Institutional Biosafety Committee (IBC)

IBC Meeting Minutes
August 27, 2025

A regular meeting of the Salk Institute for Biological Studies, Institutional Biosafety Committee (IBC) was held on Wednesday, August 27, 2025, at noon in the Laureates Room at the Institute.

Attendance

Committee Members (10 members – 6 required for quorum)		Present
Sam Pfaff, PhD	Chair	☒
Mark Bouchard, MPH	Vice Chair, Biosafety Officer (BSO)	☒
Julie Law, PhD	Plant Expert	☒
Trinka Adamson, DVM	Animal Expert	☒
Dan Gibbs, PhD	Non-affiliated Community Member	☒
Tom Evans*	Non-affiliated Community Member	☒
Shrek Chalasani, PhD		☒
Ed Callaway, PhD		☒
John Naughton		☒
Daniel Hollern, PhD		☒

*Joined via Zoom teleconference

Others Present: Suzanne Page, JD, Lisa Young, Venuz Greenfield

In accordance with the NIH Guidelines Section IV-B-2-a-(6) the meeting was open to the public.

Meeting was called to order at 12:04 pm.

Commonly Used Abbreviations

AAV: Adeno-Associated viral vector
BSL: biosafety level
BSL-2+: BSL-2 with BSL-3 practices
BSO: Biosafety Officer
DURC: Dual Use Research of Concern
HSV: Herpes Simplex Virus
IACUC: Institutional Animal Care and Use Committee
IBC: Institutional Biosafety Committee
iPSCs: induced pluripotent stem cells
LCMV: Lymphocytic choriomeningitis virus
NIH: National Institutes of Health
PI: Principal Investigator
r/sNA: recombinant or synthetic nucleic acids
RG: Risk Group
RSV: respiratory syncytial virus
SOP: standard operating procedure
VSV: vesicular stomatitis virus

General Business

1. The Committee reviewed and approved the Minutes of the May 28, 2025, IBC meeting.

2. The Committee reviewed the Action List from the May 28, 2025, IBC meeting and raised no outstanding items or concerns.

3. The Committee discussed the public posting of IBC minutes in accordance with NIH Notice NOT-OD-25-082, and the Salk process to maintain compliance. Minutes will be publicly posted following IBC approval at the next convened meeting.

4. Regulatory Update: The BSO reported on NIH Notice NOT-OD-25-127 (June 18, 2025) regarding the termination or suspension of "dangerous gain-of-function research," issued in response to Executive Order 14292, *Improving the Biosafety and Security of Biological Research*. The Notice required institutions to review all ongoing research, funded and unfunded, against the EO 14292 definition of "dangerous gain-of-function research".

5. Salk officials confirmed no current projects meet the cited definition of "dangerous gain-of-function research." It was noted that the institutional policy requiring IBC approval for all work with infectious agents and biotoxins, together with recent revisions to the biohazard protocol form ensures the Institute will continue to be a good steward of the biological materials utilized in research and the IBC will continue to capture projects meeting the definition of "dangerous gain-of-function research."

6. The Committee discussed the level of detail that should be required when listing use locations on the biohazard protocol form and whether adding specificity to the location is recommended. The Committee asked the BSO to review the current procedure for tracking agent use locations per lab and to report back to the IBC with recommendations for any needed updates to the procedure or related questions on the protocol form.

7. The Committee also discussed the training requirements for PIs and confirmed that, due to the PIs responsibility for oversight and safety, the PIs should receive all training associated with the materials listed on their protocol. Including the PIs name on the personnel table and checking all required training will be the most efficient way to facilitate and track compliance.

8. It was noted that the reference to the "TG Core" should be removed from the protocol form.

Full Committee Protocol Review - New Protocols

PI: Blum IBC-25-0002 Contribution of Plant Metabolites to Oral Tolerance and Allergy

Summary: The lab aims to dissect which proteins from plants are recognized by the immune system leading to the development of allergy or oral tolerance. To accomplish this, the lab utilizes T-cell receptors (TCRs) of interest from mice. These receptors are heterologously expressed in an immortal cell line, allowing screening of potential ligands and mapping of immunogenic epitopes. The lab also engineers plants to express seed storage proteins with mapped immune epitopes in order to address whether induction of an immune response depends on the protein itself or on the molecular context.

Agents	**Biosafety Level**
Murine retroviral vectors	BSL-2
Agrobacterium	BSL-1

Review Notes / IBC Discussion:
The protocol describes the use of murine retroviral vectors in vitro. Ecotropic, amphotropic and VSV-G pseudotyped are all used. All are handled at BSL2. Agrobacterium is used to engineer seed storage proteins in Arabidopsis thaliana and Nicotiana benthamiana. Plant work is performed using BSL1-P handling and precautions. The protocol describes the use of transgenic mice and cholera toxin. It was noted that the associated animal protocol has now been reviewed and approved by the IACUC.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol pending clarification of the item below.

- ☐ 4.16: Should read "Harvest virus and spin transduce (or spinoculate) NFAT-GFP."

NIH Guidelines Section:
III-D-1, III-D-2, III-D-3, III-E-2-a, III-F-8

Approved pending clarification For: 10 Opposed: 0 Abstain: 0
Administratively approve if wording is edited as requested.

PI: Strader IBC-25-0001 Understanding hormone responses in plants

Summary: The lab studies how plant hormones work; trying to understand their biosynthesis, transport, and signal transduction using the model plant species Arabidopsis thaliana, Physcomitrella patens, Marchantia polymorpha, and Solanum lycopersicum.

Agents	**Biosafety Level**
Baculovirus vectors	BSL-1

Review Notes / IBC Discussion:
Plant genes will be cloned into E coli and yeast, then transfected into insect cell lines and used in yeast-based flow cytometry experiments. Genes of interest are those associated with plant hormone biosynthesis, transport, and signaling. Plant work is performed using BSL1-P handling and precautions. The protocol also describes the use of baculovirus for protein expression in insect cell lines. It was noted that EH&S will reach out to Dr. Strader about a Radioactive Registration.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol pending clarification of the items below.

- ☐ Confirmation that there are no non-radioactive alternatives to the planned isotope work.
- ☐ 4.4 - Reference Baculovirus use in the summary section.
- ☐ 4.17 - Add use locations. Include greenhouse and growth chamber locations.
- ☐ 14 Personnel Table. Check viral vector training for the PI. Add new personnel as they are onboarded.

NIH Guidelines Section:
III-E-1 & III-E-2-a

Approved pending clarification For: 10 Opposed: 0 Abstain: 0
Administratively approve upon confirmation.

Full Committee Protocol Review – Protocol Renewal

PI: Bayless	IBC-23-0003	Functional characterization of experiential and sex hormone-dependent changes in neural circuits underlying social behaviors in mice

Summary: The Bayless Lab studies the neural pathways that enable animals to process complex sensory cues to seamlessly navigate in distinct social settings.

Agents	**Biosafety Level**
G-deleted rabies viral vectors	BSL-2/ABSL-2
AAV vectors	BSL-1/ABSL-2

Review Notes / IBC Discussion:
The protocol describes the use of AAV and G-deleted rabies to manipulate and trace specific neural pathways in mice. It also includes the generation of transgenic mice via UCSD Core.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol pending clarification of the item below.

- ☐ 11.2 - Uncheck Salk TG Core.

NIH Guidelines Section:
III-D-1, III-D-4, III-E-1, III-E-3, III-F-8

Approved pending clarification For: 10 Opposed: 0 Abstain: 0
Administratively approve when edited.

PI: Busch	IBC-18-0002	Molecular Signal Integration for Root Growth Control; Harnessing Plants Initiative

Summary: The Busch laboratory studies genes and molecular mechanisms that regulate plant root growth and its interaction with the soil environment.

Agents	**Biosafety Level**
Agrobacterium	BSL1-P

Review Notes / IBC Discussion
The lab utilizes agrobacterium transformation in Arabidopsis thaliana to study genes and molecular mechanisms that regulate plant root growth and interaction with the soil environment.

With consideration for the risk associated with the work, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol as written.

NIH Guidelines Section: III-E-2-a

Approved : For: 10 Opposed: 0 Abstain: 0

PI: Dixon IBC-16-0004 Understanding the Mechanisms of 3D Genome Organization

Summary: The lab studies how genomes are folded inside cells and how this folding impacts the function of the genome. The lab uses a combination of molecular and cellular biology methods, as well as high-throughput next generation sequencing to study these processes.

Agents	**Biosafety Level**
Lentivirus - 3rd Generation viral vectors	BSL-2

Review Notes / IBC Discussion:
The protocol describes the use of 3rd generation lentiviral vectors in vitro. With this renewal the lab added some work with samples of transgenic Arabidopsis thaliana provided by a collaborating Salk lab.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol pending clarification of the items below. The lab will also be reminded that they must register iPSC work with the SCRO Committee.

- ☐ Question 4.18, regarding handling precautions needs to be clarified.
- ☐ PI should be listed on the personnel table.

NIH Guidelines Section:
III-D-1, III-D-3, III-E-2

Approved pending clarification For: 9 Opposed: 0 Abstain: 0
Administratively approve if confirmed that lentiviral vectors are handled at BSL2.
Dr. Law will collaborate on the plant work and recused herself from the vote.

PI: Gage IBC-06-0029 Neural plasticity across the lifespan

Summary: The Gage lab focuses on understanding neurogenesis and neural plasticity. Their work also involves modeling diseases in vitro using stem cells and studying the genomic mosaicism that exists in the brain as a result of mobile elements that are active during neurogenesis.

Agents	**Biosafety Level**
AAV viral vectors	BSL-1/ABSL-1
Murine retroviral vectors	BSL-2/ABSL-2
Lentivirus - 2nd generation vectors	BSL-2+ /ABSL-2
Lentivirus - 3rd generation vectors	BSL-2/ABSL-2
G-deleted rabies.	BSL-2/ABSL2
Sendai virus vectors	BSL-2

Review Notes / IBC Discussion:
The protocol describes the use of various viral vectors in human and mouse cell lines and primary human cells. Genes expressed are related to neuronal development and hippocampus function and impact cognitive aging and neurodegenerative disorders. The lab treats mice directly with viral vectors to study the influence of these genes in memory function and neurogenesis. The protocol also lists a variety of sources of primary human material, as well as work with transgenic mice.

The Committee discussed tracking of training for personnel on this protocol and agreed that the attachment utilized is appropriate, given the size of the lab and the constraints of the system.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol as written.

NIH Guidelines Section:
III-D-1, III-D-2, III-D-3, III-D-4, III-E-1, III-F-8

Approved: For: 10 Opposed: 0 Abstain: 0

PI: Goulding IBC-06-0008 Developmental and Functional Analysis of Spinal and Brainstem Circuits

Summary: Laboratory studies are focused primarily on developmental genes that play key roles in regulating neuronal identity and connectivity.

Agents	**Biosafety Level**
Adeno-associated viral vectors	BSL-1/ABSL-1
Pseudorabies (Herpes) viral vectors	BSL-2/ABSL-2
G-deleted rabies viral vectors	BSL-2/ABSL-2

Review Notes / IBC Discussion:
Viral vectors are used in rodent cell lines and whole mice. Expressed genes are either fluorescent reporters or channelrhodopsin variants. Use of cholera toxin subunit B and diphtheria toxin are also described. There is a reference to using rDNA plasmids in a model of neural development that utilizes chicken eggs; however the Committee noted this is an older technology and it should be confirmed with the PI whether this is still used.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the committee voted to approve the protocol pending clarification of the item below.

- ☐ Remove reference to older experiment if it is no longer performed in the lab.

NIH Guidelines Section:
III-D-1, III-D-2, III-D-3, III-D-4-a, III-E-1, III-F-8

Approved pending clarification For: 10 Opposed: 0 Abstain: 0
Administratively approve if reference to chicken egg model is removed.

PI: Kendrick IBC-23-0004 Regulation of bidirectional cargo transport

Summary: The Kendrick lab is broadly interested in intracellular transport regulation, an integral process that allows cells to move, divide, communicate with neighboring cells, and maintain cellular homeostasis.

Agents	**Biosafety Level**
Lentivirus - 3rd generation vectors	BSL-2
Baculovirus virus vectors	BSL-2

Review Notes / IBC Discussion:

The protocol describes the use of rDNA in bacteria, insect cell lines and mammalian cell lines to study genes related to intracellular transport, cell division, proliferation, and migration. With this renewal retrovirus was removed from the protocol. The lab also works with phalloidin toxin.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol as written.

NIH Guidelines Section:
III-D-1, III-D-2, III-D-3, III-E-1

Approved: For: 10 Opposed: 0 Abstain: 0

PI: Lyumkis	IBC-15-0003	Structural biology study of the interplay between HIV-1 integrase and endogenous regulators of gene expression

Summary: The lab uses cryo-electron microscopy to determine the structure of proteins and protein-nucleic acid complexes. The procedures performed in the lab include (1) molecular cloning, (2) protein expression, (3) protein purification, (4) sample preparation for electron microscopy, and (5) computer-based data analysis.

Agents	**Biosafety Level**
Baculovirus vectors	BSL-2
Lentivirus - 3rd generation vectors	BSL-2

Review Notes / IBC Discussion:
Proteins are expressed using E. coli, insect (Sf9), and mammalian expression systems (Expi293F). Recombinant baculovirus is produced in-house for transducing insect and mammalian cells. The lab also utilizes replication incompetent lentivirus for the purpose of cryo-ET imaging. Genes of interest include HIV-1 integrase, histone protein genes and others involved in regulating and/or modifying the condensation of eukaryotic genomes.

With this renewal the lab added reference to a new collaboration that involves work with cell lines that have been transduced by phages; however the lab does not perform the phage transductions at Salk but works with the transduced cells. All work is in vitro at BSL2.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol as written.

NIH Guidelines Section:
III-D-1, III-D-2, III-D-3, III-E-1, III-F

Approved: For: 10 Opposed: 0 Abstain: 0

PI: Metallo	IBC-21-0006	The role of serine and glycine and complex lipids in skeletal muscle regeneration in aging and as metabolic targets and vulnerabilities for cancer, MacTel, and other diseases.

Summary: The Metallo Lab tracks metabolic pathways that lead to diseases like cancer, obesity, eye diseases and neuropathy, using tracer molecules and advanced mass spectroscopy techniques.

Agents	**Biosafety Level**
Adeno-associated viral vectors	BSL-1/ABSL-1
Lentivirus - 2nd generation vectors	BSL-2+
Lentivirus - 3rd generation vectors	BSL-2

Review Notes / IBC Discussion:
The protocol describes the use of AAV and Lentiviral vectors in vitro. AAV vectors are also administered to mice. Genes expressed are for metabolic enzymes or genes which regulate metabolism, including genes related to serine, glycine and lipid metabolism. The lab utilizes transgenic mice. Work with primary human material is also described.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol pending clarification of the items below.

- ☐ Clarify whether the lab is generating the 3rd generation lentiviral vectors or obtaining them from the Core. If generating, the plasmids should be listed in question 4.6.
- ☐ 5.1 check "yes" for use of CRISPR.
- ☐ 5.2 check "yes" if ZFN, TALENS are used.

NIH Guidelines Section:
III-D-1, III-D-2, III-D-3, III-D-4 III-E-1, III-F

Approved pending clarification For: 10 Opposed: 0 Abstain: 0
Administratively approve if lab is not generating 3rd generation plasmids. Return to GT3 Core Director for verification if plasmids are added to 4.6.

PI: Page	IBC-10-0009	Creation of Human iPS Cell Lines and Modifying Gene Expression in Primary and Pluripotent Stem Cells

Summary: Recombinant DNA use in the CTEC core will primarily support reprogramming technologies for the generation of iPSCs or other induced cell types (like neurons) from primary human cell populations.

Agents	**Biosafety Level**
Lentivirus - 2nd generation vectors	BSL-2+
Lentivirus - 3rd generation vectors	BSL-2+
Sendai virus vectors	BSL-2

Review Notes / IBC Discussion:
This is the Cell Technologies and Engineering Core (formerly Stem Core) protocol. It describes the use of Sendai virus and lentivirus to generate iPSCs and other induced cell types from primary human material. Activities transferred from TGC protocol include custom cloning and construction of DNA plasmids. Work with primary human material and marmoset samples is described.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol pending clarification of the item below.

☐ Please answer 4.6 regarding plasmids used.

NIH Guidelines Section:
III-D-1, III-D-2, III-D-3, III-E-1,

Approved pending clarification For: 10 Opposed: 0 Abstain: 0
BSO to verify clarification.

PI: Reynolds	IBC-10-0003	Neurobiological Correlates of Visual Cognition and Memory in Aging: A Dual Approach Using Behavior and Neurons Derived from Human Fibroblasts

Summary: The lab uses replication incompetent viruses that are modified to cause expression of fluorophores and/or light-sensitive channels that, when illuminated by laser or LED light, cause activation or inactivation of different classes of neurons. Expression is driven in select types of neurons using enhancer- or promoter-based strategies.

Agents	**Biosafety Level**
Adeno-associated viral vectors	BSL-1/ABSL-1
Lentivirus - 3rd generation vectors	BSL-2/ABSL-2
Canine Adenoviral vectors	BSL-2/ABSL-2

Review Notes / IBC Discussion:
AAV, 3rd generation lentivirus and CAV-2 are used in mice and marmosets, primarily targeting neural cells for neural tracing or optical imaging experiments.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol as written.

NIH Guidelines Section:
III-D-1, III-D-4

Approved For: 10 Opposed: 0 Abstain: 0

PI: Saghatelian	IBC-14-0002	Lipidomics and Peptidomics

Summary: This project aims to identify and characterize a novel set of human polypeptides encoded by small open reading frames (smORFs). The protocol describes a new technological process referred to as the smORF discovery pipeline (SDP) to discover and validate novel human smORFs.

The lab has generated a conditional knockout mouse against one of the smORFs identified, that may be of interest in Alzheimer's research. The lab proposes using lentiviral injections in mice to determine the pathological decline related to this protein. Another smORF may affect glucose regulation and gastric emptying and the lab proposes to use AAV injections in mice to study the peptide.

Agents	Biosafety Level
Adeno-associated virus	BSL-1/ABSL-1
Lentivirus – 3rd Generation	BSL-2/ABSL-2

Review Notes / IBC Discussion:
The protocol describes the use of AAV and 3rd generation lentivirus, in vitro and in vivo. Genes of interest are associated endogenous microproteins that play a role in glucose regulation and kidney function. The protocol includes the use of primary human material.

With consideration for the risk associated with the agents and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol pending clarification of the item below.

- ☐ Section 1 - Add titles for last two foundation grants.

NIH Guidelines Section:
III-D-1, III-D-2, III-D-3, III-D-4, III-E-1, III-F-8

Approved pending clarification For: 10 Opposed: 0 Abstain: 0
Administratively approve pending addition of grant titles.

Full Committee Review – Protocol Amendments

PI: Kaech IBC-18-0001 Regulation of Immunological Memory to Infectious Diseases

Summary: The amendment is to add the use of Herpes Simplex Virus-1, strain 17.

Agents	Biosafety Level
HSV-1	BSL2/ABSL2

Review Notes / IBC Discussion:
The virus will be utilized in a mouse model of Alzheimer's disease to study how reactivation and latency affect the course of disease. The agent is wildtype but will be administered to transgenic mice. All work will be at BSL2/ABSL2.

With consideration for the risk associated with the agent, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the protocol as written.

NIH Guidelines Section:
III-D-4 applies to the work added with this amendment.

Approved For: 10 Opposed: 0 Abstain: 0

PI: Hollern IBC-21-0004 Integrative Analysis of B Cell-Mediated Immunity in Breast Cancer to Inform the Next Generation of Immunotherapies

Summary: Amendment to add work with lentivirus in vitro.

Agents	Biosafety Level
Lentiviral vectors – 3rd generation	BSL2

Review Notes / IBC Discussion:
Lentiviral vectors will be used in vitro with BSL2 handling and precautions. Various model antigens will be expressed in tumor extracellular vesicles and B and T cell responses will be studied.

With consideration for the risk associated with the vector and the transgenes expressed, as well as the facilities, proposed procedures, training of personnel and the proposed containment and handling precautions, the Committee voted to approve the amendment as written.

NIH Guidelines Section:
III-D-3 applies to the work added with this amendment.

Approved For: 9 Opposed: 0 Abstain: 0
Dr. Hollern recused himself from the vote on this submission.

Notification of Annual Reviews

The Committee were notified that annual review submissions for the protocols listed below were reviewed and approved by the BSO since the last meeting. Only personnel and funding were updated.

Azim	IBC-16-0001	BSO approved 8/11
Towers	IBC-20-0005	BSO approved 7/29

Dual Use Research of Concern

In accordance with the US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern and Pathogens with Pandemic Potential, The Salk Institute IBC serves as the Institutional Review Entity for DURC-PEPP research. All submissions listed above were assessed by the Committee with respect to dual use and pandemic potential and none were found to present DURC concerns.

Note to the minutes:
Protocol IBC-11-0001 has been closed.

Note regarding approval periods: With the transition to the new protocol management system, protocols renewed were given approval periods between one and three years to prevent all renewals from falling within the same calendar year going forward. All protocols are subject to annual monitoring review.

Meeting was adjourned at 12:54 pm.
Minutes prepared by Lisa Young