

Office of General Counsel Gwen M. Mattison, J.D. General Counsel 3640 Colonel Glenn Hwy. Dayton, OH 45435-0001 (937) 775-2475 FAX (937) 775-3566

May 10, 2006

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

RE: Institutional Biosafety Committee (IBC) Minutes per FOIA request

Dear Mr. Hammond:

Enclosed please find the above referenced information prepared pursuant to your request. Please remit \$36.60 for 183 copies at .20 each to my attention at the above address.

Sincerely,

Tracy Silvert Paralegal



Office of Research and Sponsored Programs 3640 Colonel Glenn Hwy. Dayton, OH 45435-0001 (937) 775-2425 FAX (937) 775-3781 e-mail: rsp@wright.edu

To:

Whom It May Concern

From:

Chris Piekkola, Programs Facilitator

Research and Sponsored Programs

Date:

April 11, 2006

Re:

Sunshine Project request

Attached are photocopies of the Institutional Biosafety Committee's Minutes as requested by "the sunshine project". Please note that during a portion of the requested time period (May, 2003 to present) the Committee met on an every-other-month basis. Since the Committee did not meet in May, 2003, copies begin with June, 2003 and so forth, as follows:

January 10, 2006

December 13, 2005	December 14, 2004
November 8, 2005	November 9, 2004
October 11, 2005	October 12, 2004
September 13, 2005	August 17, 2004
July 12, 2005	June 8, 2004
June 14, 2005	April 13, 2004
May 10, 2005	February 10, 2004
April 12, 2005 March 8, 2005 February 8, 2005 January 21, 2005	December 9, 2003 October 14, 2003 September 22, 2003 August 20, 2003 August 12, 2003 June 10, 2003

Note: Minutes of the February and March, 2006 have not yet been reviewed or approved by the Committee.

Source: IBC Archive | The Superme Project / FOR Fund www.sunshine-project.org

January 10, 2006

E109 Student Union

A quorum of 7 members and 1 alternate was present. Members Present: Eugene Hern (Alternate), James Lucot (Chair), Peter Lurker, Mark Mamrack, Greg Merkle, John Paietta, Harold Stills, and Dawn Wooley.

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- A. The Chair called the meeting to order at 3:04 P.M.
- B. There were no Minutes available at the meeting.

C. Continuing Reviews Administratively Reviewed

None.

D Certifications of Current IBC Approval Received

Minutes - IBC

Source: IBC Archive | The Sunshine Project | FOI Fund | www.sunshine-project.org

E. Responses to Concerns Received, Approval Recommended

The Committee noted that the following Responses were received, reviewed by the Chair and Institutional Biosafety Officer, and final approval by the University Official is now recommended:

IBC# 133 NMR-Based Metabonomic Studies Using Biofluids From Humans Nicholas V. Reo, Ph.D.

R. Protocols Declared Inactive

The Committee noted that the following IBC protocols are now declared inactive:

IBC# 063 Replication Activity Of A Mutant c-myc Origin In The Chromosome

Michael Leffak, Ph.D.

G. Deferred/Tabled Protocols

Minutes - IBC

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

1. The Committee discussed the pending site visit of professionals to critique the Institution BioSafety's Policies and Procedures. It was noted that Robert Ellis, Ph.D., Professor and Biological Safety Officer at Colorado State University and Leslie Delpin, M.S., Biological Health & Safety Manager and Biological Safety Officer at the University of Connecticut would be contracted regarding their preferred procedures and schedules. The Committee further discussed forwarding a packet of materials for their review prior to their arrival. It was decided that 6 protocols, an application form, the annual review form, and the IBC Policies and Procedures document would complete the packet. A target date for the site visit is late February or early March.

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

2. Executive Session: On January 10, 2006, at approximately

3:52 P.M., the chair entertained a motion for the Committee to go
into Executive Session to review a charge or complaint against a
public employee, official, licensee or requested individual. The
motion was made, seconded and approved by the following roll call
vote:

Yes Eugene Hern

Yes James Lucot

Yes Peter Lurker

Yes Mark Mamrack

Yes Greg Merkle

Yes John Paietta

Yes Harold Stills

Yes Dawn Wooley

The Committee remained in Executive Session until approximately 4:08 P.M. on January 10, 2006, at which time the regular meeting resumed.

After considering and discussing a subcommittee report, the LACUC concluded that there was an incident of noncompliance and that these findings will be reported as appropriate. The Committee further noted that the incident appeared to be inadvertent and resulted in no human illness or apparent human exposure.

It was moved and seconded that the Chair correspond with the investigator reminding him of the need to secure committee approvals for any work involving biosafety material and/or procedures.

Summary of Votes to Accept the Findings of the Subcommittee as Stated:

7 voting members present (7 members and 0 alternate) 7 "yes" votes, none opposed.

Source: IBC Archive | The Sunshine Project / FOI Fund www.sunshine-project.org
3. Committee Membership was further discussed with a request for
suggestions of a community representative and an unclassified staff
member. Several suggestions (i.e., Wright Patterson Human
Directorate, the Gene Expression Lab, T. Brown's, and
Pharmacology/Toxicology) were taken for invitation of both
community member and unclassified staff.

- 4. A web-based training protocol was discussed. It is currently as a power-point presentation. The content and audience were discussed as well as implementation. Further discussion of this issue will be done.
- 5. A sample syllabus of a lab class was reviewed with positive comments regarding safety practices being spelled out in the syllabus. It was further discussed that with minor revisions, the current petition form, with a syllabus attached could serve as a "teaching protocol". Other points of discussion: notification of chairs regarding sylibus acceptable and who to notify regarding new requirements for classes involving biosafety-regulated components.
- 6. It was announced that one of the IBC members (D. Wooley) passed her Certified Safety Professional exam.

I. Amendments to Currently Approved Protocols

January 10, 2006

IBC# 136 Dynamics Of Nuclear Organization

Paula A. Bubulya, Ph.D.

After reviewing the protocol, the Institutional Biosafety Committee recommended approval of this protocol pending further clarifications as follows:

- 7a. Unanswered. Please read the indicated guidelines and indicate whether or not exempt.
- 7f. Gene function: Specify the gene functions for the cellular proteins being cloned (Btf, son, and lamin B receptor)

Vector names: Same for all constructs? How will the constructs be differentiated?

Vector type: What type of plasmid will be used?

Conc./titer: To what concentrations will the bacteria be grown?

Host and strain: Indicate the bacterial host and strain

- 7g. Section III-A is not the appropriate category of rDNA. The rDNA experiments proposed may be exempt. Please read the indicated guidelines and indicate whether or not exempt in question 7a.
- 10. HeLa cells: BSL-2, contains human papilloma virus type 18 (HPV-18), a causative agent of human cervical cancer.
- 12b. Indicate strain of E. coli.
- 13. Let Research and Sponsored Programs know when biosafety cabinet certification is complete, no work using the cabinet can be done until cabinet certified.
- 17. Project summary:
- Need to describe how the toxin will be used and disposed of.
- Live cell/imaging procedure: Need to describe how BSL2 will be maintained (e.g., closed system) during this procedure to prevent exposure to HPV-18.
- Centrifugation: Will the procedure be performed in a closed tube.

Summary of votes to approve IBC136 pending clarifications:

8 voting members present (7 members, 1 alternate); 8 "yes" votes, none opposed.

Minutes - IBC Source: IBC Archive The Sunshine Project / FOI Fund www.sunshine-project.org L New Protocols Administratively Approved	06
None.	
M. Continuing Reviews Requiring Full Review	
None.	
N. Miscellaneous New Business	
None.	
© Subsommittee Réports None.	
B. Environmental/Health & Safety	
1. Greg Merkle updated the Committee on EHS activities (see Attachment #1).	
Q. Topics Requiring Committee Action	
None.	

R. Information

The following was distributed to the IBC for their information:

1. It was announced that Dawn Wooley, Ph.D., has been certified proficient as Specialist Microbiologist in Biological Safety Microbiology by the American Society For Microbiology, as well as the American Biological Safety Association.

S. Adjournment

The Committee adjourned at 4:25 P.M.

The next scheduled meeting will be held on

Respectfully submitted.

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Vice President for Research

(Institutional Official)

Source: IBC Arch(ve | The Sunshine Project / FOI Fund | www.sunshine-project.org

WRIGHT STATE
UNIVERSITY

Department of Environmental Health & Safety (937) 775-2215

Fax (937) 775-3761

Attachment #1
IBC Minutes 1-10-06

DATE:

January 10, 2006

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the December 13, 2005 Meeting of the Institutional Biosafety Committee

For the Committee meeting of January 10, 2006:

- 1. For 2005, twenty-nine biological safety cabinets were surveyed during 2005 and the first week of January 2006. An additionally, there were three cabinets serviced by an outside company to replace filters, another three cabinets are out of service due to need for repairs, another cabinet has not been surveyed because it has a broken sash being held open by a plastic block and another is being used for PCR work. Of the cabinets surveyed, two were found to have visibly damaged areas of the supply filter, it is uncertain who or what caused the damage but repairs and very probably filter replacement is needed. Action on the damaged filters is pending.
- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols. The labs have been found generally to be in good order. Items typically found not occurring in the lab include the use of approved eye protection and non-compliant labeling of chemicals according to the Hazard Communication Standard.
- 3. There remains the question of the status of a proposed university policy for vacating lab spaces. Other universities have such a policy form in place.
- 4. On December 23, 2005, I sent a third email message to Paula Bubulya (new faculty person in the Dept. of Biological Sciences) concerning the completion of a biosafety protocol application. The message was prompted by the observation that her new biological safety cabinet was in the being used for handling materials in her lab and there was no application on file for IBC review. The biological safety cabinet was not surveyed earlier because of issues with the electrical wiring and because a protocol had not been submitted for IBC review.
- 5. As mentioned previously, the arrival of new faculty, researchers and principal investigators or even those present who want to start laboratory operations present issues of concern. This Department is looking for a means of gathering timely information so the issues mentioned may be addressed.
- 6. A training program for Biosafety is in the process of being designed. Information has been collected from the CDC web site and from 35 mm slides prepared by Dr. Stills for purpose of providing biosafety training.



Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

Institutional Biosafety Committee

December 13, 2005

E103 Student Union

A quorum of 8 members, 1 alternate, and 2 guests was present. Members Present: Susan Halm, Eugene Hern (Alternate), James Lucot (Chair), Peter Lurker, Mark Mamrack, Greg Merkle, John Paietta, Harold Stills, and Dawn Wooley. Guests included Joe Witlock, Manager of Occupational Health and Safety and William Sellers, Ph.D., Assistant Vice President for Research.

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- A. The Chair called the meeting to order at 3:01 P.M. The Chair announced appreciation for the beverages and snacks provided by Dr. Thomas in observance of the holiday season.
- B. Minutes of the July 12, September 13, October 11, and November 8, 2005 meetings were reviewed and were determined to accurately reflect the business conducted at those meetings.
 - 7 Voting Members present (7 Members and 0 Alternate); 7 "yes" votes, none opposed.

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None.

D. Certifications of Current IBC Approval Received

None.

E. Responses to Concerns Received, Approval Recommended

G, Deferred/Tabled Protocols

None.

H. Miscellaneous Old Business

A discussion of an External Review and site visit revealed that Dr. Robert Ellis of Colorado State University and Ms. Leslie Delpin of the University of Connecticut would come for a site visit in February. It was also suggested that copies of the protocol petition, IBC By-Laws and select approved protocols of various levels be forwarded to Dr. Ellis and Ms. Delpin prior to their visit.

I. Amendments to Currently Approved Protocols

None.

I. Amendments Requiring Only Notification of the Committee

1. The Committee discussed the pending site visit of professionals to critique the Institution BioSafety's Policies and Procedures. It was noted that Robert Ellis, Ph.D., Professor and Biological Safety Officer at Colorado State University and Leslie Delpin, M.S., Biological Health & Safety Manager and Biological Safety Officer at the University of Connecticut would be contacted regarding their preferred procedures and schedules. The Committee further discussed forwarding a packet of materials for their review prior to their arrival. It was decided that 6 protocols, an application form, the annual review form, and the IBC Policies and Procedures document would complete the packet. A target date for the site visit is late February or early March.

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org
IBC# 135 Chemical Modification Of Human B Cell Function

Courtney E. Sulentic, Ph.D.

After reviewing the protocol, the Institutional Biosafety Committee recommended approval of this protocol pending further clarifications as follows:

- 1. Receipt of verification of current hood certification.
- 2. Section 15a: Since you are treating the waste as infectious, the Committee agreed to administratively correct the typo from a "no" answer to "yes", indicating that infectious waste would be generated.

Summary of votes to approve IBC#135 protocol pending clarifications as follows: 8 Voting Members present (8 Members and 0 Alternate); 8 "yes" votes, none opposed

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L. New Bi	Olocois wan	umstrauvei	y Approved

None.

M. Continuing Reviews Requiring Full Review

None.

N. Miscellaneous New Business.

- 1. Committee membership was discussed with a few suggestions being made regarding committee needs and how to present an invitation to join the IBC. At this time, the Chair presented a certificate of appreciation to a member who was attending her last meeting.
- 2. A possible IBC protocol violation was briefly discussed with a subcommittee being formed to join the LACUC for a joint investigation of the matter.

None.

P. Environmental Flealth & Safety

- 1. Greg Merkle updated the Committee on EHS activities (see Attachment #1).
- 2. As part of this report, the Committee discussed their role in monitoring teaching activities (e.g., microbiology courses). There will need to be further discussion on this matter.

Q. Topics Requiring Committee Action

None.

R. Information

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

S. Adjournment

The Committee adjourned at 4:12 P.M.

The next scheduled meeting will be held on January 10, 2006

Respectfully submitted.

Jan B) min

2/14/06 Date

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Date

Vice President for Research

(Institutional Official)



Department of Environmental Health & Safety (937) 775-2215

Fax (937) 775-3761

IBC Minutes 12-13-05 Attachment #1

DATE:

December 13, 2005

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the November 8, 2005 Meeting of the Institutional Biosafety Committee

For the Committee meeting of December 13, 2005:

1. Biological safety cabinets are being surveyed.

- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols. The labs have been found generally to be in good order. Items typically found not occurring in the lab include the use of approved eye protection and non-compliant labeling of chemicals according to the Hazard Communication Standard.
- 3. There remains the question of the status of a proposed university policy for vacating lab spaces. Other universities have such a policy form in place.
- 4. I have yet to hear from Paula Bubulya (new faculty person in the Dept. of Biological Sciences) concerning the completion of the electrical wiring for her proposed tissue culture room. The biological safety cabinet in the room has not been surveyed because the electrical wiring and because there has yet to be a protocol submitted for IBC review.
- 5. The arrival of new faculty, researchers and principal investigators or even those present who want to start laboratory operations present issues of concern. There are concerns with general safety awareness, potentially the lack of regulatory review of practices and procedures for the laboratory and personnel training. This Department is looking for a means of gathering timely information so the issues mentioned may be addressed.
- 6. There has been an inquiry into the overseeing of undergraduate teaching laboratory classes where various micro organisms are being manipulated. Concerns have been expressed in regard to the organisms being manipulated, what constitutes a high risk from airborne materials, training given to the students and who is formally responsible for making determinations and decisions. I believe this is an area the Committee needs to review and provide direction.

"INFORMATION"

Subject: RE: site visit

From: "Dawn P. Wooley" <dawn.wooley@wright.edu>

Date: Wed, 04 Jan 2006 12:39:18 -0500

To: 'Chris Piekkola' <christine.piekkola@wright.edu>

Chris,

The two consultants are from different Universities as follows:

Robert Ellis, Ph.D.
Professor and Biological Safety Officer
Dept. of Microbiology, Immunology, & Pathology
Colorado State University
Fort Collins, CO 80523-1677
Phone: 970-491-5740
Fax: 970-491-1815
Robert Ellis@colostate.edu

Leslie Delpkin, M.S.
Biological Health & Safety Manager and Biological Safety Officer
Environmental Health & Safety
University of Connecticut
3102 Horsebarn Hill Road, Unit 4097
Storrs, CT 06269-4097
Phone (860) 486-2436
Fax (860) 486-1106
lm.delpin@uconn.edu

Dawn P. Wooley, PhD, SM(NRM), RBP
Associate Professor of Virology
Wright State University
3640 Colonel Glenn Highway
Dept of NCBP, Room 235c Bio Sci Bldg
Dayton, OH 45435
Phone: (937) 775-4993
Fax: (937) 775-3391
dawn.wooley@wright.edu
http://www.wright.edu/~dawn.wooley/index.htm

----Original Message----

From: Chris Piekkola [mailto:christine.piekkola@wright.edu]

Sent: Wednesday, January 04, 2006 10:55 AM

To: Dawn P. Wooley Subject: site visit

Good morning ... would you please confirm the spelling of Drs. Ellis and Delphin's names and are they Ph.D.'s from Colorado State University? Do you also have contact information? Thank you, Chris

FILE COPY

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org



Department of Environmental Health & Safety (937) 775-2215 Fax (937) 775-3761

IBC Minutes 12-13-05 Attachment #1

DATE:

December 13, 2005

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the November 8, 2005 Meeting of the Institutional Biosafety Committee

For the Committee meeting of December 13, 2005:

1. Biological safety cabinets are being surveyed.

- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols. The labs have been found generally to be in good order. Items typically found not occurring in the lab include the use of approved eye protection and non-compliant labeling of chemicals according to the Hazard Communication Standard.
- 3. There remains the question of the status of a proposed university policy for vacating lab spaces. Other universities have such a policy form in place.
- 4. I have yet to hear from Paula Bubulya (new faculty person in the Dept. of Biological Sciences) concerning the completion of the electrical wiring for her proposed tissue culture room. The biological safety cabinet in the room has not been surveyed because the electrical wiring and because there has yet to be a protocol submitted for IBC review.
- 5. The arrival of new faculty, researchers and principal investigators or even those present who want to start laboratory operations present issues of concern. There are concerns with general safety awareness, potentially the lack of regulatory review of practices and procedures for the laboratory and personnel training. This Department is looking for a means of gathering timely information so the issues mentioned may be addressed.
- 6. There has been an inquiry into the overseeing of undergraduate teaching laboratory classes where various micro organisms are being manipulated. Concerns have been expressed in regard to the organisms being manipulated, what constitutes a high risk from airborne materials, training given to the students and who is formally responsible for making determinations and decisions. I believe this is an area the Committee needs to review and provide direction.



Source: IBC Archive | The Sunshine Project FOI Fund I www.sunshine-project.org

November 8, 2005

E103 Student Union

A quorum of 6 members and 1 alternate was present. Members Present: Susan Halm, Eugene Hern (Alternate), James Lucot (Chair), Peter Lurker, Greg Merkle, Mark Mamrack, John Paietta, and a guest, Joe Witlock, Manager of Occupational Health and Safety.

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- A. The Chair called the meeting to order at 3:03 P.M.
- B. The Minutes of the June 14, 2005 meeting was reviewed and were determined to accurately reflect the business conducted at that meeting.

Summary of Votes to Recommend Approval of the June 14, 2005 Minutes.

6 Voting Members present (5 Members and 1 Alternate); 6 "yes" votes, none opposed.

C. Continuing Reviews Administratively Reviewed

None.

D. Certifications of Current IBC Approval Received

None.

E. Responses to Concerns Received, Approval Recommended

Minutes - IBC		<i>(</i> · ·	November 08, 2005
F. Protocols Declared Inactive	ve The Sunshine Project / FOI Fund ww	w.sunshine-projec	t.org

None.

G. Deferred/Tabled Protocols

None.

H. Miscellaneous Old Business

1. The Chair announced that an IBC member had reviewed the list of individuals from the Biosafety Society who expressed an interest in serving as a consultant for our program review. The list was prioritized and given to the Institutional Official for review, approval, and/or recommendation. Other input to the I.O. was encouraged.

I. Amendments to Currently Approved Protocols

IBC# 082, Amendment #1 HIV-1 Infection Of White Blood Cells

Dawn P. Wooley, Ph.D.

After reviewing the proposed amendment and complete protocol, the Committee recommended approval with the notation that while this protocol is listed as BSL2, work is to be conducted using BSL3 practices.

Summary of Votes to Recommend Approval of this Amendment:

6 voting members present (6 Members, 0 Alternate); 6 "Yes" votes, None Opposed.

The Principal Investigator for this protocol, who is a member of the IBC, was not present during the discussion and vote of this amendment.

Minutes - IBC J. Amendments Requiri	IBC Archive The Sunshing Only Notincation of the	Project / FOI Fund ww Committee	w.sunshine-projec	November 08, 2005 t.org
None.				
K. New Protocols Requi	ring Full Review			
None.				
L.: New Protocols Admi	nistratively Approved			
None.				
M. Continuing Reviews	Requiring Full Review			
None.				
N. Miscellaneous New	Business			

1. How is the purchase of biological safety cabinets to be controlled? The Committee discussed the problem of biological safety cabinets being purchased and/or unbeknownst to Environmental Health and Safety. This could occur, for example, when purchased for and/or installed in a laboratory not yet up and running.

It was suggested that EHS develop a check-list style "Welcome Pack" for new faculty, including adjuncts and research faculty, containing biosafety information, items that need to be done, and important web-sites for additional information.

O. Subcommittee Reports BC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

None.

P. Environmental Health & Safety

- 1. Greg Merkle updated the Committee on EHS activities (see Attachment #1).
- a. RSP will follow-up on the status of the laboratory vacating policy with the Institutional Official.

Q: Topics Requiring Committee Action

None.

R. Information

The following was distributed to the IBC for their information:

- 1. A copy of the 10-18-05 email between Drs. Stills and Scott Moniaci regarding the Mathematical and Microbiology Building power shutdown scheduled for October 29th and 30th was noted.
- 2. Possession, Use, and Transfer of Select Angents and Toxins Reconstructed Replication Competent Forms of the 1918 Pandemic Influenza Virus Containing Any Portion of the Coding Regions of All Eight Gene Segments", Department of Health and Human Services, Centers for Disease Control and Prevention, 42 CFR Part 73, Federal Register, Vol. 70, No. 202, Thursday, October 20, 2005, Rules and Regulations, pages 61047-61049 was distributed.

S. Adjournment Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

The Committee adjourned at 3:45 P.M.

The next scheduled meeting will be held on December 13, 2005

Respectfully submitted.

James Lucot, Ph.D., Chair

113100

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Vice President for Research

(Institutional Official)





Department of Environmental Health & Safety (937) 775-2215

Fax (937) 775-3761

IBC November 8, 2005 Minutes
Attachment #1

DATE:

November 8, 2005

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the October 11, 2005 Meeting of the Institutional Biosafety Committee

For the Committee meeting of November 8, 2005:

- 1. Biological safety cabinets are being surveyed. One cabinet surveyed in early October was found with a damaged filter. Originally, the intent was to seal the damaged spot and retest but I was asked to come back later. BSL1 IBC protocol for the materials used in the lab. I am waiting for a piece of equipment to be returned from being calibrated before scheduling to repair the damaged filter media.
- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols. The labs have been found generally to be in good order. Items typically found not occurring in the lab include the use of approved eye protection and non-compliant labeling of chemicals according to the Hazard Communication Standard.
- 3. There remain questions of the status of a proposed university policy for vacating lab spaces.
- 4. The Department purchased a new copy of the NSF Std. for Biological Safety Cabinets (NSF/ANSI 49-2004a).
- 5. Joe Whitlock, the Manager of Occupational Safety and Health in the Department started November 1, 2005.
- 6. A new faculty member in the Department of Biological Sciences called October 12 to request her new biological safety cabinet be surveyed. The faculty person (Paula Bubulya) was asked to complete and submit to RSP an application for use of biological materials. Paula was also asked to contact persons in the Department of Environmental Health and Safety for information on handling and disposal of infectious waste. As of the date of this IBC meeting I have not heard from Paula following an email message of Nov. 4 asking for information.

Source: IBC Archive | The Sunshine | FOI Fund | www.sunshine-project.org

Institutional Biosafety Committee

October 11, 2005

E103 Student Union

A quorum of 5 members and 1 alternate was present. Members Present: Eugene Hern (Alternate), Greg Merkle, Mark Mamrack, John Paietta, Harold Stills (Vice-Chair) and Dawn Wooley.

- A. The Vice-Chair called the meeting to order at 3:04 P.M.
- B. The Minutes of the March 8, April 12, and May 10, 2005 meetings were reviewed and were determined to accurately reflect, with one minor change, the business conducted at those meetings.
 - Summary of Votes to Recommend Approval of the March 8, April 12, and May 10, 2005 Minutes as corrected. 6 Voting Members present (5 Members and 1 Alternate); 6 "yes" votes, none opposed.

C. Continuing Reviews Administratively Reviewed

None.

D. Certifications of Current IBC Approval Received

None.

E. Responses to Concerns Received, Approval Recommended

October 11, 2005 Source: IBC Archive The Sunshine Project / FOI Fund www.sunshine-project.org
None.
Deferred/Tabled Protocols
None.
Viscellaneous Old Business
1. D. Wooley reported that she received 10 responses from her inquiry through the Biosafety Society list serve regarding potential WSU-IBC audit. She will forward this information to the Chair and Institutional Official for further action.
mendments to Currently. Approved Protocols
None.
vinendments Requiring Only Notification of the Committee
None.

Minutes - IBC October 11, 2005 The Sunshine Project / FOI Fund | www.sunshine-project.org

K. New Protocols Requiring

IBC# 131 Chemical Modulation Of B Cell Function

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Courtney E. Sulentic, Ph.D.

Note For The Record: This protocol, being a BSLI, was approved administratively and should have appeared under Item L. (New Protocols Administratively Approved).

IBC# 133 NMR-Based Metabonomic Studies Using Biofluids From Humans

Nicholas V. Reo, Ph.D.

After fully discussing the protocol, the Committee recommended approval pending receipt of the following:

- 1. Question 11.d.: Human or Nonhuman Tissue Section: Please provide certification of completion of training.
- 2. Questions 14.e and f.: Safety Procedures Section: Clarify that an appropriate disinfectant for the various waste types will be used (e.g., 10% bleach).
- 3. Forward a copy of the IRB approval for our records.
- 4. Question 15.a.: Correct this response as other wastes besides liquid will be generated (e.g., pipette tips and other solids).

Summary of votes for the above action on IBC#133:

6 Voting Members present, (5 Members and 1 Alternate); 6 "yes" votes, none opposed

L. New Protocols Administratively Approv

See Item K. L. (IBC#131, Countriev E. Sulentic)

Summary of votes to concur with the recommended approval of this/these protocol(s): Summary of Votes to Concur with the Recommended Approval of this/these Protocol(s):

Minutes - IBC
October 11, 2005
Mt.Continuing Reviews Requiring Fund Review Shine Project / FOI Fund | www.sunshine-project.org

None.

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N. Miscellaricous New Business

None.

© Subcommittee Reports

Minutes - IBC

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

1. Greg Merkle updated the Committee on EHS activities (see attachment #1 for details).

2. The issue of an electrical power shutdown for maintenance in the Mathematics and Microbiology Building was discussed (e-maile dated 10-06-05. Attachment #2). It was brought to the committees attention that many factors were of concern, e.g., backup generators not strong enough to handle freezer needs moving biohazards to another building could be a health and safety risk, and since doors to labs could not be locked due to extension cords being ran thru labs and along hallways, secuity issues would become a problem. After a lengthy discussion, it was decided that a letter be sent to Scott Moniaci, Ph.D., WSU Electrical Engineer, requesting alternatives and protocol for labs during electrical shutdowns. Further, a memo should be written to John Sheidler, Director of Support Operations, SOM, reminding him that the IBC should be involved in any discussions regarding protracted power outages to facilities used fro projects involving greater than BSL1 containment.

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None.

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R. Information

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

S. Adjournment

The Committee adjourned at 3:52 P.M.

The next scheduled meeting will be held on November 08, 2005

Respectfully submitted.

12/13/08 Date

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Da

Vice President for Research

(Institutional Official)



WRIGHT STATE
UNIVERSITY

Department of Environmental Health & Safety (937) 775-2215

Fax (937) 775-3761

IBC Minutes October 11, 2005 Attachment #1

DATE:

October 11, 2005

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the September 13, 2005 Meeting of the Institutional Biosafety

Committee

For the Committee meeting of October 11, 2005:

1. Biological safety cabinets are being surveyed. One cabinet was found with a damaged filter, will attempt to seal the damaged spot and retest.

- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols. The labs have been found to be in good order. Items typically found not occurring in the lab include the use of approved eye protection and non-compliant labeling of chemicals according to the Hazard Communication Standard.
- 3. The Department has given an opportunity to provide input for the lab building construction project for the Biological Sciences III Building.
- 4. There remain questions of the status of a proposed university policy for vacating lab spaces.
- 5. The NSF Steering Committee will have its annual meeting during ABSA Conference in Vancouver. There has not been a posted agenda for the meeting and I have not seen the minutes of last year's meeting. The agenda and past minutes are available just before the ABSA Conference.
- 6. The Department has hired a new employee as Manager, Occupational Safety and Health. The new employee, Joe Whitlock, comes to the university from local industry. His first day on the job will be November 1, 2005.

Agenda Item for Discussion at the October IBC Meeting

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org
Subject: Agenda Item for Discussion at the October IBC Meeting IBC Minutes October 1 IBC Minutes October 11, 2005

Attachment #2

From: Greg Merkle <greg.merkle@wright.edu>

Date: Thu, 06 Oct 2005 14:06:52 -0400

To: Chris Piekkola <christine.piekkola@wright.edu>, James Lucot <james.lucot@wright.edu>, Eugene Hern

<eugene.hern@wright.edu>

CC: "Stephen P. Farrell" <stephen.farrell@wright.edu>

The university has scheduled for the power to the Math / Micro Bldg. to be shut down at the end of this month. It has been proposed to apparently move freezers, refrigerators and incubators to the Bio. Sci. Bldq. for holding over the weekend of 10/29 & 10/30 and into Monday, 10/31. If this moving of equipment is to be put into place does the Committee have issues with biological materials that Dawn Wooley, Mark Rich, Tim Cope or Robert Fyffe are working with being moved through the hallways and tunnels both on a Friday and Monday? If they are moving ultra-low freezers, refrigerators and incubators what is the chance of equipment failure once moved to and from the temporary location in the bio. Sci. Bldq.? What happens to materials should there be equipment failure? Is there backup storage available to hold materials until repairs are made?

In addition to the biological agents that are in use there is also the guestion of the moving of transferring of chemicals.

Greg

Source: IBC Archive | The Sunshine Project FQL Fund | www.sunshine-project.org

institutional Biosafety Committee

September 13, 2005

E103 Student Union

A quorum of 7 members and 1 alternate was present. Members Present: Susan Halm, Eugene Hern (Alternate), James Lucot (Chair), Peter Lurker, Greg Merkle, Mark Mamrack, John Paietta, and Dawn Wooley.

A. The Chair called the meeting to order at 3:00 P.M.

- B. The Minutes of the February 8, 2005 meeting was reviewed and were determined to accurately reflect the business conducted at that meeting.
 - Summary of Votes to Recommend Approval of the February 8, 2005 Minutes.
 - 7 Voting Members present (6 Members and 1 Alternate); 7 "yes" votes, none opposed.

C. Continuing Reviews Administratively Reviewed

Since the last review, there have been no changes made in these protocols other than those amendments already approved. The committee noted the following administrative actions/approvals/requests.

IBC# 074 Construction Of A Mite cDNA Library And Expression Of Mite Proteins

Larry G. Arlian, Ph.D.

IBC# 098 Human Blood Monocyte Isolation And Culturing

Larry G. Arlian, Ph.D.

Minutes - IBC Source: IBC Archive The Sunshine Project / FOI Fund www.sunshine-project D. Certifications of Current IBC Approval Received	September 13, 2005
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None.

E. Responses to Concerns Received, Approval Recommended

None.

IF Protocols Declared Inactive

The Committee noted that the following IBC protocols are now declared inactive:

IBC# 062 Gene Transfer By Retroviral Delivery

Thomas L. Brown, Ph.D.

G. Deferred/Tabled Protocols

IBC# 127 Gene Transfer By Retroviral Delivery

Thomas L. Brown, Ph.D.

After reviewing the complete protocol, the Committee recomended approval.

Summary of Votes to Recommend Approval of this Protocol:

8 voting members present (7 members, 1 alternate); 8 "Yes" votes, none opposed.

Minutes - IBC September 13, 2005

H. Miscellaneous Old Business | The Sunshine Project / FOI Fund | www.sunshine-project.org

- 1. A discussion ensued regarding EHS serving as storage depository for biological agents. Among the numerous problems discussed were responsibility for assuring correct material, proper storage and handling, and subsequent transfer. A committee member related that while at a conference, inquiries of such a task from attendees resulted in negative responses as well as surprise that a university would consider such a huge task. It was concluded that there was little concensus to pursue this idea until and unless further information is obtained and studied.
- 2. An update on obtaining an external review of the IBC was discussed. At this time, no one has been contacted and one prime candidate is no longer employed by a University. A Committee member will place an inquirey on the ABSA listserve for someone who is certified, willing, and interested in serving as a consultant. It was further recommended that two persons, one from an academic background and one from a regulatory/administrative background would best serve the committee. The Committee agreed and such posting will be implemented.

I. Amendments to Currently Approved Protocols

None.

J. Amendments Requiring Only Notification of the Committee

IBC# 128 Replication Activity Of A Mutant c-myc Origin In The Chromosome

Michael Leffak, Ph.D.

After reviewing the full protocol, the Committee agreed to approve this protocol.

Summary of votes for the above action on IBC#128:

8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

IBC# 130 Use Of Adenovirus To Introduce Genes Into Adrenal Chromaffin Cells

Mark Rich, Ph.D. M.D.

After reviewing the protocol, the Institutional Biosafety Committe recommended approval this protocol pending further clarifications as follows:

- 1. Section 7b: Clarify if there are any drug resistance genes in the plasmid construct.
- 2. Section 7e: Clarify if you are expressing the adenovirus.
- 3. Section 7.f: For "Construct 3", provide what information is known concerning its "Gene Function" and/or clarify why it is being cloned.
- 4. Section 7.f and 7.g: "f" indicates that vector genome is 10% deleted/substituted (page 2) while "g" indicates a DNA experiment category of III-E indicating rDNA activities involving <2/3 of the genome present (and hence, for use at BSL1 instead of BSL2). Please clarify this discrepency and correct as appropriate.
- 5. Section i: Only answer this question if you are working with adenovirus in a nonrecombinant form.
- 6. Please complete all incomplete questions, e.g., #8, 11, and 12.
- 7. Please clarify if viral genome is in the plasmid.
- 8. Question #15 indicates no generation of infectious waste, yet the protocol indicates that this project would include working with viruses and rDNA plasmids. Please reconcile.

Summary of votes for the above action on IBC#130:

8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

Minutes - IBC September 13, 2005

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

IBC# 132 Role Of Angiotensin II In Bone Marrow Endothelial Stem Cell-Assisted Vasculogenesis In Ischemic Random Skin Flaps

Richard Simman, M.D.

After reviewing the protocol, the Institutional Biosafety Committe recommended approval of this protocol pending further clarifications as follows:

- 1. Petition Section B indicates both that "No" human tissue will be used (initial response and that human skin will be utilized (sub-response #1). Project summary does not appear to describe the use of human tissue. Please clarify and correct as appropriate. (Important: see "Note for the Record" below.)
- 2. Provide a summary that is specific to the biosafety activities and issues described in the petition/protocol including completion of Section E., containment and disposal rDNA material.
- 3. Section D initially indicates that "No" microorganisms will be used but indicates in a sub-response that BSL2 containment level will be used. Clarify and correct as appropriate.

Summary of votes for the above action on IBC#132:

8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

Note for the Record. This protocol was approved! Pending only for non-human component use (i.e., not approved for use of human tissue). If human tissue is being used, the protocol will need to be amended to fully describe all aspects of its use (e.g., source, handling, transport, etc.).

L. New Protocols Administratively Approved

M. Continuing Reviews Requiring Full Review

IBC# 077 Plasmid-Encoded DNA's As Vaccines For Stimulation Of Cytotoxic Thymocyte (CTL) Responses And Stimulation Of Protective Immunity In Primary HSV-1 Challenge And In Reactivated HSV-1 Infection

Nancy J. Bigley, Ph.D.

After reviewing the request for continuation and full protocol, the Institutional Biosafety Committee recommended approval of the request for continuation pending the following:

- 1. Update and specify your current laboratory use location.
- 2. Update listing of names of persons working with materials and/or procedures under this protocol.

Summary of Votes to Recommend Continuing Review Approval of this Protocol:

8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

IBC# 088 Gender & NKT Cell Response To Virus

Nancy J. Bigley, Ph.D.

After reviewing the request for continuation and full protocol, the Institutional Biosafety Committee recommended approval of the request for continuation pending the following:

- 1. Update and specify your current laboratory use location.
- 2. Update the names of persons working with materials and/or procedures under this protocol.
- 3. If EMCV-D is infectious material to animal, plant, or human, then shipping of materials needs to be done by trained person within the P.I.'s lab. Provide documentation of the training for the individual(s) responsible for the shipping of the EMCV-D virus to Harvard Medical School. The person shipping infectious agents, must be appropriately trained and the materials packaged as required per DOT regulations. Contact Tom Mohaupt at 775-2169 to obtain this training.

Summary of Votes to Recommend Continuing Review Approval of this Protocol:

8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

Minutes - IBC September 13, 2005

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

IBC# 101 Vasopressin Cytotoxicity In Inherited Diabetes Insipidus

David R. Cool, Ph.D.

After reviewing the request for continuation and full protocol, the Institutional Biosafety Committee recommended approval of this request.

Summary of Votes to Recommend Continuing Review Approval of this Protocol: 8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

IBC# 111 Clinical And Biophysical Studies In Human Blood

Norma C. Adragna,

After reviewing the request for continuation and full protocol, the Institutional Biosafety Committee recommended approval of the request for continuation pending the following:

- 1. Update and specify your current laboratory use location.
- 2. Please include information on how blood is being transported from MVH to WSU.

Summary of Votes to Recommend Continuing Review Approval of this Protocol: 8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

N. Miscellaneous New Business

- 1. A change of notification of amendment acceptance format was discussed and it was decided to modify Item I.A.2. to clarify that the question pertains to all personnel including students.
- 2. Finding a way to identify amendments efficiently was discussed with the suggestion that amendments bear a title. After some discussion it was decided that the current number system would be maintained for now and this topic will be further discussed at later meetings.

Minutes - IBC

September 13, 2005

Subcommittee Reports

BC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

None.

P. Environmental Health & Safety

1. Committee update by the Institutional Biosafety Officer was presented and discussed as shown in Attachment #1.

Q Topics Requiring Committee Action

None.

R. Information

S. Adjournment

The Committee adjourned at 5:01 P.M.

The next scheduled meeting will be held on October 11, 2005

Respectfully submitted.

James Lucot, Ph.D., Chair

Date

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Vice President for Research

(Institutional Official)

WRIGHT STATE
UNIVERSITY

Department of Environmental Health & Safety (937) 775-2215

Fax (937) 775-3761

IBC Minutes September 13, 2005 Attachment #1

DATE:

September 13, 2005

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the July12, 2005 Meeting of the Institutional Biosafety Committee

For the Committee meeting of September 13, 2005:

1. Biological safety cabinets are being surveyed. Some surveys have been delayed due to equipment failure which occurred in July and I was on vacation part of August.

- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 3. The Department has given input for the lab renovation project that is to involve the Biological Sciences Building.
- 4. In a follow up to the discussion EHS staff had with RSP to acquire "to be" approved MTA materials. Funding was made available to purchase a small securable ultra low freezer from New Brunswick Scientific. After considering the need, requirements and additional comments from others it became apparent more planning was needed before anything was implemented.
- 5. There remain questions of the status of a proposed university policy for vacating lab spaces.
- 6. NSF International has amended its Accreditation Policies for the Class II Biosafety Cabinet Field Certifier Accreditation Program. The revised policy states a field certifier shall not maintain more than ten years of accreditation without requalification by written and practical exam. I received a response to my questioning of the policy change. I found the response to be lacking and what I expected based on the quality of information and support given by NSF in the past nine years. My current field certification expires September 2006 and now the re-test to certify would not be due until 2011. The NSF has their annual meeting during ABSA Conference and the minutes of last year's meeting and the agenda are not available until just before the ABSA Conference.
- 7. MABioN (Midwest Area Biosafety Network) had a meeting on August 1-2. There will be an organizational meeting of this group at the annual ABSA conference in Vancouver BC, October 22 26. I will not be attending the conference this year.

MINUTES INSTITUTIONAL BIOSAFETY COMMITTEE August 9, 2005

There being no business requiring IBC actions, the IBC meeting scheduled for August 9, 2005 was canceled. Respectfully submitted. Chair, Institutional Biosafety Committee Receipt of Minutes acknowledged and recommendations approved disapproved

Dr. Joseph F. Thomas, Jr. Associate Provost for Research (Institutional Official)

Institutional Biosafety Committee

July 12, 2005

E103 Student Union

A quorum of 7 members and 1 alternate was present. Members Present: Susan Halm, Eugene Hern (Alternate), James Lucot (Chair), Peter Lurker, Greg Merkle, John Paietta, Harold Stills, Dawn Wooley, and a guest, Steven Farrell, recently appointed Director of Environmental Health and Safety.



- A. The Chair called the meeting to order at 3:00 P.M.
- B. The Minutes of the January 21, 2005 Retreat was reviewed and they were determined to accurately reflect the business conducted at that meeting with minor formatting corrections.
 - 8 Voting Members present (7 Members and 1 Alternate); 8 "yes" votes, none opposed.

C. Continuing Reviews Administratively Reviewed

Since the last review, there have been no changes made in these protocols other than those amendments already approved. The committee noted the following administrative actions/approvals/requests.

IBC# 065 Bacterial Strain Propagation

Harold Stills, DVM

IBC# 075 Molecular Biology of Cytochrome c and Ubiquinol Oxidases

Lawrence J. Prochaska, Ph.D.

IBC# 079 Examination Of Resistance Of nahG And niml-1 Arabidopsis

Don Cipollini, Ph.D.

IBC Minutes - p. 1

FILE COPY

July 12, 2005 Minutes - IBC

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

IBC# 080 Characterization Of The Engrailed Transcription Factor In The Renshaw Cell Motoneuron Connection

Francisco J. Alvarez, Ph.D.

IBC# 081 Expressing Human And Mouse Proteins In Eukaryotic Cells Steven J. Berberich, Ph.D.

IBC# 082 HIV-1 Infection Of White Blood Cells

Dawn P. Wooley, Ph.D.

IBC# 090 Hamster Proliferative Ileitus: Etiology And Pathobiology Harold F. Stills, D.V.M.

IBC# 097 Environmental Light and Retinal Membrane Development Daniel T. Organisciak, Ph.D.

D. Certifications of Current IBC Approval Received

E. Responses to Concerns Received, Approval Recommended

The Committee noted that the following Responses were received, reviewed by the Chair and Institutional Biosafety Officer, and final approval by the University Official is now recommended:

IBC# 123 The Effect Of Hyaluronic Acid On Keloid Fibroblasts

Richard Simman, M.D.

The Committee discussed the investigator's response to their biosafety cabinet repair and materials transport concerns and judged them adequate and appropriate.

F. Protocols Declared Inactive

The Committee noted that the following IBC protocols are now declared inactive:

IBC# 057 Cell Culture of neuroblastoma (N1E-115) and neuroblastoma x glioma (NG108-15) cell lines

F. J. Alvarez-Leefmans,

IBC# 060 Evaluation Of Human Blood And Tissue Samples For Apolipoprotein J Protein

Thomas L. Brown, Ph.D.

IBC# 061 Production Of Retroviruses Expressing p53, Mdm2 or MdmX Steven J. Berberich, Ph.D.

IBC# 076 Scabies: Biology, Culture, Host Specificity and Antigens

Larry G. Arlian, Ph.D.

G. Deferred/Tabled Protocols

None.

H. Miscellaneous Old Business

A revised IBC Petition was reviewed and approved with a one week time limit for additional comments and/or revisions. After these additional comments are included, RSP will mount the petition on their web site and notify faculty. Discussions at the meeting concerned primarily Material Transfer Agreements and nonrecombinant DNA/RNA information.

Summary of Votes to Recommend approval of the revised IBC Petition form: 8 Voting Members Present (7 Members, 1 Alternate; 8 "Yes" votes, None Opposed.

L Amendments to Currently Approved Protocols

None.

J. Amendments Requiring Only Notification of the Committee

IBC# 121, Amendment #1 Characterization Of Escherichia Coli Strains Isolated From Human Intestine Or Urinary Tract

Oleg Paliy,

This request, dated 06/01/05 from the P.I. to add three E coli strains to this study was reviewed by the Sr. Industrial Hygenist and IBC Chair with the recommendation to approval. This activity was approved 06-20 -05.

K. New Protocols Requiring Full Review

IBC# 127 Gene Transfer By Retroviral Delivery

Thomas L. Brown, Ph.D.

After fully discussing this protocol, the Committee deferred further action pending receipt of the following:

1. Expand Section F (Abstract/Summary) to provide more details of procedures (e.g., description of the procedures used, where conducted, etc.). Note: You can either expand Section F in your current petition or submit the revised document using the new IBC petition form which will be available after July 25th.

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None.

M. Continuing Reviews Requiring Full Review

None.

N: Miscellaneous New Business

- 1. Steve Farrell, the new EHS Director, was introduced to the Committee and briefed the Committee on his credentials. Mr. Farrell spoke to the committee regarding mutual support between IBC and EHS. He further related that he is working toward improving the EHS programs and collaborating with the various committees so that everyone's needs are met. Further topics discussed were: 1) creating a "holding" site for biologicals prior to approval of protocols and MTAs; 2) hiring a faculty/staff person who may serve as the institutional biosafety officer; 3) an audit of policies and procedures from consultants not affiliated with WSU.
- 2. The Committee briefly discussed what areas should be covered by any external review of WSU's RRB.

 Among the areas deemed important are policies and procedures, protocol and subsequent review outcomes, and an interview of "users" (e.g., faculty and staff).

), Subcommittee Reports

None.

P. Environmental Health & Safety

1. Greg Merkle updated the Committee on EHS activities (see Attachment #1).

Q. Topics Requiring Committee Action

None.

R Information

S. Adjournment

The Committee adjourned at 4:23 P.M.

The next scheduled meeting will be held on August 09, 2005

Respectfully submitted.

James B. Lucot, Ph.D.

1213101

Chair, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Data

Vice President for Research

(Institutional Official)



WRIGHT STATE
UNIVERSITY

Department of Environmental Health & Safety (937) 775-2215

Fax (937) 775-3761

IBC July 12, 2005 Minutes Attachment #1

DATE:

July 12, 2005

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the June 14, 2005 Meeting of the Institutional Biosafety Committee

For the Committee meeting of July 12, 2005:

1. Biological safety cabinets are being surveyed.

- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 3. As stated previously, lab assessments are finding areas in labs where food is being stored and/or eaten. Follow up action is being done to comply with the respective School of Medicine or College of Science and Mathematics Unrestricted Lab Space Policy.
- 4. The department is working on developing a training program for preparing packages containing diagnostic, infectious, hazardous or radiological materials for transportation according to the DOT regulations.
- 5. The Assurances Section of the IBC Protocol Application was given to Dawn Wooley so she could work into the proposed revision of the application form.
- 6. In a follow up the discussion EHS staff had with RSP to discuss acquisition of "to be" approved MTA materials. A cost quote for a small securable ultra low freezer was received from New Brunswick Scientific. The quote was forwarded to RSP for comment and possible purchase through other administrative sources.
- 7. There remain questions of the status of a proposed university policy for vacating lab spaces. There are at least two labs with biosafety protocols where the PI's are leaving the university.
- 8. NSF International has amended its Accreditation Policies for the Class II Biosafety Cabinet Field Certifier Accreditation Program. The revised policy states a field certifier shall not maintain more than ten years of accreditation without requalification by written and practical exam. No additional information has been provided to define the exams, where the exams are to be given, available dates or costs. My "ten year" field certification expires September 2006.
- 9. MABioN (Midwest Area Biosafety Network) is organizing a meeting for August 1-2. Meeting agenda will include a discussion of IBC basics presented by the NIH/OBA.

Source: IBC Archive | The Sunshing Forest / FOI Fund | www.

FOI Fund. www.sunshine-project.org

June 14, 2005

E103 Student Union

A quorum of 7 members and 1 alternate was present. Members Present: Susan Halm, Eugene Hern (Alternate), James Lucot (Chair), Peter Lurker, Greg Merkle, Mark Mamrack, John Paietta, and Harold Stills.



- A. The Chair called the meeting to order at 3:03 P.M.
- B. Due to technical problems, there were no Minutes available for review.

C. Continuing Reviews Administratively Reviewed

Since the last review, there have been no changes made in these protocols other than those amendments already approved. The committee noted the following administrative actions/approvals/requests.

IBC# 099 Cell Culturing Of Normal Human Epidermal Keratinocytes (NHEK) And Dermal Fibroblasts (NHDF)

Larry G. Arlian, Ph.D.

D. Certifications of Current IBC Approval Received

Minutes - IBC June 14, 2005

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

The Committee noted that the following Responses were received, reviewed by the Chair and Institutional Biosafety Officer, and final approval by the University Official is now recommended:

IBC# 107 Epidemiology Of Community-Acquired Methicillin-Resistant Staphylococcus Aureus

Thomas E. Herchline, M.D.

F. Protocols Declared Inactive

The Committee noted that the following IBC protocols are now declared inactive:

IBC# 056 MAP Kinase Regulation of G-CSF-Induced Neutrophil Production

Michael A. Baumann, M.D.

G. Deferred/Tabled Protocols

IBC# 124 Muscle's Role In Regulating Nerve Terminal Properties

Mark M. Rich, M.D., Ph.D.

Note For The Record, No Response Required: In Section E.5., page 5, the IBC agreed to administratively strike the second paragraph, beginning with, "I want to stress, however, that we will ..." from this protocol. Summary of Votes to Recommend Approval of this Protocol:

8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

H. Miscellaneous Old Business

None.

J. Amendments Requiring Only Notification of the Committee

None.

K. New Protocols-Requiring Full Review

IBC# 125 The Use Of Affymetrix CustomExpress Array To Compare The Microflora Composition In Feces Of Healthy Children And Children With Inflammatory Bowel Disease

Sonia Michail,

After reviewing the full protocol, the Committee agreed to approve this protocol.

Note For The Record: Verification of CMC's Biosafety Committee approval will need to be obtained.

Summary of votes for the above action on IBC#125:

8 Voting Members Present (7 members, 1 alternate); 8 "yes" votes, none opposed.

IBC# 126 Production Of Retroviruses Expressing Human And Murine **Proteins**

Steven J. Berberich, Ph.D.

After reviewing the full protocol, the Committee agreed to approve this protocol.

Summary of votes for the above action on IBC#126:

7 voting members present (7 members and 0 alternate); 7 "yes" votes, none opposed.

None.

M. Continuing Reviews Requiring Full Review

IBC# 081 Expressing Human And Mouse Proteins In Eukaryotic Cells

Steven J. Berberich, Ph.D.

After reviewing the complete protocol and requestfor continuing review, the Committee recommended approval.

Summary of Votes to Recommend Continuing Review Approval of this Protocol: 8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

N. Miscellaneous New Business

None.

O. Subcommittee Reports

P. Environmental Health & Safety

- 1. Greg Merkle updated the Committee on EHS activities (see attachment #1). Among the items discussed were:
- a. MTA & IBC Coordination
- b. Status of lab closure policy
- c. Concurrance status with a recent "open" area request in M&M
- 2. Greg distributed, "Feds: Science Paper A Terrorist's Road Map, Health Agency Seeks To Halt Scholarly Publication" from CNN. com, June 6, 2005, http://www.cnn.com/2005/US/06/06/milk. terror/index.html.

Q. Topics Requiring Committee Action

None.

R. Information

The following was distributed to the IBC for their information:

1. Article, "US Agency Fines BU \$8,100 In Safety Offenses", reprinted from The Boston Globe, May 10, 2005. http://www.auto.com/. boston.com/news/local/articles/2005/05/10>

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org
2. Article, "OSHA Regional News Release, U.S. Department of

- 2. Article, "OSHA Regional News Release, U.S. Department of Labor, Office of Public Affairs Region 1" May 09, 2005 regarding BU investigation. http://www.osha.gov
- 3. Proposed legislation regulating BSL2, BSL3, and BSL4 laboratories and agents in Massachusettes. The Commonwealth of Massachusettes House Docket No. 4249, "An Act To Protect The Public Health and Environment from Toxic Biological Agents".
- 4. It was noted that one of our IBC members was recently certified as a Registered Biological Safety Professional (RBP).

S. Adjournment

The Committee adjourned at 3:51 P.M.

The next scheduled meeting will be held on July 12, 2005

Respectfully submitted.

James B. Lucot, Ph.D.

Date

Chair, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Date

Vice President for Research

(Institutional Official)



Department of Environmental Health & Safety (937) 775-2215

Fax (937) 775-3761

DATE:

June 14, 2005

Attachment #1

TO:

Memo for the Record

IBC Minutes, 6/14/05

FROM:

Greg Merkle, Sr. Industrial Hygienis

SUBJECT:

Activities Since the May 10, 2005 Meeting of the Institutional Biosafety Committee

For the Committee meeting of June 14, 2005:

1. Biological safety cabinets are being surveyed.

- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 3. Lab assessments are finding areas in labs where food is being stored and/or eaten. Follow up action is being done to comply with the respective School of Medicine or College of Science and Mathematics Unrestricted Lab Space Policy.
- 4. Following conversations with the Fairborn Fire Dept. information lists of biological agents present in the laboratories needs to be compiled and information provided to the Fire Department.
- 5. The department is still working obtaining a training program for preparing packages containing diagnostic, infectious, hazardous or radiological materials for transportation according to the DOT regulations.
- 6. Assurances Section of the IBC Protocol Application form needs to be worked on to bring it into the proposed revision of the application form.
- 7. Isabella Gorrillot and I had a meeting to discuss appropriate information needed for an MTA application.
- 8. EHS staff met with RSP to discuss acquisition of "to be" approved MTA materials. Materials to be held in a secured area pending approval of biosafety protocol application.
- 9. Question of status of proposed vacating lab policy. There are several labs with biosafety protocols where the PI is planning to leave the university

Source: IBC Archive | The Sunshine Project.org

May 10, 2005

E107-Student-Union

A quorum of 5 members and 1 alternate was present. Members Present: Susan Halm, Eugene Hern (Alternate), James Lucot (Chair), Peter Lurker, Mark Mamrack, and Greg Merkle,

- A. The Chair called the meeting to order at 3:06 P.M.
- B. The Minutes of the December 14, 2004 and January 21, 2005 meetings were reviewed and they were determined to accurately reflect the business conducted at those meeing with minor formatting corrections.
 - 6 Voting Members present, (5 Members and 1 Alternate); 6 "yes" votes, none opposed.

C Continuing Reviews Administratively Reviewed

Since the last review, there have been no changes made in these protocols other than those amendments already approved. The committee noted the following administrative actions/approvals/requests.

IBC# 092 DNA Repair

Steve M. Patrick,

D. Certifications of Current IBC Approval Received

Minutes - IBC

Source: IBC Archive | The Sunshine Project | FOI Fund | www.sunshine-project.org

E. Responses to Concerns Received, approval Recommended

The Committee noted that the following Responses were received, reviewed by the Chair and Institutional Biosafety Officer, and final approval by the University Official is now recommended:

IBC# 104 Gene Expression Profiling Of Lung Cancers In Alcoholic Patients

Douglas E. Paull, M.D.

IBC# 121 Characterization Of Escherichia Coli Strains Isolated From Human Intestine Or Urinary Tract

Oleg Paliy,

F. Protoc	 The second second second	4-1-4	A 101

None.

G. Deferred/Tabled Protocols

None.

H. Miscellaneous Old Business

1. Revised petition application form:

Since the subcommittee chair was not able to attend this meeting, the Committee agreed to respond directly to that member should they have further comments or concerns. She anticipates being able to attend the next meeting.

Minutes - IBC	May 10, 2005
Source: IBC Archive The Sunshine Project / FOI Fund www.sunshine-project.org I. Amendments to Currently Approve. Protocols	J
None.	
J; Amendments Requiring Only Notification of the Committee	
None.	
K. New Protocols Requiring Full Review	
IBC# 123 The Effect Of Hyaluronic Acid On Keloid Fibroblasts	
Richard Simman, M.D.	
After fully discussing this protocol, the Committee recommended approval pending receipt	of the following:
1. A pre-project (consultive) meeting with Greg Merkle, Environmental Health and Safety handling and transportation schematics.	to review the
2. The biosafety cabinet used for this work will need to be certified prior to use. Please procertification.	vide a copy of this
6 Voting Members present, (5 Members and 1 Alternate); 6 "yes" votes, none opposed	
IBC# 124 Muscle's Role In Regulating Nerve Terminal Properties	
Mark M. Rich, M.D., Ph.D.	
The Committee agreed to table this request pending completion of Section F, summary of the project, of the Biosafety Protocol Application.	ne proposed
L. New Protocols Administratively Approved	
None.	

N: Miscellaneous New Business

None.

None.

O Subcommittee Reports

None.

P. Environmental Health & Safety

- 1. Greg Merkle updated the Committee on EHS activities (see attachment #1 for details).
- 2. It was announced that Steve Farrell has been named the new Director of EHS.
- 3. The Biosafety Officer discussed the need for a specific biologics inventory in terms of practical concerns (e.g., safety, emergency entrances, etc.).

Q. Topics Requiring Committee Action

The following was distributed to the IBC for their information:

- 1. A Workshop announcement from Massachusetts Society for Medical Research, "Finding Common Ground Harmonization of IACUCs and IBCs" May 4, 2005. http://msmr.org/HarmonizationWorkshop.html>
- 2. Field, Kelly, "Biosafety Committees Come Under Scrutiny", The Chronicle of Higher Education, Vol. 51, Issue 34, Page A22 (4/29/05).

S. Adjournment

The Committee adjourned at 3:41 P.M.

The next scheduled meeting will be held on June 14, 2005

Respectfully submitted.

James B. Lucot, Ph.D.

Date

Chair, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Data

Vice President for Research

(Institutional Official)

Department of Environmental Health & Safety
(937) 775-2215

Fax (937) 775-3761

WRIGHT STATE
UNIVERSITY

IBC Minutes 5-10-05 Attachment #1

DATE:

May 10, 2005

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the March 8, 2005 Meeting of the Institutional Biosafety Committee

For the Committee meeting of May 10, 2005:

- 1. Biological safety cabinets are being surveyed.
- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 3. Lab assessments are finding areas in labs where food is being stored and/or eaten. Follow up action is being done to comply with the respective School of Medicine or College of Science and Mathematics Unrestricted Lab Space Policy.
- 4. A long term goal is to establish an inventory system for biological materials (including select agents) in possession.
- 5. Following conversations with the Fairborn Fire Dept. information lists of biological agents present in the laboratories needs to be compiled and information provided to the Fire Department.
- 6. The department is still working obtaining a training program for preparing packages containing diagnostic, infectious, hazardous or radiological materials for transportation according to the DOT regulations. Resistance has come from research departments on who pays for the training.
- 7. Jerry retired from the university on March 31, 2005. Steve Farrell has been named the new Director of the Department effective April 18.
- 8. Assurances Section of the IBC Protocol Application form needs to be worked on to bring it into the proposed revision of the application form.

FILE COPY

April 12, 2005

E107 Student Union

A quorum of 6 members and 1 alternate was present. Members Present: Susan Halm, Eugene Hern (Alternate), Peter Lurker, Greg Merkle, John Paietta, Harold Stills (Vice-Chair), and Dawn Wooley. A guest, Isabelle Gorrillot, D.Sc., Associated Director for Technology Transfer was also present.



- A. The Vice-Chair called the meeting to order at 3:00 P.M.
- B. There were no Minutes available for review at this meeting. (RSP reported formatting problems which need to be corrected.)

C. Continuing Reviews Administratively Reviewed

Since the last review, there have been no changes made in these protocols other than those amendments already approved. The committee concurred with the following administrative actions/approvals/requests.

IBC# 083 The Regulation Of Protein Synthesis And Degradation

Patrick B. Dennis, Ph.D.

After reviewing the protocol and proposed continuation, the Institutional Biosafety Officer had the following request(s) for information prior to his recommendation to the IBC

1. Clarify the research laboratory location for this study.

Note: The P.I. should seek approval from the Cincinnati Biosafety Committee prior to starting this project.

IBC Minutes - p. 1

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org
IBC# 103 Transfection Of E...aryotic Cells Using Expression Plasmic.

Encoding Human And Mouse Proteins

None.

Madhavi Kadakia, Ph.D.

D. Certifications of C	urent IBC Approval	Regerved	
None.			
E. Responses to Conc	ems Received, Appro	val Recommended	
None.			
E. Protocols Declared	Inactive		
None.			
G. Defenied/Tabled P	rotocols		

- 1. The newest version of the petition application form was distributed to the Committee. The Committee reviewed the current draft. This version will be e-mailed to the Committee for review and comments not only of petition content/format but to test actual user-interactions with the e-version. Comments only can be sent via e-mail to D. Wooley within two weeks. She will be responsible for modifying the e-version.
- 2. Also discussed in relation to the information requested in the petition were issues involving material transfer agreements (MTA), pending and completed actions. It was determined that sufficient information concerning the acquisition of biological material was being requested.

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None.

J. Amendments Requiring Only Notification of the Committee

None.

K. New Protocols Requiring Full Review

None.

M. Continuing Reviews Requiring Full Review

None.

N. Miscellaneous New Business

None.

O. Subcommittee Reports

None.

P. Environmental Health & Safety

- 1. Greg Merkle updated the Committee on EHS activities (see attachment #1 for details).
- 2. The Committee was updated concerning "Select Agent Rules". At this time Greg distributed copies of an article about the new select agent rules, "Rules, Regs, and Red Tape", Marlene Cimons, The Howard Hughes Medical Institute Bulletin, Winter, 2005. (see attachment #2)

1. The Committee was notified of an application for "Unrestricted Lab Space". As part of the process, IBC review is listed as one of the requirements of space utilization. At this time, it is still under review by EHS and not yet ready for ratification.

R. Information

None.

S: Adjournment

The Committee adjourned at 4:36 P.M

The next scheduled meeting will be held on May 10, 2005

Respectfully submitted.

Vice-Chair, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

10/11/05

Vice President for Research

(Institutional Official)

WRIGHT STATE
UNIVERSITY

Department of Environmental Health & Safety (937) 775-2215

Fax (937) 775-3761

DATE:

April 12, 2005

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the Last Meeting of the Institutional Biosafety Committee,

March 8, 2005

For the Committee meeting of April 12, 2005:

1. Biological safety cabinets are being surveyed.

- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 3. A long term goal is to establish an inventory system for biological materials (including select agents) in possession.
- 4. Following conversations with the Fairborn Fire Dept. information lists of biological agents present in the laboratories need to be compiled and information provided to the Fire Department.
- 5. The department is still working obtaining a training program for preparing packages containing diagnostic, infectious, hazardous or radiological materials for transportation according to the DOT regulations. Resistance has come from research departments on who pays for the training.
- 6. Jerry retired from the university on March 31, 2005. As of this date a replacement has not yet been named.

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project organt #2

Subject: [Fwd: [CSHEMA-L] FW: Interesting article about the new select agent rules]

From: Greg Merkle <greg.merkle@wright.edu>

Date: Mon, 11 Apr 2005 16:25:29 -0400

To: Eugene Hern <eugene.hern@wright.edu>, James Lucot <james.lucot@wright.edu>

FYI

Greg-

----- Original Message -----

Subject:[CSHEMA-L] FW: Interesting article about the new select agent rules

Date:Mon, 11 Apr 2005 16:17:39 -0400

From: Gillum, David David.Gillum@UNH.EDU

Reply-To:cshema-l: Discussion list for CSHEMA members < CSHEMA-L@LISTS.UMN.EDU>

To:CSHEMA-L@LISTS.UMN.EDU

Hi All,

The Howard Hughes Medical Institute's Winter 2005 Bulletin has an article about the new select agent rules. The article is called, "Rules, Regs, and Red Tape," by Marlene Cimons and is available online at:

http://www.hhmi.org/bulletin/winter2005/bioterror/

The HHMI Bulletin can be found here:

http://www.hhmi.org/bulletin/

Cheers!

Source: IBC Archive | The Sunstine Project FQ Fund | www.sunshine-project.org

March 8, 2005

E107 Student Union.

A quorum of 7 members and one alternate was present. Members Present: Susan Halm, Eugene Hern (Alternate), James Lucot (Chair), Peter Lurker, Mark Mamrack, Greg Merkle, John Paietta, and Dawn Wooley.



- A. The Chair called the meeting to order at 3:07 P.M.
- B. There were no Minutes available for review.

C Continuing Reviews Administratively Reviewed

Since the last review, there have been no changes made in these protocols other than those amendments already approved. The committee noted the following administrative actions/approvals/requests.

IBC# 068 Cloning And Expression Of Calcium Transporters From Crayfish Procambarus Clarkii

Michele Wheatly, Ph.D.

IBC# 069 Sarcoptes Scabiei Var. Canis

Larry G. Arlian, Ph.D.

IBC# 070 Human Serum Transport, Processing and Analysis

Larry G. Arlian, Ph.D.

Minutes - IBC

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

D. Certifications of Current IBC Approval Received

None.

E. Responses to Concerns Received, Approval Recommended

The Committee noted that the following Responses were received, reviewed by the Chair and Institutional Biosafety Officer, and final approval by the University Official is now recommended:

IBC# 112 TGF beta signaling, Apoptosis And Implantation

Thomas L. Brown, Ph.D.

IBC# 114 Cultivation Of Escherichia Coli And Salmonella spp.; Preparation of DNA and RNA from Cultures

Oleg Paliy,

F. Protocols Declared Inactive

None.

G. Deferred/Tabled Protocols

IBC# 116 Cell Culture Of Neuroblastoma (N1E-115), neuroblastoma x glioma (NG108-15) Cell Lines And Rat Astrocytes

Francisco J. Alvarez-Leefmans, Ph.D.

The Committee fully reviewed this revised (3-7-05), previously deferred protocol and agreed to approve this activity.

Summary of Votes to Recommend Approval of this Protocol:

Minutes - IBC March 08, 2005

H. Miscellaneous (SR Bisiless Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

None.

I. Amendments to Currently Approved Protocols

IBC# 062 , Amendment #2 Gene Transfer By Retroviral Delivery

Thomas L. Brown, Ph.D.

After fully reviewing this proposed amendment and complete protocol, the Committee recommended approval.

Summary of Votes to Recommend Approval of this Amendment:

Minutes - IBC March 08, 2005

IBC# 103 Source: JBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org Amendment #3 Transfection Of Eukaryotic Cells Using Expression Plasmids Encoding Human And Mouse Proteins

Madhavi Kadakia, Ph.D.

After fully discussing the proposed amendment and full protocol, the Committee recommended approval pending receipt of the following:

- 1. On the first page of the application under the protocol application title all participants of the project are asked to be listed. The form application form does not list any other persons in the lab participating in this project. If others are involved please provide names, if there are no others involved please state "none".
- 2. On the first page of the application under the section titled "Biohazard Use Summary" where the summary of biohazards are listed, see Section A, the protocol biohazards are marked as being present with the exception for "Chemical and biological toxins, carcinogens, mutogens or teratogens". In the following section of the protocol application under "Specific Biohazard Summary" item A such materials are indicated to be in use (Ethidium Bromide, Retinoic Acid, etc.). Please correct to clearly identify whether or not these materials, chemical and biological toxins, carcinogens, mutogens or teratogens, are or will be in use in this protocol.
- 3. Under Section D of the "Specific Biohazard Summary", where it is asked if work involves microorganisms, it is stated "No" but an agent is listed (Ecoli DH5alpha). Please clarify or correct the provided information.
- 4. Under section E of the "Specific Biohazard Summary" where it is asked if the protocol involves work with recombinant DNA please describe procedures to be used to harvest plasmid and eukaryotic DNA for subsequent analysis.
- 5. Also under Section D, information is requested on rDNA containment method(s) to be used and to clarify the statement of "All handling of bacterial cultures and plasmid DNA will adhere to standard laboratory procedures". What are the containment practices to be used?
- ***The above restrictions have been removed upon receipt of a revised amendment dated 3-22-05 from the PI indicating that he/she has complied with the restrictions placed on this study by the IBC. This study now has final approval and the Principal Investigator may proceed with this research protocol.

Summary of Votes to Recommend Approval of this Amendment:

Minutes - IBC

March 08, 2005

J. Amendments Requiring Only Notice Little of the Committee FOI Fund | www.sunshine-project.org

None.

K. New Protocols Requiring Full Review

IBC# 119 Activity And Neurotrophin Effects On spinal Synapses

Timothy Cope, Ph.D.

After fully discussing the protocol, the Committee recommended approval pending receipt of the following:

- 1. Provide the precautions to be taken between implantation and removal (e.g., during the in-vitro phase).
- 2. Petition Cover Page: Clarify the biohazard location(s) during surgery, housing and experimentation phases.

Summary of votes to approve this protocol pending the following:

8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

IBC# 120 Cultivation Of Escherichia Coli And Overexpression Of Proteins In Fully Deuterated Minimal Medium

Oleg Paliv,

After fully discussing the protocol, the Committee recommended approved pending receipt of the following:

- 1. In the project summary clarify that aerosols will be generated and provide the containment procedures and safety precautions.
- 2. Please sign the petition.

Summary of votes to approve this protocol pending the following:

IBC# 121 Characterization of Escherichia Coli Strains Isolated From Fruman

Intestine Or Urinary Tract

Oleg Paliy,

After reviewing this complete protocol, the Committee agreed to approve this activity.

Summary of votes to approve this protocol:

8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

IBC# 122 Engineering Of Gene Circuits And Biosensors In Escherichia Coli Cells

Oleg Paliv,

After fully discussing the protocol, the Committee recommended approval pending receipt of the following:

- 1. Section D: Specify the strain of E.coli that will be used.
- 2. Sections D and E: Strike the sentence, "negligible change of creating aerosols ...".
- 3. Section E: Clarify why "III-F.6 is boxed.
- 4. Project Page: Clarify the plasmid introduced into the E.coli host strain.

Summary of votes to approve this protocol pending the following:

8 voting members present (7 members and 1 alternate); 8 "yes" votes, none opposed.

L. New Protocols Administratively Approved

None.

M. Continuing Reviews Requiring Full Review

Minutes - IBC	March 08, 2005
N. Miscellaneous New Business rchive The Sunshine Project / FOI Fund www.su	nshine-project.org
None.	
O: Subcommittee Reports	
1. The Committee was updated on revision of the petition forms. The changes discussed at the retreat are still being finalized and should be available for review at the next meeting.	

P. Environmental Health & Safety

1. Greg Merkle updated the Committee on EHS activities (see attachment #1 for details).

Q: Topics Requiring Committee Action

None.

R Information

S. Adjournment

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

The Committee adjourned at 3:42 P.M.

The next scheduled meeting will be held on April 12, 2005

Respectfully submitted.

James B. Lucot, Ph.D.

11/17/01 Date

Chair, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Date

Vice President for Research

(Institutional Official)



ce: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org
Department of Environmental Health & Safety

(937) 775-2215

Fax (937) 775-3761

IBC Minutes 3-8-05 Attachment #1

DATE:

March 8, 2005

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the Last Meeting of the Institutional Biosafety Committee,

February 8, 2005

For the Committee meeting of March 8, 2005:

- 1. Biological safety cabinets are being surveyed. There are several cabinets that are past due to be surveyed, this is being addressed.
- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 3. A long term goal is to establish an inventory system for biological materials (including select agents) in possession.
- 4. The department is working obtaining a training program for preparing packages containing diagnostic, infectious, hazardous or radiological materials for transportation according to the DOT regulations. The goal is to train two persons from each of seven other departments is being planned for the first part of 2005.
- 5. Jerry is retiring from the university on March 31, 2005. As a result, there may be a need to reevaluate priorities assigned to each individual in the Department.

February 8, 2005

Members Present: Susan Halm, Eugene Hern (alternate), James Lucot (Chair), Peter Lurker, Mark Mamrack, Greg Merkle, John Paietta, Harold Stills, and Dawn Wooley. The voting reflects that some members were not in attendance at various times.



- A. The Chair called the meeting to order at 3:01 P.M.
- B. A typo on the agenda indicated a review of Minutes, however there were no Minutes available for review.

C. Continuing Reviews Administratively Reviewed

Since the last review, there have been no changes made in these protocols other than those amendments already approved. The committee concurred with the following administrative actions/approvals/requests.

IBC# 071 Molecular Genetics Of Sulfur Metabolism In Neurospora crassa

John V Paietta, Ph.D.

After reviewing the protocol and proposed continuation, the Institutional Biosafety Officer recommended approval.

IBC# 073 Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

Mark D. Mamrack, Ph.D.

After reviewing the protocol and proposed continuation, the Institutional Biosafety Officer had the following request(s) for information prior to his recommendation to the IBC:

1. Item 2 of the cell culture room procedures do not meet the requirements of the OEPA guidelines for the disposal of infectious liquid waste. Please clarify the response by referring to the WSU BioSafety Manual Appendix D., page 6, Procedures for WSU infectious waste generators, Item #3. Should you have further questions, please contact Steve Farrell at extension 3118 or Tom Dyer at extension 3788.

IBC# 083 The Regulation Of Protein Synthesis And Degradation

Patrick B. Dennis, Ph.D.

After reviewing the protocol and proposed continuation, the Institutional Biosafety Officer had the following request(s) for information prior to his recommendation to the IBC

1. Clarify the research laboratory location for this study.

IBC# 084 Oxidative Stress And Gene Expression In Glioma Cells

James E. Olson, Ph.D.

After administrative review of this continuing review and full protocol, the request was recommended for approval.

IBC# 085 Neutrophil/Endothelium/Pathogen Injury and Atherosclerosis

Julian Gomez-Cambronero, Ph.D.

After reviewing the protocol and proposed continuation, the Institutional Biosafety Officer had the following request(s) for information prior to his recommendation to the IBC

- 1. Have all persons handling blood received bloodborne pathogen training and offered, received or had the opportunity to deline the receipt of the HBV vaccination that are part of the bloodborne standard?
- 2. Have all persons handling blood received bloodborne pathogen training? If not, training needs to be received before things continue.
- 3. Are the biological safety cabinets being used as part of this protocol to contain aerosols? If not being used, please explain why.

IBC Minutes - p. 2



IBC# 087 Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org
Cyano Bacteria (Blue-Green Algae) Toxins: Isolation and
Characterization

Wayne Carmichael, Ph.D.

After reviewing the protocol and proposed continuation, the Institutional Biosafety Officer had the following request(s) for information prior to his recommendation to the IBC

- 1. Is this the protocol that included the use of flamingo tissue samples that required the USDA permit for the tissue samples? If yes, need a copy of the letter or memo permitting possession and use of the tissue samples.
- 2. The protocol lists the use of sera and liver samples. Samples from human or other? If human tissue used, information is needed for coverage and inclussion under the OSHA Bloodborne Pathogen Standard.

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None.

E. Responses to Concerns Received, Approval Recommended

None.

F. Protocols Declared Inactive

G. Deferred/Tabled Project | C Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

IBC# 115 Brain Angiotensin AT Receptor Subtypes Regulate Blood Pressure And Heart Rate In Mice

Yangfang Chen, Ph.D.

After reviewing the revised protocol received 2-8-05, the committee recommended approval pending the following:

- 1. Reflect the correct title and IBC protocol number which correlates with work to be done. Date all revisions with the date of revision/submission.
- 2. In an earlier version (Receptor binding in tissue slices:) of this protocol, number 8 states, "...cryostat and the blade will be thawed ..." include this information in the revised protocol.

Summary of Votes to Recommend Approval of this Protocol:

A CONTRACTOR OF THE CONTRACTOR

9 Voting Members Present (8 Members, 1 Alternates); 9 "Yes" Votes, None Opposed.

** It is recommended that bleach concentrations and holding times be adjusted to one value for each, 15% bleach and holding for at least 20 minutes. Information to be consisted with the concentrations are listed in the University Infectious Waste Management Guide.

The above restrictions have been removed upon receipt of a revised protocol dated 3/9/05 from the Pl indicating that he/she has complied with the restrictions placed on this study by the IBC. This study now has final approval and the Principal Investigator may proceed with this research protocol.

H. Miscellaneous Old Business

1. A revised draft of protocol application was presented to the Committee with several suggestions for their review and comments. The Committee agreed that before approving the new form, an independent source should review the revised application.

Minutes - IBC

February 08, 2005

T. Amendments to Currently Approve rotocols hine Project / FOI Fund | www.sunshine-project.org

IBC# 062, Amendment #1 Gene Transfer By Retroviral Delivery

Thomas L. Brown, Ph.D.

After reviewing the proposed amendment and complete protocol, the Committee recommended approval with the notation that approval was only for the genes listed and that additional genes will require an approved amendment prior to use.

Summary of Votes to Recommend Approval of this Amendment:

9 voting members present (8 Members, 1 Alternate); 9 "Yes" votes, None Opposed.

		y Notification	

None.

K. New Protocols Requiring Full Review

None.

L. New Protocols Administratively Approved

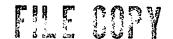
IBC# 118 Plasma Sample Processing

Yangfang Chen, M.D. Ph.D.

- ** After reviewing the protocol, the Institutional Biosafety Officer had the following request(s) for information prior to approval:
- 1. Refer to the Infectious Waste Management Guide, Appendix D of the Institutional Biosafety Manual, for proper handling procedures, definitions of infectious waste and the management of sharps. A revised statement is needed for handling of materials for disposal based on the Management Guide.

A revised protocol, dated 2-8-05 was submitted just prior to this meeting. It was determined that perhaps the IBC should review this protocol. After reviewing the complete revised protocol, the committee agreed to concur with protocol approval with one administrative change, deletion of "At this point ... inactivate any virus." from point 6 of the project summary.

IBC Minutes - p. 5



Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org Summary of votes to concur v. ... the recommended approval of this/th. protocol(s):

9 voting members present (8 members, 1 alternate

M. Continuing Reviews Requiring Full Review

IBC# 062 Gene Transfer By Retroviral Delivery

Thomas L. Brown, Ph.D.

After reviewing the continuing review request and complete protocol, the Committee recommended approval with the notation that approval was only for the genes listed and that additional genes will require an approved amendment prior to use.

Summary of Votes to Recommend Continuing Review Approval of this Protocol:

9 voting members present (8 Members, 1 Alternate); 9 "Yes" votes, None Opposed.

IBC# 067 Interactions Between HIV-1 Rev and Microtubules

Mill W. Miller, Ph.D.

After fully reviewing this request for continuation and full protocol, the committee recommended approval pending the following:

1. Specify that Level 2 practices will be maintained while working with HeLa.

Summary of Votes to Recommend Continuing Review Approval of this Protocol:

9 voting members present (8 Members, 1 Alternate); 9 "Yes" votes, None Opposed.

IBC# 095 Active Potassium Transport Across Colonic Epithelium

Dan R. Halm, Ph.D.

After fully reviewing this request for continuation and full protocol, the Committee recommended approval.

Summary of Votes to Recommend Continuing Review Approval of this Protocol:

8 voting members present (7 Members, 1 Alternate); 8 "Yes" votes, None Opposed.

S. Halm, who is a member of the Committee and listed on the protocol, was not present during deliberation and vote on this protocol.

- 1. The calendar of IBC meetings and protocol dealines was approved and will be loaded onto the RSP web page with the exception of the meeting place.
- 2. The Chair requested suggestions for a new community member to join the IBC.

Summary of Votes to Approve the 2005 IBC Schedule as follows: 9 voting members present (8 Members, 1 Alternate); 9 "Yes" votes, None Opposed.

3. The Chair and Coordinator (and possibly the biosafety officer) will meet with the institutional official regarding an outside review (e.g., 2-3 outside reviewers, review protocols and policies, possible site visit).

O. Subcommittee Reports

None.

P. Environmental Health & Safety

1. Greg Merkle updated the Committee on EHS activities (see Attachment #1).

O. Topics Requiring Committee Action

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

R' Information

None.

S. Adjournment

The Committee adjourned at 4:45 P.M.

The next scheduled meeting will be held on Mar 07, 2005

Respectfully submitted.

James B. Lucot

Date

Chairer, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Date

Vice President for Research

(Institutional Official)



WRIGHT STATE UNIVERSITY

(937) 775-2215 Fax (937) 775-3761

DATE:

February 8, 2005

Attachment #1

IBC Minutes 2-08005

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the Last Meeting of the Institutional Biosafety Committee,

January 21, 2005

For the Committee meeting of February 8, 2005:

- 1. Biological safety cabinets are being surveyed. There are several cabinets that are past due to be surveyed, this is being addressed to correct.
- 2. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 3. A long term goal is to establish an inventory system for biological materials (including select agents) in possession.
- 4. The department is working obtaining a training program for preparing packages containing diagnostic, infectious, hazardous or radiological materials for transportation according to the DOT regulations. The goal is to train two persons from each of seven other departments is being planned for the first part of 2005.
- 5. Jerry is retiring from the university on March 31, 2005. As a result, there may be a need to reevaluate priorities assigned to each individual in the Department.

FILE COPY

MINUTES

Institutional Biosafety Committee Retreat January 21, 2005

Members Present: Jack Bernstein, Susan Halm, Eugene Hern (alternate), James Lucot (Chair), Peter Lurker, Mark Mamrack, Greg Merkle, John Paietta, Harold Stills, Dawn Wooley. The voting reflects that some members were not in attendance at various times. Also in attendance was one guest, Isabelle Gorrillot, D.Sc., Associate Director for Technology Transfer.

I. Call to Order

The retreat portion of the meeting convened at 10:45 A.M. with a welcome to the Committee and guest.

II. Revision of Protocol Review Process

The Chair initiated a discussion regarding the general protocol review process. Several items were discussed including different protocol review schemes (including the current process) along with their shortcomings, the problem of investigator's adding additional materials to protocols without committee notification (e.g., without amendment), and the effects of possible reorganization of Environmental Health and Safety (EHS) on protocol review.

- A. The addition of a "Triage" step in the review process was discussed. This step would be designed to pre-screen protocols for completeness and sufficient details.
- B. After much discussion, it was decided that all protocols will be reviewed through a triage method. The biosafety officer will unofficially review protocols for potential oversights, omissions, clarifications prior to full committee review, and appropriate BSL level. Review mechanisms shall be as follows:
 - 1. BSL1 protocols may be approved administratively or deferred to full committee.
 - 2. BSL2 protocols will be reviewed by the committee using a primary reviewer.
 - 3. BSL2+ and BSL3 protocols will be reviewed using a primary & secondary reviewer.

The Biosafety Officer may recommend approval of continuing reviews and amendments or defer them to the IBC for full review.

C. Several ideas were discussed to curtail the addition of materials to protocols without amendment. Included were: a central receipt point for biologicals, notification of authorized materials at continuing review for verification, notification of authorized materials upon protocol approval with note that any additions require committee approval, investigator education, and a mechanism for agent registration before purchase.

- D. To facilitate Item C. above, it was decided that the revised petition will carry a statement indicating that it is 'approved only for the biologicals listed in the petition/approved protocol and that any changes to the protocol (e.g., in organisms, vectors, procedures, personnel, etc.) must be approved by amendment prior to use/implementation.'
- E. Several methods keeping track of biological agents on campus were discussed including upgraded protocol forms, establishment of a database, and through disposal records, It was, however, noted that the institute can only control "Select Agents".
- F. It was further noted that due to EHS' reorganization, the Biosafety Officer's work load, and the rising complexity of agents being requested, there may be a need to consider appointment of a Biosafety Officer having an expertise in the biological sciences and in the area of biological safety (e.g., Certified Industrial Hygienist).
- Note for the Record: At 11:45 A.M. the meeting was adjourned for lunch. The meeting reconvened at 1:20 P.M.
 - III. D. Wooley preceded her review of the IBC Protocol Petition with a brief discussion of Serum Banking, specifically when conducting HIV research. Several papers and documents were referenced during this discussion including:
 - 1. Igor S. Lukashevich, ET. al., Hemorrhagic Fever Occurs After Intravenous, But Not After Intragastic, Inoculation of Rhesus Macaques With Lymphocytic Choriomeningitis Virus, J. Med. Virology, 67:171-186 (2002)
 - 2. Igor S. Lukashevich, et. al., Arenavirus-Mediated Liver Pathology: Acute Lymphocytic Choriomengitis Virus Infection of Rhesus Macaques Is Characterized by High-Level Interleukin-6 Expression and Hepatocyte Proliferation, J. Virology, 77.3:1727-1737 (2003)
 - 3. Burkhard Ludewig, et. al., Hypercholesterolemia Exacerbates Virus-Induced Immunopathologic Liver Disease Via Suppression of Antiviral Cytotoxic T Cell Responses, J. Immunology, 166:3369-3376 (2001)
 - 4. University of Florida HIV Research Laboratory Occupational Medicine Policy (4/5/99)

Aspects discussed were should serum banking be mandatory (e.g., storage only, testing, voluntary) and 'escape' procedures (e.g., timing, mechanism). Special consideration should be given to the use of Lenti vectors, etc.

It was decided that this issue would be revisited as "Old Business" at upcoming meeting(s).

IBC Retreat Minutes Archive | The Sunshine Project / FOI Fund | www.sunshine project org January 21, 2005

IV. Review Of Protocol Petition Form (D. Wooley)

The remainder of the retreat was spent reviewing several models for revising our IBC petition and discussing proposed revisions. After reviewing other institution's forms and concluding the needs of WSU/IBC, the subcommittee presented a revised petition to the full IBC. Features such as electronic drop-down lists, charts, and precise questions would facilitate efficiency for the P.I. while giving the Committee a more in depth description of the materials and how they would be handled. After a lengthy presentation and discussion with further suggestions, it was decided that the committee should review the revised petition independently and submit any suggestions to the subcommittee. It was further noted that further review, discussion, and possible vote approving the revised petition would take place at a following meeting.

V. Additional Material Distributed:

- 1. MIT Document Describing BSL2+ SOP's
- 2. Upcoming PRIM&R IBC Basics workshop, March 13, 2005, San Diego, CA

X. Adjournment

There being no further meeting time, the Committee adjourned at 4:45 P.M.

The next scheduled meeting will be held on Tuesday January 4, 2005 at 3:00 P.M.

Respectfully submitted.

Jame & Luco	7/26/05
James Lucot, Ph.D.	Date
Chair, Institutional Biosafety (Committee

Receipt of Minutes acknowledged and recommendations: approved _____ disapproved ____

Joseph F. Thomas, Jr.
Vice President for Research
(Institutional Official)

January 21, 2005

WSU Kettering Center

Members Present: Susan Halm, Eugene Hern (alternate), James Lucot (Chair), Peter Lurker, Mark Mamrack, Greg Merkle, John Paietta, Cassandra Paul, Harold Stills, and Dawn Wooley. The voting reflects that some members were not in attendance at various times.



- A. This being a portion of the IBC Retreat, the Chair called the business portion of the meeting to order at 9:00 A.M.
- B. The Minutes of the October 12, 2004 and November 9, 2004 meetings were reviewed and they were determined to accurately reflect the business conducted at those meetings.
 - 8 Voting Members Present (7 Members, 1 Alternate); 8 "yes" Votes, None Opposed.

C Continuing Reviews Administratively Reviewed

IBC# 077 Plasmid-Encoded DNA's As Vaccines For Stimulation Of Cytotoxic Thymocyte (CTL) Responses And Stimulation Of Protective Immunity In Primary HSV-1 Challenge And In Reactivated HSV-1 Infection

Nancy J. Bigley, Ph.D.

IBC# 105 Motoneuron Infection In Vivo With Viral Vectors

Francisco J. Alvarez, Ph.D.

IBC Minutes - p. 1

IBC# 108 Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

John V. Paietta, Ph.D.

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None.

D. Certifications of Current BC Approval Received

None.

E. Responses to Concerns Received, Approval Recommended

F. Projects Declared Inactive Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

The Committee noted that the following IBC protocols are now declared inactive:

IBC# 054 Analysis Of Human Blood, Saliva And Urine For Genetic Risk Factors Of Cardiovascular Disease And Autism

Mariana Morris, Ph.D.

IBC# 055 TGFbeta Signaling In Apoptosis And Implantation

Thomas L. Brown, Ph.D.

IBC# 059 Expression Of Muscarinic Receptor DNA In Competent E. coli DH5a

Robert D. Grubbs, Ph.D.

IBC# 066 Use Of LA-N-1 Cell Line For Expressing recombinant DNA Constructs

Robert D. Grubbs, Ph.D.

IBC# 100 Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org Acetylcholine Receptor Function

Robert D. Grubbs, Ph.D.

eferr)			

None.

H: Miscellaneous Old Business

BSL-3 Facility Update: During a previous site visit to the level 3 facility, the IBC proposed several recommendations. With the air flow (negative pressure) confirmed per the October 12, 2004 meeting, these recommendations have been completed and the IBC is satisfied that it meets the criteria for BSL-3 use.

I Amendments to Currently Approved Protocols

IBC# 069, Amendment #1 Sarcoptes Scabiei Var. Canis

Larry G. Arlian, Ph.D.

This request to add personnel (one research associate and three M.S. students) dated 12-13-04 from the Principal Investigator was reviewed by the Senior Industrial Hygenist and Chair. Approval was granted 1/5/05.

IBC# 070 , Amendment #1 Human Serum Transport, Processing and Analysis

Larry G. Arlian, Ph.D.

This request to add personnel (one research associate and three M.S. students) dated 12-13-04 from the Principal Investigator was reviewed by the Senior Industrial Hygenist and Chair. Approval was granted 1/5/05.

IBC# 098, Amendment #1 Human Blood Monocyte Isolation And Culturing

Larry G. Arlian, Ph.D.

This request to add personnel (one research associate and 3 M.S. students) dated 12-13-04 from the Principal Investigator was reviewed by the Senior Industrial Hygenist and Chair. Approval was granted 1/11/05.

IBC# 099 , Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org Culturing Of Normal Human Epiderman Keratinocytes (NHEK) And Dermal Fibroblasts (NHDF)

Larry G. Arlian, Ph.D.

This request to add personnel (one research associate and 3 M.S. students) dated 12-13-04 from the Principal Investigator was reviewed by the Senior Industrial Hygenist and Chair. Approval was granted 1/11/05.

K. New Protocols Requiring Full Review

IBC# 112 TGF beta signaling, Apoptosis And Implantation

Thomas L. Brown, Ph.D.

After fully discussing the protocol, the Committee recommended approved pending receipt of the following:

- 1. In the project summary clarify that aerosols will be generated and provide the containment procedures and safety precautions.
- 2. Please sign the petition.
- 10 Voting members present (9 members 1 alterntate); 10 "yes" votes, none opposed.

IBC# 114 Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org Cultivation Of Escherichia Coli And Salmonella spp.; Preparation of DNA and RNA from Cultures

Oleg Paliy,

After fully discussing the protocol, the Committee recommended approved pending receipt of the following:

- 1. Please provide the species and strains.
- 2. Provide the source and catalog number.

10 Voting members present (9 members 1 alterntate); 10 "yes" votes, none opposed.

IBC# 115 Brain Angiotensin AT Receptor Subtypes Regulate Blood Pressure And Heart Rate In Mice

Yangfang Chen, Ph.D.

After fully discussing this protocol, the Committee deferred further action pending receipt of the following:

- 1. Parafilm is not acceptable to seal cage holes. Consult with the WSU Veterinarian for appropriate Method(s).
- 2. Define "air flow cabinet" as used in your response to question #9 of the previous restrictions. Note the fume hoods are not acceptable for BSL2 procedures.
- 3. Information still needs to be provided as to how the tissue will be processed after removal from the -80 degree freezer (e.g., how handled, what culture extracts made, containment methods, etc.). As an alternate, provide experimental evidence (e.g., peer-reviewed articles) proving that it is safe to go from BSL-2 to BSL -1 after the length of time proposed. It would also be helpful to discuss the differences in handling these brains compared to noninfected brain tissue.
- 4. Please have this protocol reviewed for spelling and grammar errors.

IBC# 116 Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org | Cell Culture Of New colastoma (N1E-115), neuroblastoma x | glioma (NG108-15) Cell Lines And Rat Astrocytes

Francisco J. Alvarez-Leefmans, Ph.D.

After fully discussing this protocol, the Committee deferred further action pending receipt of the following:

- 1. Page #5 (top): Clarify the concentration of the alpha toxin and the LD50 in ng/kg body weight. Please note that approval is only being given for maintenance levels of the toxin at less than 5 mg.
- 2. Provide more specific details regarding the culturing and use of the toxin. Attach the MSDS as this protocol must stand alone.
- 3. Since BSL-2 procedures as recommended are being used, change level designation to BSL-2. Discuss these handling procedures when using toxin culturing.

IBC# 117 MAP Kinase Regulation Of G-CSF-Induced Neutrphil
Proliferation

Michael A. Baumann, M.D.

After fully discussing the protocol, the Committee recommended approval of this research project.

9 Voting members present (8 members 1 alterntate) 9 "yes" votes, none opposed.

Note For The Record. A member of the Institutional Biosafety Committee who was listed as personnel was not present during the discussion nor vote of this protocol.

L.. New Protocols Administratively Approved

M, Continuing Reviews Requiring Full | The washine Project / FOI Fund | www.sunshine-project.org

IBC# 092 DNA Repair

Steve M. Patrick,

After fully discussing the request for a continuing review and the complete protocol, the Committee recommended approval for an additional year or until its five (5) year expiration (which ever comes first) pending receipt of the following:

- 1. BSL-2, not BSL-1 is the recommended biosafety level for working with HeLa cells. Please provide details of the procedures and training for work at this level.
- 2. The original review approval of 2-4-03 was conditional on the biological safety cabinet in room 243 BH being repaired and certified. Clarify the location and certification status of the hood planned for this project.

Summary of Votes to Recommend Continuing Review Approval of this Protocol: 10 Voting members present (9 members 1 alterntate); 10 "yes" votes, none opposed.

IBC# 102 Growth Of LCMV In Cell Culture

Dawn P. Wooley, Ph.D.

This request for continuation and full protocol was reviewed and the Committee recommended approval for an additional year or until its five (5) year expiration (which ever comes first). The Committee further noted that all indications are that this work can continue at the BSL2+ level and that the P.I. is commended for her conscientiouness and have no problem with the work being conducted using BSL-3 practices.

Summary of Votes to Recommend Continuing Review Approval of this Protocol: 9 Voting members present (8 members 1 alterntate); 9 "yes" votes, none opposed.

Note For The Record. The PIL being a member of the Institutional Biosafety Committee was not present during the discussion nor vote of this protocol.

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IBC Minutes - p. 9

IBC# 106 Scherning Huntahive | The Sunshine Project / FOL Fund | www.sunshine-project.org

Michael Leffak, Ph.D.

This request for a continuation and the full protocol was reviewed and the Committee recommended approval for an additional year or until its five (5) year expiration, which ever comes first.

Summary of Votes to Recommend Continuing Review Approval of this Protocol:

10 voting mem	bers present (9 memb	pers 1 alternate); 10	"yes" votes, none opp	osed.	
N. Miscellaneous New E	Business!				
None.					
O. Subcommittee Repor	ts				
None.					
P. Environmental Health	& Safety				
None.					

Q. Topics Requiring Committee Action | The Sunshine Project / FOI Fund | www.sunshine-project.org

None.

R. Information

None.

S. Adjournment

The Committee adjourned at 10:45 A.M.

The next scheduled meeting will be held on Feb 01, 2005

Respectfully submitted.

Chairer, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr. Date

Vice President for Research

(Institutional Official)

December 14, 2004

• E103 Student Union

Members Present: Susan Halm, Eugene Hern (alternate), James Lucot (Chair), Mark Mamrack, Greg Merkle, Cassancra Paul, Harold Stills, Dawn Wooley. The voting reflects that some members were not in attendance at various times. Also in attendance were two guests, Isabelle Gorrillot, D.Sc., Associate Director for Technology Transfer, RSP and Steven Berberick, Ph.D., Associate Professor, Biochemistry.



- A. The Chair called the meeting to order at 3:07 P.M.
- B. There were no Minutes available for review.

C. Continuing Reviews Approved Administratively.

None.

D. Centifications of Current IBC Approval Received.

None.

IBC Minutes - p. 1

Minutes - IBC December 14, 2004

Responses to Concerns Received Ap Thai Recommended / FOI Fund | www. unshine-project.org

The Committee noted that the following Responses were received, reviewed by the Chair and Institutional Biosafety Officer, and final approval by the University Official is now recommended:

IBC# 110

HOX Gene Expression In Endometrial Neoplasias Lawrence S. Amesse, M.D.

F. Protocols Declared Inactive

The Committee noted that the following IBC protocols are now declared inactive:

IBC# 096

Comparison Of Quanti-FERON-TB with 2 Tuberculin Reagents In Health Care Workers And Evaluation Of The Clinical Relevance Of A Positive Tuberculin Test Past 72 Hours

David Tat, D.O.

G. Deferred/Tabled Protocols

IBC# 061

Production Of Retroviruses Expressing p53, Mdm2 or MdmX Steven J. Berberich, Ph.D.

As part of its continuing review process, the IBC reviewed the investigator's December 1, 2004 responses to the IBC previously-submitted questions. After fully discussing these responses, the investigator's verbal responses, and the complete protocol, the Committee recommended approval subject to or pending receipt of the following:

- 1. Since this work involves a known or suspected oncogene(s) and there is a potential for infectious exposure, the Committee requires that the procedures be conducted at BSL 2+ (BSL 3 practices in BSL 2 facilities). Procedures not involving known or suspected oncogenes may be conducted at BSL 2.
- 2. The centrifuge cups should be disinfected before removal from the biosafety cabinet after centrifugation of biohazardous agents.
- 3. Provide a description of the procedures used for handling and disposal of potentially infectious waste.
- 4. The Committee requires, that all lab personnel complete the Biosafety Training course, once the training course is made available.

Summary of votes to approve IBC#061 pending restrictions:

8 voting members present (7 voting members, 1 alternates); 8 yes votes, none opposed.

Note:For The Record. The Principal Investigator attended this meeting and presented his concerns as expressed in his 12/1/04 memo to the Committee This was followed by an extensive question answer — session with the Committee. Among the items discussed were the 12/01/04 responses, the general protocol and questions arising therefrom, material transfer agreements (M.I.A./License requirements, and the ———— oncogencity of the expression products. Upon completion of this session, the P.I. was not present during the discussion nor voic of this continuing review request.

IBC# 093

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

Brainstem Angiotensin AT1 Receptor Subtypes Regulate Blood Pressure and Heart Rate Variability and Baroreflex Function

Yanfang Chen, M.S., Ph.D.

After fully discussing this revised protocol, the Committee deferred further action pending receipt of the following:

- 1. On the Cover Page, any receiving and material storage area(s) should be included as Biohazard Locations.
- 2. On the Cover Page: The recombinant DNA Section (E) should be checked.
- 3. Specific Biohazard Summary, Item A: The Adenovirus is not a 'compound' or 'material' as defined in this section. Correct this response.
- 4. Specific Biohazard Summary, Item C (page 3) is not completed. Please answer yes or no. If yes, list the cells.
- 5. Specific Biohazard Summary, Item D (page 4): This is the appropriate section for the adenovirus information. Fully complete this section.
- 6. Make sure that all questions and sections of the petition are completed.
- 7. Procedure, Item #9: Sealing with duct tape is adequate for maintaining BSL-2 containment at this step. However, the Committee suggests there may be better methods for achieving this containment. Consult with the Veterinarian or LAR staff regarding this issue.
- 8. Procedure, Item #12: Brain and brainstem tissue is to be stored using BSL-2 procedures. Clarify the packaging of these materials, keeping in mind safety precautions should a power outage create thawing (e. g., tube with a cap, Ziploc bag).
- 9. Since safety practices must be maintained until all material is noninfectious, please describe how the tissue will be processed after removal from the -800 freezer.
- 10. Please type information into the Petition in the future to avoid misunderstanding due to the Committee's inability to read the petition.

I. Amendments to Currently Approved | The Signishine Project / FOI Fund | www.sunshine-project.org

None.

J. Amendments Requiring Only Notification of the Committee

IBC# 057, Amendment #1

Cell Culture of neuroblastoma (N1E-115) and neuroblastoma x glioma (NG108-15) cell lines

F. J. Alvarez-Leefmans,

This request dated <u>1/16/04</u> involving the purchase and use of Alpha-Toxin from an outside lab was reviewed and approved by the Environmental Health and Safety Officer and the IBC Chair.

K. New Protocols Requiring Rull Review

IBC# 104

Gene Expression Profiling Of Lung Cancers In Alcoholic Patients Douglas E. Paull, M.D.

After fully discussing the protocol, the Committee recommended approval pending receipt of the following:

- 1. Provide an expanded protocol containing the complete details for the procedures used in this study (e.g., RNA isolation, cRNA construction, gene expression profiles, containment, etc.). In this expanded protocol, also address the questions posed in the Biosafety officer's memo of November 10, 2004.
- 2. Clarify the procedures for transfering the hazardous material between the DVA Hospital and WSU.
- 3. Clarify if the transport media (RNAlater) is a fixative. If not, then BSL-2 conditions must be followed until the tissue is either fixed or lysed.
- 4. As an aside, the latest approval for SC# 2960 was 08/27/04, not 09/08/04.

Summary of votes to approve IBC#104 pending restrictions:

8 Voting Members Present (7 Members, 1 Alternate); 7 "Yes" Votes, None Opposed, 1 "abstention".

The coxinvestigator was present during the initial discussion of this new profocol but was not present during the final discussion and vote:



Minutes - IBC December 14, 2004

IBC# 113

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

Regulation Of Cation Chloride Cotransporter Peter K. Lauf, Ph.D.

After fully discussing the protocol, the Committee recommended approval pending receipt of the following:

- 1. Clarify which human RBC (i.e., that from MVH or UofM) is the cord blood and specify the method for transporting hazardous material from MVH and for importing the material from UofM.
- 2. Clarify if IRB approval is needed for use of the two (2) human RBC samples. If not, clarify why not. If so, please provide a copy of the IRB approval to Chris Piekkola, RSP, 201J University Hall.
- 3. Specific Biohazard Summary, Section #E: A class and subdivision of rDNA activities of "III-C.2" does not exist. Provide the correct citation for the class and subdivision of rDNA activities proposed.

Summary of votes to approve IBC#113 pending restrictions:

8 voting members present (7 voting members, 1 alternates); 8 yes votes, none opposed.

L.. New Profocols Administratively Approved

None.

M. Continuing Reviews Requiring Bull Review

IBC# 062

Gene Transfer By Retroviral Delivery Thomas L. Brown, Ph.D.

This protocol was inadvertently placed on the agenda.

N. Miscellaneous New Business

1. Guest speaker Isabelle Gorrillot, SC.D., presented information (see attachment #1) and an extensive discussion regarding Material Transfer Agreement followed by a question/answer session.



Source: IBC Archive The Sunshine Project / FOI Fund | www.sunshine-project.org 2. A discussion of possible dates to hold a retreat resulted in a January date to be determined by committee poll via email.

O Subcommittee Reports

None.

P. Environmental Health & Safety

1. Greg Merkle updated the Committee on EHS activities (see attachment #3).

Q. Topics Requiring Committee Action

None.

R Information

The following was distributed to the IBC for their information:

- 1. The Committee was notified that NIH has been informed of a protocol violation involving a defective adenovirus vector. It was reported that to date, feedback from NIH had not been received.
- 2. A copy of a Dec. 6, 2004 memorandum from the NIH Office of Biotechnology Activities regarding recombinant DNA research and institutional biosafety committees was discussed with particular notice to paragraph #3 regarding "select sites" (see attachment #2).

S. Adjournment

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

The Committee adjourned at 5:45 P.M.

The next scheduled meeting will be held on Jan 11, 2005

Respectfully submitted.

James B. Lucot

1 101 01

Date

Chairer, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved

Dr. Joseph F. Thomas, Jr.

Date

Vice President for Research

(Institutional Official)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of Biotechnology Activities National Institutes of Health 6705 Rockledge Drive Sulte 750, MSC 7985 Bethesda, MD 20892-7985 (301) 496-9838 (Phone) (301) 496-9839 (Fax) http://www4.od.nih.gov/oba/

December 6, 2004

TO:

All Institutions Receiving NIH Funding

FROM:

Amy P. Patterson, M.D.

Director

NIH Office of Biotechnology Activities

SUBJECT:

Recombinant DNA Research and Institutional Biosafety Committees

The purpose of this memorandum is to remind NIH grant recipients of the importance of biosafety review and oversight for research involving recombinant DNA. This is a matter whose significance is enhanced as many institutions are undertaking new programs of research related to biodefense and emerging infectious disease threats, which often involve recombinant DNA technologies and require stringent attention to the proper containment of highly pathogenic organisms.

When institutions receive NIH funding for research involving recombinant DNA molecules, they must follow the provisions for containment and biosafety oversight set forth in the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). Compliance with the NIH Guidelines is mandatory; failure to adhere to the NIH Guidelines can result in suspension or termination of NIH funding for this type of research or lead to a requirement for prior NIH approval of any or all recombinant DNA projects at the institution. Further, compliance with the NIH Guidelines is critical to the safe conduct of research and to the fulfillment of an institutional commitment to the protection of staff, the environment, and public health.

In the coming year, the NIH will be conducting site visits at selected institutions to obtain further information on IBC compliance with the NIH Guidelines and to educate institutions more directly about requirements that apply to the conduct of recombinant DNA research. In the meantime, institutions are strongly encouraged to take stock of the portfolio of recombinant DNA research they are conducting and to verify that research projects are being registered and, as appropriate, approved by a duly-constituted Institutional Biosafety Committee (IBC).

Section IV-B-2 of the NIH Guidelines requires institutions to establish an IBC to review research subject to the NIH Guidelines and to oversee investigator compliance with the biosafety and reporting requirements set forth in the NIH Guidelines. Institutions must ensure that their IBCs are properly constituted and functioning in full compliance with the NIH Guidelines. Compliance includes:

Memorandum from Amy P. Patierson, M.D. Recombinant DNA Research and Institutional Biosafety Committees
December 6, 2004
Page 2 of 2

- Registering the IBC with the MIH Office of Biotechnology Activities; the registration must include (1) a roster of IBC members indicating their principal role on the committee (e.g., chair, contact person, expert in areas identified by the MIH the professional background and perspective of the individual. Preferably, these documents should not include private personal information (e.g., home address, Social Security Number);
- Filing a report at least annually that updates the committee roster and biosketches; and
- Ensuring that the IBC fulfills all the administrative, oversight, review and reporting functions described in Sections IV-B-2-a and IV-B-2-b of the MIH Guidelines.

The MIH Guidelines are accessible on the Internet at:

http://www4.od.nih.gov/oba/IBC/IBCnihguidelines.htm. Section III of the MIH Guidelines
describes categories of experiments subject to the MIH Guidelines and the attendant levels of
IBC notification and review. The definition of recombinant DMA is found in Section I-B.
Experiments exempted from the MIH Guidelines are listed in Section III-F. OBA is pleased to
assist with any questions concerning proper interpretation and implementation of the MIH
Guidelines.

More information about IBCs - including Frequently Asked Questions, slide presentations, and video of training sessions - can be found on OBA's Web site at http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm.

If you have questions about requirements associated with the NIH Guidelines, please contact Allan C. Shipp, Director of Outreach, at 301-435-2152 or at shippa@od.nih.gov

WRIGHT STATE UNIVERSITY

Department of Environmental Health & Safety

(937) 775-2215

Fax (937) 775-3761

DATE:

December 14, 2004

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industr

SUBJECT:

Activities Since the Last Meeting of the Institutional Biosafety Committee,

October 12, 2004

For the Committee meeting of December 14, 2004:

1. Reviewing of biosafety protocols continues.

- 2. Biological safety cabinets are being surveyed. There are several cabinets that are past due to be surveyed, this is being addressed to correct.
- 3. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 4. Dr. Carmichael's lab is seeking to become a USDA approved BSL2 facility. Paper work has been submitted to the USDA for approval. Mary Stukenberg from Dr. Camichael's lab was the contact person. On Thursday, December 9, 2004 the USDA visited the lab prior to approving it for conducting research and handling materials under USDA jurisdiction.
- 5. Continuation from the previous meeting: A long term goal is to establish an inventory system for biological materials (including select agents) in possession.
- 6. The personnel of the Department will be attending a training program on Thursday, December 16, 2004, for preparing packages containing diagnostic, infectious, hazardous or radiological materials for transportation according to the DOT regulations. Training for two persons from each of seven other departments is being planned for the first part of 2005.
- 7. Jerry is retiring from the university on March 31, 2005. There is a possibility the Department will be staffed with one less person which will result in a reevaluation of priorities assigned to each individual in the Department.

MINUTES stitutional Biosafety Committee.

November 9, 2004

Members Present: Susan Halm, Eugene Hern (alternate), James Lucot (Chair), Peter Lurker, Mark Mamrack, Greg Merkle, Dawn Wooley. The voting reflects that some members were not in attendance at various times.

r. The Chair called the meeting to order at 3:03 P.M.

B. There were no Minutes available for review.

Continuing Reviews Approved Administratively

None.

D. Certifications of Current IBC Approval Received

None.

E. Responses to Concerns Received, Approval Recommended

None.

F. Protocols Declared Inactive

None.

None.

H. Miscellancous Old Business

G. Deferred/Eabled Protocols

None.

I. Amendments to Currently Approved Protocols

None.

I. Amendments Requiring Ohly Monfacation of the Committee

None.

K. New Protocols Requiring Full Review

None.

L. New Protocols Administratively Approved

None.

M. Confinuing Reviews Requiring Full Review

None.

Miscellaneous Mew Business

None.

IBC Minutes - p. 2

November 09, 2004

O. Subcommittee Reports IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

1. Executive Session: On November 9, 2004, at approximately 3:03 P.M., the Chair entertained a motion for the Committee to go into Executive Session to review charges or complaints against a public employee, official, licensee or requested individual. The motion was made, seconded and approved by the following roll call vote:

Yes Susan Halm

Yes Eugene Hern

Yes James Lucot

Yes Peter Lurker

Yes Mark Mamrack

Yes Dawn Wooley

The Committee remained in Executive Session until approximately 5:03 P.M. on November 9, 2004, at which time the regular meeting resumed.

After thoroughly considering and discussing the subcommittee report presented to the IBC, the Committee will transmit recommendations to the Institutional Official.

Summary of votes for the above actions concerning the Executive Session:
7 voting members present (6 members and 1 alternate); 7 "yes" votes, none opposed

				Hea			

None.

Q. Topics Requiring Committee Action

None.

R. Information

None.

Vice President for Research

(Institutional Official)

October 12, 2004

E107 Student Union

Members Present: Susan Halm, Eugene Hern (alternate), James Lucot (Chair), Peter Lurker, Mark Mamrack, Greg Merkle, John Paietta, Harold Stills, and Dawn Wooley. The voting reflects that some members were not in attendance at various times.

- A. The Chair called the meeting to order at 3:00 P.M.
- B. The Minutes of the June 8, 2004 and August 17, 2004 meetings were reviewed and they were determined to accurately reflect the business conducted at those meetings.
 - 8 Voting Members Present (7 Members, 1 Alternate); 8 "yes" Votes, None Opposed.

C. Continuing Reviews Administratively Approved

Since the last review, there have been no changes made in these protocols other than those amendments already approved.

Summary of votes to concur with the following Continuing Reviews for an additional year or until their five (5) year expiration date, whichever comes first:

9 Voting Members Present (8 Members, 1 Alternate); 9 "yes" Votes, None Opposed.

IBC# 067

Ď,

Interactions Between HIV-1 Rev and Microtubules

Mill W. Miller, Ph.D.

IBC# 089

Genetic And Molecular Studies Of Caenorhabditis Elegans Scott Everet Baird, Ph.D.

IBC# 098

Human Blood Monocyte Isolation And Culturing Larry G. Arlian, Ph.D.

Minutes - IBC October 12, 2004

IBC# 099 Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

Cell Culturing Of Normal Human Epidermal Keratinocytes (NHEK) And Dermal Fibroblasts (NHDF)
Larry G. Arlian, Ph.D.

IBC# 101

Ī

Vasopressin Cytotoxicity In Inherited Diabetes Insipidus David R. Cool, Ph.D.

D. Certifications of Current IBC Approval Received

None.

E. Responses to Concerns Received, Approval Recommended

None.

F. Protocols Declared Inactive

The Committee noted that the following IBC protocols are now declared inactive:

IBC# 048

Proton & Chloride Regulation of K-C1 Transport Peter K. Lauf, M.D.

G. Deferred/Tabled Protocols

None.

H. Miscellaneous Old Business

1. A follow-up discussion of materials handled under several IBC protocols (IBC #062 and IBC #073) resulted in a request to have the Principal Investigators clarify the species. Once this information is received, a subcommittee will check the responses and determine approval. Further discussions concerning the MTA issues will be forthcoming.

Minutes - IBC	October 12, 2004
I. Amendments to Currently Approved. Ligatorolls hine Project / FOI Fund www.sunshine-project.	org
None.	
J. Amendments Requiring Only Notification of the Committee	
None.	
K. New Protocols Requiring Full Review	
. None.	
L. New Protocols Administratively Approved	
IBC# 111	
Clinical And Biophysical Studies In Human Blood	
Norma C. Adragna,	
The Committee concurred with the following administratively approved IBC protocol.	
9 voting members present (8 members, 1 alternate); 9 votes, none opposed.	
Summary of votes to concur with the recommended approval of this/these protocol(s): Some concur with the Recommended Approval of this/these Protocol(s):	ummary of Votes to
M. Continuing Reviews Requiring Full Review	
None.	
N. Miscellaneous New Business	
None.	

Minutes - IBC October 12, 2004

O. Subcommittee Reports IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

- 1. A pending continuing review for IBC#061; Production Of Retroviruses Expressing p53, Mdm2 or MdmX, was briefly discussed. Due to a preliminary discussion concerning appropriate biosafety level, the committee recommended that a full review be conducted at the next regularly scheduled meeting to discuss consideration of updated safety level, vector use, etc. It was further noted that the PI would be notified of this review and encouraged to reply to questions posed in Chair's memo dated July 29, 2004 (see attachment #1).
- 2. Executive Session: On October 12, 2004, at approximately 3:55 P.M., the Chair entertained a motion for the Committee to go into Executive Session to review charges or complaints against a public employee, official, licensee or requested individual. The motion was made, seconded and approved by the following roll call vote:

Yes Susan Halm

Yes Eugene Hern

Yes James Lucot

Yes Peter Lurker

Yes Mark Mamrack

Yes Greg Merkle

Yes John Paietta

Yes Harold Stills

Yes Dawn Wooley

The Committee remained in Executive Session until approximately 4:25 P.M. on October 12, 2004, at which time the regular meeting resumed.

During the Executive Session, the Committee was briefed on an on-going concern that was brought to the Committee's attention. A subcommittee has been appointed and is in the process of information gathering. No further action is required at this time.

P. Environmental Health & Safety

Committee update by the Institutional Biosafety Officer was presented and discussed as shown in Attachment #2 dated October 11, 2004.

Added to this report was the information that the air-flow check has been completed on the BSL-3 facility and a definite negative air-flow (i.e., negative pressure) is confirmed.

Regarding Item #4, since the five non-responding researchers had previously indicated that they have no select agents or toxins, the Committee feels that no further action if needed.

Vice President for Research (Institutional Official)

Doto

Date



IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org IBC Hinutes (10/12/64) A TACHMENT #7

Health and Safety 3640 Colonel Glenn Hwy. Dayton, OH 45435-0001 (937) 775-2215 FAX (937) 775-3761

DATE:

July 29, 2004

IBC 061

TO:

Stephen Bererich, Ph.D.

Associate Professor, Department of Biochemistry and Molecular Biology

FROM:

James Lucot, Ph.D.

Chair, Institutional Biosafety Committee

SUBJECT:

Clarification Requested for Procedures Outlined in Your IBC Protocol No. 061,

Production of Retroviruses Expressing p53, Mdm2 or MdmX, as Submitted for

Annual Review on April 4, 2004

At the request of the Institutional Biosafety Officer your IBC Protocol Application, Production of Retroviruses Expressing p53, Mdm2 or MdmX, was referred to the Institutional Biosafety Committee for review and annual approval. With the Application to be discussed by the full Committee it was assigned to a member of the Committee for review prior to the Committee's June 8, 2004 meeting. The review of the Application and the discussion during the Committee meeting produced questions or statements requiring answers or clarification before the Committee can vote to approve the annual renewal request at their next meeting.

The open questions from the June 8, 2004 Committee meeting that need to be answered or clarified are as follows:

- 1. What the species of the retrovirus being produced from the two systems listed in the project? Specifically, is it HIV-1 or MLV? If so, what vectors are being transfected into the helper cell lines (293FT and 293-derived Phoenix ampho) and what are the sources of the vectors?
- 2. What type of quality control experiments are being carried out to ensure that wild-type retrovirus has not been generated through the process of recombination?
- 3. If HIV-1 is generated then (a) what are the safety precautions to prevent accidental exposures and (b) are people working with the generated virus material aware of the potential hazards and given appropriate training for the safe handling of the virus?
- 4. Are virus stocks being centrifuged? If so, are centrifuge safety cups being used where are they being opened (due to potential aerosol development)?
- 5. While the application states that "The retroviral vectors pose no risk outside their propagating hosts (prokaryotic or eukaryotic)," but does the generated waste meet the definition of infectious waste as described by the Ohio EPA? It is also unclear how plates and solid waste that is generated by these procedures is being disposed. Is the solid waste

Subject: Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

Production of Retroviruses Expressing p53, Mdm2 or MdmX, as Submitted for Annual

Review on April 4, 2004

Date:

July 28, 2004

Page 2

going to trash or to the infectious waste box? What is the concentration of bleach and holding time used prior to disposal of liquid waste?

- 6. Does a signed Material Transfer Agreement (MTA) exist for receiving the 293-derived Phoenix ampho cell line from Tom Brown's lab? Does the Office of Research and Sponsored Programs have MTA information for the distribution of this cell line?
- 7. The Application states that chemical or biological toxins, carcinogens, mutagens or teratogens are not being used with this research. Do the experiments that are described in the Application require the use of chemicals such as acrylamide, ethidium bromide and G418 which are considered to be toxic, mutagenic or teratogenic?

The next meeting of the Institutional Biosafety Committee is scheduled for Tuesday, August 17, 2004, and the annual renewal approval for this application is on the Committee Agenda for this meeting.

Cc: Research and Sponsored Programs
Greg Merkle

Note For The Record:

The IBC meeting scheduled for August 17, 2004 was canceled due to quorum not being met.

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org



August 17, 2004 3:00 p.m.



Convene meeting at 3:00 P.M.

Review of the Minutes from the June 8, 2004, meeting.

C. Continuing Reviews Administratively Approved

IBC#067 Interactions Between HIV-1 Rev and Microtubules Mill W. Miller, Ph.D.

IBC#089 Genetic And Molecular Studies Of Caenorhabditis Elegans Scott Everet Baird, Ph.D.

IBC#098 Human Blood Monocyte Isolation And Culturing Larry G. Arlian, Ph.D.

IBC#099 Cell Culturing Of Normal Human Epidermal Keratinocytes (NHEK)
And Dermal Fibroblasts (NHDF)

Larry G. Arlian, Ph.D.

IBC#101 Vasopressin Cytotoxicity In Inherited Diabetes Insipidus David R. Cool, Ph.D.

D. Certifications of Current IBC Approval Received

None.

E. Responses to Concerns Received, Approval Recommended

None.

Source: IBC Archive The Sunshine Project /	/ FOI Fund www.sunshine-pro	ject.org
<u>(</u>	\overline{C}	August 17, 2004
.	\ .	

N. Miscellaneous New Business

None.

Agenda - IBC

O. Subcommittee Reports

None.

P. Environmental Health & Safety

Greg Merkle will pdate the Committee on EHS activities.

Q. Topics Requiring Committee Action

None.

R. Information

None.

N. Adjournment

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

August 17, 2004

There being no quorum, the IBC meeting scheduled for August 17, 2004 was canceled.

Chair, Institutional Biosafety Committee 20/62/01

Respectfully submitted.

Receipt of Minutes acknowledged and recommendations approved disapproved

(Institutional Official) Associate Provost for Research 40 /s/17

Source: IBC Archive | The Sunsh WINDIES FOLFund | www.sunshine-project.org

Institutional Biosafety Committee

June 8, 2004

E103 Student Union

Members Present: Susan Halm, Eugene Hern (alternate), James Lucot (Chairer), Peter Lurker, Mark Mamrack, Greg Merkle, John Paietta, Harold Stills, and Dawn Wooley.

A. The Chairer called the meeting to order at 3:01 P.M.

- B. The Minutes of the April 13, 2004 meeting were reviewed and were determined to accurately reflect the business conducted at that meeting.
 - 9 Voting Members Present (8 Members, 1 Alternate); 9 "yes" Votes, None Opposed.

C Continuing Reviews Administratively Approved

Since the last review, there have been no changes made in these protocols other than those amendments already approved.

Summary of votes to concur with the following Continuing Reviews for an additional year or until their five (5) year expiration date, whichever comes first:

9 Voting Members Present (8 Members, 1 Alternate); 9 "yes" Votes, None Opposed.

IBC# 048

Proton & Chloride Regulation of K-C1 Transport Peter K. Lauf, M.D.

IBC# 054

Analysis Of Human Blood, Saliva And Urine For Genetic Risk Factors Of Cardiovascular Disease And Autism

Mariana Morris, Ph.D.

IBC# 055

TGFbeta Signaling In Apoptosis And Implantation Thomas L. Brown, Ph.D.



IBC# 056

MAP Kinase Regulation of G-CSF-Induced Neutrophil Production Michael A. Baumann, M.D.

IBC# 057

Cell Culture of neuroblastoma (N1E-115) and neuroblastoma x glioma (NG108-15) cell lines

F. J. Alvarez-Leefmans,

IBC# 063

Replication Activity Of A Mutant c-myc Origin In The Chromosome Michael Leffak, Ph.D.

IBC# 069

Sarcoptes Scabiei Var. Canis Larry G. Arlian, Ph.D.

IBC# 070

Human Serum Transport, Processing and Analysis Larry G. Arlian, Ph.D.

IBC# 071

Molecular Genetics Of Sulfur Metabolism In Neurospora crassa John V Paietta, Ph.D.

IBC# 073

Production Of Retroviruses Expressing Telomerase Mark D. Mamrack, Ph.D.

IBC# 074

Construction Of A Mite cDNA Library And Expression Of Mite Proteins Larry G. Arlian, Ph.D.

IBC# 075

Molecular Biology of Cytochrome c and Ubiquinol Oxidases Lawrence J. Prochaska, Ph.D.



IBC# 076

Scabies: Biology, Culture, Host Specificity and Antigens Larry G. Arlian, Ph.D.

IBC# 078

DNA Replication And Repair John J. Turchi, Ph.D.

IBC# 079

Examination Of Resistance Of nahG And niml-1 Arabrdopsis Don Cipollini, Ph.D.

IBC# 080

Characterization Of The Engrailed Transcription Factor In The Renshaw Cell Motoneuron Connection
Francisco J. Alvarez, Ph.D.

IBC# 083

The Regulation Of Protein Synthesis And Degradation Patrick B. Dennis, Ph.D.

IBC# 084

Oxidative Stress And Gene Expression In Glioma Cells James E. Olson, Ph.D.

IBC# 085

Neutrophil/Endothelium/Pathogen Injury and Atherosclerosis Julian Gomez-Cambronero, Ph.D.

IBC# 087

Cyano Bacteria (Blue-Green Algae) Toxins: Isolation and Characterization Wayne Carmichael, Ph.D.

IBC# 088

Gender & NKT Cell Response To Virus Nancy J. Bigley, Ph.D.



Minutes - IBC

Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org June 08, 2004

IBC# 092

DNA Repair
Steve M. Patrick,

IBC# 093

Brainstem Angiotensin AT1 Receptor Subtypes Regulate Blood Pressure and Heart Rate Variability and Baroreflex Function

Yanfang Chen, M.S., Ph.D.

IBC# 095

Active Potassium Transport Across Colonic Epithelium Dan R. Halm, Ph.D.

IBC# 097

Environmental Light and Retinal Membrane Development Daniel T. Organisciak, Ph.D.

D. Certifications of Current IBC Approval Received

None.

E. Responses to Concerns Received, Approval Recommended

None.

F. Protocols Declared Inactive

None.

G. Deferred/Tabled Protocols

None.

- 1. "Application For Approval Of Activities Involving The Use Of Biohazards" Revised (4/6/04) was reviewed. In addition to several editorial modifications, additional comments included a request for the exact name and, if commercially available, catalog number under Section C., adding "A" to the Animal Biosafety level procedures in Section I.h, remove reference to chemical and radiological toxins in Section L and to clarify the NSF stands for National Sanitation Federation in I.d.
- 2. Eugene Hern, Ph.D. advised the Committee that the Institutional Official was submitting the "Policy..." for laboratory closeout/decommissioning to the Board of Trustees.
- 3. Concerns raised during continuing review of IBC#061, 062 and 073 were further discussed. The investigators have been notified and EHS collected data to make followup visits and report their findings. The responses and remaining issues were discussed. It was decided that a reminder will be mailed to the P.I.s requesting that their remaining responses become a timely priority.

			ently A		

None.

J. Amendments Requiring Only Notification of the Committee

None.

K. New Protocols Requiring Full Review

None.

Minutes - IBC Source: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org June 08, 2004

IBC# 107

Epidemiology Of Community-Acquired Methicillin-Resistant Staphylococcus Aureus Thomas E. Herchline, M.D.

After fully reviewing the protocol, it was recommended approval pending receipt of the following:

1. A copy of approval from the appropriate Miami Valley Hospital office or committee forwarded to Chris Piekkola, WSU, Research and Sponsored Programs, 201 J University Hall, Dayton, OH 45435.

Summary of votes to concur with the recommended approval of this/these protocol(s): 9 voting members present (8 members and 1 alternate); 9 "yes" votes, none opposed.

M. Continuing Reviews Requiring Full Review

IBC# 082

HIV-1 Infection Of White Blood Cells

Dawn P. Wooley, Ph.D.

This request for continuation of a BioSafety Level 2 with Level 3 practices was reviewed by the Committee with the recommendation of approval.

Summary of Votes to Recommend Continuing Review Approval of this Protocol:

9 Voting Members Present (8 Members, 1 Alternate); 8 "Yes" Votes, 1 Abstention, None Opposed.

The Pel., who is a member of the IBC, abstanted from the discussion and vote on this continuing review.

N. Miscellaneous New Business

None.

O. Subcommittee Reports

None.

P. Environmental Health & Safety

Committee update by the Institutional Biosafety Officer was presented and discussed as shown in Attachment #1 dated May 28, 2004.

IBC Minutes - p. 6

FILE COPY

Minutes - IBC	Source: IBC Archive The Sunshine Project / FOI Fund www.sunshine-project.or	g June 08,	2004
Q. Topics Requ	ilring Committee Action		

None.

R. Information

The following was distributed to the IBC for their information:

"Experts Ask Boston To Nix Bioterror Lab", Science, Wednesday, April 14, 2004

S. Adjournment

The Committee adjourned at 4:27 P.M.

The next scheduled meeting will be held on Aug 10, 2004

Respectfully submitted.

James B. Lucot Date

Chairer, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved disapproved

Dr. Joseph F. Thomas, Jr.

Data

Vice President for Research

(Institutional Official)

MINUTES

Source: IBC Archive | Titutional Brosafety Committee www.sunshine-project.org

April 13, 2004

E 103 Student Union

Members Present: Eugene Hern (alternate), James Lucot (Chairer), Greg Merkle, John Paietta, Harold Stills, and Dawn Wooley

- A. The Chairer called the meeting to order at 3:15 P.M.
- B. The Minutes of the February 10, 2004 meeting were reviewed and with one editorial correction, were determined to accurately reflect the business conducted at that meeting.
 - 6 voting Members Present (5 Members, 1 Alternate); 5 "yes" Votes, 1 Abstention, None Opposed.

C. Continuing Reviews Administratively Approved

Since the last review, there have been no changes made in these protocols other than those amendments already approved.

Summary of votes to concur with the following Continuing Reviews for an additional year or until their five (5) year expiration date, whichever comes first:

6 Voting Members Present (5 Members, 1 Alternate); 6 "Yes" Votes, None Opposed.

IBC# 063

Replication Activity Of A Mutant c-myc Origin In The Chromosome

Michael Leffak, Ph.D.

D. Certifications of Current IBC Approval Received

None.

E. Responses to Concerns Received, Approval Recommended

None.

IBC Minutes - p. 1

Minutes - IBC	April 13, 2004
Source: IBC Archive The Sunshine Project / FOI Fund www.sunshine-project.org	
None.	
G. Deferred/Tabled Protocols	
None.	
H. Miscellaneous Old Business	
None.	
I. Amendments to Currently Approved Protocols	
None.	
J. Amendments Requiring Only Notification of the Committee	
None.	
K. New Protocols Requiring Full Review	
None.	
L. New Protocols Administratively Approved	
None.	
M. Continuing Reviews Requiring Full Review	
None.	
N. Miscellaneous New Business	
None.	

IBC Minutes - p. 2

O. Subcommittee Reports: IBC Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

None.

P. Environmental Health & Safety

1. Committee update by the Institutional BioSafety Officer was presented and discussed as shown in Attachment #1 dated April 12, 2004.

Several possible actions were specifically discussed as a result of this report:

- a. RSP will check on the current status of the Laboratory Vacating Policy.
- b. EHS will send memos to faculty requesting a "report of quantities of select agents" by date and memos regarding hazardous materials shipping training.
- c. A revised "petition" draft will be reviewed at the next meeting.

Q. Topics Requiring Committee Action

None.

R. Information

The following was distributed to the IBC for their information:

1. The Sunshine Project update - The IBC minutes requested in the recent Sunshine Project FOIA request of 2-4-04 were submitted by General Counsel on 2-26-04. A preliminary report on the project was released on 3-12-04, updated 4-5-04, and a summary is included in these Minutes, labeled Attachment #2.

Dr. Joseph F. Thomas, Jr.
Vice President for Research
(Institutional Official)

IBC Minutes - p. 4

WRIGHT STATE
UNIVERSITY

DATE:

April 12, 2004

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the Last Meeting of the Institutional Biosafety Committee,

February 13, 2003

For the Committee meeting of April 13, 2004:

- 1. The offices for the Department of Environmental Health and Safety, with the exception of Radiation Safety Office, have moved to Room 129 Allyn Hall from the Health Sciences Bldg. All departmental phone numbers, email addresses and emergency contact numbers remain unchanged.
- 2. Reviewing of biosafety protocols continues.
- 3. Concerns regarding IBC protocols 061, 062 and 073 are being addressed. A response has been received addressing concerns of protocols no. 062 and 073. IBC protocol no. 061 is due for annual review and I will ask that the previously noted questions be addressed in the submitted response for review.
- 4. Biological safety cabinets are being surveyed. Several cabinets and use laboratories have been relocated. Labs that have been relocated as of this date during this year are: Rm's 012 and 014 MMS (Norma Adragna Ph.D and Peter Lauf MD), Rm. 156 and 161 BH (Steve Berberich, Ph.D) and Rm. 142 and 148 BH (new lab areas for Madhavi Kadakia, Ph.D). There are several cabinets that are past due to be surveyed (LAR, 037 MMS, 012B MMS), this is being addressed to correct.
- 5. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 6. Late last year a faculty member confirmed that they still had possession of the select agent toxin Staphylococcal enterotoxin, the exact quantity is unknown at this time. A memo dated December 5, 2003, was sent to the faculty member requesting information on the toxin in possession. As of this date no information has been received.
- 7. A long term goal is to establish an inventory system for biological materials (including select agents) in possession. The department is also investigating the need for training of appropriate personnel for preparing packages containing diagnostic, infectious, hazardous or radiological materials for shipment.

April Spurce: 200 Armive 上语 Satelate Mentet #201 Fund | www.sunshine-project.org/
Institutional Biosafety Committee Transparency Survey
(brief background information on the study, posted on January 30th)

Preliminary Statistics on IBC Response to Public Access Requests Last Updated: 5 April 2004 .

(A 'reply' noted here is not an indication of the quality of the response nor that minutes have been provided in accordance with the NIH Guidelines. It simply indicates that the IBC has contacted the Sunshine Project in response to the survey letter.)

IBCs receiving request: 389
Replies received: 212 (54.5%)
Failed to reply: 177 (45.5%)

Responses will continue to be accepted and, indeed, are required by the NIH Guidelines.

Late arriving replies will be noted as such in the final report.

Government agencies:

US Department of Agriculture, 6 IBCs surveyed, 2 replies (33%)
US Department of Defense, 5 surveyed, 2 replies (40%)
US Department of Energy, 7 surveyed, 5 replies (71%)
Health and Human Services, 3 surveyed, 2 replies (66%)

Large university systems:

University of Texas System, 9 surveyed, 9 replies (100%)
University of California System, 9 surveyed, 9 replies (100%)
State University of New York System, 6 surveyed, 2 replies (33%)
University of Massachusetts System, 4 surveyed, 1 reply (25%)

Some Institutions that have not replied (full list below):

Battelle Memorial Institute Case Western Reserve University Centers for Disease Control (NCID) Clemson University **Duke University Emory University** University of Georgia The Institute for Genomic Research **Iowa State University** Johns Hopkins University Los Alamos National Laboratory University of Michigan University of Nebraska (2x) Oak Ridge National Laboratory Pennsylvania State University (2x) Southwest Foundation for Biomedical Research Texas A & M University Uniformed Services University Waiter Reed Army Medical Center

FULL LIST OF IBCs SURVEYED AND THEIR RESPONSE STATUS

RESPONSE FILE COPY

MINUTES

Source: IBC Archive | Thinking Biosafety Committee www.sunshine-project.org

February 10, 2004

248 University Hall

Members Present: Susan Halm, Eugene Hern (alternate), Peter Lurker, Greg Merkle, John Paietta, Harold Stills (Vice-Chair).

A.	The Vice-Chair called the meeting to order at 3:03 P.M.
B.	The Minutes of the December 9, 2003 meeting were reviewed and were determined to accurately reflect the business conducted at that meeting.
	6 Voting Members Present (5 Members, 1 Alternate); 4 "Yes" Votes, 2 Abstentions, None Opposed.
C 6	Continuing Reviews Approved Administratively
	None.
Э, (Certifications of Current IBC Approval Received
	Mana
	None.
B: K	Responses to Concerns Received, Approval Recommended
	None.
	inolie.

F. Protocols Declared Inactive

None.

IBC Minutes - p. 1

Minutes - IBC February 10, 2004 G. Deferred/Tabled Protects Archive | The Sunshine Project / FOI Fund | www.sunshine-project.org

None.

H. Miscellaneous Old Business

1. Concerns as to how materials are being handled regarding IBC#061, 062 and 073 were discussed. The investigators have been notified and EHS is collecting data to make followup visits and report their findings.

I. Amendments to Currently Approved Protocols

None.

J. Amendments Requiring Only Notification of the Committee

None.

K. New Profocols Requiring Full Review

None.

L. New Protocols Administratively Approved

IBC# 105

Motoneuron Infection In Vivo With Viral Vectors Francisco J. Alvarez, Ph.D.

IBC# 106

Screening Human Tissues For DUE-B Expression Michael Leffak, Ph.D.

Summary of votes to concur with the recommended approval of this/these protocol(s): 6 Voting Members Present (5 Members, 1 Alternate); 6 "Yes" Votes, None Opposed.

M. Continuing Reviews Requiring Full Review

N. Miscellaneous New Business rchive | The Sunshine Project / FOI Fund | www.sunshine-project.org

1. The Committee discussed inventory control for biological material including select agents and failure to respond to EHS quiries. EHS reported that inventories to date haveshown no biological materials exceeding "exempt" limits. Future goals are for the university to maintain it's "exempt" status through inventory controls. A database will be developed for trailing this material.

- 2. The Committee discussed plans for EHS to offer training in packaging and transporting biological materials. This would serve to minimize potential incident during transportation and provide an assurance to authorities that safety measures had been utilized.
- 3. The status of the Level 3 lab facilities was discussed and it was reported that other than completing the SOP manual and some further staff/personnel training, the lab is ready for BSL3 activities.
- 4. It was announced that a FOIA letter from the Sunshine Project of Austin, Texas was received. They are requesting copies of IBC's October and December Minutes (i.e., the latest two IBC meeting minutes available) by March 1, 2004. The Office of General Counsel will be responding to this request. It was further noted that while WSU is registered to handle "select agents", there are no quantities on campus that would require reporting.

O. Subcommittee Reports

None.

P. Environmental Health & Safety

1. Committee update by the Institutional BioSafety Officer was presented as shown in Attachment #1 dated February 9, 2004.

Q. Topics Requiring Committee Action

None.

S. Adjournment

The Committee adjourned at 3:48 P.M.

The next scheduled meeting will be held on Apr 06, 2004

Respectfully submitted.

Harold F. Stills, Jr. D.V.M.

Co-Chairer, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved [

Dr. Joseph F. Thomas, Jr.

Vice President for Research

(Institutional Official)

WRIGHT STATE UNIVERSITY

IBC > bruary 10, 2004

IBC > bruary 10, 2004

IBC > bruary 10, 2004

Department of Lavironmental Health & Safety (937) 775-2215

Fax (937) 775-3761

DATE:

February 9, 2004

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the Last Meeting of the Institutional Biosafety Committee,

December 9, 2003

For the Committee meeting of February 10, 2004:

1. Reviewing of biosafety protocols continues.

- 2. Concerns regarding IBC protocols 061, 062 and 073 are being addressed. On February 9, 2004, an email with previously stated concerns was forwarded to each of the faculty.
- 3. Biological safety cabinets are being surveyed. Several cabinets and use laboratories have been relocated. A new cabinet has been added to Room 206 HS for use by new faculty in the Dept. Pharm. and Tox., Courtney Sulentic, Ph.D.
- 4. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 5. Nancy Bigley has confirmed that she still has the select agent toxin Staphylococcal enterotoxin that she previously presumed she no longer possessed. While the material was reported to the Department of Health and Human Services as being present the exact quantity is unknown at this time. A memo dated December 5, 2003, was sent to Dr. Bigley requesting information on the toxin in her possession. It was requested that an accounting of the material (in milligrams) in possession be given to this Department by the end of December 2003. As of this date no information has been received. If the quantity of material exceeds the exemption limits for possession then the university will be required to comply with the regulatory requirements stated in 42CFR73, the university will loose it's exemption status and be required to comply with the provisions of the regulation.
- 6. A long term goal is to establish an inventory system for biological materials (including select agents) in possession.

MINUTES Atutional Blosafety Committee

December 9, 2003

E109 Student Union

Members Present: Jarrell Hagan (Alternate), Eugene Hern (Alernate), James Lucot (Chair), Peter Lurker, John Paietta, Harold Stills, and Dawn Wooley.

- Thomas for providing holiday refreshments.

 B. The Minutes of the October 14, 2003 meeting were reviewed and were determined to accurately reflect the
- B. The Minutes of the October 14, 2003 meeting were reviewed and were determined to accurately reflect the business conducted at that meeting.

7 Voting Members Present (5 Members, 2 Alternates); 6 "Yes" Votes, 1 Abstention, None Opposed.

Continuir	io Reviet	ve-Amnroi	red Adm	mistratively
	-2 -/A 10.	is white		unsuauveny

None.

D. Certifications of Current IBC Approval Received

Minutes - IBC	Source: IBC Archive The Sunshine Project / FOI Fund www.sunshine-project.org December Concerns Received oval Recommended	09, 2003
F. Protocols Dec	None. Clared Inactive mmittee noted that the following IBC protocols are now declared inactive:	
IBC# 086 G. Deferred/Tab	Transfection Of Eukaryotic Cells Using Expression Plasmids Encoding Human And Mouse Proteins	
	None.	

Minutes-IBC

1. An update of the BSL3 laboratory was presented by EHS and Dr. Wooley. It was reported that final hood calibration and certification and writing of a safety manual was in progress and would be completed soon. It was also reported that all pipes have been sealed, washable electric circuitry installed, three coats of sealant added and ceiling check has been completed. After much discussion, it would be advantageous to install an outside warning light or other visual system (e.g., window or tv monitor) to warn a person entering the lab that work with agents was in progress and for personnel safety. The Committee also discussed restrictions on access for emergency, security, and maintenance personnel (e.g., receive EHS training). A list of authorized personnel will be made available to the WSU Police Department and a notice of final certification and access information will be sent to the Fairborn Fire Department.

	Fairborn Fire Department.
I. Amendments to C	urrently Approved Protocols
	one.
J. Amendments Reg	iliring Only Notification of the Committee
No	one.
K New Protocols R	equiring Full Review

Minutes - IBC Source: IBC Archive The Sunshine Proje	ect / FOI Fund www.sunshine-project.org	nber 09, 2003
F. New Protocols Administratively A loved		
None.		
M. Continuing Reviews Requiring Full Review		
None.		
N. Miscellaneous New Business		
None.		
D. Subcommittee:Reports		
None.		
Environmental Health & Safety		

- 1. Committee update by the Institutional BioSafety Officer was presented as shown in Attachment #1 dated December 5, 2003.
- 2. The Committee was notified of an inquiry dated 12-5-03 to order Alpha Toxin from S. aureus and the response to this inquiry by the Institutional BioSafety Officer.

R. Information

None.

S. Adjournment

The Committee adjourned at 3:38 P.M.

The next scheduled meeting will be held on Feb 10, 2004

Respectfully submitted.

James Lucot, Ph.D.

Date

Chairer, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved Minutes acknowledged and recommendations acknowledged and recommendations acknowledged and recommendations acknowledged acknowledg

Dr. Joseph/F. Thomas, Jr.

Z(11/09 Date

Vice President for Research

(Institutional Official)



Attachmen #1 (December 9, 200 3 Department of Environmental Health & Safety (937) 775-2215 Fax (937) 775-3761

DATE:

December 5, 2003

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygie

SUBJECT:

Activities Since the Last Meeting of the Institutional Biosafety Committee,

October 2003

1. Reviewing of biosafety protocols continues.

Concerns regarding IBC protocols 061, 062 and 073 need to be addressed.

3. Biological safety cabinets are being surveyed.

4. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.

5. Attended the American Biological Safety Association Conference in Philadelphia in October.

6. Nancy Bigley has confirmed that she still has the select agent toxin Staphylococcal enterotoxin that she previously presumed she no longer possessed. While the material was reported to the Department of Health and Human Services as being present the exact quantity is unknown at this time. If the quantity of material exceeds the exemption limits for possession then the university will be required to comply with the regulatory requirements stated in 42CFR73.

7. A long term goal is to establish an inventory system for biological materials (including select 8. John Sheidler reported that the BUCB facility

MINUTES Itutional Biosafety Committee

October 14, 2003 E109 Student Union

Members Present: Jarrell Hagan (Alternate), Susan Halm, Eugene Hern (Alternate), James Lucot (Chair), Peter Lurker, John Paietta, Cassandra Paul, and Dawn Wooley.

Note for the Record: The voting may reflect that some members were in attendance at various times.

- A. The Chair called the meeting to order at 3:03 P.M.
- B. The Minutes of the December 11, 2002, February 11, 2003, April 8, 2003, June 10, 2003, August 12, 2003, August 20, 2003, and September 22, 2003 meetings were reviewed and were determined to accurately reflect the business conducted at those meetings.

Summary of Votes to Approve Above Listed Minutes as drafted:

6 Voting Members Present (4 Members, 2 Alternates); 6 "Yes" Votes, None Opposed.

C. Continuing Reviews Administratively Approved

Since the last review, there have been no changes made in these protocols other than those amendments already approved.

Summary of votes to concur with the following Continuing Reviews for an additional year or until their five (5) year expiration date, whichever comes first:

6 Voting Members Present (4 Members, 2 Alternates; 6 "yes" Votes, None Opposed.

After an extensive discussion regarding three (3) of these continuing review protocols which are related, an IBC member agreed to re-review the protocols and draft a list of further questions that should be addressed. Once received, these questions will be addressed as appropriate (e.g., Chair, EHS, Principal Investigator).

IBC# 037 Active Potassium Transport Across Colonic Epithelium

IBC# 050 Cellular Role Of o-GlcNAc Addition

IBC# 061 Production Of Retroviruses Expressing p53, Mdm2 or MdmX

IBC# 062 Gene Transfer By Retroviral Delivery

IBC# 066 Use Of LA-N-1 Cell Line For Expressing recombinant DNA Constructs

IBC# 067 Interactions Between HIV-1 Rev and Microtubules

IBC# 068 Cloning And Expression Of Calcium Transporters From Crayfish Procambarus Clarkii

IBC# 069 Sarcoptes Scabiei Var. Canis

Minutes - IBC	Source: IBC Archive The Sunshine Project / FOI Fund www.sunshine-project.org
İBC# 070	Human Serum Tran., ort, Processing and Analysis
IBC# 071	Molecular Genetics Of Sulfur Metabolism In Neurospora crassa
IBC# 073	Production Of Retroviruses Expressing Telomerase
IBC# 081	Expressing Human And Mouse Proteins In Eukaryotic Cells
IBC# 082	HIV-1 Infection Of White Blood Cells
IBC# 085	Neutrophil/Endothelium/Pathogen Injury and Atherosclerosis
IBC# 088	Gender & NKT Cell Response To Virus
D. Certifications:	of Cument LBC Approval Received
None.	
E. Responses to	Concerns Received. Approval Recommended
None.	

H. Miscellaneous Old Business

1. Update of BSL3 laboratory

On September 2nd and 3rd of 2003, the BSL3 facility was inspected by a subcommittee of the IBC with the goal of providing recommendations for its final certification. At a previous meeting (9-22-03); this subcommittee report was reviewed by the full IBC following a tour of the facilities.

Following an extended discussion based on this report, information from the tour, the CDC biosafety handbook, and other assorted information, the Committee agreed with the following:

- 1. all recommended items except for sealing of the motor joints have been or are scheduled to be completed,
- 2. the facility meets the criteria for BSL-3 for the activities being proposed, and
- 3. to stipulate that, as an enhancement, sealant will be applied at the first opportunity but no later than nine (9) months (July 31, 2004).

This discussion concentrated heavily on aspects of appropriate containment needs and methods.

Summary of Votes for Agreement with the Three (3) Items:
7 Voting Members Present (5 Members, 2 Alternates); 7 "yes" votes, None Opposed.

Note for the Record: The BSL3 facility manager, who is a member of the IBC, was not present during final discussion and vote on these issues.

I. Amendments to Currently Approved Protocols

L. New Protocols Administratively Approved

None.

IBC# 080 Characterization Of The Engrailed Transcription Factor In The Renshaw Cell Motoneuron Connection

IBC# 092 DNA Repair

IBC# 093 Brainstem Angiotensin AT1 Receptor Subtypes Regulate Blood Pressure and Heart Rate Variability and Baroreflex Function

IBC# 096 Comparison Of Quanti-FERON-TB with 2 Tuberculin Reagents In Health Care Workers And Evaluation Of The Clinical Relevance Of A Positive Tuberculin Test Past 72 Hours IBC Minutes - p. 7

.auoN

M. Miscellancous New Business

None.

M. Continuing Reviews Requiring Full Review

Summary of votes to concur with the recommended approval of this/these protocol(s): 7 Voting Members Present (5 Members, 2 Alternates; 7 "yes" Votes, None Opposed.

Mouse Proteins

IBC# 103 Transfection Of Eukaryotic Cells Using Expression Plasmids Encoding Human And

IBC# 101 Vasopressin Cytotoxicity In Inherited Diabetes Insipidus

IBC# 100 Role Of Phosphorylation in Regulating Muscarinic Acetylcholine Receptor Function

IBC# 099 Cell Culturing Of Normal Human Epidermal Keratinocytes (NHEK) And Dermal

IBC# 098 Human Blood Monocyte Isolation And Culturing

IBC# 097 Environmental Light and Retinal Membrane Development

Minutes - IBC O. Subaammittee R	Source: IBC Archive The Sunshine Project / FOI Fund www.sunshine-project.or Sctober 14, 200	3
None.		
? Environmental I	iealth & Safe by	
	ee update by the Institutional BioSafety Officer was presented as shown in #1 dated October 3, 2003.	
O Nopics Requirin	g Committee Action	
None.		
R: Information		
None.		

Minutes - IBC

Vice President for Research

(Institutional Official)



Department of Euvironmental Health & Safety (937) 775-2215 Fax (937) 775-3761

DATE:

October 3, 2003

TO:

Memo for the Record

FROM:

Greg Merkle, Sr. Industrial Hygienist

SUBJECT:

Activities Since the Last Meeting of the Institutional Biosafety Committee

1. Reviewing of biosafety protocols continues. There have been 10 new protocols, 32 for annual review and 13 that were closed or expired during the year to date.

- 2. Biological safety cabinets are being surveyed.
- 3. The large Labconco biological safety cabinet that had been located in Neal Rote's lab and considered to be scrap was sold to a company in Phoenix for a dollar. The company paid to have the unit shipped to Phoenix.
- 4. The Department is continuing to perform safety assessments for the laboratories with biosafety protocols.
- 5. Phone and email contact has been made with people at Boston University, University of Cincinnati, The Ohio State University, University of Illinois at Chicago and University of Kansas, University of Hawaii and University of Michigan about how they approved their BSL3 facilities for operation.
- 6. The American Biological Safety Association Conference is taking place in Philadelphia from Saturday, Oct. 11 through Wednesday, Oct. 15.

MINUTES
Source: IBC Archive Lightning Biogatery Conditites www.sunshine-project.org

September 22, 2003

E103 Student Union

Members Present: Susan Halm, Eugene Hern (Alternate), James Lucot (Chair), Mark Mamrack, Greg Merkle, John Paietta, Cassandra Paul, Hal Stills, and Dawn Wooley (joined meeting after the BSL-3 inspection).

A .	The Chair called the meeting to order at 2:05 P.M.
	This special meeting was called to complete review of IBC #102. There were no Minutes presented for review
	•
Ċ. (ontinuing Reviews Approved Administratively
	27
	None.
D. (Certifications of Current IBC Approval Received
	None.

IBC Minutes - p. 2

Jone's

I. Amendments to Curtenly Approved Protocols

None.

H Wisgellaneous Old Business

None.

C. Deferred/Rabled Protocols

None.

B. Protocols: Declared Inactive

Minutes - IBC	September 22, 2003
J. Amendments Requiling Only Nolive ation of the Committee	FOI Fund www.sunshine-project.org
None.	
K. New Protocols Requiring Full Review	
- TO DAY WE'VE PARTICULAR AND	
IBC# 102 Growth Of LCMV In Cell Culture	
This protocol, approved pending restrictions (as outline as Attachment #1), was further reviewed and discussed For The Record" (Attachment #2). The protocol was re	with the outcome as outlined in the attached "Memo
As part of this supplemental evaluation, an IBC subcom- report of their findings to the Committee (memo dated of was then inspected by the full Committee.	
Summary of votes to approve IBC#102: 8 Voting Members Present (7 Members, 1 Alternate);	8 "Yes" Votes, None Opposed.
NOTE FOR THE RECORD: 1) Although originally rethat the protocol as written allows Level 2 containment certified level 3 facility. 2). The investigator, who is a deliberation and vote on this action.	with Level 3 practices and hence, does not require a
L New Protocols Administratively Approved	
•	
None.	

Minutes - IBC	September 22, 2003
M. Continuing Reviews Requiring live Review shine Project / F	FOI Fund www.sunshine-project.org
None.	
N. Miscellaneous New Business	,
None.	
O. Subcommittee Reports	
None.	
P. Environmental Health & Safety	
None.	
Q: Topics Requiring Committee Action .	
None.	

R. Information

None.

S. Adjournment

The Committee adjourned at 3:25 P.M.

The next scheduled meeting will be held on Oct 14, 2003

Respectfully submitted.

James Lucot, Ph.D.

Date

Chairer, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved [

Dr. Joseph F. Thomas, Jr.

Date

Associate Provost for Research

(Institutional Official)

None.

K. New Protocols Requiring Eull Review

IBC# 102 Growth Of LCMV In Cell Culture

After fully reviewing and discussing the protocol, the Committee recommended approval of this BioSafety Level #3 protocol pending receipt of the following:

- 1. An approved BSL3 lab is established.
- 2. Protocol Application Cover Page: List all biohazard locations and specify all personnel that will be involved in the protocol.
- 3. Gene Expression Experiments (Aim 1): Please include the guidelines of the RNA guidelines.
- 4. Clarify the procedure that will be followed to disinfect the outside of viles prior to the viles being transported from the hood to the Gene Expression Lab and how others involved will handle the tubes.
- 5. It is requested that all personnel involved with this protocol be offered blood banking availability.

L. New Protosols Administratively Approved

Memo For The Record

Re: IBC#102

This protocol, approved pending restrictions (as outlined in the attached page from the August 20, 2003 IBC Minutes), was brought before the IBC at a special meeting this date (September 22,2003) which included a physical inspection of the BSL3 facility. After fully reviewing and discussing the protocol, the Committee approved an amendment to the protocol to change the BioSafety level from BSL3 to BSL2 containment with BSL3 practices. Therefore, restriction No. 1 imposed on this protocol by the IBC at their August 20, 2003 meeting has been removed and the protocol is now recommended for full approval, all other restrictions having been satisfied.

[NOTE: The investigator, who is a member of the IBC, was not present during final deliberation and vote on this action.]

MINUTES

Source: IBC Archive Institutional Biosafety Committee www.sunshine-project.org

August 20, 2003

E103 Student Union

Members Present: Susan Halm, Eugene Hern (Alternate), James Lucot (Chair), Mark Mamrack, Greg Merkle, John Paietta, Cassandra Paul, Hal Stills, and Dawn Wooley.

A.	The Chai	ir called the	e meeting to	order at 2:0	7 P.M.	**	<u> </u>	
B.	There we	ere no Mini	ites present	ed for review	w.			

C. Continuing Reviews Approved Administratively

None.

D. Certifications of Current IBC Approval Received

$\rm IBC$ Minutes - p. 2

None.



None.

H. Misoellaneous Old Business

None.

G. Deferred/Habled Protocols

None.

F. Rrotocols/Declared Inactive

nutes - IBC	August 20, 2
mendments to Correctly Approvive Protocous hine Project / FOI Fund ww	w.sunshine-project.org
17	
None.	
mendments Requiring Only Notification of the Committee	
N	
None.	
New Protocols Requising Full Review	
New Protocols Requiring Full Review	
New Protocols Requiring Full Review	
New Protocols Requiring Full Review IBC# 102 Growth Of LCMV In Cell Culture	
IBC# 102 Growth Of LCMV In Cell Culture After fully reviewing and discussing the protocol, the Committee reco	ommended approval of this BioSafe
IBC# 102 Growth Of LCMV In Cell Culture After fully reviewing and discussing the protocol, the Committee reco	ommended approval of this BioSafe
IBC# 102 Growth Of LCMV In Cell Culture After fully reviewing and discussing the protocol, the Committee reco	ommended approval of this BioSafe
IBC# 102 Growth Of LCMV In Cell Culture After fully reviewing and discussing the protocol, the Committee record Level #3 protocol pending receipt of the following: 1. An approved BSL3 lab is established. 2. Protocol Application Cover Page: List all biohazard locations and	
IBC# 102 Growth Of LCMV In Cell Culture After fully reviewing and discussing the protocol, the Committee record Level #3 protocol pending receipt of the following: 1. An approved BSL3 lab is established. 2. Protocol Application Cover Page: List all biohazard locations and involved in the protocol.	specify all personnel that will be
IBC# 102 Growth Of LCMV In Cell Culture After fully reviewing and discussing the protocol, the Committee record Level #3 protocol pending receipt of the following: 1. An approved BSL3 lab is established. 2. Protocol Application Cover Page: List all biohazard locations and	specify all personnel that will be
IBC# 102 Growth Of LCMV In Cell Culture After fully reviewing and discussing the protocol, the Committee recollevel #3 protocol pending receipt of the following: 1. An approved BSL3 lab is established. 2. Protocol Application Cover Page: List all biohazard locations and involved in the protocol. 3. Gene Expression Experiments (Aim 1): Please include the guidelia. 4. Clarify the procedure that will be followed to disinfect the outside	specify all personnel that will be nes of the RNA guidelines. of viles prior to the viles being
IBC# 102 Growth Of LCMV In Cell Culture After fully reviewing and discussing the protocol, the Committee recollevel #3 protocol pending receipt of the following: 1. An approved BSL3 lab is established. 2. Protocol Application Cover Page: List all biohazard locations and involved in the protocol. 3. Gene Expression Experiments (Aim 1): Please include the guideling in the protocol.	specify all personnel that will be nes of the RNA guidelines. of viles prior to the viles being
IBC# 102 Growth Of LCMV In Cell Culture After fully reviewing and discussing the protocol, the Committee recollevel #3 protocol pending receipt of the following: 1. An approved BSL3 lab is established. 2. Protocol Application Cover Page: List all biohazard locations and involved in the protocol. 3. Gene Expression Experiments (Aim 1): Please include the guidelity. 4. Clarify the procedure that will be followed to disinfect the outside transported from the hood to the Gene Expression Lab and how other. 5. It is requested that all personnel involved with this protocol be offer.	specify all personnel that will be nes of the RNA guidelines. of viles prior to the viles being s involved will handle the tubes.
IBC# 102 Growth Of LCMV In Cell Culture After fully reviewing and discussing the protocol, the Committee recollevel #3 protocol pending receipt of the following: 1. An approved BSL3 lab is established. 2. Protocol Application Cover Page: List all biohazard locations and involved in the protocol. 3. Gene Expression Experiments (Aim 1): Please include the guidelial. 4. Clarify the procedure that will be followed to disinfect the outside transported from the hood to the Gene Expression Lab and how other	specify all personnel that will be nes of the RNA guidelines. of viles prior to the viles being s involved will handle the tubes. ered blood banking availability.

Q. Topics Requiring Committee Action

R. Information

None.

S. Adjournment

The Committee adjourned at 2:59 P.M.

The next scheduled meeting will be held on Sep 22, 2003

Respectfully submitted.

James Lucot, Ph.D.

122/01

Chairer, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved

disapproved [

Dr. Joseph F. Thomas, Jr.

Date

Associate Provost for Research

(Institutional Official)

MINUTES INSTITUTIONAL BIOSAFETY COMMITTEE August 12, 2003

There being no business requiring IBC actions, the IBC meeting scheduled for 12, 2003 was canceled.

Respectfully submitted.

James. B. Lucot, Ph.D.
Chair, Institutional Biosafety Committee

Receipt of Minutes acknowledged and recommendations approved disapproved

Assorting Theorem (1946)

Associate Provost for Research

(Institutional Official)

MINUTES INSTITUTIONAL BIOSAFETY COMMITTEE June 10, 2003

There being no business requiring IBC actions, the IBC meeting scheduled for June 10, 2003 was canceled.

Respectfully submitted.

James B. Lucot, Ph.D.
Chair, Institutional Biosafety Committee

disapproved

Receipt of Minutes acknowledged and recommendations approved

Dr. Joseph F. Thomas, Jr.
Associate Provost for Research
(Institutional Official)