



The Milton S. Hershey Medical Center
The College of Medicine

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

April 26, 2006

Dear Hammond;

Please find enclosed the minutes from our Institutional Biosafety Committee as requested in your letter of 3/15/06.

If you have any questions, please don't hesitate to contact me. Thank you.

Respectfully,

Douglas C. Kuhn, Ph.D.

Minutes of The Biological Safety and Recombinant DNA Committee Meeting
 Thursday, May 15, 2003
 Rm. C5702, 12 noon to 1PM

Meeting Date	8/02	11/14/02	2/13/03	5/15/03
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	C	P	P	P
Michael Katzman, M.D., Vice-Chair, Medicine		P	P	P
Douglas Kuhn, Ph.D., Safety		P	P	P
Edward Ruth, Milton Hershey School		P	P	E
John Neely, M.D., Pediatrics		P	A	P
Keith Verner, Ph.D., Cell. & Molec. Physiol.		E	A	A
Charles Smith, Ph.D., Pharmacology		A	R	A
David Stuart, Ph.D., Hershey Foods		E	A	P
Michael Verderame, Ph.D., Medicine		P	P	P
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.		P	E	E
Ralph Keil, Ph.D., Biochem. & Molec. Biol.		P	P	P
Douglas Ednie, Comparative Medicine		P	P	E
Ray Scheetz, Microbiol. & Immunol.		P	P	P
Kristen Eckert, Ph.D., Pathology		A	P	P
Cathy Ayers, Director of Pharmacy		P	P	E
Rosemary Polomano, Ph.D., RN, Anesthesiology		A	P	P
Alyse Fazzi, Pharmacy (for Cathy Ayers)				P

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting canceled

Old business: None

New business:

- I. **Agenda item:** Approval of minutes of the February 13, 2003 meeting (see agenda attachment).
Action or recommendation: Minutes of the November 13, 2003 meeting were approved as written.
Follow-up: None required

- II. **Agenda Item:** Meeting schedule for FY 03 - 04
Action or recommendation: The Subcommittee will be scheduled to meet on 8/14/03, 11/13/03, 2/12/04 and 5/13/04.
Follow-up: None required.

- III. **Agenda item:** Report on IBC Professional Development Conference and Implications (see agenda attachment).
Action or recommendation: Dr. Spector reviewed his summary of the IBC Professional Development Conference that he presented to the Research Mission Group. The presentation included the NIH model of IBC oversight and responsibilities, including interactions and oversight of IACUC and IRB activities. The implications of the NIH model on the College of Medicine, including the requirement for training of Subcommittee members, were discussed. Dr. Spector's presentation to the Research Mission Group included a recommendation and action plan for assuring future compliance of our IBC

with NIH standards. The action plan included the creation of a full-time BSO position.

Follow-up: Action on Dr. Spector's recommendations by COM administration is pending. Should Dr. Spector's action plan be implemented, the Subcommittee will evaluate current Subcommittee structure/function and make recommendations for improvement.

IV. Agenda item: Online Assurances Form and Protocol Review

Action or recommendation: Dr. Kuhn requested the Subcommittee members again review the draft assurances form (http://infonet/safety/draft_assurances_form) and submit comments to him. Following final review, the new online form will be used until it is determined that the form can be incorporated into a comprehensive Protocol Review and Approval Management System (PRAMS) at some point in the future (see item 1 in Report of Biosafety the Officer below)

Follow-up: Subcommittee members will review the online assurances form and forward comment to Dr. Kuhn by May 23.

VI. Agenda item: Notable Protocols (see agenda attachment).

Action or recommendation: Dr. Spector summarized aspects of four protocols submitted to his office since the last meeting.

1. Dr. Whitener: HIV recombinant vaccine – Aspects of the protocol related to biosafety were discussed. Ms. Fazzi requested clarification on whether the procedures and containment would be different for this protocol than for previously approved protocols using an adenoviral vector. Dr. Spector reviewed the obvious risks of the transmission of gene activity in this and previous protocols, and the safety assessment/requirements of the manufacturer (Merck). The Subcommittee recommended that the same stringent safety protocol be followed for this study as for previous studies.
2. Dr. Sun: Sorting of live cells transduced with retrovirus vectors; HTLV1 – Dr. Spector has communicated the results of his review of this protocol to Dr. Sun. His recommendations include the application of existing policies/procedures. However, since Dr. Sun's request to sort cells containing HTLV1 would require BL3 containment, this portion of the protocol was disapproved.
3. Dr. Wood – Dr. Wood's protocol involves the use of an adenoviral vector carrying oncogenes, a methodology that is new to Dr. Wood. Dr. Spector met with Dr. Wood to raise her awareness of the appropriate safety practices that should be followed for this protocol.
4. Dr. Christensen – This protocol involves the production of human papilloma virus antigens in tobacco mosaic virus. Dr. Spector discussed safety aspects of this protocol. At the present time, Dr. Christensen will restrict the use of this system to inactivated TMV vectors.

Follow-up: None required.

VI. Agenda item: Report of the Biological Safety Officer

Action or recommendation: In the interest of time, the report of the Biological Safety Officer was not presented but is included in the minutes as follows:

1. PRAMS (Protocol Review and Approval Management System) – Dr. Kuhn attended a demonstration of a developing paperless system, under construction by University Park IRT, for the handling of all aspects of institutional submission, review, approval and management of protocols involving biohazardous material and rDNA molecules. The program would have several benefits for any institutional group charged with oversight of investigational activities, in particular documentation and follow-up of requirements for protocol approval. The mechanism by which our current process could be integrated into this developing database is currently unclear, however, the Office of Research Affairs and COM IRT are involved in the process. Dr. Spector and Dr. Kuhn will meet with Galen Bradley and Jurek Wrzos to learn more about the system and to assess the possibility of including aspects of Subcommittee protocol approval into the development process.
2. CDC Facility Inspection Report – The BSO received a report related to a CDC site visit that was conducted in September, 2002. The recommendations of the report have been implemented.
3. COM New Employee Safety Training – A working group including the BSO, Dr. Spector, Comparative Medicine and Health Physics is developing an enhanced safety training program for new hires in the COM. The program will be presented in a 2-hr training session to be held as soon as possible after the new employee is hired.

Minutes of The Biological Safety and Recombinant DNA Subcommittee Meeting
 Thursday, August 14, 2003
 Rm. C5702, 12 noon to 1PM

Meeting Date	11/14/02	2/13/03	5/15/03	8/14/03
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	P	P	P	P
Michael Katzman, M.D., Vice-Chair, Medicine	P	P	P	P
Douglas Kuhn, Ph.D., Safety	P	P	P	P
Edward Ruth, Community Member	P	P	E	P
John Neely, M.D., Pediatrics	P	A	P	P
Keith Verner, Ph.D., Cell. & Molec. Physiol.	E	A	A	A
Charles Smith, Ph.D., Pharmacology	A	R	A	R
David Stuart, Ph.D., Hershey Foods	E	A	P	E
Michael Verderame, Ph.D., Medicine	P	P	P	P
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.	P	E	E	P
Ralph Keil, Ph.D., Biochem. & Molec. Biol.	P	P	P	P
Douglas Ednie, Comparative Medicine	P	P	E	P
Ray Scheetz, Microbiol. & Immunol.	P	P	P	P
Kristen Eckert, Ph.D., Pathology	A	P	P	P
Cathy Ayers, Director of Pharmacy	P	P	E	R
Rosemary Polomano, Ph.D., RN, Anesthesiology	A	P	P	E
Lisa Braccini-Barletta, Pharmacy (for Cathy Ayers)				P
Kenneth Miller, Hershey Foods (for David Stuart)				P

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting canceled

Old business: None

New business:

- I. **Agenda item:** Approval of minutes of the May 15, 2003 meeting (see agenda attachment).

Action or recommendation: Minutes of the November 13, 2003 meeting were approved with one minor correction.

Follow-up: None required

- II. **Agenda Item:** Announcements

a. **Action or recommendation:** A recommendation for a replacement for Dr. Charles Smith has not yet been forwarded to the subcommittee.

Follow-up: Dr. Mark Kester (Pharmacology) will forward a recommendation.

b. **Action or recommendation:** A meeting to discuss routine vs. *ad hoc* evaluation of gene therapy protocols was held. Participants included Dr. Spector, Dr. Kevin Gleeson, Dr. Mike Weitekamp, Dr. Jay Moskowitz, and Cathy Ayers. Discussion focused on Pharmacy facilities, dedicated patient space and nursing training.

Follow-up: Discussion will continue and recommendations from the working group will be implemented.

- III. **Agenda item:** New web-based registration procedure.

Action or recommendation: Dr. Spector indicated that the new Assurances Form on the Biosafety page of the Safety web site is being used to evaluate protocols

utilized in grant submissions. The Assurances Form will be assigned a unique identifying number that will be referenced on additional submissions of the same protocol (e.g. to other funding sources). Information as to the existence of the form and its use should be provided to PIs and to Administrative Assistants in COM departments in order to maximize the utility of the form and its information.

Follow-up: Dr. Kuhn will develop a mechanism for the dissemination of the appropriate information. Dr. Kuhn will also provide hard copies of the form to the community representatives on the subcommittee.

IV. Agenda item: Biosafety in the animal facility (see agenda attachment)

Action or recommendation: Drs. Spector and Kuhn toured the containment facility in the CAQ with Doug Ednie. A report/SOP for use of the facility is attached to the agenda. Several issues in the report were discussed and revisions to the SOP were recommended. In particular, use of PPE will be "required based on risk" rather than "recommended".

Follow-up: The report will be further developed into an SOP for distribution to PIs using the facility and to animal care staff.

V. Agenda item: Committee priorities (see agenda attachment)

Action or recommendation: Dr. Spector and Dr. Kuhn met to discuss priorities for the further development of the COM biosafety program based on NIH recommendations. The items identified were described and discussed by Dr. Spector.

Follow-up: Several items on the list have been or are in the process of being implemented. A program for implementation of remaining items is ongoing and will include an assessment of the need for additional staffing within the biosafety program.

VI. Agenda item: Use of human cell lines (see agenda attachment)

Action or recommendation: Dr. Spector provided the subcommittee with opposing views on appropriate biosafety practices for use of established human cell lines.

Follow-up: Subcommittee members were asked to consider a recommendation from the subcommittee for COM use of these cell lines. This item will be discussed at the next meeting.

Post-meeting note: The Dean has approved the appointment of Lisa Bracinni-Barletta to the subcommittee.

Minutes of The Biological Safety and Recombinant DNA Subcommittee Meeting
 Thursday, November 13, 2003
 Rm. C5702, 12 noon to 1PM

Meeting Date	2/13/03	5/15/03	8/14/03	11/13/03
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	P	P	P	P
Michael Katzman, M.D., Vice-Chair, Medicine	P	P	P	P
Douglas Kuhn, Ph.D., Safety	P	P	P	P
Edward Ruth, Community Member	P	E	P	P
John Neely, M.D., Pediatrics	A	P	P	A
Keith Verner, Ph.D., Cell. & Molec. Physiol.	A	A	A	A
David Stuart, Ph.D., Hershey Foods	A	P	E	P
Michael Verderame, Ph.D., Medicine	P	P	P	P
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.	E	E	P	P
Ralph Keil, Ph.D., Biochem. & Molec. Biol.	P	P	P	P
Douglas Ednie, Comparative Medicine	P	E	P	P
Ray Scheetz, Microbiol. & Immunol.	P	P	P	P
Kristen Eckert, Ph.D., Pathology	P	P	P	P
Rosemary Polomano, Ph.D., RN, Anesthesiology	P	P	E	P
Lisa Braccini-Barletta, Pharmacy			P	P
Kenneth Miller, Hershey Foods (for David Stuart)			P	P
Chris Norbury, Ph.D., Microbiol. & Immunol.				G

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting canceled

Old business: None

New business:

- I. **Agenda item:** Approval of minutes of the August 14, 2003 meeting (see agenda attachment).

Action or recommendation: Minutes of the August 14, 2003 meeting were approved as written.

Follow-up: None required

- II. **Agenda item:** Announcements

a. Action or recommendation: Drs. Spector, Kuhn, Norbury and Doug Ednie participated in a tour of the Animal Research Facility. Dr. Norbury escorted the group through the new containment wing and one of his containment rooms.

Follow-up: None required.

b. Action or recommendation: The Chair of the Institutional Safety Committee has requested that the Subcommittee develop a "Performance Improvement Project" to be implemented and reviewed annually. A Performance Improvement Project is required by the Joint Commission On Accreditation of Healthcare Organizations for all safety subcommittees functioning under the Institutional Safety Committee.

Follow-up: Dr. Spector will develop a recommendation for a Performance Improvement Project and forward the recommendation to the Chair of the Institutional Safety Committee.

III. Agenda item: Protocol Reviews (see agenda attachment)

a. Naides – Ricin in animal facility

Action or recommendation: Dr Naides summarized his proposed protocol for the use of ricin in immunization studies in mice. Aspects of safety, security, decontamination, training, and animal maintenance were also discussed. Dr. Naides assured the Subcommittee that the amount of ricin in his possession will be minimized and will not exceed the exempt amount defined in the CDC Select Agent Program. The protocol was approved by the Subcommittee.

Follow-up: The aspects of the protocol involving animal activities will be further defined in consultation with Comparative Medicine.

b. Floros – RG2 bacterial pathogen in animal facility.

Action or recommendation: Drs. Floros and Phelps summarized their protocol for the study of the role of environmental factors in host defense response to lung pathogens, in particular *Klebsiella pneumoniae*. Both morbidity and lung clearance of bacteria will be studied. Aspects of safety, security, decontamination, training, transfer and animal maintenance were also discussed. Concern was expressed in relation to possible exposure of employees to aerosolized *Klebsiella pneumoniae*, however the low level of risk/containment in a clinical setting was noted. The Subcommittee recommended that BL2 and ABL2 procedures/containment be adhered to. The protocol was approved by the Subcommittee.

Follow-up: The aspects of the protocol involving animal activities will be further defined in consultation with Comparative Medicine.

c. Bozdogan – RG2 bacterial pathogen in animal facility.

Action or recommendation: Dr. Bozdogan summarized his protocol for the study of antibiotic-resistance in *Haemophilus influenzae*. The protocol would involve instillation of 5 different strains of *H. influenzae* into mice and the subsequent isolation of tissue and fluid samples. The samples would be evaluated for the presence of mutant antibiotic-resistant strains arising *in vivo*. In particular, the investigators are interested in isolating extended spectrum beta-lactamase producing (ESBP) organisms and studying the mechanism of resistance to cephalosporin. Currently, no ESBP *H. influenzae* have been reported in the US. Concern was expressed about certain aspects of the protocol and assuring appropriate containment to minimize the risk of escape of any such organisms. Concern was expressed in relation to the possible exposure of employees to infection. The Subcommittee deferred protocol approval pending the provision of further information to the Subcommittee.

Follow-up: Dr. Katzman will discuss the protocol with Dr. John Goldman and Dr. Spector will contact Dr. Peter Appelbaum and Dr. Bozdogan for further clarification of safety aspects of the study.

IV. Agenda item: Re-registration for use of pathogens in animal facility

Action or recommendation: Dr. Spector and Doug Ednie are coordinating a re-registration of users of pathogens in the animal facility in order to further assess compliance with appropriate practices and containment.

Follow-up: Ongoing.

V. Agenda item: Report of the Biological Safety Officer

Action or recommendation: Dr. Kuhn reported that a reminder as to the requirements for filing of the online Assurances Form was sent to all COM departmental administrators.

Follow-up: The reminder will also be sent to administrators in appropriate clinical departments.

VI. Agenda item: Use of human cell lines (further discussion/action?)

Action or recommendation: Deferred

Follow-up: Deferred.

Minutes of The Biological Safety and Recombinant DNA Subcommittee Meeting
 Thursday, February 12, 2004
 Rm. C6805, 12 noon to 1PM

Meeting Date	5/15/03	8/14/03	11/13/03	2/12/04
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	P	P	P	P
Michael Katzman, M.D., Vice-Chair, Medicine	P	P	P	A
Douglas Kuhn, Ph.D., Safety	P	P	P	P
Edward Ruth, Community Member	E	P	P	P
John Neely, M.D., Pediatrics	P	P	A	P
Keith Verner, Ph.D., Cell. & Molec. Physiol.	A	A	A	A
David Stuart, Ph.D., Hershey Foods	P	E	P	A
Michael Verderame, Ph.D., Medicine	P	P	P	P
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.	E	P	P	P
Ralph Keil, Ph.D., Biochem. & Molec. Biol.	P	P	P	P
Douglas Ednie, Comparative Medicine	E	P	P	E
Ray Scheetz, Microbiol. & Immunol.	P	P	P	P
Kristen Eckert, Ph.D., Pathology	P	P	P	A
Rosemary Polomano, Ph.D., RN, Anesthesiology	P	E	P	P
Lisa Braccini-Barletta, Pharmacy		P	P	A
Kenneth Miller, Hershey Foods (for David Stuart)		P	P	
Chris Norbury, Ph.D., Microbiol. & Immunol.			G	

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting canceled

Old business: None

New business:

- I. **Agenda item:** Approval of minutes of the November 13, 2003 meeting (see agenda attachment).

Action or recommendation: Minutes of the November 13, 2003 meeting were approved as written.

Follow-up: None required

- II. **Agenda Item:** Announcements

a. Action or recommendation: Dr. Spector provided Dr. Jay Moskowitz with a summary of major Subcommittee activities (see agenda attachment). The summary focused on upgrading tracking, registration, and oversight of experiments employing biohazards, and biosafety in the animal facility.

Follow-up: None required.

b. Action or recommendation: Dr. Spector reviewed his database for monitoring research activities involving biohazards (see agenda attachment).

Follow-up: None required.

- III. **Agenda item:** Protocol Reviews (see agenda attachment)

a. Gardner – AAV2 in squirrel monkeys

Action or recommendation: The subcommittee reviewed Dr. Gardner's protocol for ocular gene transfer using AAV2. This protocol is similar to studies previously conducted by Dr. Gardner and Dr. Sarah Bronson in mice and rats. The new

studies in squirrel monkeys would be designed to characterize this animal model of diabetic retinopathy and then to utilize the model in gene transfer experiments. These studies would be conducted in the barrier wing of the Animal Research Farm. Issues including viral shedding, air filtration, cage decontamination, location of the studies within the ARF and personal protective equipment were discussed

Follow-up: Doug Ednie will consult with investigators and animal care staff at the Univ. of Pennsylvania, who are currently conducting similar studies, regarding safety precautions that should be used. Doug Ednie will provide Dr. Spector with additional information, then the Subcommittee will be polled regarding approval of the protocol. In addition, data related the viral shedding in previous rat and mouse studies will be provided by Drs. Gardner and Bronson.

IV. Agenda item: Revisions of Assurances Form

Action or recommendation: The current online assurances form was discussed (see agenda attachment). Modifications to the form, which is designed to capture all relevant information for the assessment of the protocol, were reviewed, and suggestions for improving the form were discussed.

Follow-up: Dr. Kuhn will continue to work with Dr. Spector to provide a form that is comprehensive and user-friendly.

Minutes of The Biological Safety and Recombinant DNA Subcommittee Meeting

Thursday, March 22, 2004

Rm. C6805, 12 noon to 1PM

Meeting Date	8/14/03	11/13/03	2/12/04	3/22/04
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	P	P	P	P
Michael Katzman, M.D., Vice-Chair, Medicine	P	P	A	P
Douglas Kuhn, Ph.D., Safety	P	P	P	P
Edward Ruth, Community Member	P	P	P	P
John Neely, M.D., Pediatrics	P	A	P	P
Keith Verner, Ph.D., Cell. & Molec. Physiol.	A	A	A	A
David Stuart, Ph.D., Community Member	E	P	A	A
Michael Verderame, Ph.D., Medicine	P	P	P	P
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.	P	P	P	P
Ralph Keil, Ph.D., Biochem. & Molec. Biol.	P	P	P	P
Douglas Ednie, Comparative Medicine	P	P	E	A
Ray Scheetz, Microbiol. & Immunol.	P	P	P	P
Kristen Eckert, Ph.D., Pathology	P	P	A	P
Rosemary Polomano, Ph.D., RN, Anesthesiology	E	P	P	P
Lisa Braccini-Barletta, Pharmacy	P	P	A	E
Kenneth Miller (for David Stuart)	P	P		
Chris Norbury, Ph.D., Microbiol. & Immunol.		G		

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting canceled

Old business: None

New business: This was a special meeting to consider 3 pending protocols.

- I. **Agenda item:** Final decision on containment requirements for the Gardner protocol to use AAV vectors in monkeys (see agenda attachment).

Action or recommendation: Dr. Spector had submitted additional information to the subcommittee members regarding the Gardner protocol to inject small amounts (1.5 µl) of AAV-CRE in the eyes of squirrel monkeys. The subcommittee approved the protocol based on previous and additional information indicating that 1) the air handling system in the primate wing of the ARF conforms to NIH guidelines, 2) Dr. Grant from Univ. of Pennsylvania confirmed that similar studies were conducted under BSL2 precautions, and 3) Dr. Naides confirmed that parvoviruses are spread by the airborne route.

Follow-up: Dr. Kuhn will confirm that a mechanism is in place for the routine evaluation of airflow in the primate wing.

- II. **Agenda item:** Request by Susan Nyland to relax containment requirements to BL2+ for low level infectious HIV work (see agenda attachment).

Action or recommendation: Dr Nyland reviewed her practices and containment to be used for studies of small amounts ($<2 \times 10^8$ PFU) of HIV. Supernatant samples of lysed HIV-infected cells will be generated using an aerosol-resistant centrifuge. All procedures will be conducted in a dedicated room accessible only by authorized personnel. All appropriate equipment is present in the room (BSC,

sink with pedals, eyewash, etc.) and all appropriate decontamination/sterilization procedures are in place. Sharps will not be utilized. Issues related to appropriate training, medical evaluation and blood testing for HIV prior to work on the protocol were discussed.

The subcommittee approved the protocol.

Follow-up: None required.

- III. **Agenda item:** Report on protocol submitted by Dr. Ken Lucas for immune cell therapy in humans after co-culture *in vitro*.

Action or recommendation: Dr. Lucas reviewed the scientific basis for studies and clarified that the autologous human lymphocytes of transplant patients will be shipped to Hershey, treated *in vitro* to enhance virus-specific immunity and then shipped back to Sloan Kettering for administration to patients. Drs. Katzman and Eckert reviewed the protocol. The major biosafety issue is quality assurance of inactivation of exogenous viruses and vectors introduced during immune cell stimulation *in vitro*. Additional consideration of training, SOPs, etc. were also discussed.

Follow-up: Dr. Lucas will provide data from screening of retrovirus vector stocks for contamination by replication competent virus. Revised summaries of reviews will be submitted by Drs. Katzman and Eckert and will be forwarded to the Subcommittee members for their consideration.

Other: Revised Assurances Form (see agenda attachment)

Subcommittee members are asked to review the revised assurances form attached to the agenda. It is planned to go "live" with the new form sometime in early June.

Minutes of The Biological Safety and Recombinant DNA Subcommittee Meeting
 Wednesday, August 11, 2004
 Rm. C6805, 12 noon to 1PM

Meeting Date	11/13/03	2/12/04	5/04	8/11/04
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	P	P	C	P
Michael Katzman, M.D., Vice-Chair, Medicine	P	A		P
Douglas Kuhn, Ph.D., Safety	P	P		P
Edward Ruth, Community Member	P	P		E
John Neely, M.D., Pediatrics	A	P		A
Keith Verner, Ph.D., Cell. & Molec. Physiol.	A	A		A
David Stuart, Ph.D., Hershey Foods	P	A		A
Michael Verderame, Ph.D., Medicine	P	P		P
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.	P	P		E
Ralph Keil, Ph.D., Biochem. & Molec. Biol.	P	P		P
Douglas Ednie, Comparative Medicine	P	E		P
Ray Scheetz, Microbiol. & Immunol.	P	P		P
Kristen Eckert, Ph.D., Pathology	P	A		P
Rosemary Polomano, Ph.D., RN, Anesthesiology	P	P		R
Lisa Braccini-Barletta, Pharmacy	P	A		A
Kenneth Miller, Hershey Foods (for David Stuart)	P			

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting canceled

Old business: None

New business:

- I. **Agenda item:** Approval of minutes of the February 12, 2004 meeting (see agenda attachment).

Action or recommendation: Minutes of the February 12, 2004 meeting were approved as written.

Follow-up: None required

- II. **Agenda Item:** Announcements

a. **Action or recommendation:** Dr. Polomano has resigned from the Subcommittee. Dr. Spector is requesting that a faculty member from Pharmacology replace Dr. Polomano.

Follow-up: None required.

b. **Action or recommendation:** Dr. Spector announced that Dr. Sheila Vrana is now the Assoc. Dean for Research - Basic.

Follow-up: None required.

c. **Action or recommendation:** Dr. Spector indicated that the Subcommittee's minutes have been forwarded to the Sunshine Project as requested.

Follow-up: None required.

- III. **Agenda item:** Meeting Schedule

Action or recommendation: The Subcommittee will meet at noon on the following dates for the 2004-2005 academic year: Nov. 11, 2004; February 10, 2005; May 12, 2005; August 11, 2005.

Follow-up: None required.

IV. Agenda item: Assurances Form

Action or recommendation: Dr. Spector indicated that the new online assurances form (see agenda attachment) is providing excellent information for the use of the Subcommittee in approving protocols.

Follow-up: None required.

V. Agenda item: New Protocol Data (see agenda attachment)

Action or recommendation: Dr. Bronson has submitted viral survival data related to the Bronson/Gardner protocol for the study of the affect of AAV-CRE injection in murine eyes. The data indicates that clearance is good, with no signal detected by PCR analysis 2 weeks after injection.

Follow-up: None required.

Action or recommendation: Dr. Gardner has submitted data related the Naides/Gardner protocol that evaluated the radiation dose required to effectively kill L and S forms of *S. pyogenes*. The effective dose is 5 kGy.

Follow-up: None required

VI. Agenda item: Biosafety in the Animal Facility

Action or recommendation: All investigators using biohazards in animals are now being re-registered with Comparative Medicine (see registration form in agenda attachment). Comparative Medicine and this Subcommittee will now be able to better communicate and coordinate oversight. The new system is being piloted in Microbiology & Immunology with good results. The possibility that a similar system should be initiated with regard to the multi-user facilities was discussed.

Follow-up: None required.

VII. Agenda item: Report of the Biosafety Officer

Action or recommendation: Dr. Kuhn reported that COM's response to the recommendation of the CDC site visit of Feb. were accepted and that no other action is required at present.

Action or recommendation: Dr. Kuhn requested that the Chair of the Subcommittee note that Dr. Verner has not attended a meeting in over one year.

Follow-up: Dr. Spector will contact Dr. Verner regarding the continuation of his membership on the Subcommittee.

VIII. Agenda item: Priorities for 04-05

Action or recommendation: Priorities for the coming year will include:

- Re-registration for use of biohazards in animals (and possible registration with multi-user facilities)
- Biosafety inspections, on a limited basis, by Drs. Spector, Kuhn and a Subcommittee member
- Expanded responsibility for Subcommittee members for routine protocol review
- Possible use of server space for Subcommittee data sharing and protocol review

Follow-up: Ongoing

IX. Agenda item: Miscellaneous
Action or recommendation: None

Minutes of Penn State University College of Medicine The Institutional Biosafety Committee

Thursday, November 11, 2004

Rm. C6805, 12 noon to 1PM

Meeting Date	2/12/04	5/04	8/11/04	11/11/04
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	P	C	P	P
Michael Katzman, M.D., Vice-Chair, Medicine	A		P	P
Douglas Kuhn, Ph.D., Safety	P		P	P
Edward Ruth, Community Member	P		E	E
John Neely, M.D., Pediatrics	P		A	P
Keith Verner, Ph.D., Cell. & Molec. Physiol.	A		A	R
David Stuart, Ph.D., Community Member	A		A	E
Michael Verderame, Ph.D., Medicine	P		P	P
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.	P		E	E
Ralph Keil, Ph.D., Biochem. & Molec. Biol.	P		P	P
Douglas Ednie, Comparative Medicine	E		P	P
Ray Scheetz, Microbiol. & Immunol.	P		P	P
Kristen Eckert, Ph.D., Pathology	A		P	P
Rosemary Polomano, Ph.D., RN, Anesthesiology	P		R	R
Lisa Braccini-Barletta, Pharmacy	A		A	A
Stanley Naides, M.D., Rheumatology				E
Paula Ulsh, RN, Medicine/Cardiology				P

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting
canceled

Old business: None

New business:

- I. **Agenda item:** Approval of minutes of the August 11, 2004 meeting (see agenda attachment).

Action or recommendation: Minutes of the August 11, 2004 meeting were approved as written.

Follow-up: None required

- II. **Agenda item:** Protocol Review

Action or recommendation: No new protocols requiring full Committee review were presented. Dr. Spector noted that protocol submission is low, probably due to the fact that a grant submission and approval cycle has just been completed.

Follow-up: None required

Minutes of Penn State University College of Medicine Institutional Biosafety Committee

Thursday, February 10, 2005

Rm. C6805, 12 noon to 1PM

Meeting Date	11/11/04	2/10/05	
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	P	P	
Michael Katzman, M.D., Vice-Chair, Medicine	P	P	
Douglas Kuhn, Ph.D., Safety	P	P	
Edward Ruth, Community Member	E	E	
John Neely, M.D., Pediatrics	P	P	
Keith Verner, Ph.D., Cell. & Molec. Physiol.	R	R	
David Stuart, Ph.D., Community Member	E	A	
Michael Verderame, Ph.D., Medicine	P	P	
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.	E	E	
Ralph Keil, Ph.D., Biochem. & Molec. Biol.	P	P	
Douglas Ednie, Comparative Medicine	P	P	
Ray Scheetz, Microbiol. & Immunol.	P	P	
Kristen Eckert, Ph.D., Pathology	P	E	
Rosemary Polomano, Ph.D., RN, Anesthesiology	R	R	
Lisa Braccini-Barletta, Pharmacy	A	A	
Stanley Nades, M.D., Rheumatology	E	P	
Paula Ulsh, RN, Medicine/Cardiology	P	P	

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting canceled

Old business: None

New business:

- I. **Agenda item:** Approval of minutes of the November 11, 2004 meeting (see agenda attachment).

Action or recommendation: Minutes of the November 11, 2004 meeting were approved as written.

Follow-up: None required

- II. **Agenda item:** Protocol Review (see agenda attachment)

Action or recommendation: Three protocols of interest were briefly reviewed. Dr. Sun's protocol using a laboratory strain of human influenza in animals was described. Dr. Connor's protocol using a no-shedding strain of Epstein-Barr virus in immortalized human lymphocytes was described. Dr. Hunzeker's protocol using recombinant HSV in mice under BL2+ containment was described. These and other protocols were reviewed and approved by Dr. Spector.

Dr. Spector also provided a copy of his database for tracking of protocols utilizing biohazards.

Follow-up: None required

- III. **Agenda item:** IBC Compliance (see agenda attachment)

Action or recommendation: Dr. Spector provided a copy of a notification from NIH, Office of Biotechnology Activities indicating that NIH may now

conduct site visits related to compliance with NIH guidelines and IBC
activities.
Follow-up: None required

Minutes of Penn State University College of Medicine Institutional Biosafety Committee

Thursday, June 2, 2005

Rm. C6805, 12 noon to 1PM

Meeting Date	11/11/04	2/10/05	6/2/05
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	P	P	P
Michael Katzman, M.D., Vice-Chair, Medicine	P	P	P
Douglas Kuhn, Ph.D., Safety	P	P	P
Edward Ruth, Community Member	E	E	P
John Neely, M.D., Pediatrics	P	P	P
Keith Verner, Ph.D., Cell. & Molec. Physiol.	R	R	R
David Stuart, Ph.D., Community Member	E	A	A
Michael Verderame, Ph.D., Medicine	P	P	P
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.	E	E	P
Ralph Keil, Ph.D., Biochem. & Molec. Biol.	P	P	E
Douglas Ednie, Comparative Medicine	P	P	P
Ray Scheetz, Microbiol. & Immunol.	P	P	P
Kristen Eckert, Ph.D., Pathology	P	E	P
Rosemary Polomano, Ph.D., RN, Anesthesiology	R	R	R
Lisa Braccini-Barletta, Pharmacy	A	A	A
Stanley Nades, M.D., Rheumatology	E	P	P
Paula Ulsh, RN, Medicine/Cardiology	P	P	P

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting canceled

Old business: None

New business:

- I. **Agenda item:** Approval of minutes of the February 10, 2005 meeting (see agenda attachment).

Action or recommendation: Minutes of the February 10, 2005 meeting were approved as written.

Follow-up: None required

- II. **Agenda item:** Meeting Schedule

Action or recommendation: Meeting dates for the next fiscal year will be August 11, 2005, November 10, 2005, February 9, 2006, and May 11, 2006.

Follow-up: None required

- III. **Agenda item:** Protocol Review (see agenda attachment)

Action or recommendation: Dr. Spector presented several protocols that have been reviewed and approved by the IBC. These included:

- Dr. Felinski's protocol using a primary human cell line,
- Dr. Antonetti's protocol using primary human cell lines, and MMLV and AAV vectors,
- Dr. Jefferson's protocol using HEK-293T cells and a retroviral vector,
- Dr. Spector's protocol using an replication-competent MoMLV retroviral vector,

- Dr. Schengrund's protocol using HIV-1 virus in the BL-3 facility,
- Dr. Jefferson's protocol using a lentivirus vector in mice and rats, and
- Dr. Zhu's protocol using retrovirus-infected U937 cells in the FACS.

Follow-up: Discussion of Dr. Spector's protocol raised the issue of a protocol for the assignment of biosafety level (BL-2 or BL-2+) in protocols using replication-competent amphotropic retroviruses, and for the assessment of replication-competence when non-replicating viruses are used. This discussion will follow at the next meeting, including the possible routine assignment of BL-2+ status unless replication/recombination risk is determined to be negligible.

Likewise, Dr. Spector will be revisited by Dr. Zhu's to determine how media and cell titers will be conducted to determine replication competence.

Minutes of Penn State University College of Medicine Institutional Biosafety Committee

Thursday, November 10, 2005

Rm. C6805, 12 noon to 1PM

Meeting Date	2/10/05	6/2/05	11/10/05
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	P	P	P
Michael Katzman, M.D., Vice-Chair, Medicine	P	P	P
Douglas Kuhn, Ph.D., Safety	P	P	P
Edward Ruth, Community Member	E	P	P
John Neely, M.D., Pediatrics	P	P	P
Keith Verner, Ph.D., Cell. & Molec. Physiol.	R	R	R
David Stuart, Ph.D., Community Member	A	A	A
Michael Verderame, Ph.D., Medicine	P	P	P
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.	E	P	R
Ralph Keil, Ph.D., Biochem. & Molec. Biol.	P	E	P
Douglas Ednie, Comparative Medicine	P	P	P
Ray Scheetz, Microbiol. & Immunol.	P	P	P
Kristen Eckert, Ph.D., Pathology	E	P	E
Rosemary Polomano, Ph.D., RN, Anesthesiology	R	R	R
Lisa Braccini-Barletta, Pharmacy	A	A	E
Stanley Nades, M.D., Rheumatology	P	P	E
Paula Ulsh, RN, Clinical Trials Office	P	P	P

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting canceled

Old business: None

New business:

- I. **Agenda item:** Approval of minutes of the June 2, 2005 meeting (see agenda attachment).

Action or recommendation: Minutes of the June 2, 2005 meeting were approved as written.

Follow-up: None required

- II. **Agenda item:** CV's

Action or recommendation: All CV's required for re-registration of the IBC were received and forwarded to ORA. It was noted that Dr. Quinn has been relieved of his duties on the IBC. The Committee expressed its appreciation for Dr. Quinn's service to the Committee and the College of Medicine.

Follow-up: None required

- III. **Agenda item:** Protocol Review (see agenda attachments)

Action or recommendation: Dr. Spector presented several protocols that have been reviewed and approved by the IBC. These protocols were briefly described due to the fact that they required BL-2+ or BL-3 containment/practices or involved new agents to the institution. These included:

- Dr. Schengrund's studies using HIV and EBV – nonproducer cells at BL-3,

- Follow-up:** None required.
- Dr. Katzman's updated study using HIV at BL-3,
 - Dr. Lucas' updated protocol using several vectors to infect human fibroblasts and B-cells,
 - Dr. Verderame's study using an amphotropic retroviral vector with an oncogene at BL-2+,
 - Dr. Chang's protocol using HTLV-1 retrovirus at BL-2+,
 - Dr. Zhu's revised protocol at BL-2+,
 - Dr. Meyer's study using *Molluscum contagiosum* (new agent) at BL-2,
 - Dr. Sun's protocol using influenza virus (new for the investigator).

Minutes of Penn State University College of Medicine Institutional Biosafety
Committee
Thursday, February 9, 2006
Rm. C6805, 12 noon to 1PM

Meeting Date	6/2/05	11/10/05	2/9/06
David J. Spector, Ph.D., Chair, Microbiol. & Immunol.	P	P	P
Michael Katzman, M.D., Vice-Chair, Medicine	P	P	P
Douglas Kuhn, Ph.D., Safety	P	P	P
Edward Ruth, Community Member	P	P	P
John Neely, M.D., Pediatrics	P	P	P
Keith Verner, Ph.D., Cell. & Molec. Physiol.	R	R	R
David Stuart, Ph.D., Community Member	A	A	A
Michael Verderame, Ph.D., Medicine	P	P	P
Patrick Quinn, Ph.D., Cell. & Molec. Physiol.	P	R	R
Ralph Keil, Ph.D., Biochem. & Molec. Biol.	E	P	P
Douglas Ednie, Comparative Medicine	P	P	P
Ray Scheetz, Microbiol. & Immunol.	P	P	P
Kristen Eckert, Ph.D., Pathology	P	E	P
Rosemary Polomano, Ph.D., RN, Anesthesiology	R	R	R
*Lisa Braccini-Barletta, Pharmacy	E	E	E
Stanley Naides, M.D., Rheumatology	P	E	P
Paula Ulsh, RN, Clinical Trials Office	P	P	E
Ken Lucas, M.D., Pediatrics			G

P=Present E=Excused A=Absent G=Guest R=Resigned C=Meeting
canceled

*Ad Hoc Member

Old business: None

New business:

- I. **Agenda item:** Approval of minutes of the November 10, 2005 meeting (see agenda attachment).

Action or recommendation: Minutes of the November 10, 2005 meeting were approved as written.

Follow-up: None required

- II. **Agenda item:** Announcements

Action or recommendation:

- Dr. Spector will be going on sabbatical beginning in August, 2006. The process for selecting an interim chair is underway.
- Staff support for the Committee is being sought from COM administration to aid the Committee in paper flow and in inspections of laboratories.
- Articles on viral vectors will be forwarded to Committee members to review as training.

Follow-up: None required

- III. **Agenda item:** BL3 Recertification

Action or recommendation: The management group for the BL3 laboratory will meet to recertify the BL3 lab. Activities will be directed by Dr.

Kuhn and Mr. Scheetz and will include the enhancement of the training manual for the facility.

Follow-up: Dr. Kuhn and Mr. Scheetz will meet to initiate this process.

IV. Agenda item: Protocol Review

Action or recommendation:

- Informational: Dr Schell's protocol for use of vaccinia recombinants containing simian virus antigens in mice will be conducted at BL2+.

Follow-up – None required

- Clinical Protocols:

- Dr. Lucas' previously approved protocol has been modified as follows:

- Duke University will now be the site of the clinical portion of the trial,
- The protocol now will utilize pooled human serum rather than fetal calf serum,
- The number of patients involved will now be 40,
- The use of CMV and MSCV as viral vectors is now a component of the protocol.

Follow-up: The Committee approved the protocol. Dr. Lucas will forward an updated assurances form to the Committee.

- Dr. Jiang's multi-center gene therapy protocol using heat-killed yeast containing peptide fragments of the human Ras gene as an adjuvant was discussed.

Follow-up – Dr. Jiang will receive Dr. Naides review of the protocol to assist Dr. Jiang's IRB submission. Final approval will be co-ordinated with that of the IRB.