



MAYO CLINIC

200 First Street SW  
Rochester, Minnesota 55905  
507-284-2511

April 7, 2006

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

Dear Mr. Hammond:

Enclosed are copies of Mayo Foundation Rochester, Minnesota, Intuitionl Biosafety Committee minutes as requested.

Sincerely,

David H. Senjem  
Secretary, Mayo Institutional Biosafety Committee

DHS/TAB  
Enclosure

## Institutional Biosafety Committee Minute

January 16, 2003

**12:00 Noon (Central Standard Time)**

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> December 19, 2002 Pages 1-3	All	Approve	Approved
Research Protocol <b>R84-11-12/02 (A35402)</b> "Garenoxacin Treatment of Viridans Streptococcal Experimental Endocarditis." <b>Robin Patel, M.D.</b> , Principal Investigator  Pages 4-5	Federspiel, Mark J, Ph.D.	Review and Approve	Have contacted Dr. Patel to complete the Biosafety Registration form, and to be resubmitted at the next IBC meeting.
Note items:  Foundation Committee Guidelines Pages 6-7  <b><u>Serious Adverse Events</u></b>  IRB 1582-01 "Clinical Study Protocol 304386 A Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Ad5FGF-4 in Patients with Stable Angina."  Pages 8-30		Review and Approve          Review	Noted          The committee reviewed and noted a Serious Adverse Event Report from the Mayo Foundation IRB Serious Adverse Events Board. The report was specified to clinical study IRB 1582-01 "Clinical Study Protocol 304386 A Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Ad5FGF-4 in Patients with Stable Angina.", Dr. Robert Simari, Principal Investigator.
<b><u>Carry In</u></b>  Research Protocol <b>R1-119-1/03</b> "In Vivo Control of Replicating Measles Virus Vectors Using Auger Electron Emitting Isotopes." <b>Stephen J. Russell, M.D., Ph.D. and David D. Dingli, M.D.</b> , Principal Investigators		Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and precautionary measures.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

**Institutional Biosafety Committee Minute**

February 27, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> January 16, 2003 Pages 1-2	All	Approve	Approved
Research Protocol <b>R84-11-12/02 (A35402)</b> "Garenoxacin Treatment of Viridans Streptococcal Experimental Endocarditis." <b>Robin Patel, M.D.</b> , Principal Investigator  Pages 3-5	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and precautionary measures.
Research Protocol <b>R2-59-1/03 (A1503)</b> "Radioiodine Treatment of Medullary Thyroid Carcinoma After Gene Transfer of the Sodium-Iodide Symporter Gene and Calcitonin Promoter In a Murine Model." <b>John C. Morris, III, M.D.</b> , Principal Investigator  Pages 6-7	Norman L. Eberhardt, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and precautionary measures.
Research Protocol <b>R3-256-1/03</b> "The Effects of HIV Protease Mutation and IL-2, -7, and -15 on the Pathogenesis of HIV in a hu-PBL-SCID Mouse Model." <b>Andrew D. Badley, M.D.</b> , Principal Investigator  Pages 8-9	Nancy A. Lee, Ph.D.	Review and Approve	Referred back to the principal investigator for additional information on the infectious agent and the laboratory safety provisions and practice associated with handling the virus.
Research Protocol <b>R5-5-1/03 (A2303)</b> "The role of endothelial progenitor cells and eNOS in the vascular dysfunction of diabetic rabbits with hind-limb ischemia." <b>Noel Caplice, M.D., Ph.D.</b> , Principal Investigator  Pages 10-11	Thomas F. Smith, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The committee noted that liquid infectious waste should be bleached or autoclaved prior to disposal.

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R6-11-1/03 (A3403)</b> "Impact of emerging antimicrobial resistance in viridans streptococci on prophylactic regimens for bacterial endocarditis." <b>Robin Patel, M.D.,</b> Principal Investigator  Pages 12-13	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and precautionary measures.
<b>Research Protocol R7-119-2/03 (A7003)</b> "Pilot Project For Using Oncolytic Measles Viral Therapy For Pancreatic Cancer." <b>Stephen J. Russell, M.D., Ph.D.,</b> Principal Investigator  Pages 14-16	Ralf Janknecht, Ph.D.	Review and Approve	Approves as exempt for NIH Recombinant DNA Guidelines.
<b>Research Protocol R9-119-2/03 (A10103)</b> "Edmonston CEA Measles Virus Expression in Immune Suppressed CD46/inf Mice." <b>Stephen J. Russell, M.D., Ph.D.,</b> Principal Investigator  Pages 17-18	Norman L. Eberhardt, Ph.D.	Review and Approve	Approves as exempt for NIH Recombinant DNA Guidelines.
<b>Research Protocol R10-119-2/03</b> "Does Measles Specific Immunoglobulin G (IgG) Therapy Prior To Chimeric Measles (MVeGFP) Administration in Measles Vaccinated INFARko-CD46 GE Mice Suppress the Host Immune Response." <b>Stephen J. Russell, M.D., Ph.D.,</b> Principal Investigator  Pages 19-20	Thomas F. Smith, Ph.D.	Review and Approve	Approves as exempt for NIH Recombinant DNA Guidelines.
<b>Research Protocol R4-119-1/03 (A4003)</b> "Tumor sepecificity and anti-tumor effects of oncolytic measles virus or adenovirus expressing measles H and F genes." <b>Stephen J. Russell, M.D., Ph.D.,</b> Principal Investigator  Pages 21-23	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and precautionary measures.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R11-258-2/03</b> "Does a Microporous Polysaccharide Hemospheres (MPH) Based Hemostat Enhance Abdominal Infection in a Rat Model?" <b>Mark Erath, M.D., Principal Investigator</b> Pages 24-25	Nancy A. Lee, Ph.D.	Review and Approve	Referred back to the principal investigator for information on the specific strain of E. coli. Additionally, it was noted that liquid waste associated with the project needs to be bleached or autoclaved.
<b>Note Items:</b> Notification of a Serious Adverse Event Pages 26-31 Foundation Committee Guidelines Pages 32-33 Peer Review Pages 34-35	All	Review	Noted
<b>Carry In: Breach of Biosafety 2 Procedures</b>	Norman L. Eberhardt, Ph.D.	Review	The committee reviewed a document prepared by Dr. Eberhardt related to a breach of Animal Biosafety Level 2 procedures. It was agreed that while the event very likely did not constitute a hazardous exposure to individuals directly involved in the related experiments, a breach of safety procedures did occur. It was therefore agreed that the matter should be referred for informational purposes to NIH's Office of Biotechnology. It was further agreed that procedures should be developed to lessen the likelihood of similar occurrences in the future.
<b>Next Meeting:</b> March 27, 2003 (5 weeks)	All	Note	

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

## **Membership**

N. L. Eberhardt, PhD, Chair - Present  
M. J. Federspiel, PhD - Present  
Ms. B. Borg - Present  
Mr. J. Caplette - Absent  
Mr. R. A. Aleff - Present  
C. S. Frisk, DVM, PhD - Present

Mr. P. R. Giesen - Present  
D. D. Roerish, RN - Absent  
N. A. Lee, MD, PhD - Absent  
Mr. G. P. Munson - Absent  
R. Janknecht, PhD - Present  
W. G. Buchta, M.D - Present

T. F. Smith, PhD - Present  
Mr. C. R. Yennie - Present  
Mr. D. H. Senjem, Secretary - Present

Guest: Teresa Bierbaum

---

David H. Senjem, Secretary

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

**Institutional Biosafety Committee Minute**

March 27, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> February 27, 2003 Pages: 1-4	All	Approve	Approved
Research Protocol R16-175-3/03 "Generation of Human Antibodies Against B7-H1." <b>Lieping Chen, M.D.</b> , Principal Investigator Pages: 5-8	Executive Committee	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices. The committee further recommends that the investigator works with Dr. William Buchta in the Employee Health Service on serological testing of potentially exposed EBV workers and related matters.
Research Protocol R13-119-2/03 (A7203) "Measles Virotherapy and the Immune System." <b>Kah-Whye Peng, Ph.D.</b> , Principal Investigator Pages: 9-11	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The committee noted that solid wastes should be disinfected as noted in the Registration Document and be disposed of using double, red biohazard bags.
Research Protocol R12-119-2/03 (A7103) "Targeted Measles Virotherapy for Ovarian Cancer." <b>Kah-Whye Peng, Ph.D.</b> , Principal Investigator Pages: 12-14	Ralf Janknecht, Ph.D.	Review and Approve	Referred back to the principal investigator for additional information related to where patients will be treated and how waste will be handled. Because these experiments involve clinical trials in years 4 and 5 it was noted that approval by the Recombinant DNA Advisory Committee will be needed.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R17-259-3/03</b> "Assessment of Therapeutic Effect of Measles Virus Vectors Targeted to Tumor-associated Angiogenesis in Vivo." <b>Louay K. Hallak, Ph.D.,</b> Principal Investigator Pages: 15-16	Thomas F. Smith, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The committee noted that question number three should be label "yes" for recombinant DNA.
Carry In: <b>Research Protocol R14-5-2/03 (A6103)</b> "Porcine Endothelial Progenitor Cells and Vascular Biology Study." <b>Noel Caplice, M.D., Ph.D.,</b> Principal Investigator	Norman L. Eberhardt, Ph.D.	Review and Approve	Referred back to the principal investigator for re-submittal clarifying the following points.  1) Question 3 should be checked "yes" for recombinant DNA. 2) Question 5 should be noted as RG2. 3) Question 11 should be reviewed to ensure that it accurately reflects the project. 4) Question 15 should be completed to describe specific waste management procedures.
Carry In: <b>Research Protocol R11-258-2/03 (A7603)</b> "Does a Microporous Polysaccharide Hemospheres (MPH) Based Hemostat Enhance Abdominal Infection in a Rat Model?" <b>Mark Ereth, M.D.,</b> Principal Investigator		Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The committee noted that solid wastes should be disinfected as noted in the Registration Document and that waste products should disposed of using double, red biohazard bags.
Other Business: Office of Biotechnology Activities	All	Review	Noted
Attendance		Attendance by	The committee noted the importance of the attendance by the scientific persons and the biosafety officer to ensure accurate information haring and continuity in procedures.
<b>Next Meeting:</b> April 24, 2003 (5 weeks)	All	Note	



*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

### **Membership**

N. L. Eberhardt, PhD, Chair - Present  
M. J. Federspiel, PhD - Absent  
Ms. B. Borg - Present  
Mr. J. Caplette - Present  
Mr. R. A. Aleff - Absent  
C. S. Frisk, DVM, PhD - Present

Mr. P. R. Giesen - Absent  
D. D. Roerish, RN - Absent  
N. A. Lee, MD, PhD - Absent  
Mr. G. P. Munson - Absent  
R. Janknecht, PhD - Present  
W. G. Buchta, M.D - Present

T. F. Smith, PhD - Present  
Mr. C. R. Yennie - Absent  
Mr. D. H. Senjem, Secretary - Absent

Guest: Teresa Bierbaum

---

Beth Borg, Acting Secretary

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

### Institutional Biosafety Committee Minute

April 24, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<u><b>Biosafety Committee Minutes</b></u> March 27, 2003 Pages: 1-3	All	Approve	Approved
Research Protocol <b>R12-119-2/03 (A7103)</b> "Targeted Measles Virotherapy for Ovarian Cancer." <b>Kah-Whye Peng, Ph.D.</b> , Principal Investigator Pages 4-6	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and precautionary measures.
Research Protocol <b>R14-5-2/03 (A6103)</b> "Porcine Endothelial Progenitor Cells and Vascular Biology Study." <b>Noel Caplice, M.D., Ph.D.</b> , Principal Investigator Pages 7-10	Norman L. Eberhardt, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and precautionary measures. The committee noted that liquid infectious waste should be bleached or autoclaved prior to disposal.
Research Protocol <b>R18-119-4/03</b> "Monitoring Expression of Cell Associated Transgenes" <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Pages 11-12	Mark J Federspiel, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and precautionary measures. The committee noted that liquid infectious waste should be bleached or autoclaved prior to disposal.
Research Protocol <b>R19-130-4/03</b> "Portal Hypertension In Mice With Targeted Gene Deletions." <b>Vijay H. Shah, M.D.</b> , Principal Investigator Pages 13-14	Thomas F. Smith, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and precautionary measures. The committee requested that Mr. Senjem contact Dr. Shah to ensure that his laboratory was properly equipped and prepared to undertake Biosafety Level 2 experiments.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R20-151-4/03 (A13703)</b> "Treatment of Murine Tumors Through Recombinant Adenoviral Mediated Gene Transfer of Chemokines and or Cytotoxic Genes." <b>Richard G. Vile, Ph.D.,</b> Principal Investigator Pages 15-17	Nancy A. Lee, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and precautionary measures.
<b>Carry In:</b> <b>Research Protocol R21-5-4/03 (A12503)</b> "Cell-based Gene Delivery of Prostacyclin Synthase in a Rat Model of Monocrotaline Induced Pulmonary Hypertension." <b>Noel Caplice, M.D., Ph.D.,</b> Principal Investigator	All	Review and Approve	Dr. Eberhardt will complete review and request clarification from investigator.
<b>Note Item and Discussion:</b>			Dr. Eberhardt discussed the number of errors the committee is seeing in Biosafety Registration Documents. He recommended using a process similar to IACUC, wherein corrections to protocols would be requested prior to review by the committee. Ms. Bierbaum would be the focal point for referring registration documents back to the investigator when a reviewer identifies the need for a correction and/or additional information.  The committee further recommends that reviews of "carry-in" Biosafety Registration Documents be discontinued.
<b>Next Meeting:</b> May 22, 2003 (5 weeks)	All	Note	

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

### **Membership**

N. L. Eberhardt, PhD, Chair - Present  
M. J. Federspiel, PhD - Absent  
Ms. B. Borg - Present  
Mr. J. Caplette - Present  
Mr. R. A. Aleff - Present  
C. S. Frisk, DVM, PhD - Absent

Mr. P. R. Giesen - Absent  
D. D. Roerish, RN - Absent  
N. A. Lee, MD, PhD - Absent  
Mr. G. P. Munson - Present  
R. Janknecht, PhD - Absent  
W. G. Buchta, M.D - Present

T. F. Smith, PhD - Present  
Mr. C. R. Yennie - Present  
Mr. D. H. Senjem, Secretary - Absent

Guest: Teresa Bierbaum

---

Beth Borg, Acting Secretary

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

### Institutional Biosafety Committee Minutes

May 22, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> April 24, 2003 Pages 1-3	All	Approve	Approved
Research Protocol <b>R21-5-4/03</b> “Cell-based Gene Delivery of Prostacyclin Synthase in a Rat Model of Monocrotaline Induced Pulmonary Hypertension.” <b>Noel Caplice, M.D., Ph.D.,</b> Principal Investigator	Norman L. Eberhardt, Ph.D.	Review and Approve	The committee ratified the previous action of the Executive Committee in approving this proposal at Laboratory and Animal Biosafety Level 2 provision and practices.
Research Protocol <b>R22-197-4/03</b> “SARS Coronavirus Subcloned Protein Expression and Molecular Biology.” <b>Eric Poeschla, M.D., Ph.D.,</b> Principal Investigator Pages 4-9	Norman L. Eberhardt, Ph.D.	Review and Approve	The committee approved Dr. Poeschla’s pursuit of acquiring the SARS virus from the Centers for Disease Control. It was agreed that the agent should be managed in accordance with current Select Agent Rules, that work with the virus would likely require Biosafety Level 3 provisions and practices, and that prior to specific experiments with the agent being performed the investigator would file a Registration Document with the Institutional Biosafety Committee for review and approval.
Research Protocol <b>R23-5-4/03</b> “Vascular Gene Therapy Using a Novel Cellular Stent.” <b>Noel Caplice, M.D., Ph.D.,</b> Principal Investigator Pages 10-12	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2+ provisions and practices.  The designation “2+” is intended to denote Biosafety Level 2 provisions (facilities and equipment) and Biosafety 3 practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Research Protocol R25-261-5/03 (A13903) "Image-guided Gene and Virotherapy for Pancreatic Cancer." <b>Stephanie Carlson, M.D.</b> , Principal Investigator Pages 13-18	Ralf Janknecht, Ph.D.	Review and Approve	Approval of the protocol was deferred pending further review with the principal investigator.
Research Protocol R26-100-5/03 (A14803) "Stat 4 Knockout Model of MS." <b>Larry Pease, Ph.D.</b> , Principal Investigator Pages 19-20	Ralf Janknecht, Ph.D.	Review and Approve	The committee requests additional information on disposal practices for injected animals and related infectious materials.
Research Protocol R27-201-5/03 "Recombinant Measles Virus Expressing Suicide Genes for Cancer Therapy." <b>Roberto Cattaneo, Ph.D.</b> , Principal Investigator Pages: 21-23	Federspiel, Mark J, Ph.D.	Review and Approve	Approved at Animal Biosafety Level 2 provisions and practices.
Research Protocol R28-241-5/03 "Correction of Mitotic Checkpoint Function in BuBR1 Mutant Fibroblasts." <b>Jan van Deursen, Ph.D.</b> , Principal Investigator Pages: 24-25	Nancy A. Lee, Ph.D.	Review and Approve	Approved subject Laboratory Biosafety Level 2 provisions and practices.  Follow up with the investigator will occur to ensure knowledge of Biosafety Level 2 requirements.
Research Protocol R29-85-5/03 "Pilot Study: To Investigate Kenetics of CEA Antibodies by Mode of Injection of Measles Virus-Edmonston-CEA in Susceptible Mice." <b>Evanthia Galanis, M.D.</b> , Principal Investigator Pages: 26-27	Norman L. Eberhardt, Ph.D.	Review and Approve	Deferred for further discussion with Dr. Norman L. Eberhardt.
Research Protocol R30-48-5/03 "T Cells and Aging." <b>Jorg J. Goronzy, M.D.</b> , Principal Investigator Pages: 28-29	Nancy A. Lee, Ph.D.	Review and Approve	Referred back to the investigator for correcting errors in the Registration Document which precluded review and approval.

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Other Business			The Biosafety Registration process was reviewed and discussed as a change in the policy for reviewing protocols. A memo was sent to the Research Services of the process change. Through this process no carry-in will be brought in before the Institutional Biosafety Committee.
<b>Next Meeting:</b> June 26, 2003 (5 weeks)	All	Note	

### **Membership**

N. L. Eberhardt, PhD, Chair - Present  
M. J. Federspiel, PhD - Absent  
Ms. B. Borg - Present  
Mr. J. Caplette - Present  
Mr. R. A. Aleff - Absent  
C. S. Frisk, DVM, PhD - Present

Mr. P. R. Giesen - Absent  
D. D. Roerish, RN - Absent  
N. A. Lee, MD, PhD - Absent  
Mr. G. P. Munson - Absent  
R. Janknecht, PhD - Present  
W. G. Buchta, M.D - Present

T. F. Smith, PhD - Absent  
Mr. C. R. Yennic - Absent  
Mr. D. H. Senjem, Secretary - Present

Guest: T. Bierbaum

---

David H. Senjem, Secretary

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

**Institutional Biosafety Committee Minutes**

June 26, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> May 22, 2003 Pages 1-3	All	Approve	Approved
Research Protocol R26-100-5/03 (A14803) "Stat 4 Knockout Model of MS." <b>Larry Pease, Ph.D.</b> , Principal Investigator Pages 4-5	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Animal Biosafety Level 2 provisions and precautionary measures. Laboratory work is "exempt" and may be conducted at Biosafety Level 1 provisions and practices.
Research Protocol R29-85-5/03 "Pilot Study: to investigate kinetics of CEA antibodies by mode of injection of measles virus-Edmonston-Human Carcinoembryonic Antigen (H-CEA) in susceptible mice." <b>Evanthia Galanis, M.D.</b> , Principal Investigator Pages 6-7	Norman L. Eberhardt, Ph.D.	Review and Approve	Approved as exempt from NIH Recombinant DNA Guidelines and subject to Biosafety level 1 provisions and practices.
Research Protocol R24-59-5/03 (A14503) "Radioiodine treatment of medullary thyroid carcinoma after gene transfer of the sodium-iodide symporter gene and (CEA) promoter in a murine model." <b>John C. Morris, III, M.D.</b> , Principal Investigator Pages 8-9	Federspiel, Mark J, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. It was further agreed that since the experiments involve radioactivity, a copy of the minute excerpt would be forwarded to the Radiation Safety Department.
Research Protocol R25-261-5/03 (A13903) "Image-guided Gene and Virotherapy for Pancreatic Cancer." <b>Stephanie Carlson, M.D.</b> , Principal Investigator Pages 10-13	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. It was further agreed that since the experiments involve radioactivity, a copy of the minute excerpt would be forwarded to the Radiation Safety Department.



*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Research Protocol R33-262-6/03 (A18603) “Modulation of Pathology in BRI Transgenic Mice.” Eileen McGowan, Ph.D., Principal Investigator Pages 14-15	Smith, Thomas F., Ph.D.	Review and Approve	Approved as exempt for NIH Recombinant DNA Guidelines and subject to Biosafety Level 1 provisions and practices.
Carry In: Research Protocol R30-38-5/03 “T Cells and Aging” Jorg J. Goronzy, M.D., Principal Investigator	Nancy A. Lee, Ph.D.	Review and Approve	Approved at Animal Biosafety Level 2 provisions and practices.
Other Business: Select Agents			Mr. Senjem noted that he has been working on obtaining a recertification of Mayo’s registration as a select agents laboratory. The recertification was prompted by new regulations.
<b>Next Meeting:</b> July 31, 2003 (5 weeks)	All	Note	Noted

### **Membership**

N. L. Eberhardt, PhD, Chair - Absent  
M. J. Federspiel, PhD - Absent  
Ms. B. Borg - Absent  
Mr. J. Caplette - Absent  
Mr. R. A. Aleff - Present  
C. S. Frisk, DVM, PhD - Present

Mr. P. R. Giesen - Absent  
D. D. Roerish, RN - Absent  
N. A. Lee, MD, PhD - Present  
Mr. G. P. Munson - Absent  
R. Janknecht, PhD - Present  
W. G. Buchta, M.D - Present

T. F. Smith, PhD - Absent  
Mr. C. R. Yennie - Absent  
Mr. D. H. Senjem, Secretary - Present

Guest: T. Bierbaum

**Institutional Biosafety Committee Minutes**

July 31, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> June 26, 2003 Pages 1-2	All	Approve	Approved noting the need to change the date to June 23, 2003.
Research Protocol <b>R37-240-7/03</b> “Sub-cellular Trafficking of eNOS: Implication for Nitric Oxide Production.” <b>Suvro Chatterjee, Ph.D.</b> , Principal Investigator Pages: 3-5	Executive Committee	Ratification	The committee ratified the previous action of the Executive Committee in approving this proposal as exempt from NIH Recombinant DNA Guidelines.
Research Protocol <b>R34-197-6/03</b> “SARS Coronavirus Culture” <b>Eric Poeschla, M.D.</b> , Principal Investigator Pages: 6-7	Norman L. Eberhardt, Ph.D.	Final Modified Protocol	Approved subject to Laboratory Biosafety Level 3 provisions and practices.
Research Protocol <b>R38-201-7/03 (A19403)</b> “Antibody Response to Recombinant Measles viruses Expressing the Hepatitis B Virus Surface Antigen in Genetically Modified Mice.” <b>Roberto Cattaneo, Ph.D.</b> , Principal Investigator Pages: 8-10	Ralf Janknecht, Ph.D.		Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R39-216-7/03</b> “Neuroprotection and Glaucoma: Adenoviral-mediated Gene Transfer of Anti-apoptosis Genes in Cultured Rat Retinal Ganglion Cells and in vivo.” <b>Margaret S. Good M.D.</b> , Principal Investigator Pages: 11-14	Ralf Janknecht, Ph.D.	Checklist Send	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R36-264-7/03 (A20403)</b> “AAV-mediated gene therapy for the treatment of MCAD-deficiency.” <b>David B. Schowalter, M.D., Ph.D.</b> , Principal Investigator Pages: 14-15	Marl Federspiel, Ph.d.		Approved as exempt from NIH Recombinant DNA Guidelines. The committee noted the investigator's intent to carry out the experiments at Laboratory and Animal Biosafety Level 2 provisions and practices.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Note Items:</b> 3 memo's from Colleen Garvey, Protocol Development Coordinator Pages: 16-21  Department of Health & Human Services-Office of Biotechnology Activities Page: 22	Mr. D. H. Senjem   Mr. D. H. Senjem		Noted   Noted
Other Business			Mr. Senjem reported that representative from CDC visited Mayo on July 15, 2003 to inspect safety and security related to the management of select agents. No formal report has been received. Wrap-up comments were suggestive of a very good outcome.
<b>Next Meeting:</b> August 28, 2003 (5 weeks)	All	Note	Noted

### Membership

N. L. Eberhardt, PhD, Chair - present  
M. J. Federspiel, PhD - present  
Ms. B. Borg - present  
Mr. J. Caplette - absent  
Mr. R. A. Aleff -absent  
C. S. Frisk, DVM, PhD - absent

Mr. P. R. Giesen - absent  
D. D. Roerish, RN -absent  
N. A. Lee, MD, PhD - absent  
Mr. G. P. Munson - present  
R. Janknecht, PhD -absent  
W. G. Buchta, M.D - absent

T. F. Smith, PhD -absent  
Mr. C. R. Yennie -absent  
Mr. D. H. Senjem, Secretary -present

---

David H. Senjem, Secretary

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

August 28, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> July 31, 2003 Pages: 1-2	All	Approval	Approved  Mr. Senjem reported on the outcome of onsite inspections by the Centers for Disease Control (CDC) and the U.S. Department of Agriculture on Mayo 's work with select agents. The results of both inspections were excellent. The issuance by CDC of Mayo's official registration number is immanent.
Research Protocol <b>R39-119-7/03 (A20303)</b> "The development of double tumor-targeting strategy using adenovirus vectors expressing both H and F gene of Edmonston vaccine strain of measles virus (MV-Edm)." <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Pages: 3-4	Norman L. Eberhardt, Ph.D.	Approval	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R46-266-8/03</b> "The role of the integrin alpha9beta1 in modulating VEGF-A dependent pulmonary angiogenesis." <b>Nicholas E Vlahakis, M.D.</b> , Principal Investigator Pages: 5-7	Lee, Nancy A., Ph.D.	Approval	Approved as exempt for NIH Recombinant DNA Guidelines and subject to Biosafety Level 1 provisions and practices.
Research Protocol <b>R35-201-6/03 (A18103)</b> "Efficacy of Measles Virus-Based Divalent Vaccines (Part 2 of A34002)" <b>Roberto Cattaneo, Ph.D.</b> , Principal Investigator Pages: 8-9	Smith, Thomas F., Ph.D.	Approval	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Carry In: Research Protocol <b>R48-268-8/03</b> "Routing and Turnover of Wild-Type and DF508 CFTR in the Endocytic Pathway." <b>Martina G. Gentzsch, Ph.D.</b> , Principal Investigator	Lee, Nancy A., Ph.D.	Approved	Approved subject to Laboratory Biosafety Level 2 provisions and practices.

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Carry In: Research Protocol R44-25-8/03 (A24603) "A Study Of Gene Transfer To Vascular Intima Of The Transplanted Rat Heart Using Vascular Progenitor Cells." Christopher Mc Gregor, M.D., Principal Investigator	Lee, Nancy A., Ph.D.	Approval	Approved subject to Laboratory and Animal Biosafety Level 2 provision and practices for experiments involving adenovirus, and Laboratory and Animal Biosafety level 2+ provisions and practices for experiments involving lentivirus. Biosafety Level 2+ is intended to denote Biosafety Level 2 provisions and Biosafety Level 3 practices (see NIH Guidelines). Experiments involving Adeno associated virus were approved at Biosafety Level 1 provisions and practices.
Other Business: SARS Precautions	Full Committee	Discussion	<p>The committee continued discussions related to work with the SARS virus on the Mayo campus. To date, experiments are or will be occurring in Biosafety Level 3 laboratories in two Mayo locations.</p> <p>Given the safety and security concerns related to SARS it was agreed that the agent should be managed within Mayo at Biosafety Level 3 provisions and practices and consistent with CDC Select Agent Requirements. It was further requested that Facilities Operation provide the committee with data establishing the efficacy of the biocontainment features of the laboratory and that efforts be undertaken to ensure that all persons working with the agent know and understand all related safety and security concerns.</p> <p>It was agreed that continuing information related to this matter would be reviewed at future IBC meetings.</p>
<u>Next Meeting:</u> September 18, 2003 (5 weeks)	All	Note	Noted

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

**Membership**

N. L. Eberhardt, PhD, Chair - Present  
M. J. Federspiel, PhD - Present  
Ms. B. Borg - Present  
Mr. J. Caplette - Present  
Mr. R. A. Aleff - Absent  
C. S. Frisk, DVM, PhD - Absent

Mr. P. R. Giesen - Absent  
D. D. Roerish, RN - Absent  
N. A. Lee, MD, PhD - Present  
Mr. G. P. Munson - Absent  
R. Janknecht, PhD - Present  
W. G. Buchta, M.D - Present

T. F. Smith, PhD - Absent  
Mr. C. R. Yennie - Present  
Mr. D. H. Senjem, Secretary - Present

---

David H. Senjem, Secretary

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

### Institutional Biosafety Committee Minutes

September 18, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<u>Biosafety Committee Minutes</u> August 28, 2003 Pages: 1-3	All	Approve	Approved – Dr. Federspiel noted that it has been committee practice to use of HIV lentiviral vectors at BSL-2+, but that other non-HIV vectors would be considered differently.
Research Protocol R47-201-8/03 “Assessment of the efficacy of a divalent measles/yellow fever vaccine in genetically modified mice.” <b>Roberto Cattaneo, Ph.D.</b> , Principal Investigator Pages: 4-5	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to CDC/NIH Laboratory and Animal BSL-2 provisions and practices.
Research Protocol R40-265-8/03 “Atopic Skin Response to Smallpox Vac” <b>Douglas A. Plager, Ph.D.</b> , Principal Investigator Pages: 6-8	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to CDC/NIH Laboratory and Animal BSL-2 provisions and practices. A copy of Mayo’s Vaccina Virus Policy will be forwarded to the investigator noting the importance of collaborating with Dr. G. A. Poland on educating staff with regard to medical risks and vaccination for laboratory staff and animal caretakers. It was further noted that liquid infectious waste should be decontaminated with 10% bleach.
Research Protocol R49-164-8/03 “Laser-assisted micro-dissection of plasma cells in tissues after recurrent hepatitis C.” <b>Michael McKinney, Ph.D.</b> , Principal Investigator Pages: 9-10	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to CDC/NIH Laboratory Biosafety Level 2 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R41-256-8/03</b> "The Effects of HIV Protease Mutation and IL-2, -7, and -15 on the Pathogenesis of HIV in a hu-PBL-SCID Mouse Model" <b>Andrew D. Badley, M.D.</b> , Principal Investigator Pages: 11-13	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to CDC/NIH Laboratory and Animal Biosafety Level 3 provisions and practices.
<b>Research Protocol R51-119-9/03</b> "In situ cell fusion for cancer therapy." <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Pages: 14-16	Thomas F. Smith, Ph.D.	Review and Approve	Approved subject to CDC/NIH Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Research Protocol R52-201-9/03</b> "Immune response to recombinant measles viruses expressing different hepatitis C proteins." <b>Roberto Cattaneo, Ph.D.</b> , Principal Investigator Pages: 17-18	Thomas F. Smith, Ph.D.	Review and Approve	Approved subject to CDC/NIH Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Research Protocol R42-25-8/03 (A17203)</b> "Study of Adenoviral, Aden-associated Viral and Lentiviral Vectors for Genetic Modification of Cardiac Allotransplants to Control Post-Transplant Vasculopathy." <b>Christopher Mc Gregor, M.D.</b> , Principal Investigator Pages: 19-25	Nancy A. Lee, Ph.D.	Review and Approve	Approved subject to CDC/NIH Laboratory and Animal Biosafety Level 2+ provisions and practices for work with lentiviral vectors. This designation is intended to infer Biosafety Level 2 provisions and Biosafety Level 3 Practices. Work with adenoviral vectors may be conducted at Laboratory and Animal Biosafety Level 2. Adeno-associated virus work is exempt from NIH Recombinant DNA Guidelines and maybe conduct at Biosafety Level 1.



*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Research Protocol R50-197-9/03 “Arenavirus pseudotyping” Eric M. Poeschla, M.D., Principal Investigator Pages: 26-27	Norman L. Eberhardt, Ph.D.	Review and Approve	Approved subject to CDC/NIH Laboratory Biosafety Level 2 provisions and practices. The committee agreed that the applicability of “select agent” requirements to the RNA proposed for use in these experiments should be resolved between CDC and Mayo Clinic at the time of material transfer.
Other Business: Non-Certifiable Biosafety Cabinets	David H. Senjem	Discussion	Deferred
<b>Next Meeting:</b> October 16, 2003 (5 weeks)	All	Note	

#### Membership

N. L. Eberhardt, PhD, Chair - absent  
M. J. Federspiel, PhD - present  
Ms. B. Borg - absent  
Mr. J. Caplette - present  
Mr. R. A. Aleff - present  
C. S. Frisk, DVM, PhD - present

Mr. P. R. Giesen - absent  
D. D. Roerish, RN - absent  
N. A. Lee, MD, PhD - present  
Mr. G. P. Munson - absent  
R. Janknecht, PhD - present  
W. G. Buchta, M.D - absent

T. F. Smith, PhD - present  
Mr. C. R. Yennie - present  
Mr. D. H. Senjem, Secretary - present

Guest: Ms. T. Bierbaum

---

David H. Senjem, Secretary

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

October 16, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> September 18, 2003 Pages: 1-3	All	Approve	Noting the recommended change, the minutes were approved.
Research Protocol R48-29-8/03 (A25703) "Transducing endothelial nitric oxide synthase with adeno-associated virus in rats with monocrotaline-induced pulmonary hypertension following intratracheal instillation." <b>Zvonimir S. Katusic, M.D., Ph.D.</b> , Principal Investigator Pages: 4-5	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R54-26-9/03 (A30603) "Demyelination and remyelination in Theiler's virus infected mice." <b>Moses Rodriguez, M.D.</b> , Principal Investigator Pages: 6-7	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to Animal Biosafety Level 2 provisions and practices. Since the Thieler's Virus is not a human pathogen, laboratory work is exempt from NIH Recombinant DNA Guideline's, and may be conducted at Biosafety Level 1.
Research Protocol R53-269-9/03 (A26903) "Modulation of tau pathology using AAV vectors in P302L Tau transgenic mice." <b>Michael L. Hutton, Ph.D.</b> , Principal Investigator Pages: 8-9	Nancy A. Lee, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The committee agreed that the protocol could be downgraded to Biosafety Level 1 (Exempt) if the stock was made using only plasmids to rescue the AAV Virus.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Research Protocol <b>R55-119-10/03 (A30803)</b> “Neurotoxicity of Measles Virus-CEA, intracranial delivery into CD46in <sup>ko</sup> Ge mice.” <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Pages: 10-11	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R56-21-10/03 Revision of (R21-5-4/03) (A12503)</b> “Cell-based gene delivery in a rat model of monocrotaline induced pulmonary hypertension.” <b>Noel Caplice, M.D., Ph.D.</b> , Principal Investigator Pages: 12-15	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Carry In:</b> Research Protocol <b>R58-130-10/03</b> “Use Of Retrovirally Transduced Cells in Mechanistic Studies Relating to Angiogenesis On Portal Hypertension.” <b>Vijay H. Shah, M.D.</b> , Principal Investigator	Nancy A. Lee, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Other Business: Serious Adverse Event Reports (2) 1 <sup>st</sup> report pages: 16-47 2 <sup>nd</sup> report pages: 48-81		Note	Noted

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Other Business:	Mr. Senjem		<p>Mr. Senjem updated the committee on the progress of Dr. Poeschla's work with SARS virus. He noted that a meeting with Dr. Poeschla and members of 18<sup>th</sup> floor Guggenheim BSL-3 technical staff had occurred to review the proposed work with SARS and associated risks and precaution. He also noted that a computer run listing maintenance alarms from the BSL-3 facility had been produced and that it revealed a number of very short periods over the past 12 months when negative pressure in the BSL-3 facility was less than the desired level or may have been lost. Mr. Senjem indicated that he felt a general understanding existed with Dr. Poeschla such that work with SARS or any other BSL-3 agent would not occur in the laboratory until the reason for the alarms had been clearly established and the problem corrected.</p> <p>The committee expressed strong concern with regard to the alarm history and the creditability of the laboratory to function as a true BSL-3 facility. Members formally requested that Mr. Senjem contact Dr. Poeschla to further emphasize the committee's desire that work with SARS not occur until problems with the room's capability to maintain negative pressure in a reliable, ongoing fashion had been established and documented by a history of performance.</p>
<b>Next Meeting:</b> November 20, 2003 (5 weeks)	All	Note	

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

### **Membership**

N. L. Eberhardt, PhD, Chair - Absent  
M. J. Federspiel, PhD - Present  
Ms. B. Borg - Absent  
Mr. J. Caplette - Present  
Mr. R. A. Aleff - Absent  
C. S. Frisk, DVM, PhD - Absent

Mr. P. R. Giesen - Absent  
D. D. Roerish, RN - Absent  
N. A. Lee, MD, PhD - Present  
Mr. G. P. Munson - Present  
R. Janknecht, PhD - Present  
W. G. Buchta, M.D - Absent

T. F. Smith, PhD - Present  
Mr. C. R. Yennie - Present  
Mr. D. H. Senjem, Secretary - Present

---

David H. Senjem, Secretary

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

### Institutional Biosafety Committee Minutes

November 20, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> October 16, 2003 Pages: 1-4	All	Approve	Approved
Discussion of 18 <sup>th</sup> Floor Guggenheim BSL-3 Laboratory—Pressure Alarms Representative from Facilities Engineering	All	Determine Adequacy of Resolution.	Noted
Research Protocol <b>R57-119-10/03 (A30703)</b> “Biodistribution of Measles/eGFP, Adenovirus-35/eGFP, Adenovirus-5/eGFP in CD46 transgenic pigs.” <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Pages: 5-6	Thomas F. Smith, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. It was noted that this is a ratification of a previous Executive Committee action.
Research Protocol <b>R32-85-6/03</b> “Phase I Trial of Intraperitoneal Administration of a CEA-Expressing Derivative Manufactured from a Genetically Engineered Strain of Measles Virus (IND# 10895) in Patients with Recurrent Ovarian Cancer.” <b>Evanthia Galanis, M.D.</b> , Principal Investigator Pages: 7-11	Norman L. Eberhardt, Ph.D.	Review and Approve	Approved as exempt from NIH Recombinant DNA Guidelines and subject to Biosafety level 1 provisions and practices. The committee recommends that the principle investigator notify Mayo Infection Control prior to the initiation of clinical trials.
Research Protocol <b>R60-59-11/03 (A33103)</b> “Gene Therapy of Prostate Cancer Using Radioiodine.” <b>John C. Morris, III, M.D.</b> , Principal Investigator Pages: 12-15	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<p>Research Protocol <b>R59-74-11/03</b>            “A Multinational, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Ad5FGF-4 in Patients with Stable Angina Protocol 305602.”  <b>Robert D. Simari, M.D.</b>, Principal Investigator            Pages: 16-17</p>	Mark J. Federspiel, Ph.D.	Review and Approve	Approved at Laboratory Biosafety Level 2 provisions and practices. The committee recommends that the principle investigator notify Mayo Infection Control prior to the initiation of clinical trials.
Other Business: Dr. Poeschla Update		Note	<p>Mr. Senjem updated the committee on the progress of Dr. Poeschla’s work with SARS virus. He noted that a meeting with Dr. Poeschla and members of 18<sup>th</sup> floor Guggenheim BSL-3 technical staff had occurred to review the proposed work with SARS and associated risks and precaution. He also noted that a computer run listing maintenance alarms from the BSL-3 facility had been produced and that it revealed a number of very short periods over the past 12 months when negative pressure in the BSL-3 facility was less than the desired level or may have been lost. Mr. Senjem indicated that he felt a general understanding existed with Dr. Poeschla such that work with SARS or any other BSL-3 agent would not occur in the laboratory until the reason for the alarms had been clearly established and the problem corrected.</p> <p>The committee expressed strong concern with regard to the alarm history and the creditability of the laboratory to function as a true BSL-3 facility. Members formally requested that Mr. Senjem contact Dr. Poeschla to further emphasize the committee’s desire that work with SARS not occur until problems with the room’s capability to maintain negative pressure in a reliable, ongoing fashion had been established and documented by a history of performance.</p>
<b>Next Meeting:</b> December 18, 2003 (5 weeks)	All	Note	

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

**Membership**

N. L. Eberhardt, PhD, Chair - Present  
M. J. Federspiel, PhD - Present  
Ms. B. Borg - Absent  
Mr. J. Caplette - Present  
Mr. R. A. Aleff - Present  
C. S. Frisk, DVM, PhD - Absent

Mr. P. R. Giesen - Absent  
D. D. Roerish, RN - Absent  
N. A. Lee, MD, PhD - Absent  
Mr. G. P. Munson – Present  
R. Janknecht, PhD – Present  
W. G. Buchta, M.D – Present

T. F. Smith, PhD - Absent  
Mr. C. R. Yennie - Present  
Mr. D. H. Senjem, Secretary - Present

Guest: Ms. T. Bierbaum  
Mr. L. Erdmann  
Mr. J. Schneider

---

David H. Senjem, Secretary



*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

### Institutional Biosafety Committee Minutes

December 18, 2003

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> November 20, 2003 Pages: 1-3	All	Approve	Approved
Research Protocol R62-130-12/03 (A32503) “Copy of eNos Regulation and Portal Hypertension.” <b>Vijay Shah, M.D.</b> , Principal Investigator Pages: 4-5	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R65-271-12/03 “Production of recombinant adenoviral DNA for gene knockdown studies.” <b>Gary C. Sieck, Ph.D.</b> , Principal Investigator Pages: 6-7	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The committee noted the importance of using “red bags” to contain potentially infectious waste prior to autoclaving.
Research Protocol R64-29-12/03 “Nitric Oxide and superoxide in lipid-induced vascular disease.” <b>Zvonimir S. Katusic, M.D., Ph.D.</b> , Principal Investigator Pages: 8-9	Norman L. Eberhardt, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The committee noted the importance of using “red bags” to contain potentially infectious waste prior to autoclaving.
Research Protocol R15-236-2/03 (A35B02J) <b>Modified to (A29803)</b> “In Situ Therapeutic Anti-AB Delivery By Adenoviral Vectors.” <b>Todd E. Golde, M.D., Ph.D.</b> , Principal Investigator Pages: 10-12	Nancy A. Lee, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Research Protocol <b>R63-151-12/03</b> “Immune sequelae of vaccinia virus in cancer therapy.” <b>Richard G. Vile, Ph.D.</b> , Principal Investigator Pages: 13-14	Thomas F. Smith,, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The approval is contingent upon the investigator contacting Gregory A. Poland, M.D. prior to the initiation of experiments. The purpose of the contact is to request assistance in educating laboratory and affected Veterinary Medicine personnel on the risks associated with working with vaccinia virus and to provide necessary guidance for each employee in their decision as to whether or not to proceed with vaccinia vaccination. If vaccination is rejected, a recorded written declination form should be obtained and referred to the Employee Health Service for record keeping purposes. Lastly, the investigator should additionally contact a member of the consulting staff of the Department of Veterinary Medicine prior to initiating animal experiments. A copy of the Mayo’s “Guidelines for the Use of Vaccina Virus in Research” will be referred to the principal investigator.
Other Business: 2004 IBC Schedule Page: 15		Note	Noted

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
SARS Research-Dr. Eric Poeschla			<p>The committee continued its discussion of pending SARS related research by Dr. Eric Poeschla in Molecular Medicine's 18<sup>th</sup> floor Guggenheim facility. Mr. Senjem noted that Facilities Engineering has not fully completed their work on ventilation system modifications need to ensure that the BSL-3 facility maintains a constant negative pressure. Dr. Eberhardt noted a recently published report citing SARS-associated coronavirus infection in a research scientist in Taiwan. The individual is reported to have worked in a BSL-4 laboratory in which SARS was present. To date, potential modes of transmission have not been established.</p> <p>In view of the above noted incident the committee discussed the work with SARS planed at Mayo and the importance of ensuring that all measures are taken to prevent laboratory-acquired infection. Training in BSL-3 practices was discussed. Mr. Senjem noted that he had met with Dr. Poeschela and his laboratory staff in December to review and discuss biosafety procedures. He noted that it was his intention to meet, once again, with those individuals specifically assigned to working with the agent prior to proceeding with their experiments.</p>

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
SARS Research-Dr. Eric Poeschla cont.			The committee deliberated on whether or not there may be additional resources at Mayo who would be helpful in reviewing SARS related risks and precautions as they might relate to the pending research. In this regard it was agreed to invite Dr. Gregory Poland to the next committee meeting for further discussion of this matter and any thoughts he might have on further ensuring safety.
<u>Next Meeting:</u> January 29, 2004 (5 weeks)	All	Note	

#### Membership

N. L. Eberhardt, Ph.D., Chair - Present  
M. J. Federspiel, Ph.D. - Absent  
Ms. B. Borg - Present  
Mr. J. Caplette - Present  
Mr. R. A. Aleff - Present  
C. S. Frisk, DVM, Ph.D. - Absent

Mr. P. R. Giesen - Absent  
D. D. Roerish, RN - Absent  
N. A. Lee, MD, Ph.D. - Absent  
Mr. G. P. Munson - Absent  
R. Janknecht, Ph.D. - Present  
W. G. Buchta, M.D - Absent

T. F. Smith, Ph.D. - Present  
Mr. C. R. Yennie - Present  
Mr. D. H. Senjem, Secretary - Present

Guest: M. Blanco, D.V.M.  
N. Wengenack, Ph.D.  
Ms. T. Bierbaum

---

David H. Senjem, Secretary

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

January 29, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> December 18, 2003 Pages: 1-4	All	Approve	Approved
Research Protocol R2-11-1/04 "Biofilm Formation in Staphylococcus lugdunensis: Structural characterization and functional regulation of the ica locus." <b>Robin Patel, M.D.</b> , Principal Investigator Pages: 5-7	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.
Research Protocol R3-11-1/04 "Will Exotoxin A Producing Streptococcus pyogenes Induce Toxic Shock in Mice Transgenic for Human Leukocyte Antigen-DQ8 and Human CD4 Receptors?" <b>Robin Patel, M.D. &amp; Chella S. David, Ph.D.</b> , Principal Investigators Pages: 8-9	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The committee further requests that the investigator contact a member of the staff of the Department of Veterinary Medicine prior to the initiation of animal experiments, so that agreements can be established relative to respective responsibilities and cage labeling.
Research Protocol R9-59-1/04 "Treatment of Ovarian Cancer with Radioiodide Following Targeted Expression of the Sodium Iodide Symporter." <b>John C. Morris, III, M.D.</b> , Principal Investigator Pages: 10-12	Norman L. Eberhardt, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R5-201-1/04 (A504)</b> "Retargeted measles viruses for oncolytic therapy (Replacement of A192-B-00)" <b>Roberto Cattaneo, Ph.D.</b> , Principal Investigator Pages: 13-16	Nancy A. Lee, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Research Protocol R8-73-1/04 (A704)</b> "Gene transfer of costimulatory molecules into pancreatic islet cells by non-replicating lentivirus vector." <b>Lieping Chen, M.D.</b> , Principal Investigator Pages: 17-20	Nancy A. Lee, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 + provisions and practices.  Two-plus is a category denoting Biosafety Level 2 provisions (i.e. Biosafety hoods, signage. etc.) and Biosafety Level 3 practices. The committee recommends that the investigator meet with the staff veterinary within the Department of Veterinary Medicine prior to the initiation of animal experiments to establish respective roles and responsibilities.
<b>Research Protocol R33-85-5/01 (A21503)</b> "Combination Therapy with HER Tyrosine Kinase Inhibitor and p53 Adenovirus In Preclinical Models Of Breast Cancer." <b>Evanthia Galanis, M.D.</b> , Principal Investigator Pages: 21-23	Norman L. Eberhardt, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  It was noted that solid wastes could be managed through Mayo's "red bag" program and would not require treatment with Wescodyne® as noted in the investigator's Institutional Biosafety Committee Registration Document.
<b>Research Protocol R11-151-1/04</b> "Immune Sequelae of Vesicular Stomatitis Virus in Cancer Therapy." <b>Richard G. Vile, Ph.D.</b> , Principal Investigator Pages: 24-25	Ralf Janknecht, Ph.D.		Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Other Business:</b> Re-review of the previously approved Andrew D. Badley, M.D. proposal (R41-256-8/03). Pages: 26-32	All	Confirm or amend previous approval at BSL-3.	Approved subject to Laboratory and Animal Biosafety Level 2 + provisions and practices.  Two-plus is a category denoting Biosafety Level 2 provisions (i.e. Biosafety hoods, signage, etc.) and Biosafety Level 3 practices. The committee recommends that the investigator meet with the staff veterinary within the Department of Veterinary Medicine prior to the initiation of animal experiments to establish respective roles and responsibilities.
<b>Note Item:</b> Post Bulletin Article: Xenotransplantation Research Findings. Page: 33			Noted
<b>Next Meeting:</b> February 26, 2004 (5 weeks)	All	Note	

#### Membership

N. L. Eberhardt, PhD, Chair - Present  
M. J. Federspiel, PhD - Absent  
M. C. Blanco, D.V.M. - Present  
W. G. Buchta, M.D - Present  
Ms. B. Borg - Present  
Mr. P. R. Giesen - Present

N. A. Lee, MD, PhD - Absent  
Mr. G. P. Munson - Present  
P. Sampathkumar, M.D. - Present  
Mr. D. H. Senjem, Secretary - Present  
A. H. Tang, Ph.D. - Present  
N. L. Wengenack, PhD. - Present

R. Janknecht, PhD - Present  
J. Caplette - Present  
C. Yennie - Present

---

David H. Senjem, Secretary

**Institutional Biosafety Committee Minutes**

February 26, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>New Committee Member from Jacksonville</b> Page: 1			
<b><u>Biosafety Committee Minutes</u></b> January 29, 2004 Pages: 2-4	All	Approve	Approved
Research Protocol <b>R4-5-1/04 (A304)</b> "Imaging of bone marrow derived progenitor cells in the lungs of monocrotaline treated rats." <b>Noel M. Caplice, M.D.</b> , Principal Investigator Pages: 5-7	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R14-119-2/04</b> "Retargetable oncolytic measles virus for cancer virotherapy." <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Pages: 8-10	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R10-274-1/04</b> "A Multicenter, Randomized, Double-Blind, Dose Ranging Placebo-Controlled Study Evaluating Defined Doses of Percutaneously Delivered VIA Boston Scientific Corporation Stiletto™ Endocardial Injection Catheter pVGI.1 (VEGF2) (placebo, 20, 200, or 800µg) In Patients with Class III or IV Angina With An Option For Patients To Receive Active Treatment At One Year If They Experience A Treatment Failure." <b>F. David Fortuin, M.D.</b> , Principal Investigator Pages: 11-14	Mark J. Federspiel, Ph.D.	Review and Approve	Approved as exempt from National Institutes of Health Recombinant DNA Guidelines and subject to Biosafety Level 1 provisions and practices.



SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R1-272-1/04</b> "Regulation and role of angiogenic growth factors in renal cell carcinoma and pancreatic cancer." <b>Debabrata Mukhopadhyay, Ph.D.</b> , Principal Investigator Pages: 15-16	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The committee further requests that the investigator contact a member of the staff of the Department of Veterinary Medicine prior to the initiation of animal experiments, so that agreements can be established relative to respective responsibilities and cage labeling.
<b>Research Protocol R12-11-2/04</b> "In vitro and in vivo study of antifungal agents against Candida albicans biofilms." <b>Robin Patel, M.D.</b> , Principal Investigator Pages: 17-19	Nancy A. Lee, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Research Protocol R15-119-2/04</b> "In situ cell fusion for cancer therapy (Part II of A27703)" <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Pages: 20-22	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Carry In:</b> <b>Research Protocol R17-275-2/04</b> "Adenoviral-mediated infection of osteoclast precursors and mature osteoclasts." <b>Merry Jo Oursler, Ph.D.</b> , Principal Investigator	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.  The investigator is requested to contact Mr. David Senjem prior to the initiation of experiments to review Biosafety Level 2 requirements.
<b>Other Business:</b>  <b>Dr. Wengenack</b>	All		Dr. Wengenack reported on an incident she became aware of at a recent Infectious Disease Case Conference. The incident involved a Mayo graduate student who accidentally auto inoculated herself with vaccinia virus. She will follow-up with Mr. Senjem on this matter.
<b>Next Meeting:</b> March 25, 2004 (5 weeks)	All	Note	

**Membership**

N. L. Eberhardt, Ph.D., Chair - Absent  
M. J. Federspiel, Ph.D. - Present  
M. C. Blanco, D.V.M. - Present  
W. G. Buchta, M.D. - Present  
Ms. B. Borg - Present  
Mr. P. R. Giesen - Absent

N. A. Lee, MD, Ph.D. - Absent  
Mr. G. P. Munson - Absent  
P. Sampathkumar, M.D. - Present  
Mr. D. H. Senjem, Secretary - Absent  
A. H. Tang, Ph.D. - Present  
N. L. Wengenack, Ph.D. - Present

R. Janknecht, Ph.D. - Present  
J. Caplette - Present  
C. Yennie - Present  
J. A. Copland, Ph.D. - Absent  
Guest - T. Bierbaum

---

David H. Senjem, Secretary

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

### Institutional Biosafety Committee Minutes

March 25, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
New Committee Member from Jacksonville			
<u>Biosafety Committee Minutes</u> February 26, 2004 Pages: 1-3	All	Approve	Approved
Research Protocol R18-210-3/04 "The eye in Graves' disease: Role of orbital fibroblasts." Rebecca S. Bahn, M.D., Principal Investigator Pages: 4-6	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The investigator is requested to contact the Department of Veterinary Medicine prior to commencing animal experiments.
Research Protocol R21-130-3/04 "Biology of hepatic vascular endothelium in tumor angiogenesis and protal hypertension." Vijay H. Shah, M.D., Principal Investigator Pages: 7-8	Nancy L. Wengenack, Ph.D.	Review and Approve	This protocol was related to a chemical, not a biological agent, and does not require committee actions.
Research Protocol R19-25-3/04 (A7204) "A study of sodium iodine symporter for non-invasive imaging of gene therapy to heart." Christopher G. Mc Gregor, M.D., Principal Investigator Pages: 9-11	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R20-158-3/04 "Preclinical Evaluation of Bcr/abl-Directed Tyrphostins." Scott H. Kaufmann, M.D, Ph.D., Principal Investigator Pages: 12-14	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Carry In:</b> Research Protocol R13-151-2/04 (A3704) "Antitumoral Efficacy and Toxicity Studies of Ad-E1A-COX, a Selectively Replicating Adenovirus Vector." <b>Richard G. Vile, Ph.D.,</b> Principal Investigator	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Carry In:</b> Research Protocol R22-11-3/04 "Levofloxacin treatment of viridans streptococcal experimental endocarditis." <b>Robin Patel, M.D.,</b> Principal Investigator	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Other Business:</b> 1) Committee Support Functions Page: 15  2) Videoconference Room Mayo 11-F in Rochester Page: 16-17	All		Mr. Senjem noted that Ms. Amy Goldsmith of Research Services had approached the committee to request agenda time to discuss their Human Subject Protection Enhancement Project. The committee agreed to provide such time at a future meeting.  Mr. Senjem noted that Room F would not be available for the IBC meeting of January 2005. He noted that an alternative location will be identified.
<b>Next Meeting:</b> April 22, 2004 (5 weeks)	All	Note	

#### Membership

N. L. Eberhardt, Ph.D., Chair - Present  
 M. J. Federspiel, Ph.D. - Present  
 M. C. Blanco, D.V.M. - Present  
 W. G. Buchta, M.D. - Present  
 Ms. B. Borg - Absent  
 Mr. P. R. Giesen - Absent

N. A. Lee, MD. Ph.D. - Absent  
 Mr. G. P. Munson - Absent  
 P. Sampathkumar, M.D. - Present  
 Mr. D. H. Senjem, Secretary - Present  
 A. H. Tang, Ph.D. - Absent  
 N. L. Wengenack, Ph.D. - Present

R. Janknecht, Ph.D. - Present  
 J. Caplette - Present  
 C. Yennie - Present  
 J. A. Copland, Ph.D. - Present

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat. § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

David H. Serjcm, Secretary

---

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

April 22, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Human Subjects Protection Enhancement Project – HSPEP</b>	Guest: Amy Goldsmith		Ms. Amy Goldsmith appeared before the committee to discuss the HSPEP. While the proposal involves only projects involving human subjects, it was agreed that the database established under the project would be of significant benefit to the committee's work. Mr. Senjem will work with Ms. Goldsmith on further details.
<u><b>Biosafety Committee Minutes</b></u> March 25, 2004 Pages: 1-2	All	Approve	Approved
Research Protocol <b>R24-120-4/04</b> "Dysregulated gene expression in cancer." <b>Ralf Janknecht, Ph.D.</b> , Principal Investigator Pages: 3-5	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R25-59-4/04</b> "Radioiodine therapy for Prostate cancer: A large animal study." <b>John C. Morris, III, M.D.</b> , Principal Investigator Pages: 6-8	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The investigator is requested to visit with Dr. Blanco in the Department of Veterinary Medicine prior to the initiation of animal experiments.
<b>Carry In:</b>  Research Protocol <b>R29-278-4/04</b> "Eosinophil activation by fungi in chronic rhinosinusitis." <b>Jan Sasama, M.D.</b> , Principal Investigator	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  Mr. Senjem will review the investigator's laboratory prior to the initiation of experiments.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Other Business:</b>	All		Discussion ensued related to informing investigators of the need to submit Registration Documents to the IBC prior to the initiation of Recombinant DNA projects. Mr. Senjem will develop a note and work with Research Services for appropriate distribution.
<b>Next Meeting:</b> May 20, 2004 (5 weeks)	All	Note	

#### Membership

N. L. Eberhardt, Ph.D., Chair - Absent  
M. J. Federspiel, Ph.D. - Present  
M. C. Blanco, D.V.M. - Absent  
W. G. Buchta, M.D. - Absent  
Ms. B. Borg - Present  
Mr. P. R. Giesen - Absent

N. A. Lee, MD, Ph.D. - Absent  
Mr. G. P. Munson - Present  
P. Sampathkumar, M.D. - Absent  
Mr. D. H. Senjem, Secretary - Present  
A. H. Tang, Ph.D. - Absent  
N. L. Wengenack, Ph.D. - Absent

R. Janknecht, Ph.D. - Present  
J. Caplette - Absent  
C. Yennie - Present  
J. A. Copland, Ph.D. - Present  
  
Guest: T. Bierbaum

---

David H. Senjem, Secretary

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

May 20, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> April 22, 2004 Pages: 1-2	All	Approve	Approved
Research Protocol <b>R23-277-3/04</b> “Application of oncolytic herpes mutants for treatment of medulloblastoma, glioma, and malignant peripheral nerve sheath tumor (MPNST).” <b>Corey Raffel, M.D., Ph.D.</b> , Principal Investigator Pages: 3-4	Committee	Ratify and Approve	The committee ratified the previous action of the Executive Committee in approving this proposal as subject to Laboratory and Biosafety Level 2 provisions and practices.
Research Protocol <b>R26-267-4/04</b> “Isolation and identification of fungal protein(s) from <i>Alternaria alternata</i> .” <b>Hirohito Kita, M.D.</b> , Principal Investigator Pages: 5-6	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Biosafety Level 2 provisions and practices.
Research Protocol <b>R33-280-5/04</b> “Application of oncolytic herpes mutants for treatment of lymphoma/leukemia.” <b>Faris Farassati, Ph. D.</b> , Principal Investigator Pages: 7-9	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. Mr. Senjem will visit Dr. Tefferi’s laboratory to review and certify the lab for Biosafety Level 2 experiments.
Research Protocol <b>R28-201-4/04 (A9704)</b> “Efficacy of a divalent measles virus/yellow fever virus based vaccine Part 2.” <b>Roberto Cattaneo, Ph.D.</b> , Principal Investigator Pages: 10-12	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The investigator must contact a member of the Staff of the Department of Veterinary Medicine prior to the initiation of animal experiments.



This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Research Protocol R32-100-4/04 (A12304) “Requirements for the generation of CNS-infiltrating memory CD8+ T cells: intracranial versus peripheral infection.” (vaccinia) <b>Larry R. Pease, Ph.D.</b> , Principal Investigator Pages: 16-18	Nancy A. Lee, Ph.D.	Review and Approve	<p>Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.</p> <p>The committee further requires that the investigator contact Dr. G. Poland prior to the initiation experiments involving vaccinia virus for purposes educating at-risk personnel on risks and precautions associated with vaccinia and for providing the option of vaccinia virus vaccination per Mayo policy (see attached). At-risk personnel would include in addition to laboratory staff, employees of the Department of Veterinary Medicine. Confirmation of the completion of this activity with the Institutional Biosafety Committee is required prior to working with the agent by notifying Mr. Senjem at 4-7459 or by e-mail <a href="mailto:senjem.david@mayo.edu">senjem.david@mayo.edu</a>.</p> <p>Additionally, the committee requires that all cells referred to the flow cytometry for counting be “fixed” so as to avoid placing laboratory personnel performing support studies at risk. If “fixing” the cells is not possible the investigator is requested to contact the Institutional Biosafety Committee for further consideration of this matter.</p> <p>The investigator is requested to contact a member of the staff of the Department of Veterinary Medicine prior to the initiation of animal experiments.</p>

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R31-279-4/04 (A11504)</b> "Elucidation of the Molecular Mechanisms Underlying Lymph Node Metastasis in Prostate Cancer." <b>Kaustubh Datta, Ph.D.</b> , Principal Investigator Pages: 13-15	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  Mr. Senjem will visit Dr. Datta's laboratory prior to the initiation of experiments. The investigator is requested to contact a member of the staff of the Department of Veterinary Medicine prior to the initiations of animal experiments.
<b>Other Business:</b>  Guidelines for the Use of Vaccinia Virus in Research	All		Mr. Senjem noted that the Mayo Vaccinia Virus Policy had been in effect for several years and that it may be appropriate, given recent questions, for the committee to re-review the policy with Dr. Gregory Poland. Committee members agreed and Mr. Senjem will schedule a meeting.
<b>Next Meeting:</b> June 24, 2004 (5 weeks)	All	Note	

### Membership

N. L. Eberhardt, Ph.D., Chair - Present  
 M. J. Federspiel, Ph.D. - Present  
 M. C. Blanco, D.V.M. - Present  
 W. G. Buchta, M.D. - Absent  
 Ms. B. Borg - Present  
 Mr. P. R. Giesen - Absent

N. A. Lee, MD, Ph.D. - Present  
 Mr. G. P. Munson - Absent  
 P. Sampathkumar, M.D. - Present  
 Mr. D. H. Senjem, Secretary - Present  
 A. H. Tang, Ph.D. - Present  
 N. L. Wengenack, Ph.D. - Absent

R. Janknecht, Ph.D. - Present  
 J. Caplette - Present  
 C. Yennie - Present  
 J. A. Copland, Ph.D. - Absent  
  
 Guest: T. Bierbaum

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

### Institutional Biosafety Committee Minutes

June 24, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<u>Biosafety Committee Minutes</u> May 20, 2004 Pages: 1-3	All	Approve	Approved
Research Protocol R37-119-6/04 "Evaluate oncolytic properties of Coxsackievirus A21 for multiple myeloma." <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Pages: 4-5	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.
Research Protocol R35-197-6/04 (A14904) "Injection of FIV-based Lentiviral Vectors Into the Anterior Chamber of the Feline Eye." <b>Eric M. Poeschla, M.D.</b> , Principal Investigator Pages: 6-7	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The investigator is requested to contact a member of the staff of the Department of Comparative Medicine prior to the initiation of animal experiments, so as to, resolve procedure details.  Lastly, the investigator is requested to resubmit the Registration Document on this project referencing, more specifically, the use of vesicular stomatitis virus glycoprotein (VSV-6) – pseudotyped FIV vectors in question #4 and elsewhere throughout the document as deemed appropriate.
Research Protocol R27-57-4/04 (A10204) "Pneumocystis Life Cycle Regulation." <b>Andrew Limper, M.D.</b> , Principal Investigator Pages: 8-11	Amy Tang, Ph.D.	Review and Approve	Approved as exempt from NIH Guidelines and subject to Biosafety Level 1 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Additional Buisness:</b> Vaccinia Virus Exposure			<p>The committee discussed an incident which occurred in December 2003 involving a research employee and an accidental needlestick exposure to vaccinia virus. It was noted that the employee incurred a mild reaction and that there was no evidence of further transmission to other close contacts of the individual.</p> <p>It was determined that the employee had been "counseled" on risks and precautions associated with working with vaccinia virus by her Principal Investigator. It was further determined that she had been offered vaccinia virus vaccination and declined, however, a formal declination form was not used to record her decision. The individual had been seen medically by the Employee Health Services following a localized reaction to the exposure.</p> <p>It was agreed that Mayo's response to this matter had been generally satisfactory and that a formal report to NIH would not be necessary. The committee concluded, however, that refinements may need to be considered to ensure that counseling relative to working with vaccinia virus actually occurs and that related vaccination procedures or declination are recorded.</p> <p>Mr. Senjem noted that a meeting of the Executive Committee and Dr. Gregory Poland had been scheduled to discuss these points. Further consideration of possible procedural changes related to vaccinia virus safety will await the meeting.</p>

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Dr. Charlton Incident			<p>The committee reviewed circumstances related to animal experiments involving Hepatitis C virus, conducted by Dr. Michael Charlton. Specifically it was noted that animal research with the virus had occurred in the absence of prescribed Biosafety Level 2 (including employee serum storage) requirements.</p> <p>Dr. Blanco noted that the non-compliant animal research had been noted during an IACUC audit. He further noted that more recently Dr. Charlton's work had been transferred into the Department of Comparative Medicine's Biosafety Level 2 facility.</p> <p>Dr. Eberhardt indicated that he had spoken to Dr. Charlton and that required serum samples or an appropriate declination had not yet been obtained. Dr. Charlton cited concerns related to the samples being required.</p> <p>The committee emphasized the need for Dr. Charlton to work with the Employee Health Service in the serum sample process and that declination statement's be signed by employees deciding to forego the procedure.</p> <p>Additionally, it was felt that potentially exposed animal caretakers should also participate in serum sample collection.</p> <p>In a related matter, Mr. Senjem reviewed proposed changes to the Institutional Biosafety Committee's Registration Document. The changes relate specifically to projects involving animals and are intended to assist in ensuring that investigators better understand their responsibilities when performing animal experiments at Biosafety Level 2 precautions.</p> <p>The committee was in general agreement with the direction of this effort. Mr. Senjem and Dr. Blanco will work on further language refinements prior to finalizing the document revisions.</p>

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Other Business:</b> 1) Mayo Infection Control Committee Minutes Pages: 12-19 2) NIH Communication Pages: 20-22 3) Memo to NIH Re: Committee Membership Page: 23	All		Noted
	All		Noted
	All		Noted
<b>Next Meeting:</b> July 29, 2004 (5 weeks)	All	Note	

#### Membership

N. L. Eberhardt, Ph.D., Chair - Present  
 M. J. Federspiel, Ph.D. - Absent  
 M. C. Blanco, D.V.M. - Present  
 W. G. Buchta, M.D. - Present  
 Ms. B. Borg - Present  
 Mr. P. R. Giesen - Absent

N. A. Lee, MD, Ph.D. - Absent  
 Mr. G. P. Munson - Present  
 P. Sampathkumar, M.D. - Absent  
 Mr. D. H. Senjem, Secretary - Present  
 A. H. Tang, Ph.D. - Absent  
 N. L. Wengenack, Ph.D. - Present

R. Janknecht, Ph.D. - Present  
 J. Caplette - Present  
 C. Yennie - Absent  
 J. A. Copland, Ph.D. - Absent  
 Guest: T. Bierbaum

---

David H. Senjem, Secretary

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

July 29, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> June 24, 2004 Pages: 1-4	All	Approve	Approved. Mr. Senjem noted an Executive Committee meeting with Dr. Gregory Poland to discuss Mayo's Vaccinia Virus Policy. The document will be re-written to transfer responsibility for education and vaccine issuance to the Employee Health Service.
Research Protocol R38-158-6/04 "Effect of vesicular stomatitis virus on survival of acute myelogenous leukemia cells in vitro." <b>Scott H. Kaufmann, M.D., Ph.D.</b> , Principal Investigator Pages: 5-7	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and precautions.
Research Protocol R39-11-7/04 (A18604) "DapDaptomycin Loaded Polymethylmethacrylate in the Treatment of Experimental Osteomyelitis." <b>Robin Patel, M.D.</b> , Principal Investigator Pages: 8-9	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Other Business:</b> NIH Communications Page: 10 Laboratory Biosafety Level 2 Certification Checklist Pages: 11-15	All  All		Noted  Noted with suggestions related to revised language. The committee requested that Mr. Senjem develop a list of investigator who have had research proposals approved by the committee and to identify applicable Biosafety levels associated with each investigator.
<b><u>Next Meeting:</u></b> August 26, 2004 (5 weeks)	All	Note	Noted

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

**Membership**

N. L. Eberhardt, Ph.D., Chair - Present  
M. J. Federspiel, Ph.D. - Absent  
M. C. Blanco, D.V.M. - Absent  
W. G. Buchta, M.D. - Absent  
Ms. B. Borg - Present  
Mr. P. R. Giesen - Present

N. A. Lee, MD, Ph.D. - Absent  
Mr. G. P. Munson - Absent  
P. Sampathkumar, M.D. - Present  
Mr. D. H. Senjem, Secretary - Present  
A. H. Tang, Ph.D. - Absent  
N. L. Wengenack, Ph.D. - Present

R. Janknecht, Ph.D. - Absent  
J. Caplette - Present  
C. Yennie - Absent  
J. A. Copland, Ph.D. - Absent

---

David H. Senjem, Secretary



This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

August 26, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> July 29, 2004 Page: 1-2	All	Approve	Approved
Research Protocol <b>R48-283-8/04</b> "A Multicenter, Double-Blind, Randomized, Placebo-Controlled Probe Study With an Additional Open-label Control Arm to Evaluate the Safety and Immunogenicity of a 3-Dose Regimen of the MRKAd5 HIV - 1 gag Vaccine in Subjects With Chronic Hepatitis C Virus Infection." <b>Vijayan Balan, M.D.</b> , Principal Investigator Page: 3-6	Nancy A. Lee, Ph.D.	Ratify	<p>The committee ratified the previous action of the Executive Committee in approving this proposal as: <i>Laboratory Biosafety Level 2 provisions and practices. More specifically, the committee recommends that all pharmaceutical manipulations of the vaccine, such as filling injectables, be performed in a laminar flow biologic safety cabinet utilizing Biosafety Level 2 practices.</i></p> <p><i>Additionally, it is recommended that all patients receiving the vaccine have it administered in a private room or treatment suite meeting Biosafety Level 2 isolation requirements.</i></p> <p><i>It was noted that full committee consideration of this proposal will occur on August 26, 2004.</i></p> <p><i>The committee reviewed the proposed protocol and the Executive Committee's "conditions of approval". It was agreed that final approval authority would be granted to the Executive Committee upon receipt of further information from Dr. Balan on how he plans to comply with the Executive Committee's recommendations.</i></p>
Research Protocol <b>R45-23-8/04</b> "Use of the laboratory adapted Indiana strain vesicular stomatitis virus (VSV)." <b>Kah-Whye Peng, Ph.D.</b> , Principal Investigator Page: 7-9	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Research Protocol R47-5-8/04 "Therapeutic angiogenesis of human vascular progenitor cells (hVPCs) in rat models." Noel Caplice, M.D., Principal Investigator Page: 10-13	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Biosafety Level 2 provisions and practices.
Research Protocol R46-5-8/04 (A21204) "Effects of C-reactive protein on endothelial progenitor cell mediated angiogenesis In-Vivo." Noel Caplice, M.D., Principal Investigator Page: 14-16	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R36-178-6/04 "Genomic instability and breast cancer." Junjie Chen, Ph.D., Principal Investigator Page: 17-18	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved as exempt from National Institutes of Health Recombinant DNA Guidelines and subject to Laboratory and Animal Biosafety Level 1 provisions and practices.
Research Protocol R49-236-8/04 "Protein Therapeutics Delivered by AdenoAssociated Virus for Treatment of Neurodegeneration and AAV mediated delivery of genes to the CNS a rapid and efficient method for developing novel models of neurodegenerative disease." Todd E. Golde, M.D., Ph.D., Principal Investigator Page: 19-22	Amy Tang, Ph.D.	Review and Approve	Approved as exempt from National Institutes of Health Recombinant DNA Guidelines and subject to Laboratory and Animal Biosafety Level 1 provisions and practices.
Research Protocol R66-74-12/03 (A36703) "Biodistribution of Genetically Modified Endothelial Outgrowth Cells." Robert D. Simari, M.D., Principal Investigator Page: 23-25	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R42-23-7/04 (A18704) "Enhancing Edmonston CEA Measles Virus Gene Expression and Efficacy following Intrapertioneal Administration in Nude Mice." Kah-Whye Peng, Ph.D., Principal Investigator Page: 26-27	Priya Sampathkumar, M.D.	Review and Approve	Approved as exempt from National Institutes of Health Recombinant DNA Guidelines and subject to Laboratory and Animal Biosafety Level 1 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<u><b>Carry In</b></u> Research Protocol R50-119-8/04 (A24104) "Efficacy and Imaging of Measles Virus in SCID Mice with Myeloma Tumors." <b>Stephen J. Russell, M.D.</b> , Principal Investigator Page: 28-30	All	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.
<u><b>Carry In</b></u> Research Protocol R51-119-8/04 "A Multicenter, Randomized, Double-Blind, Dose Ranging Placebo-Controlled Study Evaluating Defined Doses of Percutaneously Delivered via Boston Scientific Corporation Stiletto™ Endocardial Injection Catheter pVGI.1 (VEGF 2) (Placebo, 20, 200, or 800 ug) in Patients with Class III of IV Angina." <b>Robert D. Simari, M.D.</b> , Principal Investigator Page: 31-39	All	Review and Approve	Approved as exempt from National Institutes of Health Recombinant DNA Guidelines and subject to Laboratory and Animal Biosafety Level 1 provisions and practices.
<u><b>Note Item</b></u> New Clinical Laboratory Test Page: 28-46	All	Note	Noted
<u><b>Next Meeting:</b></u> September 30, 2004 (5 weeks)	All	Note	

### Membership

N. L. Eberhardt, Ph.D., Chair - Present  
 M. J. Federspiel, Ph.D. - Present  
 M. C. Blanco, D.V.M. - Present  
 W. G. Buchta, M.D. - Absent  
 Ms. B. Borg - Absent  
 Mr. P. R. Giesen - Absent

N. A. Lee, MD, Ph.D. - Absent  
 Mr. G. P. Munson - Absent  
 P. Sampathkumar, M.D. - Present  
 Mr. D. H. Senjem, Secretary - Present  
 A. H. Tang, Ph.D. - Present  
 N. L. Wengenack, Ph.D. - Present

R. Janknecht, Ph.D. - Present  
 J. Caplette - Absent  
 C. Yennie - Present  
 J. A. Copland, Ph.D. - Absent  
  
 Guest: Ms. Bierbaum

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

September 30, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> August 26, 2004 Page: 1-3	All	Approve	Approved
Research Protocol <b>R54-151-9/04 (A26204)</b> "VSV-G pseudotyped, MLV based replication-competent retrovirus for cancer gene therapy." <b>Richard Vile, Ph.D.</b> , Principal Investigator Page: 4-6	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R56-120-9/04</b> "Dysregulated gene expression in cancer." <b>Ralf Janknecht, Ph.D.</b> , Principal Investigator Page: 7-9	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.  Dr. Janknecht abstained from voting on this protocol.
Research Protocol <b>R53-85-8/04</b> "CT1030, " Phase I/II, Open-Label Study (With a Sequential Dose Escalation Stage Followed by an Expansion of a Selected Dose Cohort), To Evaluate the Safety and Anti-Tumor Effects of NV1020, Administered Repeatedly Via Hepatic Artery Infusion Prior to Second Line Chemotherapy, In Patients With Colorectal Adenocarcinoma Metastatic to the Liver" <b>Evanthia Galanis, M.D.</b> , Principal Investigator Page: 10-12	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.  The committee recommended that Mr. Senjem work with Dr. Galanis relative to specific precautions associated with the preparation and administration of the agent and patient isolation procedures.  Lastly, it was noted that Wescodyne <sup>®</sup> , 10% bleach, or autoclaving should be used to disinfect contaminated liquids as opposed to the 70% ethanol indicated in the Institutional Biosafety Committee's Registration Document.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<p>Research Protocol <b>R34-77-6/04 (A14004)</b>            “FVB Tg Murine Model for Xenotransplantation of Human Hepatocytes and HCV Infection.”  <b>Michael R. Charlton, M.D.</b>, Principal Investigator            Page: 13-14</p>	Mark J. Federspiel, Ph.D.	Review and Approve	<p>Approved subject to Laboratory Biosafety Level 2 provisions and practices and the collection of “baseline” serum samples on individuals working with the agent, as well as, potentially exposed Comparative Medicine personnel.</p> <p>The committee further recommended that Mr. Senjem of Mayo Biosafety and Dr. Blanco of the Department of Comparative Medicine with Dr. Charlton prior to the initiation of experiments to discuss the implementation of Biosafety Level 2 precautions.</p>
<p>Research Protocol <b>R52-268-8/04</b>            “Expression cloning to identify proteins that rescue delta F508 CFTR.”  <b>Martina Gentzsch, Ph.D.</b>, Principal Investigator            Page: 15-18</p>	Nancy A. Lee, Ph.D.	Review and Approve	<p>Approved subject to Laboratory Biosafety Level 2 provisions and practices. It was recommended that Mr. Senjem contact Dr. Gentzsch to discuss biosafety precautions associated with cell sorting.</p>
<p>Research Protocol <b>R40-151-7/04 (A20904)</b>            “Creation of Carrier Cells for Suicide Gene Therapy of Metastatic Disease.”  <b>Richard Vile, Ph.D.</b>, Principal Investigator            Page: 19-22</p>	Nancy A. Lee, Ph.D.	Review and Approve	<p>Approval subject to Laboratory and Animal Biosafety Level 2 provisions and practices.</p> <p>The committee noted that the investigator should update the project’s Registration Document prior to commencing experiments.</p>
<p>Research Protocol <b>R59-285-9/2004</b>            “A Phase III Randomized, Open-Label Study of CG1940 and CG8711 Versus Docetaxel and Prednisone in Patients with Metastatic Hormone-Refractory Prostate Cancer who are Chemotherapy-Naïve.”  <b>Thomas F. Hogan, M.D.</b>, Principal Investigator            Page: 23-25</p>	Nancy A. Lee, Ph.D.	Review and Approve	<p>Approved subject to Laboratory Biosafety Level 2 provisions and practices.</p> <p>The committee recommended that Mr. Senjem meet with Dr. Hogan prior to the initiation of experiments to review safety procedures associated with the preparation and administration of the agent, as well as, patient isolation considerations.</p>

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R58-59-9/2004 (A25504)</b> "Sodium Iodide Symporter (NIS) Mediated Radioiodine Therapy for Pancreatic Cancer." <b>John C. Morris, III, M.D.</b> , Principal Investigator Page: 26-28	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Research Protocol R61-119-9/2004</b> "Efficacy of oncolytic measles virus delivery in murine model using infected monocytic cells." <b>Stephen J. Russell, M.D.</b> , Principal Investigator Page: 29-30	Amy Tang, Ph.D.	Review and Approve	Approved as exempt from National Institutes of Health Recombinant DNA Guidelines and subject to Laboratory and Animal Biosafety Level 1 provisions and practices.
<b>Research Protocol R44-255-8/04 (A260EZ02)</b> "IACUC Protocol Title: Preclinical Pharmacological Studies of Antitumor and Anti-HIV Agents Study Title: Determination of Tissue Distribution of MV-NIS in transgenic (CD46) mice." <b>Matthew M. Ames, Ph.D.</b> , Principal Investigator Page: 31-34	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. It was recommended that Mr. Senjem and Dr. Blanco meet with the investigator to review biosafety procedures prior to the initiation of experiments.
<b>Research Protocol R60-120-9/2004</b> "Breast cancer and the role of ER81, Rcl, Miz-1 and RNA helicases." <b>Ralf Janknecht, Ph.D.</b> , Principal Investigator Page: 35-38	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to CDC/NIH Laboratory and Animal Biosafety Level 2+ provisions and practices for work with lentiviral vectors. This designation is intended to infer Biosafety Level 2 provisions and Biosafety Level 3 Practices.  Dr. Janknecht abstained from voting on this protocol.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Carry In:</u></b> Research Protocol <b>R57-284-9/04</b> “Phase II, Multi-Center, Single Arm Evaluation of Preoperative Chemoradiation Plus TNFerade Biologic Prior to Esophagectomy for Locally Advanced Resectable Esophageal Cancer.” <b>Cuong Nguyen, M.D.</b> , Principal Investigator Page:	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.  The investigator is requested to contact Mr. David Senjem prior to the initiation of experiments to review Biosafety Level 2 requirements.
<b><u>Next Meeting:</u></b> October 28, 2004 (5 weeks)	All	Note	Noted

### **Membership**

N. L. Eberhardt, Ph.D., Chair - Absent  
 M. J. Federspiel, Ph.D. - Present  
 M. C. Blanco, D.V.M. - Present  
 W. G. Buchta, M.D. - Present  
 Ms. B. Borg - Present  
 Mr. P. R. Giesen - Absent

N. A. Lee, MD, Ph.D. - Absent  
 Mr. G. P. Munson - Present  
 P. Sampathkumar, M.D. - Absent  
 Mr. D. H. Senjem, Secretary - Present  
 A. H. Tang, Ph.D. - Absent  
 N. L. Wengenack, Ph.D. - Present

R. Janknecht, Ph.D. - Present  
 J. Caplette - Present  
 C. Yennie - Present  
 J. A. Copland, Ph.D. - Present  
  
 Guest: T. Bierbaum

---

David H. Senjem, Secretary

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

October 28, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> September 30, 2004 Page: 1-4	All	Approve	Approved
Research Protocol R65-246-10/04 "Therapeutic angiogenesis for the prevention of stenosis in hemodialysis grafts." <b>Sanjy Misra, M.D.</b> , Principal Investigator Page: 8-10	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R62-119-9/2004 (A28404) "Coxsackievirus A21 therapy for multiple myeloma." <b>Stephen J. Russell, M.D.</b> , Principal Investigator Page: 11-12	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R63-137-9/04 (A27504) "Vaccination with recombinant Listeria monocytogenes expressing Her2 Fragments for the induction of Anti-Tumor T cell Responses." <b>Esteban Celis, M.D.</b> , Principal Investigator Page: 13-14	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The investigator is requested to contact a member of the staff of the Department of Comparative Medicine prior to the initiation of animal experiments resolve procedural details related to implementing Animal BSL-2 requirements.



This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Discussion:</b> Regarding Dr. Charlton proposal and serum collection and storage requirement. Page: 5-7	All		<p>The committee discussed an appeal from Dr. Charlton regarding a previously issued “condition of approval” relative to the need to perform pre-exposure serum collected and storage on personnel working with serum harboring Hepatitis C virus. Ms. Kim Viker was in attendance representing Dr. Charlton and the laboratory.</p> <p>Dr. Eberhardt began the discussion by reviewing the history and the basis of the recommendation. Ms. Viker noted that the laboratory is of the position that the risk of laboratory-acquired Hepatitis C is extremely low and that a similar requirement has not been imposed on other Mayo laboratories working with Hepatitis C.</p> <p>Ms. Kathleen Meyerle of Mayo’s Legal Department offered that whether the committee requires or does not require pre-exposure serum samples is a decision of the committee. From a legal perspective her urged consistency in the application of the requirement. Dr. Federspiel offered that the suggestion for requiring “pre-exposure” serum collection and storage may have been his. He offered that when he offered the suggestion he was under the impression that this type of activity was much more widespread than what is, in fact, the case.</p>

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<p><b>Continued:</b></p> <p>Regarding Dr. Charlton proposal and serum collection and storage requirement.</p>			<p>Following considerable additional discussion, the committee concluded its assessment of this matter by agreeing to resend the previously issued requirements on Dr. Charlton's protocols (Research Protocol R34-77-6/04 (A14004) "FVB Tg Murine Model for Xenotransplantation of Human Hepatocytes and HCV Infection." And Research Protocol R22-77-3/02 A66-B-02 "The Generation of Anti-HCV Immunoglobulins for the Prevention/Treatment of Hepatitis C Infection.") calling for the pre-exposure collection and storage of serum samples.</p>
<p><b>Carry In:</b></p> <p>Research Protocol R64-253-10/04            "Infectious etiology of arterial calcification."  <b>Virginia M. Miller, Ph.D.</b>, Principal Investigator            Page: 15-17</p>	Nancy L. Wengenack, Ph.D.	Review and Approve	<p>Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.</p> <p>The investigator is requested to contact a member of the staff of the Department of Comparative Medicine prior to the initiation of animal experiments resolve procedural details related to implementing Animal BSL-2 requirements.</p>
<p><b>Carry In:</b></p> <p>Research Protocol R67-201-10/04            "Characterization of recombinant measles viruses restricted to MMP-expressing tumor cells."  <b>Roberto Cattaneo, Ph.D.</b>, Principal Investigator            Page: 18-19</p>	Amy Tang, Ph.D.	Review and Approve	<p>Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.</p>
<p><b>Next Meeting:</b> November 18, 2004            (4 weeks)</p>	All	Note	Noted

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

### **Membership**

N. L. Eberhardt, Ph.D., Chair - Present  
M. J. Federspiel, Ph.D. - Present  
M. C. Blanco, D.V.M. - Absent  
W. G. Buchta, M.D. - Absent  
Ms. B. Borg - Absent  
Mr. P. R. Giesen - Absent

N. A. Lee, MD, Ph.D. - Absent  
Mr. G. P. Munson - Present  
P. Sampathkumar, M.D. - Absent  
Mr. D. H. Senjem, Secretary - Present  
A. H. Tang, Ph.D. - Present  
N. L. Wengenack, Ph.D. - Present

R. Janknecht, Ph.D. - Present  
J. Caplette - Absent  
C. Yennie - Present  
J. A. Copland, Ph.D. - Present

Guest: C. Kermot, M.D. V. Baker, K. Meyerle,  
and T. Bierbaum

---

David H. Senjem, Secretary

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

November 18, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<u><b>Biosafety Committee Minutes</b></u> October 28, 2004 Page: 1-4	All	Approve	Approved subject to three typographical corrections.
HIV Surveillance Program Page: 5	All		The committee considered a proposal from Dr. William G. Buchta related to personnel in Dr. Andrew Badley's HIV Research Laboratory. It specifically related to the discontinuance of a requirement that individuals working within this laboratory be screened serologically on a quarterly basis for anti-HIV antibodies. Dr. Buchta noted that compliance with the requirement by laboratory staff has been problematic and that the risk of a HIV laboratory acquired infection is extremely low. The committee considered and debated Dr. Buchta's recommendation and ultimately concluded that "required" surveillance could be reasonably suspended. The committee further recommended, however, that continued testing on a voluntary basis be available for any employee desiring to be tested.
Research Protocol R66-85-10/04 "MC044C-Phase I Evaluation of the Safety of Intravenous Infusion of a Pathotropic Retroviral Vector Bearing a Cytocidal Cyclin G1 Construct (Rexin-G) as Intervention for Locally Advanced and Metastatic Pancreatic Cancer Refractory to Standard Chemotherapy." <b>Evanthia Galanis, M.D.</b> , Principal Investigator Page: 6-8	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Research Protocol <b>R41-197-7/04 (A18804)</b> “Anti-angiogenic Effects of PEDF.” <b>Eric M. Poeschla, M.D.</b> , Principal Investigator Page: 9-10	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R69-25-11/2004</b> “A pilot study for the evaluation of Adenovirus 35 vector based gene therapy in cardiac allotransplants.” <b>Christopher G. A. McGregor, M.D.</b> , Principal Investigator Page: 11-13	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R73-240-11/2004</b> “Manipulation of cell surface crystal binding molecules.” <b>John C. Lieske, M.D.</b> , and Co-PI: <b>Christopher J. Ward, M.B.Ch.B., Ph.D.</b> , Principal Investigator Page: 14-17	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.  It was noted that the Registration Document did not provide information on the location of the proposal experiments. It was recommended that Mr. Senjem meet with Drs. Lieske and Ward prior to the initiation of experiments.
<u><b>Carry In:</b></u> Research Protocol <b>R77-122-11/2004</b> “Downregulation of p68 and p72 RNA helicase in breast and colon cancer cells.” <b>Ralf Janknecht, Ph.D.</b> , Principal Investigator Page: 18-19	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  To avoid conflict Dr. Janknecht <b>abstained</b> from voting on this proposal.
<u><b>Carry In:</b></u> Research Protocol <b>R72-288-11/2004</b> “Insulin and LH effects on LDL-R and StAR gene promoter expression in pig granulosa-luteal cells.” <b>Johannes D. Veldhuis, M.D.</b> , Principal Investigator Page: 20-23	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2+ provision and practices. Biosafety Level 2+ infers Biosafety Level 2 provisions (facilities and equipment) and Biosafety Level 3 practices. Mr. Senjem will review precautionary measure with Dr. Veldhuis prior to the initiation of experiments.

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Carry In:</u></b> Research Protocol R70-151-11/2004 "Investigation of the Cellular effects of Oncolytic Reovirus killing." <b>Richard Vile, Ph.D.</b> , Principal Investigator Page: 24-26	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

### **Membership**

N. L. Eberhardt, Ph.D., Chair - Present  
 M. J. Federspiel, Ph.D. - Present  
 M. C. Blanco, D.V.M. - Absent  
 W. G. Buchta, M.D. - Present  
 Ms. B. Borg - Present  
 Mr. P. R. Giesen - Absent

N. A. Lee, MD, Ph.D. - Absent  
 Mr. G. P. Munson - Absent  
 P. Sampathkumar, M.D. - Present  
 Mr. D. H. Senjem, Secretary - Present  
 A. H. Tang, Ph.D. - Present  
 N. L. Wengenack, Ph.D. - Present

R. Janknecht, Ph.D. - Present  
 J. Caplette - Present  
 C. Yennie - Absent  
 J. A. Copland, Ph.D. - Present  
  
 Guest: T. Bierbaum

---

David H. Senjem, Secretary

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

December 16, 2004

12:00 Noon (Central Standard Time)

Mayo 11, Room F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<u>Biosafety Committee Minutes</u> November 18, 2004 Page: 1-3	All	Approve	Approved
Research Protocol R68-280-10/04 “Application of oncolytic herpes mutants for treatment of prostate cancer.” <b>Faris Farassati, Ph. D.</b> , Principal Investigator Page: 4-5	Mark J. Federspiel, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.
Research Protocol R76-114-11/2004 (A30204) “Identification of Viral Proteins Targeted by Cellular Immune Responses Following Smallpox Vaccination.” <b>Gregory A. Poland, M.D.</b> , Principal Investigator Page: 6-8a	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  It was recommended that Dr. Poland review the Mayo Vaccinia Policy with affected staff members and meet with a member of the staff of the Department of Comparative Medicine prior to the initiation of experiments. The purpose of the meeting with the Department of Comparative Medicine would be to review respective roles and responsibilities.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<p><b><u>Carry In:</u></b>  Research Protocol R81-290-12/2004  “Evaluation of and a cellular biomaterial (Surgisis®) as a xenogenic large-caliber vascular conduit in dogs.”  <b>Manju Kalra, M.B.B.S.</b>, Principal Investigator  Page: 8b-8c</p>	Ralf Janknecht, Ph.D.	Review and Approve	<p>Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.</p> <p>The committee further recommends that the investigator amend the previously submitted Registration Document to note Risk Group 2 in question 5, Biosafety Level 2 in question 13, and the use of bleach to decontaminate infectious liquids in question 15.</p> <p>Lastly, the committee recommends that the investigator meet with Mr. Senjem to review Biosafety Level 2 requirements prior to initiating experiments.</p>
<p><b><u>Carry In:</u></b>  Research Protocol R71-287-11/2004  “Convection-enhanced delivery of novel therapeutics in animal models of glioblastoma.”  <b>Joon H. Uhm, M.D.</b>, Principal Investigator  Page: 8d-8g</p>	Priya Sampathkumar, M.D.	Review and Approve	<p>Approved as exempt from National Institutes of Health Recombinant DNA Guidelines and subject to Laboratory and Animal Biosafety Level 1 provisions and practices.</p>
<p><b><u>Carry In:</u></b>  Research Protocol R36-264-7/03 (A20403)  “AAV-mediated gene therapy for the treatment of VLCAD-deficiency.”  <b>David B. Schowalter, M.D., Ph.D.</b>, Principal Investigator  Page: 8h-8i</p>	Ralf Janknecht, Ph.D.	Review and Approve	<p>Approved as exempt from National Institutes of Health Recombinant DNA Guidelines and subject to Laboratory and Animal Biosafety Level 1 provisions and practices.</p>
<p><b><u>Carry In:</u></b>  Research Protocol R30-264-4/04 (A11204)  “AAV-mediated gene therapy for the treatment of MCAD deficiency.”  <b>David B. Schowalter, M.D., Ph.D.</b>, Principal Investigator  Page: 8j-8k</p>	Ralf Janknecht, Ph.D.	Review and Approve	<p>Approved as exempt from National Institutes of Health Recombinant DNA Guidelines and subject to Laboratory and Animal Biosafety Level 1 provisions and practices.</p>



This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Carry In:</u></b> Research Protocol <b>R80-85-12/2004 (A31904)</b> "Safety of MV-CEA in Rhesus Macaques IACUC # A31904." <b>Evanthia Galanis, M.D.,</b> Principal Investigator	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
BSL II Incident	Michael C. Blanco, D.V.M.	Information	Dr. Blanco reviewed an infraction of NIH guidelines related to the lack of precautions in caring for mice associated with an Animal Biosafety Level 2 experiment. Dr. Eberhardt noted that he will visit with the principal investigator regarding the importance of compliance to him personally and to the institution.
<b><u>Note Item:</u></b> NIH Communication Page: 9-12 Serious Adverse Events Page: 13-19	All  All		
<b><u>Next Meeting:</u></b> January 27, 2005 (6 weeks)	All	Note	

### **Membership**

N. L. Eberhardt, Ph.D., Chair - Present  
 M. J. Federspiel, Ph.D. - Present  
 M. C. Blanco, D.V.M. - Present  
 W. G. Buchta, M.D. - Present  
 Ms. B. Borg - Absent  
 Mr. P. R. Giesen - Absent

N. A. Lee, MD, Ph.D. - Absent  
 Mr. G. P. Munson - Present  
 P. Sampathkumar, M.D. - Present  
 Mr. D. H. Senjem, Secretary - Present  
 A. H. Tang, Ph.D. - Present  
 N. L. Wengenack, Ph.D. - Present

R. Janknecht, Ph.D. - Present  
 Mr. J. Caplette - Present  
 Mr. C. Yennie - Present  
 J. A. Copland, Ph.D. - Present

Guest: Y. Ikeda, D.V.M., Ph.D. and T. Bierbaum

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

January 27, 2005

12:00 Noon (Central Standard Time)

Siebens 1220

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> December 16, 2004 Page: 1-3	All	Approve	Approved
Welcome new Chair and Member Page: 4-5			Dr. Mark Federspiel welcomed Dr. Yasuhiro Ikeda as a new member and reviewed committee responsibilities.
Research Protocol <b>R3-119-1/2005 (A2705)</b> "Measles virus for cancer gene therapy of primary liver tumors." <b>Stephen J. Russell, M.D.</b> , Principal Investigator Page: 6-9	Committee	Ratify and Approve	The committee ratified a previous action of the Executive Committee in approving this proposal subject to Laboratory and Biosafety Level 2 provisions and practices.
Research Protocol <b>R1-201-1/2005</b> "Investigation of Measles Virus Replication in the Thymus of Mice Transgenic for Human SLAM or CD46 (replacement for IACUC protocol A15B02)." <b>Roberto Cattaneo, Ph.D.</b> , Principal Investigator Page: 10-11	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R4-292-1/2005 (A2105)</b> "The plasminogen activator system as a tool and a target for cancer therapies." <b>Jaime R. Merchan, M.D.</b> , Principal Investigator Page: 12-14	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R82-119-12/2004 (A33104)</b> "Targeting Radionuclides for Myeloma Therapy." <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Page: 15-18	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<p>Research Protocol <b>R8-293-1/2005 (A2905)</b>  “Molecular basis of proliferation in the nervous system.”  <b>Cynthia J. Wetmore, M.D., Ph.D.</b>, Principal Investigator  Page: 19-20</p>	Amy Tang, Ph.D.	Review and Approve	<p>Approved subject to Laboratory and Animal Biosafety Level 2 + provisions and practices.</p> <p>The committee recommends that the investigator meet with the staff veterinary within the Department of Comparative Medicine prior to the initiation of animal experiments to establish respective roles and responsibilities.</p> <p><i>Note: Two-plus is a category denoting Biosafety Level 2 provisions (i.e. Biosafety hoods, signage, etc.) and Biosafety Level 3 practices.</i></p>
<p>Research Protocol <b>R2-291-1/2005</b>  “Studies on essential and restriction factors for lentiviral replication and their application for AIDS gene therapy.”  <b>Yasuhiro Ikeda, Ph.D., D.V.M.</b>, Principal Investigator  Page: 21-25</p>	Nancy L. Wengenack, Ph.D.	Review and Approve	<p>Approved subject to Laboratory Biosafety Level 2 provision and practices for work with murine leukemia virus. Work with incompetent HIV vectors was approved at Laboratory Biosafety Level 2+. Work with replication competent HIV was approved at Laboratory Biosafety Level 3. Mr. Senjem will review precautionary measures with Dr. Ikeda prior to the initiation of experiments.</p> <p>It was noted that Dr. Ikeda abstained from voting.</p> <p><i>Note: Two-plus is a category denoting Biosafety Level 2 provisions (i.e. Biosafety hoods, signage, etc.) and Biosafety Level 3 practices.</i></p>

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Carry In:</u></b> Research Protocol R10-203-1/2005 "Pathophysiology of biliary cryptosporidiosis." <b>Nicholas F. LaRusso, M.D.</b> , Principal Investigator Page: 26-28	Yasuhiro Ikeda, D.V.M., Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The investigator is requested to contact a member of the staff of the Department of Comparative Medicine prior to the initiation of animal experiments to resolve procedural details related to implementing Animal BSL-2 requirements.
<b><u>Next Meeting:</u></b> February 24, 2005 (4 weeks)	All	Note	

### **Membership**

M. J. Federspiel, Ph.D. – Chair – Present  
 M. C. Blanco, D.V.M. – Present  
 W. G. Buchta, M.D. – Present  
 Ms. B. Borg – Present  
 Mr. P. R. Giesen – Absent  
 N. L. Wengenack, Ph.D. – Present

N. A. Lee, MD, Ph.D. – Absent  
 Mr. G. P. Munson – Absent  
 P. Sampathkumar, M.D. – Absent  
 Mr. D. H. Senjem, Secretary – Present  
 A. H. Tang, Ph.D. – Present

R. Janknecht, Ph.D. – Absent  
 J. Caplette – Present  
 C. Yennie – Absent  
 J. A. Copland, Ph.D. – Present  
 Y. Ikeda, D.V.M., Ph.D. – Present

---

David H. Senjem, Secretary

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

February 24, 2005

12:00 Noon (Central Standard Time)

Siebens 1220

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<u>Biosafety Committee Minutes</u> January 27, 2005 Page: 1-3	All	Approve	Approved
Research Protocol R11-119-2/2005 (A7003) “Pilot project for using oncolytic measles viral therapy for pancreatic cancer.” Stephen J. Russell, M.D., Ph.D., Principal Investigator Page: 4-5	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R7-119-1/2005 (A6404) “Retargetable oncolytic measles virus for cancer virotherapy.” Stephen J. Russell, M.D., Ph.D., Principal Investigator Page: 6-8	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R6-151-1/2005 (A2805) “Copy of Adoptive Therapy of Tumors with Genetically Modified Specific T Cells.” Richard G. Vile, Ph.D., Principal Investigator Page: 9-11	Yasuhiro Ikeda, D.V.M., Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R15-77-2/2005 (A7005) “The Generation of anti-HCV Immunoglobulins for the Prevention/Treatment of Hepatitis C Infection.” Michael R. Charlton, M.D., Principal Investigator Page: 12-13	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.  The committee recommends the investigator considers the use of a restraint during animal inoculation to prevent needlesticks.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R13-294-2/2005 (A7105)</b> "SLAM controls bacterial killing in innate immune cells" <b>William A. Faubion, M.D.</b> , Principal Investigator Page: 14-18	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices with the use of <i>E. coli</i> , F18; <i>Klebsiella pneumoniae</i> ; <i>Citrobacter</i> sp; <i>Pseudomonas aeruginosa</i> ; <i>Proteus vulgaris</i> ; <i>Acinetobacter</i> sp; <i>Staphylococcus aureus</i> ; <i>Streptococcus pyogenes</i> ; <i>Staphylococcus epidermidis</i> ; <i>Streptococcus pneumoniae</i> ; <i>Salomonella Typhimurium</i> (wt 14028s and attenuated sseB-).  The investigator is requested to contact a member of the staff of the Department of Comparative Medicine prior to the initiation of animal experiments resolve procedural details related to implementing Animal BSL-2 requirements.
<b>Research Protocol R9-130-1/2005</b> "Effects of pigment-epithelium derived factor (PEDF) on intrahepatic metastatic growth of human pancreatic cell carcinoma in SCID mice." <b>Vijay H. Shah, M.D.</b> , Principal Investigator Page: 19-21	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The investigator is requested to contact a member of the staff of the Department of Comparative Medicine prior to the initiation of animal experiments resolve procedural details related to implementing Animal BSL-2 requirements.
<b>Research Protocol R17-119-2/2005 (A6605)</b> "Oncolytic virotherapy with measles virus infected cells in the intraperitoneal model of human tumor growth in immunodeficient mice." <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Page: 22-23	Yasuhiro Ikeda, D.V.M., Ph.D.	Review and Approve	Approved as exempt from National Institutes of Health Recombinant DNA Guidelines and subject to Laboratory and Animal Biosafety Level 1 provisions and practices.
<b>Research Protocol R5-5-1/2005 (A405)</b> "Role of Bone Marrow-Derived Vascular Progenitors Cells in Pulmonary Hypertension." <b>Noel Caplice, M.D.</b> , Principal Investigator Page: 24-26	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and Biosafety Level 2+ practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Research Protocol <b>R14-151-2/2005 (A8505)</b> "Genetically Engineered Vesicular Stomatitis Viruses For Cancer Therapy." <b>Richard G. Vile, Ph.D.</b> , Principal Investigator Page: 27-29	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Carry In:</b> Research Protocol <b>R12-238-2/2005 (A7905)</b> "Retargeting the Tropism of Vesicular Stomatitis Virus (Indiana Strain)." <b>Kah-Whye Peng, Ph.D.</b> , Principal Investigator Page: 30-31	Amy Tang, Ph.D.	Review and Approve	Deferred until next meeting.
<b>Other Business:</b> IBC Annual Memo Page: 32-33	Mark J. Federspiel, Ph.D.	Discussion	Further discussion will continue at the March 24 <sup>th</sup> meeting.
<b>Next Meeting:</b> March 24, 2005 (4 weeks)	All	Note	

### Membership

M. J. Federspiel, Ph.D. – Chair – Present  
M. C. Blanco, D.V.M. – Present  
W. G. Buchta, M.D. – Absent  
Ms. B. Borg, Acting Secretary – Present  
Mr. P. R. Giesen – Absent  
N. L. Wengenack, Ph.D. – Present

N. A. Lee, MD, Ph.D. – Absent  
Mr. G. P. Munson – Absent  
P. Sampathkumar, M.D. – Absent  
Mr. D. H. Senjem, Secretary – Absent  
A. H. Tang, Ph.D. – Present  
Guest: Ms. T. Bierbaum

R. Janknecht, Ph.D. – Present  
J. Caplette – Absent  
C. Yennie – Absent  
J. A. Copland, Ph.D. – Absent  
Y. Ikeda, D.V.M., Ph.D. – Present

---

Beth Borg, Acting Secretary

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

March 24, 2005

12:00 Noon (Central Standard Time)

Mayo 11 F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> February 24, 2005 Page: 1-3	All	Approve	Approved
Research Protocol R12-238-2/2005 (A7905) <b>REVISED</b> on page: 15-17 in Revised agenda packet. "Retargeting the Tropism of Vesicular Stomatitis Virus (Indiana Strain)." <b>Kah-Whye Peng, Ph.D.</b> , Principal Investigator Page: 4-5	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R19-119-2/2005 (A8105) "Oncolytic Measles Virus for Cancer Virotherapy." <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Page: 6-8	Committee	Ratify and Approve	The committee ratified a previous action of the Executive Committee and approved this proposal subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R23-119-3/2005 (A10105) "Safety of an Attenuated Measles Virus in Mice IACUC A10105." <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Page: 9-11	Committee	Ratify and Approve	The committee ratified a previous action of the Executive Committee and approved this proposal subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R22-53-3/2005 "Secreted Proteins in Pulmonary Carcinoid Cancers." <b>Charles F. Thomas, Jr., M.D.</b> , Principal Investigator Page: 12-14	Ralf Janknecht, Ph.D.	Review and Approve	Approved as exempt from NIH Guidelines and subject to Laboratory Biosafety Level 1 provisions and practices.



This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Carry In:</b> Research Protocol R24-85-3/2005 (A9105) "Measles Virotherapy in Gliomas." <b>Evanthia Galanis, M.D.</b> , Principal Investigator Page: 18-20	Committee	Ratify and Approve	The committee ratified a previous action of the Executive Committee and approved this proposal subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Carry In:</b> Research Protocol R20-238-2/2005 (A8005) "Ovarian Cancer Therapy Using NIS-expressing Measles Virus." <b>Kah-Whye Peng, Ph.D.</b> , Principal Investigator Page: 21-23	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Other Business:</b> IBC Annual Memo Page: 15-16  In-depth Review and Public RAC Discussion of Protocol #0501-691 Page: 17-20 Discussion on Interim Approvals	Mark J. Federspiel, Ph.D.  All  David Senjem	Discussion  Discussion  Discussion	The committee discussed a "draft" of a letter proposed by Dr. Federspiel for Mayo research investigators detailing requirements and responsibilities as defined in NIH's Recombinant DNA Guidelines. Suggestions were offered which will be incorporated into the letter prior to issuance.  Noted  The committee discussed the practice of Interim Executive Committee approvals. It was agreed that grants would be considered for review and approval on an "interim" basis when compelling reasons dictated a need for committee action. Every proposal so considered would be subject to full committee review and approval.
<b>Next Meeting:</b> April 21, 2005 (4 weeks)	All	Note	

*This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.*

**Membership**

M. J. Federspiel, Ph.D. - Chair - Present  
M. C. Blanco, D.V.M. - Present  
W. G. Buchta, M.D. - Present  
Ms. B. Borg - Present  
Mr. P. R. Giesen - Absent  
N. L. Wengenack, Ph.D. - Present

N. A. Lee, MD, Ph.D. - Absent  
Mr. G. P. Munson - Present  
P. Sampathkumar, M.D. - Present  
Mr. D. H. Senjem, Secretary - Present  
A. H. Tang, Ph.D. - Present

R. Janknecht, Ph.D. - Present  
J. Caplette - Absent  
C. Yennie - Absent  
J. A. Copland, Ph.D. - Present  
Y. Ikeda, D.V.M., Ph.D. - Absent

---

David H. Senjem, Secretary

**Institutional Biosafety Committee Minutes**

April 21, 2005

12:00 Noon (Central Standard Time)

Mayo 11 F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> March 24, 2005 Page: 1-3	All	Approve	Approved
Research Protocol <b>R25-29-3/2005 (A11505)</b> "Therapeutic effect of human endothelial progenitor cells on recovering endothelial function in a SCID mouse carotid injury model." <b>Zvonimir S. Katusic, M.D., Ph.D.</b> , Principal Investigator Page: 4-6	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R21-151-2/2005 (A8605)</b> "Intratumoral and systemic reovirus therapy plus adoptive therapy for cancer in mice." <b>Richard Vile, Ph.D.</b> , Principal Investigator Page: 7-9	Committee	Ratify	The committee ratified a previous action of the Executive Committee and approved this proposal subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R18-29-2/2005 (A7505)</b> "Effect of Erythropoietin on Cerebral Vasospasm after Subarachnoid Hemorrhage." <b>Zvonimir S. Katusic, M.D., Ph.D.</b> , Principal Investigator Page: 10-12	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R26-238-4/2005 (A14705)</b> "Retargeted Oncolytic Measles Viruses Displaying Single-Chain Antibodies." <b>Kah-Whye Peng, Ph.D.</b> , Principal Investigator Page: 13-16	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

<b>Carry In:</b> Research Protocol R28-122-4/2005 “p68, p72, ER81 and b-catenin in breast and colon cancer” <b>Ralf Janknecht, Ph.D.</b> , Principal Investigator Page: 16a-16c	Amy H. Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provision and practices for work with retrovirus. Work with lentivirus was approved at Laboratory Biosafety Level 2+.
<b>Carry In:</b> Research Protocol R29-238-4/2005 “Comparison of antitumor efficacy of measles virus variants” <b>Kah-Whye Peng, Ph.D.</b> , Principal Investigator Page: 16d-16f	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Carry In:</b> Research Protocol R16-151-3/2005 (A13205) “Specific ablation of prostate tissue to immunize against prostate cancer” <b>Richard G. Vile, Ph.D.</b> , Principal Investigator Page: 16g-16i	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Other Business:</b> NIH Confirmation Letter Page: 17 NIH Guidelines Page: 18-22	All  All	Information  Information	Noted  Noted
<b>Next Meeting:</b> May 19, 2005 (4 weeks)	All	Note	Noted

### Membership

M. J. Federspiel, Ph.D. – Chair - Present  
M. C. Blanco, D.V.M. - Present  
W. G. Buchta, M.D. - Absent  
Ms. B. Borg - Present  
Mr. P. R. Giesen - Absent  
N. L. Wengenack, Ph.D. - Present

N. A. Lee, MD, Ph.D. - Absent  
Mr. G. P. Munson - Absent  
P. Sampathkumar, M.D. - Present  
Mr. D. H. Senjem, Secretary - Absent  
A. H. Tang, Ph.D. - Present  
Guest: T. Bierbaum

R. Janknecht, Ph.D. - Present  
J. Caplette - Present  
C. Yennie - Present  
J. A. Copland, Ph.D. - Absent  
Y. Ikeda, D.V.M., Ph.D. - Present

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

### Institutional Biosafety Committee Minutes

May 19, 2005

12:00 Noon (Central Standard Time)

Mayo 11 F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<u><b>Biosafety Committee Minutes</b></u> April 21, 2005 Page: 1-2	All	Approve	Approved
Research Protocol <b>R30-16-4/2005</b> "Effect of ONYX in conjunction with PPARgamma agonist and antagonist treatment on the growth of anaplastic thyroid cells in culture." <b>Norman L. Eberhardt, Ph.D.</b> , Principal Investigator Page: 3-6	Amy H. Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R32-210-4/2005 (A12303)</b> "Mouse Model of Graves' Disease and Ophthalmopathy" <b>Rebecca S. Bahn, M.D.</b> , Principal Investigator Page: 7-10	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The committee requested that a double red bagging procedure be used consistently throughout the period of the experiments.
<b>Carry In:</b> Research Protocol <b>R27-291-4/2005 (A14205)</b> "Effects of HRAS expression on retroviral/lentiviral infection." <b>Yasuhiro Ikeda, D.V.M., Ph.D.</b> , Principal Investigator Page: 10a-10d	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provision and practices for work with retrovirus. Work with lentivirus was approved at Laboratory Biosafety Level 2+.  It was noted that Dr. Ikeda abstained from voting.

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Carry In:</b> Research Protocol R35-119-5/2005 "Imaging MV-NIS infected squirrel monkeys with I-123" <b>Stephen J. Russell, M.D., Ph.D.,</b> Principal Investigator Page: 10e-10g	Yasuhiro Ikeda, D.V.M., Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The committee noted that Recombinant DNA was not checked in the affirmative in Question 3 of the Registration Document and requested that Ms. Bierbaum make this notation in the permanent IBC record.
<b>Other Business:</b> Infection Control Committee Minutes Page: 11-14	All	Information	Noted
<b>Next Meeting:</b> June 16, 2005 (4 weeks)	All	Note	Noted

### Membership

M. J. Federspiel, Ph.D. – Chair - Present  
 M. C. Blanco, D.V.M. - Absent  
 W. G. Buchta, M.D. - Present  
 Ms. B. Borg - Present  
 Mr. P. R. Giesen - Absent  
 N. L. Wengenack, Ph.D. - Present

N. A. Lee, MD, Ph.D. - Absent  
 Mr. G. P. Munson - Present  
 P. Sampathkumar, M.D. - Absent  
 Mr. D. H. Senjem, Secretary - Absent  
 A. H. Tang, Ph.D. - Present  
 Guest: Ms. T. Bierbaum

R. Janknecht, Ph.D. - Present  
 J. Caplette - Present  
 C. Yennie - Present  
 J. A. Copland, Ph.D. - Absent  
 Y. Ikeda, D.V.M., Ph.D. - Present

---

Beth Borg, Acting Secretary

**Institutional Biosafety Committee Minutes**

June 16, 2005

12:00 Noon (Central Standard Time)

Mayo 111 F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> May 19, 2005 Page: 1-2	All	Approve	Approved
Research Protocol R33-119-5/2005 (A15603) "Monitoring Expression of Cell-Associated Transgene" <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Page: 3-5	Nancy L. Wengenack, Ph.D.	Review and Approve	Work with adenovirus was approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. Work with lentivirus was approved at Laboratory and Animal Biosafety Level 2+. Biosafety Level 2+ involves Biosafety Level 2 facility and equipment provisions combined with Biosafety Level 3 practices.
Research Protocol R37-53-6/2005 "Azole testing of Mycobacterium avium" <b>Charles F. Thomas, Jr., M.D.</b> , Principal Investigator Page: 6-7	Amy Tang, Ph.D.	Review and Approve	Approval of the proposal was deferred pending the receipt of additional information on the MTT Assay and transfer precautions for mycobacterium avium. Dr. Tang and Mr. Senjem will follow-up with the investigator on these specific issues.
Research Protocol R34-29-5/2005 (A16705) "Therapeutic effect of human endothelial progenitor cells on neovascularization in a mouse hind limb ischemia model" <b>Zvonimir S. Katusic, M.D., Ph.D.</b> , Principal Investigator Page: 8-10	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

This document has been created by the **Institutional Biosafety Committee** for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and **privileged** pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the **Institutional Biosafety Committee**.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Carry In:</b> Research Protocol <b>R39-298-6/2005</b> "Homing of Circulating Osteoblasts into the Fracture Callus of Mice" <b>Sundeep Khosla, M.D.</b> , Principal Investigator Page: 10a-10c	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and <b>Animal Biosafety Level 2+</b> provisions and practices. Biosafety Level 2+ involves Biosafety Level 2 facility and equipment provisions combined with Biosafety Level 3 practices.  The committee recommends that the investigator meet with the staff veterinary within the Department of Comparative Medicine prior to the initiation of animal experiments to establish respective roles and responsibilities.
<b>Carry In:</b> Research Protocol <b>R36-297-6/2005</b> "RCC metastasis; Effect of smoking, targeted therapy, and development of novel prognostic markers" <b>Panagiotis Z. Anastasiadis, Ph.D.</b> , Principal Investigator Page: 10d-10h	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and <b>Animal Biosafety Level 2</b> provisions and practices.  The committee recommends that the investigator meet with Faith Conkle prior to the initiation of animal experiments to establish respective roles, responsibilities and to ensure appropriate animal housing and related handling precautions.
<b>Carry In:</b> Research Protocol <b>R38-68-6/2005</b> "Technology To Optimize scFcs For Targeting Therapeutics" <b>Mark J. Federspiel, Ph.D.</b> , Principal Investigator Page: 10i-10n	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and <b>Animal Biosafety Level 2</b> provisions and practices.  It was noted that Dr. Federspiel abstained from voting.
<b>Other Business:</b> Research Protocol <b>R55-119-10/03 (A30803)</b> "Neurotoxicity of Measles Virus-CEA, intracranial delivery into CD46in/k0Ge mice." <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator  Subject: Reconsideration of Biosafety Level Classification of MV-CEA	All	Possible Reconsiderations	The committee reclassified precautionary measures associated with the use of measles virus CEA in the noted research protocol from Biosafety Level 2 to Biosafety Level 1.



SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R80-85-12/2004 (A31904)</b> <b>“Safety of MV-CEA in Rhesus Macaques IACUC # A31904.”</b> <b>Evanthia Galanis, M.D., Principal Investigator</b> Subject: Reconsideration of Biosafety Level Classification of MV-CEA Page: 11-19	All	Possible Reconsiderations	The committee reclassified precautionary measures associated with the use of measles virus CEA in the noted research protocol from Biosafety Level 2 to Biosafety Level 1.
<b>Next Meeting:</b> July 21, 2005 (4 weeks)	All	Note	Noted

**Membership**

M. J. Federspiel, Ph.D. – Chair - Present  
 M. C. Blanco, D.V.M. - Present  
 W. G. Buchta, M.D. - Present  
 Ms. B. Borg - Present  
 Mr. P. R. Giesen - Absent  
 N. L. Wengenack, Ph.D. - Present

N. A. Lee, MD, Ph.D. - Absent  
 Mr. G. P. Munson - Present  
 P. Sampathkumar, M.D. - Present  
 Mr. D. H. Senjem, Secretary - Absent  
 A. H. Tang, Ph.D. - Present

R. Janknecht, Ph.D. - Absent  
 J. Caplette - Present  
 C. Yennie - Absent  
 J. A. Copland, Ph.D. - Present  
 Y. Ikeda, D.V.M., Ph.D. - Present

---

 David H. Senjem, Secretary

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

### Institutional Biosafety Committee Minutes

July 21, 2005

12:00 Noon (Central Standard Time)

Mayo 11 F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> June 16, 2005 Page: 1-2	All	Approve	Approved
Research Protocol <b>R37-53-6/2005</b> "Azole testing of Mycobacterium avium" <b>Charles F. Thomas, Jr., M.D.</b> , Principal Investigator Page: 4-7	Executive Committee	Ratify	The committee ratified a previous action of the Executive Committee approving this proposal subject to Laboratory and Biosafety Level 2 provisions and practices.
Research Protocol <b>R41-68-6/2005</b> "Large-scale production of recombinant measles viruses and adenoviral vectors" <b>Mark J. Federspiel, Ph.D.</b> , Principal Investigator Page: 8-11	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.
Research Protocol <b>R46-68-7/2005</b> "Avian Leukosis Viruses expressing measles virus H and F proteins, or Murine leukemia virus 4070A amphotropic envelope glycoprotein" <b>Mark J. Federspiel, Ph.D.</b> , Principal Investigator Page: 12-14	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.

*This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.*

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R47-301-7/2005</b> "Systemic delivery of oncolytic viruses to tumor" <b>Takafumi Nakamura, Ph.D.,</b> Principal Investigator Page: 15-21	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The committee requested further information on use of adenovirus in the proposal noting that it was referred to in Question 12 of the Registration Document, but not listed in Question 4.  The investigator must contact a member of the Staff of the Department of Comparative Medicine prior to the initiation of animal experiments to discuss roles and responsibilities related to the experiment.
<b>Research Protocol R45-68-7/2005</b> "Avian Leukosis Viruses expressing different forms of the Ebola Virus Glycoprotein" <b>Mark J. Federspiel, Ph.D.,</b> Principal Investigator Page: 22-24	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.
<b>Research Protocol R40-300-6/2005</b> "Cloning tumor associated antigens into mammalian expression vectors" <b>Allan B. Dietz, Ph.D.,</b> Principal Investigator Page: 25-27	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.
<b>Carry In:</b> <b>Research Protocol R48-201-7/2005</b> "Influence of Measles virus on HIV infection" <b>Roberto Cattaneo, Ph.D.,</b> Principal Investigator	Yasuhiro Ikeda, D.V.M., Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 3 provisions and practices. The Committee further specified that Dr. Cattaneo meet with staff, who will be working on the proposal to review the procedure manual which has been prepared for the 18 <sup>th</sup> floor Guggenheim Biosafety Level 3 facility.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Amendment:</b> Research Protocol R4-292-1/2005 (A2105) "The plasminogen activator system as a tool and a target for cancer therapies." <b>Jaime R. Merchan, M.D.</b> , Principal Investigator Page: 28-32	Yasuhiro Ikeda, D.V.M., Ph.D.	Review and Approve	Reviewed and approved subject to Laboratory and Animal Biosafety Level 2+ provisions and practices. Biosafety Level 2+ is defined as Biosafety Level 2 facilities and equipment and Biosafety Level 3 laboratory practices.
<b>Other Business:</b> Biosafety Level 2+ Rules and Guidelines Page: 33-39	Mark J. Federspiel, Ph.D. and Yasuhiro Ikeda, D.V.M., Ph.D.	Discussion	Deferred to next meeting.
<b>IBC Web Page</b>	David H. Senjem	Discussion	Deferred to next meeting.
<b>Next Meeting:</b> August 18, 2005 (4 weeks)	All	Note	Noted

### Membership

M. J. Federspiel, Ph.D. – Chair - Present  
M. C. Blanco, D.V.M. - Present  
W. G. Buchta, M.D. - Present  
Ms. B. Borg - Absent  
Mr. P. R. Giesen - Absent  
N. L. Wengenack, Ph.D. - Absent

N. A. Lee, MD, Ph.D. - Absent  
Mr. G. P. Munson - Absent  
P. Sampathkumar, M.D. - Present  
Mr. D. H. Senjem, Secretary - Present  
A. H. Tang, Ph.D. - Present

R. Janknecht, Ph.D. – Present  
J. Caplette - Absent  
C. Yennie - Present  
J. A. Copland, Ph.D. - Present  
Y. Ikeda, D.V.M., Ph.D. - Present  
T. Bierbaum (Guest)

---

David H. Senjem, Secretary

## Institutional Biosafety Committee Minutes

August 18, 2005

12:00 Noon (Central Standard Time)

Mayo 11 F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<u>Biosafety Committee Minutes</u> July 21, 2005 Page: 1-3	All	Approve	Approved
<b>Old Business:</b>  Biosafety Level 2+ Rules and Guidelines Page: 4-10	Mark J. Federspiel, Ph.D. and Yasuhiro Ikeda, D.V.M., Ph.D.	Discussion	The committee reviewed and approved the proposed guidelines. It was recommended that they be referred to investigators with approved BSL 2+ projects.
<b>Animal BSL 2+ Procedures</b> Page: 10a-10d	Michael C. Blanco, D.V.M.	Discussion	It was recommended that these procedures be incorporated into the BSL 2+ document.
<b>IBC Web Page</b> Page: 11-17	David H. Senjem	Discussion	Discussed
<b>New Business:</b>  Research Protocol R43-222-6/2005 (A20505) "Gene Transfer of Cocaine Hydrolase in Mice" William S. Brimijoin, Ph.D., Principal Investigator Page: 18-21	Ralf Janknecht, Ph.D.	Review and Approve	Experiments with adenoviral vectors were approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  Experiments with Lentiviral vectors were approved subject to Laboratory and Animal Biosafety Level 2+ provisions and practices.  The committee recommends that the investigator meet with a member of the Staff of Department of Comparative Medicine prior to the initiation of animal experiments to establish respective roles and responsibilities.  <i>Note: Two-plus is a category denoting Biosafety Level 2 provisions (i.e. Biosafety hoods, signage, etc.) and Biosafety Level 3 practices.</i>

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R44-222-6/2005 (A20605)</b> <b>"Gene Transfer of Cocaine Hydrolase in Rats"</b> <b>William S. Brimijoin, Ph.D., Principal Investigator</b> <b>Page: 22-25</b>	Ralf Janknecht, Ph.D.	Review and Approve	<p>Experiments with adenoviral vectors were approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.</p> <p>Experiments with Lentiviral vectors were approved subject to Laboratory and Animal Biosafety Level 2+ provisions and practices.</p> <p>The committee recommends that the investigator meet with a member of the Staff of Department of Comparative Medicine prior to the initiation of animal experiments to establish respective roles and responsibilities.</p> <p><i>Note: Two-plus is a category denoting Biosafety Level 2 provisions (i.e. Biosafety hoods, signage, etc.) and Biosafety Level 3 practices.</i></p>
<b>Research Protocol R53-119-8/2005</b> <b>"Systemic delivered oncolytic measles virus for cancer therapy"</b> <b>Stephen J. Russell, M.D., Ph.D., Principal Investigator</b> <b>Page: 26-28</b>	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b>Research Protocol Renewal R49-236-8/04 (A24804)</b> <b>"Protein Therapeutics Delivered by AdenoAssociated Virus for Treatment of Neurodegeneration and AAV mediated delivery of genes to the CNS a rapid and efficient method for developing novel models of neurodegenerative disease."</b> <b>Todd E. Golde, M.D., Ph.D., Principal Investigator</b> <b>Page: 29-30</b>	Amy Tang, Ph.D.	Review and Approve	Approved as exempt from NIH Guidelines and subject to Laboratory Biosafety Level 1 provisions and practices.
<b>Research Protocol R58-303-8/2005</b> <b>"Effects of targeting the MAP kinase pathway in human tumor cell lines"</b> <b>Alex A. Adjei, M.D., Ph.D., Principal Investigator</b> <b>Page: 31-33</b>	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.
<b>Research Protocol (Modified) R29-238-4/2005 (A15605)</b> <b>"Comparison of antitumor efficacy of measles virus variants"</b> <b>Kah-Whye Peng, Ph.D., Principal Investigator</b> <b>Page: 34-36</b>	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<p>Research Protocol <b>R59-304-8/2005</b>                      "Investigation of the functional role of LRRK2 in primary neurons and mice using a lentiviral vector for efficient transduction of the gene of interest "  <b>Matthew Farrer, Ph.D.</b>, Principal Investigator                      Page: 37-39</p>	<p>John A. Copland, III, Ph.D.</p>	<p>Review and Approve</p>	<p>Approved subject to Laboratory and Animal Biosafety Level 2 + provisions and practices.</p> <p>Mr. Senjem will follow-up with Dr. Farrer to review Biosafety Level 2+ precautions. In addition, the committee recommended that the investigator meet with Faith Conkle of the Department of Comparative Medicine prior to the initiation of animal experiments to establish respective roles, responsibilities and to ensure appropriate animal housing and related handling precautions.</p> <p>Note: Two-plus is a category denoting Biosafety Level 2 provisions (i.e. Biosafety hoods, signage, etc.) and Biosafety Level 3 practices.</p>
<p>Research Protocol <b>R56-119-8/2005</b>                      "Vesicular stomatitis virus (VSV) therapy for multiple myeloma"  <b>Stephen J. Russell, M.D., Ph.D.</b>, Principal Investigator                      Page: 40-43</p>	<p>Priya Sampathkumar, M.D.</p>	<p>Review and Approve</p>	<p>Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.</p>
<p>Research Protocol <b>R60-305-8/2005</b>                      "Role of PKC iota in Ras-mediated lung carcinogenesis"  <b>Alan P. Fields, Ph.D.</b>, Principal Investigator                      Page: 44-47</p>	<p>Amy Tang, Ph.D.</p>	<p>Review and Approve</p>	<p>Approved subject to Laboratory and Animal Biosafety Level 2 + provisions and practices.</p> <p>Mr. Senjem will follow-up with Dr. Fields to review Biosafety Level 2+ precautions. In addition, the committee recommended that the investigator meet with Faith Conkle of the Department of Comparative Medicine prior to the initiation of animal experiments to establish respective roles, responsibilities and to ensure appropriate animal housing and related handling precautions.</p> <p>Note: Two-plus is a category denoting Biosafety Level 2 provisions (i.e. Biosafety hoods, signage, etc.) and Biosafety Level 3 practices.</p>

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Carry In</u></b> Research Protocol R52-238-7/2005 (A24305) "Folate Receptor Targeted Virotherapy in Ovarian and Breast Cancer Using Recombinant Measles Virus." <b>Kah-Whye Peng, Ph.D.</b> , Principal Investigator Page: 48-50	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b><u>Carry In</u></b> Research Protocol R49-119-7/2005 "Development of rapid and efficient rescue method for recombinant measles virus." <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Page: 51-54	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.  The committee further recommended that a copy of Mayo's Vaccinia Virus Policy be forwarded to Dr. Russell.
<b><u>Carry In</u></b> Research Protocol R54-301-8/2005 "Virotherapy using oncolytic measles virus targeted to testicular cancer" <b>Takafumi Nakamura, Ph.D.</b> , Principal Investigator Page: 55-60	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The committee recommends that the investigator meet with a member of the Staff of the Department of Comparative Medicine and Radiation Safety prior to the initiation of animal experiments to establish respective roles and responsibilities.
<b><u>Carry In</u></b> Research Protocol R50-74-7/2005 (A21905) "Renewal of Regulation of the Thrombogenicity of Atherosclerosis." <b>Robert D. Simari, M.D.</b> , Principal Investigator Page: 61-63	Yasuhiro Ikeda, D.V.M., Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The committee recommends that the investigator meet with a member of the Staff of the Department of Comparative Medicine prior to the initiation of animal experiments to establish respective roles and responsibilities.
<b><u>Carry In</u></b> Research Protocol R57-236-8/2005 (A24804) "AAV mediated delivery of genes to the CNS a rapid and efficient method for developing novel models of neurodegenerative disease" <b>Todd E. Golde, M.D., Ph.D.</b> , Principal Investigator Page: 64-67	Ralf Janknecht, Ph.D.	Review and Approve	Approved as exempt from NIH Guidelines and subject to Laboratory Biosafety Level 1 provisions and practices.
<b><u>Next Meeting:</u></b> September 15, 2005 (4 weeks)	All	Note	Noted



### **Membership**

M. J. Federspiel, Ph.D. – Chair - Absent  
M. C. Blanco, D.V.M. - Present  
W. G. Buchta, M.D. - Present  
Ms. B. Borg - Present  
Mr. P. R. Giesen - Absent  
N. L. Wengenack, Ph.D. - Present

N. A. Lee, MD, Ph.D. - Absent  
Mr. G. P. Munson - Present  
P. Sampathkumar, M.D. - Absent  
Mr. D. H. Senjem, Secretary - Present  
A. H. Tang, Ph.D. - Present

R. Janknecht, Ph.D. – Acting Chair - Present  
J. Caplette - Present  
C. Yennie – Absent  
J. A. Copland, Ph.D. - Present  
Y. Ikeda, D.V.M., Ph.D. - Present  
Guest: Ms. T. Bierbaum

---

David H. Senjem, Secretary

**Institutional Biosafety Committee Minutes**

September 15, 2005

12:00 Noon (Central Standard Time)

Mayo 11 F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> August 18, 2005 Page: 1-5	All	Approve	Approved
Research Protocol R55-251-8/2005 (A23905) "Tissue engineered coils for aneurysm treatment - Study II" David F. Kallmes, M.D., Principal Investigator Page: 6-8	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol Modified R55-119-10/03 (A30803) "Neurotoxicity of Measles Virus-CEA, intracranial delivery into CD46infkoGe mice." Stephen J. Russell, M.D., Ph.D., Principal Investigator Page: 9-11	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R62-306-8/2005 "Characterization of the wpk gene" Peter C. Harris, Ph.D., Principal Investigator Page: 12-15	Executive Committee	Ratify	The committee ratified a previous action of the Executive Committee approving this proposal as exempt from NIH Guidelines and subject to Laboratory Biosafety Level 1 provisions and practices.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R65-301-8/2005</b> "Novel radiovirotherapy using fully retargeted, myeloma-specific oncolytic measles viruses" <b>Takafumi Nakamura, Ph.D.,</b> Principal Investigator Page: 16-23	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The committee noted that animal carcasses should be red bagged first then yellow bagged to conform with Radiation Safety procedures. It was further noted that since the protocol does not involve the administration of an infectious agent into a human subject, question number 3 of the Registration Document should be answered "No".
<b>Research Protocol R64-291-8/2005</b> "A novel anti-HIV-1 factor from non-primate cells" <b>Yasuhiro Ikeda, D.V.M., Ph.D.,</b> Principal Investigator Page: 24-29	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices for retroviral vectors; Biosafety Level 2+ for HIV-1-based vectors; and Biosafety Level 3 provisions and practices for replication competent HIV-1 experiments.  The committee recommended that Dr. Ikeda and staff meet with Mr. Senjem prior to initiation of experiments to review Biosafety Level 3 facility safety procedures.
<b>Research Protocol R69-255-8/2005 (A25805)</b> "Biodistribution of a attenuated Measles Virus (MV-NIS) in mice" <b>Matthew M. Ames, Ph.D.,</b> Principal Investigator Page: 30-32	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices. The committee recommends that the investigator meet with a member of the Staff of the Department of Comparative Medicine prior to the initiation of experiments.

This document has been created by the Institutional Biosafety Committee for the purpose of peer review activities as defined by Minn. Stat § 145.61 and is to be considered confidential and privileged pursuant to Minn. Stat. § 145.64. This document should not be copied, forwarded or otherwise redistributed without authorization from the Institutional Biosafety Committee.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Research Protocol R63-291-8/2005</b> <b>"Effects of Cyclosporin A and DEBIO-025 treatment on lentiviral vector infectivity in mice"</b> <b>Yasuhiro Ikeda, D.V.M., Ph.D., Principal Investigator</b> <b>Page: 33-35</b>	Ralf Janknecht, Ph.D.	Review and Approve	<p>Approved subject to Laboratory and Animal Biosafety Level 2+ provisions and practices. Biosafety Level 2+ is achieved through the implementation of Biosafety Level 2 provisions and Biosafety Level 3 practices.</p> <p>The committee further noted potential biosafety concerns associated with the use of the Xenogen IVIS imaging system. The committee recommended that a "user group" be assembled to draft biosafety recommendations associated with the use of this instrument/facility.</p>
<u><b>Carry-in</b></u> <b>Research Protocol R70-307-9/2005</b> <b>"Vaporized Hydrogen Peroxide Decontamination of Mycobacterium Tuberculosis"</b> <b>Nancy L. Wengenack, Ph.D., Principal Investigator</b> <b>Page: 36-38</b>	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 3 provisions and practices.
<b>Next Meeting:</b> October 20, 2005 (5 weeks)	All	Note	

### Membership

M. J. Federspiel, Ph.D. – Chair - Absent  
 M. C. Blanco, D.V.M. - Present  
 W. G. Buchta, M.D. - Absent  
 Ms. B. Borg - Absent  
 Mr. P. R. Giesen - Absent  
 N. L. Wengenack, Ph.D. – Present

N. A. Lee, MD, Ph.D. - Absent  
 Mr. G. P. Munson - Absent  
 P. Sampathkumar, M.D. - Absent  
 Mr. D. H. Senjem, Secretary - Present  
 A. H. Tang, Ph.D. - Present

R. Janknecht, Ph.D. – Present – Acting Chair  
 J. Caplette - Absent  
 C. Yennie - Absent  
 J. A. Copland, Ph.D. - Present  
 Y. Ikeda, D.V.M., Ph.D. – Absent  
 Guest: T.A. Bierbaum

### Institutional Biosafety Committee Minutes

October 20, 2005

Online Meeting

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> September 15, 2005 Page:	All	Approve	Deferred until November 17, 2005.
Research Protocol R68-119-8/2005 (A27805) "Oncolytic measles virus therapy in a lung metastatic model of human tumor growth in immunodeficient mice using infected cell carriers for virus delivery" Stephen J. Russell, M.D., Ph.D., Principal Investigator	John A. Copland, III, Ph.D.	Review and Approve	Approved as exempt from NIH Guidelines and subject to Laboratory Biosafety Level 1 provisions and practices.
<b><u>Next Meeting:</u></b> November 17, 2005 (4 weeks)	All	Note	

#### Membership

M. J. Federspiel, Ph.D. – Chair - Present  
M. C. Blanco, D.V.M. - Present  
W. G. Buchta, M.D. - Present  
Ms. B. Borg - Present  
Mr. P. R. Giesen - Absent  
N. L. Wengenack, Ph.D. - Present

N. A. Lee, MD, Ph.D. - Present  
Mr. G. P. Munson - Absent  
P. Sampathkumar, M.D. - Present  
Mr. D. H. Senjem, Secretary - Absent  
A. H. Tang, Ph.D. - Present

R. Janknecht, Ph.D. - Present  
J. Caplette - Absent  
C. Yennie - Present  
J. A. Copland, Ph.D. - Present  
Y. Ikeda, D.V.M., Ph.D. - Present

---

David H. Senjem, Secretary

**Institutional Biosafety Committee Minutes**

November 17, 2005

12:00 Noon (Central Standard Time)

Mayo 11 F

<b>SUBJECT</b>	<b>REVIEWER</b>	<b>REQUESTED ACTION</b>	<b>OUTCOME/PENDING</b>
<b><u>Biosafety Committee Minutes</u></b> September 15, 2005 Page: 1-3 October 20, 2005 Page: 4 Page:	All	Approve	Approved
Research Protocol <b>R73-119-10/2005</b> "Coxsackievirus A21 therapy for multiple myeloma" <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Page: 5-7	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R74- 308-10/2005 (A35405)</b> "Identification of neurons providing synaptic input to intestinofugal neurons" <b>David R. Linden, Ph.D.</b> , Principal Investigator Page: 8-11	Yasuhiro Ikeda, D.V.M., Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The committee emphasized the need for the investigator to meet with members of the Staff of the Department of Comparative Medicine prior to the initiation of experiments.
Research Protocol <b>R71-238-10/2005 (A29905)</b> "Strategies to evade immune attack on measles virotherapy." <b>Kay-Whye Peng, Ph.D.</b> , Principal Investigator Page: 12-18	Priya Sampathkumar, M.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.  The committee emphasized the need for the investigator to meet with members of the Staff of the Department of Comparative Medicine prior to the initiation of experiments.
Research Protocol <b>R61-201-8/2005 (A26605)</b> "Characterization of Measles virus (MV) tropism and pathogenesis in mice transgenic for MV receptors" <b>Roberto Cattaneo, Ph.D.</b> , Principal Investigator Page: 19-22	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Other Business:</b> Serious Adverse Event Reports from IRB <ul style="list-style-type: none"> <li>• #13-0124 Page: 23-46</li> <li>• #11-0145, #11-0149, #22-0112, #33-0213 Page: 47-75</li> </ul> Infection Control Committee Minutes Page: 76-77	Information  Information	Review  Review	Noted  Noted
<b><u>Carry In</u></b> Research Protocol R72-100-10/2005 (A34305) "Effect of B7-DC cross-linking antibody on pathological progression of H. influenza pneumonia in mice" Larry R. Pease, Ph.D., Principal Investigator Page: 78-81	Nancy L. Wengenack, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol R75-100-11/2005 "Expression of B7-DC in primary mouse dendritic cells using retroviral transduction." Larry R. Pease, Ph.D., Principal Investigator Page: 82-86	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.  The investigator should submit a revised Registration Document identifying how infectious waste from the experiment will be handled. The experiment may be downgraded to Biosafety Level 1 provided the investigator seeks the services of an outside laboratory (either within or outside of Mayo) to perform testing to establish "replication deficiency". If this option is chosen and testing is performed confirming "replication deficiency", results should be referred to the Secretary of the Institutional Biosafety Committee and the current recommendation for Biosafety Level 2 provisions and practices will be reconsidered.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b>Institutional Biosafety Web Page Update</b>			Ms. Bierbaum reviewed progress being made on the new Institutional Biosafety Committee website. Her report was well received. The project is very near completion with just a few issues remaining unresolved or uncompleted. Completion is expected prior to the end of 2005.
<b>Centers of Disease Control Visit Update</b>			Mr. Senjem reported that as part of the Select Agent Registration Permit renewal process, two investigation from the Centers for Disease Control visited Mayo on October 12 and 13 to conduct an inspection. The inspection team spoke in a complementary way to Mayo's efforts, particularly the fashion in which records were maintained.  Three "departures" were noted in their report all of which were minor in nature and promptly resolved. Mayo's current permit expires on December 5, 2005 and it is expected that the institution's renewal permit application will be approved based on the positive nature of this inspection.
<b>Next Meeting:</b> December 15, 2005 (4 weeks)	All	Note	

### Membership

M. J. Federspiel, Ph.D. – Chair – Present  
M. C. Blanco, D.V.M. – Absent  
W. G. Buchta, M.D. – Present  
Ms. B. Borg – Present  
Mr. P. R. Giesen – Absent  
N. L. Wengenack, Ph.D. – Absent

N. A. Lee, MD, Ph.D. – Absent  
Mr. G. P. Munson – Absent  
P. Sampathkumar, M.D. – Absent  
Mr. D. H. Senjem, Secretary – Present  
A. H. Tang, Ph.D. – Present

R. Janknecht, Ph.D. – Present  
J. Caplette – Absent  
C. Yennie – Absent  
J. A. Copland, Ph.D. – Present  
Y. Ikeda, D.V.M., Ph.D. – Present  
Guest: T. Bierbaum



**Institutional Biosafety Committee Minutes**

December 15, 2005

12:00 Noon (Central Standard Time)

Mayo 11 F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> November 17, 2005 Page: 1-3	All	Approve	Approved
Research Protocol <b>R76-11-11/2005 (A37105)</b> "Evaluation of Three Arpida Formulations in an Experimental Staphylococcus aureus Nasal Decolonization Model" <b>Robin Patel, M.D.</b> , Principal Investigator Page: 4-6	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
Research Protocol <b>R77-11-11/2005 (A37205)</b> "Evaluation of Three Arpida Formulations in an Experimental Staphylococcus aureus Skin Infection Model" <b>Robin Patel, M.D.</b> , Principal Investigator Page: 7-9	Ralf Janknecht, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b><u>Other Business:</u></b> Facility Inspection Report Response Page: 10-15	David H. Senjem	Information	Noted
<b>2006 IBC Schedule and Membership</b> Page: 16-17	All	Information	Noted
<b><u>Carry-In</u></b> Research Protocol <b>R80-29-12/2005</b> "Therapeutic effect of endothelial progenitor cells on endothelial dysfunction induced by aging" <b>Zvonimir S. Katusic, M.D., Ph.D.</b> , Principal Investigator Page: 18-21	John A. Copland, III, Ph.D.	Approval	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<p>Research Protocol R35-197-6/04 (A14904)            "Injection of FIV-based Lentiviral Vectors Into the Anterior Chamber of the Feline Eye."  <b>Eric M. Poeschla, M.D.</b>, Principal Investigator            Page: 22-37</p>	<p>David H. Senjem</p>	<p>Approval</p>	<p>The committee reviewed the noted proposal offered by Dr. Poeschla. Dr. Blanco indicated that this is and has been an active proposal. Mr. Senjem noted that the protocol was initially approved by the IBC on June 24, 2004. As a part of that approval the committee requested an updated Registration Document referencing more specifically the use of Vesicular Stomatitis Virus glycoprotein (VSV-G) – pseudotyped FIV vectors. This request was not honored. He further noted that the Registration Document currently before the committee had been updated with additional information and was prompted by the IACUC's three year expiration date on the protocols. In reviewing the updated Registration Document, the committee concluded that it still lacked information related to the envelop the investigator was going to be used for pseudotyping. If the envelope glycoprotein confers human tropism (e.g., VSV-G), the containment level required is BL-2 even with a defective vector. In addition, the FIV vectors proposed for use in experiments were reported as being replication defective. Members of the committee felt additional information was needed regarding the approach used to arrive at the "replication defective" status. The committee requires that a new Registration Document be submitted using the new online form clarifying the committee's questions on pseudotyping and the methodology used to establish replication defectiveness.</p> <p>It was further noted that the Registration Document currently before the committee was prompted by the IACUC three year expiration date on the protocols. In reviewing the updated Registration Document, the committee noted it lacked information related to what envelop the investigator was pseudo typing with and a referenced methodology for reporting the FIV vectors as replication defective.</p>

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
Continued: Research Protocol R35-197-6/04 (A14904) "Injection of FIV-based Lentiviral Vectors Into the Anterior Chamber of the Feline Eye." Eric M. Poeschla, M.D., Principal Investigator Page: 22-37			The committee recommended that an updated or new Registration Document be submitted with the requested additional information.
Research Protocol R35-119-5/2005 (A19905) "Imaging MV-NIS infected squirrel monkeys with I-123" Stephen J. Russell, M.D., Ph.D., Principal Investigator Page: 38-39	David H. Senjem	Approval	The committee reviewed and accepted the methodology and results of a study conducted by Dr. Russell's laboratory on the disease-free status of squirrel monkeys previously infected with MV-NIS. Tests demonstrated no evidence of viremia and high titers for anti-measles antibody.  The committee approved a proposal to ship the monkeys offsite for continued research purposes.
<u>Next Meeting:</u> January 26, 2005 (6 weeks)	All	Note	Noted

**Membership**

M. J. Federspiel, Ph.D. – Chair - Present  
M. C. Blanco, D.V.M. - Present  
W. G. Buchta, M.D. - Present  
Ms. B. Borg - Present  
Mr. P. R. Giesen - Absent  
N. L. Wengenack, Ph.D. - Present

N. A. Lee, MD, Ph.D. - Present  
Mr. G. P. Munson - Absent  
P. Sampathkumar, M.D. - Absent  
Mr. D. H. Senjem, Secretary - Present  
A. H. Tang, Ph.D. - Absent  
Guest: Ms. T. Bierbaum

R. Janknecht, Ph.D. - Present  
J. Caplette - Present  
C. Yennie - Present  
J. A. Copland, Ph.D. - Present  
Y. Ikeda, D.V.M., Ph.D. - Present

---

David H. Senjem, Secretary

**Institutional Biosafety Committee Minutes**

January 26, 2006

12:00 Noon (Central Standard Time)

Mayo 11 F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> December 15, 2005 Page: 1-3	All	Approve	Approved
Welcome New Member/IBC Orientation Page: 4-5	Mark J. Federspiel, Ph.D.		Noted
Research Protocol <b>R79-311-12/2005</b> "A Phase III Randomized, Open-Label Study of CG1940 and CG8711 Versus Docetaxel and Prednisone in Patients with Metastatic Hormone-Refractory Prostate Cancer who are Chemotherapy-Naïve" <b>Thomas R. Fitch, M.D.</b> , Principal Investigator Page: 6-8	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.
Research Protocol <b>R1-119-1/2006</b> "Generation of mouse model of systemic light chain (AL) amyloidosis using adenoviral vectors" <b>Stephen J. Russell, M.D., Ph.D.</b> , Principal Investigator Page: 9-12	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.
<b><u>Old Business:</u></b> Research Protocol <b>R35-197-6/04 (A14904)</b> "Injection of FIV-based Lentiviral Vectors Into the Anterior Chamber of the Feline Eye." <b>Eric M. Poeschla, M.D.</b> , Principal Investigator Page: 13-19	David H. Senjem	Review and Approve	Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<u>Other Business:</u> Adverse Event Expedited Report Page: 20-29  Reporting Recombinant DNA Research Guidelines Page: 30-31	All	Information	Noted  The Committee discussed a January 18, 2006 publication of "OBA News" from NIH's Office of Biotechnology Activities. The primary emphasis of this publication was reporting recombinant DNA research related accidents or violations. In reviewing the publication the committee noted that the information presented was important and should be included on the IBC website, however, it was felt that it should be presented in a modified and more clearly presented manner. Mr. Senjem will rewrite the publication to advance the suggestion of the committee members.
Needlestick Summary			The Committee more specifically discussed needlesticks related to recombinant DNA research and how access to this information might be improved to ensure prompt NIH reporting. Options for obtaining this information will be discussed at a future meeting.
<u>Next Meeting:</u> February 23, 2006 (6 weeks)	All	Note	Noted

**Membership**

M. J. Federspiel, Ph.D. - Chair - Present  
 M. C. Blanco, D.V.M. - Present  
 W. G. Buchta, M.D. - Present  
 Ms. B. Borg - Present  
 Mr. P. R. Giesen - Absent  
 N. L. Wengenack, Ph.D. - Present

N. A. Lee, MD, Ph.D. - Present  
 Mr. G. P. Munson - Absent  
 P. Sampathkumar, M.D. - Absent  
 Mr. D. H. Senjem, Secretary - Present  
 A. H. Tang, Ph.D. - Absent  
 Guest: Ms. T. Bierbaum

R. Janknecht, Ph.D. - Present  
 J. Caplette - Present  
 C. Yennie - Present  
 J. A. Copland, Ph.D. - Present  
 Y. Ikeda, D.V.M., Ph.D. - Present

# **Institutional Biosafety Committee Minutes**

February 23, 2006

12:00 Noon (Central Standard Time)

Mayo 11 F

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Biosafety Committee Minutes</u></b> January 26, 2006 Page: 1-2	All	Approve	
Research Protocol R4-11-2/2006 "Enhancement of Antimicrobials by Electrical Current" Robin Patel, M.D., Principal Investigator Page: 3-5	Nancy L. Wengenack, Ph.D.	Review and Approve	-
<b><u>Other Business:</u></b> Research Incident Summary Page: 6-7	All	Information	
<b><u>Next Meeting:</u></b> March 23, 2006 (4 weeks)	All	Note	

## **Membership**

M. J. Federspiel, Ph.D. – Chair -  
M. C. Blanco, D.V.M. -  
W. G. Buchta, M.D. -  
B. A. Borg -  
P. R. Giesen -  
N. L. Wengenack, Ph.D. -

J. C. Loftus, Ph.D. -  
G. P. Munson -  
P. Sampathkumar, M.D. -  
D. H. Senjem, Secretary -  
A. H. Tang, Ph.D. -

R. Janknecht, Ph.D. -  
J. R. Caplette -  
C. R. Yennie -  
J. A. Copland, Ph.D. -  
Y. Ikeda, D.V.M., Ph.D. -

DHS

**Institutional Biosafety Committee Minutes**

March 23, 2006

12:00 Noon (Central Standard Time)

Mayo 11 F

<b>SUBJECT</b>	<b>REVIEWER</b>	<b>REQUESTED ACTION</b>	<b>OUTCOME/PENDING</b>
<b><u>Biosafety Committee Minutes</u></b> January 26, 2006 Page: 1-2	All	Approve	Approved
Research Protocol <b>R4-11-2/2006 (A7706)</b> "Enhancement of Antimicrobials by Electrical Current" <b>Robin Patel, M.D.</b> , Principal Investigator Page: 3-5	Nancy L. Wengenack, Ph.D.	Review and Approve	Work with Stapholcoccus aureus approved subject to Laboratory Biosafety Level 2 provisions and practices.  Animal work maybe conducted at Animal Biosafety Level 1 provisions and practices.
Research Protocol <b>R2-256-1/2006 (A2106)</b> "The Effects of HIV Protease Mutations, and IL-2, -7, and -15 on the Pathogenesis of HIV in a hu-PBL-SCID Mouse Model" <b>Andrew D. Badley, M.D.</b> , Principal Investigator Page: 6-9	Amy Tang, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 3 and Animal Biosafety Level 2+ provisions and practices. The designation 2+ is intended to denote Biosafety Level 2 provisions and Biosafety Level 3 practices.  The committee recommends that the investigator meet with the staff veterinary within the Department of Comparative Medicine prior to the initiation of animal experiments to establish respective roles and responsibilities.
Research Protocol <b>R5-41-2/2006</b> "Oncogenic signaling via the MUC1 cytoplasmic tail (CT)" <b>Sandra J. Gendler, Ph.D.</b> , Principal Investigator Page: 10-13	John A. Copland, III, Ph.D.	Review and Approve	Approved subject to Laboratory Biosafety Level 2 provisions and practices.

SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<p>Research Protocol <b>R3-119-2/2006</b>            "Does measles specific immunoglobulin G (IgG) therapy prior to chimeric measles (MVeGFP) administration in measles vaccinated INFAR ko-CD46 Ge mice suppress the host immune response?"  <b>Stephen J. Russell, M.D., Ph.D.</b>, Principal Investigator            Page: 14-16</p>	<p>Ralf Janknecht, Ph.D.</p>	<p>Review and Approve</p>	<p>Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.</p>
<p>Research Protocol <b>R7-291-3/2006</b>            "Ras/Raf-1/MEK/ERK signaling pathway may dictate the oncolytic property of VSV"  <b>Yasuhiro Ikeda, D.V.M., Ph.D.</b>, Principal Investigator            Page: 17-19</p>	<p>Ralf Janknecht, Ph.D.</p>	<p>Review and Approve</p>	<p>Approved subject to Laboratory Biosafety Level 2 provisions and practices.</p>
<p><u><b>Carry In:</b></u>            Research Protocol <b>R6-96-3/2006</b>            "Effect of RunX2 adenoviral expression in TIEG-null osteoblast cultures"  <b>Thomas C. Spelsberg, Ph.D.</b>, Principal Investigator            Page: 22-24</p>	<p>Yasuhiro Ikeda, D.V.M., Ph.D.</p>	<p>Review and Approve</p>	<p>Approved subject to Laboratory Biosafety Level 2 provisions and practices.</p> <p>The committee recommends that the investigator meet with the staff veterinary within the Department of Comparative Medicine prior to the initiation of animal experiments to establish respective roles and responsibilities.</p> <p>The committee further recommends that Mr. Senjem meet with Dr. Spelsberg and staff prior to initiation of experiments to review Biosafety Level 2 facility safety procedures.</p>
<p><u><b>Carry In:</b></u>            Research Protocol <b>R9-197-3/2006 (A4406)</b>            "Injection of Feline Immunodeficiency Virus (FIV)-based lentiviral vectors into the subretinal space of the rat eye"  <b>Eric M. Poeschla, M.D.</b>, Principal Investigator            Page: 25-31</p>	<p>John A. Copland, III, Ph.D.</p>	<p>Review and Approve</p>	<p>Approved subject to Laboratory and Animal Biosafety Level 2 provisions and practices.</p> <p>The committee recommends that the investigator meet with the staff veterinary within the Department of Comparative Medicine prior to the initiation of animal experiments to establish respective roles and responsibilities and orientation on animal housing.</p>



SUBJECT	REVIEWER	REQUESTED ACTION	OUTCOME/PENDING
<b><u>Carry In:</u></b> Research Protocol R8-261-3/2006 "Molecular Imaging-guided Gene and Radiovirotherapy for Pancreatic Cancer" <b>Stephanie K. Carlson, M.D., M.S.,</b> Principal Investigator Page: 32-37	Amy Tang, Ph.D.	Review and Approve	The committee recommended that approval be deferred pending the need for additional information. Dr. Tang will contact the investigator and the protocol will be re-reviewed at the committee's April meeting.
<b><u>Other Business:</u></b> Research Incident Summary Page: 20-21	All	Information	Noted
<b><u>Next Meeting:</u></b> April 20, 2006 (4 weeks)	All	Note	Noted

### **Membership**

M. J. Federspiel, Ph.D. – Chair - Absent  
 M. C. Blanco, D.V.M. - Present  
 W. G. Buchta, M.D. - Present  
 B. A. Borg - Absent  
 P. R. Giesen - Absent  
 N. L. Wengenack, Ph.D. - Present

J. C. Loftus, Ph.D. - Absent  
 G. P. Munson - Absent  
 P. Sampathkumar, M.D. - Absent  
 D. H. Senjem, Secretary - Present  
 A. H. Tang, Ph.D. - Present  
 Guest: T. A. Bierbaum

R. Janknecht, Ph.D. – Present (*Acting Chair*)  
 J. R. Caplette - Absent  
 C. R. Yennie - Present  
 J. A. Copland, Ph.D. - Absent  
 Y. Ikeda, D.V.M., Ph.D. - Present

---

David H. Senjem, Secretary