Caltech

California Institute of Technology
Administrative Committee on Biosafety
Minutes of the Institutional Biosafety Committee (IBC)

Date: July 1, 2025 **Time: 2:30 PM** **Location: Zoom Videoconference**

Voting Members:	R. Ismagilov, L. Cai, M. Doshi, W. Gao, L. Quenee, S. Chatterjee, M. Barsever, K. Lencioni, C. Cortese, E. Hisserich, M. Coleman
Nonvoting:	3 attendees
Guests:	1 attendee
Other:	1 attendee

Called to order at 2:35pm, with a quorum in attendance.

1. Announcements
2. Old Business

A. Protocols - Approved Pending Modification, Modification Complete

The following protocol was previously approved pending modifications at the May 6 meeting. The modifications have been completed and the protocol is approved:

Protocol:	25-065	De Novo	Expiration Date:	5/12/2028
Title:	Viral Vectors for dissecting neural circuits for Social Interactions.			
PI Name:	Anderson			
Modifications Completed: 6/10/2025				

The following protocol was previously approved pending modifications at the June 3 meeting. The modifications have been completed and the protocol is approved:

Protocol:	25-315	De Novo	Expiration Date:	6/12/2028
Title:	Genome Engineering in Bacteria			
PI Name:	Wang			
Modifications Completed: 6/10/2025				

B. Protocols - Approved Pending Modification, Modification Pending

The following protocols were approved pending modifications at the May 6 meeting. The labs are still working on completing the modifications for validation from the BSO. If it is past the expiration date, all work on the protocol has ceased until the modifications are completed.

Protocol:	25-261	De Novo	Expiration Date:	5/12/2025
Title:	Engineering and evaluation of anti-viral therapeutics in vitro and in vivo			

PI Name:	Bjorkman		De Novo	
Anticipated Completion: 7/1/2025; Note: Modifications have been completed. SOP for occupational risks and considerations is pending review by the occupational health physician. This project is not currently active.				

Protocol:	24-381-A2	Amendment	Expiration Date:	7/12/2027
Title:	Identifying Phages that Target Antibiotic-Resistant Bacteria			
PI Name:	Karthikeyan		Amendment	
Anticipated Completion: 7/1/2025				

3. New Business

A. Approval of Minutes: June 3, 2025

The June 3 meeting minutes were approved by a majority of the IBC. There were 3 abstentions from members who were not present at the June 3 meeting.

B. Occupational Health Updates

The BSO reported that there were no occupational health items to review at this time.

C. Protocols – Full Committee Review

The IBC reviewed the following protocols and conducted a robust risk assessment. The assessment included a determination of the appropriate biocontainment levels for the proposed research and confirmation that the research is compliant with the NIH Guidelines, as applicable.

Protocol:	25-317	De Novo	Expiration Date:	7/29/2025
Title:	Mechanisms behind early mouse embryo development			
PI Name:	Zernicka-Goetz			
Brief Description of Project: The goal of this study is to gain insight into the growth and development of early mammalian embryos. To better observe cell dynamics and the mechanisms governing mammalian developmental stages, we will isolate early mouse embryos from uterine tissue.				
Biological Materials Review Summary: In this study, lentiviral plasmids carrying nonhazardous transgenes, along with human cell lines for viral vector packaging and transfection, will be employed to generate genetically modified mouse lines. These modified mice will express a fluorescent protein marker, allowing visualization of spatial events during embryonic development. All procedures involving viral vectors and animals will be conducted in accordance with institutional biosafety and animal ethics guidelines.				
NIH Guidelines:	III-D	Highest BSL Level:		BSL2 w/ BSL3 practices
Training: This protocol requires the following biosafety training: Basic Principles of Biosafety (BSL1) or Comprehensive Biosafety (BSL2), Bloodborne Pathogens, and Viral Vector Training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.				

Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.
IBC Action/Decision: Approved with Stipulations
❖ The committee reviewed and unanimously approved the protocol subject to the adherence to the standard stipulations along with the following special stipulations: • The lab must identify a lentivirus training lead that has previous experience working with viral vectors and report to the BSO. • Safety training must be completed prior to handling the relevant hazardous materials.

Protocol:	25-324	De Novo	Expiration Date:	7/29/2025
Title:	Early Embryo Development			
PI Name:	Zernicka-Goetz			
Brief Description of Project: The objective of this study is to uncover the mechanisms underlying human implantation and early post-implantation development by leveraging advanced technologies such as high-resolution time-lapse imaging, single-cell RNA sequencing (scRNA-seq), seqFISH+, MERFISH, and functional assays. We will employ CRISPR/Cas9 to introduce fluorescent markers into cultured human embryos, enabling lineage tracing and gene expression studies. Fluorescently tagged stem cell lines will be used to create chimeras with natural embryos or incorporated into synthetic embryo-like models. Cell lines will express nuclear (GFP-Histone H3) and membrane (RFP-tagged protein) markers, and reporter lines will be developed to monitor key developmental genes. Modified hypoblast and trophoblast lines will also be included. Embryos will be tracked using confocal and time-lapse microscopy, and endpoint analyses will include scRNA-seq, seqFISH+, MERFISH and functional assays up to day 14 of development.				
Biological Materials Review Summary: Human embryonic stem cell lines used in this study are approved by the UK Human Fertilisation and Embryology Authority (HFEA) and include one genetically modified line, RUES2, which carries reporters for key cell fate transcription factors. Cells will be cultured in small volumes and genetically manipulated—via electroporation or lentiviral transduction—to insert, delete, or modify genes involved in early embryogenesis, creating specific gene reporters. All tissue culture and imaging work will be performed under Biosafety Level 2 (BSL2) conditions, following standard BSL2 practices.				
NIH Guidelines:	III-D	Highest BSL Level:		BSL2 w/ BSL3 practices
Training: This protocol requires the following biosafety training: Basic Principles of Biosafety (BSL1) or Comprehensive Biosafety (BSL2), Bloodborne Pathogens, and Viral Vector Training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.				
Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.				
IBC Action/Decision: Approved with Stipulations				
❖ The committee reviewed and unanimously approved the protocol subject to the adherence to the standard stipulations and the following special stipulations: • The lab must identify a training lead with previous experience and report to the BSO. • Safety training must be completed prior to handling the relevant hazardous materials. The lab must demonstrate to the BSO that they are able to handle viral vectors expressing non-hazardous gene sequences safely within the first 6 months of approval of this protocol before proceeding to potential onocogenic targets.				

Protocol:	25-352	De Novo	Expiration Date:	9/12/2025
Title:	Resnick Ecology and Biosphere Engineering Facility			
PI Name:	Glasser			

Brief Description of Project: This protocol covers microbe and plant cultivation in Resnick Ecology and Biosphere Engineering Facility.

Biological Materials Review Summary: This project aims to study and engineer interactions between microbial life and the biosphere. The following biological materials are used:

1. Non-hazardous environmental isolates of bacteria and fungi: For example, algae and microbes from the rhizosphere. This work is performed under BSL-1 conditions.
2. Opportunistic human pathogens: Some studies use model opportunistic human pathogens, for example to study their lifecycle or develop new environmental monitoring strategies. This work is performed under BSL-2 conditions.
3. Non-invasive plants, including transgenic plants: This work is performed under BSL-1 conditions with additional precautions to prevent the release of seeds, pollen, or plant-associated microbes.
4. Soil and low-risk plant pathogens imported from outside California: This work is performed under BSL-2 conditions. Researchers must obtain a PPQ526 permit from USDA-APHIS before performing this work.

NIH Guidelines:	III-D, III-E, III-F	Highest BSL Level:	BSL2

Training: This protocol requires the following biosafety training: Basic Principles of Biosafety (BSL1) or Comprehensive Biosafety (BSL2) Training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.

Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.

IBC Action/Decision: Approved with Stipulation

- ❖ The committee reviewed and unanimously approved the protocol subject to the adherence to all standard stipulations along with the following special stipulation:
  - The Core Facility must update their Project Intake Form to require users to disclose the point of origin for all soils used in the project and provide a risk assessment evaluating the likelihood of human pathogens present in the samples. Soil samples that may contain human pathogens must be reported to the BSO for review prior to project initiation.

Protocol:	25-268	De Novo	Expiration Date:	9/12/2025
Title:	Engineering small conditional DNAs and RNAs in vitro, in situ, and in vivo			
PI Name:	Pierce			

Brief Description of Project: We are developing dynamic nanotechnologies based on the mechanism of hybridization chain reaction (HCR) for multiplex, quantitative, high-resolution imaging of the programmable molecules of life (DNA, RNA, proteins, and complexes thereof) and for amplified, instrument-free, at-home pathogen detection. We are engineering small conditional RNAs (scRNAs) for cell-selective spatiotemporal control of regulation in living cells and organisms to enable selective treatment of diseased cells leaving healthy cells untouched.

Biological Materials Review Summary: We use DNA and RNA oligomers, DNA plasmids, fluorescent proteins, primary and secondary antibodies, nanobodies, CRISPR/Cas, cultured human cells, cultured

bacteria, chicken embryos, zebrafish embryos, and mouse tissue sections.			
NIH Guidelines:	III-E	Highest BSL Level:	BSL2
Training: This protocol requires the following biosafety training: Basic Principles of Biosafety (BSL1) or Biosafety (BSL2) and Bloodborne Pathogens Training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.			
Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.			
IBC Action/Decision:	Approved		
❖ The committee reviewed and unanimously approved the protocol subject to the adherence to the standard stipulations.			

Protocol:	25-271	De Novo		Expiration Date:	10/10/2025
Title:	Analysis of zebrafish development and behavior				
PI Name:	Prober				
Brief Description of Project: The objective of the project is to use zebrafish to (1) study genes and neurons that regulate sleep, (2) identify genes that mediate behavioral responses to nicotine, and (3) identify genes that mediate inflammation.					
Biological Materials Review Summary: We use molecular biology, including E. coli cultures, and recombinant DNA approaches in order to generate transgenic and mutant zebrafish. In some experiments we use tetrodotoxin to block neuronal action potentials in zebrafish, and/or use alpha-bungarotoxin to paralyze zebrafish, for imaging and electrophysiology. We will also treat zebrafish with nicotine and drugs that induce inflammation in order to identify genes involved in nicotine addiction and inflammation.					
NIH Guidelines:	III-D	Highest BSL Level:	BSL2		
Training: This protocol requires the following biosafety training: Basic Principles of Biosafety (BSL1) or Biosafety (BSL2), and Biological Toxins Training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.					
Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.					
IBC Action/Decision:	Approved with Stipulation				
❖ The committee reviewed and unanimously approved the protocol subject to the adherence to all standard stipulations and the following special stipulation : • The lab must amend their IACUC protocol to be congruent with the materials approved on the IBC protocol.					

Protocol:	25-389	New		Expiration Date:	TBD
Title:	Genome Engineering in Bacteria in Plant Leaves and Soil				
PI Name:	Wang				
Brief Description of Project: This project aims to develop methods to efficiently move large segments of DNA between safe bacterial species and downstream delivery of these large pieces of DNA into either varied microbiomes, plant leaves, and/or soil microbes.					
Biological Materials Review Summary: This project aims to develop tools for the construction and delivery of DNA between distinct organisms. The study utilizes the following biological materials:					

RG1 bacterial strains are used for construction of recombinant DNA and production of P1-like phage particles. Plant leaves are detached from RG1 laboratory plant strains and experiments are carried out on non-propagating leaves in enclosed petri dishes. Soil Models: Soils are extracted from locations in campus and used for assessment of DNA delivery using P1-like phage particles. All work is conducted under BSL-2 conditions. Phage P1 Particles as indicated above.
NIH Guidelines: III-E, III-F Highest BSL Level: BSL2
Training: This protocol requires the following biosafety training: Basic Principles of Biosafety (BSL1) or Biosafety (BSL2) Training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.
Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.
IBC Action/Decision: Approved pending Modifications
❖ The committee reviewed and unanimously approved the protocol subject to the adherence to the standard stipulations, as well as pending the following modifications: • The lab must modify their protocol to clarify that there will be no concurrent handling of plant material and plant pathogens. • The lab must clarify in their protocol that all DNA transfers include only genes or gene clusters of known non-hazardous function.

Protocol:	23-363-A1	Amendment	Expiration Date:	6/12/2026
Title:	Effect of microgravity and microbes on Caenorhabditis elegans			
PI Name:	Gonzalez-Serricchio			
Brief Description of Project: This project investigates how microgravity analogs and environmental microbes affect the physiology and microbial colonization of Caenorhabditis elegans. The study uses non-pathogenic microorganisms and GFP-labeled E. coli under BSL-2 conditions, with all work conducted at Caltech to support future space biology research.				
Biological Materials Review Summary: This protocol involves the use of Caenorhabditis elegans (wild-type and transgenic), Escherichia coli OP50 (wild-type and GFP-labeled), and non-pathogenic environmental microbes (Bacillus pumilus, Naganishia spp., and Cystobasidium onofrii). These materials are used to investigate host-microbe interactions and stress responses in microgravity analog environments.				
NIH Guidelines:	III-D	Highest BSL Level:		BSL1
Training: This protocol requires the following biosafety training: Basic Principles of Biosafety (BSL1) Training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.				
Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.				
IBC Action/Decision:	Approved			

❖ The committee reviewed and unanimously approved the protocol subject to the adherence to the standard stipulations.

Protocol:	23-214-A1	Amendment	Expiration Date:	6/12/2026
Title:	Understanding the neural basis of motivated behavior for homeostatic regulation			
PI Name:	Oka			
Brief Description of Project: This study evaluates renal responses to ligands using unfixed human kidney tissues.				
Biological Materials Review Summary: This project aims to evaluate renal responses to various ligands using human kidney tissues. This study utilizes the following biological materials: Human Tissue Samples - This study utilizes unfixed human kidney tissues and nonhazardous reagents. All work is conducted under BSL-2 conditions.				
NIH Guidelines:	III-D	Highest BSL Level:		BSL2 w/ BSL3 practices
Training: This protocol requires the following biosafety trainings: Basic Principles of Biosafety (BSL1) or Biosafety (BSL2), Bloodborne Pathogens, Viral Vector, and Biological Toxins Training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.				
Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.				
IBC Action/Decision:	Approved with Stipulations			

❖ The committee reviewed and unanimously approved the protocol subject to the adherence to all standard stipulations and the following special stipulations:

- The lab must identify an appropriate laboratory location with a biosafety cabinet (BSC) for their use and the laboratory/BSC must be inspected/approved for BSL-2 work by BSO prior to commencing work.
- Hands-on Biosafety Cabinet Training by the BSO must be completed prior to work commencing.

D. Protocols - Expedited Review

Protocol:	25-353	De Novo	Expiration Date:	7/12/2028
Title:	Recombinant Protein Expression of Wildtype and Mutant Paramagnetic Proteins			
PI Name:	Hadt			
Brief Description of Project: This protocol renewal is focused on producing and purifying wildtype and modified paramagnetic proteins for characterization via various spectroscopic techniques.				
Biological Materials Review Summary: This project utilizes a lab strain of nonpathogenic E. coli to express nonpathogenic proteins for characterization.				
NIH Guidelines:	III-E, III-F	Highest BSL Level:		BSL1
Training: This protocol requires the following biosafety training: Basic Principles of Biosafety (BSL1) Training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.				
Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.				

IBC Action/Decision:	Chair Approved
❖ The Chair reviewed and approved the protocol subject to the adherence to the standard stipulations.	

Protocol:	25-320	De Novo	Expiration Date:	7/12/2028
Title:	Cortical Mechanisms for Perception and Action			
PI Name:	Andersen			
Brief Description of Project: The purpose of this study will be to examine neural processing mechanisms for the sensory motor cortex of animals. The study will advance knowledge of the functioning of the brain and cortical mechanisms for sensory processing and guidance of movements in animals.				
Biological Materials Review Summary: Vertebrate animals are used in these studies because the neural processes examined resemble those in humans.				
NIH Guidelines:	N/A	Highest BSL Level:	BSL2	
Training: This protocol requires the following biosafety training: Comprehensive Biosafety (BSL2), Bloodborne Pathogens, and animal-specific training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.				
Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.				
IBC Action/Decision:	Chair Approved with Stipulation			
❖ The Chair reviewed and approved the protocol subject to the adherence to all standard stipulations and the following special stipulation: • Biosafety Refresher and BBP Training must be completed within 30 days.				

Protocol:	23-369-A12	Amendment	Expiration Date:	10/12/2026
Title:	Detection and characterization of bacteria in human samples and cultures.			
PI Name:	Ismagilov			
COI/Recusal:	R. Ismagilov was recused from the discussion of this protocol.			
Brief Description of Project: We develop methods to detect and characterize small quantities of whole RG1 and RG2 bacteria and fungi in solutions and clinical samples. This amendment involves handling and processing of clinical specimens obtained from healthy humans, where RG1 or RG2 organisms may be present in the samples. This work involves manipulation of small volumes of samples (~100µL to a few mL), inactivation steps that may include chemical and or mechanical lysis, extraction of nucleic acids from these samples, and then performing quantitative measurements on the extracted nucleic acids. Note that the presence of some RG3 microorganisms (such as HIV) cannot be excluded in human clinical samples, precautions will be taken accordingly.				
Biological Materials Review Summary: This amendment utilizes the following biological materials: - Human vaginal swabs				
NIH Guidelines:	N/A	Highest BSL Level:	BSL2 w/ BSL3 practices	
Training: This protocol requires the following biosafety training: Basic Principles of Biosafety (BSL1) or Biosafety (BSL2), Bloodborne Pathogens, Viral Vector, and Aerosol Transmissible Diseases Training. Personnel who have not completed the required training will not begin this work until all appropriate training has been completed and documented.				

Review Summary: All facilities, procedures, and practices have been reviewed by the IBC and are considered appropriate and acceptable.
IBC Action/Decision: Vice Chair Approved
❖ The Vice Chair reviewed and approved the protocol subject to the adherence to the standard stipulations.

E. Personnel/Admin Amendments

- 22-278 Hoelz
- 23-286 Phillips
- 23-287 Voorhees
- 23-327 Shan
- 24-093 Hsieh-Wilson
- 24-301 Arnold
- 24-310 Parker
- 24-341 Tissot
- 24-343 Chong
- 25-183 Meister

4. Other Business

A. IBC Protocols Training Requirements

The BSO presented the committee with the training matrix to assist labs in identifying biosafety training requirements for their research. The committee reviewed and unanimously approved the training matrix, subject to the following modifications:

- Confirmation by the EH&S Director and BSO that training frequency is in alignment or modified to be in alignment with peer institutions.
- The document clearly indicates training must be completed prior to commencing work.

B. IBC Policy & Procedures

The IO and BSO updated the committee that the IBC Policy & Procedures will be updated and presented at the next IBC meeting to reflect the new guidelines set forth by the NIH regarding public posting of meeting minutes.

C. IBC PAS

The BSO updated the committee that the IBC PAS system will be going into beta testing within the next couple of months.

D. Quarterly Inspection Report

No significant updates to report.

Next Meeting – September 2, 2025

Meeting adjourned at 3:58pm

Approved 9/2/25 by IBC