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SAINT LOUIS
UNIVERSITY

Institutional Biosafety Committee (IBC)

January 18, 2007

Edward H. Hammond, Director
The Sunshine Project
PO Box 41987
Austin, TX 78704

RE: Institutional Biosafety Committee Minutes

Dear Mr. Hammond:

The NIH Guidelines under which Saint Louis University responded were those regarding recombinant DNA research and the Institutional Biosafety Committee's oversight of such research. Please note that the University's response on June 1, 2006 to your previous request for IBC minutes dated March 15, 2006 specifically stated: "Please note that information not reportable to the NIH or otherwise restricted by federal regulations is redacted from the meeting minutes".

The majority of redacted materials from the minutes you received did not pertain to recombinant DNA research. In addition, and consistent with NIH's May 14, 2004 publication titled "Questions and Answers Concerning Institutional Biosafety Committee Meeting Minutes", specific information whose disclosure would directly compromise institutional or national security was also redacted.

Thank you,

Mark J. Campbell, M.S., RBP, CBSP
Biological Safety Officer and
IBC Executive Secretary



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SAINT LOUIS
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Institutional Biosafety Committee (IBC)

June 1, 2006

Edward H. Hammond, Director
The Sunshine Project
PO Box 41987
Austin, TX 78704

RE: Institutional Biosafety Committee Minutes

Dear Director Hammond:

Pursuant to The Sunshine Project's correspondence of March 15, 2006, please find enclosed the approved minutes of Saint Louis University's Institutional Biosafety Committee meetings from May 01, 2003 to February 08, 2006.

Please note that information not reportable to the NIH or otherwise restricted by federal regulation is redacted from the meeting minutes.

Very Truly Yours,

Mark J. Campbell
Biological Safety Officer

Enclosures

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
May 14, 2003

Location: LRC 113 **Time:** 10:00 a.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Thomas J. Chambers, M.D.	Associate Professor, Molecular Microbiology & Immunology
Steven Cummings, M.D.	Medical Director - Employee Health
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Pharmacia Corporation (c/o G.D. Searle & Company)
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

Excused:

Jeffrey H. Grubb, B.S.	Laboratory Supervisor, Biochemistry & Molecular Biology
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center

I. Introductions

IBC members introduced themselves to Steven Cummings, M.D., Medical Director for Employee Health and the newest member of the Institutional Biosafety Committee.

II. Old Business

- A. Approval of Minutes:** The minutes of the January 31, 2003 IBC meeting were fully approved by members present. **APPROVED, 13-0** by members present.
- B. Closed Items: Amendments to Existing Applications.**





2. **Lechner, Andrew J., Ph.D.** (Department of Pharmacological and Physiological Science) and **Matuschak, George, M.D.** (Department of Internal Medicine/Pulmonary) amendment to previously approved Research Application to add:

- **Biological agents**

[Drs. Lechner and Matuschak have added two lcr⁺ strains of *Yersinia pestis* to the approved application for work with *E. coli*, serotype 055:B5 and *Streptococcus pneumoniae*. As noted by Saint Louis University's Responsible Official (designated under the select agent program), these well-characterized, avirulent (plasmid-cured) organisms have been exempted from DHHS/USDA Select Agent status and do not require registration with the select agent program. See attached amendment document.]

- **Scope of procedure**

[Drs. Lechner and Matuschak have amended the scope of their current research application to include the use of Dr. Mark Buller's laboratory facility to complete a portion of the research project involving the avirulent strains of *Yersinia pestis*. See attached amendment document.]

C. Closed Items: Follow-up from Unapproved or Contingently Approved Applications Considered at the Previous Meeting, now fully approved.

1. **Shah, Maulik, M.D., Ph.D.** (Department of Internal Medicine/Division of Pediatrics and Medical Genetics) for use of:

- AD-HSP70 (Recombinant Adenovirus)
- AD-Bgal; AD-GFP (Adenovirus)
- ONYX-15; ADHE (Adenovirus)
- Moloney Murine Leukemia Virus (Murine Retrovirus)
- Lentivirus-FANC cDNA (HIV-1)
- Human Tumor Cell Lines (Cancer)

2. **Frey, Sharon, M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:

- Adenovirus serotype 5 vector (Ad5) Human Immunodeficiency Virus, Type 1 (HIV-1 gag vaccine)

D. Open Items: Follow-up from Unapproved or Contingently Approved Applications Considered at Previous Meeting.

1. **Subramanian, Thirugnana, Ph.D.** (Institute for Molecular Virology) for use of:

- pUC18-E1A (Adenovirus E1A)
- pcDNA3-T24 ras (Human ras)

- pRcCMV-19K-(Adenovirus E1B19K)
- pcDNA3HA-BclXL (Human BclXL)
- pcDNA3HA-Bfl-1 (Human Bfl-1)
- p53DD (Human p53)

[The Biosafety Officer is coordinating the final review and approval of this application with the investigator and the IBC Chairperson.]

III. New Business

A. Research Application Requiring 2nd Full Committee Review

1. **R. Buller, Mark L., Ph.D.** (Department of Molecular Microbiology and Immunology) and **Corbett, John, Ph.D.** (Department of Biochemistry) for use of:
 - Encephalomyocarditis virus (EMC)
 - Vesicular stomatis virus (VSV, Indiana)

Refer to attached letter addressed to Drs. Buller and Corbett for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that issues have been satisfactorily resolved in a revised application from the investigators.

B. New Applications

1. **Macarthur, Heather, Ph.D.** (Department of Pharmacological and Physiological Sciences) for use of:
 - *Escherichia coli* (055:B5)

Refer to attached letter addressed to Dr. Macarthur for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that issues have been satisfactorily resolved in a revised application from the investigators.

2. **Panneton, W. Michael, Ph.D.** (Department of Anatomy and Neurobiology) for use of:
 - Herpes Simplex Virus, type 1 (HSV-1, strain 129)

Refer to attached letter addressed to Dr. Panneton for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that issues have been satisfactorily resolved in a revised application from the investigators.

C. Other New Business

1. The Biosafety Officer noted that the current IBC members will be receiving reappointment letters.
2. The amendment submitted by **Lechner, Andrew J., Ph.D.** (Department of Pharmacological and Physiological Science) and **Matuschak, George, M.D.** (Department of Internal Medicine/Pulmonary) for work with avirulent *Yersinia pestis*, dated April 14, 2003 was reviewed by the full committee and was noted to reference use of a hazardous chemical,

glutaraldehyde, as a disinfectant and fixative. Refer to attached letter addressed to Drs. Lechner and Matuschak for details regarding committee review and follow-up.

There being no further business brought before the Committee, the meeting was adjourned at approximately 11:15 a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM(NRM), CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

DATE: May 29, 2003

TO: R. Mark L. Buller, Ph.D.
Department of Molecular Microbiology
& Immunology

FROM: Geoffrey Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Revised Research Application Dated May 22, 2003**

During the last meeting of the Institutional Biosafety Committee, your revised application for the use of specified biological agents was considered. The committee identified several items requiring follow-up. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. **Please type the information on the form.** Thank you.

Item 1 on page 1 of 11 (Date): Please indicate the date that the application is being revised.

Item 11 on page 3 of 12 (Protocol summary): Please correct the room number specified in line 13 of paragraph 3 from the stated 423b to the more accurate 432b.

Item A on page 9 of 12 (Table information): Please add room M93 to table and list appropriate information.

DATE: May 29, 2003

TO: Heather Macarthur, Ph.D.
Department Pharmacological
& Physiological Sciences

FROM: Geoffrey Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Revised Research Application Dated May 3, 2003**

During the last meeting of the Institutional Biosafety Committee, your revised application for the work with *Escherichia coli* (055:B5) was considered. The committee identified several items requiring follow-up. They are listed below. Please respond to these items by providing the requested information in an **updated** application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. **Please type the information on the form.** Thank you.

Item 10a on page 2 of 11 and Item A on page 9 of 11 (Room numbers): You have indicated you will be using M333 as noted on your room diagram. Please list M333 in both tables.

Item 11 on page 2 of 11 (Protocol summary): Please indicate what is being done with the organ preparations including manipulations and disposal.

On page 4 of 11, second full paragraph, you indicate that "All culture tubes and nutrient agar plates exposed to *E. coli* will be sealed within biohazard bags for removal and offsite incineration by members on the Office of Environmental Safety at SLU." Please clarify that the tubes will be capped and by stating the liquid volumes will be disposed of within the biohazard bags. Also, please remove reference to offsite incineration. Biohazard waste that is taken offsite is autoclaved.

Item 22 on page 8 of 11 (Autoclave): Comparative medicine will be incinerating the animal carcasses and the Office of Environmental Safety will be removing your laboratory generated biohazard waste for appropriate offsite disposal. Please indicate this section as non-applicable and delete the information you have provided.

DATE: May 29, 2003

TO: W. Michael Panneton, Ph.D.
Department of Anatomy and Neurobiology

FROM: Geoffrey Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Revised Research Application Dated April 14, 2003**

During the last meeting of the Institutional Biosafety Committee, your revised application for the work with *Herpes Simplex virus*, type 1 (HSV-1, strain 129) was considered. The committee identified several items requiring follow-up. They are listed below. Please respond to these items by providing the requested information in an **updated** application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. **Please type the information on the form. Thank you.**

Item 5 on page 1 of 11 (Biological agents): Please consistently identify the common name of your agent as HSV-1, strain 129 on all tables within the application. Strain 129 designation was not included on table A on page 8 of 11 and table located on the approval page.

Item 10a on page 2 of 11 (Room numbers): Please list the biohazard isolation room number as R542.

Item 11 on page 2 of 11 (Protocol summary): It is not clear if the mouse brains will be fixed and virus killed before sectioning. Please clarify. If the virus is not killed, provide a procedure for decontamination of the microtome and tools.

Please delete the sentence "Neither the experimental animals, nor the experimenters, will be fitted with respiratory protection; the animals because they are being sacrificed and the humans because the vapors are less than those present in the human gross anatomy laboratory."

Please indicate any mutations that would make HSV-1, strain 129 sensitive to particular

May 29, 2003

antiviral agents. The committee would like information regarding sensitivity of this strain to acyclovir. If you do not know the antiviral sensitivity characteristics of this strain, please arrange to have this testing completed and attach the results to your revised application. The following laboratory can provide the sensitivity testing:

ViroMed Laboratories
6101 Blue Circle Drive
Minnetonka, MN 55343
Phone: 800-582-0077, ext. 4081 or 952-563-3300
Fax: 952-939-4215
Email: information@viomed.com

The committee is not clear if HSV-1 will be grown in tissue culture in your laboratory. If so, please indicate this in the application. If not, please state that only frozen, previously prepared viral stocks will be accessed.

Item 21 on page 6 of 11 (Biological waste): Your application is not clear regarding what liquid waste you will be generating. Please describe.

Cidex is not approved for use in treating liquid infectious waste. Please indicate an approved method for liquid waste disposal (e.g., fresh 10% bleach treatment, 1:10 final dilution).

The committee is unclear regarding what items will be autoclaved. Please describe.

Item 24 on page 7 of 11 (Accidental injection): Please indicate the individual's skin will be thoroughly washed with soap or eyes flushed **continually for 15 minutes**.

Indicate that accidental exposures will be reported to Employee Health per University policies.

Please indicate the Biological Safety Officer will be notified and delete reference to Mark Campbell.

If you will be utilizing Cidex as the final choice of disinfectant in your laboratory, indicate that contact lenses will not be worn in the laboratory when this disinfectant is in use. Eye damage can result when splashes of cidex occur in the eye and the contact lenses fuse with the cornea. Please see Item C below regarding Cidex use.

Item C on page 9 of 11 (Disinfectant): The committee considers the disinfectant Cidex to be an extremely hazardous chemical to be used in the laboratory, for which alternatives exist. The Saint Louis University Department of Employee Health has indicated that special provisions are required to use this disinfectant safely in the laboratory. The provisions include the establishment of standard operating procedures geared towards safety and monitoring requirements of individuals exposed to this chemical. The committee recommends that you propose a safer alternative to the use of Cidex, especially since you are using this as a disinfectant. A broad spectrum disinfectant such as freshly prepared 10% bleach solution is one alternative.

May 29, 2003

Tools that need to be sterilized can be done so in an autoclave. If you plan to use an autoclave within your department (outside of comparative medicine), indicate the required information in item 22 on page 6 of 11.

DATE: May 29, 2003

TO: Andrew J. Lechner, Ph.D.
Department of Pharmacology and
Physiological Sciences

George Matuschak, M.D.
Department of Internal Medicine
Division of Pulmonary

FROM: Geoffrey Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: Committee Review and Risk Assessment regarding use of
glutaraldehyde.

During the last meeting of the Institutional Biosafety Committee, your approved amendment dated April 14, 2003 for use of avirulent *Yersinia pestis* was reconsidered. Although you were approved for working with this agent in your laboratory, as part of the amendment, the committee is concerned with the hazards associated with the use of glutaraldehyde to kill and fix materials. The committee considers glutaraldehyde to be an extremely hazardous chemical to be used in the laboratory, for which alternatives exist. The Saint Louis University Department of Employee Health has indicated that special provisions are required to use this disinfectant in the laboratory. The provisions include the establishment of standard operating procedures geared towards safety and monitoring requirements of individuals exposed to this chemical.

In consideration of the carcinogenicity and the required safety procedures for use of this agent, the committee would like you to consider an alternate chemical for use in this procedure (e.g., paraformaldehyde). If you feel that the use of glutaraldehyde is a necessary component to successfully complete your research projects, please provide your procedure for its use and safety precautions to avoid exposure to it. Please provide your procedure for preparing if for use to assure its cidal activity. The IBC will work with you as necessary to develop safe operating procedures to address chemical exposure issues while working with this agent. This is consistent with Saint Louis University Employee Health policy and the OSHA standard for glutaraldehyde use.

If you have any questions regarding this request, please contact the Biological Safety Officer, Mark Campbell, at 577-8608.

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
June 20, 2003

Location: Caroline 108

Time: 9:00 a.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Pharmacia Corporation (c/o G.D. Searle & Company)
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

Excused:

Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Thomas J. Chambers, M.D.	Associate Professor, Molecular Microbiology & Immunology
Steven Cummings, M.D.	Medical Director - Employee Health
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology

I. Old Business

A. Approval of Minutes: The minutes of the May 14, 2003 IBC meeting were fully approved by members present. **APPROVED, 9-0** by members present.

B. Closed Items: Amendments to Existing Applications.

1. **Lechner, Andrew J., Ph.D.** (Department of Pharmacological and Physiological Science) and **Matuschak, George, M.D.** (Department of Internal Medicine/Pulmonary) amendment to previously approved Research Application to add:

➤ **Biological agents**

[Drs. Lechner and Matuschak have added two lcr⁻ strains of *Yersinia pestis* to the approved application for work with *E. coli*, serotype 055:B5 and *Streptococcus pneumoniae*. As noted by Saint Louis University's Responsible Official (designated under

Source: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org
the select agent program), these well-characterized, avirulent (plasmid-cured) organisms have been exempted from DHHS/USDA Select Agent status and do not require registration with the select agent program. See attached amendment document.]

➤ Scope of procedure

[Drs. Lechner and Matuschak have amended the scope of their current research application to include the use of Dr. Mark Buller's laboratory facility to complete a portion of the research project involving the avirulent strains of *Yersinia pestis*. See attached amendment document.]

[The above amendments were approved by the IBC, however, the use of glutaraldehyde by these investigators remains an issue to be resolved. The Biological Safety Officer indicated that he is working with the University's Chemical Hygiene Officer to address the safety issues for use of this hazardous chemical. Once an SOP for the use of glutaraldehyde has been developed, the Biological Safety Officer will forward the document to the committee for review.]

C. Closed Items: Follow-up from Unapproved or Contingently Approved Applications Considered at the Previous Meeting, now fully approved or no longer being considered for approval.

1. Macarthur, Heather, Ph.D. (Department of Pharmacological and Physiological Sciences) for use of:

➤ *Escherichia coli* (055:B5)

[Approved between meetings]

2. Subramanian, Thirugnana, Ph.D. (Institute for Molecular Virology) for use of:

- pUC18-E1A (Adenovirus E1A)
- pcDNA3-T24 ras (Human ras)
- pRcCMV-19K (Adenovirus E1B19K)
- pcDNA3HA-BclXL (Human BclXL)
- pcDNA3HA-Bfl-1 (Human Bfl-1)
- p53DD (Human p53)

[The Biological Safety Officer (BSO) confirmed with Dr. Subramanian that the project involving the above agents will not be funded and the investigator is no longer seeking IBC review and approval for this project. The BSO indicated that Dr. Subramanian would notify the IBC if this project is funded and request IBC review and approval for this project.]

D. Open Items: Follow-up from Unapproved or Contingently Approved Applications Considered at Previous Meeting.

1. R. Buller, Mark L., Ph.D. (Department of Molecular Microbiology and Immunology) and **Corbett, John, Ph.D.** (Department of Biochemistry) for use of:

- Encephalomyocarditis virus (EMC)
- Vesicular stomatitis virus (VSV, Indiana)

2. **Panneton, W. Michael, Ph.D.** (Department of Anatomy and Neurobiology) for use of:
 - Herpes Simplex Virus, type 1 (HSV-1, strain 129)

II. New Business

A. New Applications:

1. **Tavis, John, Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Hepatitis B virus (HBV)
 - Hepatitis C virus (HCV)

Refer to attached letter addressed to Dr. Tavis for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that issues have been satisfactorily resolved in a revised application from the investigator.

2. **Wright, Lorinda, Ph.D.** (Department of Pharmacological and Physiological Sciences) for use of:
 - Human peripheral blood, bone tissue, and bone marrow

Refer to attached letter addressed to Dr. Wright for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that issues have been satisfactorily resolved in a revised application from the investigator.

3. **Di Bisceglie, Adrian, M.D.** (Department of Internal Medicine/Division of Gastroenterology and Hepatology) for use of:
 - Human serum containing Hepatitis C virus (HCV)
 - Human tissue (liver) containing HCV
 - Cell line derived from *Cercopithecus aethiops* (monkey, African green) (COS-7)
 - Cell line derived from *Homo sapiens* (humans) (293 cells)

Refer to attached letter addressed to Dr. Di Bisceglie for details regarding committee review. The committee tabled this application until issues have been satisfactorily resolved in a revised application from the investigator. This application will require full committee review during next scheduled IBC meeting.

B. Other New Business

1. IBC member Mr. Mark Haenchen noted to the committee that the university has completed the development of a select agent security plan that was mandated by the select agent rule (42 CFR Part 73). Mr. Haenchen indicated that the security plan was finalized on June 12, 2003 and would be fully implemented by September 12, 2003, in accordance with the select agent rule.

There being no further business brought before the Committee, the meeting was adjourned at approximately 11:15 a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM(NRM), CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

DATE: July 1, 2003

TO: John Tavis, Ph.D.
Department of Molecular Microbiology & Immunology

FROM: Geoffrey Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Revised Research Application Dated May 12, 2003**

During the last meeting of the Institutional Biosafety Committee, your research application for the use of Hepatitis viruses B and C was considered. The committee identified several items requiring follow-up. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Thank you.

Item 1 on page 1 of 13 (Date): Please indicate the date that the application is being revised.

Item 5 on page 1 of 13 (Agents): Please list the HepG2 2.2.15 cells on this table and also on the table located on certification and approval pages 12 and 13.

Item 6 on page 1 of 13 (Source): Please list the source of the cell line and attach a description of it (e.g., from ATCC).

Item 24 on page 8 of 13 (Accidental infection): Please delete your answer to this item and indicate that you will contact Employee Health in the event of an accidental injection with the listed agents.

Emergency Procedures on pages 10 and 11 of 13: Please add the HepG2 2.2.15 cell line to the list of agents and its location. Please indicate that bleach will be used for spills involving this cell line.

DATE: July 1, 2003

TO: Lorinda Wright, Ph.D.
Department Pharmacological
& Physiological Sciences

FROM: Geoffrey Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: Committee Review and Follow-up Regarding Your Revised Research
Application Dated June 5, 2003

During the last meeting of the Institutional Biosafety Committee, your revised application for the work with specified agents was considered. The committee identified several items requiring follow-up. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Please type the information on the form. Thank you.

Item 11 on page 3 of 15 (Protocol summary): You have noted in the section labeled "Immunohistochemistry with Bone Tissue" that you will be fixing bone tissue in 10% formalin within a biosafety cabinet in M335 for 12-24 hours. Unless your biosafety cabinet is a Class II, type B (hard-ducted to the outside) the committee recommends that the work with 10% formalin be performed within a fume hood.

Please remove the sentence: "This procedure will render non-viable any biological agents that may be present, and from this point forward this material will not be considered to be biohazardous." The committee feels that this statement cannot be confirmed because of the possibility of prions being present, however unlikely, which are not inactivated by 10% formalin.

Please verify the type of biosafety cabinet you have listed under "Isolation and Culture of Bone Marrow Cells". According to the Centers for Disease Control and Prevention's "Primary Containment for Biohazards: *Selection, Installation and Use of Biological Safety Cabinets*, 2nd ed. September 2000, a biosafety cabinet that is vented to the room and with no canopy, is a Class II, type A1 cabinet. You have indicated "type A2", which is a canopy cabinet.

Wright, L.

On page 6 of 15, under section labeled "Disposal of Liquid Waste" you have indicated the use of 1% CiDecon within a vacuum flask to be used as a disinfectant for waste. The committee has noted in the product description you have provided that this chemical is approved for use on lab surfaces and equipment only. Please remove reference to the use of this chemical for purposes other than lab surfaces and equipment. An alternative to the use of 1% CiDecon for this process is to replace the disinfectant with fresh 10% bleach.

Item 18 on page 10 and page 13: Please review the instructions for dilution of CiDecon and clarify if 1% solution is a 1:128 dilution. Explain that disinfectants including bleach and CiDecon will be prepared daily. If not, please describe and justify.

Item 22 on page 11 of 15 (Autoclave): Please provide a product insert describing the Prospore Self-Contained Biological Indicator (Fisher). The committee is unfamiliar with this brand of autoclave validation testing kit. Please remove Rose Bradley, a Sr. Financial Assistant, from those who will test the efficiency of the autoclave.

Additional clean-up precautions on page 13 of 15: Please indicate what is meant by 1% CiDecon (i.e., 2% is 2ml/98ml v/v, 1% is 1ml/99ml v/v, etc).

DATE: July 1, 2003

TO: Adrian M. Di Bisceglie, M.D.
Department of Internal Medicine/
Division of Gastroenterology & Hepatology

FROM: Geoffrey Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: Committee Review and Follow-up Regarding Your Revised Research Application Dated June 6, 2003

During the last meeting of the Institutional Biosafety Committee, your revised application for the work with specified agents was considered. The committee identified several items requiring follow-up. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Please type the information on the form. Thank you.

Item 5 on page 1 of 11 and on pages 8 and 11 (Agents): Please write the full name of Hepatitis C virus in the first column of the table as indicated (i.e., replace HCV with full name). Write HCV as the common name under column labeled Common name of agent in rows A and B.

Item 6 on page 1 of 11 (Source): Please provide information sheets from ATCC describing the cell lines.

Item 11 on page 2 of 11 (Protocol summary): The committee did not feel that your protocol summary was sufficient in detail to provide them with enough information to complete an acceptable risk analysis. The committee would like more detail in the protocol summary as would be provided in a grant application. As one component of the detailed protocol summary, describe the process of homogenization of tissues in greater detail.

Please describe what is being done with the COS-7 and 293 cells. You have provided no explanation for the use of these cells.

Item 15 on page 5 of 11 (Protective gear): You have indicated that personal protective equipment is worn as needed, depending on the risk. Please indicate specific PPE for the risk you are referring (i.e., Define when it is appropriate).

Item 17a on page 5 of 11 (Laboratory restriction): The committee would like more detail describing restricted access to your particular laboratories (e.g., closed doors, investigator or lab supervisor restricting access while work is in progress, etc.).

Item 22 on page 7 of 11 (Autoclave): Please indicate the location of the autoclave, the type of spore test that is being used to validate its function and indicate how often it will be spore tested. As indicated on the application, if you will be using the Autoclave Testing Protocol adapted by the Institutional Biosafety Committee (IBC), please so state.

Please verify that the person responsible for checking the operating efficiency of the autoclave (doing the spore testing) is really the person you have indicated.

Page 9 of 11 (Clean-up): Please indicate that the 10% bleach will be prepared fresh daily.

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
August 15, 2003

Location: Caroline 108

Time: 2:00 p.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Thomas J. Chambers, M.D.	Associate Professor, Molecular Microbiology & Immunology
Steven Cummings, M.D.	Medical Director – Employee Health
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology

Excused:

Paul J. Hippenmeyer, Ph.D.	Pharmacia Corporation (c/o G.D. Searle & Company)
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

I. Old Business

- A. Approval of Minutes:** The minutes of the June 20, 2003 IBC meeting were fully approved by members present. **APPROVED, 10-0** by members present.
- B. Closed Items:** Amendments to previously approved applications, fully approved. See attached documentation.
1. **Gorse, Geoffrey J., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for:
 - Adding personnel to list of laboratory workers trained for work with HIV within the BSL-3 laboratory located on the 10th floor of the Bordley complex. [Approved between meetings]
 2. **Shah, Maulik R., M.D., Ph.D.** (Department of Pediatrics/Medical Genetics) for:
 - Adding person to currently approved application for work with specified agents.

3. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) for:

- Adding person to currently approved application for work with specified agents.

[Approved between meetings]

C. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting, now fully approved.

1. **R. Buller, Mark L., Ph.D.** (Department of Molecular Microbiology and Immunology) and **Corbett, John, Ph.D.** (Department of Biochemistry) for use of:

- Encephalomyocarditis virus (EMC)
- Vesicular stomatis virus (VSV, Indiana)

2. **Wright, Lorinda, Ph.D.** (Department of Pharmacological and Physiological Sciences) for use of:

- Human peripheral blood, bone tissue, and bone marrow.

3. **Tavis, John, Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:

- Hepatitis C virus (HCV)
- Hepatitis B virus (HBV)
- HepG2 2.2.15 cells

D. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meeting.

1. **Panneton, Michael W., Ph.D.** (Department of Anatomy and Neurobiology) for use of:

- Herpes Simplex Virus, type 1 (HSV-1, strain 129)

[The Biological Safety Officer (BSO) indicated that the investigator is gathering the information requested by the IBC and the revised application will be submitted shortly.]

2. **Di Bisceglie, Adrian, M.D.** (Department of Internal Medicine/Division of Gastroenterology and Hepatology) for use of:

- Human serum containing HCV
- Human tissue (liver) containing HCV
- Cell line derived from Cercopithecus aethiops (monkey, African green) (COS-7)

- Cell line derived from Homo sapiens (humans) (293 cells)

[The BSO indicated the investigator submitted a revised application to be reviewed by the IBC. However, the application was incomplete as determined by the BSO and was forwarded back to the investigator for further revisions.]

II. New Business

A. New Applications

1. **Tolbert, Daniel L., Ph.D.** (Department of Anatomy and Neurobiology) for use of:

- AD-glial cell line neurotrophic factor (AD-GDNF)
- AD-Heat shock protein 70 (AD-SHP70)

- AD-Green Fluorescent protein (AD-GFP)
- AD-beta-galactosidase (AD-Bgal)

Refer to the attached letter addressed to Dr. Tolbert for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

2. **Ray, Ranjit, Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) and **Ray, Ratna B., Ph.D.** (Department of Pathology) for use of:
 - HCV replicon
 - Non-pathogenic E. coli (DH 5alpha)
 - HepG2, Hep3B, TPH and Huh-7 cells (Hepatoma cell lines)

Refer to the attached letter addressed to Drs. Ray for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

3. **Tomatsu, Shunji, M.D., Ph.D.** (Department Pediatrics) for use of:
 - MoMLV recombinant retrovirus expressing b-glucuronidase (Amphotrophic envelope pseudotyped).
 - MoMLV recombinant retrovirus expressing N-acetylgalactosamine-6-sulfate sulfatase (Amphotrophic envelope pseudotyped).

Refer to the attached letter addressed to Dr. Tomatsu for details regarding committee review. The committee granted approval contingent upon determination by the IBC Chairperson and other committee members that committee concerns have been satisfactorily resolved in a revised application from the investigator.

B. Other New Business

Mark Haenchen briefly indicated that the Select Agent Security Plan was in the process of being implemented and will be fully operational by the September 12, 2003 deadline as noted in the Select Agent Ruling.

There being no further business brought before the Committee, the meeting was adjourned at approximately 3:15 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM(NRM), CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

DATE: August 28, 2003

TO: Daniel L. Tolbert, Ph.D.
Department of Anatomy and Neurobiology

FROM: Geoffrey J. Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Research
Application Dated July 23, 2003**

During the last meeting of the Institutional Biosafety Committee, your research application for the use of Adenoviruses was considered. The committee identified several items requiring follow-up. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Thank you.

Item 1 on page 1 of 13 (Date): Please indicate the date that the application is being revised.

Item 5 on page 1 of 13 (Agents): Please correct the spelling of "AD-SHP70" to "AD-HSP70".

Item 10b on page 2 of 13 (Diagrams): Please provide a full page detailed diagram of each laboratory noted in Item 10a.

Item 11 on page 2 of 13 (Protocol summary): Please indicate if the adenoviruses are replication deficient. Also, indicate how long the microliter syringes will be flushed with fresh 10% bleach for decontamination. The committee has noted that a minimum of 5 minutes of flushing with fresh 10% bleach followed by 70% alcohol would be adequate for decontamination of the microliter syringes.

You indicate that "During exsanguinations for perfusion fixation blood will be collected in a container of 10% bleach." Please clarify that the collected blood will be in 10% bleach by volume.

Please provide a detailed description of histological processing of tissues to ensure safe

Tolbert, D.

handling prior to tissue fixation.

Please indicate what "PC" and "GDNF" abbreviate.

Item 14 on page 6 of 13 (Licensed vaccine): Please indicate "No" in regards to the availability of a licensed vaccine to adenovirus. The committee has noted that a vaccine does exist for said agent but it is no longer in production and not readily available.

Item 17b on page 6 of 13 (Unauthorized access): It is not clear who has access or keys to the room. Please indicate the approximate number of persons who possess a key for the room. For security reasons, the committee recommends that the freezer be locked if a broad population has access to the room. Please indicate that the room is locked when not in use. "secured" is not specific enough.

Item 20 on page 7 of 13 (Transport): The committee is concerned with the transport of dry ice within a sealed container. Under these circumstances, as the dry ice sublimates, the sealed transport vessel will become pressurized. The committee recommends that an alternate cooling method be used (i.e., use frozen transport carriers, regular ice, or place the dry ice around the pre-cooled and sealed transport container).

Item 21 on page 7 of 13 (Solid biological waste): Please indicate how plastic ware or disposables (e.g., pipets, pipet tips, etc.) are disposed of.

Item A on page 9 of 13 (Principal Investigator): Please insert your name and date of application where this information is requested.

DATE: August 28, 2003

TO: Ranjit Ray, Ph.D.
Department Internal Medicine/Division of Infectious Diseases

Ratna B. Ray, Ph.D.
Department of Pathology

FROM: Geoffrey J. Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: Committee Review and Follow-up Regarding Your Research
Application Dated August 8, 2003

During the last meeting of the Institutional Biosafety Committee, your revised application for the work with specified agents was considered. The committee identified several items requiring follow-up. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Please type the information on the form. Thank you.

Item 1 on page 1 of 12 (Date): Please indicate the date that the application is being revised.

Item 5 on page 1 of 12 and on pages 11 and 12 (Agents): Please specify "Hepatitis C Virus replicon (HCV replicon)" in the tables where referenced for clarification purposes.

Item 10a/10b on page 2 of 12 (Table and diagrams): You have listed rooms 1031, 1032, 1101, and 1108 on the table located in item 10a. You have listed room 1123 and not 1101 on the table located in section A on page 9 of 12. If work will not be completed in room 1123, please remove this from the table and replace it with room 1101. All tables and diagrams must be consistent.

The diagrams for Dr. Ranjit Ray's laboratories indicate rooms 1030 and 1031. You have listed rooms 1031 and 1032 on the tables located on pages 2 and 9. Please review the room designations and make the necessary corrections so that room numbers are consistently

Ray, R.
Ray, R.B.

listed throughout the application.

The diagram provided for room 1108 has the following statement: "(Not our: No samples here)". Please clarify or delete if not applicable.

Item 11 on page 2 of 12 (Protocol summary): The detailed ATCC cell line summaries were very helpful for the description of the noted hepatoma cells. However, the committee has found it difficult to locate an adequate description on the TPH cell line within the journal articles you have provided. Please provide a concise and detailed description of the TPH cell line within the Protocol Summary and what infectious agents may be expressed by it. Please clarify if infectious virions are produced by the hep3B cell line.

Please provide a description of G418.

In sentence 9 and 10 of the first paragraph you indicate: "...all precautions will be taken and waste will be discarded properly". Please change this sentence to: "...all BSL-2 precautions will be taken and waste will be discarded properly as described elsewhere in this application".

Item 14 on page 5 of 12 (Licensed vaccine): The committee recommends that your laboratory personnel show evidence of having Hepatitis B vaccination. The Occupational Health and Safety Administration (OSHA) requires that employees be offered this vaccination series if they are at risk personnel working with blood borne pathogens or other potentially infectious materials (including human cell lines).

Item 17b on page 6 of 12 (Unauthorized access): Please provide the location of the freezer where the biological agent (replicon cDNA) will be stored. Is the freezer locked?

Item 21 on page 7 of 12 (Autoclave): Please indicate that liquid waste will be disinfected in bleach at least 10% final dilution by volume overnight prior to disposal in the sink.

Item 24 on page 8 of 12 (Accidental injection): The Hep3B cell line possesses an integrated hepatitis B virus genome as indicated in the comments section of the ATCC reference document. It is presumed that this cell line does not produce infectious virus. Please indicate if this is so and provide evidence that the cell line does not produce infectious virus. Also, please provide information regarding the expression products from the HCV Replicon (i.e., Are these structural proteins? Is infectious HCV being produced? Any risks? If not, explain). Please provide information regarding the chances that accidental exposure to HCV replicon might cause HCV infection in those exposed.

Page 9 of 12 (Contact information): Please change the phone number for Tenet Facilities from x2222 to x22222. This revision will be incorporated in future applications.

Page 12 of 12 (Biological agents): Please provide the full name of the immortalized hepatocytes as you have listed in the table located in item 5 on page 1 of 12.

The names of the agents and cell lines must be the same in item 5, in the table on page 11 and the table on page 12.

DATE: August 28, 2003

TO: Shunji Tomatsu, M.D., Ph.D.
Department of Pediatrics

FROM: Geoffrey J. Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: Committee Review and Follow-up Regarding Your Revised Research Application Dated August 8, 2003

During the last meeting of the Institutional Biosafety Committee, your revised application for the work with specified agents was considered. The committee identified several items requiring follow-up. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Please type the information on the form. Thank you.

Item 1 on page 1 of 13 (Date): Please indicate the date that the application is being revised.

The committee found the application grammatically challenging to read because many words were split up at the ends of sentences. Please retype the application so that words within the document are not incorrectly split up within syllables.

Please remove all references to animal work being completed within the PRI and replace it with reference to the 5th floor biocontainment laboratory within Comparative Medicine. Make these changes throughout the entire application.

Item 10a on page 2 of 13 (Table): Please remove reference for the use of room 157 in the PRI. All animal work should be completed within the animal containment room in Comparative Medicine. An animal containment room in Comparative Medicine should be added to the table. Also, this room should be added to the table on page 10 of 13.

Item 10b on page 2 of 13 (Diagrams): Please remove reference to the animal facility within the PRI. Also, please provide a full page detailed diagram of each laboratory noted in Item 10a.

Item 11 on page 3 of 13 (Experimental procedure): Please clarify non-murine receptor usage by the amphotropic viruses.

Please define "MPS" in the text.

Please provide details of conventional histological assays to be used for tissues from sacrificed animals and describe any safety concerns inherent in these procedures and precautions to be taken.

You have noted the use of expression vectors for VSV-G. The VSV attenuated strains are controlled agents under the USDA's Commerce Control List (CCL) and require permits for transport and possession. Exotic VSV is considered a Select Agent and requires further regulatory actions. The committee would like confirmation that you do not possess VSV (attenuated or exotic). If you do, please contact the Biological Safety Officer (BSO) as soon as possible to devise a plan to obtain approval for their retention and use.

Item 14 on page 7 of 13 (Licensed vaccine): Please clarify what is meant by "is not an acute pathogen for primates". Please provide a copy of pages from the cited reference germane to this issue.

Please provide literature references regarding inactivation of the virus by human complement.

Item 21 on page 8 of 13 (Solid biological waste): Please note that all cell culture and other solid biohazard materials generated within the PRI are required to be autoclaved within the PRI. Remove reference indicating that "All waste will be autoclaved in the 5th floor biocontainment facility" and replace with reference to the PRI. If you plan another method of biohazard waste disposal, please provide details.

Item 22 on page 8 of 13 (Autoclave): Please indicate the location of the autoclave including building and room number. Also, indicate that you will be using the Autoclave Testing Protocol adapted by the Institutional Biosafety Committee (IBC). Please provide the title and name of the person operating the autoclave.

Item 24 on page 8 of 13 (Accidental injection): Please make the correction indicating that Recombinant retrovirus is inactivated by human serum complement and provide documentation of this from the literature. Is there any potential for infection in persons with complement deficiencies?

Page 11 (Disinfectant): Please indicate that the 10% bleach is prepared daily.

Pages 12 and 13 (Tables): Please provide the full names of the agents that is consistent with the listing in Item 4 on page 1 and also provide the footnotes to Item 4 with the tables on pages 12 and 13.

Page 13 of 13 (Approval): Please sign application in appropriate place and date.

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
September 29, 2003

Location: Caroline 108

Time: 11:30 a.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Thomas J. Chambers, M.D.	Associate Professor, Molecular Microbiology & Immunology
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Pharmacia Corporation (c/o G.D. Searle & Company)
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

Excused:

Steven Cummings, M.D.	Medical Director – Employee Health
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center

I. Old Business

- A. Approval of Minutes:** The minutes of the August 15, 2003 IBC meeting were fully approved by members present. **APPROVED, 11-0** by members present.

[REDACTED]

- C. Closed Items:** Follow-up from unapproved or contingently approved applications considered at the previous meeting.

1. **Panneton, Michael W., Ph.D.** (Department of Anatomy and Neurobiology) for use of:
 - Herpes Simplex Virus, type 1 (HSV-1, strain 129)[This investigator has withdrawn his application from IBC review. He is not convinced that experimentation with this agent is necessary to meet his experimental goals. This investigator indicated that should he need to use this agent in the future, he would pursue the IBC application process.]

D. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meeting.

1. **Tolbert, Daniel L., Ph.D.** (Department of Anatomy and Neurobiology) for use of:
 - AD-glial cell line neurotrophic factor (AD-GDNF)
 - AD-Heat shock protein 70 (AD-SHP70)
 - AD-Green Fluorescent protein (AD-GFP)
 - AD-beta-galactosidase (AD-Bgal)[The revised application has been submitted and is being reviewed.]
2. **Ray, Ranjit, Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) and **Ray, Ratna B., Ph.D.** (Department of Pathology) for use of:
 - HCV replicon
 - Non-pathogenic E. coli (DH 5alpha)
 - HepG2, TPH and Huh-7 cells (Hepatoma cell lines)[The revised application has been submitted and is being reviewed.]
3. **Tomatsu, Shunji, M.D., Ph.D.** (Department Pediatrics) for use of:
 - MoMLV recombinant retrovirus expressing b-glucuronidase (Amphotrophic envelope pseudotyped).
 - MoMLV recombinant retrovirus expressing N-acetylgalactosamine-6-sulfate sulfatase (Amphotrophic envelope pseudotyped).[The Revised application has not been submitted for final review. The Biosafety Officer will follow-up with this application before next meeting.]

II. New Business

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

B. New Applications:

1. **Chinnadurai, Govindaswamy (G), Ph.D.** (Institute for Molecular Virology) for use of:
 - Adenovirus type 2 & 5 wild-type and mutants with deletions in the E1B region.
 - Human tumor cell lines:

- A549 (lung carcinoma)
- HCT116 (colon carcinoma)
- MCF-7 (mammary carcinoma)
- 293 (adenovirus-transformed human cell line)

Refer to the attached letter addressed to Dr. Chinnadurai for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

[REDACTED]

There being no further business brought before the Committee, the meeting was adjourned at approximately 1:00 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM(NRM), CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

[REDACTED]

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DATE: October 2, 2003

TO: Govindaswamy Chinnadurai, Ph.D.
Institute for Molecular Virology

FROM: Geoffrey J. Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Revised Research Application Dated September 11, 2003**

During the last meeting of the Institutional Biosafety Committee, your research application for the work with specified agents was considered. The committee granted approval to your application contingent upon satisfactorily answering the following committee concerns. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Please type the information on the form. Thank you.

Item 1 on page 1 of 12 (Date): Please indicate the date that the application is being revised.

Item 11 on page 3 of 12 (Protocol summary): You have stated "The virus will be released from infected cells by freeze-thaw and clarified by low speed centrifugation." Please indicate that the low speed centrifugations will utilize a rotor with a sealable lid or screw cap buckets to contain aerosols during this process.

At the bottom of page 3 of 12, please remove the sentence "The group C Ads are considered non-pathogenic to humans." The committee does not agree with this statement.

Please indicate where the animals will be irradiated and what procedures you will employ to avoid environmental contamination since the animals are infected with adenovirus constructs prior to irradiation.

Item 14 on page 6 of 12 (Licensed vaccine): Please remove the sentence "Immunization against group C Ads is not required as most humans carry neutralizing adenovirus antibodies." The committee feels that this statement undermines the safety considerations for work with this biological agent.

Chinnadurai, G.

Page 2 of 2

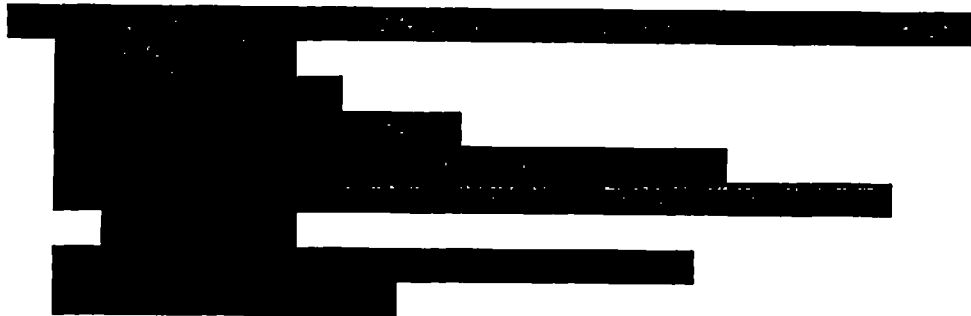
October 2, 2003

Item 21 on page 7 of 12 (Solid waste): Please indicate how liquid waste will be treated to render it non-infectious and the mode of disposal after disinfection. The committee recommends that you treat liquid waste with a 1:10 dilution final volume of freshly made bleach overnight.



C. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting; now fully approved.

1. Tolbert, Daniel L., Ph.D. (Department of Anatomy and Neurobiology) for use of:
 - AD-glial cell line neurotrophic factor (AD-GDNF)
 - AD-Heat shock protein 70 (AD-SHP70)
 - AD-Green Fluorescent protein (AD-GFP)
 - AD-beta-galactosidase (AD-Bgal)
2. Ray, Ranjit, Ph.D. (Department of Internal Medicine/Division of Infectious Diseases) and Ray, Ratna B., Ph.D. (Department of Pathology) for use of:
 - Hepatitis C virus replicon (HCV Replicon)
 - Non-pathogenic E. coli (DH 5alpha)
 - HepG2, TPH and Huh-7 cells (Hepatoma cell lines)



D. Open Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting.

1. Tomatsu, Shunji, M.D., Ph.D. (Department Pediatrics) for use of:
 - MoMLV recombinant retrovirus expressing b-glucuronidase (Amphotrophic envelope pseudotyped).
 - MoMLV recombinant retrovirus expressing N-acetylgalactosamine-6-sulfate sulfatase (Amphotrophic envelope pseudotyped).

[The Biological Safety Officer met with Dr. Tomatsu on November 10, 2003 to discuss the status of the application. Dr. Tomatsu has indicated that as a result of the physical relocation of his laboratory, he had misplaced the letter from the committee requesting additional information. The Biological Safety Officer forwarded Dr. Tomatsu a copy of the original letter and requested that he submit a revised application incorporating the changes requested by the committee.]
2. Chinnadurai, Govindaswamy (G), Ph.D. (Institute for Molecular Virology) for use of:
 - Adenovirus type 2 & 5 wild-type and mutants with deletions in the E1B region.
 - Human tumor cell lines:
 - A549 (lung carcinoma)
 - HCT116 (colon carcinoma)
 - MCF-7 (mammary carcinoma)
 - 293 (adenovirus-transformed human cell line)



II. New Business

A. New Applications:

- [REDACTED]
2. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
- rBCG30 (recombinant BCG): Live, attenuated vaccine
 - Parental Tice® BCG: Live, attenuated, non recombinant vaccine

Refer to the attached letter addressed to Dr. Hoft for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

3. **Buller, Mark L., Ph.D.** (Department Molecular Microbiology & Immunology) for use of:
- [REDACTED]
- [REDACTED]

Submitted as a separate application (5 year update review):

- Cowpox virus
- Vaccinia virus
- CV-1 cells
- BSC-1 cells

Refer to the attached letter addressed to Dr. Buller for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

Dr. Buller excused himself from the final discussion and vote by the committee regarding these two applications.

[REDACTED]

[REDACTED]

[REDACTED]

There being no further business brought before the Committee, the meeting was adjourned at approximately 11:15 a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM(NRM), CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

[REDACTED]

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[REDACTED]

DATE: November 26, 2003

TO: Daniel F. Hoft, M.D., Ph.D.
Internal Medicine/Division of Infectious Diseases

FROM: Geoffrey J. Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Research
Application Dated October 21, 2003**

During the last meeting of the Institutional Biosafety Committee, your research application for the work with specified agents was considered. The committee granted approval contingent upon satisfactorily answering the following committee concerns. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Please type the information on the form. Thank you.

Item 1 on page 1 of 11 (Date): Please indicate the date that the application is being revised.

Item 7 on page 1 of 11 (Use in humans): The committee has noted that the IRB protocol numbered r30-001 you have included for review is 17OCT03 Draft Version 0.1. Please submit the final version of the IRB document with the revised application.

On page 14 of 46 (Exclusion Criteria) of the draft IRB protocol numbered r30-001: The committee would like justification indicating why the exclusion criteria do not exclude participants with an immuno-suppressed household contact.

The committee does not see indication that if an ulcer results from vaccination, it will be covered with a barrier dressing. Please state if the BCG vaccine strains are culturable from the ulcer and drainage from the ulcer site following vaccination and how long viable organisms persist.

Item 10a and 10b on page 2 of 11 and item 17a on page 6 of 11 (Room numbers and diagram): You have indicated on table 10a that you will be using room E on the attached diagram. The committee is unable to locate room E on the diagram. Please identify where room E is located on the diagram. Please provide a detailed depiction of that room in a new diagram.

Item 13 on page 5 of 11 (Biological safety cabinet): Please provide literature references or other documentation that there is no risk of aerosol transmission of the vaccine strains. Please provide a copy of the Investigator's Brochure.

Item 18 on page 6 of 11 (Additional precautions): How will access only be limited to authorized personnel? Which areas will be limited to access by only authorized personnel and at what times vis a vis study procedures?

Item 19 on page 6 of 11 (Periodic blood samples): Please specify the frequency that the serial PPD skin tests will be done and by whom.

Item 24 on page 7 of 11 (Accidental injection): Please state that you will also contact Employee Health for further guidance and requisite incident reports per University policy will be completed.

Page 8, 10, and 11 on 11: The names of the biological agents should correspond on these pages with the listing in item 5 on page 1.

Page 9 of 11 (Disinfectant): Please attach a copy of the product information sheet for LpHse in addition to the MSDS.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

DATE: November 26, 2003

TO: Mark L. Buller, Ph.D.
Molecular Microbiology and Immunology

FROM: Geoffrey J. Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: Committee Review and Follow-up Regarding Your Research
Application Dated November 10, 2003

During the last meeting of the Institutional Biosafety Committee, your research application for the work with specified agents was considered. The committee granted approval to your application contingent upon satisfactorily answering the following committee concerns. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Please type the information on the form. Thank you.

Item 1 on page 1 of 12 (Date): Please indicate the date that the application is being revised.

Item 5 on page 1 of 12 (Biological agents): Please include a copy of the ATCC information sheet for each of the cell lines you have listed.

Please also list the viruses that are recombinant strains. Be sure that all agents listed in items 5 and on pages 9, 11, and 12 correspond exactly.

Item 14 on page 6 of 12 (Licensed vaccine): The committee is unclear regarding the purpose of the waiver. Please clarify. Please state that all persons working with these viruses have been vaccinated with vaccinia virus vaccine in the past 10 years.

Item 21 on page 7 of 12 (Solid and Liquid waste): Please indicate if you will be generating radioactive, infectious waste and describe the disposal procedures for this material. Please indicate which radionuclides will be used. Include a description of their use in item 11, as well.

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
January 21, 2004

Location: Caroline Rm. 108

Time: 9:00 a.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Ernest G. Jaworski, Ph.D. (Late Arrival)	Scientist-in-Residence, St. Louis Science Center
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

Excused:

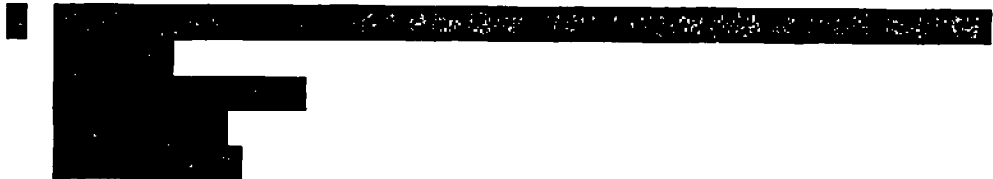
Thomas J. Chambers, M.D.	Associate Professor, Molecular Microbiology & Immunology
Steven Cummings, M.D.	Medical Director - Employee Health
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology

I. Old Business

- A. Approval of Minutes:** The minutes of the November 14, 2003 IBC meeting were fully approved by members present with 1 abstention. **APPROVED, 7-0** by members present.
- B. Closed Items: Amendments to previously approved applications, fully approved. See attached documentation, if applicable.**
- Gorse, Geoffrey J., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for:
 - Adding additional laboratory personnel to applications previously reviewed and approved by the Institutional Biosafety Committee (IBC).
[Approved between meetings]

2. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Clade B gag DNA/PLG and env DNA/PLG Microparticles Prime with a Clade B Recombinant, Oligomeric gp140/MF59 Adjuvant Boost
 - Multiclade HIV-1 DNA Plasmid Vaccine, VRC-HIV DNA 009-00-VPThese agents were added to the investigator's previously reviewed and approved application for work with HIV-1 gag Vaccine with procedures for manipulation and handling remaining unchanged.
[Approved between meetings]

C. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting(s), now fully approved.



- Buller, Mark L., Ph.D.** (Department Molecular Microbiology & Immunology) for use of: **5 year update review**
- Cowpox virus
 - Vaccinia virus
 - CV-1 cells
 - BSC-1 cells
 - Cowpox murine IL-4 recombinant
2. **Chinnadurai, Govindaswamy (G), Ph.D.** (Institute for Molecular Virology) for use of:
 - Adenovirus type 2 & 5 wild type and mutants with deletions in the E1B region.
 - Human tumor cell lines:
 - A549 (lung carcinoma)
 - HCT116 (colon carcinoma)
 - MCF-7 (mammary carcinoma)
 - 293 (adenovirus-transformed human cell line)
 3. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - rBCG30 (recombinant BCG): Live, attenuated vaccine
 - Parental Tice® BCG: Live, attenuated, non recombinant vaccine[This investigator has submitted a revised application and is pending final approval]
 4. **Di Bisceglie, Adrian, M.D.** (Department of Internal Medicine/Division of Gastroenterology and Hepatology) for use of:
 - Human serum containing Hepatitis C virus
 - Human tissue (liver) containing Hepatitis C virus
 - Cell line derived from cercopithecus aethiops (monkey, African green) (COS-7)
 - Cell line derived from Homo sapiens (humans) (293 cells)
 - *Escherichia coli* (E. coli)

D. Closed Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at the previous meeting.

1. **Tomatsu, Shunji, M.D., Ph.D.** (Department Pediatrics) for use of:
 - MoMLV recombinant retrovirus expressing b-glucuronidase (Amphotrophic envelope pseudotyped).
 - MoMLV recombinant retrovirus expressing N-acetylgalactosamine-6-sulfate sulfatase (Amphotrophic envelope pseudotyped).[This investigator has indicated that he will no longer pursue work with the above agents in his laboratory]

II. New Business

A. Revised Applications:

1. **Green, Michael, Ph.D.** (Department Molecular Microbiology & Immunology) for use of:
 - Murine PrP^{Sc} (Mouse prions)
 - Murine neuroblastoma cell line (N2a cells)[After a brief discussion of this application by the IBC, Dr. Green was invited to join the meeting to discuss and clarify details regarding his work with the above agents. Dr. Green was excused after his participation in the discussion of his application was completed]

Refer to the attached letter addressed to Dr. Green for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

B. New Applications:

1. **Perlman, Harris, Ph.D.** (Department Molecular Microbiology & Immunology) for use of:
 - Adenovirus type 5 (Ad5)
 - Human rheumatoid arthritis and osteoarthritis synovial fibroblasts (RA-fibroblasts and OA fibroblasts)[Dr. Perlman was invited to attend the IBC meeting to discuss his application but was unable to attend]

Refer to the attached letter addressed to Dr. Perlman for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

2. **Egan, Terrance, Ph.D.** (Department Pharmacological & Physiological Sciences) for use of:
 - Replication deficient Semliki Forest Virus (SFV)
 - Baby Hamster Kidney Cells (BHK-1)[After a brief discussion of this application by the IBC, Dr. Egan was invited to join the meeting to discuss and clarify details regarding his work with the above agents. Dr. Egan was excused after his participation in the discussion of his application was completed]

Refer to the attached letter addressed to Dr. Egan for details regarding committee review. The committee granted approval contingent upon the IBC Chairperson's

C. Other New Business

1. **The Fink Report** – Due to time constraints the committee proposed to discuss this document at the next scheduled IBC meeting.
2. **Pathogen Exposure Control Plan-DRAFT** – A draft version of the Pathogen Exposure Control Plan was distributed to all members present. The Biological Safety Officer provided a brief description of the changes that were included in the draft document. The Plan will be discussed during the next scheduled IBC meeting.

There being no further business brought before the Committee, the meeting was adjourned at approximately 11:30 a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM(NRM), CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

DATE: February 2, 2004

TO: Harris Perlman, Ph.D.
Molecular Microbiology and Immunology

FROM: Geoffrey J. Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Research
Application Dated January 1, 2004**

During the last meeting of the Institutional Biosafety Committee, your research application for the work with specified agents was considered. The committee granted approval contingent upon satisfactorily answering the following committee concerns. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Please type the information on the form. Thank you.

Item 1 on page 1 of 12 (Date): Please indicate the date that the application is being revised.

Item 5 on page 1 of 12 (Biological agents): The committee would like clarification indicating if you will be working with wild type adenovirus type 5 or only replication-deficient recombinant strains. If you will only be working with replication-deficient adenovirus type 5, please so state in the table as well as the tables located at the top of pages 11 and 12 of 12. Please indicate that the cells are Human rheumatoid arthritis and osteoarthritis synovial fibroblasts in the same places.

Item 10b on page 2 of 12 (Diagram): The committee would like to see a full page, detailed diagram of room 433 describing the facility and where items such as freezers, incubators, lab benches, and other relevant items are located.

The committee would like further details regarding why you require a warm room shaker you have identified in M420.

Please describe in more detail what is being done in the M424 cold room when you dialyze

Perlman, H.
Page 2 of 3
February 2, 2004

viruses in tubing. Please describe in more detail the tubing and procedure.

You have indicated the use of a biosafety cabinet and a laminar flow hood on the diagram you have provided as well as in a number of locations within the application. As you are probably aware, there are a number laminar flow cabinets and biosafety cabinets used for various purposes within the laboratory, depending on the activities. Laminar flow cabinets can be separated into two groups: Horizontal Laminar Flow "Clean Bench" and Vertical Laminar Flow "Clean Bench". These "Clean Bench" cabinets offer only product protection and expose workers to materials being manipulated. The committee recommends that work with the adenovirus be performed within a biosafety cabinet (Standard is a Class II, Type A, recirculating unit). Please confirm the type of laminar flow cabinet you are referring to throughout your application. If the laminar flow cabinet is really a biosafety cabinet, please make the changes within your application to reflect this.

It is unclear where virus and cells will be stored and manipulated. Please indicate this information on table in item 10a.

Item 11 on page 2 of 12 (Protocol summary): Please provide more detail describing the expression system you are using and provide information on how you will grow, purify, and titer the virus.

Please provide the titer of the adenovirus that you are striving to attain.

Will you be using cells other than the RA and OA fibroblasts in conjunction with your laboratory work? If so, please list them as biological agents on the relevant tables throughout the application.

Provide a brief description about the genes you have listed and indicate if any code for a toxin or virulence factor. Please indicate why the table of recombinant adenoviruses expressing foreign genes have column headings for date, particles/ml, etc., without further information.

In the last paragraph, you indicate that media is pipetted into a container containing undiluted bleach and that undiluted bleach is changed after each experiment by dispensing it down the drain. Please indicate that you will maintain a final concentration of not less than 10% bleach and you will let this solution sit overnight before dispensing it down the commercial sewer drain.

Item 14 on page 5 of 12 (Licensed vaccine): Please remove the explanation provided under "No" and indicate that laboratory personnel that are known to be immuno-compromised will not participate in activities involving manipulation of adenoviruses.

Item 21 on page 7 of 12 (Autoclave): Please indicate "All biological waste generated in the laboratory is autoclaved and then disposed of in the regular trash". The committee would like the autoclave parameters regarding the time and temperature of your standard autoclave cycle.

Perlman, H.
Page 3 of 3
February 2, 2004

Please specify the title of each person listed, as requested.

On page 9 of 12 (Emergency contacts): Please update the Biological Safety Officer's phone number (977-6888) on both pages 9 and 10, and the phone number for Tenet (x22222) on page 9.

On page 10 of 12 (Concentration): Please indicate that you will be using bleach 10% final concentration (by volume) prepared fresh on the day of use.

On page 11 of 12 (Signatures): Please provide all signatures and relevant information.

DATE: February 2, 2004

TO: Michael Green, Ph.D.
Molecular Microbiology & Immunology

FROM: Geoffrey J. Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Revised Research Application Dated September 19, 2003**

During the last meeting of the Institutional Biosafety Committee, your revised research application for the use of prions and N2a cells was reconsidered. The committee granted approval contingent upon satisfactorily answering the following committee concerns. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Thank you.

Item 1 on page 1 of 13 (Date): Please indicate the date that the application is being revised.

Item 4 on page 1 of 13 (Phone number): Please provide your updated phone number.

Item 5 on page 1 of 13 (Biological agents): Please list the strain designation RML (Rocky Mountain Laboratory) as part of the agent description throughout the application where this agent is listed.

Please list ScN2a cells as a separate biological agent throughout the application where applicable.

Item 9 on page 2 of 13 (Radioactive materials): Please state that if you need to utilize radioactive materials in conjunction with prion work, you will contact the Saint Louis

Green, M.
Page 2 of 2
February 2, 2004

Item 11 on page 2 of 13 (Protocol summary): Please provide a short statement of the sequences of species that the prions you will be using were passaged in. Please change your second sentence to read: "All experiments in R413a will use a tissue culture model system for prion infection using only murine prions, which are not known to infect human cells and, therefore should not be transmissible to humans". The committee feels that however low the probability of inter species transfer of murine prions to humans, it is not zero.

Item 11 on page 3 of 13 (Protocol summary): Within your summary you have stated: "In these cases, the prion samples will be inactivated prior to gel analysis by boiling in sample buffer containing 3% SDS and 5% beta-mercaptoethanol". Please replace "inactivated" with "treated". Please modify the next sentence to read: "The prion, a protein only infectious agent, is theoretically inactivated by treatments that denature proteins (See Appendix C)".

Please add statement that all treated materials will be considered infectious until incineration.

Item 3 on page 3 of 13 (Safety protocol): Please indicate that personnel will wear disposable lab coats and booties, which are kept in the prion room and are discarded into the prion room solid waste after working with infectious cells or lysates.

Item 8 on page 3 of 13 (Safety protocol): Provide the name of the company that will decontaminate the biosafety cabinet as part of the yearly certification requirement and include their standard operating procedure used for prions.

Item 11 on page 4 of 13 (Safety protocol): Please indicate that liquid waste will be treated to a final concentration of freshly made 2N NaOH. Also indicate that the NaOH treated liquid waste will be sealed in plastic bottles and placed in the biohazard waste containers along with the solid waste to be picked up by Stericycle for incineration at an off-site location. Some of the literature references refer to the use of 2M NaOH and others to 2N NaOH solutions for use as a disinfectant. Which preparation is more concentrated, and which do you plan to use?

Remove reference indicating that treated liquid waste will be disposed of as chemical waste.

Provide the temperature that is reached during the incineration process used by Stericycle.

Item 12 on page 4 of 13 (Decontamination): Please indicate that freshly made 2N NaOH will be used to treat contaminated surfaces and equipment for at least 1 hour following the LpH germicidal detergent treatment.

Page 9 of 13 (Emergency contacts): Please update the Biological Safety Officer's phone number (977-6888) on pages 9 and 10. Please list other lab personnel in addition to yourself who can be contacted in an emergency.

Page 10 of 13 (Disinfectant): Indicate that following the LpH germicidal detergent treatment, you will treat the area with freshly made (daily) 2 N NaOH final concentration to disinfect the spill. You can then wash the area with water as you have indicated.

DATE: February 2, 2004

TO: Terrance Egan, Ph.D.
Molecular Microbiology and Immunology

FROM: Geoffrey J. Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Research
Application Dated January 07, 2004**

During the last meeting of the Institutional Biosafety Committee, your research application for the work with specified agents was considered. The committee granted approval to your application contingent upon satisfactorily answering the following committee concerns. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Please type the information on the form. Thank you.

Item 1 on page 1 of 11 (Date): Please indicate the date that the application is being revised.

Item 6 on page 1 of 11 (Source): Provide documentation from Dr. Paul Werten describing the material being sent with indication that it is replication deficient, how it was generated, what genes are expressed, the titer and the volume.

Item 10a on page 2 of 11 (Rooms): Please indicate room numbers M365-M367 on the table.

Item 10b on page 2 of 11 (Diagram): The committee would like to see a full page, legible,

Source: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org
detailed diagram of rooms M365-M367 describing the facility and where items such as
freezers, incubators, lab benches, and other relevant items are located.

Item 11 on page 2 of 11 (Protocol summary): Please describe the cloned genes. Please describe the amount of SFV that will be used to transfect cells.

Egan, T.
Page 2 of 2
February 2, 2004

Please provide more detail describing the electrophysiology procedure and the procedure for the use of amphotericin antibiotic.

Item 17b on page 6 of 11 (Access): Please indicate that the biological agents will be stored frozen in a locked freezer located in room M367a.

Item 21 on page 6 of 11 (Solid waste): Please indicate that solid waste will be disposed of in a biohazard waste container, packaged and delivered to a medical waste vendor and autoclaved offsite.

Page 8 of 11 (Emergency contacts): Please list yourself as an individual to be contacted in the event of an emergency in your laboratory and provide the requested information.

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
February 24, 2004

Location: Caroline Rm. 108

Time: 1:30 p.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Steven Cummings, M.D.	Medical Director – Employee Health
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Ernest G. Jaworski, Ph.D. (Late Arrival)	Scientist-in-Residence, St. Louis Science Center
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology

Excused:

Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Thomas J. Chambers, M.D.	Associate Professor, Molecular Microbiology & Immunology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

I. Old Business

A. Approval of Minutes: The minutes of the January 21, 2004 IBC meeting were fully approved by members present with 1 abstention. The abstaining member did so because he was not present at the January meeting. **APPROVED, 10-0-1** by members present.

B. Closed Items: Amendments to previously approved applications, now fully approved.

1. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - ALVAC-HIV (vCP1452)
 - LIPO-5

These agents were added to the investigator's previously reviewed and approved application for work with HIV-1 gag Vaccine with procedures for manipulation and handling remaining unchanged.

2. **Gorse, Geoffrey J., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for:
 - Two human coronaviruses (ATCC designated as HcoV-229E and HcoV-OC43)These agents were added to the investigator's Safety Procedure Manual for the Division of Infectious Diseases entitled: "Laboratory Protocol for Work with Human Pathogens".
[Approved between meetings]
3. **Shah, Maulik R., M.D., Ph.D.** (Department of Pediatrics) for:
 - Change in designated laboratory space relative to his Research Application that was previously reviewed and approved by the Institutional Biosafety Committee (IBC).[Approved between meetings]

C. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting(s), now fully approved.

None

D. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at the previous meeting.

1. **Egan, Terrance, Ph.D.** (Department Pharmacological & Physiological Sciences) for use of:
 - Replication deficient Semliki Forest Virus (SFV)
 - Baby Hamster Kidney Cells (BHK-1)
2. **Green, Michael, Ph.D.** (Department Molecular Microbiology & Immunology) for use of:
 - Murine PrP^{Sc} (Mouse prions)
 - Murine neuroblastoma cell line (N2a cells)
3. **Perlman, Harris, Ph.D.** (Department Molecular Microbiology & Immunology) for use of:
 - Adenovirus type 5 (Ad5)
 - Human rheumatoid arthritis and osteoarthritis synovial fibroblasts (RA-fibroblasts and OA fibroblasts)

II. New Business

A. New Applications:

1. **Visconti, John, D.O.** (Department of Hematology and Oncology) for use of:
 - TNFerade™ ADGVE_{GR}-TNF.11D (TNFerade™ biologic)
 - Cis-Diaminedichloroplatinum (Cisplatin)
 - Fluorouracil (5-FU)

The IBC will forward correspondence to Dr. Visconti regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

B. Other New Business

1. **Pathogen Exposure Control Plan-DRAFT** – A draft version of the Pathogen Exposure Control Plan, which had previously been distributed was discussed by the committee. The Biological Safety Officer provided a brief description of the changes that were included in the draft document and asked for committee input. Following a short discussion, Mr. Mark Haenchen suggested that a Pathogen Exposure Control Plan development sub committee be formed to proceed with the development of the plan. The sub committee members are Mr. Mark Haenchen, Dr. Ella Swierkosz, Dr. Steven Cummings, and Mr. Mark Campbell. The sub committee will meet to discuss the development of the plan and will report to the committee at a future date. Updates regarding the sub committee's progress on the plan will be discussed during the next scheduled IBC meeting.

There being no further business brought before the Committee, the meeting was adjourned at approximately 3:15 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM(NRM), CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

DATE: March 8, 2004

TO: John Visconti, D.O.
Hematology and Oncology

FROM: Geoffrey J. Gorse, M.D.
Chairperson, Institutional Biosafety Committee

SUBJECT: **Committee Review and Follow-up Regarding Your Research
Application Dated January 24, 2004**

During the last meeting of the Institutional Biosafety Committee, your research application for the work with specified agents was considered. The committee granted approval contingent upon satisfactorily answering the following committee concerns. They are listed below. Please respond to these items by providing the requested information in an updated application. For your convenience, a blank application form is included with this letter. Please submit your revised application to the Office of Environmental Safety, Caroline Bldg. Rm. 307. An electronic file for the form is available from the Office of Environmental Safety. Please type the information on the form. Thank you.

Item 1 on page 1 of 19 (Date): Please indicate the date that the application is being revised.

Item 5 on page 1 of 19 (Biological agents): The committee recommends removing Cis-Diaminedichloroplatinum (Cisplatin) and Fluorouracil (5-FU) from this table and the tables located on pages 11 and 14 because they are not specific biological agents. The use and disposal of Cisplatin and 5-FU should be done in accordance with Tenet policy.

Item 7 on page 1 of 19 (IRB): Please provide a copy of the IRB protocol and a copy of the protocol provided by the sponsor. According to the NIH Guidelines for Research Involving Recombinant DNA Materials, the Saint Louis University IBC is required to review the clinical protocol provided by the sponsor for studies where recombinant DNA is being put into humans.

Item 10a on page 2 of 19, and 26a on page 11 of 19 (Room numbers): You are removing the listings for both Cisplatin and 5-FU and are no longer required to list the areas where these materials will be prepared and administered. Please remove the listings for the Investigational Pharmacy and the Infusion area.

Visconti, J.

Please list the endoscopy suite on this table on page 11. On the attached diagram of the area in the revised application, please clarify if this is a separate room, if the door is closed during the planned procedure to limit entry of non-authorized personnel and how the room will be cleaned after the procedures involving injection of TNFerade™. The diagram provided shows multiple "TV's" suggesting a common area without controlled access. Please provide an explanation of how access to the area will be limited to authorized personnel during study procedures.

Item 11 on pages 2 and 3 of 19 (Protocol summary): Please indicate how the adenoviral construct will be administered. Indicate the volume and infectious units of virus you are injecting and the frequency of injections.

Please describe the endoscopy procedure and include the procedures used for cleaning the instruments associated with this procedure or state that the hospital procedure will be followed for endoscopy cleaning. Please clarify the types of specimens to be collected and sent for adenovirus culture and how these are to be collected, transported and stored. Where will they be sent for culture and analysis?

Vector preparation manual: This manual frequently references the use of a cannula. Please describe the procedures used for the safe removal of the cannula.

You have provided detailed information regarding a Sterile Scrub Procedure. Please indicate when this is performed and by whom.

Please include the Vector Preparation Manual as an appendix to the revised application.

The MSDS sheet provided for the TNFerade™ biologic indicates, under Section IV – Medical (First Aid/Treatment), that "A serum sample should be taken as soon as possible." The IBC is unclear why this practice is necessary and would like clarification. Also, please state what is done with the serum sample once it has been taken (e.g., testing, storage, etc.).

You have indicated within the last sentence on page 3 of 19 that "All staff handling TNFerade™ should use personal protection equipment and universal precautions to include surgical gown/lab coat, gloves, and safety goggles. Please change "should" to "will".

You have indicated within the second sentence on page 4 of 19 that "Site staff preparing and administering TNFerade™ will be asked to follow Biosafety Level 2 Guidelines. Please change "asked" to "instructed".

Item 17a on page 8 of 19 (Access): Please change "a sign should be posted" to "a biohazard sign will be posted" with information regarding agent in use, personal protective equipment required for entry, prophylactic requirements (if applicable), and emergency response contact phone numbers. Delete the sentence "Any other requirements from the biosafety committee should also be in place".

Item 20 on page 9 of 19 (Transport): Please describe the primary and secondary containers. The primary and secondary container should be puncture resistant and leak proof. Please describe the path of transport geographically within the institution for the TNFerade™ prior to and following its mixture with diluent. Indicate the location of the procedure room.

Item 21 on page 9 of 19 (Solid waste): Please describe the procedure used to dispose of solid biological waste (i.e., point of segregation, bagging, boxing, manifesting, delivery to waste vendor, method of sterilization, and landfilling).

You have indicated within this section that Needles, syringes and any other receptacles used during the vector dilution and administration should be decontaminated before disposal using chemical disinfection. Please change "should" to "will". Please indicate the final concentration of chlorine bleach and length of exposure for chemical disinfectants.

Item 24 on page 10 of 19 (Accidental injection): Please indicate during regular business hours, you will report to the Saint Louis University Employee Health Department. After hours, you will report to the Saint Louis University Hospital emergency room.

Page 11 of 19 (Emergency contact): Please list the individuals noted in section 2 of table B also on page 13 of 19 (i.e., Certification of Laboratory Workers & Students).

Please maintain original margins throughout document. The certification and approval pages should be able to serve as stand alone documents.

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
March 25, 2004

Location: LRC Rm. 110

Time: 9:30 a.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Steven Cummings, M.D.	Medical Director - Employee Health
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

Excused:

Mark R. Buller, Ph.D.	Professor - Molecular Microbiology & Immunology
Thomas J. Chambers, M.D.	Associate Professor, Molecular Microbiology & Immunology

I. Old Business

A. Approval of Minutes: The minutes of the February 24, 2004 IBC meeting were approved by members present contingent upon minor correction. **APPROVED, 11-0** by members present.

B. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting(s), now fully approved.

None

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at the previous meeting.

1. **Green, Michael, Ph.D.** (Department Molecular Microbiology & Immunology) for use of:

- Murine PrP^{Sc} (Mouse prions)
- Murine neuroblastoma cell line (N2a cells)

This application has been submitted to the IBC Chairperson with revisions addressing committee concerns and is pending final approval.

2. **Perlman, Harris, Ph.D.** (Department of Molecular Microbiology & Immunology) for use of:
 - Adenovirus type 5 (Ad5)
 - Human rheumatoid or osteoarthritis arthritis synovial fibroblasts (RA-fibroblasts and OA fibroblasts)

This application is currently being amended by the investigator and is pending final submission to the IBC Chairperson.

3. **Egan, Terrance, Ph.D.** (Department of Pharmacological & Physiological Sciences) for use of:
 - Replication deficient Semliki Forest Virus (SFV)
 - Baby Hamster Kidney Cells (BHK-1)

This application has been submitted to the IBC Chairperson with revisions addressing committee concerns and is pending final approval.

4. **Visconti, John, D.O.** (Department of Hematology and Oncology) for use of:
 - TNFeradeTM ADGVE_{GR}.TNF.11D (TNFeradeTM biologic)

This application is currently being amended by the investigator and is pending final submission to the IBC Chairperson.

II. New Business

A. New Applications:

1. **Buller, R. Mark L., Ph.D. and Bellone, Cliff, Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Epstein-Barr Virus (EBV)

The IBC will forward correspondence to Dr. Buller and Dr. Bellone regarding committee review. The committee tabled the application with a number of safety concerns that still need to be addressed.

2. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - MVA-BN (Modified Vaccinia Ankara) (MVA-BN)
 - Dryvax

The IBC will forward correspondence to Dr. Frey regarding committee review. The committee granted approval contingent upon the IBC Vice Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

Dr. Gorse, a co-investigator of the clinical study, abstained from the vote.

3. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:

- TBC-M358: rMVA-HIV env/gag (TBC-M358)
(MVA, Modified Vaccinia Ankara)
- TBC-M335: rMVA-HIV rev/nef-RT (TBC-M335)
- TBC-F357: rFPV-HIV env/gag (TBC-F357)
(FP, fowlpox)
- TBC-F349: rFPV-HIV tat/env/nef-RT (TBC-F349)

The IBC will forward correspondence to Dr. Frey regarding committee review. The committee granted approval contingent upon the IBC Vice Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

Dr. Gorse, a co-investigator of the clinical study, abstained from the vote.

B. Other New Business:

1. **IBC member leaving.** It was announced during the meeting that Dr. Thomas Chambers would be changing his status of full time faculty member to part time faculty member and would be resigning from his post as IBC member with the Saint Louis University IBC.

[REDACTED]

[REDACTED]

There being no further business brought before the Committee, the meeting was adjourned at approximately 12:00 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM(NRM), CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
May 14, 2004

Location: Caroline 108

Time: 10:00 a.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark R. Buller, Ph.D. (Late arrival)	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Steven Cummings, M.D.	Medical Director – Employee Health
Richard E. Doyle, D.V.M. (Late arrival)	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Late arrival) (Vice-Chairperson)	Professor - Pathology

Excused:

Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration
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I. Old Business

A. Approval of Minutes: The minutes of the March 25, 2004 IBC meeting were approved by members present contingent upon minor correction. **APPROVED, 9-0** by members present.

B. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting(s), now fully approved.

1. **Green, Michael, Ph.D.** (Department Molecular Microbiology & Immunology) for use of:
 - Murine PrP^{Sc} (Mouse prions)
 - Murine neuroblastoma cell line (N2a cells)

2. **Egan, Terrance, Ph.D.** (Department of Pharmacological & Physiological Sciences) for use of:
 - Replication deficient Semliki Forest Virus (SFV)
 - Baby Hamster Kidney Cells (BHK-1)

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at the previous meeting.

1. **Buller, R. Mark L., Ph.D. and Bellone, Cliff, Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Epstein-Barr Virus (EBV)

This application is currently being amended by the investigators and is pending final submission to the IBC Chairperson.

2. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - MVA-BN (Modified Vaccinia Ankara) (MVA-BN)
 - Dryvax

This application has been submitted to the IBC Vice-Chairperson with revisions addressing committee concerns and is pending final approval.

3. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - TBC-M358: rMVA-HIV env/gag (TBC-M358)
(MVA, Modified Vaccinia Ankara)
 - TBC-M335: rMVA-HIV rev/nef-RT (TBC-M335)
 - TBC-F357: rFPV-HIV env/gag (TBC-F357)
(FP, fowlpox)
 - TBC-F349: rFPV-HIV tat/env/nef-RT (TBC-F349)

This application has been submitted to the IBC Vice-Chairperson with revisions addressing committee concerns and is pending final approval.

4. **Perlman, Harris, Ph.D.** (Department of Molecular Microbiology & Immunology) for use of:
 - Adenovirus type 5 (Ad5)
 - Human rheumatoid arthritis or osteoarthritis synovial fibroblasts (RA-fibroblasts and OA fibroblasts)

This application has been submitted to the IBC Chairperson with revisions addressing committee concerns and is pending final approval.

5. **Visconti, John, D.O.** (Department of Hematology and Oncology) for use of:
 - TNFerade™ ADGVE_{GR}.TNF.11D (TNFerade™ biologic)

This application is currently being amended by the investigator and is pending final submission to the IBC Chairperson.

II. New Business

A. New Applications:

1. **Heineman, Thomas C., M.D., Ph.D.** (Department of Internal Medicine/Division

- Varicella-zoster virus (VZV)

The IBC will forward correspondence to Dr. Heineman regarding committee review. The committee tabled the application with a number of concerns that still need to be addressed.

2. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:

- BCG Bacille Calmette Guerin (BCG), Copenhagen strain 1331 (BCG)

The IBC will forward correspondence to Dr. Hoft regarding committee review. The committee tabled the application with a number of concerns that still need to be addressed.

3. **Lodge, Jennifer K.** (Department of Biochemistry) for use of:

- *Cryptococcus neoformans*

The IBC will forward correspondence to Dr. Lodge regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

4. **Visconti, John L., D.O.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:

- PANVACTMVF (recombinant vaccinia virus and recombinant fowlpox virus.)

The IBC will forward correspondence to Dr. Visconti regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

B. Other New Business:



2. **Centers for Disease Control and Prevention (CDC) inspection results.** The Biosafety Officer indicated that the results of the CDC inspection, which occurred on January 29, 2004, were received recently. The Biosafety Officer indicated that the CDC inspection team identified no major issues.
3. **IBC Meeting Schedule.** The Biosafety Officer/IBC Executive Secretary suggested that the meeting schedule for the Saint Louis University IBC be conducted on a regularly scheduled basis (e.g., monthly) to handle the increasing number of IBC Research Applications that are being submitted by Investigators. The Biosafety Officer/IBC Executive Secretary will generate a schedule with meeting times and forward this document to the IBC members for their review.

There being no further business brought before the Committee, the meeting was adjourned at approximately 12:00 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM, RBP, CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
June 22, 2004

Location: Caroline 108

Time: 1:30 p.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark R. Buller, Ph.D. (Late arrival)	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology

Excused:

Steven Cummings, M.D.	Medical Director - Employee Health
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

I. Old Business

A. Approval of Minutes: The minutes of the May 14, 2004 IBC meeting were approved by members present contingent upon minor correction. **APPROVED, 10-0** by members present.

B. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting(s), now fully approved.

1. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - TBC-M358: rMVA-HIV env/gag (TBC-M358)
(MVA, Modified Vaccinia Ankara)
 - TBC-M335: rMVA-HIV rev/nef-RT (TBC-M335)
 - TBC-F357: rFPV-HIV env/gag (TBC-F357)
(FP, fowlpox)
 - TBC-F349: rFPV-HIV tat/env/nef-RT (TBC-F349)

2. **Perlman, Harris, Ph.D.** (Department of Molecular Microbiology & Immunology) for use of:
 - Adenovirus type 5 (Ad5)
 - Human rheumatoid arthritis or osteoarthritis synovial fibroblasts (RA-fibroblasts and OA fibroblasts)
3. **Visconti, John, D.O.** (Department of Internal Medicine/Division of Hematology and Oncology) for use of:
 - TNFerade™ ADGVE_{GR}.TNF.11D (TNFerade™ biologic)

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Buller, Mark L., Ph.D. and Bellone, Cliff, Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Epstein-Barr Virus (EBV)

This application was tabled in a previous meeting and is pending resubmission by these investigators.

2. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - MVA-BN (Modified Vaccinia Ankara) (MVA-BN)
 - Dryvax

This application is currently being revised by the investigator and is pending final submission to the IBC Vice-Chairperson for review and approval.

3. **Heineman, Thomas C., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Varicella-zoster virus (VZV)

A letter from the IBC requesting additional information was forwarded to this investigator on June 2, 2004.

4. **Lodge, Jennifer K.** (Department of Biochemistry) for use of:
 - Cryptococcus neoformans

This investigator has revised her initial application and has forwarded it to the IBC Chairperson for final review and approval.

5. **Visconti, John L., D.O.** (Department of Internal Medicine/Division of Hematology and Oncology) for use of:
 - PANVAC™VF (recombinant vaccinia virus and recombinant fowlpox virus.)

A letter from the IBC requesting additional information was forwarded to this investigator on June 2, 2004.

II. New Business

A. Revised Applications:

1. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:

- BCG Bacille Calmette Guerin (BCG), Copenhagen strain 1331 (BCG)

The IBC will forward correspondence to Dr. Hoft regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

B. New Applications:

1. **Barenkamp, Stephen J., M.D.** (Department of Pediatrics/Division of Infectious Diseases) for use of:
 - Nontypable *Haemophilus influenzae*
 - Replication-defective recombinant adenovirus 5 ΔE1,E3 derivatives

The IBC will forward correspondence to Dr. Barenkamp regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

[REDACTED]

C. Other New Business:

None

There being no further business brought before the Committee, the meeting was adjourned at approximately 3:30 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM, RBP, CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
July 27, 2004

Location: Caroline 108

Time: 1:30 p.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non-voting member)	Associate Provost for Research Administration

Excused:

Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Steven Cummings, M.D.	Medical Director - Employee Health
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)

I. Old Business

A. Approval of Minutes: The minutes of the June 22, 2004 IBC meeting were approved by members present contingent upon minor correction. **APPROVED, 8-0** by members present.

B. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting(s), now fully approved or withdrawn from review.

1. **Buller, Mark L., Ph.D. and Bellone, Cliff, Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Epstein-Barr Virus (EBV)

The investigators have withdrawn this application and will not be working with EBV.

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Barenkamp, Stephen J., M.D.** (Department of Pediatrics/Division of Infectious Diseases) for use of:
 - Nontypable *Haemophilus influenzae*
 - Replication-defective recombinant adenovirus 5 ΔE1,E3 derivatives

This application is currently being revised by the investigator and is pending final submission to the IBC Chairperson for final review and approval.

2. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - MVA-BN (Modified Vaccinia Ankara) (MVA-BN)
 - Dryvax

This application is currently being revised by the investigator and is pending final submission to the IBC Vice-Chairperson for review and approval.

3. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - BCG Bacille Calmette Guerin (BCG), Copenhagen strain 1331 (BCG)

This application is currently being revised by the investigator and is pending final submission to the IBC Chairperson for final review and approval.

4. **Lodge, Jennifer K.** (Department of Biochemistry) for use of:
 - *Cryptococcus neoformans*

This investigator has revised her initial application and it has been forwarded to the IBC Chairperson for review. The revised application is currently being further revised by the investigator and will be forwarded again to the IBC Chairperson for final review and approval.

5. [REDACTED]

6. **Visconti, John L., D.O.** (Department of Internal Medicine/Division of Hematology and Oncology) for use of:
 - PANVACTMVF (recombinant vaccinia virus and recombinant fowlpox virus.)

A letter from the IBC requesting additional information was forwarded to this investigator on June 2, 2004.

II. New Business

A. Revised Applications:

1. **Heineman, Thomas C., M.D., Ph.D.** (Department of Internal Medicine/Division

- Varicella-zoster virus (VZV)
- Vaccinia virus

The IBC will forward correspondence to Dr. Heineman regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

B. New Applications:

1. **Buller, Mark L., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - *Streptococcus gordonii*

The IBC will forward correspondence to Dr. Buller regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

C. Other New Business:

None

There being no further business brought before the Committee, the meeting was adjourned at approximately 3:00 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM, RBP, CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
August 18, 2004

Location: Caroline 108

Time: 9:30 a.m.

Present:

Name	Affiliation
Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

Excused:

Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Steven Cummings, M.D.	Medical Director - Employee Health
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology

I. Old Business

A. Approval of Minutes: The minutes of the June 27, 2004 IBC meeting were fully approved by members present. **APPROVED, 8-0** by members present.

B. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting(s), now fully approved.

1. **Barenkamp, Stephen J., M.D.** (Department of Pediatrics/Division of Infectious Diseases) for use of:
 - Nontypable *Haemophilus influenzae*
 - Replication-defective recombinant adenovirus 5 Δ E1, E3 derivatives

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Buller, Mark L., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - *Streptococcus gordonii*

The revised application is currently being revised by the investigator and will be forwarded to the IBC Vice-Chairperson for final review and approval.

2. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - MVA-BN (Modified Vaccinia Ankara) (MVA-BN)
 - Dryvax

The revised application is currently being further revised by the investigator and will be forwarded again to the IBC Vice-Chairperson for final review and approval.

3. **Heineman, Thomas C., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Varicella-zoster virus (VZV)
 - Vaccinia virus (Vaccinia)

This application is currently being revised by the investigator and is pending final re-submission to the IBC Chairperson for review and approval.

4. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - BCG Bacille Calmette Guerin (BCG), Copenhagen strain 1331 (BCG)

This application has been revised by the investigator and has been submitted to the IBC Chairperson for final review and approval.

5. **Lodge, Jennifer K.** (Department of Biochemistry) for use of:
 - *Cryptococcus neoformans*

The revised application is currently being further revised by the investigator and will be forwarded again to the IBC Chairperson for final review and approval.

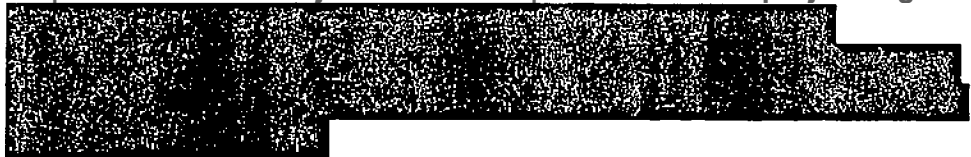
6. **Visconti, John L., D.O.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - PANVACTMVF (recombinant vaccinia virus and recombinant fowlpox virus.)

This application has been revised by the investigator and has been submitted to the IBC Chairperson for final review and approval.

7.

[REDACTED]

[REDACTED]



II. New Business

A. New Applications:

1. **George, Sarah L., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - GB Virus C/Hepatitis G virus (GBV-C)
 - Hepatitis C virus (HCV)
 - Human Immunodeficiency Virus-1 (HIV-1)
 - Jurkat cells
 - 293-T cells
 - Daudi cells
 - Competent *E. coli* cells
 - GBV-C cDNA genome
 - HCV cDNA genome
 - Primary human white blood cells

The IBC will forward correspondence to Dr. George regarding committee review.
The IBC granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

B. Other New Business:

None

There being no further business brought before the Committee, the meeting was adjourned at approximately 10:30 a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM, RBP, CBSP
Executive Secretary/Biological Safety
Officer, Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
September 15, 2004

Location: Caroline 108

Time: 9:30 a.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

Excused:

Steven Cummings, M.D.	Medical Director – Employee Health
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center

Guest:

John L. Visconti, D.O.	Associate Professor – Internal Medicine/Hematology/Oncology: Attended the portion of the meeting related to his protocol to answer questions and discuss his application. He left prior to final discussion and vote.
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I. Old Business

- A. Approval of Minutes:** The minutes of the August 18, 2004 IBC meeting were fully approved by members present with 1 abstention. The abstaining member did so because this member was not present at the August meeting. **APPROVED, 9-0-1** by members present.
- B. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting(s), now fully approved.**
1. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Additional laboratory space

See attached amendment.

2. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - BCG Bacille Calmette Guerin (BCG), Copenhagen strain 1331 (BCG)
 - BCG expressing green fluorescence protein (rBCG-GFP)
 - BCG expressing *T. cruzi* cruzipain or trans-sialidase (rBCG-CP and rBCG-TS)
 - Eukaryotic expression plasmid expressing Mtb72F (Mtb72F DNA)
 - Eukaryotic expression plasmid expressing Mtb41 (Mtcc2 DNA)
 - Cholera toxin

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - MVA-BN (Modified Vaccinia Ankara) (MVA-BN)
 - Dryvax

The revised application is currently being further revised by the investigator and will be forwarded again to the IBC Vice-Chairperson for final review and approval.

2. **George, Sarah L., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - GB Virus C/Hepatitis G virus (GBV-C)
 - Hepatitis C virus (HCV)
 - Human Immunodeficiency Virus-1 (HIV-1)
 - Jurkat cells
 - 293-T cells
 - Daudi cells
 - Competent *E. coli* cells
 - GBV-C cDNA genome
 - HCV cDNA genome
 - Primary human white blood cells

This application is currently being revised by the investigator and is pending final submission to the IBC Chairperson for review and approval.

3. **Heineman, Thomas C., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Varicella-zoster virus (VZV)
 - Vaccinia virus (Vaccinia)

This application is currently being revised by the investigator and is pending final submission to the IBC Chairperson for review and approval.

4. **Lodge, Jennifer K.** (Department of Biochemistry) for use of:
 - *Cryptococcus neoformans*

The revised application is currently being further revised by the investigator and will be forwarded again to the IBC Chairperson for final review and approval.
Note: The BSO has been in contact with this investigator regarding the contingencies set forth to be addressed prior to approval.

5. **Visconti, John L., D.O.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - **PANVACTMVF** (recombinant vaccinia virus and recombinant fowlpox virus.)

The revised application is currently being further revised by the investigator and will be forwarded again to the IBC Chairperson for final review and approval.
Note: The BSO has been in contact with this investigator regarding the contingencies set forth to be addressed prior to approval, but left prior to final committee discussion and vote.

[REDACTED]

II. New Business

A. New Applications:

1. **Belshe, Robert B., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - *Streptococcus pneumoniae* type 6B, CDC culture #DS2212-94, (*S. pneumoniae*)
 - *Streptococcus pneumoniae* type 14, CDC culture #DS2214-94, (*S. pneumoniae*)
 - *Streptococcus pneumoniae* type 23F, CDC culture #DS2216-94), (*S. pneumoniae*)

The IBC will forward correspondence to Dr. Belshe regarding committee review. The IBC granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

B. Other New Business:

[REDACTED]

[REDACTED]

[REDACTED]

2. The committee proposed to include in the SOP for this committee that we make a recommendation regarding whether vaccination is required or recommended or not and that be communicated to the PI via the IBC application form and to any other university committees that need to know. This document was voted on and fully approved by members present. The Biosafety Officer will generate the document and present it to the IBC at the next scheduled meeting.

There being no further business brought before the Committee, the meeting was adjourned at approximately 10:30 a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM, RBP, CBSP
Executive Secretary/Biological Safety Officer,
Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

Institutional Biosafety Committee

Meeting Minutes

October 5, 2004

Location: Caroline 306

Time: 10:00 a.m.

Present:

Name	Affiliation
Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Steven Cummings, M.D.	Medical Director – Employee Health
Richard E. Doyle, D.V.M. (Late arrival)	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Ernest G. Jaworski, Ph.D. (Late arrival)	Scientist-in-Residence, St. Louis Science Center
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

Excused:

Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)

Guest:

John L. Visconti, D.O.	Associate Professor – Internal Medicine/Hematology/Oncology: Attended the portion of the meeting related to his protocol to answer questions and discuss his application. He left prior to final discussion and vote.
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I. Old Business

A. Approval of Minutes: The minutes of the August 18, 2004 IBC meeting were fully approved by members present. **APPROVED, 9-0** by members present.

B. Closed Items: Follow-up from unapproved or contingently approved applications considered at the previous meeting(s), now fully approved.

1. **Buller, Mark L., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - *Streptococcus gordonii*
2. **George, Sarah L., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - GB Virus C/Hepatitis G virus (GBV-C)
 - Hepatitis C virus (HCV)
 - Human Immunodeficiency Virus-1 (HIV-1)
 - Jurkat cells
 - 293-T cells
 - Daudi cells
 - Competent *E. coli* cells
 - GBV-C cDNA genome
 - HCV cDNA genome
 - Primary human white blood cells
3. **Lodge, Jennifer K.** (Department of Biochemistry) for use of:
 - *Cryptococcus neoformans*

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Belshe, Robert B., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - *Streptococcus pneumoniae* type 6B, CDC culture #DS2212-94, (*S. pneumoniae*)
 - *Streptococcus pneumoniae* type 14, CDC culture #DS2214-94, (*S. pneumoniae*)
 - *Streptococcus pneumoniae* type 23F, CDC culture #DS2216-94), (*S. pneumoniae*)

This application is currently being revised by the investigator and is pending final submission to the IBC Chairperson for review and approval.

2. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - MVA-BN (Modified Vaccinia Ankara) (MVA-BN)
 - Dryvax

The revised application is currently being further revised by the investigator and

3. **Heineman, Thomas C., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Varicella-zoster virus (VZV)
 - Vaccinia virus (Vaccinia)

This application is currently being revised by the investigator and is pending final submission to the IBC Chairperson for review and approval.

II. New Business

A. Revised Applications:

1. **Visconti, John L., D.O.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - PANVACTMVF (recombinant vaccinia virus and recombinant fowlpox virus.)

The IBC will forward correspondence to Dr. Visconti regarding committee review. The committee granted approval contingent upon review and approval by the IBC Chairperson, IBC Vice-Chairperson and one other committee member that committee concerns have been satisfactorily resolved in a revised application from the investigator. Dr. Visconti participated in the discussion of his application, but left prior to final committee discussion and vote.

[REDACTED]

[REDACTED]

B. New Amendments:

[REDACTED]

[REDACTED]

C. New Applications:

1. **Wittgen, Catherine, M.D.** (Department of Surgery/SoLUtions) for use of:
 - Ad2/Hypoxia Inducible Factor (HIF)-1alpha/VP15; adenovirus

The IBC will forward correspondence to Dr. Wittgen regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

[REDACTED]

[REDACTED]

D. Other New Business:

1. Vaccination policy letter (draft). This document was distributed during the meeting and will be reviewed and discussed by the committee during the next scheduled meeting.

There being no further business brought before the Committee, the meeting was adjourned at approximately 12:40 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM, RBP, CBSP
Executive Secretary/Biological Safety Officer,
Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee
Administration

Robert O. Webster, Ph.D.
Associate Provost for Research

Institutional Biosafety Committee

Meeting Minutes
November 16, 2004

Location: Caroline 306

Time: 2:30 p.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Ernest G. Jaworski, Ph.D. (Late arrival)	Scientist-in-Residence, St. Louis Science Center
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

Excused:

Steven Cummings, M.D. Medical Director – Employee Health

I. Old Business

- A. Approval of Minutes:** The minutes of the October 5, 2004 IBC meeting were fully approved by members present. **APPROVED, 11-0** by members present.
- B. Closed Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings, now fully approved or withdrawn.**

Belshe, Robert B., M.D. (Department of Internal Medicine/Division of Infectious Diseases) for use of:

- *Streptococcus pneumoniae* type 6B, CDC culture #DS2212-94, (*S. pneumoniae*)
- *Streptococcus pneumoniae* type 14, CDC culture #DS2214-94, (*S. pneumoniae*)
- *Streptococcus pneumoniae* type 23F, CDC culture #DS2216-94), (*S. pneumoniae*)

- [REDACTED]
- [REDACTED]
3. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
- MVA-BN (Modified Vaccinia Ankara) (MVA-BN)
 - Dryvax
4. **Heineman, Thomas C., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
- Varicella-zoster virus (VZV)
 - Vaccinia virus (Vaccinia)

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Visconti, John L., D.O.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
- PANVACTMVF (recombinant vaccinia virus and recombinant fowlpox virus.)

This application is currently being revised by the investigator and is pending final submission with additional documentation to the IBC Chairperson, IBC Vice-Chairperson and one other committee member for review and approval.

- [REDACTED]
- [REDACTED]
3. **Wittgen, Catherine, M.D.** (Department of Surgery/SoLUtions) for use of:
- Ad2/Hypoxia Inducible Factor (HIF)-1alpha/VP15; adenovirus

This application is currently being revised by the investigator and is pending final submission to the IBC Chairperson for review and approval.

[REDACTED]

[REDACTED]

II. New Business

A. Amendments to Existing Applications:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

B. New or Revised Applications:

[REDACTED]

[REDACTED]

2. **Frey, Sharon, M.D.** (Department of Internal Medicine/Division of Infectious Diseases)
for use of:
 - > LC16m8 (LC16)
 - > Dryvax

The IBC will forward correspondence to Dr. Frey regarding committee review. The committee granted approval contingent upon the IBC Vice-Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator. Dr. Gorse abstained from voting.

3. **Frey, Sharon, M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
- Merck Adenovirus Serotype 5 HIV-1 gag/pol/nef Vaccine (MRKAd5 HIV-1 gag/pol/nef)
 - Placebo (diluent alone)

The IBC will forward correspondence to Dr. Frey regarding committee review. The committee granted approval contingent upon the IBC Vice-Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator. Dr. Gorse abstained from voting.

4. **Frey, Sharon, M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
- VRC HIVADV014-00-VP (VRC Adenovirus)

The IBC will forward correspondence to Dr. Frey regarding committee review. The committee granted approval contingent upon the IBC Vice-Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator. Dr. Gorse abstained from voting.

C. Other New Business:

1. Vaccination policy letter (draft).

(Due to time constraints, the vaccination policy letter was not discussed during this meeting and will be scheduled as an agenda item at the next IBC meeting.)

There being no further business brought before the Committee, the meeting was adjourned at approximately 4:45 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., SM, RBP, CBSP
Executive Secretary/Biological Safety Officer,
Institutional Biosafety Committee

Reviewed:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Robert O. Webster, Ph.D.
Associate Provost for Research Administration

Institutional Biosafety Committee

Meeting Minutes

December 15, 2004

Location: Caroline 306

Time: 9:30 a.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory St. Louis County Department of Health
Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Steven Cummings, M.D.	Medical Director – Employee Health
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S., J.D.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Ella M. Swierkosz, Ph.D. (Vice-Chairperson)	Professor - Pathology
Robert O. Webster, Ph.D. (Ex-Officio-non voting member)	Associate Provost for Research Administration

Excused:

Ernest G. Jaworski, Ph.D. Scientist-in-Residence, St. Louis Science Center

I. Old Business

- A. Approval of Minutes:** The minutes of the November 16, 2004 IBC meeting were fully approved by members present. **APPROVED, 11-0** by members present.
- B. Closed Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings, now fully approved.**

1. **Frey, Sharon, M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - LC16m8 (LC16)
 - Dryvax

[REDACTED]

II. New Business

A. Revised Applications:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

B. Other New Business:

1. Vaccination policy letter (draft). The IBC briefly discussed the letter. The letter will be modified and re-circulated to several IBC members including Drs. Geoffrey Gorse, Ella Swierkosz, Richard Doyle and Steven Cummings before reconsideration and approval by the committee.
2. NIH Compliance Letter (FYI).

There being no further business brought before the Committee, the meeting was adjourned at approximately 11:45 a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., RBP, CBSP
Executive Secretary, Institutional Biosafety Committee

Approved:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Joseph Weixlmann, Ph.D.
Provost

Institutional Biosafety Committee

Meeting Minutes

January 19, 2005

Location: LRC 104 A&D

Time: 9:30 a.m.

Present:

Name	Affiliation
Mark R. Buller, Ph.D.	Associate Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Ernest G. Jaworski, Ph.D. (late arrival)	Scientist-in-Residence, St. Louis Science Center
Mark G. Haenchen, M.S., J.D.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology

Excused:

Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory, St. Louis County Department of Health
Steven Cummings, M.D.	Medical Director - Employee Health

I. Old Business

- A. Approval of Minutes:** The minutes of the November 16, 2004 IBC meeting were contingently approved by members present pending minor revisions and assigning a new administrative signatory official. **APPROVED, 8-0** by members present.
- B. Closed Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings, now fully approved.**

[REDACTED]

[REDACTED]

3. **Buller, Mark L., Ph.D.** (Department of Molecular Microbiology and Immunology) for:
 - Amending scope for work with vesicular stomatitis virus and encephalomyocarditis virus: To include additional personnel.

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Visconti, John L., D.O.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - PANVACTMVF (recombinant vaccinia virus and recombinant fowlpox virus.)

This application is currently being revised by the investigator and is pending final submission with additional documentation to the IBC Chairperson and one other committee member for review and approval.

[REDACTED]

II. New Business

A. New Applications:

1. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Human Adenovirus Serotype 5 (Ad5)
 - VRX-007 (VRX-007, GZ3)
 - Replication defective adenovirus vector (AdCMVpA)

The IBC will forward correspondence to Dr. Wold regarding committee review. The committee granted approval contingent upon the IBC Chairperson's determination that committee concerns have been satisfactorily resolved in a revised application from the investigator.

B. Other New Business:

1. Revised facility plan for work within R408b, a BSL-3 laboratory.

The committee briefly reviewed a portion of the revised facility plan and recommended to the investigator (Dr. Robert M. Buller, Ph.D) that the document be further developed incorporating a number of revisions and correcting typos. Committee members forwarded their comments to the investigator during the meeting. The investigator will revise the facility plan and resubmit it as an agenda item at a future IBC meeting.

2. Vaccination policy letter (draft).

The committee discussed the policy letter and recommended a number of revisions. The Biosafety Officer will revise the document and present it at the next IBC meeting. The committee recommended that IBC member Steve Cummings, M.D., be present to participate in the discussion.

3. IBC Membership: Current and future changes.

Mark Haenchen, Director of the Office of Environmental Safety and Services and IBC member, described structural and operational changes planned for the IBC. Changes in the committee membership and the review process for applications are anticipated to be effective in March of 2005.

4. IBC schedule for 2005.

Mark Campbell announced that the IBC meeting schedule for 2005 will not be set with specific meeting dates until after the anticipated changes in committee membership have occurred in March of 2005.

There being no further business brought before the Committee, the meeting was adjourned at approximately 11:30 a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., RBP, CBSP
Executive Secretary, Institutional Biosafety Committee

Approved:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Joseph Weixelmann, Ph.D.
Provost

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
March 11, 2005

Location: Caroline Bldg. Rm. C108

Time: 11:00 a.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory, St. Louis County Department of Health
Mark R. Buller, Ph.D. (late arrival)	Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Steven Cummings, M.D.	Medical Director – Employee Health
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S., J.D.	Director/Radiation Safety Officer, Office of Environmental Safety
Paul J. Hippenmeyer, Ph.D.	Formerly: Pharmacia Corporation (c/o G.D. Searle & Company)
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Irene T. Schulze, Ph.D. (late arrival)	Professor Emeritus - Molecular Microbiology and Immunology
Michael W. Nickells, Ph.D. (Guest)	Assistant Research Professor – Molecular Microbiology & Immunology

Excused:

Ernest G. Jaworski, Ph.D. Scientist-in-Residence, St. Louis Science Center

I. Old Business

A. Approval of Minutes: The minutes of the January 19, 2005 IBC meeting were fully approved by members present. **APPROVED, 10-0** by members present.

B. Closed Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings, now fully approved.

1. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Human Adenovirus Serotype 5 (Ad5)
 - VRX-007 (VRX-007, GZ3)
 - Replication defective adenovirus vector (AdCMVpA)

2. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Amendment approval to add new animal model to previously approved application.

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Visconti, John L., D.O.** (Department of Internal Medicine/Division of Hematology/Oncology) for use of:
 - PANVACTMVF (recombinant vaccinia virus and recombinant fowlpox virus.)

This application is currently being revised by the investigator and is pending final submission with additional documentation to the IBC Chairperson, IBC Vice-Chairperson and one other committee member for review and approval

[REDACTED]

[REDACTED]

II. New Business

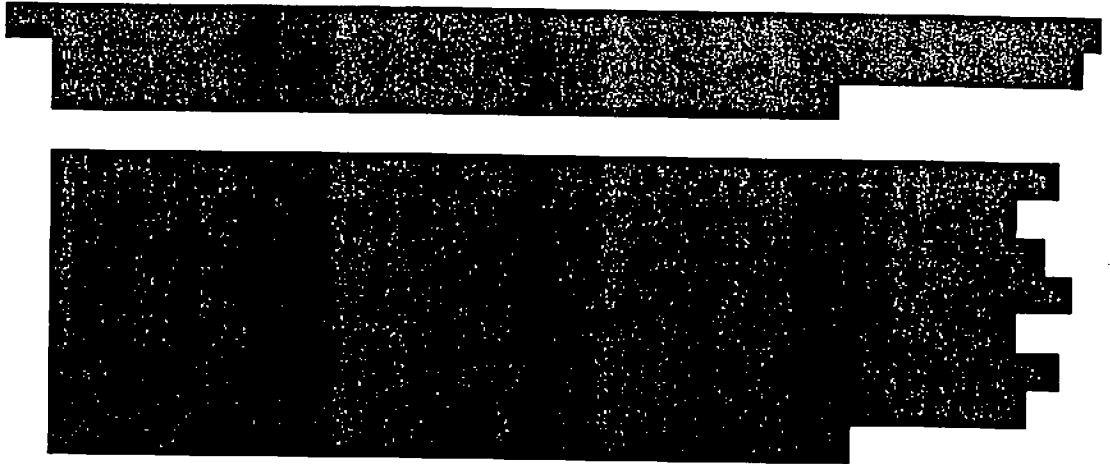
A. Revised Applications:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



B. New Applications:

1. **Bellone, Clifford J., Ph.D.** (Department of Molecular Microbiology and Immunology)
for use of:
 - *Aspergillus fumigatus*

The IBC forwarded correspondence to Dr. Bellone regarding committee review. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending final submission with additional documentation to the IBC Chairperson for review and approval.

2. **Bellone, Clifford J., Ph.D.** (Department of Molecular Microbiology and Immunology)
for use of:
 - Vaccinia virus
 - Ectromelia virus

The IBC forwarded correspondence to Dr. Bellone regarding committee review. The committee tabled the application with a number of concerns that still need to be addressed.

3. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Infectious Diseases)
for use of:
 - Molluscipox virus
 - Vaccinia virus

The IBC forwarded correspondence to Dr. Hoft regarding committee review. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending final submission with additional documentation to the IBC Chairperson for review and approval.

4. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology)
for use of:
 - Rift Valley fever virus recombinant M segment [RVFV M (in WRG-7077)]
 - Adenovirus serotype 5 expressing RVFV G2 (a subset of M segment) [Ad-G2]

The IBC forwarded correspondence to Dr. Wold regarding committee review. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending final submission with additional documentation to the IBC Chairperson for review and approval.

5. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
 - ACAM3000 MVA
 - MVA-BN
 - Dryvax

The IBC forwarded correspondence to Dr. Frey regarding committee review. Dr. Gorse removed himself from the meeting prior to the committee voting. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending final submission with additional documentation to the newly nominated IBC Vice-Chairperson (Dr. Mark Buller) for review and approval.

C. Other New Business:

1. Mark Haenchen nominated Mark Buller, Ph.D. as the IBC Vice-Chairperson to fill this recently vacated position. The committee voted unanimously to appoint Dr. Buller to the position. Mark Haenchen indicated that he would generate the appointment letter and forward it to the Provost for approval.

There being no further business brought before the Committee, the meeting was adjourned at approximately 1:45 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., RBP, CBSP
Executive Secretary, Institutional Biosafety Committee

Approved:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Joseph Weixelmann, Ph.D.
Provost

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
August 10, 2005

Location: LRC Rm. 110

Time: 11:00 a.m.

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory, St. Louis County Department of Health
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Terrance M. Egan, Ph.D.	Associate Professor – Pharmacological & Physiological Sciences
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Michael Green, Ph.D.	Professor – Molecular Microbiology and Immunology
Mark G. Haenchen, M.S., J.D.	Director/Radiation Safety Officer, Office of Environmental Safety
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Jennifer K. Lodge, Ph.D.	Associate Dean for Research Professor - Biochemistry
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Frances K. Newman, M.S.	Assistant Research Professor – Internal Medicine/Infectious Diseases
Judith M. Ogilvie, Ph.D.	Assistant Professor - Biology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology

Excused:

Mark R. Buller, Ph.D.	Professor - Molecular Microbiology & Immunology
Steven Cummings, M.D.	Medical Director – Employee Health
Lynda A. Morrison, Ph.D.	Associate Professor – Molecular Microbiology and Immunology
Brent A. Neuschwander-Tetri, M.D.	Associate Professor – Internal Medicine/Gastroenterology
Harris R. Perlman, Ph.D.	Assistant Professor – Molecular Microbiology and Immunology

I. Old Business

A. Approval of Minutes: The minutes of the March 11, 2005 IBC meeting were fully approved by members present. **APPROVED, 12-0** by members present.

B. Closed Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings, now fully approved.

1. [REDACTED]
2. **Bellone, Clifford J., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - *Aspergillus fumigatus*
3. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
 - ACAM3000 MVA
 - MVA-BN
 - Dryvax
4. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
 - Molluscipox virus
 - Vaccinia virus
5. **Lewis, Roger, Ph.D.** (School of Public Health) for use of:
 - *Dermatophagoides farinae* (Dust Mite)
 - *Cladosporium sphaerospermum* (Mold)
6. **Visconti, John L., D.O.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - PANVACTMVF (recombinant vaccinia virus and recombinant fowlpox virus.)
7. [REDACTED]
8. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology), **Buller, Mark L., Ph.D.** (Department of Molecular Microbiology and Immunology) for:
 - Facility Plan for BSL-3 Suite (Doisy R408A and R408B)
9. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:

- Rift Valley fever virus recombinant M segment [RVFV M (in WRG-7077)]
- Adenovirus serotype 5 expressing RVFV G2 (a subset of M segment) [Ad-G2]

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Bellone, Clifford J., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Vaccinia virus
 - Ectromelia virus

II. New Business

A. New Applications (Renewals):

1. [REDACTED]

[REDACTED]

2. **Gorse, Geoffrey J., M.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
 - Human Coronavirus-229E (HCoV-229E)
 - Human Coronavirus-OC43 (HCoV-OC43)
 - MRC-5 cells
 - HCT-8 cells

The IBC forwarded correspondence to Dr. Gorse regarding committee review. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending final submission with additional documentation to the primary reviewer and the acting IBC Vice-Chairperson for review and approval.

3. **Gorse, Geoffrey J., M.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
 - Vaccinia virus and recombinant vaccinia viruses
 - Epstein-Barr virus (EBV)
 - Human Cytomegalovirus (AD-169 strain) viral lysate
 - H9 cells (T cell lymphoma, human)
 - SUP-T1 cells (Non-Hodgkins T-cell lymphoma)
 - Human Immunodeficiency Virus type 1 (primary isolates and lab-adapted strains)

The IBC forwarded correspondence to Dr. Gorse regarding committee review. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending final submission with additional documentation to the primary reviewer and the acting IBC Vice-Chairperson

for review and approval.

B. Other New Business:

1. Vaccination policy letter (draft): The draft vaccination policy letter was not reviewed during the IBC meeting. The committee felt that committee member Steven Cummings, M.D. should be present for the discussion. Dr. Cummings was excused from this meeting.
2. IBC Member Resignation: Dr. Paul Hippenmeyer has accepted a position with a Bio.Tech. company located out of state and has regretfully resigned from the Saint Louis University IBC. (See newly revised membership roster).

The Biosafety Officer also noted that new IBC member Robert E. Fleming, M.D., has requested that he be removed from this committee for personal reasons.

3. IBC schedule for 2005. Although on the agenda, this item was not discussed..

There being no further business brought before the Committee, the meeting was adjourned at approximately 12:00 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., RBP, CBSP
Executive Secretary, Institutional Biosafety Committee

Approved:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Joseph Weixlmann, Ph.D.
Provost

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
October 12, 2005

Location: Caroline 306

Time: 10:00am

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory, St. Louis County Department of Health
Mark R. Buller, Ph.D.	Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Steven Cummings, M.D.	Medical Director – Employee Health
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Terrance M. Egan, Ph.D.	Associate Professor – Pharmacological & Physiological Sciences
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Michael Green, Ph.D.	Professor – Molecular Microbiology and Immunology
Mark G. Haenchen, M.S., J.D.	Director/Radiation Safety Officer, Office of Environmental Safety
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Lynda A. Morrison, Ph.D.	Associate Professor – Molecular Microbiology and Immunology
Brent A. Neuschwander-Tetri, M.D.	Associate Professor – Internal Medicine/Gastroenterology
Frances K. Newman, M.S.	Assistant Research Professor – Internal Medicine/Infectious Diseases
Judith M. Ogilvie, Ph.D.	Assistant Professor - Biology
Harris R. Perlman, Ph.D.	Assistant Professor – Molecular Microbiology and Immunology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology

Excused:

Jennifer K. Lodge, Ph.D.	Associate Dean for Research Associate Professor - Biochemistry
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I. Old Business

A. Approval of Minutes: The minutes of the August 10, 2005 IBC meeting were fully approved by members present. **APPROVED, 17-0** by members present.

B. Closed Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings, now fully approved.

[REDACTED]

[REDACTED]

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Bellone, Clifford J., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Vaccinia virus
 - Ectromelia virus

The Biological Safety Officer contacted the investigator via email to request the status of this submission. This application is currently being revised by the investigator and will be submitted at the next scheduled IBC meeting.

2. **Gorse, Geoffrey J., M.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
 - Human Coronavirus-229E (HCoV-229E)
 - Human Coronavirus-OC43 (HCoV-OC43)
 - MRC-5 cells
 - HCT-8 cells

This application is pending final submission to the primary reviewers as a follow up to verify that IBC contingencies have been met. Full approval is pending.

3. **Gorse, Geoffrey J., M.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
 - Vaccinia virus and recombinant vaccinia viruses
 - Epstein-Barr virus (EBV)
 - Human Cytomegalovirus (AD-169 strain) viral lysate
 - H9 cells (T cell lymphoma, human)
 - SUP-T1 cells (Non-Hodgkins T-cell lymphoma)
 - Human Immunodeficiency Virus type 1 (primary isolates and lab-adapted

strains)

This application is pending final submission to the primary reviewers as a follow up to verify that IBC contingencies have been met. Full approval is pending.

II. New Business

A. New Applications (Renewals):

1. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - DNA: pGA2/JS7 DNA vaccine (DNA)
 - MVA: Recombinant modified vaccinia Ankara/HIV62 vaccine (MVA)

The IBC forwarded correspondence to Dr. Frey regarding committee review. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending final submission with additional documentation to the IBC Chairperson for review and approval.

2. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Adenovirus type 5 expressing beta-gal (Ad5-beta-gal)
 - Adenovirus type 5 expressing *Trans*-sialidase (Ad5-TS)
 - Human Embryonic Kidney 293 cells (HEK 293)

The IBC forwarded correspondence to Dr. Hoft regarding committee review. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending final submission with additional documentation to the IBC Chairperson for review and approval.

3. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Human Influenza virus

The IBC forwarded correspondence to Dr. Hoft regarding committee review. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending final submission with additional documentation to the IBC Chairperson for review and approval.

4. **Li, Dechun, M.D., Ph.D.** (Department of Internal Medicine/Division of Pulmonary) for use of:
 - Adenoviral construct (Adeno-HIMF)
 - Retroviral construct (Retro-HIMF)
 - Human Embryonic Kidney 293 cells (HEK 293)
 - E. coli DH5alpha (DH5alpha)

The IBC forwarded correspondence to Dr. Li regarding committee review. The committee tabled the application with a number of concerns that still need to be addressed.

B. Other New Business:

1. Vaccination policy letter (draft)

The vaccination policy letter was reviewed and discussed by the committee. The committee recommended that the policy letter be tabled pending several issues that need to be resolved.

There being no further business brought before the Committee, the meeting was adjourned at approximately 11:45a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., RBP, CBSP
Executive Secretary, Institutional Biosafety Committee

Approved:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Joseph Weixelmann, Ph.D.
Provost

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
November 15, 2005

Location: Caroline 306

Time: 1:30pm

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory, St. Louis County Department of Health
Mark R. Buller, Ph.D.	Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S., J.D.	Director/Radiation Safety Officer, Office of Environmental Safety
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Jennifer K. Lodge, Ph.D.	Associate Dean for Research Associate Professor - Biochemistry
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Lynda A. Morrison, Ph.D.	Associate Professor – Molecular Microbiology and Immunology
Frances K. Newman, M.S.	Assistant Research Professor – Internal Medicine/Infectious Diseases
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology

Excused:

Steven Cummings, M.D.	Medical Director – Employee Health
Terrance M. Egan, Ph.D.	Associate Professor – Pharmacological & Physiological Sciences
Michael Green, Ph.D.	Professor – Molecular Microbiology and Immunology
Brent A. Neuschwander-Tetri, M.D.	Associate Professor – Internal Medicine/Gastroenterology
Judith M. Ogilvie, Ph.D.	Assistant Professor - Biology
Harris R. Perlman, Ph.D.	Assistant Professor – Molecular Microbiology and Immunology

I. Old Business

A. Approval of Minutes: The minutes of the October 12, 2005 IBC meeting were fully approved by members present. **APPROVED, 11-0** by members present.

B. Closed Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings, now fully approved.

1. **Gorse, Geoffrey J., M.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
 - Human Coronavirus-229E (HCoV-229E)
 - Human Coronavirus-OC43 (HCoV-OC43)
 - MRC-5 cells
 - HCT-8 cells
2. **Gorse, Geoffrey J., M.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
 - Vaccinia virus and recombinant vaccinia viruses
 - Epstein-Barr virus (EBV)
 - Human Cytomegalovirus (AD-169 strain) viral lysate
 - H9 cells (T cell lymphoma, human)
 - SUP-T1 cells (Non-Hodgkins T-cell lymphoma)
 - Human Immunodeficiency Virus type 1 (primary isolates and lab-adapted strains)

C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.

1. **Bellone, Clifford J., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Vaccinia virus
 - Ectromelia virus
2. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - DNA: pGA2/JS7 DNA vaccine (DNA)
 - MVA: Recombinant modified vaccinia Ankara/HIV62 vaccine (MVA)
3. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Adenovirus type 5 expressing beta-gal (Ad5-beta-gal)
 - Adenovirus type 5 expressing *Trans*-sialidase (Ad5-TS)
 - Human Embryonic Kidney 293 cells (HEK 293)
4. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Human Influenza virus

II. New Business

A. New or Revised Applications:

1. **Li, Dechun, M.D., Ph.D.** (Department of Internal Medicine/Division of Pulmonary) for use of:
 - Adenoviral construct (Adeno-HIMF)
 - Retroviral construct (Retro-HIMF)
 - Human Embryonic Kidney 293 cells (HEK 293)
 - E. coli DH5alpha (DH5alpha)

The IBC forwarded correspondence to Dr. Li regarding committee review. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending final submission with additional documentation to the IBC Chairperson for review and approval.

B. Amendments to Approved Applications:

1. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - West Nile 25 A strain (WNV 25A)

The IBC forwarded correspondence to Dr. Wold regarding committee review. This amendment was tabled by the committee. The committee considers an amendment to add WNV 25A strain to be inadequate. The IBC recommended that a full application be submitted to the committee. The application is currently being completed by the investigator and will be submitted for a second committee review at the next scheduled IBC meeting.

2. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Construction and use of new oncolytic adenovirus vectors

The IBC forwarded correspondence to Dr. Wold regarding committee review. The committee fully approved the amendment.

C. Other New Business: The following items were placed on the agenda for discussion or comment.

1. **Select Agent Interim Final Rule Regarding the Department of Health and Human Services (DHHS) select agents and toxins.**

The Biological Safety Officer included an email regarding proposed rule making to add "Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments" to the list of HHS select agents and toxins. Also included was a copy of the Select Agent interim final rule.

2. **Interim CDC-NIH Recommendation for Raising the Biosafety Level (BSL) for Laboratory Work Involving Non-contemporary Human Influenza Viruses**

The Biological Safety Officer included an excerpt from the draft CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, 5th edition that are considered the minimum containment for experiments utilizing the agent listed in number 1.

There being no further business brought before the Committee, the meeting was adjourned at approximately 3:15 p.m.

Respectfully Submitted,

Mark J. Campbell, M.S., RBP, CBSP
Executive Secretary, Institutional Biosafety
Committee

Approved:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Joseph Weixlmann, Ph.D.
Provost

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
December 14, 2005

Location: Caroline 306

Time: 10:00 am

Present:

Name	Affiliation
Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory, St. Louis County Department of Health
Mark R. Buller, Ph.D.	Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Environmental Safety
Steven Cummings, M.D.	Medical Director – Employee Health
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Terrance M. Egan, Ph.D.	Professor – Pharmacological & Physiological Sciences
Michael Green, Ph.D.	Professor – Molecular Microbiology and Immunology
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S., J.D.	Director/Radiation Safety Officer, Office of Environmental Safety
Jennifer K. Lodge, Ph.D.	Associate Dean for Research Associate Professor - Biochemistry
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Lynda A. Morrison, Ph.D.	Associate Professor – Molecular Microbiology and Immunology
Frances K. Newman, M.S.	Assistant Research Professor – Internal Medicine/Infectious Diseases
Judith M. Ogilvie, Ph.D.	Assistant Professor - Biology
Harris R. Perlman, Ph.D.	Assistant Professor – Molecular Microbiology and Immunology
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology

Excused:

Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Brent A. Neuschwander-Tetri, M.D.	Associate Professor – Internal Medicine/Gastroenterology

I. Old Business

- A. Approval of Minutes:** The minutes of the November 15, 2005 IBC meeting were fully approved by members present. **APPROVED, 15-0** by members present.
- B. Closed Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings, now fully approved.**
1. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Construction and use of new oncolytic adenovirus vectors
 2. **Frey, Sharon E., M.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - DNA: pGA2/JS7 DNA vaccine (DNA)
 - MVA: Recombinant modified vaccinia Ankara/HIV62 vaccine (MVA)
- C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.**
1. **Bellone, Clifford J., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Vaccinia virus
 - Ectromelia virus
 2. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Adenovirus type 5 expressing beta-gal (Ad5-beta-gal)
 - Adenovirus type 5 expressing *Trans*-sialidase (Ad5-TS)
 - Human Embryonic Kidney 293 cells (HEK 293)
 3. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Human Influenza virus
 4. **Li, Dechun, M.D., Ph.D.** (Department of Internal Medicine/Division of Pulmonary) for use of:
 - Adenoviral construct (Adeno-HIMF)
 - Retroviral construct (Retro-HIMF)
 - Human Embryonic Kidney 293 cells (HEK 293)
 - E. coli DH5alpha (DH5alpha)
 5. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - West Nile 25 A strain (WNV 25A)

II. New Business

A. New Applications:

None

B. Amendments to Approved Applications:

1. **Ray, Ratna, Ph.D.** (Department of Internal Medicine/Pathology) and **Ranjit Ray, Ph.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
➤ Hepatitis C Virus (Growth in cell culture)

The IBC forwarded correspondence to Drs. Ray regarding committee review. The committee approved the application amendment contingent upon answers to a number of concerns that still need to be addressed. The application amendment is pending final submission with additional documentation to the IBC Chairperson for review and approval.

C. Other New Business:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. **Saint Louis University's Draft Exposure Control Plan (ECP).** The Biological Safety Officer provided a brief description of the ECP and asked the committee to provide comments. The IBC reviewed the plan and granted approval with the stipulation that minor revisions would be completed and the ECP would be brought before the committee for review and approval before annual renewal.

There being no further business brought before the Committee, the meeting was adjourned at approximately 10:50 a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., RBP, CBSP
Executive Secretary, Institutional Biosafety
Committee

Approved:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Joseph Weixlmann, Ph.D.
Provost

Saint Louis University
Institutional Biosafety Committee
Meeting Minutes
February 8, 2006

Location: Caroline 306

Time: 10:00 am

Present:

Name	Affiliation
Mark R. Buller, Ph.D.	Professor - Molecular Microbiology & Immunology
Mark J. Campbell, M.S.	Biological Safety Officer, Office of Env. Safety
Richard E. Doyle, D.V.M.	Professor and Chairperson - Comparative Medicine
Terrance M. Egan, Ph.D.	Professor – Pharmacological & Physiological Sciences
Michael Green, Ph.D.	Professor – Molecular Microbiology and Immunology
Geoffrey J. Gorse, M.D. (Chairperson)	Professor - Internal Medicine/Infectious Diseases
Mark G. Haenchen, M.S., J.D.	Director/Radiation Safety Officer, Office of Env. Safety
Ernest G. Jaworski, Ph.D.	Scientist-in-Residence, St. Louis Science Center
Jennifer K. Lodge, Ph.D.	Associate Dean for Research Associate Professor - Biochemistry
Paul M. Loewenstein, B.S.	Assistant Research Professor - Institute for Molecular Virology
Lynda A. Morrison, Ph.D.	Associate Professor – Molecular Microbiology and Immunology
Frances K. Newman, M.S.	Assistant Research Professor – Internal Medicine/Infectious Diseases
Irene T. Schulze, Ph.D.	Professor Emeritus - Molecular Microbiology and Immunology
Cheri West, D.V.M (Guest)	Assistant Professor – Comparative Medicine

Excused:

Wayne E. Black, Ph.D.	(Retired) Laboratory Director - Environmental Health Laboratory, St. Louis County Department of Health
Steven Cummings, M.D.	Medical Director – Employee Health
Judith M. Ogilvie, Ph.D.	Assistant Professor - Biology
Harris R. Perlman, Ph.D.	Assistant Professor – Molecular Microbiology and Immunology
Brent A. Tetri, M.D.	Professor – Internal Medicine/Gastroenterology

I. Old Business

- A. Approval of Minutes:** The minutes of the December 14, 2005 IBC meeting were fully approved by members present. **APPROVED, 12-0** by members present.
- B. Closed Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings or between meetings, now fully approved.**

1. **Li, Dechun, M.D., Ph.D.** (Department of Internal Medicine/Division of Pulmonary) for use of:
 - Adenoviral construct (Adeno-HIMF)
 - Retroviral construct (Retro-HIMF)
 - Human Embryonic Kidney 293 cells (HEK 293)
 - E. coli DH5alpha (DH5alpha)**Full application**
2. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Adenovirus type 5 expressing beta-gal (Ad5-beta-gal)
 - Adenovirus type 5 expressing *Trans*-sialidase (Ad5-TS)
 - Human Embryonic Kidney 293 cells (HEK 293)
 - Human Lung Carcinoma cell line (A549)
 - Control pcDNA or pcDNA expressing *Trans*-sialidase (pcDNA, pcDNA3-TS)**Full application**
3. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Human Influenza Virus type A subtypes H1N1 and H3N2
 - Human Influenza Virus type B
 - Madin-Darby canine kidney cell line (MDCK cell line)**Full application**
4. **Hoft, Daniel F., M.D., Ph.D.** (Department of Internal Medicine/Division of Infectious Diseases) for use of:
 - Modified Vaccinia Ankara (MVA) Strain (ATCC: VR-1508)**Amendment**

- C. Open Items: Follow-up from unapproved or contingently approved applications or amendments to existing applications considered at previous meetings.**

1. **Ray, Ratna, Ph.D.** (Department of Internal Medicine/Pathology) and **Ranjit Ray, Ph.D.** (Department of Internal Medicine/Infectious Diseases) for use of:
 - Hepatitis C Virus (Growth in cell culture)

The IBC forwarded correspondence to Drs. Ray regarding committee review. The committee approved the application amendment contingent upon answers to a number of concerns that still need to be addressed. The application amendment is pending final submission with additional documentation to the IBC Chairperson for review and approval.

II. New Business

A. Amendments to Approved Applications:

1. **Morrison, Lynda A., Ph.D.** (Department of Molecular Microbiology and Immunology) amendment for use of:
 - BAC-derived HSV strains
 - Add personnel

The IBC forwarded correspondence to Dr. Morrison regarding committee review. The committee granted full approval to the application amendment with no contingencies.

2. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) amendment for use of:
 - Human derived biological materials

The IBC forwarded correspondence to Dr. Wold regarding committee review. The committee granted full approval to the application amendment with no contingencies.

B. Revised Applications:

1. **Bellone, Clifford J., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Vaccinia virus
 - Ectromelia virus (Mousepox)
 - IL-4 ECTV (IL-4 Mousepox)

The IBC forwarded correspondence to Dr. Bellone regarding committee review. The committee granted full approval to the application with no contingencies. It was noted during the meeting that the PI has been unable to verify vaccinia vaccination status of one of his employees. The committee recommended that this matter be addressed by the Medical Director of Employee Health. The Biological Safety Officer noted that he would follow-up on this issue until resolved.

C. New Applications:

1. **Buller, Robert M., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
 - Human corona virus (strain Urbani)-Severe Adult Respiratory Syndrome (HCRV-SARS)
 - Vero cells

The IBC forwarded correspondence to Dr. Buller regarding committee review. The committee approval to the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending re-submission with additional documentation to the primary reviewers for approval and then final review and approval by the IBC Chairperson.

2. **Wold, William S.M., Ph.D.** (Department of Molecular Microbiology and Immunology) for use of:
➤ West Nile 25 A strain (WNV 25A)

The IBC forwarded correspondence to Dr. Wold regarding committee review. The committee approved the application contingent upon answers to a number of concerns that still need to be addressed. The application is pending re-submission with additional documentation to the primary reviewers for approval and then final review and approval by the IBC Chairperson.

D. Other New Business:

1. The committee reviewed the proposed work with inactivated *Yersinia pestis* submitted by Dr. Harris Perlman.

The IBC forwarded correspondence to Dr. Perlman regarding committee review. The committee approved the proposed work. The committee determined that this work will not involve a viable biological agent, because anything being received by Saint Louis University is documented to be inactivated prior to leaving the site of origination.

2. The Biological Safety Officer announced that the CDC would be inspecting Saint Louis University facilities registered with the Select Agent Program as part of the 3 year annual renewal process. The inspection is scheduled for February 23, 2006.

There being no further business brought before the Committee, the meeting was adjourned at approximately 11:30 a.m.

Respectfully Submitted,

Mark J. Campbell, M.S., RBP, CBSP
Executive Secretary, Institutional Biosafety
Committee

Approved:

Reviewed:

Geoffrey J. Gorse, M.D., FACP
Chairman, Institutional Biosafety Committee

Joseph Weixlmann, Ph.D.
Provost