



UNIVERSITY OF MARYLAND

April 25, 2006

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

Dear Mr. Hammond;

Pursuant to your request for copies of the minutes of the meetings of the University's Institutional Biosafety Committee (IBC) since May 1, 2003, I am providing you with a username and password to access the on-line catalog of IBC minutes maintained on a bulletin board at the following URL:

<http://www.boards.umaryland.edu/~ibcminutes>

Username: ehammond

Password: 483k927

Please let me know if you have any difficulty accessing the documents.

Sincerely,

A handwritten signature in blue ink, appearing to read "James J. Jaeger", with a long, sweeping flourish extending to the right.

James J. Jaeger, Ph.D.  
Director

**Minutes of UMB IBC Meeting: March 3, 2006**  
**12:00 noon to 1:30 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Louis DePaola, Louis DeTolla, James Jaeger, Claudia MacAuley, Robert Myers, Melissa Moore, Janet Peterson, Maria Salvato

**Approval of IBC Minutes from February 3, 2006**  
Approved unanimously

**Discussion of protocols before the committee.**

The following protocols (identified by registration numbers) were approved by committee vote with the following recommendations:

2109: Approved unanimously. BSL-2. Implement sharps reduction program limiting use of sharps to animal use only.

2077: Approved unanimously. BSL-2.

2106: Approved unanimously pending the receipt and approval of answers to the following questions: 1) What is the origin? 2) What was helper virus? 3) What makes it invisible to host immune system? BSL-2.

2177: Approved unanimously. ABSL-1.

2023: Amendment approved unanimously. BSL-2.

**New Business**

1. A description of what is expected to be submitted as a lay abstract will be added to the research registration form.
2. As a demonstration of one of the training tools used in the BSL-3 Course, the committee played a round of "Biosafety Jeopardy."
3. The University is moving forward with the purchase of Click Commerce. EHS will be buying the modules for both the IBC and the Radiation Safety Committee.

**Minutes prepared by:**  
Melissa A. Moore  
Biosafety Officer  
UMB

**Minutes of UMB IBC Meeting: February 3, 2006**  
**12:00 noon to 1:30 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Louis DePaola, Robert Hawley, Joan Hebden, James Jaeger, Claudia MacAuley, Robert Myers, Melissa Moore, Maria Salvato

**Approval of IBC Minutes from December 2, 2005**  
Approved unanimously

**Discussion of protocols before the committee.**

The following protocols (identified by registration numbers) were approved by committee vote with the following recommendations:

2076: Approved unanimously. BSL-2. Reusable surgical tools must be autoclaved.

2099: Approved unanimously. BSL-3. PI must update SOP to include animal use, housing, and husbandry.

2080: Approved unanimously pending the receipt and approval of SOP and edits to the submission. BSL-3.

**New Business**

1. There was a discussion regarding experimental procedures in submissions. It was agreed that a new section would be added to the registration form asking for a brief overview of experimental procedures.
2. Melissa Moore has been named Biosafety Officer for the University of Maryland Baltimore. The committee agreed that she should be added to the committee as a voting member.

**Minutes prepared by:**  
Melissa A. Moore  
Biosafety Officer  
UMB

**Minutes of UMB IBC Meeting: December 2, 2005**  
**12:00 noon to 1:30 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Louis DePaola, Hamid Ghandehari, Robert Hawley, James Jaeger (Biosafety Officer), Claudia MacAuley, Robert Myers, Melissa Moore (Assistant Biosafety Officer), Glenn Morris, Maria Salvato

**Approval of IBC Minutes from September 2, 2005**

Approved unanimously as amended.

**Discussion of protocols before the committee.**

The following protocols (identified by registration numbers) were approved by committee vote with the following recommendations:

2047: Approved unanimously. ABSL-2

2010: Approved unanimously pending the PI's resubmission after correction of numerous spelling errors. BSL-2

2054: Approved unanimously pending the receipt of further information regarding aerosol containment for centrifugation. BSL-2

2049: Approved unanimously. BSL-1

**New Business**

1. Robert Myers from the Department of Health and Mental Hygiene was introduced as a new member of the UMB IBC. Dr. Myers graciously accepted our invitation to serve as a non-affiliated member and brings great experience from the central state public health laboratory. We look forward to working with him.
2. A motion was made, seconded, and carried to cancel the January 6, 2006 meeting due to the historically low number of submissions during the holiday season. Our next meeting will be on Friday, February 3, 2006.

**Minutes prepared by:**

Melissa A. Moore  
Assistant Biosafety Officer  
UMB

**Minutes of UMB IBC Meeting: October 7, 2005**  
**12:00 noon to 1:30 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Robert Hawley, James Jaeger (Biosafety Officer), Melissa Moore (Assistant Biosafety Officer), Janet Peterson, Maria Salvato, Glenn Morris

**Approval of IBC Minutes from September 2, 2005**

Approved unanimously as amended.

**Discussion of protocols before the committee.**

The following protocols (identified by registration numbers) were approved by committee vote with the following recommendations:

2013: Approved unanimously. BSL-2

2025: Approved unanimously pending the PI's agreement; 1) to perform work with infectious materials in a class II biosafety cabinet, and 2) to document that all personnel had received the booster DT vaccination within the past 10 years. BSL-2

2023: Approved unanimously pending the PI providing additional information regarding training and/or experience of the persons working with this particular virus vector system. If training and/or experience can not be documented, the PI should describe his plan for obtaining training from laboratory staff who have such expertise. Dr. Azad may be contacted for the names of such individuals.

2011: Approved unanimously pending the PI's agreement to eliminate sharps and replace glassware with plastic in his work with pathogens. The PI must report all needle sticks and suspected pathogen exposures to the Bloodborne Pathogen Hotline (410-328-2337, x7845). BSL-2

2026: Approved unanimously pending the PI's clarification of facility issues. The protocol should be revised to eliminate references to containment features where they do not exist. BSL-2

2038: Approved unanimously. BSL-2

2047: This protocol was distributed at the meeting for preliminary review. The committee recommends that the PI address the following issues:

1. A SOP should be developed to document the use of PPE and the biosafety practices to be employed.
2. The IBC registration information should be edited to address the potential for transmission of the virus to the home environment.
3. The SOP should describe how PI and technician immunity will be determined or documented.
4. The SOP should describe how PPE and outer protective garments will be removed while inside ABSL-2 containment.
5. The IBC registration information should be edited to discuss the potential for the animals to cough during the instillation of the infectious materials.

**Old Business**

1. The committee discussed possible sources and names for a new non-affiliated member of the committee.

**New Business**

1. None

**Minutes prepared by:**

James Jaeger  
Biosafety Officer  
UMB

**Minutes of UMB IBC Meeting: September 2, 2005**  
**12:00 noon to 1:30 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Louis DeTolla, Joan Hebden, James Jaeger (Biosafety Officer), Melissa Moore (Assistant Biosafety Officer), Janet Peterson, Maria Salvato

**Approval of IBC Minutes from July 8, 2005**  
Approved unanimously as amended.

**Discussion of protocols before the committee.**

The following protocols (identified by registration numbers) were approved by committee vote with the following recommendations:

1815: Approved unanimously pending receipt of host range and safety of constructs, implementation of sharps precautions, and daily dilutions of Clorox®.

1819: Approved unanimously pending clarification of "hood" and face shield, implementation of sharps precautions, and prohibiting spraying of Clorox®.

Protocol 2013 was not approved due to the following committee concerns: a) more information is needed regarding the lentivirus vector, the use of prostate cancer cells, and animal use; b) location of work (HSF I or II); c) Risk assessment needs clarification.

**Old Business**

1. The new Research Registration Form was discussed. A webpage for committee review will be an added feature.

**New Business**

1. The UMB select agent program was audited by the CDC. The majority of findings were related to paperwork.
2. We are currently in need of an additional community member to satisfy the NIH guidelines. The committee discussed possible members.
3. The meeting adjourned at 1:15 PM.

**Minutes prepared by:**

Melissa Moore  
Assistant Biosafety Officer  
UMB

**Minutes of UMB IBC Meeting: July 8, 2005**  
**12:00 noon to 1:30 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Glenn Morris (Vice Chairman), Gerald Cole, James Jaeger, Claudia MacAuley, Melissa Moore (Assistant Biosafety Officer), Maria Salvato

**Approval of IBC Minutes from May 6, 2005**  
Approved unanimously with no changes.

**Discussion of protocols before the committee.**

The following protocols (identified by registration numbers) were approved by committee vote with the following recommendations:

1787: Approved unanimously.  
1813: Approved unanimously

**New Business**

1. The new Research Registration Form was discussed. The following recommendations for improvement were made:
  - a. Create the ability for a PI to assign "rights" to others for data entry purposes.
  - b. Create a preformatted risk assessment statement for studies or those portions of studies that involve work with human bloodborne pathogens
  - c. In the risk Assessment section, revise the wording of question #1, "been offered".
  - d. The wording of question #2 should be changed ~ Have all personnel been advised of potential hazards and how they may interact with certain medical conditions".
  - e. Allow printing while in progress of completion
  - f. Check spelling
2. The meeting adjourned at 1:15 PM.

**Minutes prepared by:**  
Jim Jaeger  
Biosafety Officer  
UMB



**Minutes of UMB IBC Meeting: May 6, 2005**  
**12:00 noon to 1:30 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Louis DeTolla, James Jaeger, Claudia MacAuley, Robert Hawley, Maria Salvato

**Not Present:** Louis DePaola, Hamid Ghandehari, Joan Hebden, Glenn Morris.

**Guests:** none

**Approval of IBC Minutes from April 8, 2004**  
Approved unanimously with no changes.

**Discussion of protocols before the committee.**

The following protocols (identified by registration numbers) were approved by committee vote with the following recommendations:

1778: Approved unanimously with the requirement that the PI specify that "surgical masks" will be used instead of "masks".

1787: Answers to the following questions are needed:

1. Your comments submitted on the IBC registration form state that "Bleach treatment of needles, slides, tubes, etc., will degrade the DNAs as well as the enzyme.". Then you state "I believe the test solutions poses no risk to personnel". The IBC would like you to reconcile those two statements. Are the bleach decontamination procedures simply SOP in your lab, or is there really some hazard associated with the test solutions?
2. If it is not proprietary information (if it is, so state), please tell us more about the induced mutations. The IBC would like to know the mechanism of action that will produce coat color modifications and alterations in blood cell development. With regard to the latter, what alterations in blood cell development are anticipated? What are the implications of these alterations if the mutations are heritable and the mutant animals were to be inadvertently released to the environment? Perhaps this information is contained in the IACUC submission. If so, please reference and copy the information in your reply.

1789: Answers to the following questions are needed:

1. The IBC would like to have more information on the *F. tularensis* Schu S4 strain
  - a. describe the lineage of the strain
  - b. describe how will you characterize the strain that you receive prior to use
  - c. describe the protocol for determining the antibiotic susceptibility of the strain prior to use
  - d. describe the protocol that will demonstrate the effectiveness of Wescodyne as a disinfectant
2. The IBC requests that you share with them the data developed for 1. b, c, and d above, prior to proceeding with the remainder of the proposed work.

3. Where do you propose to do the animal work associated with this project? Presently, no animal work is permitted in the HSF II BSL-3 facility. If the animal exposures are to be conducted at UMB, please describe the protocol for the production of *F. tularensis* aerosols and the inhalation exposure of mice.

#### **New Business**

1. The new Research Registration Form was discussed. It was recommended that "ABSL-3" be added to the drop down list for Biosafety Facilities. Also, abstract length should be limited to 500 words.
2. The meeting adjourned at 1:15 PM.

#### **Minutes prepared by:**

Jim Jaeger  
Biosafety Officer  
UMB

**Minutes of UMB IBC Meeting: 8 April 2005**

**12:00 noon to 1:00 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, James Jaeger, Hamid Ghandehari, Robert Hawley, Joan Hebden, and Claudia MacAuley

**Non-attendees:** Louis DePaola, Louis DeTolla, David Karaolis, Glenn Morris, and Hinrich Staecker

**Guests:** Melissa Moore

**Approval of IBC Minutes from 4 March 2005**

Approved unanimously with no changes.

**Discussion of protocols:**

1. 1750: Approved, BSL-2. Surgical masks are not allowed. Respirators are not recommended.
2. 1769: Approved, BSL-2.

**Old Business:**

1. Final touches are being applied to this form by the IT group. Once finished the form will be available to the committee for beta testing.

**Minutes prepared by:**

Melissa A. Moore, MS, RBP

Assistant Biosafety Officer

UMB

**Minutes of UMB IBC Meeting: 4 March 2005**  
**12:00 noon to 1:00 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Louis DePaola, James Jaeger, Joan Hebden, Claudia MacAuley, and Maria Salvato

**Non-attendees:** Louis DeTolla, Hamid Ghandehari, Robert Hawley, David Karaolis, Glenn Morris, and Hinrich Staecker

**Guests:** Melissa Moore

**Approval of IBC Minutes from 4 February 2005**

Approved unanimously with no changes.

**Training:** The MARCE BSL-3 Course was held February 14-16, 2005 at the University of Maryland Baltimore. This course will be held again June 27-30, 2005.

**Discussion of protocols:**

1. 1750: Deferred pending receipt of additional information defining "masks."

**New Business:**

1. A draft of the new Research Registration Form was reviewed. Members were pleased with the new form. Comments and suggestions from the committee will be incorporated. The beta version will then be sent to committee members.
2. Announcement of ChABSA Seminar to be held March 24, 2005. This will be an update on National Science Advisory Board for Biosecurity NIH Office of Biotechnology Activities.
3. Announcement of ChABSA Scientific Symposium to be held June 2, 2005. A call for abstracts for this event was handed out.

**Minutes prepared by:**

Melissa A. Moore

Assistant Biosafety Officer

UMB

**Minutes of UMB IBC Meeting: 4 February 2005**  
**12:00 noon to 1:00 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Louis DePaola, Louis DeTolla, James Jaeger, Robert Hawley, Claudia MacAuley, and Maria Salvato

**Non-attendees:** Gerald Cole, Hamid Ghandehari, Joan Hebden, David Karaolis, Glenn Morris, and Hinrich Staecker

**Guests:** Melissa Moore

**Approval of IBC Minutes from 7 January 2005**

Approved unanimously with no changes.

**Training:** The agenda for the MARCE BSL-3 Course to be held February 14-16, 2005 at the University of Maryland Baltimore was distributed.

**Discussion of protocols:**

1. 1738: Conditionally approved pending receipt of safety testing data.
2. 1722: Approved.

**New Business**

1. Member Issues:
  - a. The potential use of a BSL-3 laboratory to expose and house guinea pigs to risk group 2 agents was discussed. This BSL-3 is not up to recommended standards of an ABSL-3 (i.e. no personnel shower in anteroom). If this is a BSL-2 protocol, it is better suited for an ABSL-2 facility.
  - b. Security for research laboratories around campus as well as animal facilities was discussed.

**Minutes prepared by:**

Melissa A. Moore

Assistant Biosafety Officer

UMB

**Minutes of UMB IBC Meeting: 7 January 2005**

**12:00 noon to 1:00 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Louis DePaola, Hamid Ghandchari, James Jaeger, Robert Hawley, Claudia MacAuley, Hinrich Staecker, and Glenn Morris

**Non-attendees:** Louis DeTolla, Joan Hebden, David Karaolis, and Maria Salvato

**Guests:** Melissa Moore

**Approval of IBC Minutes from 5 November 2004**

Approved unanimously with no changes.

**Training:** Dr. Jaeger demonstrated our new web based training. Current applications include Bloodborne Pathogens Training, Animal Workers Training, and Hazard Communication.

**Discussion of protocols:**

No nonexempt protocols requiring committee review and approval were before the committee at this time.

**New Business**

1. An announcement was made that Dr. Anne Hirshfield has submitted her resignation to the University and therefore will no longer be a member of the IBC.

**Minutes prepared by:**

Melissa A. Moore

Assistant Biosafety Officer

UMB

**Minutes of UMB IBC Meeting: 1 October 2004**  
**12:00 noon to 2:00 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Louis DeTolla, Hamid Ghandehari, James Jaeger, Robert Hawley, Claudia MacAuley, Glenn Morris, and Maria Salvato

**Non-attendees:** Louis DePaola, Joan Hebden, Anne Hirshfield, David Karaolis, and Hinrich Staecker.

**Guests:** Melissa Moore

**Approval of IBC Minutes from 6 August 2004**

Approved unanimously with no changes.

**Training:** Dr. Jaeger gave members an overview of new information posted by the Office of Biotechnology Activities (OBA) regarding the IBC roles and responsibilities. This information impacts the way we currently do business and was discussed in more detail under New Business.

**Discussion of protocols:**

Protocol 1663 was approved.

Protocol 1661 was approved as amended.

**New Business**

1. Based on the information posted in OBA FAQ #5 stating that in person voting is required, it was agreed that meeting frequency should be increased to monthly. The next meeting will be held November 5, 2004.
2. Melissa Moore, Gerry Cole, and James Jaeger have been working to update the current Research Registration Form. The committee reviewed a draft of the new form. Suggested changes will be incorporated and a new draft will be posted.
3. The IBC Charter was reviewed and updated. A motion was made, seconded and carried to approve the Charter as amended.
4. An announcement was made that Melissa Moore is now recognized by the American Biological Safety Association as a Registered Biological Safety Professional (RBP).
5. The meeting adjourned at 1:30 PM.

**Minutes prepared by:**

Melissa A. Moore

Assistant Biosafety Officer

UMB

**Minutes of UMB IBC Meeting: 6 August 2004**

**12:00 noon to 2:00 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Louis DeTolla, James Jaeger, Robert Hawley, Joan Hebden, Anne Hirshfield, Claudia MacAuley, and Glenn Morris,

**Non-attendees:** Gerald Cole, Louis DePaola, Hamid Ghandehari, David Karaolis, Maria Salvato, and Hinrich Staecker.

**Guests:** Melissa Moore

**Approval of IBC Minutes from 4 June 2004**

Approved unanimously with no changes.

**Training:** Dr. Jaeger gave members an introduction to the National Science Advisory Board for Biosecurity and the potential impact on research at UMB as well as the proposed role of the IBC. Dr. Jaeger also reviewed the existing Export Administration Regulations. 15 CFR Parts 745 and 774 were handed out.

**Discussion of protocols:**

Protocol 1446 and SOP were approved.

Protocol 1653 is on hold pending receipt of terminology clarification from the PI.

Protocol 1586 previously approved at BSL-3 pending receipt of SOP must be resubmitted with specific language speaking to the risk, practices, and containment equipment to be used.

**New Business**

1. Dr. DeTolla is developing an Occupational Safety and Health program for employees who work with animals. A risk assessment is currently done during the IACUC protocol review. However, a more formal check list documenting this procedure will be developed. Dr. Colgan will be responsible for seeing employees and clearing them to work with animals.
2. The meeting adjourned at 1:10 PM.

**Minutes prepared by:**

Melissa A. Moore

Assistant Biosafety Officer

UMB



**Minutes of UMB IBC Meeting: 4 June 2004**  
**12:00 noon to 1:30 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Louis DeTolla, James Jaeger, Anne Hirshfield, Claudia MacAuley, and Maria Salvato,

**Non-attendees:** Daqing Li, Louis DePaola, Hamid Ghandehari, Robert Hawley, Joan Hebden, David Karaolis, Glenn Morris, and Hinrich Staecker.

**Guests:** Melissa Moore

**Approval of IBC Minutes from 2 April 2004**

Approved unanimously with no changes.

**Training:** Dr. Jaeger reviewed NIH's guidance on IBC minutes. Dr. Jaeger presented a diagram depicting the relationship between the IACUC, the IBC, and the IRB.

**Discussion of protocols before the committee via the WebBoard:**

The following protocols (identified by registration numbers) were approved by committee vote with the following recommendations: 1542 and 1543 -need updated SOP; 1586 -need SOP; 1611 - recommend N95 for animal handlers and any work that can not be conducted in a BSC and PI must meet with Vet Resources before beginning work; 0401290210- no further recommendations.

**New Business**

1. The committee discussed the current process for review of protocols. Everyone appreciated the reduction in the number of protocols to review and approve.
2. It was suggested that we speak with Irma Robins regarding guidance on committee minutes that she drafted for the IRB. She is familiar with the Maryland Sunshine Laws and what can be redacted from a Public institution's minutes.
3. Dr. Jaeger requested CV's from those members who have not yet turned them in.
4. Dr. Azad announced that EHS and MRCE will present a training course in July. The course will cover elements of SOP's, respiratory protection, certification of a BSL-3 and other information regarding how to run and work in a BSL-3.
5. Committee members were informed that Howard Hall ABSL-3 planning is underway and that plans are being reviewed by Dr. DeTolla, Dr. Jaeger, and Ms. Moore.
6. The meeting adjourned at 1:15 PM.

**Minutes prepared by:**

Melissa A. Moore

Assistant Biosafety Officer

UMB

**Minutes of UMB IBC Meeting: 13 February 2004**  
**12:00 noon to 1:45 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Robert Hawley, James Jaeger, Claudia MacAuley, Maria Salvato, Louis DeTolla, Hamid Ghandehari, and Joan Hebden.

**Non-attendees:** Daqing Li, Louis DePaola, Anne Hirshfield, Glenn Morris, David Karaolis, Hinrich Staecker.

**Guests:** None

**Approval of IBC Minutes from 07 November 2003**

Approved unanimously with no changes.

**Training:** Dr. Jaeger presented a review of the structure of the IBC webboard and a demonstration of how to reply to posted messages both via the webboard and email clients. All members will be sent a reminder of their webboard log-in credentials.

**Discussion of protocols before the committee via the WebBoard:**

The following protocols (identified by registration numbers) were approved: Srivastava (310280201 and 310130201); Shirliff (310020201); Makar (310020501); Bond (0312220301); Srivastava (0401140201).

Action on the following protocols was deferred:

1. Fried (0312220101). The committee approved this protocol but authorized the Biosafety Officer to withhold the approval letter until it could be verified that all persons conducting this work had attended bloodborne pathogens training.
2. Sauk (0401210101). Questions remain unanswered.
3. Qiu (0401290201). More information has been requested.

**New Business**

1. The committee engaged in a general discussion of how to increase member participation in the protocol review process. Dr. Azad proposed assigning non-exempt protocols to a primary and secondary reviewer. After weighing the pros and cons of the proposal, consensus was reached on the following process:
  - a. Ms. Moore, Dr. Cole, and Dr. Jaeger will conduct a preliminary review of all submitted protocols and identify those that are exempt from committee review and those that are not. In general, only non-exempt protocols will be forwarded to the committee for review. Protocols not requiring review under the NIH recombinant DNA guidelines may still be forwarded to the committee based on a preliminary determination that there are significant biosafety issues.
  - b. In general, non-exempt protocols will be posted to the webboard for consideration by all committee members. At the discretion of the chairman, certain protocols may be assigned to specific committee members for review.
2. Related to the issue of bloodborne pathogens training for the protocol submitted by Dr. Fried, the committee directed that the new on-line submission form include a requirement for the PI to

identify relevant training for all participating staff.

3. The committee discussed the request for information from the “the sunshine project”. The biosafety officer was directed to seek an opinion from University Counsel and then advise the committee of any proposed action or response.
4. Dr. Hawley related some of his impressions and learning experiences from the CDC National Symposium on Biosafety; “Biosafety and Biosecurity: A New Era in Laboratory Science”. There was a general discussion of biosecurity at UMB.
5. Agenda items 4.f. and 4.g were deferred until a future meeting.
6. The committee agreed to restart the alternating month meeting schedule in April. The next meeting is scheduled for Friday, April 2, 2004. Subsequent meetings are set for June 4<sup>th</sup>, August 6<sup>th</sup>, October 1<sup>st</sup>, and December 3<sup>rd</sup>. Please mark your calendars for 12 to 2 pm on those days.
7. The meeting adjourned at 1:45 PM.

**Minutes prepared by:**

James J. Jaeger, PhD

Biosafety Officer

UMB

**Minutes of UMB IBC Meeting: 07 November 2003**  
**12:00 noon to 1:30 p.m.; 714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Abdu Azad (Chairman), Gerald Cole, Robert Hawley, James Jaeger, Claudia MacAuley, Maria Salvato, and Hamid Ghandehari.

**Non-attendees:** Daqing Li, Louis DePaola, Anne Hirshfield, Louis DeTolla, Glenn Morris, Jane Atkinson, Joan Hebden, David Karaolis, Hinrich Staecker.

**Guests:** Melissa Moore

**Approval of IBC Minutes from 05 September 2003**

Approved unanimously with no changes.

**Training:** Dr. Jaeger presented an overview of IBC roles and responsibilities as well as the IBC process as it is implemented at UMB. There was significant discussion regarding review of protocols deemed exempt from IBC review by the Guidelines. No change in the current process (submission required with administrative review and approval) was recommended.

**Discussion of protocols before the committee via the WebBoard:**

The following protocols (identified by registration numbers) were approved: Baskakov (310060201), Judge (310020401), Richards (310021001), Digate (310021101), Krueger (310140101), Kirsch (310230201), Galen (D0208210501), Pasetti (310130101), Richman (310021901), Karaolis (310060301), Flajnik (0310020101).

Action on the following protocols (identified by registration numbers) was deferred:

Richards (310070101)- Waiting for information from PI (Note: As of 02/10/04, the PI is waiting for funding before sending additional information)

Srivastava (310280201 and 310130201)- These are the same protocols which were sent to two different agencies for funding (UMB and VAMC). Dr. DeTolla asked for information regarding human xenograft transplantation. (Angela Peiser (Administrator for the IACUC) has sent the information requested by Dr. DeTolla to Ms. Moore. Dr. Jaeger recommends administrative approval at the 02/13/04 meeting).

Shirliff (310020201)- Waiting for information from PI. (Note-this was received and posted for committee review.)

Makar (310020501)- PI listed does not match IACUC registration. (Note: The PI has been changed to Dr. Fishman and the protocol has since been approved by both the IACUC and the VAMC Biohazards Committee. Dr. Jaeger recommends administrative approval at the 02/13/04 meeting)

Nataro (308260101)- PI has failed to respond to multiple requests for information.

Radulovic (S0209170101) The PI has requested that the challenge phase of this approved protocol with select agents be conducted in a flexible film isolator in the MSTF animal facility. The committee directed the Biosafety Officer to conduct a thorough risk assessment and report back to the committee.

(Note – The PI and her collaborators have not been able to provide the Biosafety Officer with a complete description of the engineering controls to be used in this application. Thus, the risk assessment has not been conducted. The challenge phase of this work is on hold until the risk assessment can be conducted, reported, and approved by the IBC.)

**New Business**

1. There was consensus that the webboard notices be sent out in digest form rather than message-by-message. Dr. Jaeger will change the settings. He will also look into the ability of members to post responses anonymously to the webboard.
2. The next meeting is scheduled for Friday, January 9, 2004.
3. The meeting adjourned at 1:40 PM.

**Minutes of UMB IBC Meeting**  
**05 September 2003**  
**12:00 noon to 1:00 p.m.**  
**714 West Lombard Street (EHS Bldg), Room 309**

**Attendees:** Glenn Morris (Acting Chairman), Jane Atkinson, Abdu Azad, Gerald Cole, Robert Hawley, Joan Hebden, James Jaeger, David Karaolis, Claudia MacAuley, Maria Salvato, Hinrich Staecker.

**Non-attendees:** Daqing Li, Louis DePaola, Anne Hirshfield, Louis DeTolla.

**Guests:** Melissa Moore

**Approval of IBC Minutes from 09 May 2003**

Approved unanimously with no changes.

**Old Business**

Discussion of protocols already before the committee via the WebBoard:

**0308260101, Enterotoxigenic E. coli: Role of chromosomal loci in pathogenesis:** Consensus of the committee was that the protocol be given tentative approval for execution at BSL-2 pending receipt of more information from the PI.

1. The PI should discuss safety practices for laboratory personnel and animal handlers in more detail.
2. The PI should acknowledge that the NIH Guidelines considers ETEC H10407, as it does all enteropathogenic strains of E. coli, as Risk Group 2 pathogens.

**0308250101, Vaccine Development for Shigellosis:** Action on this submission was deferred until the PI submits the information requested in the on-line research registration form (<http://www.ehs.umaryland.edu/biosafety/rrformdirect.cfm>). In answering question 26 of that form, the PI should address

1. risks to personnel associated with the study to include animal handlers
2. mitigation of personnel risks by facility design and/or engineering controls and by personnel safety practices.
3. medical surveillance program in place for personnel associated with this study.
4. treatment protocols that will be followed should personnel associated with this study become infected.

**New Business**

1. Dr. Jaeger briefly reviewed some biosafety-related news that had been communicated to committee members prior to the meeting (attachment 1).
2. Dr. Azad will be giving tours of the new HSF II BSL-3 for those IBC members who are interested.
3. The committee reviewed the IBC Charter dated April 2001 and approved a number of changes. Then old charter and the revised version are attached (attachments 2 and 3).
4. Dr. Morris led a discussion among the committee members regarding their concern that the UMB biosafety program was no longer supported by a credentialed, full-time biosafety officer.

Dr. Morris agreed to draft a “letter of concern” outlining the problem. Committee members offered the following comments and observations for his consideration:

- a. The size and nature of the biomedical research program at UMB requires a full-time biosafety officer. The recently announced Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE) award intensifies this need.
- b. One component of the RCE is the requirement to conduct biosafety training beyond current EHS training offerings.
- c. Was there indirect cost recovery money in the RCE grant to fund or partially fund a position?
- d. Was it possible to charge for biosafety services required in clinical trials (as the Dental School does)?
- e. Regulatory biosafety and biosecurity requirements are increasing.
- f. Biosafety program continuity is an important factor to consider.
- g. Potential fines for violations of the select agent regulations are large compared to the salary for a biosafety officer.
- h. Dr. Jaeger handed out a fact sheet that outlines the resources that EHS has committed to the biosafety program (attachment 4).

5. The meeting adjourned at 1 PM. The next meeting is scheduled for Friday, November 7, 2003.

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**Minutes UMB IBC Meeting of Friday May 9, 2003**  
**12:00 to 1:00 p.m.**  
**714 West Lombard Street (EHS Bldg), Room 309**

**NOTE: FUTURE FRIDAY IBC LUNCH MEETINGS:**

**[July 11 '03] [September 5 '03] [November 7 '03] [January 9 '04] [March 5 '04]**

**Attendees:** Jane Atkinson, Abdu Azad, Gerald Cole, Louis DeTolla, Richard Gilpin, Robert Hawley, Joan Hebden, Anne Hirshfield, James Jaeger, Daqing Li, Claudia MacAuley, Glenn Morris, Hinrich Staecker, John Warren

**Non-attendees:** Louis DePaola, David Karaolis, Bert O'Malley, Maria Salvato

**Call to order and approval of IBC Minutes from November 11, 2002**      **Glenn Morris**  
***[Minutes approved unanimously without changes]***

**Old Business**

**Richard Gilpin**

1) D0302100101.

Title: USE OF IN VIVO EXPRESSION TECHNOLOGY TO IDENTIFY VIRULENCE FACTORS AND PROTECTIVE ANTIGENS OF VIBRIO CHOLERAЕ 01

IIIC1 R-DNA (Experiments involving deliberate transfer of R-DNA into human research participants)...no R-DNA delivered to human cells. Not a human therapeutic trial.

R-DNA transferred into non-toxigenic V. cholerae 01 vector to ID in vivo-produced promoters during human infection.

RAC #0301-570 review of the proposal on March 5-7, Bethesda MD

BSL-2. [IBC Approved 04/02/03]. Mailed 4/16/03. ***Brief discussion of RAC process and approval.***

**Unfinished Business**

**Richard Gilpin**

1) S0207190501. Title: The Ecology of Bacillus anthracis in the Environment.

Facility BSL-3, Practices BSL-3. No animals. No recombinant DNA.. *B. anthracis* strain 9131, soil isolates (possibly wt). Pending. Mailed 4/16/03. ***Project pending receipt of BSL-3 SOP.***

2) Annual UMB IBC report to NIH/OBA

Mailed 4/16/03. ***Information only.***

**Richard Gilpin**

3) Approved/Voted Protocols (428) at the WebBoard

Mailed 4/16/03. ***Information only.***

**Richard Gilpin**

**Review of project(s) Under Review requiring IBC vote**

**Glenn Morris**

**Details at the IBC WebBoard <http://www.boards.umaryland.edu/~ibc>**

1) D0305070301 05/08/2003

***[13 Approve, 1 Abstention]***

Title: Safety, tolerability and immunogenicity of measles and rubella DNA vaccines

IIID-4a. R-DNA (R-DNA introduced into non-human vertebrate). BSL-2. Recombinant

pSINH (Chiron) DNA vaccine. ABSL-2. BALB/c mice. HSF 1 Animal Facility # 0403008 conditional



- 2) D0305050401 05/06/2003 (4) ***[Unanimously Approved]***  
 Title: A Model to Evaluate E.coli as Vaccine Vectors  
 IIID-1a. R-DNA (R-DNA introduced into Risk Group 2 agents). BSL-2. Recombinant rabbit enteropathogenic E. coli. ABSL-2. Rabbits. VAMC Animal Facility # 0402003
- 3) D0305050301 05/06/2003 (4) ***[Unanimously Approved]***  
 Title: A model to evaluate interventional strategies for hemorrhagic colitis  
 IIID-1a. R-DNA (R-DNA introduced into Risk Group 2 agents). BSL-2. Recombinant rabbit enteropathogenic E. coli. ABSL-2. Rabbits. VAMC Animal Facility # 040202
- 4) D0305050601 05/06/2003 (5) ***[Discussion of the applicability of registering select agents used at other institutions by UMB faculty (one project at VAMC involves an E. coli K-12 select agent). Consensus was that institution where select agent is used and stored should be the select agent institution of record.] [Unanimously Approved]***  
 Title: Quorum Sensing Regulation of REPEC Virulence  
 IIID-1a. R-DNA (R-DNA introduced into Risk Group 2 agents). BSL-2. Recombinant rabbit enteropathogenic E. coli. ABSL-2. Rabbits. VAMC Animal Facility # 0403002
- 5) D0305051301 05/06/2003 (5) ***[Unanimously Approved]***  
 Title: Novel HIV Vaccine  
 IIID-D4a. R-DNA (R-DNA from any source into any non-human vertebrate). BSL-2. Recombinant Salmonella typhi. ABSL-2. Mice, rabbits, & non-human primates. MBC Animal Facility # 0026-97
- 6) D0304230101 04/24/2003 (10) ***[Unanimously Approved]***  
 Title: Functional studies of Ubiquilin  
 IIID-E3. R-DNA (Transgenic & knock out rodents with stable introduction of R-DNA into the animal's genome). BSL-2. Human tissue. Viral vectors. ABSL-1.
- 7) D0303070201 04/04/2003 (8) ***[13 Approve, 1 Abstention]***  
 Title: HIV-dengue interactions  
 IIID-1a R-DNA (Introduction of R-DNA into Risk Group 2 agents).  
 BSL-2, Sera containing Dengue virus, HIV, Human tissue. No animals.

**New Business:**

**Richard Gilpin**

- 1) **Health Science Facility II BSL-3 Laboratory Issues**  
*Faculty and Safety committees have been formed and are meeting to plan policies and procedures for the BSL-3 laboratories. Dedication of HSF 2 was on 5/8/03.*
- 2) **Select Agent Security Issues** **Jim Jaeger/Richard Gilpin**  
*[Brief discussion of CDC Select Agent Program and Facility Audit on 5/7/03 and previous audit during Winter of 2001-2. Security recommendations are not coordinated between CDC LSAT and HHS Auditor General Offices. Current level of security at UMB may be adequate. Expect written report from the CDC LSAT Audit within a month.]*
- 3) **UMB IBC interactions with UMB S/M & VAMC IACUC** **Richard Gilpin**  
*The IBC needs a representative (BSO-biosafety officer) to interact with the Schools of Dentistry and Pharmacy Institutional Animal Care and Use Committees. IACUC submissions to School of Dentistry will be forwarded to BSO. BSO will follow up on interactions with the IACUC at the Institute for Human Virology and Maryland Biotechnology Center*
- 4) *[UMB faculty medical surveillance issues related to non-UMB clinical settings were discussed.]*

**Adjourned at 1:07 pm**

**Minutes050903**