Minutes
INSTITUTIONAL BIOSAFETY COMMITTEE
September 23, 2025
3:00 PM

Remote Meeting via Zoom

Members Present	Members Absent
Rumela Chakrabarti, PhD**	Sophia George, Ph.D.
Ellen Kapsalis, Ph.D.	Kevin Folta, Ph.D (ad hoc member)
Micheline McCarthy, M.D., Ph.D	Minh Tran, Ph.D
Susanne Doblecki-Lewis, MD	Dan Rothen, D.V.M
Shane Gillooly	Kevin Sanders, D.V.M.
Mercina Drake[1]	Pantelis Tsoulfas, M.D.*
Jennifer Laine, PhD***	Kevin Mullen[1]
Ela Koncza	Julia Zaias, D.V.M, Ph.D
Lizzeth Meza ***	

* Denotes Chair
** Denotes Vice-Chair
*** Denotes BSO Alternate
[1] Denotes Community Representatives

1. **Call to Order and Announcements:**
   The IBC meeting was held on August 26th via Zoom. Dr. Chakrabarti chaired the meeting. After determining that there was a quorum, Dr. Chakrabarti called the meeting to order at 3:00 p.m.

   - Minutes from August 26th meeting – approved by vote 6-0
     - Minutes will be uploaded to the website

2. **Discussion:**
   - Laceration with scalpel used on rat infected with pseudorabies virus (IBC protocol 22-028)
     - Incident reported to IBC on September 11th
     - Preliminary report sent to the NIH on September 15th
       - Accepted as final report

   - Trend of more incidents being reported
     - This may be due to more people knowing how to report incidents properly. Due to educating the research community. EHS and IBC will continue to track incidents for an assessment.
     - Change in Biosafety Framework being presented by NIH
     - Listening session for region 1 available
       - We are in region 2

- Pending upgrade to BioRaft/SciSchield

3. Old Business

Protocol Number: 25-089 (Renewal of IBC 22-135)
Principal Investigator name: Dr. Liu, Zhao-Jun
Project title: Affordable and rapid AAV gene therapy for highly prevalent vascular disease
NIH Guidelines: IIID / BL 1
Agent characteristics: Adeno-associated virus (AAV2/9); low virulence and pathogenicity; typical environmental stability for AAV
Types of manipulations: Intramuscular injection of AAV vectors carrying E-selectin transgenes; surgical induction of hindlimb ischemia in mice
Source(s) of the nucleic sequences: Mouse and human E-selectin (E-Sel) transgenes; GFP control
Nature of the nucleic acid sequences: Structural gene (E-selectin); control gene (GFP)
Host(s) and vector(s) to be used: FVB mice; AAV2/9 vectors; Swine model (submitted independently)
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that will be produced: Yes; E-selectin protein promotes angiogenesis and tissue repair
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL1 containment
Review: Renewal of previous protocol; survey questions pending (DURCC and rDNA survey need updating)
Recommendation: Conditional approval recommended; unanimously approved (6-0)

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4. New Submissions

Protocol Number: 25-095 (NEW PI)
Principal Investigator name: Dr. Marteymyanov, Kirill
Project title: Regulation of Neuronal GPCR Signaling
NIH Guidelines: IIID / BL 2
Agent characteristics: Recombinant DNA encoding GPCRs, G proteins, RGS proteins; low biohazard risk
Types of manipulations: Cloning, overexpression, down-regulation, viral delivery, electroporation, phage display
Source(s) of the nucleic sequences: Mus musculus, Homo sapiens
Nature of the nucleic acid sequences: Structural genes for GPCRs, G proteins, RGS proteins
Host(s) and vector(s) to be used: E. coli K-12, insect Sf-9 cells, mammalian cell lines (NG108-15, HEK293), mice; lentivirus, AAV2/5/8/9, adeno virus, pseudorabies virus, G-deleted rabies virus
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that will be produced: Yes; function is to study neuronal signaling regulation
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL2 containment
Review: Risk assessment updated; additional details requested on lentivirus production, plasmid maps,

AAV serotypes, host range changes, and gene drive questions
Recommendation: Conditional approval recommended; unanimously approved (6-0)

**** Revised entry received – study approved September 26th**

Protocol Number: 25-096
Principal Investigator name: Dr. Vazquez-Padron, Roberto
Project title: New DNA Molecules to Improve DNA Transfection in Vascular Cells Signaling
NIH Guidelines: IIID / BL 2
Agent characteristics: Linear DNA constructs; EGFP gene; low biohazard risk
Types of manipulations: DNA transfection using standard techniques
Source(s) of the nucleic sequences: EGFP gene; Col8A1 gene
Nature of the nucleic acid sequences: Structural gene (EGFP); Col8A1 gene
Host(s) and vector(s) to be used: Vascular cells; no viral vectors unless clarified
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that will be produced: Yes; EGFP protein for efficiency testing
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL2 containment
Review: Clarification requested on use of viral vectors and associated maps
Recommendation: Conditional approval recommended; unanimously approved (6-0)

**** Revised entry received – study approved September 25th**

Protocol Number: 25-097
Principal Investigator name: Dr. Dave, Kunjan
Project title: Cerebral ischemia and exposure to recurrent hypoglycemia in diabetes – AAV2/61
NIH Guidelines: IIID / BL 1
Agent characteristics: AAV2/6 viral vector; GFP; shRNA against PLCgamma
Types of manipulations: In vivo injection of AAV2/6 into rat bone marrow; gene expression analysis
Source(s) of the nucleic sequences: Human and rat genes (PLCgamma, GFP)
Nature of the nucleic acid sequences: Structural gene (GFP); shRNA
Host(s) and vector(s) to be used: Rats; AAV2/6 vector
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that will be produced: Yes; GFP and PLCgamma protein
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL1 containment
Review: Additional details requested on ischemia induction, gene overexpression, harvesting, imaging, and vector maps
Recommendation: Conditional approval recommended; unanimously approved (6-0)

****Revised entry received – the study was approved September 30th**

Protocol Number: 25-098
Principal Investigator name: Dr. Green, Damian
Project title: D8310C00001: A Phase 1b/2 Study of GC012F (AZD0120), a Chimeric Antigen Receptor T-cell (CAR T) Therapy Targeting CD19 and BCMA in Subjects With Relapsed/Refractory Multiple Myeloma
NIH Guidelines: IIIC / BL 1
Agent characteristics: Autologous T cells genetically engineered with lentiviral vector; CARs targeting CD19 and BCMA
Types of manipulations: Ex vivo transduction; IV infusion; blood and tissue sampling
Source(s) of the nucleic sequences: Murine (scFv); human (CD28, 4-1BB, CD3ζ)
Nature of the nucleic acid sequences: Chimeric antigen receptor genes; costimulatory and signaling domains
Host(s) and vector(s) to be used: Human subjects; lentiviral vector
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that will be produced: Yes; CAR protein for immunotherapy
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL1 containment; SOP and biosafety procedures detailed
Review: Protocol version and SOP updates requested; additional details on gene transfer, vector maps, containment, and patient information
Recommendation: Conditional approval recommended; unanimously approved (6-0)

**** Revised forms pending as of October 23rd**

Protocol Number: 25-099
Principal Investigator name: Dr. Rivas, Martin
Project title: Role of GATA1s and STAG2 in Leukemia Development
NIH Guidelines: IIID / BL 2
Agent characteristics: Human induced pluripotent stem cells (iPSC) edited with CRISPR for GATA1 and STAG2 mutations; low biohazard risk
Types of manipulations: CRISPR editing, electroporation, differentiation into hematopoietic stem cells, injection into mice
Source(s) of the nucleic sequences: Human iPSC lines DS1, DS4, DS2U; GATA1 and STAG2 genes
Nature of the nucleic acid sequences: Structural genes (GATA1, STAG2, RAD21)
Host(s) and vector(s) to be used: Human iPSC lines; NBSGW mice; no viral vectors for CRISPR
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that will be produced: Yes; to study the role of cohesin and chromosomal architecture in leukemia development
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL2 containment
Review: Clarification requested on IRB approval, mosaicism, electroporation, CRISPR process, vector

maps, and animal work
Recommendation: Conditional approval recommended; unanimously approved (6-0)

**** Revised entry received – study approved October 10th**

Protocol Number: 25-100
Principal Investigator name: Dr. Rivas, Martin
Project title: Role of GATA1 and RAD21 in Leukemia Development using CMY cell lines
NIH Guidelines: IIID / BL 2
Agent characteristics: Human leukemic CMY cell line with GATA1s and Rad21 mutations; low biohazard risk
Types of manipulations: CRISPR knock-in to revert Rad21 mutation, electroporation, injection into NSG mice
Source(s) of the nucleic sequences: Human CMY cell line; GATA1 and Rad21 genes
Nature of the nucleic acid sequences: Structural genes (GATA1s, Rad21)
Host(s) and vector(s) to be used: CMY cell line; NSG mice; no viral vectors for CRISPR
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that will be produced: Yes; to compare the effect of cohesin mutations in leukemia progression
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL2 containment
Review: Clarification requested on electroporation, CRISPR process, vector maps, and DNA introduction
Recommendation: Conditional approval recommended; unanimously approved (6-0)

**** Revised entry received – study approved on October 10th**

Protocol Number: 25-101
Principal Investigator name: Dr. Shah, Ashish
Project title: HERV-K envelope as a target for CAR T immunotherapy glioblastoma
NIH Guidelines: IIID / BL 2
Agent characteristics: G10VHH nanobody-based CAR T cells targeting HERV-K (HML-2) envelope protein; low biohazard risk
Types of manipulations: Engineering CAR T cells, in vitro cytotoxicity assays, intracranial injection into NSG mice
Source(s) of the nucleic sequences: Humanized VHH nanobody; HERV-K envelope protein
Nature of the nucleic acid sequences: CAR construct; nanobody sequence
Host(s) and vector(s) to be used: Human T cells; NSG mice; vector details requested
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that will be produced: Yes; CAR protein for immunotherapy
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL2 containment

Review: Additional details requested on CAR T cell engineering, vector type, replication competent virus testing, and biohazard SOP
Recommendation: Study tabled pending additional details; unanimously approved (6-0)

**** Revised entry pending as of October 23rd**

Protocol Number: 25-102
Principal Investigator name: Dr. Sabater, Alfonso
Project title: Comparative study of limbal stem cell-based therapies and smart contact lens performance using a rabbit model of LSCD
NIH Guidelines: IIID / BL 2
Agent characteristics: Human limbal stem cells transduced with lentiviral vector containing GFP; low biohazard risk
Types of manipulations: Lentiviral transduction, cell expansion, contact lens engineering, in vivo placement in rabbits
Source(s) of the nucleic sequences: Human limbal stem cells; GFP gene
Nature of the nucleic acid sequences: Structural gene (GFP)
Host(s) and vector(s) to be used: Human limbal stem cells; rabbits; lentiviral vector
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that will be produced: Yes; GFP protein for cell tracking
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL2 and ABSL-2 containment
Review: Amendments requested for biosafety levels, PPE, viral vector registration, and survey questions
Recommendation: Conditional approval recommended; unanimously approved (6-0)

**** Revised entry received – study approved October 7th**

Protocol Number: 25-103 (New PI)
Principal Investigator name: Dr. Alcaide, Pilar
Project title: The role of endothelium in organ specific immune cell recruitment and organ dysfunction
NIH Guidelines: IIID / BL 2
Agent characteristics: Trypanosoma cruzi parasites; adenoviral and lentiviral vectors; low biohazard risk
Types of manipulations: Infection of mice, adenoviral and lentiviral transduction, immune profiling, tissue harvest
Source(s) of the nucleic sequences: Mouse and parasite genes; AHR, iCre, EGFP
Nature of the nucleic acid sequences: Structural genes (AHR, iCre, EGFP)
Host(s) and vector(s) to be used: Mice; adenoviral and lentiviral vectors
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that

will be produced: Yes; AHR and iCre proteins for immune studies
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL2 containment
Review: Biohazard exposure form requested; clarification on lentivirus use, vector maps, and survey questions
Recommendation: Conditional approval recommended; unanimously approved (6-0)

**** Entry revised, and comments addressed - study was approved October 2nd**

Protocol Number: 25-104 (New PI)
Principal Investigator name: Dr. Weinberger, Leor
Project title: Determining viral gene-regulatory circuits governing cell-fate using cellular model systems
NIH Guidelines: IIID / BL 2
Agent characteristics: Lentiviral vectors with HPV early gene E2 and fluorescent reporter; low biohazard risk
Types of manipulations: Lentiviral vector production, transduction, pseudovirus and quasivirus infection, gene circuit analysis
Source(s) of the nucleic sequences: HPV E2 and E8^E2 genes; mScarlet reporter; packaging plasmids
Nature of the nucleic acid sequences: Regulatory and structural genes (HPV E2, E8^E2, mScarlet)
Host(s) and vector(s) to be used: 293T cells, keratinocytes, W12 cells, NIKS cells; lentiviral vectors
Study will attempt to obtain expression of a transgene, and if so, the function of the protein that will be produced: Yes; E2 and E8^E2 proteins for gene regulation studies
Verification that the PI and laboratory staff have received training: Confirmed
Containment conditions: BL2 containment
Review: Updates requested for risk assessment, plasmid maps, vector generation, host range, and biohazard forms
Recommendation: Conditional approval recommended; unanimously approved (6-0)

**** Revised entry received – study will be approved October 24th**

5. Addenda:

Number:	**25-041 IIIC ad01**
Title:	SUPRAME - ACTengine® IMA203 vs. investigator's choice of treatment in previously treated, unresectable or metastatic cutaneous melanoma
Principal Investigator:	Hernandez Aya, Leonel
Primary Reviewer:	**Tsoulfas, Pantelis**

6. Exemptions: None

7. Renewals-Closures

Number: **19-092 – CLOSURE**

Title: A Phase 2 Study of combination therapy with an IL-15 Superagonist (N-803), off-the-shelf- CD16-targeted natural killer cells (HANK), and avelumab without cytotoxic chemotherapy in subjects with merkel cell carcinoma (MCC) that has progressed on or after treatment with a checkpoint inhibitor

Principal Investigator: Feun, Lynn

Primary Reviewer: **Tsoulfas, Pantelis**

Number: **21-174 – Renewal**

Title: A Phase I/II Study of the SV-BR-1-GM Regimen in Metastatic or Locally Recurrent Breast Cancer Patients in Combination With Retifanlimab

Principal Investigator: Calfa, Carmen

Primary Reviewer: **Tsoulfas, Pantelis**

Number: **24-044 – Renewal**

Title: An Open-label, Phase 1/2 Trial of Gene Therapy 4D-710 in Adults with Cystic Fibrosis

Principal Investigator: Tupayachi Ortiz, Maria

Primary Reviewer: **Tsoulfas, Pantelis**