Quorum: 7

IBC MEETING COMMENTS

Attendance – IBC Committee			
Present	Name	Expertise	Role
	Paul Gulig	Microbiology	Member
x	Luis Martinez	Microbiology	Member
x	Jason Clements		Member
	Norman Beatty	Infectious Diseases	Member
x	Steeve Boulant	Virology	Member
x	Sanford L. Boye	Virology	Member
	Amber Duren		Community Member
	[redacted]	Microbiology	Member
x	Gary Heil		Member
	Michael McIntosh	Virology	Member
	John D. McVay	Plants	Community Member
x	Mark Moehle	Microbiology	Member Joined at 1:18pm
x	Kamal A. Mohammed	Microbiology	Member
x	Christopher Overend		Member
	[redacted]	Animals	Member
x	Jeffrey Rollins		Member
	Elias J. Sayour	Clinical Trials	Member
x	Clay Smith	Virology	Chair
	[redacted]	Arthropods	Member
	Amy Vittor	Infectious Diseases	Member

August 6, 2025 – Zoom Conference Call

Attendance – Staff and Guests		
Present	Name	Affiliation/Position
x	Asha Rani	UF EHS
x	Laurence Prunetti	UF EHS
x	Artiom Chacon	UF EHS
x	Pratibha Srivastava	UF EHS
x	Laura Castillo	UF EHS
x	Erica Gonzaga	UF EHS
x	[redacted]	PI Guest Left at 1:16pm
x	Craig Moneypenny	UF EHS
x	Matt Lee	PI Guest Left at 1:40pm
x	Ellyse Thomas	PI Guest Left at 1:30pm
x	Shailendra Singh	UF EHS Left at 2:00pm
x	Savannah Hardiman	UF EHS
x	Alek Aranyos	UF EHS

			Attendance – UFO IBC: Apopka, Orlando, Lake Alfred, Lake Nona
Present	Name	Expertise	Affiliation/Position
x	Annette R. Khaled		Community member - Covers Apopka, Orlando, Lake Alfred and Lake Nona. Left at 1:11pm
	Norman Beatty	Infectious Diseases	Other: Infectious Disease
	Mariola J. Ferraro	Microbiology	Other: Microbiology and Cell Science
x	Dean W. Gabriel	Plants	Plant Expert
x	Gary L. Heil		Other: Bio-Safety / Alternate Responsible Official
x	Kindra A. Kelly-Quagliana		BSO, Voting Contact
	Michael T. McIntosh	Virology	Other: infectious disease
	[redacted]	Animals	Animal Expert
	Hubert Salvail		Community member - Covers Apopka, Orlando, Lake Alfred and Lake Nona
x	Wesley Clay Smith	Insects	Chair

Agenda:

	Full Committee Projects	PI
1	Strain Maintenance – Will be voted on by Orlando IBC	Nils Averesch
2	A Two-Part Open-Label Study of REGV131-LNP1265, a CRISPR/Cas9 Based Coagulation Factor IX Gene Insertion Therapy in Participants with Hemophilia B	Tung Wynn
3	Drug Treatment in Combination for Cancer Protocol	[redacted]

4	A Phase 1/2a, Open Label, Dose Escalation Study to Evaluate the Safety and Preliminary Efficacy of TRX103 in Subjects with Moderate to Severe Treatment-Refractory Crohn's Disease.	Angela Pham
5	PRMT5 N-Terminus isolation and structure determination for drug design	Chenglong Li RD4405 transcription
6	Identification, exploration and improvement of enzyme involved in primary and secondary plant metabolism.	Andrew Hanson
7	~~Viral transduction in the rodent brain~~	[redacted] ~~BIO5610 Renewal~~
8	Investigation of pancreatic islet physiology in the context of type 1 diabetes	[redacted] BIO5666 Renewal
9	Generation of pluripotent stem cells from somatic cells using Sendai virus	Clayton Mathews RD3933 transcription
	Amendments	**PI**
1	Gene Therapy for Muscular Dystrophies and Cardiomyopathies	[redacted] BIO5766
2	Developing medical countermeasures against SARS-CoV-2	[redacted] BIO6501
3	Mechanisms regulating immune responses in the Gram-negative infections	[redacted] BIO6075

Minutes

Meeting was called to order at: 1:03pm

Project Review

Principal Investigator: Nils Averesch

Project Title: Strain Maintenance – Will be voted on by Orlando IBC

BIO number not yet assigned

Vector/Agent(s) to be used: Plasmids

Name and Function of Transcribed Nucleic Acids: bla (beta-lactamase), LacZα; Ampicillin Resistance, β-galactosidase breakdown into galactose and glucose.

Host(s) to be used: *E. coli* DH5α, TOP10, XL1-Blue, JM109, MC1061, NEB 5-alpha, Stbl2, Stbl3, GT115, BL21, BL21(DE3), BL21(DE3)pLysS, Rosetta(DE3), C41(DE3), C43(DE3), ArcticExpress(DE3), Shuffle T7 Express, S17-1, MFDpir, WM3064, SM10, DY380, EL350, EL250, GB2005, EPI300, MG1655, W3110, HB101, ER2566, CLM24, C600, REL606, REL607

NIH Guidelines: III-E for cloning plasmids containing recombinant/synthetic nucleic acids into non-K-12 strains of *E. coli* (e.g. BL21(DE3)). III-F-8 Appendix C-II for cloning and storage of plasmids containing recombinant/synthetic nucleic acids into K-12 *E. coli* (e.g. DH5α)

Biosafety Level and Any Additional Requirements: Experiments involving the use of recombinant/synthetic nucleic acids cloned into both K-12 and non-K-12 strains of *E. coli* can safely be performed at BSL-1 containment and practices.

Concerns or Discussions: Are they using Class 1 or Class 2 type biosafety cabinets? Does not affect safety but will confirm and edit if needed.

Training: All training completed

Approval: This was voted on by the Orlando IBC. All approved as recommended (Yes-5, No-0, Abstain-0)

Principal Investigator: Tung Wynn

Project Title: A Two-Part Open-Label Study of REGV131-LNP1265, a CRISPR/Cas9 Based Coagulation Factor IX Gene Insertion Therapy in Participants with Hemophilia B

BIO number not yet assigned

Vector/Agent(s) to be used: Adeno-associated virus (AAV)

Name and Function of Transcribed Nucleic Acids: The insert consists of a F9 DNA template containing the F9 gene encoding for the full-length human coagulation Factor IX protein, without a promoter and with AAV2-derived inverted terminal repeats (ITRs) and Albumin splice acceptor. F9 gene encodes for wildtype human FIX protein, which is involved in blood coagulation.

Host(s) to be used: Human

NIH Guidelines: Section III-C-1 of the NIH Guidelines for the administration of recombinant/synthetic nucleic acids to human patients.

Biosafety Level and Any Additional Requirements: The delivery of REGV131-LNP1265 can be safely performed under BSL-1 containment and practices. However, the handling of human specimens must be done at BSL-2 containment and practices.

Concerns or Discussions: none

Training: All project personnel must complete annual Bloodborne Pathogens. All training completed

Approval: All approved as recommended (Yes-10, No-0, Abstain-0)

Principal Investigator: [redacted]

Project Title: Drug Treatment in Combination for Cancer Protocol

BIO number not yet assigned

Vector/Agent(s) to be used: Plasmids

Name and Function of Transcribed Nucleic Acids: spCas9; 3xFLAG (tag); creates gRNA guided double strand DNA breaks at targeted sites. DNAJB1-PRKACA fusion; small restricted sequence of the fusion site of the DNAJB1-PRKACA fusion gene mutation that causes rare FL-HCC.

Host(s) to be used: rodents, *E. coli* STBL2, STBL3, or STBL4

NIH Guidelines: III-D-4-a for the injection of the plasmid pX330 into rodents. III-E for the application of genome editing in eukaryotic hosts (such as CRISPR/Cas-9 technologies). III-F-8 Appendix C-II for the maintenance of plasmids in K12 *E. coli*.

Biosafety Level and Any Additional Requirements: BSL-2 for handling human patient tumor cells. ABSL-2 for inoculation of patient cells/tissue/xenograft in mice, and any invasive procedures on animal and for any procedures on animal with active hemorrhage/seeping wounds (animal wastes are to be collected and disposed of as biomedical waste). ABSL-1+Hu for the housing of the xenograft rodents (Notification of ACS by the PI prior to initiation and Label “Use of Human Cells in Animals” on caging and at the entrance of the room). BSL-1 for plasmid maintenance in K12 *E. coli*.

Special considerations include substitution of glassware with plasticware, annual bloodborne pathogens training, use of safe sharps, and wiping of the injection site for invasive animal procedures

Concerns or Discussions: none

Training: All training completed

Approval: All approved as recommended (Yes-9, No-0, Abstain-0)

Principal Investigator: Angela Pham

Project Title: A Phase 1/2a, Open Label, Dose Escalation Study to Evaluate the Safety and Preliminary Efficacy of TRX103 in Subjects with Moderate to Severe Treatment-Refractory Crohn's Disease.

BIO number not yet assigned

Vector/Agent(s) to be used: Previously generated genetically modified cells

Name and Function of Transcribed Nucleic Acids: IL-10 and ΔNGFR; IL-10 expression in TRX103 cells recapitulates the major features of naturally occurring Tr1 cells. IL-10 is considered the major mediator of the regulatory functions of naturally occurring Tr1 cells and Tr1 cells generated in vitro. Truncated (non-signaling) NGFR is used both for purification of TRX103 cells during manufacturing and as a pharmacokinetic marker for the study.

Host(s) to be used: Humans

NIH Guidelines: Section III-C-1 of the NIH Guidelines for the administration of recombinant/synthetic nucleic acids to human patients.

Biosafety Level and Any Additional Requirements: BSL-2 biosafety containment and practices for the work with handling and administering TRX103 and for collecting and handling patient samples. All project personnel must complete annual Bloodborne Pathogens.

Concerns or Discussions: none

Training: All training completed

Approval: All approved as recommended (Yes-10, No-0, Abstain-0)

Principal Investigator: Chenglong Li

Project Title: PRMT5 N-Terminus isolation and structure determination for drug design

BIO number not yet assigned – RD-4405 Transcription

Vector/Agent(s) to be used: Plasmids

Name and Function of Transcribed Nucleic Acids: PRMT5 N-terminus; will be expressed and purified in order to conduct ligand-binding assays and determination of its structure.

Host(s) to be used: DH5alpha and BL21(DE3) strains of *E. coli*

NIH Guidelines: III-E for the use of laboratory strains of non-K-12 *E. coli* [BL21(DE3)] for protein expression. III-F-8 Appendix C-II for cloning, transforming, and propagating plasmids in K-12 *E. coli* [DH5a].

Biosafety Level and Any Additional Requirements: The work outlined in this project may safely be conducted at BSL-1 safety and containment practices.

Concerns or Discussions: none

Training: All training completed

Approval: All approved as recommended (Yes-10, No-0, Abstain-0)

Principal Investigator: Andrew Hanson

Project Title: Identification, exploration and improvement of enzyme involved in primary and secondary plant metabolism.

BIO number not yet assigned

Vector/Agent(s) to be used: Plasmids

Name and Function of Transcribed Nucleic Acids: pal1; production of PAL enzyme. AlsE; Production of enzyme Allulose epimerase. RPE; RPE: ribulose-5-phosphate 3-epimerase

Host(s) to be used: *E.coli* top10, *Saccharomyces cerevisiae*

NIH Guidelines: III-E for work with plasmids harbored in non-K-12 BL21 *E. coli*. III-F-8 Appendix C-II for work with exempt TOP10 (K-12 derived) *E. coli* and Appendix C-III for the use of plasmids in *Saccharomyces cerevisiae*.

Biosafety Level and Any Additional Requirements: BSL-1 for work with *E. coli* and *Saccharomyces cerevisiae*.

Concerns or Discussions: Deleted sentence describing plant genome editing since this is not happening.

Training: All training completed

Approval: All approved as recommended (Yes-10, No-0, Abstain-0)

Principal Investigator: [redacted] – BIO5610 Renewal

Project Title: Viral transduction in the rodent brain

Approval: Pulled from Agenda

Principal Investigator: [redacted]

Project Title: Investigation of pancreatic islet physiology in the context of type 1 diabetes

BIO5666 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: d2EGFP; a fluorescent reporter that is rapidly degraded. F-luc, GFP-puromycin; luciferase expression with GFP reporter and puromycin selection. CD63-FLAG/HA-mScarlet; CD63, also known as lysosome-associated membrane protein 3 (LAMP-3), is a type II transmembrane protein and a member of the tetraspanin superfamily. It's located on the cell surface and within intracellular compartments like late endosomes and lysosomes. CD63 is involved in various cellular processes, including cell activation, adhesion, intracellular trafficking, and cargo sorting. It also plays a role in the formation and release of extracellular vesicles (EVs). FLAG and HA are pulldown tags that allow for purification. mScarlet is a fluorescent reporter.

Host(s) to be used: HEK293T cells, K-562 human lymphoblast cells, rodents, K-12 E. coli (TOP10), rat INS1 insulinoma cells; mouse MIN6 beta cells; mouse MIN6-LRRC8A-KO beta cells, primary mouse islets, primary human islets, human ENDOC beta cell line, mouse beta cell LRRC8A-KO transgenic islets, mouse beta cell GAD1::GAD2-KO transgenic islets, primary rat islets.

NIH Guidelines: III-D-1-a for use of adenoviral vectors; III-D-3-a for the packaging of adenovirus and lentiviral vectors utilizing HEK293T cells; III-D-4-a for the introduction of recombinant/synthetic material into whole animals; III-E-1 for use of Lentiviral vectors in cells (*in vitro* only); and III-F-8 appendix C-II for molecular cloning and storage using K-12 lineage *E. coli*.

Biosafety Level and Any Additional Requirements: BSL-2 for implantation of all adenoviral transfected cells and animal procedures at ABSL-2 for housing rodents implanted with any adenoviral transfected cells; BSL-2 for *in vitro* work with TALEN and plasmid-transfected modified human-derived cells and animal procedures with housing being permitted at ABSL-1+Hu; BSL-2 for *in vitro* work with lentivirus-transduced rodent cells, and ABSL-1 housing for rodents implanted with 3rd generation lentivirus-transduced rodent cells; BSL-2 for *in vitro* work with lentivirus-transduced human-derived cells and animal procedures at ABSL-1+Hu for housing animals receiving lentivirus-transduced human cells.

Additional precautions for work with lentiviral and adenoviral vectors including transduced/transfected cells, animal procedures with these materials and any work involving human derived cells must include mucous membrane protection, use of safe engineered sharps substitution of glass ware with plastic lab ware, and annual completion of Blood Borne Pathogens training (EHS850G) by all lab personnel.

Concerns or Discussions: none

Training: All training completed

Approval: All approved as recommended (Yes-10, No-0, Abstain-0)

Principal Investigator: Clayton Mathews

Project Title: Generation of pluripotent stem cells from somatic cells using Sendai virus

BIO number not yet assigned – Transcription of RD-3933

Vector/Agent(s) to be used: Sendai

Name and Function of Transcribed Nucleic Acids: Oct4, Klf4, Sox2, c-Myc; transcription factors.

Host(s) to be used: human blood and fibroblast cells

NIH Guidelines: III-D-1-a for the cloning of transgenes into the RG2 Sendia virus. III-E-1 for the *in vitro* work with the adding the Sendia virus to iPSC's.

Biosafety Level and Any Additional Requirements: BSL-2 for the handling of human cells and work with a risk group 2 virus (Sendia). Blood-borne pathogens training is required annually for staff.

Concerns or Discussions: none

Training: All training completed

Approval: All approved as recommended (Yes-10, No-0, Abstain-0)

Amendments

Principal Investigator: [redacted]

Title: Gene Therapy for Muscular Dystrophies and Cardiomyopathies

BIO5766

Summary: 4 AAV-micro-dystrophin constructs are being added. Personnel changes. This will not alter the previous determined biosafety containment practices

NIH Guidelines:

- III-D-1-a for the cloning of r/sNA molecules into RG2 agents
- III-D-3-e for packaging of AAV's using Expi293F cells to test for activity prior to outsourced production
- III-D-4-a for injecting rodents with AAV's
- III-E for the components utilizing baculovirus vector.

Biosafety containment practices:

- BSL-1 for use of baculovirus expression system and Sf9 insect cell line .
- BSL-2 for all other *in vitro* work with Expi293F cells
- ABSL-1+ for animal inoculations, also adhering to including use of mucous membrane protection, safe engineered sharps, and wiping of the injection site and ABSL-1i for subsequent animal housing for bedding collected for 72 hours post administration.

Concerns or Discussions: Risk mitigations will need to be more clearly stated as applies to injections and human cells.

Training: All training completed

Approval: Conditionally approved pending mitigation information (Yes-10, No-0, Abstain-0)

Principal Investigator: [redacted] BIO6501

Title: Developing medical countermeasures against SARS-CoV-2

BIO6501

Summary: This amendment corrects the project scope to include recombinant/synthetic nucleic acids work subject to the NIH Guidelines: administration of lipid nanoparticle Pan-CoV DNA vaccine to rodents under section III-D-4-a.

To summarize biocontainment requirements:

- BSL-1/ABSL-1 for immunization of rodents with the Pan-CoV DNA vaccine.
- BSL-2+/ABSL-2 for all work involving SARS-CoV-2, with the '+' indicating use of primary containment equipment for manipulation of virus-containing materials, including use of a BSC for all open manipulation of viable agents and use of aerosol-tight rotors or safety buckets for centrifugation.
- BSL-2 for maintenance of human/NHP cell cultures.
- BSL-1 with additional precautions for handling extracted nucleic acids from virus-containing materials, including samples from infected animals. Additional precautions should include minimizing the use of sharps and excluding the use of permissive mammalian cells which could result in the rescue of viable virus due to direct translation of viral RNA.
- BSL-1 for all other lab procedures.

Annual bloodborne pathogens training is required for handling human cell lines.

Concerns or Discussions: Suggestion of intact viral genome. It is listed as RG2. BSL1 with additional precautions.

Training: All training completed

Approval: All approved as recommended (Yes-10, No-0, Abstain-0)

Principal Investigator: [redacted] BIO6075

Title: Mechanisms regulating immune responses in the Gram-negative infections

BIO6075

Summary: This amendment adds two additional bacterial strains to be used under the same experimental conditions as previously approved. It also updates the room list and lab personnel.

This work falls under the following sections of the NIH Guidelines:

- III-D-1-a, for the use of *Salmonella typhimurium* as a host-vector
- II-F-8 appendix C-I, for the use of recombinant nucleic acid molecules in tissue culture

This work remains approved at BSL-2 for *in vitro* work with human cells and RG-2 bacterial strains and ABSL-2 for *in vivo* work with rodents and subsequent housing. Initial and annual bloodborne pathogens training is required for handling human cell lines.

Concerns or Discussions: none

Training: All training completed

Conflicts: [redacted] is an IBC Member but was not present at today's meeting so did not need to be removed for discussion.

Approval: All approved as recommended (Yes-10, No-0, Abstain-0)

The meeting adjourned at 2:23pm