

Institutional Biosafety Committee - Regular Meeting

Thursday, June 05, 2025

Zoom

Meeting Minutes

VOTING MEMBERS PRESENT:	S. Apewokin, G. Babcock, K. Burns, M. Espinola, G. Dean, S. Kasper, R. Larson, T. Rausch, F. Schaefer, E. Serafin
VOTING MEMBERS NOT PRESENT:	J. Corcoran, D. Elsaesser, E. Otten, J. Yu
AD HOC MEMBERS/CONSULTANTS/GUESTS:	T. Gulley, J. Lambers, J. Strasser
IBC STAFF:	D. Healy, B. Kesavalu

K. Burns convened the meeting at 12:00 p.m.

- I. **Conflicts of Interest** – No conflicts
- II. **Minutes** - Minutes from the previous IBC meeting (05/01/25) were approved (8:YES/0:NO/0:Abstained)
- III. **Old Business** - No old business was discussed
- IV. **New Business**

A. **Primary Protocols*** (3 protocols)

IBC Protocol Number	PI's Link	Type of Submission	IBC Items	
1. 25-05-21-01	Leddon	New Clinical	Recombinant Herpes Simplex Virus 1 (KB707-02)	
IBC Requests:	<u>IBC Form</u> <ol style="list-style-type: none">Section I. A - Same phone number has been listed for office phone and cell phone. Please correct it;Section I. B - Clinical staff need to provide their BBP transcripts - Emily Daugherty, Abby Nienaber;Section II. B - Replace "study doctor" with the name of UC PI for this study;Section II. B - Second Paragraph - Indicate what type of drug "Keytruda" is;Section II. B - Include a statement regarding viral shedding evaluation;Section III. A - Location #2 - Provide the building and room for the administration of the IP;Section III. A - Location #2 – The “Administration Guide” document (page 9) states that patients should be wearing PPE during nebulization. What PPE are those? Include this info in the “other PPE” field;Section III. A - Location #2 - Specific Location Features - Room signage restricting access and indicating type of agent should be posted on door. Also it is strongly recommended that the room be at negative pressure during the procedure. The number of staff involved in the nebulization should be the minimum as possible (one). Please include statements regarding those issues in this section;Section V - Although virus is replication defective, individuals accidentally exposed to KB707 should be offered with post-exposure prophylaxis. Please revise section to reflect this;Section VII - Complete section and provide signature.			
	Motion	Approve upon modification of pending requests		
Voting Result & Dual Use	YES: 10	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI's Link	Type of Submission	Biosafety Level	IBC Items
2. 24-06-22-01	Hoilett	Amendment	BSL2	<i>in vitro</i> : HDM (breast milk), microbial survey (agents to be determined) AMENDMENT: <i>in vitro</i>: Staphylococcus epidermidis, E. coli (RG1), Klebsiella pneumoniae: Project #2 (4)
IBC Requests:	<u>Main Form – General Safety:</u> 1. Section VIII - This section is related to materials that are not part of ongoing research activities and are only maintained in storage. Please revise section accordingly. 2. The IBC raised a concern about the large number of students listed in your protocol and was unsure if all are going to participate in the project involving bacteria, particularly <i>K. pneumoniae</i> . The IBC strongly advises that this organism be handled only by experienced and trained staff.			
Motion	Approve upon modification of pending requests			
Voting Result & Dual Use	YES: 10	NO: 0	Abstained: 0	Dual Use? No

S. Apewokin left the meeting at 12:18 p.m.

B. Secondary Protocols (9 protocols)

IBC Protocol Number	PI's Link	Type of Submission	Biosafety Level	IBC Items
1. 25-04-30-01	Fichtenbaum	New	BSL2 Plus	<i>in vitro</i> : HDM (e.g. blood, tissues, urine, bodily fluids) Core Protocol
IBC Requests:	<u>Main Form – General Safety:</u> 1. Section II. B – Expand CLIA and PBMCs; 2. Section III. B - Check YES for "Additional Information" and indicate which activities involving biological hazardous materials are conducted inside of a fume hood; 3. Section III. B - In "Additional Information", please list types of sharps that are disposed of in the sharps containers; 4. Section III. C - In "Additional Information", please indicate why face (surgical) mask, safety goggles and face shield are used. <u>Form C – Human and NHP Derived Materials:</u> 5. Section I - Table - Description column - Instead of indicating that the source is human, provide from where the different materials come from (e.g. UCMC); 6. Section I - Table - Enter "Species" info for tissues; 7. Section I. A - Primary cells are either deidentified (no identification) or identified. Please revise this section.			
Motion	Approve upon modification of pending requests			
Voting Result & Dual Use	YES: 9	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI's Link	Type of Submission	Biosafety Level	IBC Items
2. 25-04-16-01	Smulian	Amendment	BSL1	<i>in vitro</i> : <i>Pneumocystis carinii</i> , <i>Pneumocystis murina</i> AMENDMENT: <i>in vivo</i>: <i>Pneumocystis murina</i>
IBC Requests:	Main Form – General Safety: <ol style="list-style-type: none"> Section I. D - Please list each experimental location separately if they have different functions; Section II. B - To avoid confusion, please have Project 1 and Project 2 described separately. Also, please define in vitro work for each project. What is analyzed with infected animal samples? Form B - Microbial/infectious agents <ol style="list-style-type: none"> Agent #2 - <i>in vivo</i> - Indicate the infection route(s) for the agent; Form D – Biohazard in Animals: <ol style="list-style-type: none"> Section II - Check the box for "Standard Housing"; Section II - Additional Information - Indicate what is the route of <i>P. murina</i> infection. Also, please confirm that no mice samples/carcasses are sent directly to UC lab. 			
Motion	Approve upon modification of pending requests			
Voting Result & Dual Use	YES: 9	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI's Link	Type of Submission	Biosafety Level	IBC Items
3. 25-04-28-01	Zhang X	Renewal	BSL2	<i>in vitro</i> : Lentiviral vector <i>In vitro</i> and <i>in vivo</i> : HDM (established and primary tumor cells - including virally transduced cells) and synthetic RNA (pRNA/siRNA)
IBC Requests:	Main Form – General Safety: <ol style="list-style-type: none"> Section I. B - If secondary contact does not have an office, enter "N/A". Form D – Biohazard in Animals: <ol style="list-style-type: none"> Section I - Update IACUC protocol number (i.e. 25-02-24-01); Section III. C - In "Additional Information", please list types of sharps that are disposed of in the sharps container. 			
Motion	Approve upon modification of pending requests			
Voting Result & Dual Use	YES: 9	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI's Link	Type of Submission	Biosafety Level	IBC Items
4. 25-05-06-01	Madala	Renewal	BSL2	<i>in vitro</i> : Lentiviral and gamma-retroviral vectors, <i>Escherichia coli</i> (RG1) and HDM (blood, tissues, primary cells including samples from COVID-19 patients) <i>in vitro</i> and <i>in vivo</i> : Adenoviral vector, HDM (established cells)
IBC Requests:	<ol style="list-style-type: none"> Lab staff need to complete their BBP training; Main Form – General Safety: Section I. D - Please confirm that you have now a biosafety cabinet in CARE 5830; Section II. B - please update the COVID19 information to be up to date; Section II. C - Please note that the safety guards for COVID-19 patient derived materials have been relaxed and no longer require enhanced BSL2 practices. Please select the " BSL2" box instead; Section III. A - Pipet - In addition to using a containment equipment (i.e. BSC) there are safety measures that need to be followed while performing activities with potential for aerosol generation. For information on aerosol mitigation procedures, please consult the eManual (link provided on the top of this section); Section III. B - Additional Information - Please remove the sentence regarding double gloves since it was already provided in the PPE section; Section III. C - In "Additional Information", please indicate when face (surgical) mask will be used; Form A – Recombinant or Synthetic Nucleic Acid: Section II. B - System #2 - Helper Plasmids - Include the plasmid for the envelope for the system; Section II. B - System #3 - Remove “GFP” from the list of genes that are inhibited; Section II. B - System #3 - Additional Information - The last sentence regarding helper plasmids is not related to system #3; Section III - Uncheck box #7. Form B - Microbial/infectious agents Section I - Table - Tissues - In description, indicate type of tissues (only lungs?); Section II. A - List the experiments involving human cells, blood and tissues and remove the last sentence regarding COVID 19 samples; Section II. A - Change failure to breath as failure to breathe; Section II. A – Modify the BSL2+ statement to reflect updates in studying COVID19. Form D – Biohazard in Animals: Section I – Update IACUC number (i.e. 22-05-20-01); Section II - Additional Information - Confirm that adenoviral vectors used <i>in vivo</i> only expresses TGFbeta; Section III. B - Provide the routes of administration of human cells and/or adenovirus which animals need anesthesia; Section III. C - In "Additional Information", please list types of sharps that are disposed of in the sharps container. 			
Motion	Approve upon modification of pending requests			
Voting Result & Dual Use	YES: 9	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI's Link	Type of Submission	Biosafety Level	IBC Items
5. 25-05-20-01	Bernstein J	Renewal	BSL2	<i>in vitro</i> : HDM (blood, serum, plasma, skin, seminal fluid, established and primary cell lines)
IBC Requests:	<p><u>Main Form – General Safety:</u></p> <ol style="list-style-type: none"> Section I. B - If no office nor a lab phone exists, enter "N/A"; Section I. D - Check YES or NO for "non-UC Facilities"; Section II. B - Last paragraph - provide the meaning of "HAE" when first mentioned; Section III. A – Centrifuge – For clarity, remove statement about closing lid and not using BSC. Section III. A – Pipet - In addition to using a containment equipment (i.e. BSC) there are safety measures that need to be followed while performing activities with potential of aerosol generation. For information on aerosol mitigation procedures, please consult the eManual (link provided on the top of this section); Section III. B - Additional Information - Please remove statements about surgical masks, N95, and double gloves since they don't belong to this section; Section III. C - Additional Information - Remove reference to "COVID time"; Section VIII - This section is reserved for materials that are not being used in ongoing (nor in a near-future planned) research. Please revise the section if necessary. <p><u>Form C – Human and NHP Derived Materials:</u></p> <ol style="list-style-type: none"> Section II. A - Include the experiments that use human cell lines. 			
Motion	Approve upon modification of pending requests			
Voting Result & Dual Use	YES: 9	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI's Link	Type of Submission	Biosafety Level	IBC Items
6. 25-05-20-01	Phoenix	Renewal	BSL2	<i>in vitro</i> : Escherichia coli (RG1) and HDM (cell lines) <i>in vitro</i> and <i>in vivo</i> : plasmid DNA
IBC Requests:	<p><u>Main Form – General Safety:</u></p> <ol style="list-style-type: none"> Section II. B - Project #3 - Describe the in vivo project involving plasmid DNA; Section II. B - Remove last paragraph since projects involving AAV vector is no longer used; Section III. A - Pipet - Please change "plugged pipettes" to "cotton-plugged" pipettes; Section V - Additional Information - Remove reference regarding use of AAV. <p><u>Form A – Recombinant or Synthetic Nucleic Acid:</u></p> <ol style="list-style-type: none"> Section I - Gene #5 - Verify spelling of gene. In section II. B. this gene is spelled as H3.3K27M instead. Please revise this or Section II.B accordingly; Section I - Gene #22 - Indicate if gene is expressed and/or inhibited; Section II. B - Some genes listed in Section I were indicated as expressed by viral vectors but are not listed in this section (i.e. genes #8, #10, #18). <p><u>Form D – Biohazard in Animals:</u></p> <ol style="list-style-type: none"> Section III. A - Transfer information to the "Additional Information" of Section II. In this section, indicate if any risk of exposure exists; 			

	9. Section III. C - In "Additional Information" indicate what kind of sharps are disposed of in sharps containers.			
Motion	Approve upon modification of pending requests			
Voting Result & Dual Use	YES: 9	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI's Link	Type of Submission	Biosafety Level	IBC Items
7. 25-05-23-01	Lewis	Renewal	BSL2	<i>in vitro</i> : gamma-retroviral vector, HDM (blood, serum, plasma, tissues) and <i>Escherichia coli</i> (RG1) <i>in vitro</i> and <i>in vivo</i> : HDM (established cell lines, including virally transduced cells)
IBC Requests:	<p>1. Lab staff need to complete their BBP, viral vector and BSC trainings; <u>Main Form – General Safety:</u></p> <p>2. Section I. B - If no phone is present in the lab, enter "N/A";</p> <p>3. Section II. B - The description provided is confusing/truncated please revise section for clarity;</p> <p>4. Section III. A - Tissue Grinder & Sonicator - Mitigation provided is related to splash and not to aerosol generation. Please consult the eManual (link provided on the top of this section);</p> <p>5. Section III. B - Check YES for "Additional Information" and indicate what type of sharps will be discarded in the sharps containers. <u>Form C – Human and NHP Derived Materials:</u></p> <p>6. Section I - Table - Primary cells - Description - Indicate from where hepatocytes are obtained. <u>Form D – Biohazard in Animals:</u></p> <p>7. Section III. C - Check YES for "Additional Information" and indicate what type of sharps will be discarded in the sharps containers.</p>			
Motion	Approve upon modification of pending requests			
Voting Result & Dual Use	YES: 9	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI's Link	Type of Submission	Biosafety Level	IBC Items
8. 25-05-23-02	Ulrich-Lai	Renewal	BSL2	<i>in vivo</i> : AAV vector
IBC Requests:	<ol style="list-style-type: none"> 1. Lab staff needs to complete their viral vector training; Main Form – General Safety: 1. Section III. A - Centrifuge - Does your lab centrifuge have a rotor that can be sealed? If so, please state; 2. Section V – In “Additional Information”, include statement about wiping off bleach with alcohol for avoiding corrosion of metallic surfaces; IBC Form A: Recombinant or Synthetic Nucleic Acid 3. Section II. B – Systems #4 and #5 – “Parent Virus” should be “AAV2”. Then, in “Additional Information” please say that the serotype of the vector (cap gene) is AAV. Form D – Biohazard in Animals: 4. Section I - Update your IACUC protocol number (i.e. 23-05-30-01); 5. Section III. C - Check YES for "Additional Information" and indicate what type of sharps will be discarded in the sharps containers. 			
Motion	Approve upon modification of pending requests			
Voting Result & Dual Use	YES: 9	NO: 0	Abstained: 0	Dual Use? No

IBC Protocol Number	PI's Link	Type of Submission	Biosafety Level	IBC Items
9. 25-05-28-01	Holland	Renewal	BSL2	<i>in vitro</i> : <i>Staphylococcus aureus</i> and HDM (whole blood and plasma)
IBC Requests:	<ol style="list-style-type: none"> 1. Lab staff's BBP training expiring tomorrow; Main Form – General Safety: 2. Section III. A - Pipet - In addition to using a containment equipment (i.e. BSC) there are safety measures that need to be followed while performing activities with potential of aerosol generation. For information on aerosol mitigation procedures, please consult the eManual (link provided on the top of this section); 3. Section V – In “Additional Information, name the way the 10% household bleach is being rinsed away after the appropriate contact time; 4. Section III. C - Additional Information - Remove statement about mucosal protection PPE for COVID-19. Form B - Microbial/infectious agents 5. In vitro use - Describe how clots are infected with <i>S. aureus</i> 			
Motion	Approve upon modification of pending requests			
Voting Result & Dual Use	YES: 9	NO: 0	Abstained: 0	Dual Use? No

***Primary Protocol** - continuation

IBC Protocol Number	PI's Link	Type of Submission	IBC Items	
3. 25-05-21-02	Martini	New Clinical	Adenoviral vector (CORE-008)	
IBC Requests:	<u>IBC Form</u> <div><div>1. Section I. A - Same phone number has been listed for office phone and cell phone. Please correct it;</div><div>2. Section II. C. 1: Gene Table - The E2F-1 promoter in "Natural function..." sentence seems to not be finished;</div><div>3. Section II. C. 3 - Technical Name - Include "cretostimogene grenadenorepvec" as another name for the vector;</div><div>4. Section III - Location #2 - Replace biosafety cabinet "splash shield' with "sash";</div><div>5. Section III. D - The description of the procedure is not clear. What will be in contact for 10 minutes? Just absorbent towels without a disinfectant?</div><div>6. Section VII - Complete section and provide signature.</div></div>			
	Motion	Approve upon modification of pending requests		
Voting Result & Dual Use	YES: 9	NO: 0	Abstained: 0	Dual Use? No

V. Protocol Updates (APRIL 23rd to May 29th) - 13 protocols

- IBC# 22-11-17-01 - PI: Kotagiri - Personnel
- IBC# 23-12-19-01 - PI: Huang W - Personnel
- IBC# 25-04-15-01 - PI: Wise-Draper- Personnel
- IBC# 24-12-09-01 - PI: Deepe - Personnel
- IBC# 24-09-11-01 - PI: Supp - Personnel
- IBC# 25-02-14-01 - PI: Drosatos - Personnel
- IBC# 24-08-21-03 - PI: Johnson - Location
- IBC# 24-06-22-01 - PI: Hoilett - Project #2 (4), Personnel
- IBC# 24-08-14-01 - PI: Conforti- Personnel
- IBC# 23-01-27-01 - PI: Srivastava - PI Reassignment, Personnel
- IBC# 23-09-13-01 - PI: Gao - Personnel
- IBC# 24-06-18-02 - PI: Byrd - Personnel
- IBC# 23-09-28-01 - PI: Zimmermann - Personnel

VI. Reports

A. **IBC** (M. Espinola)

- IBC roster was posted by NIH/OSP and is available for public access as of June 2025.

B. **BSOf** (M. Espinola)

- The new DURC and PEPP policies did not become effective in May 2025. Instead, the Executive Order (EO) of 05/05/25 requires that the policy be revised and replaced within 120 days. This EO includes funding restrictions and pause of some Gain-of-Function research.
- UC will be hosting the Annual MABioN Symposium from August 4 to August 6, 2025.

- The BSO of will sponsor the Symposium registration for IBC members. Interested members must contact the BSO of by 06/06/25.
- The symposium agenda is not complete, but the majority of the local speakers will focus on field research.

VII. Educational Materials/Updates

- A. [IMPROVING THE SAFETY AND SECURITY OF BIOLOGICAL RESEARCH](#) The White House, May 2025
- B. [Fact Sheet: President Donald J. Trump Achieves Improved Safety and Security of Biological Research](#) The White House , May 2025
- C. [Trump freezes 'gain of function' pathogen research — threatening all US virology, critics say](#) Nature, May 2025

K. Burns adjourned the meeting at 12:43 p.m.

