in developing ASD-like behaviors. Our anticipated results will have important implications for understanding gene-environment interactions in neural circuit assembly during brain development. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable **IBC Vote: Conditionally Approved (14:0:0)[1]** Conditions: 1. Include vivarium location in Locations Section and Addendum B	
19-079	De, Subhajyoti	**Title:** Genomic investigation of cancer **Materials:** rDNA, CRISPR-Cas12a, human materials The main goal of this project is to develop and apply genomic approaches to track cancer progression. Previously approved for genomic investigation of multiple types of cancer using deidentified tissue, blood, and urine samples. Isolation of tissue-derived and cell-free nucleic acids including cell-free DNA and cell-free RNA	2 / III-E

		have been standardized. This amendment adds CRISPR-Cas12 based approach to allow sensitive and non-invasive detection of cancer with fast turnaround time. The genomic approaches will be benchmarked and evaluated using CRISPR, sequencing, and PCR-based approaches. Deidentified genomic data will be securely stored and analyzed to provide status on the tumor burden and genetic differences therein. Sonication will be performed inside a certified biological safety cabinet (BSC) whenever possible to provide protection from potential aerosol generation. When a BSC is not available, sealed or capped tubes will be used, and samples will be allowed to rest for several minutes after sonication before opening to allow aerosols to settle. Lab personnel will wear appropriate personal protective equipment (PPE), including a lab coat, gloves, and eye/face protection at all times. The equipment and surrounding area will thoroughly disinfected after use to minimize contamination risks. **IBC Vote: Tabled** **The assigned reviewers were unable to attend, so this amendment will need go to the December IBC Meeting.**	
12-061	Kwan, Kelvin	**Title:** Inner Ear Damage and Repair **Materials:** rDNA, AAV, mice **Submission Summary:** The focus of the protocol is to investigate methods to regenerate hair cells and auditory neurons from mouse auditory progenitor cells. Genes that promote regeneration are identified and their cellular function is tested by introducing DNA into mouse and human cells using conventional molecular biology and tissue culture methods such as plasmids and viral vectors. Previously approved methods include retroviral vectors,	2 / III-D-1, III-D-4

		lentiviral vectors, CRISPR/Cas9 protein and CRISPR/Cas9 plasmids. This amendment is to expand the scope to include adeno-associated virus (AAV) vectors, with the goal of developing enhancer-driven AAV vectors for gene therapy. AAVs are not associated with causing human disease and are notable for their efficiency and safety. AAVs or constructs to produce AAVs will be purchased from Addgene. The goal is to restrict AAV expression in specific types of cochlear cells to treat patients with congenital hearing loss. Nucleic acid sequences will be obtained from either mouse or human cells and cloned into AAV transfer plasmids to regulate expression. The AAVs will be used to deliver functional genes into animals that have a defective gene that causes hearing loss in order to rescue the defective gene in the animal. One such gene is Gjb2, a gene that is found mutated in many patients with congenital deafness. AAVs will be used to infect cochlear explants or injected into the inner ear to validate gene delivery to cochlear cell types. The endpoints for cochlear explants will be 1 week after infection and for animals it will be up to 6 months. Worker exposure to AAV vectors (e.g., accidental needlestick) is the primary risk for the new work with AAV. All virus work will be completed under BSL2 working conditions inside biosafety cabinets, including loading and unloading of gasketed safety cups for centrifugation. Bleach will be used to decontaminate or disinfect the agents or contaminated materials. Sharps such as needles may be used for the transfer or injection of AAVs into anesthetized animals. All sharps (syringes, needles, etc.) will be immediately placed in a red sharps container. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable **IBC Vote: Conditionally Approved (14:0:0)[1]**	

		Conditions: 1. Address the gene target names in the project description and A1, GJB2	

[1] Voting Decision (Yay: Nay: Abstain)
[2] Member(s) joined the meeting
[3] Member(s) left the meeting