

Quorum: 7

IBC Meeting Comments

January 7, 2026 – Zoom Conference Call

Attendance – IBC Committee			
Present	Name	Expertise	Role
	Paul Gulig	Microbiology	Member
x	Luis Martinez	Microbiology	Member
x	Jason Clements		Member
x	Norman Beatty	Infectious Diseases	Member
	Steeve Boulant	Virology	Member
x	Sanford L. Boye	Virology	Member
	Amber Duren		Community Member
x	Mariola Ferraro	Microbiology	Member
x	Gary Heil		Member
x	Michael McIntosh	Virology	Member
x	John D. McVay	Plants	Community Member
x	Mark Moehle Joined at 1:13pm	Microbiology	Member
x	Kamal A. Mohammed	Microbiology	Member
x	Christopher Overend		Member
x	██████████	Animals	Member
x	Jeffrey Rollins	Plants	Member
	Elias J. Sayour	Clinical Trials	Member
x	Clay Smith	Virology	Chair
	Daniel R. Swale	Insects	Member
	Amy Vittor	Infectious Diseases	Member

Attendance – Staff and Guests		
Present	Name	Affiliation/Position
x	Christine Lashley	UF EHS
x	Asha Rani	UF EHS
x	Alek Aranyos	UF EHS
x	Pratibha Srivastava	UF EHS
x	Jennifer Jackson	UF EHS
x	Savannah Hardiman	UF EHS
x	Laura Castillo Left at 1:45pm	UF EHS
x	Erica Gonzaga	UF EHS
x	Kindra Kelly-Quagliana	UF EHS
x	██████████ Left at 1:29 pm	PI Guest
x	██████████	UF IACUC
x	Craig Money Penny	UF EHS
x	Anna Gioseffi	UF EHS
x	Raies Mir	UF EHS
x	Artiom Chacon Joined at 1:06pm	UF EHS
x	Laurence Prunetti Joined at 1:11pm	UF EHS
x	██████████ Joined at 1:42pm	PI Guest

Attendance – UFO IBC: Apopka, Orlando, Lake Alfred, Lake Nona		
Present	Name	Affiliation/Position
	Annette R. Khaled	Community member - Covers Apopka, Orlando, Lake Alfred and Lake Nona
x	Norman Beatty	Other: Infectious Disease
x	Mariola J. Ferraro	Other: Microbiology and Cell Science
x	Gary L. Heil	Other: Bio-Safety / Alternate Responsible Official
x	Kindra A. Kelly-Quagliana	BSO, Voting Contact
x	Michael T. McIntosh	Other: infectious disease
x	[REDACTED]	Animal Expert
x	Jeffrey Rollins	Plant Expert
x	Hubert Salvail Left at 1:23pm	Community member - Covers Apopka, Orlando, Lake Alfred and Lake Nona
x	Wesley Clay Smith	Chair

Agenda:

	Full Committee Projects	PI
1	Structure and function of the human b-globin locus control region	Jorg Bungert RD-1649 and RD-2028

2	Models for Tumor Metastasis	████████ BIO5682 renewal
3	Interplay of Epigenetic Mechanism in Gene Regulation	Michael Kladde RD-3783
4	Metabolic and reproductive hormone regulation of CNS function and structure in aging and AD	██████████ BIO5791 renewal
5	Isolation and characterization of bacteriophages	██████████ BIO5673 renewal
Amendments		PI
1	BSL-2 In-vitro and in-vivo pharmacodynamic studies for antibiotic optimization and resistance suppression -UF Orlando IBC	██████████ BIO6751
2	Leveraging Immunological Mechanisms to Mediate Tumor response	██████████ BIO6653
3	Gene Therapy Applications for Glycogen Storage Diseases	██████████ BIO6834
4	Ubiquitin ligases and B cells	██████████

Minutes

Meeting was called to order at: 1:02pm

Project Review

Principal Investigator: Jorg Bungert

Project Title: Structure and function of the human b-globin locus control region

BIO number not yet assigned. Transcription of RD-1649 and RD-2028.

Vector/Agent(s) to be used: Lentivirus, second-generation (Gag/Pol/Rev expressed in a single helper plasmid)

Name and Function of Transcribed Nucleic Acids: 8ZF-Y (gamma), 8ZF-Y-VP16/VP64; synthetic transcription factor to activate fetal hemoglobin. 8ZF-Y will bind to a specific genomic site and displaced the binding of a repressor. 8ZF-Y-VP16/VP64 contains strong transactivation domains and is expected to provide long-term activation of fetal hemoglobin.

Host(s) to be used: Production of lentivirus: *E. coli* STBL2 Packaging: HEK293T Host cell line: HUDEP-2 (Human umbilical cord blood derived erythroid progenitor-2)

NIH Guidelines: III-D-3-a for the generation of the Lentiviral vectors using a helper system; III-E for expression in non-exempt *E. coli* strains (BL21); III-F-8 Appendix C-II for maintenance of plasmids in *E. coli* K12 strains.

Biosafety Level and Any Additional Requirements: BSL-1 for plasmid maintenance using nonpathogenic *E. coli* strain; BSL-2+ for experiments involving *in vitro* experiments with LVV (packaging and transduction of cells) including additional practices for work with LVV include mucous membrane protection and substituting plastic labware for glassware where possible. BSL-2 containment and practices for culture of non-transduced human derived cells/cell lines. The pMD2.G plasmid encoding the VSV-G gene is subject to export control regulations.

Concerns or Discussion: None

Training: All training completed.

Approval: All approved as recommended (Yes-14, No-0, Abstain-0)

Principal Investigator: [REDACTED]

Project Title: Models for Tumor Metastasis

BIO5682 Renewal

Vector/Agent(s) to be used: Genetically modified Cells

Name and Function of Transcribed Nucleic Acids: luciferase/GFP; imaging marker

Host(s) to be used: rodents

NIH Guidelines: III-D-4-a for the administration of genetically modified cell lines to whole animals (Rodents); III-E for modification of *L. lactis*; III-F-8 Appendix C-I for propagation of RCV negative lentiviral vector transduced cells.

Biosafety Level and Any Additional Requirements: This project is approved at the following biosafety containment and practices: BSL-1 with use of a BSC for good microbiological practices for the propagation of the RCV negative transduced cells and work involving *L. lactis*; BSL-2 for *in vitro* experiments involving human cell lines, and RG2 agents (Human Papillomavirus); ABSL-2 for work with HPV+ human cervical cancer patient derived xenograft lines and their implantation into rodents. These cervical cancer PDX lines, are transformed by the chromosomal integration of the genomes of HPV-16 and/or -18 in multiple copies into cellular chromosomes. As HPV only produces infectious virions in differentiated cells these cell lines are not likely to produce infectious viruses while being propagated *in vitro*. However, in very specific situations, published studies indicate that fully formed virions do form when the cells are implanted in SCID rodents. Virion production under these circumstances increases the risk of not only parenteral exposure, but dermal exposure to HPV as well. To facilitate the use of the X-ray irradiator required for this work which is housed in the CRGC ABSL-1 facility in a room where other animals will be housed and handled under ABSL-1, the following practices will be required: Animals will be housed in a dedicated NexGen containment caging rack operating under negative pressure. All procedures invasive or otherwise including regular cage changes will take place in an annually certified Class II Biological Safety Cabinet (BSC). In addition to standard ABSL-2 PPE, research and ACS husbandry staff will wear a second pair of gloves for all procedures, invasive or otherwise, that involve handling animals or tissues or blood from animals that have received HPV transformed human cervical cancer cells in the BSC in the ACS animal housing room. Prior to removing their hands from the BSC the outer pair of gloves will be disinfected and removed inside the BSC to avoid the potential of contaminating surfaces outside the BSC. A second pair of gloves would be donned prior to reentering the BSC. The outer surfaces of all research materials (e.g. caging, animal restraint devices, sample vials, liquid transfer devices, surgical instruments, bagged and sealed biomedical waste, etc.) must be surface decontaminated using a disinfectant effective against HPV prior to being removed from the BSC following the manipulation of animals having received HPV transformed human cervical cancer cells. All animals exhibiting signs of ulcerating lesions must be euthanized and removed from the study. Tissues may be harvested from these animals' post euthanasia. Procedures conducted in ACS space are limited to inoculations, x-ray beam treatments, sampling, point of care manipulation, euthanasia, and necropsy. Any other procedures and handling of samples must be performed in the PI's laboratory in an annually certified class II biosafety cabinet using BSL-2 containment and practices. ABSL-1 containment and practices for the injection of genetically modified murine cell lines transduced with RCV negative Lentiviral vectors, additional precautions to include use of safe engineered sharps and wiping for injection site, Subsequent housing at ABSL-1. ABSL-1 for administration of *L. lactis* to rodents via gavage with housing at ABSL-1i for the first 72 72 hours fir inactivation of bedding then ABSL-1 thereafter. ABSL-2 for administration of human cells transduced with RCV negative Lentiviral vectors in rodents with additional precautions for mucous membrane protection, use of safe engineered sharps and wiping of injection site. Subsequent housing to be at ABSL-1+Hu Notify ACS prior to start of experiment and label "Use of Human Cells in Animals" on caging and at the entrance of the room. Second-generation lentiviral vectors certified as replication-competent virus RCV-negative by testing, with supporting records attached, were approved under previous approvals and were used to transduce cells that are administered to animals in this current submission.

Due to the handling of human source cell lines, initial and annual BBP training is required by all personnel.

Concerns or Discussion: None

Training: All training completed.

Approval: All approved as recommended (Yes-14, No-0, Abstain-0)

Principal Investigator: Michael Kladde

Project Title: Interplay of Epigenetic Mechanism in Gene Regulation

BIO number not yet assigned. Transcription of RD-3783

Vector/Agent(s) to be used: Plasmids

Name and Function of Transcribed Nucleic Acids: M.CviPI, M.SssI, and M.NCN - DNA methyltransferases; Sequence-specific methylation of DNA to make 5-methylcytosine. Wild-type BACH1, Wild-type MAFG, MAFG (S124D) with Serine 124 mutated to Aspartate, and MAFG (S124E) with Serine 124 mutated to Glutamate; BACH1 and MAFG encode human sequence-specific transcription factors. MAFG (S124D) and MAFG (S124E) encode MAFG with phosphomimetic amino acids (E & D) substituted for a phosphorylated Serine (S).

Host(s) to be used: *Saccharomyces cerevisiae*, NEB® 5-alpha competent *E. coli* and 10beta competent cells, Caco-2, a colon adenocarcinoma cell line; HCT116 and RKO, colorectal cancer cell lines.

NIH Guidelines: III-E for the use of CRISPR to modify human cell lines; III-F-8, Appendix C-1 for the use and maintenance of genetically modified cell lines; III-F-8, Appendix C-II for the use of K-12 *E. coli* (NEB® 5-alpha competent *E. coli* and 10beta competent cells) to clone and propagate plasmids; III-F-8, C-III for the use of plasmids in *S. cerevisiae*.

Biosafety Level and Any Additional Requirements: BSL-2+ for *in vitro* work with human cancer cell lines transduced with lentiviral vectors (the '+' necessitates the use mucous membrane protection and substituting glassware for plasticware when possible); BSL-2 for experiments involving CRISPR and human cell lines; BSL-1 for cloning and propagation of plasmids in K-12 *E. coli* and *S. cerevisiae*.

Concerns or Discussion: None

Training: All training completed.

Approval: All approved as recommended (Yes-13, No-0, Abstain-0)

Principal Investigator: [REDACTED]

Project Title: Metabolic and reproductive hormone regulation of CNS function and structure in aging and AD

BIO5791 Renewal

Vector/Agent(s) to be used: Lentivirus, third-generation (Gag/Pol and Rev are expressed in two separate helper plasmids)

Name and Function of Transcribed Nucleic Acids: Calcitonin Receptor G-protein coupled receptor. Receptor Activity Modifying Protein 1; Calcitonin Receptor together with Receptor Activity Modifying Protein 1 (RAMP1) form one of the amylin receptor subtypes expressed in the brain. Its role in the brain is not well understood. Calcitonin receptor, mCherry, and Receptor Activity Modifying Protein 3; Calcitonin Receptor together with Receptor Activity Modifying Protein 3 (RAMP3) form one of the amylin receptor subtypes expressed in the brain. Its role in the brain is not well understood. Transient Receptor Potential Cation Channel Subfamily V Member 4; Transient Receptor Potential Cation Channel Subfamily V Member 4 is a calcium permeable, nonselective cation channel, involved in multiple physiologic functions including pain signaling.

Host(s) to be used: SHS5Y5, HEK293FT

NIH Guidelines: III-D-4-a for the administration of AAV to whole animals; III-E-1 for the transduction of cells with 3rd generation lentiviral vectors; III-F-8, Appendix C-I for the transfection of cells with plasmids.

Biosafety Level and Any Additional Requirements: BSL-2+ for the *in vitro* use of LVV (the + necessitates the use of mucous membrane protection, substitution of glassware with plastic whenever possible, and the use of safe engineered sharps); BSL-2 for the handling of human derived tissues and cell lines; BSL-1 for the handling of packaged AAV; ABSL-1 for the administration of AAV to rodents and subsequent housing.

Concerns or Discussion: None

Training: All training completed.

Approval: All approved as recommended (Yes-13, No-0, Abstain-0)

Principal Investigator: [REDACTED]

Project Title: Isolation and characterization of bacteriophages

BIO5673 Renewal

Vector/Agent(s) to be used: Transposon Mutagenesis by mating with *E. coli* strains

Name and Function of Transcribed Nucleic Acids: *E. coli* strain SM10pir/ pCM639 (ISphoA/hah insertions) or SM10pir/pIT2 (ISlacZ/hah insertions)

Host(s) to be used: *Pseudomonas aeruginosa* PAO1

NIH Guidelines: III-D-1-a for use of r-DNA in RG2 vector (*P. aeruginosa* genome-wide knockout library).

Biosafety Level and Any Additional Requirements: BSL-2 for *in vitro* work with RG2 bacteria; ABSL-2+ for administering non-genetically modified *P. aeruginosa* to rodents with subsequent housing at ABSL-2 (the extra + precautions include the use of safe engineered sharps and wiping of injection sites with disinfectants). Because the oral ID₅₀ in humans for Shigella agents is low (180 organisms for *S. dysenteriae*), it is recommended that special emphasis be placed on personal protective equipment (i.e. gloves), handwashing, hygienic manipulation of faucet handles, and decontamination of work surfaces to decrease the risk of LAI in addition to including the use of primary containment for aerosol generating activities (use of an annually certified Class II biosafety cabinet (BSC) and centrifugation in aerosol tight rotors and buckets that are only opened in the BSC). *Shigella dysenteriae* is on the US Department of Commerce's list of export controlled biological agents and is subject to all applicable regulations under this designation including securing from access by restricted persons.

Concerns or Discussion: None

Training: All training completed.

Approval: All approved as recommended (Yes-13, No-0, Abstain-0)

Amendments

Principal Investigator: [REDACTED] BIO6751

Title: BSL-2 *In vitro* and *in vivo* pharmacodynamic studies for antibiotic optimization and resistance suppression

BIO6751

Summary: Adding a select agent obtained from another PI. This amended project is approved at ABSL2/BSL2 containment and practices (Dr. Louie already has received approval for the reduction from BSL3 to BSL2 for exempt *Burkholderia pseudomallei* Bp82 of which this strain is a subset). This project falls under the following sections of the NIH Guidelines: III-D-1 for Experiments Using Risk Group 2 agents and III-D-4 for Experiments Involving Whole Animals.

Concerns or Discussion: None

Training: All training completed.

Approval: All approved as recommended. Voted on by UF Orlando IBC (Yes-8, No-0, Abstain-0)

Principal Investigator: [REDACTED] BIO6653

Title: Leveraging Immunological Mechanisms to Mediate Tumor response

BIO6653

Summary: Adding new strains. This amended project is approved at the following safety and containment practices: BSL-2+ for work with transduced cell lines and *in vitro* experiments with LVV (the '+' designates the use of mucous membrane protection and substituting plastic labware for glassware where possible). ABSL-2+ for animal inoculations with transduced cell lines (the "+" requires the use of safe sharps and wiping of the injection sight, mucous membrane protection) and ABSL-2 for subsequent housing (for rodents treated with stably transduced cell lines, housing may be reduced to ABSL-1 if data is provided to the biosafety office demonstrating that the cell lines do not produce replication competent viruses); ABSL-1 for rodent cell lines and for the transfer of genetically modified materials from donor rodents into recipient rodents, with subsequent ABSL-1 housing; ; ABSL1-Hu+ for human cell lines transplanted into animals (Notify ACS prior to start of experiment and label "Use of Human Cells in Animals" on caging and at the entrance of the room). The following sections of the NIH Guidelines apply to this project: III-D-4-a, for transfer of genetically modified materials from donor rodents into recipient rodents; III-D-4-b, for the use of recombinant modified cell lines in rodents; III-E-1 for cell line transduction by lentiviruses; III-F-8 Appendix C-1 for the maintenance of genetically modified cells in culture.

Concerns or Discussion: None

Training: All training completed.

Approval: [REDACTED] had a conflict and was put in waiting room during discussion and vote. All approved as recommended (Yes-12, No-0, Abstain-0)

Principal Investigator: [REDACTED] BIO6834

Title: Gene Therapy Applications for Glycogen Storage Diseases

BIO6834

Summary: Adding 2 AAV vectors. This amended project is approved at the following biosafety containment and practices: BSL-1 for *in vitro* work with AAV; BSL-2 for *in vitro* work with HEK293; ABSL-1 for the injection of AAV in animals (additional required practices include the use of safe engineered sharps, mucous membrane protection, substitution of plasticware for glassware whenever feasible, and wiping of the injection site with an appropriate disinfectant) with subsequent ABSL-1i for animal housing, with inactivation of bedding materials for the first 72 hours post-inoculation for rodents, and disinfection of bedding. The following sections of the NIH Guidelines apply to this project: III-D-3-e for the production of AAV vectors; III-D-4-a for the administration of AAV vectors to whole animals (rodents and rats); III-F-8 appendix C-II for the propagation of plasmids in K-12 derived *E. coli*

Concerns or Discussion: None

Training: All training completed.

Approval: [REDACTED] had a conflict and was put in waiting room during discussion and vote. All approved as recommended (Yes-12, No-0, Abstain-0)

Principal Investigator: [REDACTED]

Title: Ubiquitin ligases and B cells

BIO5752

Summary: This amended project is approved at the following safety and containment practices: BSL-1 for studies involving the mRNA-LNP and CRISPR/Cas9; BSL-2 for experiments involving HEK-293 cells; BSL-2+ for *in vitro* experiments involving lentiviral vectors (the '+' designates the use of mucous membrane protection, and substitution of plastic for glassware); ABSL-1 for systemic injection of mRNA-LNP into rodents ABSL-1 for injection of bone marrow or B cells from transgenic donor rodents into recipient rodents with recipient animals housed at ABSL-1; ABSL-2 for the administration of recombinantly modified MHV68 to rodents, with subsequent ABSL-2 housing; ABSL-2+ for the injection of cell lines transduced with Lentiviral vectors in rodents with subsequent ABSL-2 for housing (the '+' designates the use of safe engineered sharps and wiping of the injection site). The work falls under the following sections of the NIH Guidelines: III-D-3-a for packaging of the lentiviral vectors; III-D-4-a for the introduction of recombinant/synthetic nucleic acids in rodents, as well as the transfer of genetically modified materials from donor rodents into recipient rodents; III-D-4-b for the administration of genetically modified MHV68 to rodents; III-E for the application of CRISPR/Cas9 technology in eukaryotic systems; III-E-1 for the transduction of human and rodent cell lines with lentiviral vectors; III-F-1 for studies involving the mRNA-LNP

vaccine candidates (comprised of influenza HA mRNA encapsulated in a lipid nanoparticle). ****NOTE**** Packaging plasmids containing the VSV-G are subject to export control regulations.

Concerns or Discussion: None

Training: All training completed.

Approval: All approved as recommended (Yes-14, No-0, Abstain-0)

The meeting adjourned at 2:01pm