



INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes  
Thursday, January 15<sup>th</sup>, 2026; 1:00PM

**Teleconference**

| Present          | Present                | Excused       |
|------------------|------------------------|---------------|
| C. Aston         | S. Morse (Chair)       | T. McConville |
| H. Blumm         | D. Ng                  | P. Muranski   |
| L. Butaud-Rebbaa | E. Peterson            | M. Underwood  |
| C. Cameron       | C. Pitoscia            | Q. Wang       |
| K. Crowley       | M. Quick               |               |
| S. Hughes        | E. Riber (Coordinator) |               |
| S. Joussef Pina  | V. Racaniello          |               |
| B. Karolewski    | A. Romanov             |               |
| J. Kaushal       | Y. Wojcicki            |               |
| L. Kam           |                        |               |
| J.J Miranda      |                        |               |

S. Morse convened the Institutional Biosafety Committee (the **Committee**) at 1:03 PM.

S. Morse asked the Committee to approve the minutes of the December 4<sup>th</sup>, 2025 meeting.

- **The minutes were approved unanimously.**

S. Morse reminded the Committee of the Conflict of Interest Policy and asked all members to confirm that there were no conflicts of interest with regard to any of the protocols to be discussed at the meeting.

- **There were no conflicts of interest noted.**

**DURC Review**

- No protocols requiring DURC review were submitted to the Biosafety Officer or to the Committee since the previous meeting.

**Human Gene Therapy**

- Brannagan\_IRB-ACYY0251\_APM-ACYY0264: A Phase 1 Open-label, Multiregional, Multicenter, Basket Study Evaluating the Safety and Efficacy of KITE-363, an Autologous Anti-CD19/CD20 CAR T-cell Therapy in Participants with Relapsed/Refractory Autoimmune Neurologic Diseases.
  - S. Joussef Pina introduced Dr. Brannagan’s human use protocol for participants with relapsed/refractory Autoimmune Neurologic Diseases. Details of the study regarding the preparation of the agent, dosage, route of administration, inclusion criteria, quality assurance testing, and informed consent were included in relevant materials distributed to the Committee.
  - No concerns were identified by the Committee Human Gene Transfer Experts.
  - The Appendix M was voted upon and approved unanimously.
- Ulane\_IRB-AAAV9449\_APM-ACYY0184: A Randomized, Double-Blind, Placebo Controlled Phase 3 Trial of Descartes-08 in Patients with Generalized Myasthenia Gravis (Mg)
  - S. Joussef Pina introduced Dr. Ulane’s human use protocol for patients with generalized Myasthenia Gravis (Mg). Details of the study regarding the preparation of the agent, dosage, route of administration, inclusion criteria, quality assurance testing, and informed consent were included in relevant materials distributed to the Committee.
  - No concerns were identified by the Committee Human Gene Transfer Experts.
  - The Appendix M was voted upon and approved unanimously.



**Biosafety Office Reviews**

- No renewals for Coronavirus Research have been submitted to the Biosafety Office since the last meeting.

**Coronavirus Research**

- No new Coronavirus research proposals were received by the Biosafety Office since the previous meeting.

**rDNA**

Five rDNA and infectious agent appendices requiring work at the BSL-1 containment level were presented and discussed. A table describing each BSL-1 Appendix A was shown to the Committee and is available at the Biosafety Office.

- Four appendices were returned to the investigator for further information as shown in a Table presented to the Committee describing the nature of each hold comment.
- After Discussion by the Committee, all BSL-1 Appendices were voted upon collectively and approved unanimously.

Eight rDNA and infectious agent appendices requiring work at the BSL-2 containment level were presented and discussed. A table describing each BSL-2 Appendix A was shown to the Committee and is available at the Biosafety Office.

- Three appendices were returned to the investigator for further information as shown in a Table presented to the Committee describing the nature of each hold comment.
- Dr. Porotto’s Appendix A were referred to the Institutional Biological Research Activities Committee (IBCRAC) for additional review.
- After Discussion by the Committee, seven BSL-2 appendices were voted upon collectively and approved unanimously.

**Announcements**

- C. Aston announced the publication of the winter edition of the Environmental Health & Safety *SafetyMatters* newsletter, Volume 20 Issue 1.

**Report**

- C. Aston briefed the committee on the commencement of the Columbia’s Internal Review Entity (IRE)

**rDNA Incidents**

- There were no incidents reported.

**Action Items**

| Action Items from 01-15-26 IBC meeting |             |                    |
|--|-------------|--------------------|
| Status                                 | Description | Group/Investigator |
| N/A                                    | N/A         | N/A                |

With there being no further business S. Morse adjourned the meeting at 2:43 PM. The next meeting will be held by teleconference on February 12<sup>th</sup>, 2026.



COLUMBIA UNIVERSITY  
IN THE CITY OF NEW YORK

INSTITUTIONAL BIOSAFETY COMMITTEE



**2026 Meeting Calendar**

| Date                         |
|------------------------------|
| Thursday, January 15, 2026   |
| Thursday, February 12, 2026  |
| Thursday, March 12, 2026     |
| Thursday, April 9, 2026      |
| Thursday, May 7, 2026        |
| Thursday, June 4, 2026       |
| Thursday, July 9, 2026       |
| Thursday, August 6, 2026     |
| Thursday, September 10, 2026 |
| Thursday, October 8, 2026    |
| Thursday, November 5, 2026   |
| Thursday, December 3, 2026   |



# COLUMBIA UNIVERSITY

## IN THE CITY OF NEW YORK

### INSTITUTIONAL BIOSAFETY COMMITTEE



IBC Meeting: January 15, 2026  
Table 1: Recombinant DNA proposals

| Proposals for Work at BSL-1 |                        |   |  |                        |                 |                    |  |            |              |          |
|-----------------------------|------------------------|---|--|------------------------|-----------------|--------------------|--|------------|--------------|----------|
| PI                          | Insert                 | Vector  | Host   | Animal Biosafety Level | NIH category    | Use/Comments       | Year   | Protocol # | Appendix A   |          |
| 1                           | Cheng, Ke              | BMP2 mRNA: encodes the bone morphogenetic protein receptor type 2; siBRD4: inhibit the expression of BRD4; Cas9-Fbn1-targeting gRNA plasmid.  | CRISPR   | Mouse                  | ABSL-1          | III-E-1            | Human lung tissues were provided by hospital and tested for HIV/Hep B/Hep A free. Lung cell lines were derived and kept in the lab and will not be injected to rodents directly. Cell secretomes or exosomes will be collected and filtered through a 0.22 um filter in a BSL2 cabinet before usage, and the solution will be shipped to a third company for endotoxin and mycoplasma test before usage. Human mesenchymal stem cell lines will be purchased from ATCC. The vendor will provide the safety certifications. mRNA loaded liposome: mRNA is available commercially. The loading process will be performed in a BSL2 cabinet and prepared in sterile saline right before usage.  | Y1 M13     | AC-AAB0652   | BSIW0202 |
| 2                           | Harris, Alexander      | Channel rhodopsin, Archarrhodopsin  | AAV  | Mouse                  | ABSL-1          | III-E-1            | The aim is to understand the neural circuitry underlying cognitive impairment following stress. We will use in vivo neural recordings combined with optogenetic manipulations, which involves using AAV-viral vectors to express opsins.   | Y1 M0      | LS-ACY0056   | BSIW0262 |
| 3                           | Izar, Benjamin         | CRISPR Library, different gene CRISPR Knockouts   | CRISPR   | Mouse                  | ABSL-1          | III-E-1            | Different mouse and human tumor cell will be first modified in vitro via CRISPR/CAS9 gene editing, viral transduction of fluorescent proteins or target gene over expression, and once the tumor cells are free of viral particles tumor cells will be injected into the animals for in vivo studies.  | Y1 M9      | AC-AAB6570   | BQVF8801 |
| 4                           | Rayport, Stephen       | AAV1g-FLEX-EGFP (addgene #51502)<br>AAV1-syn-FLEX-jGCaMP8m-WPRE (addgene #1623)<br>AAV9-syn-FLEX-jGCaMP8m-WPRE (addgene #162375)<br>AAV9-FLEX-GCaMP8s (addgene #162377)<br>AAV-FDIO-Cre (addgene #121675)<br>AAV-rTh.PI.Cre.SV40 (addgene #107788)  | AAV  | Mouse                  | ABSL-1          | III-E-1            | AAV vectors are used for cell-specific expression of fluorescent reporters, optogenetic activators or cell activity reporters.   | Y1 M0      | LS-ACY0023   | BSIW0144 |
| 5                           | Shepard, Kenneth       | Channelrhodopsin (ChR2) and Enhanced Yellow Fluorescent Protein (EYFP) (AAV2), ChR2 and tdTomato (AAV2), ARCh and EYFP (AAV5), GCaMP6s (AAV1), CaMP6 (AAV1), ArcLight GFP (AAV1), ChETA (AAV5), C1V1 (AAV8), C1V1 (AAVd) The AAV-DJ is a synthetic serotype made from DNA family shuffling of 8 wild type serotypes of AAV, including AAV2, 4, 5, 8, 9, avian, bovine and goat AAV. AAV-DJ outperformed standard AAV serotype 1-8 in                      | AAV  | Mouse                  | ABSL-1          | III-E-1            | Two types of adeno-associated virus (AAV), (AAV-DJ CaMKIIa-GCaMP6s) purchased from Stanford University and pAAV.Syn.Flex.GCaMP6.WPRE.SV40 purchased from Addgene will be injected in the cortex of mice to label and alter activity of genetically defined neuronal populations.   | Y1 M0      | AC-AAB1663   | BSIW0316 |
| Proposals for work at BSL-2 |                        |   |  |                        |                 |                    |  |            |              |          |
| PI                          | Insert                 | Vector  | Host   | Animal Biosafety Level | NIH category    | Use/Comments       | Year   | Protocol # | Appendix A   |          |
| 6                           | Acharya, Swarnali      | GFP, dtomato, mCherry, Luciferase, Thymidine kinase used to identify dividing cells, shRNA complexes used to silence genes, CRE used to flox out genes flanked by loxp sites  | AAV, AV, LV  | Mouse                  | ABSL-1 (Note 3) | III-E-1, III-D-1-a | Our tumor cell lines are stably infected with retroviral or lentiviral vectors. Examples would be the TGL construct, overexpression of genes of interest, or shRNA constructs. Pleural effusion from human cancer patients will be injected into mice by different routes. Intramuscular injections of Adeno or Adenoassociated virus in mice.   | Y1 M0      | AC-AAB3700   | BSIW0374 |
| 7                           | Cardoso, Wellington    | Pitx1, mCherry  | H1N1 (PR8), AAV  | Mouse                  | ABSL-2          | III-E-1, III-D-1-a | H1N1 (PR8 INFECTION). 120pfu of H1N1 virus will be diluted in 30ml PBS (50 ml conical tubes) and placed in a closed ice box. The box will be transported from B8-810 to ICRC. Adult mice (2-3 months old) will be anesthetized by isoflurane using an ICM vaporizer and then be intranasally administered 30ml (120pfu H1N1). Mock-infected animals will receive 30ml PBS. AAV EXPERIMENTS: Adult mice will be intratracheally injected with AAV carrying a Pitx1 cDNA construct (5x10 <sup>8</sup> vg per adult mouse suspended in 50 ul of PBS) or an mCherry construct (control). Animals will be first anesthetized using ICM vaporizer as (described for the H1N1 studies, in this protocol) and placed supine over an intubation platform with their incisors secured with an O-ring. Mice will be intubated by sliding a small catheter over a guiding wire threaded into the mouse trachea and liquid will be injected using a precision syringe with a blunt needle. Mice will be monitored daily and euthanized. | Y1 M8      | AC-AAB2567   | AFBP6267 |
| 8                           | Farber, Donna          | COVID-19 spike protein was used in the production of the COMIRNATY <sup>®</sup> bivalent PfizerBioNTech COVID-19 mRNA vaccine   | Influenza A virus strains A/PR8/34, WSN, X31<br>Influenza B virus strain B/Lee/40<br>M2WR II | Mouse                  | ABSL-2          | III-E-1, III-F     | The goal of this project is to identify the cellular mechanisms that control the memory immune response to influenza virus and how protective immunity can be generated and functionally maintained. To do this we will infect mice with various strains of influenza virus and study various aspects of T cell involvement.   | Y1 M1      | AC-AAB54607  | BSIW0226 |
| 9                           | Porotto, Matteo        | The plasmid encodes the full-length viral genome with a fluorescent reporter protein (either EGFP or mCherry) inserted at genome position 1. Transcription of viral RNA is driven by a T7 RNA polymerase promoter, and cotransfection with plasmids expressing the viral RNA-dependent RNA polymerase complex (P and L) and the nucleoprotein initiates viral replication and infection. Once infection is started the virus is propagated in cell lines. | EGFP and mCherry<br>Measles, WT Measles virus, vaccine, and clinical isolates strains        | In vitro               | N/A             | III-D-1-a, III-F   | Using a reverse genetics system, we are generating recombinant measles viruses that express viral envelope glycoproteins derived from wild-type, vaccine, and clinical isolate strains (including neuropathogenic isolates). All recombinant viruses also encode a fluorescent reporter gene (either EGFP or mCherry), which enables facile tracking of infection and, importantly, results in attenuation relative to the unmodified parental viruses. These recombinant viruses will be evaluated both in vitro and ex vivo to compare their relative pathogenicity and to assess the efficacy of exploratory antiviral interventions, including small molecules, peptides, and monoclonal antibodies. Selected experiments will further examine the potential for viral resistance in response to these antiviral pressures. Studies of viral resistance will be conducted in established cell lines or in human induced pluripotent stem cell-derived organoid models.   | Y1 M0      | LS-ACY0063   | BSIW0284 |
| 10                          | Porotto, Matteo        | The plasmid encodes the full-length viral genome with a fluorescent reporter protein (either EGFP or mCherry). Transcription of viral RNA is driven by a T7 RNA polymerase promoter, and co-transfection with plasmids expressing the viral RNA-dependent RNA polymerase complex (P and L) and the nucleoprotein initiates viral replication and infection. Once infection is started the virus is propagated in cell lines.                              | EGFP and mCherry<br>Mumps, WT Mumps virus and vaccine  | In vitro               | N/A             | III-D-1-a, III-F   | Using a reverse genetics system, we are generating recombinant mumps viruses that express viral envelope glycoproteins derived from wild-type, vaccine. All recombinant viruses also encode a fluorescent reporter gene (either EGFP or mCherry), which enables facile tracking of infection and, importantly, results in attenuation relative to the unmodified parental viruses. These recombinant viruses will be evaluated both in vitro and ex vivo to compare their relative pathogenicity and to assess the efficacy of exploratory antiviral interventions, including small molecules, peptides, and monoclonal antibodies. Selected experiments will further examine the potential for viral resistance in response to these antiviral pressures. Studies of viral resistance will be conducted in established cell lines or in human induced pluripotent stem cell-derived organoid models.  | Y1 M0      | LS-ACY0064   | BSIW0302 |
| 11                          | Porotto, Matteo        | The plasmid encodes the full-length viral genome with a fluorescent reporter protein (either EGFP or RFP). Transcription of viral RNA is driven by a T7 RNA polymerase promoter, and co-transfection with plasmids expressing the viral RNA-dependent RNA polymerase complex (P and L) and the nucleoprotein initiates viral replication and infection. Once infection is started, the virus is propagated in cell lines.                                 | EGFP or RFP<br>RSV virus, WT RSV virus   | In vitro               | N/A             | III-D-1-a, III-F   | We are using a respiratory syncytial virus (RSV) that expresses viral envelope glycoproteins derived from wild-type. All recombinant viruses also encode a fluorescent reporter gene (either EGFP or RFP), which enables facile tracking of infection and, importantly, results in attenuation relative to the unmodified parental viruses. These recombinant viruses will be evaluated both in vitro and ex vivo to assess the efficacy of exploratory antiviral interventions, including small molecules, peptides, and monoclonal antibodies. Selected experiments will further examine the potential for viral resistance in response to these antiviral pressures. Studies of viral resistance will be conducted in established cell lines or in human induced pluripotent stem cell-derived organoid models.   | Y1 M0      | LS-ACY0065   | BSIW0303 |
| 12                          | Steckelberg, Anna-Lena | Viral genomes containing GFP or Luciferase reporter genes   | ZIKV (MR766, PRVABC59), WNV (pWNV lineage I), DENV2  | In vitro               | N/A             | III-D-1-a          | This study will explore the effect of mutations in RNA structures in the 3' UTR of ZIKV and DENV2. Mutations will be generated by site-directed cloning using a mutagenized primer library and DNA plasmids containing the viral genome. Viruses will be produced through transfecting the mutagenized DNA plasmid library into cultured mammalian cells (HEK293, A549, SH-SY5Y). Viruses will be serially cultured for up to 7 days, and harvested at different time points through lysis in Trizol, RNA extraction and short read sequencing. No mutagenized viral stocks will be kept in the lab after the experiment is completed. No selective pressure will be introduced during viral culturing, and we expect most mutations to be neutral or detrimental for viral replication.   | Y1 M0      | LS-ACY0064   | BSIW0252 |
| 13                          | Zorn, Emmanuel         | Human cell lines will be transfected with plasmid including the cDNA of the following SARS-COV-2 genes: nucleocapsid, envelope, membrane, spike S1 and spike S2.  | Plasmid  | In vitro               | N/A             | III-F              | We will test healthy donor blood antibody reactivity to SARS-COV-2 antigens. The antibodies will be tested for their reactivity to commercially available SARS-COV-2 proteins and then human cell lines transfected with plasmid vector including cDNA of SARS-COV-2 genes. Healthy blood specimens were collected before December 2019. We will also use ELISA to detect antibody to adducts in specimens collected from subjects who have tested positive for Covid-19 and controls (BSL2+).   | Y7 M0      | IRB-AAAS9373 | BSIW0259 |

Note 1: The Biosafety Office allows Stereotaxic injections to be designated as ABSL-1  
 Note 2: The Biosafety Office allows Transduced cell injections that are free from virus to be designated as ABSL-1  
 Note 3: The Biosafety Office allows the administration of replication deficient vectors or attenuated strains to be designated as ABSL-1  
 Note 4: BSL-2 practices for Fish procedures: store rVSV-infected fish within BSL2 satellite facility (JLG), in sealed disposable containers on a designated rack clearly labeled for PI handling only. Following euthanasia, water and containers will be decontaminated with >10% bleach  
 Note 5: BSL-2 agent handled with risk mitigation measures