February 13, 2026

San Diego BioMed

**Date**: February 13, 2026

**Location**: Zoom Meeting

**Start time:** 12:03 PM

**Chair**: Sylvie Blondelle

**Attendees**: Sylvie Blondelle (Chairperson), Roberto Baccala, James Binley, Emma Crook, Grishma Acharya.

**Absent:** Clara Szeto.

1. **Approval of IBC previous meeting minutes**

The minutes from August 27, 2025 were displayed and reviewed; no corrections were requested, a motion was made and seconded, and the minutes were approved.

2. **Protocol reviews**

New registration:

**Principal Investigator:** Gregory Seumois
**Protocol #:** BHR-26-001-GS
**Title:** Study of immune inflammation in models of allergic (Type 2) airway and skin chronic diseases
**Project summary (from form)**: The goal of this project is to study allergic inflammation, fibrosis, airway remodeling and hyperresponsiveness, and immune cell activation, exposure of dust mite extract sensitization. In vivo cutaneous inflammation resembling human atopic dermatitis will be monitored using epicutaneous staphylococcal enterotoxin B and dust mite extract exposure in rodents.
**Agent**: Dust mite extract, Staphylococcal enterotoxin B
**Additional details from the protocol**:
**Manipulations planned**: flow cytometry for fixed cells, injection
**Recombinant or synthetic nucleic acid molecules**: None
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Information and monitoring for potential allergy
**Assigned Biosafety Level:** BSL-2 and ABSL-2
**CA ATP-L** : No
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No

**Discussion**: Requested information regarding the Biosafety Cabinet in the animal room. Added inhalation as a risk of transmission.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels with the discussed modifications.

**Three year rewrite**: None

**Annual renewal:**

**Principal Investigator:** Bruno Conti
**Protocol #:** rDNA-24-001-BC
**Title:** Anti-inflammatory signals and neurodegeneration
**Project summary (from form)**: Having established that activation of the heterodimeric interleukin-13 receptor alpha 1, IL-13Rα1, signaling can affect the survival of dopaminergic neurons during neuroinflammation, this study aims at determining the molecular and cellular mechanisms by which this occurs. This will help determining whether targeting IL-13Rα1 signaling may be a viable approach to slow neurodegeneration in humans affected by α-synucleinopathies such as Parkinson's disease. Adeno-associated viral particles expressing either GFP or human alpha-synuclein will be injected in the brain of a rodent model for Parkinson's disease to measure the extent IL-13 and IL-13Rα1contribute to neurodegeneration.
**Additional details from the protocol**: The viral vectors will be purchased.
**Source of nucleic sequences (e.g., species)**: Human
**Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene)**: alpha synuclein
**Host(s) and Vector(s):** Rodent
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** none
**Assigned Biosafety Level:** ABSL-1 with BSL-2 practices
**CA ATP-L** : No
**NIH Guidelines:** III-D4
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Requested the handling of the vector solution at BSL2.

**IBC Approval:**
The protocol was unanimously approved at the requested biosafety levels.

**Principal Investigator:** Bruno Conti
**Protocol #:** BHR-24-001-BC
**Title:** Neuroimmunology of cytokines

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**Project summary (from form)**: The goal of this project to determine in vivo whether targeting IL-13Rα1 signaling may be a viable approach to slow neurodegeneration in humans affected by α-synucleinopathies such as Parkinson's disease. This is the BHR portion of the protocol listed above.
**Agent**: Adeno-associated viral vector.
**Additional details from the protocol**: The vectors will be purchased or received from vetted centers.
**Manipulations planned**: Pipetting, centrifugation
**Recombinant or synthetic nucleic acid molecules**: alpha-synuclein.
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** none
**Assigned Biosafety Level:** ABSL-1 with BSL2 practices
**CA ATP-L** : No
**NIH Guidelines:** III-D4
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Requested BSL2 practices to handle the viral vector.

**IBC Approval:**
The protocol was unanimously approved at the requested biosafety levels.

**Principal Investigator:** Takanori Otomo
**Protocol #:** rDNA-24-001-TO
**Title:** Molecular mechanisms of autophagy
**Project summary (from form)**: The goal of this project is to determine structural, biochemical and cellular mechanisms of the autophagy and SMC5/6 complex genes. Specifically, proteins produced in bacteria, insect cell, and mammalian cells will be used in structural studies using NMR, X-ray crystallography, and cryo-electron microscopy. They will also be expressed in mammalian cells for imaging studies. The expression will be mediated by transient transfection or stable integration using retroviruses.
**Additional details from the protocol**: Baculoviral and murine retroviral vectors will be used.
**Source of nucleic sequences (e.g., species)**: Human
**Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene)**: essential components of autophagy and the SMC5/6 complex in human cells
**Host(s) and Vector(s):** E. coli, insect and human cells
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for handling human cells
**Assigned Biosafety Level:** BSL-1 and BSL-2
**CA ATP-L** : No
**NIH Guidelines:** III-D1 and E1
**Category 1 Research:** No
**Category 2 Research:** No

**Discussion**: No concern.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety.

**Principal Investigator:** Takanori Otomo
**Protocol #:** BHR-24-001-TO
**Title:** Expression of autophagy and SMC5/6 proteins in cells
**Project summary (from form)**: The goal of this project is to elucidate the molecular mechanisms underlying autophagy and the functions of the SMC5/6 complex. This is the BHR portion of the protocol listed above.
**Agent**: E. coli K12, baculoviral and murine retroviral vectors, insect cells, human cells
**Additional details from the protocol**: none
**Manipulations planned**: Pipetting, centrifugation, cell culture, shaking
**Recombinant or synthetic nucleic acid molecules**: None
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B for handling human cells
**Assigned Biosafety Level:** BSL-1 and BSL-2
**CA ATP-L** : No
**NIH Guidelines:** III-D1 and D2
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: No concern.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels.

**Principal Investigator:** James Binley
**Protocol #:** rDNA-24-001-JB
**Title:** Inducing broadly neutralizing antibodies to protect against HIV
**Project summary (from form):** The goal of this project is to mimic authentic HIV particles in the form of virus-like particles (VLPs) that are not infectious to see if we can induce the same or better broad neutralizing responses seen in some infections. DNA plasmids and mRNA-lipid nanoparticles (mRNA-LNP) will be used to generate VLPs bearing HIV Env on their surfaces.
**Additional details from the protocol:** The mRNA-LNP constructs will be received from a collaboartor at Univresity of Pennsylvania.
**Source of nucleic sequences (e.g., species):** Viral
**Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene):** viral proteins
**Host(s) and Vector(s):** Human cells
**Risk Assessment:** Medium
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for handling human cells

**Assigned Biosafety Level:** BSL-2 with BSL3 practices to capture aerosols
**CA ATP-L :** Yes
**NIH Guidelines:** III-D1 and D2
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion:** No concern.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels. Dr Binley abstained.

**Principal Investigator:** James Binley
**Protocol #:** BHR-24-001-JB
**Title:** Inducing broadly neutralizing antibodies to protect against HIV
**Project summary (from form)**: The goal of this study is to mimic authentic HIV particles in the form of virus-like particles (VLPs) that are not infectious to see if we can induce the same or better broad neutralizing responses seen in some infections. Cell lines will be used for checking expression of plasmids and mRNA-LNPs. Lead clones will be made as mRNA-LNPs. PBMCs, and hepatocytes will be used to check mRNA-LNPs expression. Brochiolavage (BAL) samples will be used to assay mucosal immune responses. This is the BHR portion of the protocol listed above.
**Agent**: Human, rhesus and rodent cell lines, human PBMCs, human, rhesus and rodent hepatocytes, human plasma and serum, rhesus BAL samples.
**Additional details from the protocol**: The title has been changed to reflect change in focus and to match related grant proposal. Animal samples were added. Agents will come from commercial sources or vetted repositories.
**Manipulations planned**: Pipetting, centrifuging, shaking
**Recombinant or synthetic nucleic acid molecules**: Pseudoviruses and mRNA-lipid nanoparticles covered under Protocol #: rDNA-25-001-JB
**Risk Assessment:** Medium
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human material
**Assigned Biosafety Level:** BSL-2 with BSL3 practices to capture aerosols
**CA ATP-L** : Yes
**NIH Guidelines:** III-D1 and D2
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Removed mentions of Tommy Tong.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels with the discussed modifications.

**Principal Investigator:** Charles D. Murin
**Protocol #:** rDNA-24-001-DCM

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**Title:** HIV antibodies and NK cell ADCC: nanometer scale tracking of immune synapse dynamics
**Project summary (from form):** The goal is to better understand the molecular mechanisms that drive antibody-ba effector functions, specifically how Natural Killer (NK) cells perform antibody dependent cellular cytotoxici (ADCC) on virally infected cells. Target cell line expressing viral proteins on their cell surface will be generated using the PiggyBac system or retroviral vectors. NK cell lines that express the IgG1 receptor CD16, along with versions that have tags to label this protein with a fluorescent tag will also be produced. The target cells lines will be used to complete in vitro ADCC assays and monitor NK cells during ADCC using fluoromicroscopy techniques.
**Additional details from the protocol:** The protocol was modified to add murine amphotropic retroviral vectors.
**Source of nucleic sequences (e.g., species):** Viral, human
**Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene):** receptor, viral proteins, immunoglobins
**Host(s) and Vector(s):** Established rodent and human cells
**Risk Assessment:** low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for handling human cells
**Assigned Biosafety Level:** BSL-2
**CA ATP-L :** No
**NIH Guidelines:** III-D1 and D2
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion:** The other researchers must read and signed the modified protocol.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels with the discussed modifications.

**Principal Investigator:** Charles D. Murin
**Protocol #:** BHR-24-001-DMC
**Title:** Mechanisms of natural killer cell mediated ADCC
**Project summary (from form)**: The goal of this project to acquire a more detailed understanding of how antibodies recruit Fc mediated cellular activity and to develop novel strategies to engineer treatments that can recruit specific effector functions with maximal potency in vivo. This is the BHR portion of the protocol listed above.
**Agent**: Human cell lines, PBMCs, and blood, recombinant murine stem cell virus (MSCV).
**Additional details from the protocol**: The cells will be purchased or received from vetted repositories and centers. The protocol was modified to add MSCV vector and lipid nanoparticles.
**Manipulations planned**: Pipetting, tissue culture, centrifugation, shaking, flow cytometry, HPLC/FPLC, spectrophotometry
**Recombinant or synthetic nucleic acid molecules**: None
**Risk Assessment:** Low

**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human cells
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** III-D2
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Added lipid nanoparticles in the list of agents.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels with the discussed modifications.

**Principal Investigator:** Céline DerMardirossian
**Protocol #:** BHR-24-001-CDM
**Title:** Compound #26 as a novel strategy to inhibit breast cancer metastasis
**Project summary (from form)**: The goal is to identify agents that inhibit filopodia's ability to sense ECM stiffness, thereby preventing tumor invasion and metastasis. To this end, we have developed a high-throughput drug screen that identifies small molecules capable of disrupting the Myo10/integrin interaction within filopodia.
**Agent**: Cell lines
**Additional details from the protocol**: none
**Manipulations planned**: Pipetting, centrifugation, shaking, spectrophotometer
**Recombinant or synthetic nucleic acid molecules**: none
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human cells
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: No concern.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels.

**Principal Investigator:** Roberto Baccala
**Protocol #:** BHR-24-001-RB
**Title:** Environmental and genetic factors in systemic autoimmunity
**Project summary (from form)**: The goal is to study the effect of viral infection and crystalline silica as environmental triggers of lupus-like autoimmunity, particularly in individuals with a level of genetic predisposition that is insufficient for spontaneous disease. For such experiments, we

are using the lymphocytic choriomeningitis virus (LCMV), a very well characterized murine virus, and selected rodent models displaying different levels of genetic predisposition to systemic autoimmunity.
**Agent**: Lymphocytic choriomeningitis virus (LCMV), crystalline silica (in liquid emulsion).
**Additional details from the protocol**: none
**Manipulations planned**: Pipetting, centrifugation, sonication, flow cytometry of fixed cells
**Recombinant or synthetic nucleic acid molecules**: none
**Risk Assessment:** Medium
**Training:** Verified and on record
**Occupational Medicine:** none
**Assigned Biosafety Level:** BSL-2 with BSL3 practices to capture aerosols
**CA ATP-L** : Yes
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: No concern.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels. Dr Baccala abstained.

**Principal Investigator:** Gregory Seumois
**Protocol #:** BHR-24-001-GS
**Title:** Human blood processing and BHP PBMC cell experimentation
**Project summary (from form)**: The goal is to characterize immune cells by isolating PBMCs from blood for sequencing, culture, and flow cytometry.
**Agent**: Human and non-human primate blood and blood-derived components (PBMC, PMNs, pure population of blood immune cells, in vitro derived cells from primary blood cells).
**Additional details from the protocol**: Modified title. Added animal samples.
**Manipulations planned**: Pipetting, centrifugation, shaking, flow cytometry of fixed cells
**Recombinant or synthetic nucleic acid molecules**: none
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human material
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Requested clarification on the room number where the samples will be stored.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels with the discussed modifications.

**Principal Investigator:** Gregory Seumois
**Protocol #:** BHR-24-002-GS
**Title:** Airway clinical sample: SPUTUM processing
**Project summary (from form)**: The goal is to use sputum to characterize the cellular and molecular features of immune and structural cells from human sputum, particularly in various disease states such as asthma, EGPA, COPD.
**Agent**: Human sptuum samples.
**Additional details from the protocol**: none
**Manipulations planned**: Pipetting, centrifugation, shaking, sonication, flow cytometry of fixed cells
**Recombinant or synthetic nucleic acid molecules**: none
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human material
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: No concern.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels.

3. **NIH Reportable Incidents**: None

4. **DURC/PEPP**: None

5. **Other matters and adjournment**

The BHR form will be modified to request the type of immunization to be offered when applicable in section IX.b. The meeting was adjourned at 12:50 PM with thanks to all participants.

August 27, 2025

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**Date**: Aug 27, 2025

**Location**: Zoom Meeting

**Chair**: Sylvie Blondelle

**Attendees**: Committee members including Sylvie Blondelle, Roberto Baccala, James Binley, Emma Crook (new member), Grishma Acharya (new member)

Clara Szeto was absent.

1. **Update on IBC Roster.**

The Chair opened the meeting, welcomed all members, and noted the addition of Emma and Grishma to the committee.

2. **Approval of IBC meeting minutes from December 17, 2024**

The minutes from December 17, 2024, were displayed and reviewed; no corrections were requested, a motion was made and seconded, and the minutes were approved.

3. **NIH transparency and minutes format**

The committee discussed NIH expectations to post minutes publicly and to include clearer protocol summaries, risk assessments, training and biosafety levels. Going forward, minutes will capture protocol title, concise summary, agent or source, risk assessment, training, biosafety level, committee discussion, and decision.

4. **Protocol reviews**

**New registration**:

**Principal Investigator:** Maria Cecilia Marcondes
**Protocol #:** rDNA-25-001-MCM
**Title:** Methamphetamine, HIV integration and latency in the brain
**Project summary (from form)**: Study modifiers of HIV integration.
**Additional details from the protocol**: This study will use a reporter (GFP or luciferase) tagged pseudovirus that can infect but is not able to replicate.
**Source of nucleic sequences (e.g., species)**: Synthetic
**Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene)**: viral proteins, fluorescent protein
**Host(s) and Vector(s):** Human cells
**Risk Assessment:** Low
**Training:** Verified and on record

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**Occupational Medicine:** Hepatitis B immunization for working with human cells
**Assigned Biosafety Level:** BSL-2 with BSL-3 practices aimed at containing the aerosols
**CA ATP-L** : Yes
**NIH Guidelines:** III-D
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: The PI was asked to provide clarity on the following: 1. The host strain; 2. Source of the nucleic acid sequences; 3. Expend on the summary of overall goals of proposed research.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

**Principal Investigator:** Richard Milner
**Protocol #:** BHR-25-002-RM
**Title:** Evaluating integrin expression in human brain samples
**Project summary (from form)**: The goal of this project is to define the expression pattern of specific integrins in blood vessels and microglia in postmortem samples of human brain. We are particularly interested in studying the integrin expression pattern on microglia in human brain tissue to ascertain if it corresponds to what we observe in rodent brain tissue. In addition, the samples provided are 4 normal controls with 4 samples where advanced vascular inflammation and artherosclerosis have been detected, which will allow us to determine if microglia (and blood vessels) show inflammation-associated changes in integrin expression on microglia and vascular cells.
**Agent**: Human brain tissue
**Additional details from the protocol**: The cells will be purchased from vetted repositories
**Manipulations planned**: cryostat, microscopy
**Recombinant or synthetic nucleic acid molecules**: None
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human material
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Cryostat sectioning does not require a biosafety cabinet, but standard practices apply. Requested corrections include specifying the agent as postmortem human brain tissue, confirming personnel training and initials, marking risk to immunosuppressed personnel as unknown, and naming hepatitis B immunization.

**IBC Approval:**

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The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

**Three-year rewrite**:

**Principal Investigator:** David M. Gilbert
**Protocol #:** rDNA-25-001-DMG
**Title:** cis-Acting Elements Regulating Developmental Control of Replication Timing, Computational Methods for Next-Generation Comparative Genomics
**Project summary (from form)**: We are making deletions/insertions to investigate cis-acting DNA elements regulating developmental control of replication timing or genome 3D structure. We also introduce degron tags to the candidate proteins to see the effect of knockdown of the protein on replication timing or genome 3D structure.
**Additional details from the protocol**: Cell lines will be engineered using Cas9 in combination with guide RNA. The effect of engineering in replication timing or nuclear compartmentalization by repli-seq and other genomics analysis.
**Source of nucleic sequences (e.g., species)**: Synthetic
**Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene)**: Guide RNA, enzyme, fluorescent proteins
**Host(s) and Vector(s):** Established rodent and human cells
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human cells
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** III-E
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: No viral vectors are used. Corrections were requested to mark vector related questions as “not applicable”.
**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

**Principal Investigator:** David M. Gilbert
**Protocol #:** BHR-25-001-DMG
**Title:** Chromosome Replication and Epigenome Regulation in Mammalian Cells
**Project summary (from form)**: The goal of this project is i) to reveal mechanisms by which perturbation of cancer-relevant cellular pathways produce unique patterns of fragile sites in cell culture and match these patterns to specific cancer types; ii) to identify mechanisms by which ERCEs coregulate RT, chromatin architecture and transcription; iii) to in vitro differentiate then produce and analyze genomics data from various cell lines; iv) to develop a tool to detect the 3D

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architecture of replisomes in living cells and their responses to stress; and v) to provide various genomics data from cell lines to computational labs.
**Agent**: Established human cell lines and primary human cells.
**Additional details from the protocol**: The cells will be purchased or received from vetted repositories and centers.
**Manipulations planned**: Pipetting, tissue culture, centrifugation, flow cytometry, HPLC/FPLC, spectrophotometry
**Recombinant or synthetic nucleic acid molecules**: None
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human cells
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Requested corrections: 1. Indicating human cells as potential pathogens to human and checking Skin Absorption and Inoculation as potential route of exposure; 2. Identifying centrifugation as an aerosol generating procedure; 3. Clarifying if cells are already in the lab; 4. Updating personnel involved in the project; 5. Marking risk to immunosuppressed personnel as unknown, and naming hepatitis B immunization; 6. Indicating that entry into tissue culture rooms must require at least lab coat and gloves for all individuals including observers.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

**Annual renewal:**

**Principal Investigator:** Charles D. Murin
**Protocol #:** rDNA-24-001-DMC
**Title:** HIV antibodies and NK cell ADCC: nanometer scale tracking of immune synapse dynamics
**Project summary (from form)**: The goal is to better understand the molecular mechanisms that drive antibody-ba effector functions, specifically how Natural Killer (NK) cells perform antibody dependent cellular cytotoxici (ADCC) on virally infected cells. Target cell line expressing viral proteins on their cell surface will be generated using the PiggyBac system. We will also produce NK cell lines that express the IgG1 receptor CD16, along with versions that have tags to label this protein with a fluorescent tag. We will be using target cells lines to complete in vitro ADCC assays, and we will also observe NK cells during ADCC using fluoromicroscopy techniques.
**Additional details from the protocol**: No viral vectors are used.
**Source of nucleic sequences (e.g., species)**: Human and viruses
**Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene)**: receptor, viral proteins, immunoglobins

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**Host(s) and Vector(s):** Established rodent and human cells
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human cells
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** III-D2
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: This annual renewal reported no protocol changes other than updates to personnel.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels.

**Principal Investigator:** Charles D. Murin
**Protocol #:** BHR-24-001-DMC
**Title:** Mechanisms of Natural Killer cell mediated ADCC
**Project summary (from form)**: The goal of this project to acquire a more detailed understanding of how antibodies recruit Fc mediated cellular activity and to develop novel strategies to engineer treatments that can recruit specific effector functions with maximal potency in vivo.
**Agent**: Human cell lines, PBMCs, and blood.
**Additional details from the protocol**: The cells will be purchased or received from vetted repositories and centers.
**Manipulations planned**: Pipetting, tissue culture, centrifugation, shaking, flow cytometry, HPLC/FPLC, spectrophotometry
**Recombinant or synthetic nucleic acid molecules**: None
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human cells
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Requested corrections: 1. Indicating human cells as potential pathogens to human and checking Skin Absorption and Inoculation as potential route of exposure; 2. Identifying centrifugation as an aerosol generating procedure; 3. Clarifying if cells are already in the lab; 4. Correcting date of hiring and/or immunization of personnel involved in the project; 5. Marking risk to immunosuppressed personnel as unknown, and naming hepatitis B immunization.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels, with the modification discussed.

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**Principal Investigator:** Joanna Davies
**Protocol #:** BHR-23-002-JD
**Title:** A study to identify immunological markers to predict/monitor disease progression in patient populations with chronic disorders
**Project summary (from form)**: The goal of this project is to better understand the T cell immune response in type 1 diabetes progression to develop biomarkers for prognosis and prediction, as well as therapies to treat, delay, or prevent the disease.
**Agent**: Human plasma, PBMCs, and blood.
**Additional details from the protocol**: The cells will be received from vetted repositories and centers.
**Manipulations planned**: Pipetting, tissue culture, centrifugation, sonicating, flow cytometry, spectrophotometry
**Recombinant or synthetic nucleic acid molecules**: None
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human cells
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Requested corrections: 1. Transferring the summary of the project from the original protocol; 2. Indicating that it is not a transforming agent and no lab testing/blood sampling is done prior working with the agent materials; 3. Marking risk to immunosuppressed personnel as unknown, and naming hepatitis B immunization.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

**Principal Investigator:** Richard Milner
**Protocol #:** BHR-24-001-RM
**Title:** Evaluating the protective roles of mild hypoxia and integrins in inflammatory demyelinating disease
**Project summary (from form)**: The goal of this project is to define the optimal dose of the hypoxia mimetic FG-4592 in the EAE model and then evaluate the role of HIF1α and HIF-2α-mediated vascular remodeling in conferring this protection. The protocol to induce disease in the chronic progressive EAE model requires in vivo intraperitoneal injections of pertussis toxin.
**Agent**: Pertussis toxin
**Additional details from the protocol**: The toxin will not be stored but purchased as part of the kit for each experiment.
**Manipulations planned**: Pipetting, injecting, microscopy
**Recombinant or synthetic nucleic acid molecules**: None

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**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Pertussis immunization
**Assigned Biosafety Level:** BSL-2
**CA ATP-L** : No
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Requested corrections: 1. Indicating that no lab testing/blood sampling is done prior working with the agent materials; 2. Adding the initials of personnel involved in the project.

**IBC Approval:**
The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

**Principal Investigator:** Maria Cecilia Marcondes
**Protocol #:** BHR-24-001-MCM
**Title:** Deciphering Drivers of Chronic COVID Syndrome
**Project summary (from form)**: The goal of this project is to understand a new health condition that is prevalent in the growing 2019 SARS CoV-2 (COVID19) convalescent population, known as PASC (Post-Acute sequelae of COVID). PASC is detectable based on a diversity of symptoms, including but not restricted to cardiovascular, gastrointestinal and neurological, which could result from unmasking underlying co-morbidities, residual damage from acute infection or persistent immune activation. In this study we will develop a panel of peripheral biomarkers that can be combined with clinical and structural measures to increase fill the gap of knowledge about this novel disease while offering a complete assessment of the symptoms etiology and to aid in the identification of risk factors and potential therapeutic strategies.
**Agent**: Blood from long COVID patients
**Additional details from the protocol**: The blood is received from the Huntington Hospital, samples are covered and approved by the Institute IRB.
**Manipulations planned**: Pipetting, injecting, microscopy
**Recombinant or synthetic nucleic acid molecules**: None
**Risk Assessment:** Low
**Training:** Verified and on record
**Occupational Medicine:** Hepatitis B immunization for working with human material
**Assigned Biosafety Level:** BSL-2 with BSL-3 practices aimed at containing aerosols
**CA ATP-L** : Yes
**NIH Guidelines:** n/a
**Category 1 Research:** No
**Category 2 Research:** No
**Discussion**: Personnel lists and biosafety cabinet certification must be updated.

**IBC Approval:**

San Diego BioMed

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| The protocol was unanimously approved at the current biosafety levels, with the modifications discussed. |
| **Principal Investigator:** Maria Cecilia Marcondes<br>**Protocol #:** BHR-23-001-MCM<br>**Title:** Metamphetamine abuse and immune system interactions in neuroAIDS<br>**Project summary (from form)**: The goal of this project is to examine the hypothesis that Methamphetamine exposure aggravates molecular changes that happen as a result of viral infection in innate immune cells that are derived from the brain. Methamphetamine will be added to innate immune cell lines, human macrophages, and latently infected U1 macrophages, together with different non-infectious peptides, for the examination of molecular phenotypes that are triggered by those interactions.<br>**Agent**: Blood, brain tissue, peripheral blood cells and cell lines<br>**Additional details from the protocol**: The samples are commercially available or from vented repositories.<br>**Manipulations planned**: Pipetting, centrifuging, flow cytometry<br>**Recombinant or synthetic nucleic acid molecules**: Pseudoviruses covered under Protocol: rDNA-25-001-MCM<br>**Risk Assessment:** Low<br>**Training:** Verified and on record<br>**Occupational Medicine:** Hepatitis B immunization for working with human material<br>**Assigned Biosafety Level:** BSL-2<br>**CA ATP-L** : No<br>**NIH Guidelines:** n/a<br>**Category 1 Research:** No<br>**Category 2 Research:** No<br>**Discussion**: Personnel lists and biosafety cabinet certification must be updated. Inhalation as a potential route of transmission for this agent needs to be marked. They need to clarify what the hypothesis is with latency.<br><br>**IBC Approval:**<br>The protocol was unanimously approved at the current biosafety levels, with the modifications discussed. |

**5. Proposed revised SOPs**

The committee reviewed updates required by federal policy changes including new categories one and two and the concept of pathogens with enhanced pandemic potential. SOPs were revised accordingly. Application forms were reorganized to begin with agent information followed by project information, storage and use, decontamination and disposal, personnel and training, biosafety practices, and emergency procedures. Non applicable fields were added.

Immunization entries will specify vaccine names when marked yes. The committee agreed that approvals will be recorded as by majority unless otherwise specified.

a. Policy on Research Involving Recombinant or Synthetic Nucleic Acid Molecules and Biohazardous Materials
b. IBC Review Procedures
c. IBC Policy and Procedures on Dual Use Research of Concern and Pathogen of Enhanced Pandemic Potential

6. **NIH Reportable Incidents**: None

7. **DURC/PEPP**: None

8. **Next meeting and adjournment**

No additional question was raised. The next meeting is tentatively planned for January or February. Celine will confirm availability. The meeting was adjourned at 12:56 PM with thanks to all participants.