



THE PUBLIC HEALTH RESEARCH INSTITUTE
AT THE INTERNATIONAL CENTER FOR PUBLIC HEALTH

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March 31, 2006

Edward H. Hammond
The Sunshine Project
PO Box 41987
Austin TX, 78704
Fax: +1512 494 0545

Re: Response to request of PHRI-IBC minutes

Dear Mr. Hammond

The Public Health Research Institute (PHRI) has received your request of the minutes of all Institutional Biosafety Committee (IBC) meetings of PHRI since 1 May 2003.

Your fax was addressed to Ms. Gaitree McNab and I would like to clarify that Ms. McNab was never been an employee of PHRI and therefore she never been responsible for the PHRI-IBC at PHRI.

The PHRI-IBC was established on May 13, 2004 and registered with the Office of Biotechnology Activities (OBA). Submission of the IBC roster was done on November 9, 2004. This is the date in which the OBA officially recognized the establishment of the PHRI-IBC in compliance with Section IV-B-2-a(1) of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

Before May 2004 all the applications from PHRI were submitted to and approved by the University of Medicine and Dentistry of New Jersey (UMDNJ)-IBC. Ms. McNab was responsible for the UMDNJ-IBC. Once the PHRI established its own IBC all the applications previously approved by UMDNJ-IBC were transferred to PHRI.

As requested we are mailing you copies of all the IBC minutes held at PHRI from the time the committee was established. However for security reasons sensitive information in these documents has been redacted.

Sincerely,

A handwritten signature in cursive script, appearing to read "Claudia Manca".

Claudia Manca, Ph.D
PHRI-IBC Chairperson

the sunshine project

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13 March 2006

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Gaitree McNab
Public Health Research Institute, Newark
225 Warren Street W230R
Newark NJ 07103
By fax: (973) 854-3101

Dear Gaitree McNab

Pursuant to the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (NIH Guidelines), Section IV-B-2-a-(7),¹ the Sunshine Project hereby requests the Minutes of all meetings of the Public Health Research Institute, Newark Institutional Biosafety Committee (IBC) since 1 May 2003.

Please send the minutes to the address above. The NIH Guidelines require that minutes be made available "upon request". I request that you send your reply by Friday, 28 April 2006.

This letter is sent to you because IBC registration records of the National Institutes of Health Office of Biotechnology Activities indicate that you are responsible for the Public Health Research Institute, Newark IBC.

This letter is sent to you as part of a national survey of compliance with the NIH Guidelines.

When you respond, I would appreciate your answer to the following question (please circle one):

The Public Health Research Institute, Newark IBC HAS / HAS NOT implemented written policies for the identification, review, and oversight of research involving any of the seven categories of experiments of concern identified by the National Academies of Science in its report *Biotechnology Research in an Age of Terrorism* (the "Fink Committee" report).

Please feel free to attach any additional explanatory materials that you feel are appropriate. Thank you very much for your attention to this request.

Sincerely,



Edward H. Hammond
Director

¹ Section IV-B-2-a-(7). Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes...

Public Health Research Institute
225 Warren Street Newark, NJ 07103



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: Thursday, May 13, 2004

Present: Claudia Manca – Chair
Natalia Kurepina, Ismael Calderón, Richard Burger, Larry Barbour, Steve Park,
Gaitree McNab, Bernadette Alisantosa, Bernice Fulton (Administrative
Assistant)

Observers: Tinia Davis, David Perlin

Absent: Rachel Sheppard, Marta Figueras

This was the first meeting of the Committee and Chairperson took some time to explain the role and responsibility of the IBC, and governing info from NIH guidelines.

Forms to be used are (IBC#:01 – Request for review), (IBC#:02 – Amendment), and (IBC#:03 – Annual Review). Protocols for review will be submitted Bernice Fulton by the PI and distributed to the committee members for review by e-mail. Comments by Committee members must be emailed to Bernice Fulton within 1 week of receiving the emailed protocol.

IBC minutes will record the approval or rejection of submitted protocols. At the start of each IBC meeting the minutes of the previous meeting will be tabled and, if approved, signed by the Chairperson. These signed minutes will serve as a record of the IBC protocol approvals.

IBC meetings will be held on the same day as, and immediately after, the IACUC meetings. The aim is to hold these meetings in the middle of each month.

Information relating to Select Agents must be kept confidential.

Protocols already submitted to, and pending approval or approved by UMDNJ IBC, will be adopted as approved for PHRI.

The next meeting is scheduled for Thursday, June 17, 2004 – 2:30 p.m.

Signed: Claudia Manca **Date:** 6-17-04

Title: Chairman

Public Health Research Institute
225 Warren Street Newark, NJ 07103



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: June 17, 2004

Present: Claudia Manca, Ph.D (Chair)
Rachel Sheppard, Ph.D; Natalia Kureprina, Ph.D; Larry Barbour, BS;
Steve Park, BS; Bernadette Alisantosa, DVM, MPVM; Richard Burger,
Ph.D; Ismael Calderon, Ph.D; Marta Figueroa, CIH; Gaitree McNab,
CBSP and Bernice Fulton (Administrative Assistant).

Observers: Tinia Davis (Scientific Affairs Administrator)

Absent: None

Minutes of the previous meeting were approved by the Committee and signed by the Chairperson.

The Committee approved the protocols IBC#001 and IBC#002. Dr. Alisantosa and Mr. Steven Park abstained from voting on protocol IBC#001 due to a potential conflict of interest.

The Chairperson requested that color-coded comments be entered directly on the IBC Form 01 by committee members. IBC members decided to email their comments to all of the Committee members, with "IBC comments" as the "subject" of the email.

Some suggestions were given to improve the Form 01. Under "Brief overview of the project and its goals" add a request for a description of the pathogen, a flow sheet of the experiments that will be performed, symptoms of the infection and treatment if available.

The Committee members requested that the IBC meeting be held before the IACUC meeting each month.

Signed: *Pete Jany* **Date:** 8-12-04

Title: PhD

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225 Warren Street Newark, NJ 07103



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: July 2, 2004

Present: Claudia Manca, Ph.D (Chair)
Rachel Sheppard, Ph.D; Natalia Kureprina, Ph.D; Larry Barbour, BS;
Steve Park, BS; Bernadette Alisantosa, DVM, MPVM; Gaitree McNab,
CBSP and Bernice Fulton (Administrative Assistant).

Observers: None

Absent: Richard Burger, Ph.D; Ismael Calderon, Ph.D; Marta Figueroa CIH.

The Committee reviewed 34 protocols received from UMDNJ-IBC for incorporation into the PHRI-IBC system. Of those 32 were approved and assigned PHRI-IBC numbers:

UMDNJ #	PHRI #
E-03-08-04-1	IBC# 005
E-03-08-04-3	IBC# 006
E-03-29-04-4	IBC# 007
E-03-08-04-2	IBC#008
E-03-29-04-5	IBC# 009
E-02-20-04-4	IBC# 010
E-02-20-04-2	IBC# 011
E-02-20-04-1	IBC# 012
E-02-20-04-3	IBC# 013
E-03-18-04-6	IBC# 014
E-03-18-04-7	IBC# 015
E-04-30-04-01	IBC# 016
E-04-30-04-02	IBC# 017
E-01-06-04	IBC# 018
E-12-18-03	IBC# 019
E-04-15-04-02	IBC# 020

E-01-06-04-02	IBC# 021
E-04-30-04-04	IBC# 022
E-05-14-04-03	IBC# 023
E-05-14-04-04	IBC# 024
E-05-14-04-05	IBC# 025
E-04-15-04-01	IBC# 026
E-05-14-04-01	IBC# 027
E-03-18-04-2	IBC# 028
E-03-18-04-1	IBC# 029
E-03-18-04-5	IBC# 030
E-03-18-04-4	IBC# 031
E-03-18-04-3	IBC# 032
E-03-17-04-1	IBC# 033
E-03-17-04-2	IBC# 034
E-03-17-04-4	IBC# 035
E-03-17-04-3	IBC# 036

The Committee observed that the UMDNJ-IBC approvals of protocols # E-05-07-03 (PHRI-IBC# 037 from Dr. Gennaro) and E-03-12-03 (PHRI-IBC#038 from Dr. Smith) have expired.

The Committee decided to conditionally approve protocol # E-05-07-03 and E-03-12-03 for 45 days starting from July 2, 2004 to allow the investigators to submit a new IBC application.

Signed: Cheryl J. J. J. Date: 8-12-04
Title: PHD



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: August 12, 2004

Present: Claudia Manca, Ph.D (Chair)
Ismael Calderon, Ph.D., Richard Burger, Ph.D., Larry Barbour, BS;
Steve Park, BS; Bernadette Alisantosa, DVM, MPVM; Gaitree McNab,
CBSP and Bernice Fulton (Administrative Assistant).

Observers: Tinia Davis, Scientific Administrator

Absent: Natalia Kurepina, Ph.D. and Rachel Sheppard, Ph.D.

The meeting was opened by Claudia Manca. Protocols IBC #003, #004, # 039, #040 and #041 were e-mailed and asked for comments by 8/10/04 to which there was no comments received on #003 and #004, the protocols were okay and signed for approval.

Further discussion – Larry Barbour asked if there were any radioactive isotopes. Claudia replied that there was none.

Questions on #039, #040, #041 - Safety training has to be done before protocols that are not clear if personnel has been trained can move forward. A time period of 2 months was suggested before access will be denied for Animal Facility. Therefore approval of the protocols are pending satisfactory training. Tinia will sign staff up for training at the next Lab Safety date which is August 24, 2004. If they do not attend, restriction will be applied.

Claudia stressed that any change to protocol has to be sent to the administrative assistant for circulation to the chair person.

There were no comments from the committee after reviewing the minutes of 6/17/04. They were signed by the Chair person. The meeting of 7/2/04 which was the review

committee for the protocols transferred from UMDNJ to PHRI's IBC was accepted as is and signed by the Chair person. 32 protocols were approved and 2 were not considered.

Small typos need to be corrected in the wording of the protocols; such as shoe covers. The protocols will not be changed monthly but if there are further typos they will be changed yearly.

Dr. Burger suggested that the IBC and IACUC use the same numbering system. It is not possible because some of the protocols use different strains and therefore will not come out equally.

The next IBC meeting will be Thursday, September 16, 2004 at 1:30 p.m.

Meeting adjourned at 1:15 pm.

Signed: _____

John J. Jones

Date: _____

9-23-04

Title: _____

Chair



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: September 23, 2004

Present: Claudia Manca, Ph.D (Chair)
Natalia Kurepina, Ph.D. and Rachel Sheppard, Ph.D, Richard Burger,
Ph.D., Larry Barbour, BS; Steve Park, BS; Bernadette Alisantosa, DVM,
MPVM; Gaitree McNab, CBSP and Bernice Fulton (Administrative
Assistant).

Observers: None

Absent: Ismael Calderon, Ph.D.

The meeting started at 1.30pm.

The minutes of the previous meeting (August 12, 2004) were approved by the Committee and signed by the Chairperson.

The Committee approved the protocols IBC#042, IBC#043, IBC#044, IBC#045, IBC#046, IBC#047, IBC#048 and IBC#049.

The Committee noted that Natalia E. Kurepina, Ph.D. and Claudia Ferreira, B.A., listed in the IBC#045, IBC#046 and IBC#047 have not completed the Bloodborne Pathogen Training and Safety Training at UMDNJ. The Committee decided that they may not work in the PHRI-BSL2 Facility until documentation of completion of these requirements is presented.

The IBC agree to ask to each Principal Investigator working at PHRI to submit a list of pathogens stored in their laboratory.

The next IBC meeting has been scheduled for Thursday, October 14, 2004 at 1:30 p.m.

Meeting adjourned at 2:30 pm.

Signed: *Claudia Manca* **Date:** 10-14-04
Title: PhD



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: October 14, 2004

Present: Claudia Manca, Ph.D (Chair)
Natalia Kurepina, Ph.D; Rachel Sheppard, Ph.D; Richard Burger, Ph.D;
Larry Barbour, BS; Bernadette Alisantosa, DVM, MPVM;
Ismael Calderon, Ph.D; Marta Figueroa, CIH and Bernice Fulton,
(Administrative Assistant)

Observers: Tinia Davis, Scientific Administrator

Absent: Steve Park, BS and Gaitree McNab, CBSP

The meeting started at 1.30pm.

The Committee approved the protocols IBC #050 "Growth Defects of *M. tuberculosis* Mutants in Mice (H37Rv)"; IBC #054 "Growth Defects of *M. tuberculosis* Mutants in Mice (H₃₇Rv *narG::aphI* + pNarGHJ11)" and IBC #051 "Establishing an LD₅₀ base line for *Aspergillus fumigatus* infection in a murine model using intranasal, intratracheal and aerosol routes (strain R21)".

Dr. Alisantosa abstained from voting on protocol IBC#051 due to a potential conflict of interest.

The Committee did not approve protocols IBC #052 "Identification of human cytomegalovirus (HCMV) genes required for replication *in vivo* (Toledo, pathogenic strain)" and IBC #053 "Identification of human cytomegalovirus (HCMV) genes required for replication *in vivo* (AD169, vaccine strain)". The reasons were the following:

- 1) Personnel listed in the application have not completed the Blood Borne Pathogen Training and the Laboratory Safety Training. Completion of the appropriate training by at least one of the investigators listed in the application is required in order to approve the protocol.
- 2) The investigator has not provided the required IRB approval from UMDNJ to obtain fresh human foreskin tissues. (It was not clear from the application if the investigator already had the viral stock or if he needed the foreskin tissues for the preparation of new stock.).

The minutes of the previous meeting (September 23, 2004) were approved by the Committee and signed by the Chairperson.

The next IBC meeting has been scheduled for Thursday, November 18, 2004 at 1:30 p.m.

Meeting adjourned at 2:30 pm.

Signed: *John J. ...* Date: 10-14-04
Title: PHD - Chairperson



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: November 18, 2004

Present: Claudia Manca, Ph.D (Chair)
Natalia Kurepina, Ph.D; Rachel Sheppard, Ph.D; Richard Burger, Ph.D;
Bernadette Alisantosa, DVM, MPVM; Ismael Calderon, Ph.D; Marta
Figueroa, CIH, Judy Arra, (Administrative Assistant), Steve Park, BS and
Gaitree McNab, CBSP

Observers: Tinia Davis, Scientific Administrator, Amy Ryan (UMDNJ-Biosafety
Officer)

Absent: Larry Barbour, BS

The meeting started at 1.40pm.

Ms. Figueroa, introduced to the committee the new UMDNJ-Biosafety Officer (Ms. Ryan). She requested that her name be added to the IBC committee roster and Ms. McNab's removed.

The minutes of the previous meeting (October 14, 2004) sent out by email to the IBC members were not the correct version, therefore copies of the corrected minutes were passed around, reviewed and approved by the Committee.

The Committee approved the protocols IBC #052 "Identification of human cytomegalovirus (HCMV) genes required for replication *in vivo* (Toledo, pathogenic strain)" and IBC #053 "Identification of human cytomegalovirus (HCMV) genes required for replication *in vivo* (AD169, vaccine strain)". The PI has responded to the comments (see minutes October 14, 2004):

1. All the investigators listed in both applications have now completed the Blood Borne Pathogen Training and the Laboratory Safety Training.
2. The PI has already a stock of foreskin tissue and since he is not going to receive any new tissue he does not need an IRB approval. In addition IRB approval is not required to issue the IBC approval.

The Committee approved the protocols IBC#055 " Studies of hepatic stages of Plasmodium berghei" and #056 "Studies of hepatic stages of Plasmodium yoelii". It was decided that when a study involves microorganisms that are not pathogenic for humans the PI will be required to send a letter to the IBC indicating the name,

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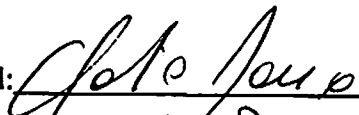
characteristics of the pathogen used, and any useful reference. The IBC will consider if completion of the IBC application is required.

The applications IBC #057, IBC #058 and IBC #059 were approved. The IBC members required from the PI correction of the nomenclature of the mutants strains. Dr. Alisantosa and Mr. Park abstained from voting on protocol IBC #057, IBC #058 and IBC #059 due to a potential conflict of interest.

It was discussed whether the use of SporeKlenz was appropriate when working with non-spore forming bacteria and it was decided that this is a decision for the Institute and the Director of the (A)BSL3.

The next IBC meeting is scheduled for Thursday, December 16, 2004 at 1:30 p.m.

Meeting adjourned at 2:40 pm.

Signed:  Date: 11-18-04
Title: PHI - Chair Person



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: December 16, 2004
Present: Claudia Manca, Ph.D (Chair)
Natalia Kurepina, Ph.D; Rachel Sheppard, Ph.D; Richard Burger, Ph.D;
Bernadette Alisantosa, DVM, MPVM; Ismael Calderon, Ph.D; Judy Arra,
(Administrative Assistant), Steve Park, BS and Amy Ryan (UMDNJ-
Biosafety Officer), Larry Barbour, BS, Barbara Barbour, BS
Observers: None
Absent: Marta Figueroa, CIH

The meeting started at 1.30pm.

The meeting started with the introduction of Ms. Barbara Bourbour who has been appointed as second non-affiliated member.

The Chairperson informed the meeting that she has received from the Office of Biotechnology Activities (OBA) confirmation of the registration for review of recombinant DNA work for the PHRI IBC.

The minutes of the previous meeting (November 18, 2004) were approved.

The IBC decided that if different strains or mutants of a given pathogen are used in a particular project is not necessary to submit a separate application for each strain or mutant.

The applications (IBC #062) "Establishing LD50 for *Yersinia pseudotuberculosis* strain MC1 infection in murine models of infection using intranasal, intratracheal instillation and aerosol routes" and (IBC #063) "*Salmonella* type III secretion as an antigen delivery system to protect against " were approved. Dr. Alisantosa and Mr. Park abstained from voting on protocol IBC #062 and IBC #063 due to a potential conflict of interest.

The Committee approved the protocols IBC#060 "Genetics and expression of *M. tuberculosis* iron regulated genes " and #061 "Virulence of *M. tuberculosis* mutant strains in mice" but requested clarification of the following points:

Applications IBC#060

- 1) The PI should clarify to which genes he refers with *these genes* on page 4 "The specific steps of these experiments is: 1) clone PCR fragment containing *these genes* into suicide vector pSM270, which contains both *sacB*".
- 2) The pSM316 mentioned under **Brief Overview**, page 4 line 11 should be included in the Section 5 (Recombinant DNA) under "Specify if the vector has species specificity".
- 3) Name of the PI should be removed from the IATA training section (page 10) since the PI is not an approved BSL3 person. In addition the name of Dr. Dubnau, the only BSL3 approved person that can receive and ship infectious material, should be added in the Section 8 page 9 under Blood Borne Pathogen Training, Safety Training, and on page 2 under Personnel Involved in the Project.

Application IBC#061

- 1) The PI should clarify to which genes he refer with *these genes* on page 3 "The specific steps of these experiments is: 1) clone PCR fragment containing *these genes* into suicide vector pSM270, which contains both *sacB*".
- 2) In Section 3 page 6 list mutant strains used in the project.
- 3) Name of the PI should be removed from the IATA training section (page 10) since the PI is not an approved BSL3 person.

The next IBC meeting is scheduled for Thursday, January 27, 2004 at 1:30 p.m.

Meeting adjourned at 2:30 pm.

Signed: John J. Perry Date: 12-16-04
Title: PhD - Chairperson



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 1-27-05
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Bernadette Alisantosa, DVM, MPVM; Ismael Calderon, Ph.D; Judy Arra, (Administrative Assistant), Steve Park, BS and Amy Ryan (UMDNJ-Biosafety Officer), Larry Barbour, BS.
Observers: None
Absent: Natalia Kurepina, Ph.D; Richard Burger, Ph.D

The meeting started at 1.35pm.

The applications (IBC #064) "Analysis of pks 2 gene in *Mycobacterium avium*" and (IBC #065) "Analysis of pks2gene in *Mycobacterium paratuberculosis*" were approved. The minutes of the previous meeting (December 16, 2004) were approved.

The committee revised the old IBC Form 01 and the Chair Person combined the suggestions.

Meeting adjourned at 2:40 pm.

Signed: Ato Jones **Date:** 4-21-05
Title: PhD Chair Person



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 4-21-05
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Ismael Calderon, Ph.D; Judy Arra, (Administrative Assistant), Amy Ryan (UMDNJ-Biosafety Officer), Natalia Kurepina, Ph.D and Richard Burger, Ph.D.
Observers: Tinia Davis, Scientific Administrator
Absent: Steve Park, BS, Larry Barbour, BS, Bernadette Alisantosa, DVM, MPVM.

The meeting started at 1.35pm.

The applications (IBC #066) "*Inoculation with Recombinant Vesicular Stomatitis Virus-Based Vaccine Vectors*" was approved. The minutes of the previous meeting (January 27, 2005) were approved.

The request by Dr. Sheppard to amend the IBC#006 entitled "The Role of Cytokines in the Pathogenesis of . . . Infection" was approved.

Dr. Kurepina requested to see, at the next IBC meeting, the list of pathogens that each Principal Investigator has in their laboratory at PHRI.

The committee agreed to: 1) prepare a specific Form for the Annual Renewal of the IBC applications approved by the UMDNJ-IBC 2) renew the old IBC Forms #02 and #03.

The next IBC meeting is scheduled for Thursday, May 19, 2005 at 1:30 p.m.

Meeting was adjourned at 2:00 pm.

Signed: Clarke Jones Date: 5-19-05
Title: Ph.D

Public Health Research Institute
225 Warren Street Newark, NJ 07103



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 5-19-05
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Ismael Calderon, Ph.D; Judy Arra, (Administrative Assistant), Amy Ryan (UMDNJ-Biosafety Officer), Natalia Kurepina, Ph.D and Richard Burger, Ph.D. Steve Park, BS, Larry Barbour, BS, Bernadette Alisantosa, DVM, MPVM
Observers: None
Absent: Marta Figueroa, CIH, Barbara Barbour, BS.

The meeting started at 1.35pm.

The minutes of the previous meeting (April 21, 2005) were approved.
The annual renewal applications (IBC #001) "*Establishing LD50 for Y. enterocolitica ATCC 27729 infection in murine model infection using intranasal, intratracheal instillation and aerosol routes*" was approved.

The IBC decided to ask to the Principal Investigators working at PHRI for a list of non-pathogenic organisms stored in their laboratory. Drs. Drilica and Kramer did not respond to the previous IBC request for a list of pathogens and therefore they will be asked to send the list of pathogenic in addition to the non-pathogenic organisms.

Claudia Manca and Steve Park suggested small changes in the Form 01.

The committee authorized the Chairperson to approve applications for the annual renewal in the event that they do not contain any major changes.

The next IBC meeting is scheduled for Thursday, June 16, 2005 at 1:00 p.m.

Meeting was adjourned at 2:15 pm.

Signed: Steve Jancy Date: 6-16-05
Title: Chair Person.

Public Health Research Institute
225 Warren Street Newark, NJ 07103



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 6-16-05
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Ismael Calderon, Ph.D; Amy Ryan (UMDNJ-Biosafety Officer), Natalia Kurepina, Ph.D and Richard Burger, Ph.D, Steve Park, BS, Larry Barbour, BS.
Observers: None
Absent: Marta Figueroa, CIH, Barbara Barbour, BS, Bernadette Alisantosa, DVM, MPVM

The meeting started at 1.00 pm.

The minutes of the last meeting (May 19,2005) were read, and approved unanimously.
The next meeting is scheduled for July 28, 2005.

Application IBC#069 "*Quinolone action during mycobacterial growth arrest*" was approved. Two applications: IBC#067 and IBC#068 will be considered when the P.I. provides responses to the concerns and questions addressed by the IBC.

The IBC unanimously agreed to allow Dr. Manca to sign administrative approval for renewals in which there have been no changes submitted, when changes include addition of personnel who have completed the required training necessary for approval, or when personnel have left employment at PHRI.

Annual renewals of existing IBC applications IBC#005 to # 033 included were administratively approved by Dr. Manca.

Renewal of IBC # 002 (from Dr. Pancholi) will be considered after clarification of rDNA status of his protocol. If rDNA work is not being performed (as originally indicated on the protocol), Dr. Manca will provide administrative approval. If rDNA status has changed, the P.I. will be asked for modifications to the protocol and full committee review. Dr. Manca will contact the P.I. for clarification.

The IBC voted to approve Dr. Manca to provide administrative approval for protocol close outs in which there are no remaining research materials at PHRI.

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225 Warren Street Newark, NJ 07103

Dr. Hornig's IBC applications #034, 035, and 036 were closed out due to inactivity by administrative approval by Dr. Manca. No work was done at PHRI, and no materials were brought into PHRI.

Discussion:

How to gain compliance of Dr. Kreiswirth who has not responded to email requests to complete IBC application for registration of his infectious materials. It was decided that Dr. Kurepina would complete the necessary forms for submission by Dr. Kreiswirth. If needed, Dr. Manca will speak with Dr. Kreiswirth to facilitate the application process.

Short-term visitors to PHRI must have approved training in BBP, Lab Safety, Animals, etc. prior to observation or participation. Since affiliation with UMDNJ is near, and PHRI would come under their legal umbrella on regulatory affairs, we discussed the possibility of developing guidelines for accreditation (such as online) with UMDNJ to accommodate our international and other outside visiting scientists. It was decided that a small sub-group of IBC members meet to formulate a plan for Amy Ryan to discuss and explore with UMDNJ.

Meeting was adjourned at 2:10 pm.

Signed: Pete Perry Date: 7/28/05
Title: Chair



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 7-28-05
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Ismael Calderon, Ph.D; Amy Ryan (UMDNJ-Biosafety Officer), Natalia Kurepina, Ph.D and Larry Barbour, BS, Barbara Barbour, BS, Bernadette Alisantosa, DVM, MPVM and Carla Lopez (Administrative assistant)
Observers: Tinia Davis
Absent: Marta Figueroa, CIH, Richard Burger, Ph.D, Steve Park, BS.

The meeting started at 1.30 pm.

The Chairperson introduced to the committee the new IBC-Administrative assistant (Ms. Lopez).

The minutes of the last meeting (June 16, 2005) were read, and approved unanimously.

Applications: IBC #067 "Tissue colonization and damage by Lyme disease spirochete, *Borrelia burgdorferi*"; IBC #068 "Tissue colonization and damage by *Pseudomonas aeruginosa*"; IBC #070 "DNA uptake in *Neisseria gonorrhoeae*" and IBC #071 "Novel Targets for Vaccines against Tuberculosis" were approved.

The IBC decided that when an application is modified to include rDNA work it cannot be automatically renewed and a submission of a new application is required. On this basis the renewal of the application #041 submitted by Dr. Smith was not accepted.

The Chairperson indicated that the IBC need to look for a new member with experience in rDNA work and proposed to invite Dr. Dorothy Fallows. Dr. Kurepina suggested other candidates as: Marcela Rodriguez and Xilin Zhao, this issue will need further discussion.

The UMDNJ Biosafety Officer (Amy Ryan) informed the committee that visiting scientists may complete BBP and lab safety online.

The next meeting is scheduled for August 18, 2005 at 1.30 pm.

Meeting was adjourned at 2:30 pm.

Signed: *John J. Pera* Date: 8/18/05
Title: Chair Person



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 8-18-05
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Ismael Calderon, Ph.D; Amy Ryan (UMDNJ-Biosafety Officer), Larry Barbour, BS, Bernadette Alisantosa, DVM, MPVM, Richard Burger, Ph.D, Steve Park, BS.
Observers: None
Absent: Marta Figueroa, CIH, Natalia Kurepina, Ph.D., Barbara Barbour, BS.

The meeting started at 1.30 pm.

The minutes of the last meeting (7-28-05) were read, and approved unanimously.
Application IBC # 073 entitled " *mediated clearance and immunogenicity of SHIV*" was approved.

The Chairperson informed the committee that in October the IBC will need to file with the NIH an annual report, which includes a roster of the IBC members, this would be a good time to make any change among the committee members.

The IBC decided to postpone to the next meeting the discussion on adding a new member with knowledge in rDNA since Dr. Kurepina was not present.
The IBC asked for clarification of the status of Marta Figueroa from EOHSS.

The IBC decided to include in the IBC Form 01 an additional section on human tissue and human cell lines. The modified Form 01 with the new changes will be circulated for comments.

The next meeting is scheduled for September 22, 2005.

Meeting was adjourned at 2:00 pm.

Signed: Claudia Manca Date: 9/22/05
Title: Ph.D - Chairperson

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Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 9-22-05
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Ismael Calderon, Ph.D; Amy Ryan (UMDNJ-Biosafety Officer), Bernadette Alisantosa, DVM, MPVM, Richard Burger, Ph.D, Steve Park, BS, Natalia Kurepina, Ph.D.,
Observers: None
Absent: Marta Figueroa, CIH, Barbara Barbour, BS and Larry Barbour, BS

The meeting started at 1.30 pm.

The minutes of the last meeting (8-18-05) were approved unanimously. The new applications: IBC # 074 entitled "Virulence of *M. tuberculosis* mutant strains in mice"; IBC#075 entitled "Avirulent *Yersinia pestis* infection models in mice" and the amendment for the application IBC#12 entitled "Acquisition of Drug resistance in Mice infected with *M. tuberculosis* and treated with Antibiotics (*M. tuberculosis* H37Rv)" were approved.

The Chairperson informed the committee that Dr. Pancholi requested to terminate the applications IBC# 002 and IBC#044. The Chairperson informed the committee that the annual renewal and amendments for the following applications were administratively approved as previously established by the IBC:

IBC#45 "Prevention and treatment of Staphylococcal bacteremia with heteropolymers (*Staphylococcus epidermidis*, 10683)"; IBC#46 "Prevention and treatment of Staphylococcal bacteremia with heteropolymers (*Staphylococcus aureus*, strain MW2)"; IBC#47 "Prevention and treatment of Staphylococcal bacteremia with heteropolymers (*Staphylococcus aureus*, strain 11301)"; IBC# 042 entitled "In vivo growth control of *M. tuberculosis* by glutathione (GSH) and other related compounds (strain H37ggTA)"; IBC#043 entitled "Role of glutathione (GSH) in macrophage killing of mycobacteria (strain H₃₇Rv)"; IBC#049 "In vivo growth control of *M. tuberculosis* by glutathione (GSH) and other related compounds (strain H37Rv)"; IBC#051 entitled "Establishing an LD₅₀ base line for *Aspergillus fumigatus* infection in a murine model using intranasal, intratracheal and aerosol routes (strain R21)"; IBC#057 entitled "Murine model of pathogenesis and protection ()"; IBC#058 entitled "Murine model of pathogenesis and protection ()"; IBC#059 "Murine model of pathogenesis and protection ()"; IBC#062 entitled "Establishing LD50 for *Yersinia pseudotuberculosis* strain MC1 infection in murine models of infection using intranasal, intratracheal instillation and aerosol routes".

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Amy Ryan gave the OK to remove Marta Figueroa from the IBC roster.

The next meeting is scheduled for October 20, 2005 at 1.30 pm.

Meeting was adjourned at 2:00 pm.

Signed: *Steve Jones* Date: *10/20/05*
Title: *Chair*

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Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 10-20-05
Present: Claudia Manca, Ph.D (Chair); Rachel Sheppard, Ph.D; Ismael Calderon, Ph.D; Amy Ryan (UMDNJ-Biosafety Officer); Bernadette Alisantosa, DVM, MPVM; Richard Burger, Ph.D; Steve Park, BS; Natalia Kurepina, Ph.D and Larry Barbour, BS.
Observers: None
Absent: Barbara Barbour, BS

The meeting started at 1.30 pm.

The minutes of the last meeting (9-22-05) were approved.

The Chairperson informed the committee about an event that occurred on the 3rd Floor BSL3. The committee carefully reviewed and discussed the event and unanimously decided that what was reported was not to be considered an Incident and the facility will not need to be fogged or fumigated. The committee feels that the heat and the time the infectious material was kept inside the autoclave were sufficient to kill mycobacteria. A surface decontamination of the anteroom and discard of open PPE will be effected before reopening the facility. It was also decided that an SOP is needed for dealing with similar future problems on the 3 Floor BSL3.

The next meeting is scheduled for November 17, 2005 at 1.30 pm.

Meeting was adjourned at 2:30 pm.

Signed: *John J. Jones* **Date:** 11/17/05
Title: Chair



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 11-17-05
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Amy Ryan (UMDNJ-Biosafety Officer), Bernadette Alisantosa, DVM, MPVM, Richard Burger, Ph.D, Natalia Kurepina, Ph.D. and Larry Barbour, BS.
Observers: None
Absent: Barbara Barbour, BS; Ismael Calderon, Ph.D; and Steve Park, BS

The meeting started at 1.30 pm.

The minutes of the last meeting (10-20-05) were approved.
The annual renewal for the following applications: IBC # 052 entitled "Identification of human cytomegalovirus (HCMV) genes required for replication *in vivo* (Toledo, pathogenic strain)" and IBC#053 entitled Identification of human cytomegalovirus (HCMV) genes required for replication *in vivo* (AD169, vaccine strain) were approved.

The committee agrees that:

- 1) Investigators not in compliance with the mandatory trainings *Blood Borne Pathogen Training* and *Laboratory Safety Training* will be not allowed to work in the laboratories.
- 2) Use of N95 to work in the BSL2 animal facility is mandatory.

Dr. Burger informed the committee that during the IACUC inspection the portable BSC located in room was found with the re-certification record expired. However, since the gauge of the BSC shows functionality and the users wear PAPR there is no need to stop any work at this time. The BSC will be re-certified during the shutdown scheduled for January 2006.

The next meeting is scheduled for December 15, 2005 at 1.30 pm.

Meeting was adjourned at 2:15 pm.

Signed: Clotilde Junc Date: 12/15/05
Title: Chair Person



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 12-15-05
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Amy Ryan (UMDNJ-Biosafety Officer), Bernadette Alisantosa, DVM, MPVM, Richard Burger, Ph.D, Natalia Kurepina, Ph.D. and Larry Barbour, BS, Ismael Calderon, Ph.D; and Steve Park, BS
Observers: None
Absent: None

The meeting started at 1.30 pm.

The minutes of the last meeting (11-17-05) were approved.

The Chairperson informed the committee to have administratively approved the annual renewal for the following applications: IBC # 064 entitled "Analysis of pks2 gene in *Mycobacterium avium*" and IBC#065 entitled "Analysis of pks2 gene in *Mycobacterium paratuberculosis*".

The new application IBC#076 entitled "Comparative virulence of strains in hamsters and mice models using intraperitoneal (IP) route" was approved.

The Chairperson informed the committee that the NIH Office of Biotechnology Activities (OBA) requested to remove the non-affiliated member, Ms. Barbara Barbour, from the IBC roster since she does not live in the proximity of the Institute. The Committee will identify a new non-affiliated member, in the mean time the IBC will not review or approve applications that involve recombinant DNA work.

The next meeting is scheduled for January 19, 2005 at 1.30 pm.

Meeting was adjourned at 2:00 pm.

Signed: Pat Manca Date: 2/16/06
Title: Chairperson



Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 2-16-06
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Amy Ryan (UMDNJ-Biosafety Officer), Richard Burger, Ph.D, Natalia Kurepina, Ph.D., Larry Barbour, BS, Ismael Calderon, Ph.D; and Steve Park, BS
Observers: None
Absent: None

The meeting started at 1.30 pm.

The minutes of the last meeting (12-15-05) were approved.

The Chairperson informed the committee that the annual renewal for the applications: IBC # 003 entitled " challenge " and IBC#004 entitled " challenge " were administratively approved.

The new application IBC#077 entitled "Pharmacokinetic analysis of cochleates containing amphotericin B (CAMB) in a murine model of candidasis" was approved.

The Chairperson informed the committee that the NIH Office of Biotechnology Activities (OBA) reviewed our updated IBC- roster and found it compliant with the NIH guidelines. Mr. Barbour will be the new non-affiliated member of the committee.

Applications IBC#078 "Recombinant *Mycobacterium tuberculosis* attenuated strain MC²6030 + (H37Rv *ΔlysA* and *ΔpanCD* expressing antigen) as a live vaccine for ", IBC#079 "Recombinant non-pathogenic New Castle Disease Virus Hitchner B1 strain + as a vaccine vector for " and IBC#080 "Recombinant non-pathogenic *Mycobacterium smegmatis* attenuated strain MC²155 + antigen as a live vaccine for " were not approved because Section 6 of the Form 01 was not completed.

The next meeting is scheduled for February 23, 2006 at 1.30 pm.

Meeting was adjourned at 2:20 pm.

Signed: Late Jency Date: 2/23/06

Title: Chair

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Minutes of the meeting of the Institutional Biosafety Committee (IBC)

Date: 2-23-06
Present: Claudia Manca, Ph.D (Chair), Rachel Sheppard, Ph.D; Amy Ryan (UMDNJ-Biosafety Officer), Larry Barbour, BS and Ismael Calderon, Ph.D.
Observers: None
Absent: Richard Burger, Ph.D, Natalia Kurepina, Ph.D., and Steve Park, BS.

The meeting started at 1.30 pm.

The minutes of the last meeting (2-16-06) were approved.

The new applications IBC#078 "Recombinant *Mycobacterium tuberculosis* attenuated strain MC²6030 + (H37Rv Δ lysA and Δ panCD expressing antigen) as a live vaccine for ", IBC#079 "Recombinant non-pathogenic New Castle Disease Virus Hitchner B1 strain + antigen as a vaccine vector for " and IBC#080 "Recombinant non-pathogenic *Mycobacterium smegmatis* attenuated strain MC²155 + antigen as a live vaccine for " were approved.

The committee decided to do not modify the Section 6 of the IBC Form 01.

The next meeting is scheduled for March 16, 2006 at 1.30 pm.

Meeting was adjourned at 2:00 pm.

Signed: Claudia Manca Date: 3/16/06
Title: chairperson