



THE UNIVERSITY  
of NORTH CAROLINA  
at CHAPEL HILL

ENVIRONMENT, HEALTH & SAFETY

CAMPUS BOX 1650  
CHAPEL HILL, NC 27599 -1650

T 919.962.5507  
F 919.962.0227  
[ehs.unc.edu](http://ehs.unc.edu)

May 23, 2006

Edward H. Hammond  
Director  
The Sunshine Project  
P.O. Box 41987  
Austin TX 78704

Dear Sir:

Enclosed are minutes of our Institutional Biosafety Committee, as you requested in your letter of March 15, 2006. We respectfully decline to respond to the "Fink Committee" report question posed in your letter.

Sincerely yours,

A handwritten signature in blue ink, reading "Raymond W. Hackney, Jr." with a stylized flourish at the end.

Raymond W. Hackney, Jr., DrPH, CIH, CBSP  
Industrial Hygiene Manager  
Dept. of Environment Health and Safety

Enclosures

Monday, May 5, 2003

### Minutes

Members present: Ray Hackney, Tom Kawula, Nancy Davis, John Olsen, John Worthington

Members absent: Robert Bosworth, Andrew Kaplan, Ed Holland, Xiaohuai Zhou

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
Gary	Johnson	04/09/2003	Approved
Adrienne	Cox	04/05/2003	Approved
Joseph	Kieber	04/19/2003	Approved
Manzoor	Bhat	04/07/2003	Not approved. Must provide: specific indication of the inserted sequences, description, lab location
R.J.	Samulski	04/01/2003	Approved
Terry	Van Dyke	04/28/2003	Approved
Tim	Nichols	04/08/2003	Approved

Monday, June 9, 2003

## Minutes

Members present: Ray Hackney, Tom Kawula, Andrew Kaplan, Ed Holland, John Olsen, John Worthington

Members absent: Robert Bosworth, Nancy Davis, Xiaohuai Zhou

The annual memo to rDNA researchers was reviewed and approved with minor revisions. Experiments that require IBC approval to include: transfer of cells modified by rDNA material

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
Ivan	Rusyn	05/06/2003	Approved
Michael	Wheeler	05/28/2003	<u>Lipid metabolism and hepatic fibrosis</u> : Approved <u>Hepatic stellate cell activation and HCV</u> : Not approved. (1) indicated amount of viral genome present within germline of transgenic animal (2) indicate whether mice are viremic for HCV and if HCV is shed in feces (3) indicate potential risk of HCV transmission to lab personnel (4) indicate animal biosafety level
Dhaval Kumar	Patel	05/01/2003	Approved
Manzoor	Bhat	04/07/2003	Not approved. Must clarify answer to question 10 regarding the use of pathogenic organisms in rDNA work
Kiyoshi	Miki	05/08/2003	Approved
C. William	Davis	05/22/2003	Approved
Patrick	Flood	05/27/2003	Approved
Andrew	Kaplan	05/15/2003	Approved
Timothy	Nichols	05/15/2003	2 protocols approved
Yi	Zhang	05/12/2003	Approved
Ralph	Baric	04/28/2003	Approved. Directed to conduct > 2/3 length of SARS DNA at BSL-3

### Minutes

Members present: Andrew Kaplan, Tom Kawula, Ed Holland, John Olsen, John Worthington

Members absent: Robert Bosworth, Xiaohuai Zhou, Ray Hackey

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
Da-Zhi	Wang	07/08/2003	Not Approved: Comments: <ul style="list-style-type: none"> <li>Section III, 1. Provide a more detailed description of the adenoviral vector.</li> <li>Section III, 6. Provide a description of assays used to determine that replication competent viruses are excluded.</li> </ul>
John	Sondek	Not dated	Not Approved: Comments: <ul style="list-style-type: none"> <li>Does require IBC approval</li> <li>Complete current version of Schedule G, date and sign</li> <li>Provide more detailed description of vector</li> <li>Indicate recipient cells</li> </ul>
William	Kaufmann	07/20/2003	Approved
Timothy	Nichols	06/27/2003	Approved
Ellen	Weiss	07/03/2003	Approved
Terry	Van Dyke	06/17/2003	Approved
Michael	Wheeler	05/28/2003	Approved; to be conducted at BL-2
P. Kay	Lund	06/17/2003	Approved; to be conducted at BL-2
Joyce	Harp	06/24/2003	Approved
Tal	Kafri	06/30/2003	Approved
Bruce	Caims	07/01/2003 07/02/2003	Approved Approved
Mark	Majesky	07/17/2003	Approved
Sri	Edupunganti	05/16/2003 05/20/2003	Approved Approved
Aravinda	de Silva	07/16/2003	Approved
Randy	Thresher	06/25/2003	Approved
Manzoor	Bhat	04/07/2003	Approved as described. Any use of additional vectors, genes must be approved by IBC



Minutes

Members present: Tom Kawula, Ray Hackney, Nancy Davis, John Olsen, John Worthington, Dwight Bellinger

Members absent: Robert Bosworth, Ed Holland, Andy Kaplan, Xiaohuai Zhou

Tom Kawula presented documents requesting approval to work with *F. tularensis* LVS in a BL-2 lab using BL-2 procedures and containment. The committee requested that an amended Laboratory Safety Plan be submitted.

first name	last name	Registration Date	IBC comments
James	Mohler	09/25/2003	Requested location of production of lentivirus vector. Approved
Terry	Van Dyke	09/19/2003	Requested location of production of lentivirus vector. Approved
Thomas J.	McCown	09/23/2003	Requested location of production of lentivirus vector. Approved
Gary	Johnson	09/10/2003	Approved two protocols
Marcus	Mall	09/30/2003	Approved
Robert	Johnston	09/22/2003	Approved
Rachel T.	Noble	10/02/2003	Approved
Jeffery	Dangl	07/15/2003	Approved

## Minutes

Members present: Tom Kawula, Nancy Davis, Ray Hackney, John Olsen, Ed Holland, Dwight Bellinger, John Worthington

Members absent: Robert Bosworth, Andy Kaplan, Xiaohuai Zhou

Following review and discussion of an addendum to his Laboratory Safety Plan, Tom Kawula's request to work with *F. tularensis* (LVS) in a BL-2 lab using BL-2 procedures and containment was approved.

Robert Marriott of the School of Medicine Planning office presented preliminary SOPs for the planned BL-3 suite to be built on the 9<sup>th</sup> floor of the Burnett-Womack building. The concept for this laboratory area was approved by the IBC. A letter from the IBC chair indicating approval will be forwarded to B. Marriott.

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
Young	Whang	10/15/2003	Dr. Kaplan indicated that he had reviewed and approved the human vaccine protocol. Approved
Terry	Van Dykel	10/22/2003	Approved
Eva	Anton	10/02/2003	Approved
Mohanish	Deshmukh	10/22/2003	Approved
Lola	Reid	10/13/2003	Approved
W. Kimryn	Rathmell	10/07/2003	Approved
Christopher	Gregory	10/10/2003	Approved at BL-2

## Minutes

**Members present:** Tom Kawula, Nancy Davis, Ray Hackney, John Olsen, Ed Holland, Dwight Bellinger, John Worthington

**Members absent:** Robert Bosworth, Andy Kaplan, Xiaohuai Zhou

Ralph Baric attended the meetings to discuss his proposed work with SARS coronavirus in BL-3 facilities in McGavran-Greenberg and short-term work in the BL-3 lab in MBRB. Discussion included:

- the need for communication with the Dept. of Infectious Diseases regarding the work in MBRB.
- security of MBRB BL-3 lab.
- transport of infectious materials from MBRB to Rosenau.

The proposed work was approved contingent upon final approval of the Laboratory Safety Plan by EHS and an exposure follow-up plan by UEOHC.

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
R.J.	Samulski	12/03/2003	Comments: Signature and date required, do require approval, GFP is a foreign protein, approved 12/03/2003
Barbara	Grubb	11/11/2003	Approved
Ben	Philpot	11/07/2003	Approved
Mark	Majesky	10/23/2003	Approved
Shawn	Ahmed	10/24/2003	Approved; Comments: experiments do require IBC approval, are to be conducted at BL-1
Christian	Jobin	10/30/2003	Approved
Randy	Thresher	11/04/2003	Approved
Timothy	Nichols	11/11/2003	Approved; Comments: indicate the envelop genes that are on the retroviral vectors, clarify if gene transfer will be in cells or in animals. The requested information was provided by T. Nichols on 12/02/2003
M.	Cordeiro-Stone	11/11/2003	Approved; Comments: indicate the envelop genes that are on the retrovirus. The requested information was received on 12/04/2003.
Robert	Johnston	11/14/2003	Approved; Comments: Indicate the mutations that will be included in the SIV envelop gene being inserted into the vector. The requested information was received on 12/03/2003.
Christopher	Elkins	09/15/2003	Approved contingent on answers to question 8 & 9 of registration. Has been contacted. A response has not been received.



Minutes

Members present: Ray Hackney, Nancy Davis, John Olsen, John Worthington

Members absent: Robert Bosworth, Andrew Kaplan, Xiaohuai Zhou, Ed Holland, Dwight Bellinger, Tom Kawula

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
Larry	Johnson	12/12/2003	Approved
Robert	Mueller	11/13/2003	Approved
Idramuddin	Aukil	10/24/2003	Approved. Experiments are to be conducted at BL-1
Terry	Van Dyke	12/04/2003	Approved
Timothy	Nichols	11/24/2003	Approved. Experiments with adenovirus vectors are to be conducted at BL-2
Robert	Johnston	11/26/2003	Approved. Comments: The same four mutant forms that were approved in the 12/1/04 meeting will also be used in this protocol
Cornelis	Beckers	11/19/2003	Approved after receiving Dr. Kawula's approval. Toxoplasma GAP45 will be produced as a foreign protein
Shelton	Earp	12/16/2003	Approved
Kevin	Behms	11/17/2003	Not approved. Requested answer to questions Section II: 8, 9, 10 of Schedule G
Stephen	Crews	11/20/2003	Not approved. Requested clarification of experiments that will be done in E. coli and Drosophila
JrGang	Cheng	12/02/2003	Not approved. Specific experiments to be done in the core lab must be registered and approved. "Blanket" approval of all work can not be given.

### Minutes

Members present: Dwight Bellinger, Tom Kawula, Nancy Davis, John Olsen, John Worthington

Members absent: Robert Bosworth, Andrew Kaplan, Xiaohuai Zhou, Ed Holland, Ray Hackney

A letter from the Sunshine Project requesting IBC minutes and information regarding Select Agents was presented to the committee. The committee agreed that University Counsel should make a decision regarding the request.

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
James	Anderson	01/30/2004	Approved
Marion	Couch	12/18/2003	Approved
Richard	Samulskil	12/31/2003	Approved
Kevin	Behrms	11/17/2003	Approved
Roland	Tisch	01/29/2004	Two protocols approved
Karl	Simin	01/15/2004	Approved
Dhaval Kumar	Patel	01/01/2004	Approved
Tal	Kafri	01/20/2004	Approved
Zhelong	Xu	01/08/2004	Approved
Sarah	Liljegren	01/05/2004	Approved
Randy	Thresher	01/20/2004	Approved
Zhijian	Wu	02/12/2004	Not approved. Clarification needed regarding the use of adenovirus vectors. If Ad vectors are to be used, the experiments are to be performed at BL-2. Answer to Section III, question 6, must describe in detail experiments that will be done to indicate exclusion of replication competent Ad virus.

### Minutes

Members present: Robert Bosworth, Dwight Bellinger, Tom Kawula, Nancy Davis, John Olsen, Ray Hackney

Members absent: Andrew Kaplan, Xiaohuai Zhou, Ed Holland

Ray Hackney reported on University Counsel's advice regarding the Sunshine Project's request for minutes of the December and January IBC meetings. Copies of the minutes were forwarded to the Sunshine Project. The University respectfully declined to answer the question of whether the University was registered for select agents.

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
Edward	Collins	02/10/2004	approved
Bernard	Weissman	02/11/2004	approved
Bernard	Weissman	02/11/2004	approved
Bernard	Weissman	02/11/2004	approved
Dhaval Kumar	Patel	02/03/2004	approved
Dhaval Kumar	Patel	02/03/2004	approved
Dhaval Kumar	Patel	02/03/2004	approved
Dhaval Kumar	Patel	02/03/2004	approved
Dhaval Kumar	Patel	02/03/2004	approved
Dhaval Kumar	Patel	02/03/2004	approved
Dhaval Kumar	Patel	02/03/2004	approved
Dhaval Kumar	Patel	02/03/2004	approved
Dhaval Kumar	Patel	02/03/2004	Approved
Zhijian	Wu	02/12/2004	Approved with the stipulation that the registration document is submitted with the PI's name and signature
Tal	Lewin	02/18/2004	Approved with the stipulation that the registration document is submitted with the PI's name and signature

Minutes

Members present: Robert Bosworth, Dwight Bellinger, Tom Kawula, Nancy Davis, John Olsen, Ray Hackney

Members absent: Andrew Kaplan, Xiaohuai Zhou, Ed Holland

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
Raymond	Pickles	02/20/2004	approved
Raymond	Pickles	03/02/2004	approved
Raymond	Pickles	03/02/2004	approved
Raymond	Pickles	03/02/2004	approved
Kathleen	Caron	03/24/2004	approved
Kathleen	Caron	03/24/2004	approved
Jenny	Ting	03/24/2004	approved
Ben	Philpot	04/27/2004	approved
Kimryn	Rathmell	04/21/2004	approved
Kimryn	Rathmell	04/21/2004	approved
Kimryn	Rathmell	04/21/2004	approved
Kimryn	Rathmell	04/21/2004	approved
Kimryn	Rathmell	04/21/2004	approved
Kimryn	Rathmell	04/21/2004	approved
Kimryn	Rathmell	04/21/2004	approved
Kimryn	Rathmell	04/21/2004	approved
Leslie	Parise	04/09/2004	approved ; not rDNA
Leslie	Morrow	04/27/2004	approved
Leslie	Morrow	04/27/2004	approved
Todd	Thiele	04/28/2004	approved

## Minutes

Members present: Robert Bosworth, John Olsen, Ray Hackney, Andrew Kaplan, Ed Holland

Members absent: Xiaohuai Zhou, Dwight Bellinger, Tom Kawula, Nancy Davis,

Minutes for April 5, 2004 and May 3, 2004 were approved.

Open meeting requirements were discussed. The IBC will generally operate with its meeting open to the public. A closed meeting may be designated if there is proprietary information to be discussed. The committee may also go into closed meeting to discuss biosecurity issues. The committee felt that the conditions for closed meetings should be communicated to principal investigators who may be submitting registration documents to the IBC.

A form used by the UNC Vector Core was reviewed. This form is completed by PIs who are ordering vectors to be made by the Vector Core and would be reviewed by the IBC. The committee approved this form.

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
Thomas	McCown	06/01/2004	Approved; BSL-2 containment for human cells
Elizabeth	Wilson	05/11/2004	Questions 8, 9, and 10 need to be answered. Approved after revised Schedule G submitted.
Richard	Samulski	05/03/2004	Approved; BSL-2 containment for human cells
Terete	Borras	05/31/2004	Questions 8, 9, and 10 need to be answered. Question 6 of section IV needs to be completed. Resubmitted Schedule G approved.
Albert	Baldwin	05/19/2004	Approved
Mark	Wightman	05/19/2004	Approved
Fullton	Crews	05/03/2004	Approved
Joseph	Muenzer	04/29/2004	Approved
Sri	Edupuganti	04/06/2004	Approved

## Minutes

Members present: John Olsen, Ray Hackney, Andrew Kaplan, Dwight Bellinger, Nancy Davis, Jennifer Giles

Members absent: Robert Bosworth, Tom Kawula, Ed Holland

Also present: Peter Reinhardt

Jennifer Giles was introduced as a new member of the IBC.

Minutes for June 3, 2004 was approved as corrected.

Pete Reinhardt explained the NIH's new National Science Advisory Board on Biosecurity, and their guidance to expand the scope of IBCs. An executive summary of a National Research Board report was discussed.

The following registration documents were reviewed:

first name	last name	Registration Date	IBC comments
Frank	Longo	12/15/2003	Approved; provide map
Richard	Samulski	07/29/2004	Approved
Richard	Samulski	07/28/2004	Approved
Richard	Samulski	07/29/2004	Approved
Richard	Samulski	07/29/2004	Approved
Richard	Samulski	06/07/2004	Approved; BSL-2 for human cells
Rosalind	Coleman	05/20/2004	Approved
John	Olsen	06/30/2004	Approved
John	Olsen	06/30/2004	Approved
John	Olsen	06/30/2004	Approved
Terry	Magnuson	06/28/2004	Approved
James	Bear	06/25/2004	Approved
James	Bear	06/25/2004	Approved
Charles	Perou	06/30/2004	Approved
Tal	Kafri	06/14/2004	Approved
Thomas	McCown	06/01/2004	Approved; BSL-2 for human cells
Marion	Couch	07/12/2004	Approved
Timothy	Nichols	07/27/2004	Approved
Timothy	Nichols	07/27/2004	Approved
Timothy	Nichols	07/27/2004	Approved
Jonathan	Serody	06/25/2004	"Are there any risks of accidental inoculation of laboratory workers resulting in an increased risk for tumorigenesis? If so, what precautions are taken to minimize the risk?" Revised registration document approved.



## Meeting Minutes October 4, 2004, 3:30 p.m.

### Members Present:

John Olsen  
Nancy Davis  
Ray Hackney  
Donii Fox

### Members Absent:

Andrew Kaplan  
Jennifer Giles  
Ed Holland  
Tom Kawula  
Robert Bosworth  
Dwight Bellinger

The following registration documents were reviewed:

last name	Title	Registration Date	IBC comments
Caron	Phenotype of Genetically Reduced Adrenomedulin in Pregnancy	09/03/2004	Approved
Pickles	Nasal Instillation of Sendai Virus in Mice	09/21/2004	Approved
Pickles	Nasal Instillation of Sendai Virus in Mice (Transgenic Animals)	09/21/2004	Approved
Arendshorst	Renal Vascular Reactivity in Genetic Hypertension	08/31/2004	Approved
Takahashi	Renal Vascular Reactivity in Genetic Hypertension	08/31/2004	Approved
Styblo	Arsenic, Oxidative Stress, and Transcriptional Control and Mechanism of Arsenic-Induced Diabetes	09/27/2004	Approved
Styblo	Arsenic, Oxidative Stress, and Transcriptional Control and Mechanism of Arsenic-Induced Diabetes (Transgenic Animals)	09/27/2004	Approved
Zhang	ARF MDM2 P53 Tumor Suppression Pathway (Transgenic Animals)	09/03/2004	Approved with additional info. Need info about where transgenic animal was made and what other transgenic animal will it be crossed with.
Zhang	ARF MDM2 P53 Tumor Suppression Pathway	09/03/2004	Approved with additional info. Provide reference for vector.
Baric	Synthetic Biology and Homeland Defense	09/02/2004	Will review at next meeting. Ralph Baric will be invited to attend and provide additional information to the committee.

Meeting adjourned at 4:45 p.m.



## Meeting Minutes November 1, 2004, 3:30 p.m.

### Members Present:

John Olsen	Andrew Kaplan
Nancy Davis	Jennifer Giles
Ray Hackney	Ed Holland
Donii Fox	Tom Kawula
Dwight Bellinger	Robert Bosworth

### Members Absent:

### Guests:

Robert Johnston  
Ralph Baric  
Pete Reinhardt  
Deborah Howard

### I. Presentation by Ralph Baric

Ralph Baric attended to give a presentation about the three proposed projects he has submitted for IBC approval and to answer questions about the projects. Dr. Baric left the meeting prior to IBC discussion of his registration documents. The following concerns were raised for each project:

#### **Synthetic Biology and Homeland Defense**

This project involves the reconstitution of Human Coronavirus-NL63 from synthetically derived cDNAs purchased from commercial vendors. Designer and ancestral viruses will be made by replacing the ORF3 site with influenza NS1 and Ebola VP35 and replacing the wildtype S glycoprotein with ancestral S glycoproteins.

#### **IBC Discussion and Concerns:**

Flu NS1 and Ebola VP35 are interferon antagonists and may enhance replication or pathogenesis of HuCoV-NL63 even if virus is attenuated. Essentially, an unknown virus with unknown properties will be developed. Worst case would be that the virus would be replication competent and be more virulent due to the NS1. It was suggested that lab procedures should be observed by EHS.

#### **Safety Measures Outlined in Protocol:**

Assembly of the "designer virus" will be done in a BSL3 laboratory. Once the viruses are made, replication will be measured in Vero cells and then the viruses will be destroyed.

#### **Recommendations:**

In addition to the safety measures outlined in project proposals, IBC also recommends that 1) HuCoV-NL63 cDNA fragments containing Flu NS1 and Ebola VP35 sequences be destroyed when the project is complete, 2) destruction of virus and cDNA be witnessed by EHS and documented by laboratory personnel, 3) current inventory records be maintained for all virus and cDNA, and 4) human corona virus antibody titer surveillance of lab employees. It is suggested that, if practical, employees working on the project should have neutralizing antibody titers to HuCoV-NL63.

#### **Synthetic Reconstruction of a Full Length HuCoV-NL63 genome**

This project involves the reconstitution of Human Coronavirus-NL63 from synthetically derived cDNAs purchased from commercial vendors. Candidate vaccine strains will also be synthetically assembled by deletion of HuCoV-NL63 group specific ORF 3 and inserting either ectodomain of the Marburg virus GP glycoprotein or green fluorescent protein.



### **IBC Discussion and Concerns:**

Recombination is common in coronaviruses. There could be increased pathogenesis if recombination occurs with the inserted Marburg GP glycoprotein ectodomain. Questions were raised about the applicability of the select agent rule to the Marburg GP glycoprotein. Genetic elements from select agent viruses are regulated if they encode infectious or replication competent forms of the select agent viruses. This would not apply in this case.

The NIH Guidelines (Section III-D-2) require BSL4 containment if DNA from risk group 4 agents (i.e. Marburg) is transferred into nonpathogenic prokaryotes. However, if the fraction of the agent's genome is demonstrated to be totally and irreversibly defective BSL 2 is acceptable. DNA from Marburg will be transferred into a pathogenic virus, but the DNA will be totally and irreversibly defective (it is only the ectodomain of the Marburg GP glycoprotein). It was suggested that lab procedures should be observed by EHS.

### **Safety Measures Outlined in Protocol:**

Assembly of recombinant vaccine viruses encoding the Marburg GP glycoprotein will be done in a BSL3 laboratory. Once the viruses are made, replication will be measured in Vero cells and then the viruses will be destroyed.

### **Additional IBC Requirements:**

IBC also requires that 1) HuCoV-NL63 cDNA fragments containing Marburg GP sequences be destroyed when the project is complete, 2) destruction of virus and cDNA be witnessed by EHS and documented by laboratory personnel, 3) current inventory records be maintained for all virus and cDNA, and 4) It is suggested that, if practical, employees working on the project should have neutralizing antibody titers to HuCoV-NL63.

### **Marburg Virus Reverse Genetics and Pathogenesis**

This project involves cDNA cloning of fragments of the Marburg virus genome.

### **IBC Discussion and Concerns:**

Questions were raised as to the applicability of the Select Agent Rule to this research. It is not likely considered a select agent because the lab will not possess, at any time, replication competent forms of the Marburg virus. However, EHS has requested feedback from the CDC. It was suggested that lab procedures should be observed by EHS.

### **Safety Measures Outlined in Protocol:**

USAMRIID safety tests all RNA provided to Dr. Baric to insure destruction of all infectious virus. Handling of this Marburg RNA and work with the unassembled recombinant plasma set will be done under BSL2 conditions. The recombinant plasmids will be sent to USAMRIID for full length cDNA assembly under BSL4 conditions. All plasmid clones created at UNC will be less than 2/3 genome length. Full length MARV cDNA is not infectious because it lacks the replicase proteins for replication and transcription. In addition, cells must express four helper genes to increase infectivity. The MARV A clone is required for infectivity as well. The MARV A clone has already been developed and all of it has been sent to USAMRIID to prevent assembly of the entire cDNA at UNC.

### **Recommendations:**

In addition to the safety measures outlined in project proposals, IBC also recommends that 1) send the MARV D cDNA to USAMRIID to ensure that there is never more than 2/3 of genome in the UNC lab, 2) transfer all cDNA to USAMRIID or destroy at the end of the project, 3) transfer or destruction of any cDNA be witnessed by EHS and documented by laboratory personnel, and 4) current inventory records be maintained for all cDNA.

## II. The following registration documents were reviewed:

Last name	Title	Registration Date	IBC comments
Baric	Synthetic Biology and Homeland Defense	09/02/2004	Conditional Approval. Additional safety measures regarding disposal and surveillance.
Baric	Marburg Virus Reverse Genetics and Pathogenesis	09/15/2004	Conditional Approval. At no time can lab have greater than 2/3 genome.
Baric	Synthetic Reconstruction of a Full Length HuCoV-NL63 genome	09/02/2004	Conditional Approval. Additional safety measures regarding disposal and surveillance.
Mitchell	Nucleoside and Nucleotide Metabolizing Enzymes	09/30/2004	Approved
Pollack	P-gp Modulates Opioid Peptide Pharmacodynamics	10/05/2004	Approved
Livraghi	Sodium Hyperabsorption and Oxygen Radical Production in Airway Epithelia	10/06/2004	Approved
Samulski	Pharmacodynamics of genes and oligonucleotides; To understand the biodistribution and pharmacodynamics of genes and oli	10/06/2004	Approved
Dittmer	Regulation of the KSHV LANA Promotor (CA109232)	09/30/2004	Approved
Cook	Initiation of DNA replication in mammalian cells	10/05/2004	Conditional Approval. Need page 2 of registration
Miller	Quinolone resistance in Salmonella	10/07/2004	Approved
Miller	Viral controls for clinical real time PCR assays	10/07/2004	Approved

Meeting adjourned at 5:20 p.m.



## Meeting Minutes January 3, 2005, 3:30 p.m.

### Members Present:

John Olsen  
Nancy Davis  
Dwight Bellinger  
Andrew Kaplan  
Jennifer Giles

### Members Absent:

Robert Bosworth

### Guests:

Deborah Howard

I. The minutes of the 12/06/04 IBC meeting were reviewed and approved.

### II. Agenda Items

1. Frequency of registration renewals. The IBC members agreed that renewals of previously approved Schedule G's should not be required. A letter will be drafted to be sent to all Principal Investigators with approved Schedule G's greater than 5 years old requesting that they notify us of the current status of their project.
2. Update on Jonathan Serody's *F. tularensis* protocol. As recommended by the IBC, Dr. Serody revised his Schedule F for *F. tularensis* LVS and resubmitted the form to EHS for approval. The aerosol chamber equipment will be set up in the ABSL3 laboratory in the McGavran-Greenberg DLAM facility for use with LVS. EHS needs to approve the equipment once it has been set up.
3. SARS Laboratory Incident. EHS notified the committee of a potential exposure event in the SARS laboratory. An employee was viewing mutant strains of SARS-CoV in closed containers under the microscope. She adjusted her PAPR hood and the faceshield cracked but her PAPR maintained positive pressure. She immediately decontaminated and left the laboratory. The medical monitoring procedure for "potential exposure events" was implemented, requiring the employee to monitor her temperature and call in to UEOHC daily for 10 days. No illness resulted.
4. NIH Guidelines Reminder Letter to Principal Investigators. A letter was drafted by EHS to remind all Principal Investigators of their responsibilities under the NIH Guidelines. The letter was approved by the IBC and will be sent out by EHS.

### III. The following registration documents were reviewed:

Last name	Title	Registration Date	IBC comments
Malouf	Adult Stem Cell Differentiation in the Heart	11/01/2004	Approved
Rippe	Collagen Gene Regulation	12/01/2004	Approved
Baric	Developing vaccine candidates for the SARS Coronaviruses	11/29/2004	Approved pending EHS approval of facility.
Baric	Developing vaccine candidates for the SARS	11/29/2004	Approved pending EHS

Science IBC Archive | Sunshine Project | C.F. Institute

Last name	Title	Registration Date	IBC comments
	Coronaviurs		approval of facility.
Baric	Lab Safety Plan-Hooker BSL3	11/29/2004	Approved pending EHS approval of facility and staff.
Juliano	Pharmacodynamics of Genes and Oligonucleotides	12/01/2004	Approved
Magnuson	Gene Dissection of Autism-related Behaviors in Mice (Mice from USC)	12/01/2004	Approved
Magnuson	Gene Dissection of Autism-related Behaviors in Mice (Mice from Sulik, UNC)	12/01/2004	Approved
Magnuson	Gene Dissection of Autism-related Behaviors in Mice (Mice from Uof Illinois)	12/01/2004	Approved
Lemasters	Transplantation of Reduced-size Fatty Livers	12/16/2004	Approved with BSL2 containment.

Meeting adjourned at 4:15 p.m.



## Meeting Minutes

### February 7, 2005, 3:30 p.m.

**Members Present:**

John Olsen  
Nancy Davis  
Dwight Bellinger  
Andrew Kaplan  
Jennifer Giles

**Members Absent:**

Robert Bosworth  
Ed Holland  
Tom Kawula

**Guests:**

Deborah Howard

- I. The minutes of the 01/03/05 IBC meeting will be provided to committee members via email and approved at the March IBC meeting.

II. Agenda Items

1. NIH Guidelines Reminder Letter to Principal Investigators. This letter was sent out via the Principal Investigator email listserv.
2. Medical Surveillance for BSL3 Laboratories. EHS presented a policy outlining medical surveillance requirements for BSL3 laboratories for the committee's review and approval. The policy was approved.

III. The following registration documents were reviewed:

last name	Registration Date	Title	IBC comments
O'Neal	01/04/2004	UDPase Retrovirus	Approved pending submission of page 2 of schedule G.
Wolfgang	06/21/2004	Pseudomonas aeruginosa gene expression in response to host environmental cues	Approved pending 1) submission of page 2 of schedule G, 2) review and approval by Tom Kawula. The work must be conducted at BSL2.
Smithies	12/28/2004	Targeted Correction of Faulty Beta Globin Gene	Approved
Smithies	12/28/2004	Genetic Control of Protein Structure and Synthesis	Approved
Smithies	12/28/2004	Animal Models for Studying the Genetics of Hypertension	Approved
Lee	01/12/2005	Alphavirus encoding HSP70 as HNSCC immunotherapy	Registration requires a faculty co-signature.
Dittmer	01/12/2005	West Nile Virus Lab Safety Plan	Approved BSL2 work with clinical specimens provided
Dittmer	01/12/2005	West Nile Virus Schedule F	

last name	Registration Date	Title	IBC comments
			that no culturing of virus is done. BSL3 work cannot be approved until a space has been identified.
Mohler	01/20/2005	Interference with androgen receptor and its ligands in prostate cancer	Not approved. Some issues need further clarification. Clarify whether AAV or adenovirus vectors are going to be used. Please revise Section III, #5.
Marston	01/20/2005	A Phase II, Open-Label Study to Assess the Angiogenic Response of AMG0001 by Measuring Improvement of Lower Extremity Perfusion in Subjects with Peripheral Arterial Disease as Determined by MRI	The consent form and non-technical abstract indicate that the HGF plasmid does not incorporate into DNA. The committee believes that, while it is rare, the plasmid could incorporate into the patient's cellular DNA at the site of injection. This statement should be removed from the non-technical abstract and the consent form should be modified to address the rare possibility of incorporation into patient DNA. The IBC requests documentation stating that the test material (AMG0001) was manufactured in accordance with the FDA Good Manufacturing Practices.

Meeting adjourned at 4:30 p.m.



## Meeting Minutes March 7, 2005, 3:30 p.m.

### Members Present:

John Olsen  
Nancy Davis  
Dwight Bellinger  
Andrew Kaplan  
Jennifer Giles

### Members Absent:

Robert Bosworth

### Guests:

Deborah Howard

- I. The minutes of the 01/03/05 and 02/07/05 IBC meetings were approved.
- II. A letter has been received from Dr. William Marston stating that the project titled A Phase II Open-Label Study to Assess the Angiogenic Response of AMG0001 by Measuring Improvement of Lower Extremity Perfusion in Subjects with Peripheral Arterial Disease as Determined by MRI is on hold indefinitely. This was reviewed at the February IBC meeting. IBC approval is not needed at this time.

### III. Agenda Items

1. Department of the Army Inspection. The Department of the Army inspected [REDACTED] 415 Taylor Hall and 1204 McGavran-Greenberg in January. These laboratories received a grant through the University of Tennessee at Memphis that is funded by the army. The laboratories will be inspected annually. No major deficiencies were noted.

3. Johnston Laboratory - proposal to change rabbit VRP protocol. The committee reviewed the labs proposal. The lab is proposing to have DLAM staff provide husbandry services for the rabbits that have been injected with VEE replicon particles (VRPs) starting at 48 hours following inoculation. Currently, lab staff are responsible for cage changing and caring for the rabbits for 1 week after inoculation. 1/10 of the VRP sample is tested for replication competent virus prior to use in animals. This testing should detect as little as 10 PFU. Each sample could have 10<sup>8</sup> VRPs (10<sup>7</sup> are safety tested) and rabbits would be inoculated with about 10<sup>7</sup> VRPs. Some concerns the committee expressed:

Source: There is a small risk of a replication competent virus being injected into the rabbits. Even if the virus is replication competent, it would be attenuated.

- There is less containment in the rabbit cages than with the mouse cages. The cages are open and cannot fit into a biological safety cabinet for changing. There have been documented lab-acquired infections associated with exposure to animal waste.
- There are no VEE transmission studies in rabbits. While there are studies that indicate that VEE is not transmitted from rabbit to rabbit in close quarters, it is unknown whether the rabbits shed the virus.

The committee agreed that the laboratory should continue to use their current protocol that requires the lab personnel to provide husbandry services in the rabbit room for 1 week post inoculation and then allow DLAM staff to take over these services. During this process, lab personnel will be monitored for symptoms associated with exposure to VEE. The proposal to change the rabbit VRP protocol can then be re-evaluated after a period of time.

4. **Update – Dirk Dittmer’s West Nile Virus work.** Dr. Dittmer has been given permission to share Susan Fiscus’ BSL3 laboratory space (714 MEJ). Prior to obtaining IBC approval for his project, EHS will meet with Dr. Fiscus and then with Dr. Dittmer. Dr. Dittmer also needs to update his BSL3 laboratory safety plan prior to approval.

**III. The following registration documents were reviewed:**

<b>last name</b>	<b>Title</b>	<b>Registration Date</b>	<b>IBC comments</b>
Randell	Airway Epithelial Adaptation to Infectious Stimuli	02/14/2005	Approved.
Pickles	Viral-Bacterial Interactions in the Airway Epithelium	02/10/2005	Approved
Gabriel	How much CFTR is required to restore function to CF airway epithelium	02/10/2005	Approved.
Weiss	Desensitization of Cone Signaling Pathways	01/19/2005	Approved at BSL1. Need vector map.
Weiss	Desensitization of Cone Signaling Pathways	01/19/2005	Approved at BSL1. Need vector map.
Van Dyke	Combined Loss of Hereditary Breast Cancer Genes and Prb Signaling in Mice: A Genetic Analysis	01/24/2005	Approved
Van Dyke	Combined Loss of Hereditary Breast Cancer Genes and Prb Signaling in Mice: A Genetic Analysis	01/24/2005	Approved
Lauder	Pharmacological Treatment of Social Deficits in a Mouse Model for Fragile X Syndrome	01/25/2005	Approved
Milgram	Renal Scaffolding Proteins	02/01/2005	Approved. Need vector map.
Morin-Kensicki	Role of Yap65 in Cardiovascular Disease	02/01/2005	Approved. Needs Co-PI signature and vector map.



last name	Title	Registration Date	IBC comments
Morin-Kensicki	Role of Yap65 in Cardiovascular Disease (transgenic animals)	02/01/2005	Approved. Needs Co-PI signature and vector map.
Morin-Kensicki	Role of Yap65 in Cardiovascular Development (transgenic animals)	02/01/2005	Approved. Needs Co-PI signature and vector map.
Kole	Restoration of Globin Gene Expression in Thalassemia	02/01/2005	Approved.
Kole	Restoration of Globin Gene Expression in Thalassemia (transgenic animals)	02/01/2005	Approved
Kafri	Regulation of Transgene Expression from Episomal Lentiviral Vectors	02/04/2005	Approved.
Muenzer	Neurological Correction of MPS by AAV Gene Therapy	02/04/2005	Approved at BSL2. Need vector maps.
Sekelsky	Meiotic Recombination in <i>Drosophila Melanogaster</i>	02/02/2005	Approved.
O'Neal	NTP-1 Retrovirus	02/04/2005	Approved at BSL2.
O'Neal	UDPG-Transporter Retrovirus	02/04/2005	Approved at BSL2.
O'Neal	UDP-Nac-glc Transporter Retrovirus	02/04/2005	Approved at BSL2.
Zhang	Role of hDOT1L, ahistone methyltransferase, on MLL-related leukemogenesis	02/08/2005	Not approved. Need more information. <ul style="list-style-type: none"> <li>• Need answers to questions 8 and 9 on page 2.</li> <li>• Need to address how they will insure that replication competent viruses are excluded. If infectious virus vector is created, will it be amplified in mice?</li> <li>• Need to address risk of illness if inoculated with vector.</li> <li>• Some safety concerns could be alleviated if SIN retrovirus vector were used.</li> </ul>
Meshnick	Rare <i>P.falciparum</i> dhfr and pfcr alleles	02/09/2005	Approved.
Johnson	Gene Transfer Strategies for Pulmonary Hypertension	02/04/2005	Approved.
Johnson	Gene Transfer Strategies for Pulmonary Hypertension	02/04/2005	Approved.
Patel	G Protein Coupled Receptor Regulatory Mechanisms in Arthritis	01/30/2005	Approved at BSL1.
Patel	G Protein Coupled Receptor Regulatory Mechanisms in Arthritis	01/30/2005	Approved at BSL1.
Patel	G Protein Coupled Receptor Regulatory Mechanisms in Arthritis	01/30/2005	Approved at BSL1.

last name	Title	Registration Date	IBC comments
Patel	G Protein Coupled Receptor Regulatory Mechanisms in Arthritis	01/30/2005	Approved at BSL1.
Patel	G Protein Coupled Receptor Regulatory Mechanisms in Arthritis	01/30/2005	Approved at BSL1.
Patel	G Protein Coupled Receptor Regulatory Mechanisms in Arthritis	01/30/2005	Approved at BSL1.
Patel	G Protein Coupled Receptor Regulatory Mechanisms in Arthritis	01/30/2005	Approved at BSL1.
Patel	G Protein Coupled Receptor Regulatory Mechanisms in Arthritis	01/30/2005	Approved at BSL1.
Patel	G Protein Coupled Receptor Regulatory Mechanisms in Arthritis	01/30/2005	Approved at BSL1.
Patel	G Protein Coupled Receptor Regulatory Mechanisms in Arthritis	01/30/2005	Approved at BSL1.

Meeting adjourned at 5:10 p.m.



## Meeting Minutes April 4, 2005, 3:30 p.m.

### Members Present:

John Olsen  
Nancy Davis  
Dwight Bellinger  
Jennifer Giles  
Ed Holland  
Tom Kawula  
Fred Sparling  
Donii Fox

### Members Absent:

Robert Bosworth  
Andrew Kaplan  
Ray Hackney

### Guests:

Deborah Howard

- I. The minutes of the 3/7/05 IBC meeting were approved.
- II. Agenda Items

1. Incident in 415 Taylor Hall (*Mycobacterium tuberculosis* BSL3 laboratory). On 3/19/05, the exhaust fan for this laboratory failed. The fan exhausted both the general laboratory space and two of the biological safety cabinets in the lab. The cabinet did not have an interlock system, designed to turn off the blower fan when the exhaust fan fails, and both primary and secondary containment was lost in the laboratory. An employee was working in one of these cabinets at the time of failure and was unaware because the audible alarms had been turned off on the cabinets and air pressure monitors. The employee was wearing appropriate personal protective equipment (PPE), including N95 respirator. He followed appropriate procedures and immediately decontaminated the work area, removed PPE and left the laboratory. The employee has been evaluated by UEOHC. The employees were restricted from using the vented biological safety cabinets. The cabinet has subsequently been replaced with a non-vented cabinet. The laboratory will be renovated to bring it up to current standards. Because the employee was using rDNA at the time of the incident, we are required to send a report to the NIH. The committee was provided with a draft of the letter.
2. Evaluation of BSL3 Facilities at UNC. As a result of the incident, EHS has been asked to evaluate each current and potential BSL3 facilities and provide a report of what will be required to bring these laboratories up to current design standards. The committee supports this report and updating of the spaces and will provide a memo stressing the importance of upgrading these facilities.
3. Leptospirosis in animals at the Francis Owen Blood Lab. Leptospirosis was identified in the pigs at the Francis Owen Blood Lab. The dogs are currently being tested. The animals will be treated with the appropriate antibiotics and will be vaccinated to prevent further infection. The facility is looking into rodent control to prevent future infections. Employees working at the Blood Lab already follow "Universal Precautions" when working with the animals. Employees will be provided with serological testing if they are concerned about exposure.

5. Review of James Mohler's revised Schedule G. Dr. Mohler revised his Schedule G as requested by the committee in February. There was still a reference to adenovirus in Section II, # 9. The committee requested he change this to AAV and agreed to approve the registration once this change has been made.

III. The following registration documents were reviewed:

last name	Title	Registration Date	IBC comments
Mohler	Interference with androgen receptor and its ligands in prostate cancer	03/10/2005	Approved
Sancar	Structure/Function of DNA Photolyase	02/23/2005	Approved
Sancar	Structure/Function of DNA Photolyase	02/23/2005	Approved
Cyr	Inhibition of ERQC and Rescue of CFTRDF508 misfolding	02/21/2005	Approved. Committee commented on use of 293 cells. Other culture may be more appropriate.
Perez-Vilar	HCLCA1 Regulation of Airway Mucous	03/03/2005	Approved
Perez-Vilar	Detection and Role of C-Mannosylation in Mucins	03/03/2005	Approved
Perez-Vilar	Early Stages in Mucin Biosynthesis	03/03/2005	Approved
Maeda	Apolipoprotein Genes and Atherogenesis in Mice	02/28/2005	Approved
Maeda	CYP3A Regulation of Blood Pressure	02/28/2005	Approved
Snider	Expression of GSK3B and ILK cDNAs and siRNAs with a Lentiviral Vector	03/04/2005	Conditional approval. Need answers to Section III #4 & #6
Boucher	Generation of Alveolar Cell Specific Beta-ENaC Mice	03/14/2005	Approved
Borras	Regulation of Outflow Facility by Gene Transfer (Adh MGP and Adh BMP2 vectors)	03/17/2005	Approved
Xiong	The INK4 Family of CDK4 Inhibitors	03/22/2005	Approved
Xiong	The INK4 Family of CDK4 Inhibitors (Use of Transgenic Animals)	03/22/2005	Approved
Samulski	Study of the Mechanism for Liver Transduction by Serotype AAV Vectors	03/28/2005	Approved
Archdeacon	Role of ALK3 Receptors in Kidney Homeostasis	03/31/2005	Approved. Need PI signature.

Meeting adjourned at 4:45 p.m.



**Meeting Minutes (Draft)**  
**May 2, 2005, 3:30 p.m.**

**Members Present:**

John Olsen  
Nancy Davis  
Dwight Bellinger  
Jennifer Giles  
Ray Hackney

Ed Holland  
Tom Kawula  
Fred Sparling  
Donii Fox  
Deborah Howard

**Members Absent:**

Robert Bosworth  
Andrew Kaplan

**Guests:**

Bob Lowman, Associate  
Vice Chancellor of  
Research  
Rich Cravener, CIIT

**Open Meeting**

I. The minutes of the 4/4/05 IBC meeting were approved.

II. Agenda Items

1. ABSL3 Laboratory in McGavran-Greenberg, Room 1204. Dr. John Bradfield, DLAM director, contacted EHS regarding an upcoming AAALAC inspection. He expressed concerns about possible deficiencies in this laboratory space. The committee agreed that the following items need to be addressed in the lab space to bring it to current BMBL requirements:
  - a. Hands-free handwashing sinks are necessary in the animal cubicle room, necropsy room and in the clothes changing area.
  - b. Eyewashes should be installed in the animal cubicle area and necropsy room.
  - c. Audible alarms should be installed to indicate pressurization of the laboratory space.
  - d. An HVAC control system to prevent sustained pressurization of the lab will be costly and may require shutdown of the lab for an extended period of time. The committee recommended that a positive seal damper be installed in the supply air that can be manually shut by laboratory staff in the event of a pressure alarm. A laboratory employee will always be present in the laboratory during aerosol studies and would be able to close the damper.
2. The committee agreed that additional information on the Use of Transgenic Animals Form would be helpful. Specifically, what the gene does and what are the potential consequences to the animal or safety risk to personnel. EHS will develop some wording for questions 2, 3 and 5 of the form.

## III. The following registration documents were reviewed:

last name	Title	Registration Date	IBC comments
Su	A Novel RhoA Effector in HIV-1 Replication and Pathogenesis	04/04/2005	Dr. Su sent an email stating that he has decided not to do these experiments.
Su	HIV-1 Replication and Pathogenesis in the Human Thymus	04/04/2005	
Smyth	Platelet Membrane Proteins in Thrombosis	04/08/2005	Approved
Boucher	Generation of Alveolar Cell Specific Gamma-ENaC Mice	04/14/2005	Approved
Van Dyke	p53 and THM in Thymic Lymphoma Suppression	04/14/2005	Approved
Van Dyke	p53 and ATM in Thymic Lymphoma Suppression	04/14/2005	Approved
Cuevas	Role of MEKKs in Breast Tumor Metastasis	04/15/2005	Not approved. The registration needs to be modified: <ul style="list-style-type: none"> <li>• Section II, #3 needs to be marked "Yes".</li> <li>• Section II, #7-reference to BSL1 needs to be changed to BSL2.</li> <li>• Section III needs to be completed.</li> </ul>
O'Neal	Generation of Transgenic Mice with Relevance for Pulmonary Disease	04/17/2005	Approved
Dittmer	BSL3 Standard Operating Procedure- West Nile Virus	04/28/2005	Requested changes to SOP: <ul style="list-style-type: none"> <li>• Replace "should" with "will".</li> <li>• Remove references to animal work.</li> <li>• Add information about making fresh 10% bleach solution daily.</li> </ul> The committee agreed via email that Dr. Dittmer could begin his BSL3 West Nile work once he has completed the required EHS training.

Mr. Cravener was asked to step out of the room while the following items were discussed.

I. Agenda Items

1. BSL3 Facility Design Guidelines and Status of Current BSL3 Laboratories. EHS provided a presentation of recommended BSL3 Facility Design Guidelines and how our current BSL3 laboratories meet these guidelines. The committee had the following comments and action items:
  - a. All BSL3 laboratories on campus (including new laboratories) should be held to the same standards.
  - b. [REDACTED]
  - c. EHS will develop a list of the minimum requirements each BSL3 laboratory must meet. A list of desirable but optional requirements will also be developed. EHS will present this information at the June 2005 IBC meeting for committee consideration.
  - d. EHS will gather information about BSL3 facility design requirements from other universities to present at the June 2005 meeting.
  - e. The committee agreed that we should request a report from Bob Marriott, Medical School Planning Office, of the status of the MBRB 8343/8345 renovation project. The committee has concerns that grant money will be lost if the project is not completed soon. EHS will request a report from Bob Marriott.

[REDACTED]

II. Registrations for Review

last name	Title	Registration Date	IBC comments
Johnston	BSL3 Laboratory Standard Operating Procedure-736 Mary Ellen Jones	03/02/2005	Approved.
Johnston	A VRP Vaccine for Rhesus Lymphocryptovirus (LCV) - An Animal Model for Epstein-Barr Virus Infection in Humans	04/20/2005	Approved. Nancy Davis left the room during voting.
Johnston	A VEE Replicon Vaccine for Equine Infectious Anemia Virus (EIAV)	04/20/2005	Approved. Nancy Davis left the room during voting.

Meeting adjourned at 5:30 p.m.



## Meeting Minutes June 6, 2005, 3:30 p.m.

### Members Present:

John Olsen  
Jennifer Giles  
Ray Hackney

Ed Holland  
Donii Fox

### Members Absent:

Robert Bosworth  
Andrew Kaplan  
Nancy Davis  
Dwight Bellinger

Tom Kawula  
Fred Sparling  
Deborah Howard

### Open Meeting

- I. The minutes of the 5/2/05 IBC meeting were approved.
- II. Agenda Items
  1. Update - ABSL3 Laboratory in McGavran-Greenberg, Room 1204. Renovations are underway to add the hands-free handwashing sinks and audible alarms. A positive seal damper in supply will be added at a later date.
- III. The following registration documents were reviewed:

last name	Title	Registration Date	IBC comments
Cuevas	Role of MEKKs in Breast Tumor Metastasis	05/04/2005	Approved
Dittmer	BSL3 Standard Operating Procedure-West Nile Virus	04/28/2005	Approved
Blancafort	Discovery of novel transcription factors regulating cancer progression	05/05/2005	Conditionally approved. Need additional information for Section II, #6. Experiments must be conducted at BSL2.
O'Brien	Function of glyceraldehyde 3-phosphate dehydrogenase-S (GAPDS) during spermatogenesis & fertilization	05/04/2005	Approved
Dykstra	NCCU/UNC CH Initiative in Genomics of Drug Dependence	05/03/2005	Approved
Pickles	CFTR Delivery to Ciliated Airway Cells by PIV Vectors	05/11/2005	Approved
Heise	Developing Immune Assays for SARS Coronavirus and Rift Valley Fever Virus	05/15/2005	Conditionally approved. Need: <ul style="list-style-type: none"><li>o info on strain of VSV,</li><li>o cosigned by Bob Johnston</li><li>o approval from Nancy Davis.</li></ul>
Zhou	UNC Vector Core/Paul Epstein, University of Louisville - BiFDM	03/10/2005	Approved
Zhou	UNC Vector Core/Paul Epstein, University of Louisville BiFKD	03/10/2005	Approved
Flood	Biology of Ly6A deficient lymphocytes	05/20/2005	Approved

Meeting adjourned at 4:20 p.m.





## Meeting Minutes July 11, 2005, 3:30 p.m.

### Members Present:

John Olsen  
Ray Hackney  
Nancy Davis  
Dwight Bellinger  
Fred Sparling

Ed Holland  
Donii Fox

### Members Absent:

Robert Bosworth  
Andrew Kaplan  
Jennifer Giles  
Tom Kawula  
Deborah Howard

### Guests:

Robert Lowman  
Mary Sechreist  
Nancy King

### Open Meeting

I. The minutes of the 6/6/05 IBC meeting were approved.

### II. Agenda Items

1. BSL3 Facility Design Guidelines. EHS provided the committee with the latest draft of the design guidelines. In this draft, the design requirements are divided into three sections: 1) Required for all BSL3 labs by BMBL, NIH Facility Design Guidelines or UNC, 2) Required by UNC to meet performance-based requirements, and 3) Recommended by UNC-design features that must be considered for new BSL3 laboratories. EHS attempted to gather information from other universities about their BSL3 design requirements. A request was posted to the Biosafety Listserv. EHS was only able to obtain information from Duke University, University of Kansas and University of Virginia. University of Virginia does not have any written design requirements. The requirements from Duke University and the University of Kansas will be emailed to committee members for informational purposes. The committee suggested the following actions:
  - a. Additional information should be gathered from other organizations with extensive experience with BSL3 (i.e. Ft. Collins, Galveston, University of Alabama at Birmingham). Committee members with contacts at these organizations agreed to provide contact information to Donii.
  - b. The committee agreed to wait until the revised BMBL comes out in the Fall before we finalize the requirements.
  - c. A draft of the requirements will be circulated to all BSL3 users for comments.
  - d. The committee agreed that laboratories may request exceptions for some of the requirements by submitting justification to the committee.
  - e. There will be some laboratories that the committee will have more limited requirements for. For example, the HIV BSL3 laboratories are required to use BSL3 practices, but BSL3 facilities are not required by the Bloodborne Pathogen Standard for the work being conducted in these laboratories.
2. NIH Response to TB Incident Report. Ray Hackney provided a summary of the NIH Response to our report of the incident in the TB laboratory. The report was provided to the committee. In addition, UNC has sent a letter to the NIH providing the results of the PPD skin test for the employee involved in the incident. The PPD skin test was negative.

3. **SERCEB BSL3 Training.** Fred Sparling provided the committee with information about the new BSL3 and BSL4 training courses being offered by CDC through Emory University. Any universities that are participating in SERCEB can send employees to this training. However, Emory University is requesting that we certify that employees are legally entitled to work in a BSL3 laboratory. The committee discussed how we would satisfy this requirement. SRA approvals are only conducted for employees working in select agent labs. Criminal history checks are required for UNC employees, but not Faculty. UNC does not have an official policy for certifying employees for BSL3 work, but each BSL3 laboratory is required to address minimum experience and other entry requirements in their laboratory biosafety plans and EHS requires that each employee complete EHS training courses (i.e. BSL3 Safety, Respirators, Lab Orientation). Fred Sparling will request guidance from Emory and a BSL3 certification policy will be drafted based on the information received from Emory.
4. Registrations received after the submission deadline. The committee agreed that registrations received after the 15<sup>th</sup> of the month will not be reviewed at the following month meeting unless the PI has provided some justification for an urgent review.
5. Conditional approvals from the 6/6/05 meeting.
  - a. Blancafort. EHS has not received the additional information requested by the committee and an approval letter has not been sent.
  - b. Heise. EHS has received the information about the strain of VSV used and approval from Nancy Davis. We are waiting on the registration co-signed by Bob Johnston to send the approval letter.

III. The following registration documents were reviewed:

Last name	Title	Registration Date	IBC Comments
Serody	Multimodality Therapy for Metastatic Breast Cancer	05/24/2005	Not approved. Need to complete Section III and provide maps of vector.
Serody	Multimodality Therapy for Metastatic Breast Cancer	05/24/2005	Not approved. Need to complete Section III and provide maps of vector.
Erickson	Molecular Interactions Modulating Targeting of Procathepsin L	06/01/2005	Approved. Need to describe what PHSP6 is.
Wilson	Androgen Receptor Regulation of Reproductive Function	06/01/2005	Approved.
Elkins	Expression of the Haemophilus ducreyi Hemoglobin Receptor, HgbA, in attenuated Salmonella vaccine strains	06/01/2005	Not approved. Need to know what are the attenuated mutations in addition to HemA. Once received, this information will be forwarded to Fred Sparling and John Olsen for approval.
Rathmell	AAV cre recombinase delivery to kidney cells	06/02/2005	Approved.
Rathmell	scAAV cre recombination	06/02/2005	Approved.
Matsushima	Inflammation		Not approved. Need to know if the poly diphtheria toxin sequence referenced in the registration a diphtheria toxin resistance marker or a diphtheria toxin gene. Also need map of vector and signature on document.
Godfrey	Maintenance of Mouse Models of Immune Dysfunction	06/01/2005	Approved. Need signed Use of Transgenic Animals form.

last name	Title	Registration Date	Comments
Zhou	Regulated and Local Expression of HGF in Liver for the Gene Therapy of Liver Cirrhosis	06/09/2005	Approved.
Pedersen	Alcohol and Opiate Neuroadaptation in Oxytocin Knockout Mice	06/06/2005	Approved at BSL1.
Arendshorst	Renal Vascular Reactivity in Genetic Hypertension	06/07/2005	Approved.
Jaspers	Diesel Exhaust-Induced Alterations of Influenza Pathogenesis	06/01/2005	Not approved. Need updated form and list of genes that will be put in cells.
Salmon	Mechanisms of Mitotic Spindle Assembly and Function	05/25/2005	Not approved. Need information about what proteins are expressed in each of the vectors. Need to complete Section II, #8, 9 and 10. Need to assign a containment condition.

Meeting adjourned at 5:15 p.m.



## Meeting Minutes August 1, 2005, 3:30 p.m.

### Members Present:

John Olsen  
Nancy Davis  
Dwight Bellinger  
Andrew Kaplan

Donii Fox  
Deborah Howard

### Members Absent:

Robert Bosworth  
Ed Holland  
Jennifer Giles  
Tom Kawula

Ray Hackney  
Fred Sparling

**Guests:**  
Nancy King

### Open Meeting

- I. The minutes of the 7/11/05 IBC meeting were approved.
- II. Agenda Items
  1. The renovation of Taylor Hall 415 & 421 (BSL3-TB) has been completed. The laboratory was commissioned on July 22 and alarms were tested on July 29.
  2. Conditional approvals from the 6/6/05 meeting.
    - a. Heise. EHS has received the registration co-signed by Bob Johnston. The document was signed by John Olsen and an approval letter will be sent.
  3. Registrations reviewed at 7/11/05 meeting needing further information.

last name	Title	Registration Date	IBC Comments
Serody	Multimodality Therapy for Metastatic Breast Cancer	05/24/2005	Not approved. Need to complete Section III and provide maps of vector. Registration of transgenic animal use that was previously approved. Completed wrong form.
Serody	Multimodality Therapy for Metastatic Breast Cancer	05/24/2005	Not approved. Need to complete Section III and provide maps of vector. Registration of transgenic animal use that was previously approved. Completed wrong form.
Erickson	Molecular Interactions Modulating Targeting of Procathepsin L	06/01/2005	Approved. Need to describe what PHSP6 is. Information was provided. Approval letter sent.
Elkins	Expression of the Haemophilus ducreyi Hemoglobin Receptor, HgbA, in attenuated Salmonella vaccine strains	06/01/2005	Not approved. Need to know what are the attenuated mutations in addition to HemA. Once received, this information will be forwarded to Fred Sparling and John Olsen for approval. Have not received information.
Matsushima	Inflammation		Not approved. Need to know if the poly diphtheria toxin sequence referenced in the registration a diphtheria toxin resistance marker or a diphtheria toxin gene. Also need map of vector and signature on document. Information was provided. EHS contacted NIH/OBA and they requested a copy of the registration to be reviewed at the next OBA meeting on 8/12/05. The IBC agreed to wait for information from the OBA before approving the registration.

last name	Title	Registration Date	IBC Comments
Godfrey	Maintenance of Mouse Models of Immune Dysfunction	06/01/2005	Approved. Need signed Use of Transgenic Animals form. Have not received signed form.
Jaspers	Diesel Exhaust-Induced Alterations of Influenza Pathogenesis	06/01/2005	Not approved. Need updated form and list of genes that will be put in cells. Provided updated form.
Salmon	Mechanisms of Mitotic Spindle Assembly and Function	05/25/2005	Not approved. Need information about what proteins are expressed in each of the vectors. Need to complete Section II, #8, 9 and 10. Need to assign a containment condition. Have not received information.

### III. Registrations for review

last name	Title	Registration Date	IBC Comments
Jaspers	Diesel Exhaust-Induced Alterations of Influenza Pathogenesis	07/19/2005	Approved.
Madamanchi/ Runge	Adenovirus-mediated gene transfer of LAR phosphatase prevents injury-induced neointima formation	06/20/2005	Approved.
Runge	Adenovirus-mediated gene transfer of NOXA1-specific siRNA prevents injury-induced neointima formation	06/20/2005	Approved.
Whinna	Glycosylphosphatidylinositol (GPI)-Anchored Antithrombins	01/27/2005	Approved.
Anderson	Role of Claudin-14 in Renal Tubule Transport and Bile Secretion	06/28/2005	Approved.
Anderson	NIH DK 45134 Molecular Analysis of Tight Junctions in Liver and Gut, NIH DK 61397 ZO-1	06/28/2005	Approved.
Dittmer	Kaposi's Sarcoma-associated herpesvirus (KSHV) lymphomagenesis	06/20/2005	Not approved. Need additional clarification. In Section II, #9, he states that he will be generating transgenic mice with single or multiple genes of KSHV. What multiple genes does he intend to insert? Will he be expressing more than 2/3 of the genome in the animals?
Dittmer	Kaposi's Sarcoma-associated herpesvirus (KSHV) lymphomagenesis (Use of Transgenic Animals)	06/20/2005	Approved.
Jones	Evolutionary Genetics and Genomics	05/21/2005	Not approved. Need answers to #8 and 9 of Section II and maps of the vectors.
Perl	Spinal and Projection Mechanisms Related to Pain	06/22/2005	Approved at BSL1.
Falk	ANCA Glomerulonephritis: From Molecules to Man	06/28/2005	Conditionally approved. Need to change answer of #3 to "No", #4 to "BSL2" and remove references to animals in #5 and submit revised form.

last name	Title	Registration Date	IBC Comments
Huang	Gene Therapy Against Bladder Inflammation	07/05/2005	Not approved. Need map of the vector. Need to list the vectors to be used and provide a signed copy of the form.
Huang	Immuno/Gene Therapy for Cervical Cancer	07/06/2005	Not approved. Need map of the vector. The link provided does not work.
Huang	Immuno/Gene Therapy for Cervical Cancer (Use of Transgenic Animals)	07/06/2005	Not approved. Need clarification whether he intends to create the HLA-A*201 transgenic mice here at UNC. If he will, page 1 and 2 of the Schedule G form need to be completed to explain how he intends to make them. If these animals have already been created and he has brought them from Pittsburgh, the form completed is appropriate but he needs to state under #1 that the animals were made at his other lab.
Huang	Non-viral Gene Delivery to Conducting Airway Epithelial Cells	07/06/2005	Not approved. Need map of vector.
Huang	Structure, Function and Toxicity of Non-Viral Vectors	07/06/2005	Not approved. Need map of vector.
Huang	Targeted Nanoparticles for Lung Cancer Therapy and Imaging	07/06/2005	Not approved. Need map of the vector. Request clarification of what vector will be used. The article listed for the physical map references an adenoviral vector but pBR322 is listed under #6 "Vectors to be used". Ask if Huang intends to grow the vector here or will he be obtaining it from Tokyo?
Schaller	Pyk2 and Paxillin Function in Macrophages	07/10/2005	Approved
Serody	Use of VEE replicon particles to generate antigens in infected dendritic cells	07/12/2005	Conditionally approved. Need to answer #5 and explain why all the plasmids are listed in #6.
Smith	Intestinal UGTs in the Rat	07/12/2005	Conditionally approved. Need signed form. Because AV vectors are not tested to ensure they are replication incompetent, the animals that will be shipped to Smith from UVA will be live infected animals. The shipper will need a DOT Authorization to Ship Live Infected Animals prior to shipment. The shipper and receiver are responsible for ensuring all shipments are in compliance with all shipping regs.

Meeting adjourned at 4:30 p.m.



## Meeting Minutes September 12, 2005, 3:30 p.m.

### Members Present:

John Olsen  
Ray Hackney  
Fred Sparling  
Tom Kawula  
Donii Fox  
Deborah Howard

### Members Absent:

Robert Bosworth  
Ed Holland  
Jennifer Giles  
Nancy Davis  
Dwight Bellinger  
Andrew Kaplan

### Guests:

Liz Crowley, IACUC

### Open Meeting

- I. The minutes of the 8/1/05 IBC meeting were approved.
- II. Agenda Items
  1. David Margolis HIV SOP. The committee requested the following revisions:
    - o Prior to Section I, please provide a description of the experiments you intend to conduct with HIV. Also, please list the high risk (for exposure) procedures that will be conducted as part of your experiments and how you intend to reduce the risk. This will be considered your risk assessment which is required for work with infectious agents.
    - o Please clarify what personal protective equipment is required for working with HIV. You list "face mask, gowns, booties and double gloves" in one section and gowns, booties, double gloves and "faceshield" in another. When you say face mask, do you mean surgical mask or respirator? Is a faceshield required as well? Some type of eye protection is required, whether it be a faceshield, safety glasses or goggles.
    - o The committee requested that your -80 freezer, used for sample storage, be locked and in a secure location.
    - o You did not fill in information about what to do in the event of a power failure under Section 11 – Emergency Procedures. Will your biological safety cabinet be on emergency power? If not, we need to address containment issues in the event of a power failure.
    - o Under Section 14 – Maintenance Procedures, you did not describe the specific safety procedures that will be implemented prior to maintenance work in the laboratory. Please describe what procedures will be followed if maintenance personnel must enter the laboratory to do maintenance on equipment, plumbing, electrical. This should include information provided to maintenance personnel, personal protective equipment, decontamination of equipment, etc. If you need assistance with this section, please let me know.

## 2. Registrations reviewed at 7/11/05 meeting needing further information.

<b>last name</b>	<b>Title</b>	<b>Registration Date</b>	<b>IBC Comments</b>
Godfrey	Maintenance of Mouse Models of Immune Dysfunction	06/01/2005	Approved. Need signed Use of Transgenic Animals form. Information was provided. Approval letter sent.
Salmon	Mechanisms of Mitotic Spindle Assembly and Function	05/25/2005	Not approved. Need information about what proteins are expressed in each of the vectors. Need to complete Section II, #8, 9 and 10. Need to assign a containment condition. Have not received information.
Elkins	Expression of the Haemophilus ducreyi Hemoglobin Receptor, HgbA, in attenuated Salmonella vaccine strains	06/01/2005	Not approved. Need additional information. Additional information was provided. Approval letter sent.
Dittmer	Kaposi's Sarcoma-associated herpesvirus (KSHV) lymphomagenesis	06/20/2005	Not approved. Need additional information. Information has been provided. Need to discuss again at IBC meeting.
Falk	ANCA Glomerulonephritis: From Molecules to Man	06/28/2005	Conditionally approved. Make changes to #3, 4 and 5. Have not received information.
Jones	Evolutionary Genetics and Genomics	05/21/2005	Not approved. Need answers to #8 and 9 and map of vector. Provided updated form.
Smith	Intestinal UGTs in the Rat	07/12/2005	Conditionally approved. Need signed form. Information was provided. Approval letter sent.



last name	Title	Registration Date	IBC Comments
Matsushima	Inflammation	06/28/2005	Approved at BSL2. Please update form to indicate BSL2 and send revision.
Jones	Evolutionary Genetics and Genomics	05/21/2005	Approved.
Van Dyke	Mechanisms of Epithelial Cell Tumorigenesis in the Mouse (pBACe3.6)	07/20/2005	Approved.
Van Dyke	Mechanisms of Epithelial Cell Tumorigenesis in the Mouse (transgenic mouse)	07/20/2005	Approved.
Van Dyke	Mechanisms of Epithelial Cell Tumorigenesis in the Mouse (pTg-1)	07/20/2005	Approved.
Van Dyke	Mechanisms of Epithelial Cell Tumorigenesis in the Mouse (transgenic mouse)	07/20/2005	Approved.
O'Neal	Generation of Inducible, Tissue-Specific Tg Mice Expressing Gamma-ENaC Subunit in the Lungs	07/20/2005	Approved.
O'Neal	Generation of Inducible Tg Mice Expressing the Sodium Channel Beta-ENaC Subunit in the Lungs (Use of transgenic animals form)	07/20/2005	Approved.
O'Neal	Generation of Tg Mice Expressing Muc5ac Tagged with GFP in the Lungs	07/20/2005	Approved.
O'Neal	Generation of Tet-Responsive Transgenic Mice Expressing Muc5ac	07/20/2005	Approved.
O'Neal	Generation of Inducible Tg Mice Expressing Muc5ac in the Lungs (Use of Transgenic Animals form)	07/20/2005	Approved.
O'Neal	Generation of Tet-Responsive Mice Expressing Muc5ac-GFP	07/20/2005	Approved.
O'Neal	Generation of Inducible Tg Mice Expressing the Sodium Channel Beta-ENaC Subunit in the Lungs (Use of Transgenic Animals form)	07/20/2005	Approved.
O'Neal	Generation of Inducible, Tissue-Specific Tg Mice Expressing Beta-ENaC Subunit in the Lungs	07/20/2005	Approved.
O'Neal	Generation of Inducible Tg Mice Expressing Beta-ENaC Subunit in the Lungs (Use of Transgenic Animals form)	07/20/2005	Approved.
Thiele	Neuropeptide Control of Ethanol Intake	07/25/2005	Conditional approval pending submission of registration on current Schedule G form.
Nichols	Novel Therapeutic Approach for Hemophilia Using Secreted FVIIa	07/25/2005	Approved.

last name	Title	Registration Date	IBC Comments
Sharpless	Role of p16, p19 and p53 in Murine Cancer (p53 conditional KO)	07/26/2005	Not approved. Reference is made in registration that p53 is inactivated in animals by the expression of CRE-recombinase (using either adenovirus or transgenic mouse strain). Use of adenoviral vectors will require submission of Schedule G.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (RB conditional KO)	07/26/2005	Not approved. Reference is made in registration that RB is inactivated in animals by the expression of CRE-recombinase (using either adenovirus or transgenic mouse strain). Use of adenoviral vectors will require submission of Schedule G.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (p107 KO)	07/26/2005	Approved.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (Tyrosinase-RAS)	07/26/2005	Approved.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (Mx1-CRE)	07/26/2005	Approved.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (Tyrosinase-CRE-ER (T))	07/26/2005	Approved.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (ApoE KO)	07/26/2005	Approved.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (ARF KO)	07/26/2005	Approved.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (p18INK4c KO)	07/26/2005	Approved.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (INK4a/ARF KO)	07/26/2005	Approved.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (p16 KO)	07/26/2005	Approved.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (p16 transgenic)	07/26/2005	Approved.
Sharpless	Role of p16, p19 and p53 in Murine Cancer (p16 conditional KO)	07/26/2005	Approved.
Nichols	Gene Therapy of Hemophilia A Using Recombinant AAV Vectors	07/28/2005	Approved.
Homeister	T-cell and Monocyte-specific alpha (1, 3) fucosyltransferase-dependent Selectin Ligand Contributions to Atherogenesis	07/28/2005	Not approved. Needs to clarify whether he will be creating transgenic animals.
Homeister	T-cell and Monocyte-specific alpha (1, 3) fucosyltransferase-dependent Selectin Ligand Contributions to Atherogenesis (Use of Transgenic Animals)	07/28/2005	Approved.
Alcorta	Analysis of Vascular Inflammation Using Single-Photon Emission Computed Tomography in a Mouse Model of ANCA Small Vessel Vasculitis	08/01/2005	Approved.

last name	Title	Registration Date	IBC Comments
Styblo	Arsenic, Oxidative Stress and Transcriptional Control & Metabolism and Toxicity of Arsenic in the Human Liver	06/29/2005	Approved.
Kaufmann	Study of DNA Metabolism in Normal Human Cells	06/21/2005	Approved. Need to spell out the acronyms for the genes listed in #7.
Bear	The Role of Coronin 1B in Cell Motility	08/02/2005	Approved.
Aitsebaomo	p68RacGAP Signaling in Endothelial Cell Differentiation and Angiogenesis	08/08/2005	Not approved. Need map of vector and signature of Principal Investigator. Need to clarify which vector core he is referring to.
Liu	Non-Viral Gene Transfer for Hemophilia B Gene Therapy & Non-Viral for Liver Gene Transfer	08/08/2005	Approved. Need signature of Principal Investigator.
Kafri	Regulation of Transgene Expression from Episomal Lentiviral Vectors (HIV minus env and nef)	07/23/2005	Approved.
Kafri	Regulation of Transgene Expression from Episomal Lentiviral Vectors (HIV-1 genes)	08/08/2005	Not approved. Needs to provide HIV SOP for approval. Committee concerned about the shared lab space he wants to use for this work. Should check with other HIV containment labs to see if he can conduct the work in one of these labs.
Zylka	Mechanisms of Somatosensation	08/10/2005	Conditionally approved. Needs to be reviewed by NIH/OBA. Needs to provide information about how he knows the diphtheria toxin gene is not secreted from the transgenic mice.
Reid	Transplantation of Human Hepatic Stem Cells in Immunocompromised Mice	08/10/2005	Approved.
Su	A Novel RhoA Effector in HIV-1 Replication and Pathogenesis	04/04/2005	Conditionally approved. Needs to modify form to indicate that BSL3 practices will be followed in BSL2 containment. Needs to clarify the location of the BSL2, BSL3 and space for animal work.
Huang	Gene Therapy Against Bladder Inflammation	07/05/2005	Approved.
Huang	Immuno/Gene Therapy for Cervical Cancer	07/06/2005	Approved.
Huang	Non-viral Gene Delivery to Conducting Airway Epithelial Cells	07/06/2005	Approved.
Huang	Targeted Nanoparticles for Lung Cancer Therapy and Imaging	07/06/2005	Conditionally approved. Vector listed is not the same as the map provided. Needs to provide revised registration or map.
Huang	Structure, Function and Toxicity of Non-Viral Vectors	07/06/2005	Approved.
Huang	Immuno/Gene Therapy for Cervical Cancer	07/06/2005	Approved.
Sealock	Rescue Analysis of Utrophin and NMJ Support by Syntrophin	08/15/2005	Approved.
Burridge	Endothelial Regulation of Leukocyte Transendothelial Migration	08/15/2005	Approved.





## Meeting Minutes October 3, 2005, 3:30 p.m.

### Members Present:

John Olsen  
Ray Hackney  
Fred Sparling  
Tom Kawula  
Donii Fox  
Deborah Howard

Nancy Davis  
Jennifer Giles  
Dwight Bellinger

### Members Absent:

Robert Bosworth  
Ed Holland  
Andrew Kaplan

### Guests:

Liz Crowley  
Nancy King  
Megan Davidson

### Open Meeting

- I. The minutes of the 9/12/05 IBC meeting were approved.
  - II. Agenda Items
    1. Tal Kafri- Regulation of Transgene Expression from Episomal Lentiviral Vectors (HIV-1 genes). Tal Kafri attended the meeting and provided the following information:
      - a. He has checked with the other HIV BSL3 labs. Ron Swanstrom has agreed to allow him to use LCCC 140 to conduct his HIV work on a temporary basis.
      - b. He would still like to use Thurston-Bowles room 7120. The lab is not opened to everyone and the doors are lockable. The department currently using this room has agreed that the room could be restricted during the 5 times per year that Dr. Kafri would use the HIV in the lab. He would then have the biological safety cabinet and incubator decontaminated with formaldehyde before others began working in the lab again.
- The committee has approved Dr. Kafri's use of Ron Swanstrom's lab on a temporary basis. Dr. Kafri needs to find a BSL2 laboratory that can be dedicated to BSL3 practices as a more permanent solution. Jennifer Giles agreed to check with Dr. Samulski to see if Thurston-Bowles 7120 could be dedicated to BSL3 practices to accommodate Dr. Kafri.
2. Dirk Dittmer – Work with Kaposi's Sarcoma-associated Herpesvirus. KSHV should be handled at BSL2. If he intends to express more than 2/3 of the KSHV genome in animals, the animals will need to be handled at ABSL2 and placed in an ABSL2 cubicle. If he intends to express less than 2/3 of the genome in the animals, ABSL1 containment is appropriate. The committee agreed to approve experiments with less than 2/3 of the genome. Dr. Dittmer needs to clarify if he intends to express 2/3 of the genome in animals.

## 3. Registrations reviewed at 9/12/05 meeting needing further information.

last name	Title	Registration Date	IBC Comments
Matsushima	Inflammation	06/28/2005	Approved at BSL2. Please update form to indicate BSL2 and send revision. <b>Have not received updated form.</b>
Thiele	Neuropeptide Control of Ethanol Intake	07/25/2005	Conditional approval pending submission of registration on current Schedule G form. <b>Revised form submitted. Approval letter sent.</b>
Sharpless	Role of p16, p19 and p53 in Murine Cancer (p53 conditional KO)	07/26/2005	Not approved. Reference is made in registration that p53 is inactivated in animals by the expression of CRE-recombinase (using either adenovirus or transgenic mouse strain). Use of adenoviral vectors will require submission of Schedule G. <b>Have not received response.</b>
Sharpless	Role of p16, p19 and p53 in Murine Cancer (RB conditional KO)	07/26/2005	Not approved. Reference is made in registration that RB is inactivated in animals by the expression of CRE-recombinase (using either adenovirus or transgenic mouse strain). Use of adenoviral vectors will require submission of Schedule G. <b>Have not received response.</b>
Homeister	T-cell and Monocyte-specific alpha (1, 3) fucosyltransferase-dependent Selectin Ligand Contributions to Atherogenesis	07/28/2005	Not approved. Needs to clarify whether he will be creating transgenic animals. <b>Have not received response.</b>
Kaufmann	Study of DNA Metabolism in Normal Human Cells	06/21/2005	Approved. Need to spell out the acronyms for the genes listed in #7. <b>Received information. Approval letter sent.</b>
Aitsebaomo	p68RacGAP Signaling in Endothelial Cell Differentiation and Angiogenesis	08/08/2005	Not approved. Need map of vector and signature of Principal Investigator. Need to clarify which vector core he is referring to. <b>Have not received information.</b>
Liu	Non-Viral Gene Transfer for Hemophilia B Gene Therapy & Non-Viral for Liver Gene Transfer	08/08/2005	Approved. Need signature of Principal Investigator. <b>Received revised form. Approval letter sent.</b>
Kafri	Regulation of Transgene Expression from Episomal Lentiviral Vectors (HIV-1 genes)	08/08/2005	Not approved. Needs to provide HIV SOP for approval. Committee concerned about the shared lab space he wants to use for this work. Should check with other HIV containment labs to see if he can conduct the work in one of these labs. <b>Will attend next IBC meeting to discuss.</b>
Zylka	Mechanisms of Somatosensation	08/10/2005	Conditionally approved. Needs to be reviewed by NIH/OBA. Needs to provide information about how he knows the diphtheria toxin gene is not secreted from the transgenic mice. <b>Information received. NIH/OBA approval received. Approval letter sent.</b>
Su	A Novel RhoA Effector in HIV-1 Replication and Pathogenesis	04/04/2005	Conditionally approved. Needs to modify form to indicate that BSL3 practices will be

last name	Title	Registration Date	IBC Comments
			followed in BSL2 containment. Needs to clarify the location of the BSL2, BSL3 and space for animal work. Received revised form. Approval letter sent.
Huang	Targeted Nanoparticles for Lung Cancer Therapy and Imaging	07/06/2005	Conditionally approved. Vector listed is not the same as the map provided. Needs to provide revised registration or map. Received revised form. Approval letter sent.

## III. Registrations for review

last name	Title	Registration Date	IBC Comments
Meeker	CHIP in Murine Models of Cerebral Ischemia	08/18/2005	Approved.
Patel	Role of CX3CR1 in Vascular Inflammation (CX3CR1 KO)	08/22/2005	Approved at BSL1.
Patel	Role of CX3CR1 in Vascular Inflammation (hCX3CR1-GFP KI)	08/22/2005	Approved at BSL1.
Gabriel	Delta F 508	08/26/2005	Approved at BSL2.
Ostrowski	Conditional Deletion of Dnaic1 as a Model of Primary Ciliary Dyskinesia (Tg(cre/Esr1)5Mmc/J)	09/06/2005	Approved.
Ostrowski	Conditional Deletion of Dnaic1 as a Model of Primary Ciliary Dyskinesia (lox-p flanking Dnaic1 gene)	09/06/2005	Approved.
Esther	Release of Purinergic Compounds in Yeast	09/02/2005	Need to specify what genes will be expressed and if large scale quantities will be used.
Philpot	Mechanisms of Metaplasticity (NMDA receptor KO)	09/06/2005	Approved.
Philpot	Mechanisms of Metaplasticity (NMDA receptor NR3A subunits overexpressed)	09/06/2005	Approved.
Philpot	Mechanisms of Metaplasticity (NR2B-CKO)	09/06/2005	Approved.
Philpot	Mechanisms of Metaplasticity (KO of NR2A)	09/06/2005	Approved.
Philpot	Mechanisms of Metaplasticity (NR2A-slow)	09/06/2005	Approved.
Singleton	Understanding Homology in Genetic Recombination	09/01/2005	Approved.
Boucher	Generation of Alveolar Cell Specific Alpha-ENaC Mice	09/06/2005	Approved.
Gentzsch	Routing and Turnover of Wild-Type and DeltaF508 CFTR in the Endocytic Pathway (adenoviral vector)	09/14/2005	Approved.
Gentzsch	Routing and Turnover of Wild-Type and DeltaF508 CFTR in the Endocytic Pathway (retroviral vector)	09/14/2005	Approved.
Park	Carbohydrate Metabolism	08/23/2005	Answer questions 8 and 9.
Park	Carbohydrate Metabolism (Use of Transgenic Animals)	08/23/2005	Answer questions 4 and 5.
Price	Prevention of Neonatal Brain Injury by Insulin-like Growth Factor-I (Use of Transgenic Animals)	09/06/2005	Approved.
Deng	Interleukin-6 Expression and Function in Adipose Cells	08/19/2005	Approved at BSL2.
Deng	Interleukin-6 Expression and Function in Adipose Cells (Use of Transgenic Animals)	08/19/2005	Approved.
McCown	Gene Therapy and Seizures	09/23/2005	Approved. Vectors must be produced at BSL2. Animal work can be conducted at BSL1.



last name	Title	Registration Date	IBC Comments
Baldwin	Crossregulation of Cytokine-Induced Signaling by IKKalpha and mTOR	09/27/2005	Approved.

Meeting adjourned at 5:00 p.m.



**Meeting Minutes (draft)**  
**November 7, 2005, 3:30 p.m.**  
**Thurston-Bowles Room 7033**

**Members Present:**

John Olsen  
Nancy Davis  
Ray Hackney  
Donii Fox  
Deborah Howard

**Members Absent:**

Jennifer Giles  
Dwight Bellinger  
Andrew Kaplan  
Fred Sparling  
Tom Kawula

**Guests:**

Nancy King  
Megan Davidson  
Dave Margolis

**Open Meeting**

- I. The minutes of the 10/03/05 IBC meeting were approved.
- II. Agenda Items
  1. SERCEB Dual-Use Educational Module. Nancy King and Megan Davidson provided an overview of the educational module available at <http://sercebtraining.duhs.duke.edu>. The goal of this training is to raise awareness of dual use issues so that scientists can "take reasonable steps to minimize the possibility of contributing to the advancement of biowarfare or bioterrorism." EHS will put a link on our website so that the training will be accessible to all UNC researchers that are interested. Deb Howard mentioned the training that she has developed to address dual use issues from a shipping/permitting/licensing prospective.
  2. David Margolis-Work with HIV-GFP cell lines. Dr. Margolis would like to work with these cell lines and is requesting guidance on where he can conduct this work. The cells show increased RNA expression after a promoter is added and can produce a maximum of  $10^4$  to  $10^5$  virus particles. This would be a long term project done about 4 hours per week. Dr. Margolis did not think that he could do this work in his existing BSL2/BSL3 practices space due to the volume of his other HIV research conducted in the space. Donii Fox spoke with Dr. Ed Geddie of NC OSHA and this work would have to comply with the HIV Research Laboratory section of the Bloodborne Pathogen standard. This requires a BSL2 facility with BSL3 practices. Dr. Margolis provided 2 possible locations to conduct his work: 1) Remodel or partition an existing shared tissue culture room or 2) remodel his existing lab and put in a biological safety cabinet.

The IBC discussed the proposed work and agreed that the concern is not containment of the virus (this will be accomplished by the biological safety cabinet), but clearly demarcating a BSL3 practices area so that unauthorized persons do not enter and all employees know that BSL3 practices are required. The IBC will provide the following options to Dr. Margolis:

- o A biological safety cabinet can be installed in his BSL2 laboratory and BSL3 practices can be implemented for the entire lab.
- o A biological safety cabinet can be installed in his BSL2 laboratory and partitions or walls can be used to define the area as a BSL3 practices area. If partitions are used, they must be approved by EHS prior to installation.
- o The IBC agreed that renovation of the shared tissue culture space for this work was not the best option due to cost concerns and the requirement to modify HVAC.

## 3. Registrations reviewed at 10/03/05 meeting needing further information.

last name	Title	Registration Date	IBC Comments
Esther	Release of Purinergic Compounds in Yeast	09/02/2005	Need to specify what genes will be expressed and if large scale quantities will be used. <b>Have not received response.</b>
Park	Carbohydrate Metabolism	08/23/2005	Answer questions 8 and 9. <b>Have not received response.</b>
Park	Carbohydrate Metabolism (Use of Transgenic Animals)	08/23/2005	Answer questions 4 and 5. <b>Have not received response.</b>

## III. Registrations for review

last name	Title	Registration Date	IBC Comments
Kim	Role of VHL and HIF in Tumorigenesis (gGT-Cre)	09/29/2005	Approved. Need Principal Investigator's signature.
Kim	Role of VHL and HIF in Tumorigenesis (Ink f/f)	09/29/2005	Approved. Need Principal Investigator's signature.
Kim	Role of VHL and HIF in Tumorigenesis (Keratin14-CreERT2)	09/29/2005	Approved. Need Principal Investigator's signature.
Kim	Role of VHL and HIF in Tumorigenesis (LSL-HIF1)	09/29/2005	Approved. Need Principal Investigator's signature.
Kim	Role of VHL and HIF in Tumorigenesis (LSL-HIF2)	09/29/2005	Approved. Need Principal Investigator's signature.
Kim	Role of VHL and HIF in Tumorigenesis (LSL-Kras)	09/29/2005	Approved. Need Principal Investigator's signature.
Kim	Role of VHL and HIF in Tumorigenesis (p48-Cre)	09/29/2005	Approved. Need Principal Investigator's signature.
Kim	Role of VHL and HIF in Tumorigenesis (PB-Akt)	09/29/2005	Approved. Need Principal Investigator's signature.
Kim	Role of VHL and HIF in Tumorigenesis (PB-Cre4)	09/29/2005	Approved. Need Principal Investigator's signature.
Kim	Role of VHL and HIF in Tumorigenesis (PTEN f/f)	09/29/2005	Approved. Need Principal Investigator's signature.
Kim	Role of VHL and HIF in Tumorigenesis (VHL f/f)	09/29/2005	Approved. Need Principal Investigator's signature.
Nichols	Gene Correction of Factor VIII Deficiency in Hemophilia A Dogs	09/23/2005	Approved.
Grubb	The Role of Stress-Induced Nucleotide Release in ASL Volume Homeostasis	09/27/2005	Approved. Please clarify where animals were created and provide documentation of approval to make/use animals.
Heise	Vector Based Vaccines for Rift Valley Fever Virus	09/28/2005	Approved.
Smyth	Platelet Membrane Proteins in Thrombosis	10/04/2005	Approved.
O'Neal	Generation of Mice with Loss of Muc16 Transmembrane Mucin	10/12/2005	Approved.
O'Neal	Generation of Tissue-Specific Transgenic Mice Expressing CD39/NTPDase1 in the Lungs (pTg1 with CCSP promoter)	10/10/2005	Approved.

last name	Title	Registration Date	IBC Comments
O'Neal	Generation of Tissue-Specific Transgenic Mice Expressing Conditional/Regulated Target Genes in Lung	10/11/2005	Approved.
O'Neal	Generation of Tissue-Specific Transgenic Mice Expressing Conditional/Regulated Expression of CFTR (pBOOAD3)	10/11/2005	Approved.
O'Neal	Generation of Tissue-Specific Transgenic Mice Expressing Conditional/Regulated Expression of CFTR (pTg1 pBluescript)	10/11/2005	Approved.
O'Neal	Generation of Tissue-Specific Transgenic Mice Expressing Truncated Soluble CD39/NTPDase1 in the Lungs (pTg1 with HFH4 promoter)	10/10/2005	Approved.
O'Neal	Generation of Tissue-Specific Transgenic Mice Expressing Truncated Soluble CD39/NEPDase1 in the Lungs (pTg1 with CCSP promoter)	10/10/2005	Approved.
O'Neal	Generation of Tissue-Specific Transgenic Mice Expressing CD39/NTPDase1 in the Lungs (pTg1 with FOXJ1 promoter)	10/10/2005	Approved.

Meeting adjourned at 5:00 p.m.



THE UNIVERSITY  
of NORTH CAROLINA  
at CHAPEL HILL

**INSTITUTIONAL BIOSAFETY COMMITTEE**

212 FINLEY GOLF COURSE ROAD  
CAMPUS BOX 1650  
CHAPEL HILL, NC 27517-4440

T 919.962.5507  
F 919.962.0227  
ehs.unc.edu

**Meeting Minutes  
December 5, 2005, 3:30 p.m.  
Thurston-Bowles Room 7033**

**Members Present:**

John Olsen  
Dwight Bellinger  
Tom Kawula  
Ed Holland  
Ray Hackney  
Donii Fox

**Members Absent:**

Andrew Kaplan  
Fred Sparling  
Robert Bosworth  
Nancy Davis  
Deborah Howard

**Open Meeting**

- I. The minutes of the 11/07/05 IBC meeting were approved.
- II. Agenda Items
  1. Jennifer Giles will be leaving UNC and will no longer be able to serve on the IBC. EHS will pursue a replacement for Jennifer. Suggestions from the committee included asking Jude Samulski or Ralph Baric for a recommended replacement.
  2. Registrations reviewed at 11/07/05 meeting needing further information.

last name	Title	Registration Date	IBC Comments
Kim	Role of VHL and HIF in Tumorigenesis (gGT-Cre)	09/29/2005	Approved. Need Principal Investigator's signature. Information was provided. Approval letter sent.
Grubb	The Role of Stress-Induced Nucleotide Release in ASL Volume Homeostasis	09/27/2005	Approved. Please clarify where animals were created and provide documentation of approval to make/use animals. Information was provided. Approval letter sent.

1. Registrations for review

last name	Registration Date	Title	IBC Comments
Juliano	10/10/2005	Carolina Center of Cancer Nanotechnology Excellence	Approved. These experiments do not involve the use of rDNA.
Thresher	10/19/2005	Fga Knock-In of Human Intron 1	Approved.
Godfrey	10/26/2005	Chemoprevention of Breast Cancer by Rose Bengal	Approved.
Blancafort	10/25/2005	Isolation of Artificial Transcription Factors Regulating Tumor Progression Genes	Needs to list the animals that will be used in these experiments.
Zhang	10/31/2005	Analysis of NuRD: A Nucleosome Remodeling Histone Deacetylase	Not approved. Needs to list in Section II, #9 the specific safety concerns associated with the use of these retroviral vectors. Needs to provide a physical map of the vector (Section III, #2), describe how the cells are packaged and the viral envelope in Section III, #5 and describe the experiments used to determine that there is no replication competent virus in Section III, #6.
Monroe	11/02/2005	Pharmacokinetics of Factor IX im Hemophilia B Mice	Approved.
Monroe	11/02/2005	Models of Hemostasis and Healing	Approved.
Huang	11/02/2005	An Inducible Ex-vivo Dendritic Cell Vaccine for HPV	Approved.
Parise	11/04/2005	Virus-Mediated Overexpression and Knockdown in Mouse Blood Cells	Not approved. Additional signaling molecules need to be registered as they become of interest. Plaque assays can be conducted to show that replication competent adenoviruses are excluded (Section III, #6). Needs to elaborate on Section II, #9 about the safety concerns. If no testing for replication competent viruses is conducted, the safety concerns are similar to working with the live viruses (assuming there could be a replication competent virus in the mix). These safety concerns must be addressed in your Laboratory Safety Plan and in your lab-specific training.

last name	Registration Date	Title	IBC Comments
Anderson	11/03/2005	NIH DK 45134 Molecular Analysis of Tight Junctions in Liver and Gut, NIH DK 61397 ZO-1 and Cytoplasmic Scaffolding	Approved.
Anderson	11/03/2005	Role of Claudin-14 in Renal Tubule Transport and Bile Secretion	Approved.
Edwards	11/10/2005	CLIC Family Chloride Channel Knockout Mice	Approved.

last name	Registration Date	Title	IBC Comments
Edwards	11/10/2005	CLIC Family Chloride Channel Knockout Mice	Approved.
Perou	11/10/2005	Profiles of Susceptibility to Toxicant Stress: Project #1	Approved.
McGowan	11/14/2005	Murine Appendage Stem Cells	Approved. Needs to specify what genetic alterations will be made to the animal (Question 2).
Sharpless	11/09/2005	Role of p16, p19 and p53 in Murine Cancer	Approved.
O'Neal	10/21/2005	Transmembrane and Secreted Mucin Function in the Mouse Airways	Not approved. Needs to provide a signed copy of the registration form and a map of the vector. Needs to confirm the location where these experiments will be conducted. Dr. O'Neal listed in Section II, #7 that the beta galactosidase gene will be under the control of CFV promoter. Needs to clarify whether she meant CMV promoter.
Kirby	11/29/2005	Chemokines in Radiation Fibrosis	Approved.
D. Huang	11/22/2005	CHIP in Murine Models of Cerebral Ischemia	Approved.

### III. Closed Meeting

[REDACTED]

2. [REDACTED] EHS presented this policy to the committee. This policy will be put into the UNC Biosafety Manual. It does not contain any sensitive information about security, etc. The committee approved the policy.

Meeting adjourned at 5:00 p.m.

*cardinal*  
??





**Meeting Minutes**  
**January 9, 2006, 3:30 p.m.**  
**Thurston-Bowles Room 7033**

**Members Present:**

John Olsen  
Tom Kawula  
Ed Holland  
Ray Hackney  
Donii Fox

**Members Absent:**

Fred Sparling  
Nancy Davis  
Deborah Howard  
Andrew Kaplan  
Robert Bosworth  
Dwight Bellinger

**Guests:**

Nancy King

**Open Meeting**

- I. The minutes of the 12/5/05 IBC meeting were approved.
- II. Registrations reviewed at 12/5/05 meeting needing further information.

<b>Last name</b>	<b>Registration Date</b>	<b>Title</b>	<b>IBC Comments</b>
Blancafort	10/25/2005	Isolation of Artificial Transcription Factors Regulating Tumor Progression Genes	Needs to list the animals that will be used in these experiments.
Zhang	10/31/2005	Analysis of NuRD: A Nucleosome Remodeling Histone Deacetylase	Resubmitted for review at 1/9/06 meeting.
Parise	11/04/2005	Virus-Mediated Overexpression and Knockdown in Mouse Blood Cells	Not approved. Additional signaling molecules need to be registered as they become of interest. Plaque assays can be conducted to show that replication competent adenoviruses are excluded (Section III, #6). Needs to elaborate on Section II, #9 about the safety concerns. If no testing for replication competent viruses is conducted, the safety concerns are similar to working with the live viruses (assuming there could be a replication competent virus in the mix). These safety concerns must be addressed in your Laboratory Safety Plan and in your lab-specific training. Have not received information.

last name	Registration Date	Title	IBC Comments
McGowan	11/14/2005	Murine Appendage Stem Cells	Approved. Needs to specify what genetic alterations will be made to the animal (Question 2). <b>Provided. Approval letter sent.</b>
O'Neal	10/21/2005	Transmembrane and Secreted Mucin Function in the Mouse Airways	Not approved. Needs to provide a signed copy of the registration form and a map of the vector. Needs to confirm the location where these experiments will be conducted. Dr. O'Neal listed in Section II, #7 that the beta galactosidase gene will be under the control of CFV promoter. Needs to clarify whether she meant CMV promoter. <b>Have not received information.</b>

### III. Registrations for review

last name	Registration Date	Title	
Zhang	12/16/05	Analysis of NuRD: A Nucleosome Remodeling Histone Deacetylase (previously reviewed in Dec. 2005)	The IBC has requested answers to the following questions: 1. What envelope will the virus have on its surface? 2. What packaging system is being used for the retrovirus? 3. You state that Clontech advises that you check for retroviral expression periodically. How do you intend to do this?
Johnston		A New HIV Vaccine Concept (previously approved on 8/5/02)	The IBC has several questions about this registration and has requested that Dr. Johnston attend the next IBC meeting to discuss his project.
Lund	11/30/2005	Intestinal Adaptation: Role of Hormones and Growth Factors	Approved.
Lund	11/30/2005	Intestinal Adaptation: Role of Hormones and Growth Factors	Approved.
Lund	11/30/2005	Intestinal Adaptation: Role of Hormones and Growth Factors	Approved.
Lund	11/30/2005	Intestinal Adaptation: Role of Hormones and Growth Factors	Approved.
Lund	11/30/2005	Intestinal Adaptation: Role of Hormones and Growth Factors	Approved.
Lund	11/30/2005	Intestinal Adaptation: Role of Hormones and Growth Factors	Approved.

last name	Registration Date	Title	
Lund	11/30/2005	Intestinal Adaptation: Role of Hormones and Growth Factors	Approved.
Lund	11/30/2005	Intestinal Adaptation: Role of Hormones and Growth Factors	Approved.
Lund	11/30/2005	Intestinal Adaptation: Role of Hormones and Growth Factors	Approved.
Lund	11/30/2005	Intestinal Adaptation: Role of Hormones and Growth Factors	Approved.
Randell	12/01/2005	Identification of Airway Epithelial Stem Cells	Approved.
Pickles	12/01/2005	Generation of Mouse Airway Epithelial Cell Cultures for Paramyxovirus Infection	Approved. Need signed registration form.
Huang	12/01/2005	Evaluation the Therapeutic Efficacy of Drug Formulation in Mouse with Cystitis	Approved. Need signed registration form and map of the vector.
Crews	12/01/2005	Effects of Ethanol Neurotransmission in Brain Slice Cultures	Approved. Need signed registration form.
Grubb	12/02/2005	Regulation of ENaC by Proteases and SGK1	Approved.
Whinna	12/02/2005	The (Patho) Physiology of Murine Hemostasis and Thrombosis (03-349.0)	Approved.
Whinna	12/02/2005	Physiologic and Pharmacologic Regulation of Factor IXa (03-349.3)	Approved.
Su	12/02/2005	Modeling HCV Immunopathogenesis and Therapy	Approved.
Su	12/02/2005	Modeling HCV Immunopathogenesis and Therapy	Not approved. Needs to answer question #7 in Section II, question #7 in Section III and provided a more detailed map of the vector with promoter. In Section III #6 AD-239 cells are listed. Needs to confirm that he meant AD-293 and correct.
Hartnett	12/06/2005	Endothelial Transmigration in Neovascular Age-Related Macular Degeneration	Approved.
McGowan	12/08/2005	Murine Appendage Stem Cells	Approved.
Bautch	12/13/2005	Integrating Cell Division and Morphogenesis in Vessels	Approved.
Stafford	12/14/2005	VKOR Knock-Out	Not approved. Needs to answer questions 2,4,6,7,8 in Section II, questions 3, 4 in Section III and provide a physical map of the vector (Section III, #2).
Rathmell	12/14/2005	Kidney Proximal Tubule Specific Expression of Tumor Promoting Proteins	The IBC has requested answers to the following questions:
Rathmell	12/14/2005	Kidney Proximal Tubule Specific Expression of Tumor Promoting Proteins	<ol style="list-style-type: none"> <li>1. Please clarify what ER is.</li> <li>2. Please provide additional information about the GGT2 promoter you intend to use.</li> <li>3. Please provide information as to why you classified these experiments as BSL2.</li> </ol>

last name	Registration Date	Title	
Hartnett	12/16/2005	The Knockdown of VEGF Isoform 189	Approved at BSL2 (for work with adenovirus)
Tarran	12/19/2005	Ion and Mucus Transport in CF Airways	Not approved. Needs to answer questions 8, 9, 10 in Section II.
Kafri	11/30/2005	Lentiviral Vector Based Gene Therapy for Liver Diseases	Approved.
Kafri	12/21/2005	Lentiviral Vector Based Gene Therapy for Liver Disease	Not approved. If transgenic animals are to be created, a Schedule G form must be completed.
Fried	12/22/2005	Structure of Mammalian Signal Recognition Particle SRP68/SRP72 Domain	Approved.
Hammond	01/05/06	A link between RNAi and fragile X mental retardation	Not approved. Needs to provide a more complete description of experiments (#8, Section II) and explain why the experiments are BSL2.

Meeting adjourned at 4:45 p.m.



**Meeting Minutes**  
**February 6, 2006, 3:30 p.m.**  
**Thurston-Bowles Room 7033**

**Members Present:**

John Olsen  
Ray Hackney  
Donii Fox  
Dwight Bellinger  
Jeff Beecham

Fred Sparling  
Nancy Davis  
Deborah Howard

**Members Absent:**

Andrew Kaplan  
Robert Bosworth  
Tom Kawula  
Ed Holland

**Guests:**

Nancy King  
Robert Johnston  
Christy Jurgens

**Open Meeting**

I. Introduction of new member - Jeff Beecham, Director of the Gene Therapy Center's Joint Vector Labs

II. The minutes of the 1/9/06 IBC meeting were approved.

III. Discussion of Robert Johnston's protocol A New HIV Vaccine Concept

Robert Johnston and Christy Jurgens attended the meeting to discuss this project. The project involves the use of a VEE virus vector that will express SHIV gag and env. This will make a particle that can be used for vaccination against HIV. The particles are infectious in cell culture and will infect human cells. They cause an acute infection but cannot integrate into DNA. Worst case scenario if an employee became infected would include decrease of CD4 cells causing transient immunosuppression. A mutation could be added to the VEE vector that makes it more sensitive to interferon. If the vector is found to be lethal in mice or deplete their CD4 cells, mutations will be added. It is unknown whether the mice will shed viral particles. This will be evaluated in animal experiments and the information should be provided to the IBC when it is available. Because this is a chimeric virus, Johnston laboratory employees will perform all animal husbandry duties and all work will be conducted in the BSL3 laboratory. The committee suggested that a medical surveillance plan be developed to test for infection to this virus and employees working with this virus be tested monthly while doing the initial animal infections. A medical surveillance plan will be submitted by the Johnston lab at the next IBC meeting.

## IV. Registrations reviewed at 1/9/06 meeting needing further information.

last name	Registration Date	Title	
Zhang	12/16/05	Analysis of NuRD: A Nucleosome Remodeling Histone Deacetylase (previously reviewed in Dec. 2005)	The IBC has requested answers to the following questions: 1. What envelope will the virus have on its surface? 2. What packaging system is being used for the retrovirus? 3. You state that Clontech advises that you check for retroviral expression periodically. How do you intend to do this? <b>No information provided.</b>
Pickles	12/01/2005	Generation of Mouse Airway Epithelial Cell Cultures for Paramyxovirus Infection	Approved. Need signed registration form. <b>Received. Approval letter sent.</b>
Huang	12/01/2005	Evaluation the Therapeutic Efficacy of Drug Formulation in Mouse with Cystitis	Approved. Need signed registration form and map of the vector. <b>No information provided.</b>
Crews	12/01/2005	Effects of Ethanol Neurotransmission in Brain Slice Cultures	Approved. Need signed registration form. <b>No information provided.</b>
Su	12/02/2005	Modeling HCV Immunopathogenesis and Therapy	Not approved. Needs to answer question #7 in Section II, question #7 in Section III and provided a more detailed map of the vector with promoter. In Section III #6 AD-239 cells are listed. Needs to confirm that he meant AD-293 and correct. <b>No information provided.</b>
Stafford	12/14/2005	VKOR Knock-Out	Not approved. Needs to answer questions 2,4,6,7,8 in Section II, questions 3, 4 in Section III and provide a physical map of the vector (Section III, #2). <b>No information provided.</b>
Rathmell	12/14/2005	Kidney Proximal Tubule Specific Expression of Tumor Promoting Proteins	The IBC has requested answers to the following questions: 1. Please clarify what ER is. 2. Please provide additional information about the GGT2 promoter you intend to use. 3. Please provide information as to why you classified these experiments as BSL2. <b>Information provided. Approval letter sent.</b>
Rathmell	12/14/2005	Kidney Proximal Tubule Specific Expression of Tumor Promoting Proteins	
Tarran	12/19/2005	Ion and Mucus Transport in CF Airways	Not approved. Needs to answer questions 8, 9, 10 in Section II. <b>No information received.</b>
Kafri	12/21/2005	Lentiviral Vector Based Gene Therapy for Liver Disease	Not approved. If transgenic animals are to be created, a Schedule G form must be completed. <b>Transgenic animals are not going to be created. Submission of the form was a mistake.</b>

## V. Registrations reviewed.

last name	Registration Date	Title	IBC comments
Hartnett	12/29/2005	Endothelial Transmigration in neovascular Age-related Macular Degeneration	Approved.
Monroe	12/29/2005	Low Intensity Lasers in Wound Healing	Approved.
Deng	01/03/2006	Interleukin-6 expression and function in adipose cells	Approved. Need PI co-signature
Baldwin	01/03/2006	The Role of the transcription factor NF-kappaB in lung tumorigenesis	Approved.
Baldwin	01/03/2006	The role of the transcription factor NF-kappaB in lung cancer	Not approved. Complete Section III.
Bankaitis	01/04/2006	Rose of phosphoinositides in cellular homeostasis	Approved.
HAMMOND	01/05/2006	A link between RNAi and fragile X mental retardation	Approved.
Ting	01/05/2006	Plexins and Semaphorins in Immune Regulation	Approved.
Ting	01/05/2006	Plexins and Semaphorins in Immune Regulation	Approved.
Ting	01/05/2006	Plexins and Semaphorins in Immune Regulation	Approved.
Cairns	01/05/2006	CD8+ Tcell response after burn injury	Approved.
Ting	01/05/2006	Plexins and Semaphorins in Immune Regulation	Approved.
O'Brien	01/07/2006	Novel centrosomal proteins in spermatogenesis and sperm	Not approved. Missing page 2 and map of vector.
Parise	01/09/2006	Activation of cAMP-Mediated Sickle Cell Adhesion	Not approved. Provide more complete information for #6, #7 and #8.
Huang	01/09/2006	Evaluation the therapeutic efficacy of drug formulation in mouse with cystitis	Approved.
Ke	01/09/2006	Phosphodiesterase	Approved at BSL1. Clarify what is meant by "large scale".
Baric	01/11/2006	Susceptibility and Protective Immunity against Noroviruses	Approved.
Faber	01/12/2006	Mechanisms of Arteriogenesis in Ischemia	Approved.

Meeting adjourned at 5:10 p.m.

first name	last name	Registration Date	IBC comments
Dhaval Kumar	Patel	08/23/2004	approved
Dhaval Kumar	Patel	08/23/2004	approved
W. Kimryn	Rathmell	08/23/2004	approved
Raymond	Pickles	08/11/2004	approved
Raymond	Pickles	08/11/2004	approved
Raymond	Pickles	08/11/2004	approved
Raymond	Pickles	08/11/2004	Submit a registration document for the gene transfer experiments described
Cam	Patterson	08/10/2004	approved for genes stated
Wanda	O'Neal	07/29/2004	approved
Wanda	O'Neal	07/29/2004	approved
Wanda	O'Neal	08/02/2004	approved
Wanda	O'Neal	08/02/2004	approved
Wanda	O'Neal	08/02/2004	approved
Terry	van Dyke	08/02/2004	approved
Terry	van Dyke	08/02/2004	approved
Terry	van Dyke	08/02/2004	approved
Bruce	Cuevas	07/28/2004	approved
Bruce	Cuevas	07/28/2004	approved
Terete	Borras	08/24/2004	approved
Da-Zhi	Wang	07/08/2003	provide map and targeting vector
Eric	Everett	08/31/2004	Needs laboratory safety plan; transgenic mice approved after submission of LSP
Joseph	Pagano	09/09/2004	approved

The following registration documents were reviewed:

Members absent: Robert Bosworth, Ed Holland

Members present: John Olsen, Ray Hackney, Andrew Kaplan, Dwight Bellinger, Nancy Davis, Jennifer Giles, Tom Kawula,

Minutes

Monday,

Institutional Biosafety Committee Meeting