August 24, 2026

Institutional Biosafety Committee (IBC)

Minutes of Annual Program and Facilities Review Meeting

Date: August 24, 2026

Location: Hybrid Meeting (in person and via Zoom)

Chair: Dr. Laurence Cagnon

Attendees: IBC committee members including Laurence Cagnon, Roberto Baccala, James Binley, Fahumiyad Samad, Emma Crooks , Grishma Acharya.

Sylvie Blondelle was absent.

More than 50% of the voting members were present.

1. Update on IBC Roster.

Laurence Cagnon was introduced as the new IBC Chair. Dr. Cagnon summarized a background in biology, biosafety, BSL-3 operations, and institutional compliance, including current work at the La Jolla Institute for Immunology and previous biosafety responsibilities at Scripps. The committee discussed the transition in IBC leadership and welcomed Dr. Cagnon as Chair.

2. Approval of IBC meeting minutes from February 2026

The minutes from the February 13, 2026, IBC meeting were reviewed. No corrections were requested; a motion was made and seconded, and the minutes were approved.

3. IBC review procedures and annual monitoring

The committee discussed the distinction between a three-year registration rewrite and a continuing renewal (annual monitoring). A three-year rewrite is a full renewal of the registration, whereas annual monitoring is intended to document the current status of an active protocol and identify changes that may require IBC review. The committee noted that the current form places questions regarding protocol modifications and adverse events only under the continuing renewal section. These questions are also relevant to three-year rewrites and should be moved or revised so that they apply to both types of renewal. The committee agreed that future routine annual monitoring submissions may be reviewed administratively by Dr. Céline DerMardirossian, Dr. Laurence Cagnon, and one rotating IBC committee member. Submissions involving substantive scientific or biosafety changes will be brought to the full committee. The committee also agreed that the forms should be revised to remove ambiguity between renewal types and to place questions regarding modifications and adverse events where they apply appropriately.

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4. Protocol reviews

New registration:

None

Three-year rewrite:

Principal Investigator: Joanna Davies
Protocol #: BHR-26-002-JDD (rewrite of BHR-23-002-JDD)
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 disease.
Agent: Human plasma, PBMCs, and blood.
Additional details from the protocol: Human materials are received from vetted repositories and centers.
Manipulations planned: Pipetting, tissue culture, centrifugation, sonication, flow cytometry, and spectrophotometry.
Recombinant or synthetic nucleic acid molecules: None.
Risk Assessment: Low.
Training: Verified and on record.
Occupational Medicine: Hepatitis B immunization is offered for personnel working with human blood or other potentially infectious human material.
Assigned Biosafety Level: BSL-2.
CA ATP-L: No.
NIH Guidelines: N/A
Category 1 Research: No.
Category 2 Research: No.
Discussion: The committee reviewed the routes of exposure listed for human blood. Intact-skin absorption was not considered an appropriate routine route of exposure, and inhalation and ingestion were also not considered primary routes for routine blood handling. The committee agreed that percutaneous inoculation and mucous-membrane exposure, including splashes to the eyes or mouth, are the principal relevant exposure routes. Mucous-membrane exposure should be added to the form when it is revised. The committee noted that the laboratory personnel table appeared to be missing from the PDF under review and requested confirmation that all personnel working under the protocol are listed. Liquid-blood disposal was discussed, including whether blood is disinfected directly with bleach or solidified before disposal; the PI/laboratory will clarify the current method. The PPE section

was reviewed. A surgical mask is not a routine BSL-2 requirement for handling human blood unless required by a specific procedure, and the meaning of “foot protection” should be clarified to distinguish closed-toe footwear from shoe covers.

The committee also agreed that adverse-event and modification questions should apply to three-year rewrites where relevant, rather than appearing only under annual monitoring.

IBC Approval:
The protocol was unanimously approved at BSL-2, with the modifications and clarifications discussed.

Principal Investigator: Maria Cecilia Marcondes
Protocol #: BHR-26-001-MCM (BHR-23-001-MCM)
Title: Metamphetamine abuse and immune system interactions in neuroAIDS
Project summary (from form): The goal is to examine the hypothesis that methamphetamine exposure aggravates molecular changes associated with viral infection in innate immune cells derived from the brain. Methamphetamine is added to innate immune cell lines, human macrophages, and latently infected U1 macrophages together with non-infectious peptides to examine molecular phenotypes triggered by these interactions.
Agent: Human blood, brain tissue, peripheral blood cells, cell lines, and HIV-related experimental material.
Additional details from the protocol: Samples are commercially available or obtained from vetted repositories.
Manipulations planned: Pipetting, tissue culture, centrifugation, flow cytometry, and related cell-based procedures.
Recombinant or synthetic nucleic acid molecules: HIV-related recombinant material is addressed under the associated rDNA registration.
Risk Assessment: Low, with enhanced practices for applicable HIV procedures.
Training: Verified and on record.
Occupational Medicine: Hepatitis B immunization is offered for work with human material. No approved HIV vaccine is available.
Assigned Biosafety Level: BSL-2 with BSL-3 practices for applicable HIV-related procedures.
CA ATP-L: No.
NIH Guidelines: n/a for the BHR registration; recombinant work is addressed under the associated rDNA protocol.
Category 1 Research: No.
Category 2 Research: No.
Discussion: The committee requested that the protocol clearly identify which blood, tissues, and cell lines are human-derived. The phrase “BSL-3 practices” should be expanded to

identify the specific practices being used, particularly measures intended to contain aerosols generated during centrifugation and related procedures, including aerosol-containment measures, safe centrifugation procedures, and sealed rotors or safety cups as applicable. The vacuum-system configuration should also be clarified, including the liquid trap, overflow protection, and in-line HEPA filtration. The vaccination section should distinguish hepatitis B vaccination associated with work involving human blood from HIV, for which no approved vaccine is available; SARS-CoV-2 vaccination was considered unrelated to the agents in this registration. The committee recommended that the vaccination section clearly indicate vaccine availability for each relevant agent (hepatitis B: Yes; HIV: No). The committee again discussed clarifying PPE terminology, including the distinction between closed-toe shoes and shoe covers.

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

Continuing Renewals (Annual monitoring):

Principal Investigator: Daniel Murin
Protocol #: BHR-24-001-DCM
Title: Mechanisms of Natural Killer cell mediated ADCC (including addition of in vitro experiments with HIV-1 infected human central memory T cells – HIV infections done at UCSD)
Project summary (from form): The goal is to acquire a more detailed understanding of how antibodies recruit Fc-mediated cellular activity and to develop strategies that recruit specific effector functions with maximal potency. The annual monitoring includes an amendment adding in vitro experiments with HIV-1-infected human central memory T cells.
Agent: Human cell lines, PBMCs, blood, and HIV-1-infected human central memory T cells.
Additional details from the protocol: HIV infection, spinoculation, and viral expansion are performed at UCSD. SDBRI receives the infected cells for ADCC and microscopy assays.
Manipulations planned: Pipetting, tissue culture, centrifugation, ADCC assays, microscopy, and flow cytometry.
Recombinant or synthetic nucleic acid molecules: None under this BHR registration.
Risk Assessment: Low to moderate depending on the material; enhanced practices are required for HIV-infected cells and are designed to lower the risk of exposure.
Training: Verified and on record.
Occupational Medicine: Hepatitis B immunization is offered for work with human material.

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Assigned Biosafety Level: BSL-2 for non-infected cells; BSL-2 with BSL-3 practices for HIV-infected cells.
CA ATP-L: No
NIH Guidelines: N/A
Category 1 Research: No.
Category 2 Research: No.
Discussion: The committee reviewed the amendment adding HIV-1-infected central memory T cells. Containment should be identified for centrifugation and other procedures capable of generating aerosols. The annual-monitoring section should indicate that the protocol has been modified because the HIV-infected T-cell work was added. The committee requested clarification regarding whether sharps are used and agreed that the IBC form should include a specific place to document sharps use. Exposure routes should emphasize inoculation and mucous-membrane exposure rather than intact-skin absorption. The vaccination section should identify hepatitis B vaccination as applicable to human material and should state that there is no approved HIV vaccine.

IBC Approval:
The protocol and amendment were unanimously approved. Non-infected cell work remains at BSL-2; HIV-infected cell work is approved at BSL-2 with BSL-3 practices, with the modifications discussed: clarify containment during centrifugation and other aerosol-generating procedures, address sharps use, and correct the vaccination information.

Principal Investigator: Daniel Murin
Protocol #: rDNA-24-001-DCM
Title: HIV antibodies and NK cell ADCC: nanometer scale tracking of immune synapse dynamics
Project summary (from form): The goal is to better understand molecular mechanisms that drive antibody-based effector functions, specifically how Natural Killer cells perform antibody-dependent cellular cytotoxicity on virally infected cells. Engineered target and NK-cell systems are used for in vitro ADCC and fluorescence microscopy.
Additional details from the protocol: The submission describes engineered expression systems and an MSCV construct; the exact use of viral-vector components requires clarification.
Source of nucleic sequences (e.g., species): Human, viral, and jellyfish (*Aequorea victoria*) sequences used for fluorescent tagging.
Nature of nucleic acid (n.a.) sequences (e.g., enzyme, oncogene): Receptors, viral proteins, immunoglobulins, and fluorescent tags.

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Host(s) and Vector(s): Established rodent and human cells; vector details to be clarified as discussed.
Risk Assessment: Low.
Training: Verified and on record.
Occupational Medicine: Hepatitis B immunization is offered for work with human cells.
Assigned Biosafety Level: BSL-2.
CA ATP-L: No.
NIH Guidelines: Previously listed under Section III-D2; exact applicable subsection to be verified after clarification of vector production/pseudotyping.
Category 1 Research: No.
Category 2 Research: No.
Discussion: The committee requested verification of the R01 grant number referenced in the submission. The MSCV construct requires clarification regarding how it is used, including whether it is used only as a plasmid for transfection or is packaged as a viral vector. If a viral vector is produced, the envelope/pseudotype should be identified because it affects host range and risk assessment. The committee also discussed ambiguity in the current viral-vector questions because replication-defective vectors can transduce cells but do not independently replicate. The committee reviewed the section concerning experiments involving infectious or defective DNA/RNA viruses in tissue-culture systems and noted that the current "No" response may need to be changed to "Yes" if viral vector particles are produced. The applicable NIH Guidelines section and the corresponding responses on the form should then be confirmed based on how the MSCV construct is used. The animal-related category was considered not applicable.

IBC Approval:
The protocol was unanimously approved at BSL-2, with the modifications and clarifications discussed.

Principal Investigator: Maria Cecilia Marcondes
Protocol #: BHR-24-001-MCM
Title: Deciphering Drivers of Chronic COVID Syndrome
Project summary (from form): The project investigates post-acute sequelae of COVID (PASC/long COVID) and seeks peripheral biomarkers that can be combined with clinical and structural measures to improve understanding of disease mechanisms and potential therapeutic strategies.
Agent: Blood from long-COVID patients.

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Additional details from the protocol: Blood is received from Huntington Hospital under the applicable IRB-approved study.
Manipulations planned: Pipetting, cell-based assays, centrifugation, microscopy, and related procedures.
Recombinant or synthetic nucleic acid molecules: None.
Risk Assessment: Low.
Training: Verified and on record.
Occupational Medicine: Hepatitis B immunization is offered for work with human material.
Assigned Biosafety Level: BSL-2 with BSL-3 practices aimed at containing aerosols where applicable.
CA ATP-L: Yes where applicable to human blood work.
NIH Guidelines: N/A
Category 1 Research: No.
Category 2 Research: No.
Discussion: The committee requested that the specific BSL-3 practices referenced in the protocol be identified rather than stated generically. The route-of-exposure section should be revised to remove intact-skin absorption and other routes that are not applicable to routine handling of the blood specimens, and mucous-membrane exposure should be added to the form. The vacuum-system configuration should be clarified. Because the project uses human blood from long-COVID patients but does not involve active SARS-CoV-2, the vaccination section should focus on hepatitis B occupational-health requirements rather than SARS-CoV-2 vaccination. Incomplete vaccination and laboratory-testing fields should also be completed.

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 project defines an optimal dose of the hypoxia mimetic FG-4592 in the EAE model and evaluates the role of HIF-1α/HIF-2α-mediated vascular remodeling. The EAE induction procedure includes intraperitoneal injections of pertussis toxin.
Agent: Pertussis toxin.

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Additional details from the protocol: Pertussis toxin is purchased as part of a kit for individual experiments.
Manipulations planned: Pipetting, animal injection, and microscopy.
Recombinant or synthetic nucleic acid molecules: None.
Risk Assessment: Low.
Training: Verified and on record.
Occupational Medicine: Pertussis immunization as applicable.
Assigned Biosafety Level: BSL-2.
CA ATP-L: No.
NIH Guidelines: N/A
Category 1 Research: No.
Category 2 Research: No.
Discussion: The committee noted that some questions regarding pathogenic potential do not apply directly to a purified toxin and should allow an "N/A" response rather than requiring an inaccurate "No." A committee member noted that pertussis toxin may need to be held temporarily because the EAE dosing schedule from the purchased kit can extend over more than one day. The protocol should therefore identify the temporary storage location and describe the storage conditions between uses. The question asking whether the agent is already in the laboratory should be clarified to reflect that the toxin is ordered and received as needed for individual experiments rather than routinely maintained in stock.

IBC Approval:
The protocol was unanimously approved at BSL-2, with the modifications discussed.

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 Genomic
Project summary (from form): Deletions and insertions are made to investigate cis-acting DNA elements regulating developmental control of replication timing and three-dimensional genome structure. Degron tags and related genetic perturbations are introduced to candidate proteins.
Additional details from the protocol: Cell lines are engineered using Cas9 and guide RNA; effects are evaluated using replication-timing and genomics analyses.
Source of nucleic sequences (e.g., species): Synthetic.

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Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene): Guide RNA, enzymes, and fluorescent proteins.
Host(s) and Vector(s): Established rodent and human cells; no viral vectors are used.
Risk Assessment: Low.
Training: Verified and on record.
Occupational Medicine: Hepatitis B immunization is offered for work 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: The committee confirmed that viral vectors are not used. Therefore, the subsequent viral-vector-specific questions are not applicable and do not need to be completed. The committee discussed revising the form so this conditional logic is clearer. The current form also does not clearly accommodate CRISPR/Cas9 work, and other genome-editing approaches, and the committee discussed revising the form to better accommodate these approaches.

IBC Approval:
The protocol was unanimously approved at BSL-2, with the form corrections and clarifications 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 project examines mechanisms linking cancer-relevant cellular pathways to fragile sites, replication timing, chromatin architecture, transcription, and three-dimensional replisome organization using established cell lines and primary human cells.
Agent: Established human cell lines and primary human cells.
Additional details from the protocol: Cells are purchased or received from vetted repositories and centers.
Manipulations planned: Pipetting, tissue culture, centrifugation, flow cytometry, HPLC/FPLC, and spectrophotometry.
Recombinant or synthetic nucleic acid molecules: None under this BHR registration.
Risk Assessment: Low.
Training: Verified and on record.

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Occupational Medicine: Hepatitis B immunization is offered for work 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: Discussion: The route of exposure section should be revised to remove skin absorption and to include mucous membrane exposure when the form is updated. The committee noted that pipetting, vortexing, centrifugation, and related procedures can generate aerosols; the aerosol-generating-procedure question should therefore be marked "Yes." The protocol should more clearly describe the cell-culture procedures performed before the cells are fixed and the containment used for these procedures. The vacuum-aspiration system should specify the liquid-waste trapping arrangement, including whether a two-flask system or guarded canister is used, and the in-line HEPA filter. The vaccination section should identify hepatitis B as the available vaccine for work with human material. Laboratory personnel performing bench work should be listed. Unanswered laboratory-testing fields should be completed, and required biohazard signage should be confirmed.

IBC Approval:
The protocol was unanimously approved at BSL-2, with the modifications discussed.

Principal Investigator: Maria Cecilia Marcondes
Protocol #: rDNA-25-001-MCM
Title: Methamphetamine, HIV integration, and latency in the brain
Project summary (from form): The project studies modifiers of HIV integration and latency using HIV-dependent reporter systems and related recombinant constructs.
Additional details from the protocol: Reporter constructs include HIV-derived regulatory elements and are used with pseudotyping/packaging approaches that require additional clarification.
Source of nucleic sequences (e.g., species): Synthetic and HIV-derived.
Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene): Viral regulatory/protein sequences and fluorescent or other reporter sequences.
Host(s) and Vector(s): Human cells and HIV-derived reporter/vector systems; exact construct and packaging details to be clarified.
Risk Assessment: Low to moderate depending on the final construct/particle configuration.
Training: Verified and on record.
Occupational Medicine: Hepatitis B immunization is offered for work with human cells.

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Assigned Biosafety Level: BSL-2 with BSL-3 practices for applicable HIV-related procedures.
CA ATP-L: Yes.
NIH Guidelines: Previously listed under Section III-D; final subsection to be confirmed after construct clarification.
Category 1 Research: No.
Category 2 Research: No.

Discussion: The committee identified uncertainty in the description and classification of the HIV-based reporter constructs. It was not clear whether the constructs should be classified as lentiviral vectors, plasmids, single-round infectious systems, or another recombinant HIV-based system. The PI should provide a more precise description of the constructs, including the HIV genes and regulatory elements retained or deleted, what components are supplied in trans, the packaging method, pseudotyping/envelope used, and whether infectious particles can be produced. The protocol should also clarify whether any resulting particles are replication competent or limited to a single round of infection. If the system is pseudotyped with VSV-G and produces single-round infectious particles, the NIH Guidelines classification and containment requirements should be based on that actual design. The applicable NIH Guidelines classification and biosafety classification will be confirmed after these details are clarified.

IBC Approval:
The protocol received conditional approval pending clarification of the HIV-based constructs and vector system, and additional review before final approval.

Principal Investigator: Richard Milner
Protocol #: BHR-25-002-RM
Title: Evaluating Integrin Expression in Human Brain Samples
Project summary (from form): The goal is to define the expression pattern of specific integrins in blood vessels and microglia in postmortem human brain samples and determine whether inflammatory vascular changes are associated with altered integrin expression.
Agent: Postmortem human brain tissue.
Additional details from the protocol: Human brain samples are obtained from established sources for sectioning and microscopy.
Manipulations planned: Cryostat sectioning and microscopy.
Recombinant or synthetic nucleic acid molecules: None.
Risk Assessment: Low.
Training: Verified and on record.

Occupational Medicine: Hepatitis B immunization is offered for work 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: The committee discussed hazards associated with cryostat sectioning of frozen/postmortem human brain tissue. The protocol should identify the cryostat location, describe cleaning and decontamination procedures, and explain how other personnel are warned when the instrument is in use with human tissue. Inoculation remains a relevant exposure route because of potential cuts or sharps injuries; intact-skin absorption and ingestion should be removed when not applicable, and mucous-membrane exposure should be added when the form is revised. The aerosol-generating-procedure response should be corrected as appropriate if tissue processing can generate droplets or aerosols. The section describing how the tissue is processed in the laboratory should also be completed.

IBC Approval:
The protocol was unanimously approved at BSL-2, with the modifications discussed. No additional committee review was considered necessary after the corrections are made.

5. IBC form and procedural revisions

The committee discussed several recurring issues in the current IBC forms. “Skin absorption” is not an appropriate default exposure route for many biological agents when referring to intact skin; the committee agreed that “mucous membranes” should be added as a distinct exposure route and that broken-skin/percutaneous exposure should be captured more accurately. PPE terminology will be reviewed, including clarification of “foot protection” as closed-toe footwear versus shoe covers. The committee also discussed adding a specific place to document sharps use and ensuring that aerosol-generating procedures such as pipetting, vortexing, and centrifugation are captured. Vacuum-system questions should request enough detail to document liquid traps, overflow protection, and filtration. Vaccination language will be reviewed so that the IBC documents that applicable vaccination is offered without unnecessarily collecting individual medical information regarding acceptance or declination. The committee also agreed that editable Word versions of protocol forms should be maintained during review; a final PDF may be generated for signature and the official record.

6. Proposed NIH biosafety policy changes

Dr. Laurence Cagnon briefed the committee on proposed NIH changes affecting institutional biosafety oversight. The proposed revisions discussed would expand registration and oversight beyond recombinant or synthetic nucleic-acid research to include certain wild-type biological agents that cause disease in humans and would broaden reporting requirements for exposures, loss of containment, and other incidents. The proposal may also require additional institutional documentation and public-facing reporting of certain lower-risk incidents, including some incidents associated with animal research. The comment period was noted as extending into October 2026. Dr. Cagnon will continue to follow these developments through the biosafety community and report relevant changes to the IBC. The committee also briefly discussed the new U.S. Government policy governing high-risk life-science research and the need to monitor its implementation for future applicability to SDBRI research.

7. NIH Reportable Incidents: None

8. DURC/PEPP: None

9. Next meeting and adjournment

No additional questions were raised. The next IBC meeting is tentatively planned for January or February 2027. Dr. Céline DerMardirossian will confirm committee availability. Dr. Laurence Cagnon thanked the committee members for their participation and adjourned the meeting at 2 pm.

February 13, 2026

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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.

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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

The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.
Principal Investigator: Maria Cecilia Marcondes **Protocol #:** BHR-23-001-MCM **Title:** Metamphetamine abuse and immune system interactions in neuroAIDS **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. **Agent**: Blood, brain tissue, peripheral blood cells and cell lines **Additional details from the protocol**: The samples are commercially available or from vented repositories. **Manipulations planned**: Pipetting, centrifuging, flow cytometry **Recombinant or synthetic nucleic acid molecules**: Pseudoviruses covered under Protocol: rDNA-25-001-MCM **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**: 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. **IBC Approval:** 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.