

**Institutional Biosafety Committee  
Icahn School of Medicine Mount Sinai**

**MEETING MINUTES**

| <b>MEETING TIME RECORDS</b>  |                                                                                                                    |
|------------------------------|--------------------------------------------------------------------------------------------------------------------|
| <b>Meeting date:</b>         | 7/16/2026 2:30 PM                                                                                                  |
| <b>Meeting time</b>          | 2:30-3:30 PM                                                                                                       |
| <b>Meeting type</b>          | Hybrid / Videoconference                                                                                           |
| <b>Call to order</b>         | 2:35 PM                                                                                                            |
| <b>Adjournment</b>           | 3:30 PM                                                                                                            |
| <b>Conflicts of interest</b> | The IBC Chair reminded all members present to identify any conflicts of interest as each registration is reviewed. |

| <b>ATTENDANCE</b>                             |                |
|-----------------------------------------------|----------------|
| <b>Name</b>                                   | <b>Present</b> |
| V. SIMON (IBC Chair; Scientist)               | YES            |
| B. LEE (IBC vice-Chair; Scientist)            | YES            |
| T. BANIA (IBC member; Human Gene Therapy)     | NO             |
| C. BERMUDEZ (Institutional Observer)          | YES            |
| R. BRODY (IBC member; Scientist)              | YES            |
| L. CHAUHAN (Biological Safety Officer)        | YES            |
| J. COHEN (IBC member, Attending Veterinarian) | YES            |
| H. DONG (IBC member; Human Gene Therapy)      | YES            |
| A. DOSUNMU (Biological Safety Officer)        | YES            |
| D. D'SOUZA (IBC member; Employee Health)      | YES            |
| C. NAPIER (IBC member; Employee Health)       | YES            |
| C. SHOR (Local Non-affiliated)                | YES            |
| S. STRAUSS (Legal Counsel)                    | NO             |
| N. TZAVARAS (IBC member; Scientist)           | NO             |
| S. ROSA (Administrative)                      | YES            |

| <b>QUORUM</b>                                                                              |
|--------------------------------------------------------------------------------------------|
| The IBC has 10 voting members. 6 members are required to conduct business. Quorum was met. |

| OTHER INDIVIDUALS IN ATTENDANCE |                     |
|---------------------------------|---------------------|
| Name                            | Affiliation / Title |
| K. JIANG                        | ISMMS PHD STUDENT   |
|                                 |                     |
|                                 |                     |

| REVIEW OF PRIOR MEETING MINUTES |                                       |
|---------------------------------|---------------------------------------|
| Date of meeting minutes         | 6-18-2026                             |
| Motion                          | To approve the minutes as written     |
| Votes                           | (7) For<br>(0) Against<br>(1) Abstain |
| Result                          | Approved                              |

**COMMITTEE REVIEW SUBMISSIONS**

**1. Review of SPROTO202600000043**

|                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | Biologic consequences of HIV-1 interaction with bacteria                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Investigator:              | CATARINA HIOE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Submission ID:             | SPROTO202600000043                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Submission Type:           | Initial Protocol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Project Overview           | This study tests the novel hypothesis that direct interaction of HIV-1 with certain bacteria in the urogenital tract and oral cavities promotes virus infectivity and transmissibility. In vitro studies involve testing infectivity of HIV-1 and HIV-1 pseudoviruses upon treatment with bacteria or bacterial proteins. Pseudoviruses expressing SARS-CoV-2 spike are used for comparison. The study also will use mice, a model that have been used to study bacterial urinary tract infection in vivo. |
| NIH Guidelines Section     | III-D-1, III-D-1-a, III-D-3-a                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Risk Assessment discussion | Description of work describes the use of HIV-1. However, HIV-2 was selected as agent. Requires agent name correction.<br>No CCMS concerns.                                                                                                                                                                                                                                                                                                                                                                 |
| Training                   | No deficiencies were noted in staff training records. OR<br>Corrective actions were identified to address minor deficiencies.                                                                                                                                                                                                                                                                                                                                                                              |
| Occupational Health        | Some protocol team members require annual OHSQ                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Biosafety Level Assignment | BL-2; BL-2N                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Highest BSL Practices      | BSL-2+                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Highest ABSL Practices     | ABSL-2+                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| IBC Vote                   | A motion was made to approve the registration after resolution of requested modifications.<br><br>Votes:<br>(8) For<br>(0) Against<br>(0) Abstain<br><br>Conflict(s) of Interest: None                                                                                                                                                                                                                                                                                                                     |

## 2. Review of SPROTO202600000058

|                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | Mechanisms of nerve regeneration after injury                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Investigator:              | HONGYAN ZOU                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Submission ID:             | SPROTO202600000058                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Submission Type:           | De Novo Review                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Project Overview           | The laboratory is interested in molecular mechanisms of how neurons extend axons and how to promote them to regenerate axons after injury. We combine in vivo axon injury models, 3D organoid cultures, molecular biology, and various imaging and tissue engineering techniques to study novel signaling pathways and epigenetic mechanisms that promote neurogenesis and axonogenesis. Such knowledge will be crucial for targeting molecules for effective CNS regeneration. |
| NIH Guidelines Section     | III-D-1-a<br>III-E-3                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Risk Assessment discussion | Viral vector maps provided; LV generation and replication capability information required.<br>No CCMS concerns.                                                                                                                                                                                                                                                                                                                                                                 |
| Training                   | No deficiencies were noted in staff training records.                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Occupational Health        | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Biosafety Level Assignment | BL-2<br>BL2-N                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Highest BSL Practices      | BSL-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Highest ABSL Practices     | ABSL-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| IBC Vote                   | A motion was made to require post-mod review by BSO reviewer after resolution of requested modifications.<br><br>Votes:<br>(8) For<br>(0) Against<br>(0) Abstain<br><br>Conflict(s) of Interest: None                                                                                                                                                                                                                                                                           |

### 3. Review of SPROTO202600000052

|                            |                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | Phase 3 Cellular Therapy Study (BMT CTN 2303)                                                                                                                                                                                                                                                                                                                                                                               |
| Investigator:              | JOHN LEVINE                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Submission ID:             | SPROTO202600000052                                                                                                                                                                                                                                                                                                                                                                                                          |
| Submission Type:           | Initial Protocol                                                                                                                                                                                                                                                                                                                                                                                                            |
| Project Overview           | This study is a randomized, double-blind, placebo-controlled, multicenter Phase III trial to compare the efficacy and safety of remestemcel-L-rknd (remestemcel-L), ex-vivo cultured adult human mesenchymal stromal cells (MSC), combined with ruxolitinib vs. ruxolitinib combined with placebo as second-line therapy in adult patients with Grade III-IV steroid-refractory acute graft-versus-host disease (SR-aGVHD). |
| NIH Guidelines Section     | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                              |
| Risk Assessment discussion | No concerns                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Training                   | No deficiencies were noted in staff training records.                                                                                                                                                                                                                                                                                                                                                                       |
| Occupational Health        | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                              |
| Biosafety Level Assignment | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                              |
| Highest BSL Practices      | BSL-2                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Highest ABSL Practices     | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                              |
| IBC Vote                   | <p>A motion was made to approve the registration as is</p> <p>Votes:</p> <p>(8) For</p> <p>(0) Against</p> <p>(0) Abstain</p> <p>Conflict(s) of Interest: None</p>                                                                                                                                                                                                                                                          |

#### 4. Review of SPROTO202600000030

|                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | Research with retroviruses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Investigator:              | VIVIANA SIMON                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Submission ID:             | SPROTO202600000030                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Submission Type:           | De Novo Review                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Project Overview           | <p>The lab investigates a number of different aspects of how HIV damages the human immune system. We investigate how HIV counteracts intracellular inhibitors as well as how HIV establishes latency. We introduce mutations in different HIV molecular clones to interrogate the contribution of viral genes to a specific phenotype. We infect primary human cells (e.g., T cells, macrophages, microglia) with HIV isolates to determine phenotypes and fitness.</p> <p>Recombinant HIV molecular clones: Transfection of DNA plasmids encoding molecular HIV clones into HEK293T to generate infectious HIV, single cycle HIV or retro/lentiviral vectors for transduction of mammalian cells. There are no reverse genetics systems for retroviruses/lentiviruses</p> |
| NIH Guidelines Section     | III-D                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Risk Assessment discussion | No concerns noted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Training                   | No deficiencies were noted in staff training records.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Occupational Health        | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Biosafety Level Assignment | BL-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Highest BSL Practices      | BSL-2+                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Highest ABSL Practices     | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| IBC Vote                   | <p>A motion was made to approve the registration as is</p> <p>Votes:<br/>(7) For<br/>(0) Against<br/>(1) Abstain</p> <p>Conflict(s) of Interest: Simon</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

## 5. Review of SPROTO202600000032

|                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | Cognition and Neurological Disorder Studies                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Investigator:              | ROBERTO GULLI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Submission ID:             | SPROTO202600000032                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Submission Type:           | Initial Protocol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Project Overview           | <p>To advance our understanding of how individual neurons in the hippocampus, prefrontal cortex, and associated areas encode features of experience to form coherent memories. To advance our understanding of how these distinct brain regions communicate and synchronize their activity to retrieve memories and guide decision-making. To advance our understanding of how targeted neuromodulation of these circuits can be used to affect learning, memory, and generalization.</p> <p>To achieve these goals, we will combine sophisticated behavioral testing, large-scale recording of neural activity, neuromodulation, and brain imaging in rhesus macaque monkeys. The following techniques will be used alone or in combination:</p> <ol style="list-style-type: none"> <li>1. Behavioral testing, including navigation in complex virtual or physical environments</li> <li>2. Recordings of neural activity using high-density electrophysiology</li> <li>3. Neuromodulation, including intracortical micro-stimulation and closed-loop Deep Brain Stimulation (DBS)</li> <li>4. Brain imaging</li> <li>5. Injections of viruses or neurochemicals into brain regions to determine their causal role in memory and cognition</li> </ol> |
| NIH Guidelines Section     | III-D-4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Risk Assessment discussion | <p>No biosafety concerns</p> <p>No CCMS concerns</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Training                   | Corrective actions were identified to address minor deficiencies.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Occupational Health        | No occupational health concerns were noted                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Biosafety Level Assignment | <p>BL-2</p> <p>BL2-N</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Highest BSL Practices      | BSL-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Highest ABSL Practices     | ABSL-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| IBC Vote                   | <p>A motion was made to approve the registration after resolution of requested modifications.</p> <p>Votes:</p> <p>(8) For</p> <p>(0) Against</p> <p>(0) Abstain</p> <p>Conflict(s) of Interest: None</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

## 6. Review of SPROTO202600000066

|                            |                                                                                                                                                                                                                                                                                    |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | Exocrine development, homeostasis and regeneration.                                                                                                                                                                                                                                |
| Investigator:              | ALISON MAY                                                                                                                                                                                                                                                                         |
| Submission ID:             | SPROTO202600000066                                                                                                                                                                                                                                                                 |
| Submission Type:           | De Novo Review                                                                                                                                                                                                                                                                     |
| Project Overview           | The Lab explores how cells communicate to build, maintain, and repair organs. We investigate how immune signals, rare cell populations, and dynamic cellular interactions coordinate exocrine gland development, homeostasis, and regeneration in the airway and salivary systems. |
| NIH Guidelines Section     | Not applicable                                                                                                                                                                                                                                                                     |
| Risk Assessment discussion | No concerns noted.<br>Registration does not meet IBC review requirements.                                                                                                                                                                                                          |
| Training                   | No deficiencies were noted in staff training records.                                                                                                                                                                                                                              |
| Occupational Health        | Not applicable                                                                                                                                                                                                                                                                     |
| Biosafety Level Assignment | Not applicable                                                                                                                                                                                                                                                                     |
| Highest BSL Practices      | BSL-1                                                                                                                                                                                                                                                                              |
| Highest ABSL Practices     | ABSL-1                                                                                                                                                                                                                                                                             |
| IBC Vote                   | <p>A motion was made to approve the registration after resolution of requested modifications.</p> <p>Votes:<br/>(8) For<br/>(0) Against<br/>(0) Abstain</p> <p>Conflict(s) of Interest: None</p>                                                                                   |

## 7. Review of SPROTO202600000056

|                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | Characterization of Chikungunya virus Antibodies                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Investigator:              | FLORIAN KRAMMER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Submission ID:             | SPROTO202600000056                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Submission Type:           | Initial Protocol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Project Overview           | The aim of this project is to identify and characterize novel protective human monoclonal antibodies that display heterosubtypically binding of diverse coronavirus spike glycoproteins. Spike glycoproteins use specialized cell receptors and act as a chief mediator of attachment with the host cell and viral entry. Chikungunya virus envelopes glycoproteins E1 and E2, each containing a single transmembrane domain, are responsible for mediating viral attachment (E2) and membrane fusion (E1). |
| NIH Guidelines Section     | III-D                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Risk Assessment discussion | CCMS: additional IACUC protocol will be required when non-BSL-3 in vivo work begins.<br>Biosafety: separate and clarified description of BSL-2 vs BSL-3 work required                                                                                                                                                                                                                                                                                                                                       |
| Training                   | No deficiencies were noted in staff training records.                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Occupational Health        | Protocol team members require annual OHSQ.<br>Chikungunya vaccination recommended to staff.                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Biosafety Level Assignment | BL-2<br>BL-2N                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Highest BSL Practices      | BSL-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Highest ABSL Practices     | ABSL-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| IBC Vote                   | A motion was made to require post-mod review by BSL-3 BSO after resolution of requested modifications.<br><br>Votes:<br>(8) For<br>(0) Against<br>(0) Abstain<br><br>Conflict(s) of Interest: None                                                                                                                                                                                                                                                                                                          |

## 8. Review of SPROTO202600000086

|                            |                                                                                                                                                                                                                                                                                                                              |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | Phase 1 CAR-T Study (Azer-cel)                                                                                                                                                                                                                                                                                               |
| Investigator:              | FRED LUBLIN                                                                                                                                                                                                                                                                                                                  |
| Submission ID:             | SPROTO202600000086                                                                                                                                                                                                                                                                                                           |
| Submission Type:           | Initial Protocol                                                                                                                                                                                                                                                                                                             |
| Project Overview           | This is a phase 1 open-label trial of azercabtagene zapreleucel anti-CD19 CAR-T cells at various dosing levels for patients with progressive multiple sclerosis (PMS) and neuromyelitis optica spectrum disorder (NMOSD). The multi-site trial includes other indications; Dr. Lublin's site will only enroll PMS and NMOSD. |
| NIH Guidelines Section     | III-C-1                                                                                                                                                                                                                                                                                                                      |
| Risk Assessment discussion | No concerns noted.                                                                                                                                                                                                                                                                                                           |
| Training                   | No deficiencies were noted in staff training records.                                                                                                                                                                                                                                                                        |
| Occupational Health        | Not applicable                                                                                                                                                                                                                                                                                                               |
| Biosafety Level Assignment | BL-2                                                                                                                                                                                                                                                                                                                         |
| Highest BSL Practices      | BSL-2                                                                                                                                                                                                                                                                                                                        |
| Highest ABSL Practices     | Not applicable                                                                                                                                                                                                                                                                                                               |
| IBC Vote                   | <p>A motion was made to approve the registration as is</p> <p>Votes:<br/>(8) For<br/>(0) Against<br/>(0) Abstain</p> <p>Conflict(s) of Interest: None</p>                                                                                                                                                                    |

## 9. Review of SAMENDCR202500000159

|                            |                                                                                                                                                                                 |
|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | Amendment/CR for SPROTO202400000129                                                                                                                                             |
| Investigator:              | HEARN CHO                                                                                                                                                                       |
| Submission ID:             | SAMENDCR202500000159                                                                                                                                                            |
| Submission Type:           | Amendment/CR                                                                                                                                                                    |
| Project Overview           | Added additional plasmids used for transfection in order to express the genes of interest in HEK293 cells.                                                                      |
| NIH Guidelines Section     | III-D-1-A<br>III-E-1<br>III-F-8-C-II                                                                                                                                            |
| Risk Assessment discussion | new pCMV work will be done in Lentivirus system.<br>No concerns noted.                                                                                                          |
| Training                   | No deficiencies were noted in staff training records.                                                                                                                           |
| Occupational Health        | Not applicable                                                                                                                                                                  |
| Biosafety Level Assignment | BL-2                                                                                                                                                                            |
| Highest BSL Practices      | BSL-2+                                                                                                                                                                          |
| Highest ABSL Practices     | Not applicable                                                                                                                                                                  |
| IBC Vote                   | A motion was made to approve the registration as is<br><br>Votes:<br>(8) For<br>(0) Against<br>(0) Abstain<br><br>Conflict(s) of Interest: Committee Member Name(s); or “none.” |

## 10. Review of SPROTO202600000081

|                            |                                                                                                                                                                                                                                                                                                                                                                                              |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | Mouse leukemia modeling and treatment.                                                                                                                                                                                                                                                                                                                                                       |
| Investigator:              | ALAN SHIH                                                                                                                                                                                                                                                                                                                                                                                    |
| Submission ID:             | SPROTO202600000081                                                                                                                                                                                                                                                                                                                                                                           |
| Submission Type:           | De Novo Review                                                                                                                                                                                                                                                                                                                                                                               |
| Project Overview           | Lab uses cell culture experiments of leukemia cell lines and primary leukemia samples. We treat them with standard and novel drug therapies. We evaluate cell growth and differentiation using viability assays and flow cytometry. We extract DNA, RNA, and protein and assess the expression of target genes. We use ELISA and biochemistry assays to assess analytes and enzyme activity. |
| NIH Guidelines Section     | III-E-1                                                                                                                                                                                                                                                                                                                                                                                      |
| Risk Assessment discussion | No concerns                                                                                                                                                                                                                                                                                                                                                                                  |
| Training                   | No deficiencies were noted in staff training records.                                                                                                                                                                                                                                                                                                                                        |
| Occupational Health        | Not applicable                                                                                                                                                                                                                                                                                                                                                                               |
| Biosafety Level Assignment | BL-2<br>BL2-N                                                                                                                                                                                                                                                                                                                                                                                |
| Highest BSL Practices      | BSL-2                                                                                                                                                                                                                                                                                                                                                                                        |
| Highest ABSL Practices     | ABSL-2                                                                                                                                                                                                                                                                                                                                                                                       |
| IBC Vote                   | A motion was made to approve the registration as is<br><br>Votes:<br>(8) For<br>(0) Against<br>(0) Abstain<br><br>Conflict(s) of Interest: None                                                                                                                                                                                                                                              |

## 11. Review of SPROTO202600000089

|                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                     | neurobiological mechanisms underlying addiction and depression                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Investigator:              | ERIC NESTLER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Submission ID:             | SPROTO202600000089                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Submission Type:           | Initial Protocol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Project Overview           | The goal of research is to better understand the molecular mechanisms of addiction and depression. We use animal models of these disorders to identify the ways in which long-term exposure to drugs of abuse or stress changes the brain to lead to addiction- or depression-like syndromes. A major focus of our work is on drug- and stress-induced changes in gene expression and chromatin structure within the brain's reward circuitry, and the mechanisms by which those lasting adaptations alter neuronal and circuit function to produce behavioral abnormalities. |
| NIH Guidelines Section     | III-D-1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Risk Assessment discussion | Clarification regarding chemical usage required.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Training                   | Corrective actions were identified to address minor deficiencies.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Occupational Health        | protocol team members require annual OHSQ<br>tamoxifen hazards for pregnancy provided                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Biosafety Level Assignment | BL-2<br>BL1-N                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Highest BSL Practices      | BSL-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Highest ABSL Practices     | ABSL-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| IBC Vote                   | A motion was made to approve the registration after resolution of requested modifications.<br><br>Votes:<br>(8) For<br>(0) Against<br>(0) Abstain<br><br>Conflict(s) of Interest: None                                                                                                                                                                                                                                                                                                                                                                                        |

## **OTHER AGENDA ITEMS**

### **12. Review of Review 2026 Charter Draft:**

|              |                                 |
|--------------|---------------------------------|
| Description: | Annual Review of IBC Charter    |
| Notes:       | Review and Discussion Postponed |

### **13. Review of Review of Confidentiality Form:**

|              |                                                                                                                                             |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Description: | First review of 2025 Confidentiality Form.<br><br>Recommend updates to be general to the public.<br><br>Separate Conflict of Interest form? |
| Notes:       | Review and Discussion Postponed                                                                                                             |

#### **Review of Incidents**

Nothing to report

#### **Inspections / Ongoing Oversight**

Nothing to report

#### **IBC Training**

Nothing to report

#### **Public Comments**

There were no public comments