

Office of Institutional Research
and Evaluation



1030 N. Mountain
P.O. Box 210134
Tucson, AZ 85721
(520) 621-7807

Arizona's First University.

May 9th, 2006

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

Ref: Public Records Request dated 15 March 2006

Dear Mr. Hammond:

This letter is to formally acknowledge the receipt of your public records request of 3/15/2006, made to the University of Arizona, which was recently forwarded to this office.

Your request has been directed to the University officials most likely to have responsive documents. Those documents will be reviewed to eliminate matters whose inspection is restricted by law. This process will be completed as promptly as circumstances permit.

Requests may take longer to process if redactions are needed or when records must be collected from multiple sources or archived files. Please be advised that we will provide incremental responses to your request as soon as possible beginning with the earliest records requested.

I will contact you when the requested records are available.

Sincerely,

Anna Wilkinson
University Reports Coordinator



Vice President for Research
Institutional Biosafety Committee
(520) 621-3441
FAX: (520) 621-6159

1230 North Park Avenue, #205
P.O. Box 210420
Tucson, AZ 85721-0420

March 20, 2007

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

Re: Public Records Request Dated March 15, 2006

Dear Mr. Hammond:

Enclosed please find a fourth response to your public records request of March 15, 2006 for Minutes of the University of Arizona Institutional Biosafety Committee.

The minutes of this committee document the University of Arizona's compliance with Section IV-B-2-a-(7) of the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules, from April 2002.

The enclosed material represents minutes from January through December of 2006, excluding May and July 2006, which contain material to be reviewed externally before release. These should follow shortly. As indicated in our previous correspondence, these documents constitute the fourth installment of an incremental response because of the significant amount of time and effort that has been required to complete the request. As in our previous responses, all unfunded proposals have been redacted from the "Proposal Title" portion of each month's minutes, in accordance with Arizona public records law. This constitutes the majority of the redacted material.

Also, sections of the Minutes have been redacted, in accordance with Arizona law and the guidelines from the NIH Office of Biotechnology Activities general letter of May 14, 2004, to remove information whose disclosure would directly compromise institutional or national security. Also redacted were a few instances of names or other identifying information of students in accordance with the 1974 Family Educational Rights and

Edward Hammond
March 20, 2007
Page Two

Privacy Act (FERPA) guidelines, one instance of information deemed attorney-client privileged, and any personnel information protected from release by Arizona Board of Regents policy 6-912. (You can find this policy at: <http://www.abor.asu.edu/> in Chapter 6, Part 2 on the Policy Manual.)

Sincerely,

A handwritten signature in black ink, appearing to read "Mark J. Grushka". The signature is fluid and cursive, with the first name "Mark" and last name "Grushka" clearly distinguishable.

Mark J. Grushka, M.S., CSP
Manager, Biosafety and Biosecurity
520-621-5279 (O); 520-621-6159 (F)
mgrushka@u.arizona.edu

Enclosures

Institutional Biosafety Committee**MINUTES**

Meeting January 17, 2006

On January 17, 2006, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Nafees Ahmad, Don Bourque, James Collins, Robert Fleming, Mark Grushka, Sue Hopf, David Madison, Leland Pierson III (Chair), Michael Rand, Michael Riehle, Mike Riggs, Randy Ryan, Margaret Stalker, Glenn Songer, Herbert Wagner, Jr. and Bruce Walsh. Also attending were Alice Langen, Vice President for Research Office, Lana Hudgins and guest Charles Schable. Not in attendance were: David Besselsen (on sabbatical), Richard Friedman, John Galgiani, Jeannie Nordstrom, and Kris Orsborn.

Chair, Dr. Leland (Sandy) Pierson introduced guest, Charles A. Schable, a prospective new Committee member. Mr. Schable recently retired as Director of the Coordinating Office of Terrorism Preparedness and Emergency Response at the Centers for Disease Control. He also was previously Chief of the HIV Serology Section, Immunology Branch of DASTLR, National Center for Infectious Diseases. His undergraduate degree in Microbiology and graduate degree in Microbiology/Immunology are from Arizona State University. Mr. Schable told the Committee the budget for his office on his last position was \$1.6 billion and he had a staff of over 350 people.

The minutes of the December 20, 2005 Institutional Biosafety Committee meeting were approved as submitted. Dr. Rand thanked Dr. Songer for bringing it the Committee's attention at the last meeting that Leptosporosis could be a concern in field mice and precautions should be taken when handling them. IACUC has already acted on this information.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Mark Grushka subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Mark Grushka's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 17, 2006

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee
continued:

[illegible]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 17, 2006

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 17, 2006

Page 5

MUAs reviewed with comments, continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The Committee discussed whether the changes to the Biosafety Handbook on Cell Culture that Mark Grushka made accurately reflect what the Committee voted on at the September 20, 2005 Institutional Biosafety Committee meeting. The wording deleted from the original version indicates investigators do not need to use Biosafety Level 2 when using animal cell lines. That was not the intent of the Committee vote.

The following wording does reflect what the Committee intended:

If a Principal Investigator desires to work with cell culture at less than Biosafety Level Two (BSL-2), he/she must provide following information to the Institutional Biosafety Committee.

- * A description of every biological component of the cell culture system.
- * Utilization of a risk assessment model that identifies the specific hazards associated with a laboratory-acquired infection and the mitigation strategy for reducing or eliminating the risks associated with the cell culture use.

Under Old Business, Mark Grushka reported on the following follow-ups:

Follow-up from the November 15, 2005 IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
Thomas Dragovich Cancer Center	A Randomized, Phase II Study of TNFerade Biologic with 4-FU and Radiation Therapy for First-line Treatment of Unresectable Locally Advanced Pancreatic Cancer (Gen Vec, Inc.)	HGT

The Committee was satisfied that Dr. Dragovich had responded to their questions and provisionally approve his Memorandum of Understanding and Agreement form. The NIH Guidelines require that the Human Subjects Committee approve it first. Once that approval is received, the IBC will approve this project.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 17, 2006

Page 6

Also under Old Business, Mark Grushka reported on the following follow-up:

Follow-up from the August 23, 2005 IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
Robert Arnold Chem & Env Engr	TRIF 1: Estrogenic Activity in Reclaimed Water and Stormwater (<i>TRIF</i>)	BL2
	Polybrominated Diphenyl Ethers in Biosolids: Assessment of Relative Risk after Land Application (<i>Technology and Research Initiative Fund – TRIF</i>)	BL2
	Fate of Pharmaceutically Active Compounds in Sludges and Biosolids Derived from Wastewater Treatment (<i>USGS</i>)	BL2

Mark reported the Dr. Arnold had finally submitted the requested SOPs for this research.

There was insufficient time to get to all items on the Agenda. The Committee requested that the item regarding a "Vote on the use of alternate voting Committee members" be put at the top of next month's Agenda.

Mark Grushka said he would give information about the Flu Pandemic at the next meeting and have Dr. Mike Riehle give an update on the status of his ACL-2 mosquito laboratory.

Two proposal routing sheets from labs covered under BSL-1 registration were submitted in January.

The next IBC meeting will be February 21, 2006 in the **Pima Room** of the Student Union.

Institutional Biosafety Committee**MINUTES**

Meeting February 21, 2006

On February 21, 2006, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Nafees Ahmad, Don Bourque, John Galgiani, Robert Fleming, Mark Grushka, Sue Hopf, Kris Orsborn, Jeannie Nordstrom, Leland Pierson III (Chair), Michael Rand, Michael Riehle, Margaret Stalker, Glenn Songer, Herbert Wagner, Jr. and Bruce Walsh. Also attending were Alice Langen, Vice President for Research Office, Lana Hudgins and guests Charles Schable, Stephen Billington and Vice President for Research, Dr. Leslie Tolbert. Not in attendance were: David Besselsen (on sabbatical), James Collins, Richard Friedman, David Madison, Mike Riggs, and Randy Ryan,

Dr. Pierson, Chair of the Committee, welcomed guests and prospective new Committee members Charles A. Schable former Director of the Coordinating Office of Terrorism Preparedness and Emergency Response at the Centers for Disease Control and Stephen Billington, Associate Professor, Veterinary Science and Microbiology. Dr. Pierson also welcomed guest, Dr. Leslie Tolbert, Vice President for Research, Graduate Studies and Economic Development. Dr. Tolbert expressed her appreciation to the Committee for their service to the University.

The minutes of the January 17, 2006 Institutional Biosafety Committee meeting were approved with a correction to page 4 under Dr. Melissa Halpern to read "is *using* a genetically modified mouse".

At previous meetings a quorum (a majority) had been lost when a member or members had to leave before all items requiring a vote were completed. To alleviate this problem, the Committee discussed the option of using alternates as voting members. It was suggested that the definition of a quorum could be changed. The Committee voted and approved that the Chair can declare quorum of at least five people (the minimum Committee members required by NIH Guidelines) at a regularly scheduled meeting.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Mark Grushka subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Mark Grushka's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 21, 2006

Page 2

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee
continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED]
[REDACTED] [REDACTED]	[REDACTED] [REDACTED]	[REDACTED]
[REDACTED] [REDACTED]	[REDACTED] [REDACTED]	[REDACTED]
[REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED]
[REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED]
[REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED]
[REDACTED] [REDACTED]	[REDACTED] [REDACTED]	[REDACTED]
[REDACTED] [REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 21, 2006

Page 3

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 21, 2006

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 21, 2006

Page 6

The following MUAs were reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	()
[REDACTED]	[REDACTED] [REDACTED] [REDACTED]	()
[REDACTED]	[REDACTED] [REDACTED] [REDACTED]	()

It was also noted that her safety cabinet appeared to be a laminar flow hood and that the certification was out of date. The Committee asked that Mark Grushka, Biosafety Officer, visit the lab to be sure Dr. Andreansky had the proper type of biological safety cabinet and that certification was up to date. The Committee also requested that Dr. Andreansky provide a copy of her Standard Operating Procedures (SOPS).

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 21, 2006

Page 7

Under Old Business, Mark Grushka reported on the following follow-up from the January 17, 2006 IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
Melissa Halpern Pediatrics	Bile Acids in the Pathogenesis of Necrotizing Enterocolitis (NIH)	BL2

Dr. Halpern was advised that she needs to use Biosafety Level 2 when handling the rat cell culture and changed her Memorandum of Understanding and Agreement (MUA) form to BSL2. Dr. Halpern also changed her MUA form to indicate "Yes" for the question "Does this project involve the use of Genetically Modified Organisms?" since she is using a genetically modified mouse.

Dr. Mike Riehle gave an update on the status of his [REDACTED] He reported that they anticipated completion by the end of the month. The design meets or exceeds the level 2 Arthropod Containment Guidelines established by the American Society of Tropical Medicine and Hygiene. He showed the Committee diagrams of the lab.

One proposal routing sheet from labs covered under BSL-1 registration was submitted in February.

The next IBC meeting will be March 21, 2006 in the **Pima Room** of the Student Union.

Institutional Biosafety Committee**MINUTES**

Meeting March 21, 2006

On March 21, 2006, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Nafees Ahmad, Don Bourque, Robert Fleming, Mark Grushka, Sue Hopf, David Madison, Leland Pierson III (Chair), Michael Riehle, Mike Riggs, Margaret Stalker, Herbert Wagner, Jr. and Bruce Walsh. Also attending were Alice Langen, Vice President for Research Office and guest Stephen Billington. Not in attendance were: David Besselsen (on sabbatical), James Collins, Richard Friedman, John Galgiani, Kris Orsborn, Jeannie Nordstrom, Michael Rand, Randy Ryan, and Glenn Songer,

Committee members were given a memorandum from Dr. Leslie Tolbert, Vice President for Research, regarding the scope of the Committee and liability coverage.

The minutes of the February 21, 2006 Institutional Biosafety Committee meeting were approved as submitted.

The Committee voted on and unanimously approved the revised wording for the Cell Culture Section in Chapter 6 of the Biosafety Handbook. The revised wording submitted for Committee approval is attached to these minutes.

Under Old Business, Mark Grushka reported that Human Subjects had approved Dr. Thomislav Dragovich's Human Gene Therapy (HGT) proposal, "A Randomized, Phase II Study of TNFerade Biologic with 4-FU and Radiation Therapy for First-line Treatment of Unresectable Locally Advanced Pancreatic Cancer", sponsored by Gen Vec, Inc. At the January 17, 2006 IBC Meeting the Committee had conditionally approved this Memorandum of Understanding and Agreement form pending Human Subject's approval.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Mark Grushka subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Mark Grushka's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
Danny Brower Mol/Cell Biology	Structure-function Studies of the PS Integrins (NIH)	BL1
Melanie Culver SRNR	Genetic Diversity in the Flat-Tailed Horned Lizard (T & E)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 21, 2006

Page 2

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 21, 2006

Page 3

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 21, 2006

Page 4

The following MUA was reviewed by the Committee and unanimously approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 21, 2006

Page 5

[REDACTED]

The following MUAs were reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
Randy Burd Nutritional Sciences	Tumor Radiosensitization by Quercetin (American Institute for Cancer Research)	BL2

The Committee asked for information about what isotope is being used to irradiate the cells. Additional information is requested about what safety precautions he will follow and what he will do with his cells once he is done. Will they still be radioactive and need to be stored until they decay before they can be disposed? He also needs a biohazards sign on the door (according to his MUA he doesn't have one).

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business Mark Grushka told the Committee he had received an amendment to Dr. Lee Cranmer's HGT protocol "A Phase I Study to Evaluate the Safety and Pharmacokinetics of Pro-1, A Liposome-Encapsulated Thymidine Kinase Gene Formulation in Patients with Stage IV Metastatic Melanoma", sponsor Protiva Biotherapeutics, Inc. Protiva Biotherapeutics, Inc. received FDA approval for these changes. Mark sent the amendment to the ad hoc committee members, Drs. Pierson, Galgiani and Nafees for their review on February 10, 2006. At the IBC meeting Drs. Pierson and Ahmad agreed that the amendment be approved. The Committee agreed with their recommendation.

The next IBC meeting will be April 18, 2006 in the **Pima Room** of the Student Union.

Institutional Biosafety Committee

MINUTES

Meeting April 18, 2006

On April 18, 2006, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Stephen Billington, Don Bourque, John Galgiani, Mark Grushka, Sue Hopf, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Michael Riehle, Charles Schable, Glenn Songer, Margaret Stalker, and Herbert Wagner, Jr. Also attending were Alice Langen, Vice President for Research Office and guest Dan Silvain, Director of Radiation Control. Lana Hudgins, Graduate Student, IBC office also attended. Not in attendance were: Nafees Ahmad, David Besselsen (on sabbatical), James Collins, Robert Fleming, Richard Friedman, (on medical leave), David Madison, Jeannie Nordstrom, Mike Riggs, Randy Ryan, and Bruce Walsh.

Chair, Sandy Pierson welcomed new IBC members Stephen Billington and Charles Schable. He also introduced and welcomed, guest, Dan Silvain, the new Director of Radiation Control.

Mark Grushka announced that [REDACTED] graduate student who is doing an internship with the IBC office, had completed a training module on Biological Safety Cabinets and it is now available on the IBC website. Mark reported that [REDACTED] had been matching certification documentation for biological safety cabinets from Facilities Management with our data base and asked [REDACTED] to report on her findings. She said there appears to be approximately 100 cabinets from our database that are not currently certified. Jack Mutchler, with Facility Management notifies departments when cabinets need to be recertified. The department must provide funding before certification is performed.

The minutes of the March 21, 2006 Institutional Biosafety Committee meeting were approved as submitted.

Under Old Business, Mark Grushka reported from the March 21, 2006 meeting the following follow-ups requests:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
April 18, 2006

Page 2

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
Randy Burd Nutritional Sciences	Tumor Radiosensitization by Quercetin (<i>American Institute for Cancer Research</i>)	BL2

The Committee asked for information about what isotope is being used to irradiate the cells and where the work is being done. Additional information is requested about what safety precautions he will follow and what he will do with his cells once he is done. Will they still be radioactive and need to be stored until they decay before they can be disposed? He also needs a biohazard sign on the door. [Mark Grushka contacted the Director of Radiation Control who responded: "The irradiation can only be done at one of our two irradiation facilities. We do not monitor the samples irradiated only the unit. The samples are not radioactive after the irradiation. If Dr. Burd wishes to use the facility, he will require additional training."]

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Mark Grushka subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Mark Grushka's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
April 18, 2006

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Victor Hruby Henry Yamamura Chemistry/Pharm	New Modalities for the Treatment of Pain and Drug Abuse: Project B: Molecular Mechanisms of the Human Delta-Opioid Receptor Down-Regulation (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
April 18, 2006

Page 4

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
Jorge Giron Micro/Immunology	Novel YcbQ Pili of Enterohemorrhagic E. coli O157:H7 (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business Mark Grushka reported to the Committee that the Institutional Biosafety Committee had received notice of Serious Adverse Events (SAEs) relating to Dr. Tom Dragovich's study "A Randomized, Phase II Study of TNFerade Biologic with 5-FU and Radiation Therapy for First-line Treatment of Unresectable Locally Advanced Pancreatic Cancer". No patients have been enrolled at Dr. Dragovich's site. Mark sent out this notice to the subcommittee members Drs. Ahmad, Galgiani and Pierson to review. Dr. Pierson said that the local investigator assessments were: "unrelated to study drug", "possibly related to study drug", "probably unrelated to study drug", "possibly related to study drug", "possibly related to study

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
April 18, 2006

Page 5

drug" and one "probably related to study drug". This information did not change anything in the Institutional Biosafety Committee review of this project. One Committee member pointed out that the Consent Forms might need to be changed to give patients more information but this falls under Human Subject's jurisdiction.

It was reported that Dr. Dragovich also submitted an amendment to his protocol. The changes were in response to Serious Adverse Events at other institutions. The Committee acknowledges receipt of modification to the original protocol.

Also under New Business, Mark gave a status report on the UA Pandemic Planning Project. It is not possible to predict accurately when an influenza pandemic will occur or how severe they will be. Because of migration patterns, birds in Alaska are being watched as sentinels for the spread of the outbreak of avian influenza in Asia and Europe to this country.

Governor Napolitano held a meeting January 6 to cover preparing the government and preparing the community in the event of a pandemic. The University of Arizona formed a working group to discuss authority and responsibility for UA Pandemic planning, defining essential services and to brainstorm on the various impacts to the University from a pandemic. A Campus Emergency Response Team (CERT) UA Pandemic Response Planning Subgroup was formed in February. They are using the Centers for Disease Control (CDC) Colleges and Universities Pandemic Influenza Planning Checklist. <http://www.pandemicflu.gov/plan/collegeschecklist.html> The CERT US Pandemic Response Planning Subgroup wants a working plan by the end of the fiscal year. They will be addressing the following areas: levels of alert and response, travel, faculty and students, research impacts, isolation and quarantine, medication and vaccine dispensing, communications, etc. The group will be meeting every two weeks to meet their goal for a working plan by July 1. A website resource page for the campus community is a priority. One of the Committee members asked if the University already has a plan for emergency vaccinations. This is an area currently being worked on.

Because of limited time, Mark Grushka said he would send Committee members the PowerPoint presentation on the Autoclave Policies for Preventive Maintenance and Biological Testing to be discussed when there was more time at a future meeting. Randy Ryan brought the issue of autoclave testing at the University to Mark's attention in February. Currently autoclave testing is each department's responsibility and policy varies. There is no uniformity.

The next IBC meeting will be May 16, 2006 in the **Pima Room** of the Student Union.

Institutional Biosafety Committee

MINUTES

Meeting June 20, 2006

On June 20, 2006, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Nafees Ahmad, David Besselsen, John Galgiani, Mark Grushka, David Madison, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Michael Riehle, Charles Schable, Margaret Stalker, and Herbert Wagner, Jr. Also attending were Alice Langen, Vice President for Research Office and [REDACTED], IBC office. Not in attendance were: Stephen Billington, Don Bourque, Robert Fleming, Richard Friedman (on medical leave), Sue Hopf, Jeannie Nordstrom, Mike Riggs, Randy Ryan, Glenn Songer, and Bruce Walsh.

The minutes of the May 16, 2006 Institutional Biosafety Committee meeting were approved as submitted.

Research Assistant Professor, Dr. Miranda Adelman of the Arizona Arthritis Center was a guest of the Committee. Mark Grushka invited her to attend as a prospective Committee member. Dr. Adelman shared with the Committee that she received her Ph.D. in Microbiology and Immunology at the University of Arizona and originally joined the Arthritis Center as a postdoctoral researcher. Her research focuses on understanding the causative pathways of autoimmune disease. Her work is focused on the role of human endogenous retroviruses in autoimmune disease and what role these retroviruses play in autoimmune disease. She collaborates extensively with faculty in Microbiology and Immunology, the Arizona Cancer Center and the Arizona Arthritis Center.

Under Old Business, Dr. Ahmad reported the following follow up request the Committee asked Mark Grushka, Biosafety Officer, to handle after the May 16, 2006 meeting:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 20, 2006

Page 2

Also under Old Business, Dr. Riehle reported the following request the Committee asked Mark Grushka, Biosafety Officer to follow up after the April 18, 2006 meeting:

[illegible]

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Mark Grushka subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Mark Grushka's pre-review.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 20, 2006

Page 3

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Bernard Futscher Cancer Center	Phase I/II Trial of Subcutaneous Decitabine (5-aza-2'deoxyctidine) Maximizing Genomic Demethylation in Patients with Myelodysplastic Syndrome (MGI Pharma, Inc.)	BL2
Eugene Gerner Cancer Center	SPORE in GI Cancers. Project 1. Genetic Variability as Prognostic or Predictive Factors in Colorectal Intraepithelial Neoplasia (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 20, 2006

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Joyce Schroeder Mol & Cell Biology	Molecular Therapeutic Targeting of MUC1/beta-catenin Interactions in Invasive Breast Carcinoma (AACR, ABRC)	BL2
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 20, 2006

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
David Alberts Cancer Center	Cancer Center Support Grant (NIH/NCI)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 20, 2006

Page 6

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Committee members were reminded that the University of Arizona Institutional Biosafety Committee has historically reviewed research projects for the Tucson Veterans Affairs Medical Center. In February 1991, the Institutional Biosafety Committee agreed to review research protocols

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 20, 2006

Page 6

involving biohazards submitted by the Tucson Veterans Affairs Medical Center. The VAMC already had an agreement that all VA protocols using human subjects are reviewed by the Human Subjects Committee at the University. The VAMC requested a similar arrangement for projects involving biohazards conducted at the VA as has been the practice for our DOD contract since 1987.

It was also pointed out that the VA now has its own Biohazard Committee and may not need the University of Arizona IBC's continued expertise. This agreement should be revisited.

Alice Langen and Mark Grushka explained to the Committee that they were currently meeting in Phoenix to discuss future compliance over sight for the new College of Medicine research facilities.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The next IBC meeting will be July 18, 2006 in the **Presidio Room** of the Student Union at 1:30 pm.
PLEASE NOTE THE CHANGE OF ROOM AND TIME FOR THIS UPCOMING MEETING.

MINUTES

Meeting August 15, 2006

On August 15, 2006, a meeting of the Institutional Biosafety Committee was held in the Picacho Room of the Student Union from noon to 1:15 pm. In attendance were: Nafees Ahmad, Miranda Adelman, David Besselsen, Stephen Billington, John Galgiani, Mark Grushka, Robert Perrill, Leland Pierson III (Chair), Michael Riehle, Randy Ryan, Charles Schable, Glenn Songer, Margaret Stalker and Herbert Wagner, Jr. Also attending was [REDACTED] IBC office. Not in attendance were: Don Bourque, Robert Fleming, Richard Friedman (on medical [REDACTED]), Sue Hopf, David Madison, Jeannie Nordstrom, Mike Riggs, Michael Rand, and Bruce Walsh.

The minutes of the July 18, 2006 Institutional Biosafety Committee meeting were approved as submitted.

Chair, Sandy Pierson announced to the Committee that he will be attending the conference, "IBC Basics: An Introduction to the NIH Guidelines and the Oversight of RecDNA Research" in San Francisco, California on September 18. He will take this opportunity to ask for clarification on Committee oversight and review and asked Committee members to share with him any questions they might have regarding the role of the Committee.

Mark Grushka gave Committee members training packets that include the Roles and Responsibilities of the Committee and a summary of the Guidelines from Harvard (The Guidelines Explained). There was also information about Exempt Categories. Sandy asked Committee members to look at this information and be prepared for future discussion to consider ways in which we could more efficiently handle review. He pointed out that when he recently met with Vice President for Research, Dr. Leslie Tolbert, she said with current budget cuts there are no funds to provide additional staff support. Our workload continues to increase and we need to look at alternate ways for processing MUAs.

Under Old Business, Lana reported the following follow up from the July 18, 2006 meeting:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 20, 2006

Page 2

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Lana Hudgins subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Lana Hudgins' pre-review.

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

Bradley Davidson
Molecular/Cell Biol

Deciphering the Initial Events of Chordate Heart Specification
(AHA)

BL1

Al Kaszniak
Carol Barnes
Psychology

Arizona Alzheimer's Research Center
(AARC)

BL1

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES

August 15, 2006

Page 3

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Lana Hudgins pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Lana's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Linda Meade-Tollin Surgery	Stem Cell Fusion Model of Carcinogenesis <i>(Ouregen, Inc.)</i>	BL2

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 15, 2006

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Alexander Simon Physiology	Gap Junction Mediated Signaling and Vascular Responses (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Mark Grushka recommended the following Principal Investigator's labs be approved for BSL-1 Registration.

Principal Investigator	Comments:
Patricia Stock Entomology	New application
Ramin Yadegari Plant Sciences	Renewal

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 15, 2006

Page 5

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUA was reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
Paul Boehmer Basic Med Sci COM/Phx	Mechanisms of DNA Replication and Recombination in HSV-1 (National Institute of General Medical Sciences)	BL2

This is a new researcher who is transferring funding from another institution. He does not yet have assigned lab space. He will eventually be moving into the new College of Medicine buildings in Phoenix but until they are completed will probably be assigned temporary space at ASU.

If the researcher has lab space at ASU, the Committee felt oversight would fall to the ASU Biosafety Committee and require their approval of his research. Once he moves into the new quarters, then the Committee would like the laboratory space approved either by Mark Grushka or an approved representative. The Vice President for Research is still working on getting clarification as to how compliance oversight will be handled at this remote campus site.

The Committee proposed that the biological part of this proposal be approved but that full approval will require inspection of the lab by either someone from ASU if it is ASU space or by a University representative once he is moved into the new College of Medicine building. The Committee did not give full approval at this time.

The next IBC meeting will be September 19, 2006 in the **Pima Room** of the Student Union at noon.

Institutional Biosafety Committee

MINUTES

Meeting September 19, 2006

On September 19, 2006, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from noon to 1:15 pm. In attendance were: Miranda Adelman, Nafees Ahmad, David Besselsen, Robert Fleming, Mark Grushka, Robert Perrill, Michael Riehle, Charles Schable, Glenn Songer, (Acting Chair), Margaret Stalker, Herbert Wagner, Jr. and Bruce Walsh. Not in attendance were: Stephen Billington, Don Bourque, Richard Friedman (on medical leave), John Galgiani, Sue Hopf, David Madison, Jeannie Nordstrom, Leland Pierson III, Michael Rand, Mike Riggs, and Randy Ryan.

The minutes of the August 15, 2006 Institutional Biosafety Committee meeting were approved as submitted.

Acting Chair, Glenn Songer asked that everyone introduce themselves to guests, Drs. Tom Doetschman and Phil Sanford. Mark Grushka then introduced the guests to the Committee. Dr. Thomas Doetschman, Professor of Molecular Genetics is currently in the Cell Biology and Anatomy Department and with the BIO5 Institute as Senior Faculty Advisor. He comes to the University of Arizona from University of Cincinnati, College of Medicine. Mark also noted that Dr. Doetschman worked in Zurich and also at Max Planck in Germany. Dr. Philip Sanford, Research Assistant Professor is the Director of the Genetically Engineered Mouse Core Facility at the BIO5. Dr. Sanford also comes to the University of Arizona from the University of Cincinnati.

Mark Grushka reported that since the last Institutional Biosafety Committee meeting he had visited the labs of Martha Hawes, Rod Wing, Vince Guerriero, Indraneel Ghosh and Karen Schumaker. These are BSL1 Registered laboratories that are coming up for a 3-year renewal. Mark reported he had found no significant problems in these labs. He did say that when he visited Dr. Schumaker's lab this morning, the training records were incomplete. Dr. Schumaker thought her employees had all had training so Mark advised her to check with Risk Management to verify and/or get any missing records. Dr. Wing's lab will be moving to the new BIO5 building in November so Dr. Pierson asked that Mark extend the registration until then and visit the lab when it is in the new location.

Mark also reported he had done an annual audit of Dr. Nafee's Ahmad's BSL3 laboratory. Under positive findings, he report that baseline HIV voluntary testing has now been done. He also reported that laboratory housekeeping continues to improve. (Dr. Walsh suggested Mark might want to change the wording of this statement as it suggests that housekeeping needed improvement.) Under recommendations from last year, Mark reported that while the staff had received baseline-HIV testing from the Pima County Health Department, this was a one time service and other arrangements would have to be made for any further baseline testing. Mark recommended that a complete HIV medical surveillance program including post exposure prophylaxis protocols be pursued. He also suggested Dr. Ahmad consider using a BSL-3 checklist as a self-audit tool. Autoclaves are still not periodically tested with biological indicators and Mark recommended they be tested.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 19, 2006

Page 2

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Lana Hudgins subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Lana Hudgins' pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Lana Hudgins pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Lana's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 19, 2006

Page 3

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 19, 2006

Page 4

Mark Grushka recommended the following Principal Investigator's labs BSL-1 Registration extended until they move into the Thomas Keating Building.

Principal Investigator

Comments:

[REDACTED]
[REDACTED]

[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator

Proposal Title

Biosafety Level

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]

The following MUA was reviewed by the Committee with the following comments:

Principal Investigator

Proposal Title

Biosafety Level

[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Also under new business, Dr. Tom Doetschman gave a presentation on the Genetically Engineered Mouse (GEM) Core Facility which is a component of the [REDACTED]
[REDACTED]

Dr. Doetschman explained that the GEM Core deals with two basic approaches for genetically engineering mice. The first approach is "Transgenic Mice" where they add an exogenous gene to the mouse genome. This is in a random fashion and untargeted. The second approach is "Gene Targeted (Knockout) Mice" where they mutate an endogenous gene within the mouse genome. With this approach there is a loss of function, and it is highly specific.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 19, 2006

Page 5

Dr. Doetschman explained that with a generic transgenic construct there are no viral genes. He said they take a gene and a promoter (human or mouse) and construct a gene. The DNA microinjection is put into the pronucleus. 50-80 % of the fertilized eggs cloned with foreign DNA survives and are injected into a foster mother mouse. 10-30% of the fertilized eggs survives after injection and creates first generation mice.

The uses of transgenic mice were described as: 1) gene function for over expression or ectopic expression; 2) promoter characterization for deletion analysis on promoter; and 3) mutational analysis for sequence and domain analysis.

Dr. Doetschman then explained more about their work with gene targeted (knockout) mice. He described how embryonic stem (ES) cell lines are established and about the embryonic stem cell-mediated gene modification in the mouse. The genetically modified ES cells are injected into the mice with a blastocyst injection which hopefully will become part of the inner cell mass. Success is determined by the coat color of the chimeric mice.

The uses of gene-targeted (knockout) mice are for: 1) tissue specific gene knockout; 2) inducible gene knockout; 3) gene knockin of reporter gene; 4) gene knockin of human sequences to humanize a gene; 5) subtle mutations for protein structure/function studies; 6) subtle mutations for functional studies of human polymorphisms and; 7) chromosomal engineering to study disease with large chromosomal aberrations for dominant screens

The services provided by the GEM Core for Gene Target (GT) Mice are: design and construct targeting vector, gene targeting in ES cells, screening for GT ES cell lines, blast injection, embryo transfer and breeding and screening. For Transgenic (TG) Mice the Core services provided are: design and construct TG vector, DNA microinjection, embryo transfer and screen for TG founders. Other services include embryo re-derivation, cryopreservation of new strains and colony maintenance. The investigator is billed for these services and can have a full package of services for a set fee or request partial services. Half of the Core's requests for services in the past have historically been from investigators outside the University of Arizona

Dr. Doetschman addressed the safety issues by explaining: 1) Recombinant DNA techniques are used to make targeting constructs; 2) New sequences introduced into genome are not infectious antibiotic resistance genes; 3) Introduction of infectious agents not used; 4) After new mouse strain is made by CORE it goes to PI and 5) Mouse treatments would be done by PI and not CORE facility

Bruce Walsh suggested the Committee consider certifying CORE labs. It could be established that certain things would not be allowed. Routine requests could be handled following certain guideline. At the University of Cincinnati the GEM Core Facility was given a blanket use permit with no specific biosafety level. They followed what was applicable for a recombinant DNA protocol.

The Committee asked when the facility would be running and was told they anticipate occupation of the [REDACTED] in about two months but it takes months of training before services will begin. Typically the training has taken from 6 months to a year.

The next IBC meeting will be October 17, 2006 in the **Pima Room** of the Student Union at noon.

MINUTES

Meeting October 17, 2006

On October 17, 2006, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from noon to 1:10 pm. In attendance were: Miranda Adelman, David Besselsen, Sue Hopf, David Madison, Robert Perrill, Leland S. Pierson III (Chair), Michael Riehle, Charles Schable, and Herbert Wagner, Jr. Not in attendance were: Nafees Ahmad, Stephen Billington, Don Bourque, Robert Fleming, Richard Friedman, John Galgiani, Mark Grushka, Jeannie Nordstrom, Michael Rand, Mike Riggs, Randy Ryan, Glenn Songer, Margaret Stalker, and Bruce Walsh.

Since there was not a quorum, the Chair suggested holding the meeting but revisiting the MUAs for final approval as old business next month.

The minutes of the September 19, 2006 Institutional Biosafety Committee meeting were approved as submitted.

The chair told Committee members about his recent trip to the IBC Basics conference in San Francisco. Dr. Pierson discussed topics that were raised and suggestions made to the NIH. The model IBC presented by the NIH was from UCSD, which has 7 full time IBC staff. The meeting generated much discussion of quorums and electronic MUA forms and relational databases linking oversight committees. The chair requested that NIH design a database program to link all oversight committees and make it available to all IBCs. He mentioned that it seemed inefficient to ask each institution to use costly manpower to re-design the wheel each time, especially since the NIH knew what they required in such a program. The NIH is also offering to come do a site-inspection to suggest improvements for individual IBCs since IBCs usually are considered the "poor cousins" to most of the oversight committees.

Dr. Pierson reported that since the last Institutional Biosafety Committee meeting Mark Grushka had visited four labs. Mark visited Drs. Gang and Heidenreich's labs for BSL-1 Registration renewals. He found that Dr. Heidenreich was doing BL2 research and was using a biological safety cabinet in the designated BL1 lab so his registration will not be renewed. Since Dr. Gang will be moving to the new [REDACTED] building in a few months, his current registration will be extended until he moves and an inspection can be made of his new lab space.

Under Old Business, Dr. Pierson reported on the following MUA from the September 19, 2006 meeting:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 17, 2006

Page 2

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and [REDACTED] subject to the following conditions: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. Due to a lack of a quorum, the Committee gave conditional approval on the basis of the pre-review. Full approval will be given under old business at the next meeting.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Karen Shumaker Plant Sciences	Specificity in Calcium-mediated Plant Development: The Role of Calcium-binding Protein Interactions (Department of Energy)	BL1
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 17, 2006

Page 3

To expedite review, Dr. Sandy Pierson, Margaret Stalker and Lana Hudgins pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. Due to a lack of a quorum, the Committee conditionally approved them on the basis of Dr. Pierson's, Margaret's and Lana's pre-review. .Due to a lack of a quorum, the Committee gave conditional approval on the basis of the pre-review. Full approval will be given under old business at the next meeting.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 17, 2006

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and conditionally approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 17, 2006

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and conditionally approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

To expedite review, Dr. Sandy Pierson and Margaret Stalker and [REDACTED] pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. . Due to a lack of a quorum, the Committee gave conditional approval on the basis of the pre-review. Full approval will be given under old business at the next meeting.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 17, 2006

Page 7

The following MUAs were reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

The next IBC meeting will be November 21, 2006 in the **Pima Room** of the Student Union at noon.

Institutional Biosafety Committee

MINUTES

Meeting November 21, 2006

On November 21, 2006, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from noon to 1:00 pm. In attendance were: David Besselsen, Don Bourque, John Galgiani, Mark Grushka, Sue Hopf, Robert Perrill, Leland S. Pierson III (Chair), Michael Riehle, Randy Ryan, Charles Schable, Glenn Songer, and Margaret Stalker. Not in attendance were: Miranda Adelman, Nafees Ahmad, Stephen Billington, Robert Fleming, David Madison, Jeannie Nordstrom, Michael Rand, Mike Riggs, Herbert Wagner, Jr. and Bruce Walsh.

Mark Grushka handed out to each Committee member a CD from Sandia National Laboratories on "Biological Threat Reduction". He got the CDs at the 49th Annual Biological Safety Conference which he attended in October.

The minutes of the October 17, 2006 Institutional Biosafety Committee meeting were approved as submitted.

Under Old Business the Memorandum of Understanding and Agreement forms from the October meeting that were conditionally approved because there had not been a quorum were approved.

Also under Old Business, Margaret Stalker reported on the following MUA from the September 19, 2006 meeting:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under Old Business, Dr. Pierson reported that he still had not gotten comments from all the sub committee reviewers on the following MUA from the October 17, 2006 meeting:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 21, 2006

Page 2

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Lana Hudgins subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Lana Hudgins' pre-review.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 21, 2006

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
Bruce Tabashnik Entomology	Molecular Monitoring of Pink Bollworm Resistance to Bt Cotton (Cotton Incorporated State Support System)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Lana Hudgins subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Lana Hudgins' pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 21, 2006

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and conditionally approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
Bernard Futscher Cancer Center	Epigenetic Remodeling by Environmental Arsenicals (NIEHS)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Howard Lien/ Li-WenLai Medicine	Gene Expression in Osteoblasts Over-Expressing Calbindin- D28K (WAESO)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 21, 2006

Page 6

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and conditionally approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Georg Wondrak Pharm/Toxicology	Targeting Glycolytic Control of Melanoma Cell Survival (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 21, 2006

Page 7

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and conditionally approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson and Margaret Stalker and Lana Hudgins pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Lana Hudgins' pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Felicia Goodrum Immunobiology	Human Cytomegalovirus Latency in Hematopoietic Cells (ABRC)	BL2

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 21, 2006

Page 8

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and conditionally approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
Donald Lightner Veterinary Science	Shrimp Disease Research: Etiological Studies, Diagnostic Procedure Development and Disease Prevention (USDA/GCRL Marine Shrimp Farming Consortium)	BL2

[REDACTED]

Mark Grushka pointed out there has been a pattern on the BSL-1 registrations of needing to ask for documentation of training. The following BSL-1 Registration applications are as noted:

Principal Investigator	Comments:
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 21, 2006

Page 9

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

[REDACTED]

[REDACTED]

This once again raised the question of responsibility for review of research being done in Phoenix. Alice Langen reported meetings are ongoing with the Hausslers team and there will probably be shared oversight. There are no operational labs yet at the new College of Medicine facility in Phoenix. The building is due to open in May. The facilities will fall under the Dean of the College. There is a proposal to have a facilitator and job descriptions for this position are currently being drafted.

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 21, 2006

Page 7

Also under New Business, Mark Grushka reported since the last IBC meeting he had visited three labs. Dr. Judy Brown's BSL-1 registration is up for renewal. Mark revisited Dr. Ghosh's lab as part of his BSL-1 registration process. Dr. Parker is applying for BSL-1 registration. Mark also reported he visited the greenhouses on campus.

The next IBC meeting will be December 19, 2006 in the **Pima Room** of the Student Union at noon.

Institutional Biosafety Committee

MINUTES

Meeting December 19, 2006

On December 19, 2006, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from noon to 1:10 pm. In attendance were: Miranda Adelman, Nafees Ahmad, David Besselsen, Don Bourque, Robert Fleming, John Galgiani, Mark Grushka, Sue Hopf, David Madison, Jeannie Nordstrom, Robert Perrill, Leland S. Pierson III (Chair), Michael Rand, Michael Riehle, Charles Schable, Glenn Songer, Margaret Stalker and Bruce Walsh. Not in attendance were: Stephen Billington, Mike Riggs, Randy Ryan, and Herbert Wagner, Jr.

Dr. Pierson, Chair, explained to the Committee that at the IBC Basics conference he attended this past September he learned the definition of a quorum to be used by IBC's is 50% plus one of the total Committee membership. This is what will be practiced.

Committee members were given a packet of Education Materials provided by the Office of Biotechnology Activities, National Institutes of Health that included information on biosafety consideration for research with lentiviral vectors and frequently asked questions about the NIH review process for Human Gene Transfer trials.

The minutes of the November 21, 2006 Institutional Biosafety Committee meeting were approved as submitted.

Also under Old Business, Committee Chair, Dr. Leland "Sandy" Pierson reported on the following MUA from the October 17, 2006 meeting:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 19, 2006

Page 2

The suggestion was made the a check list of these types of concerns be designed by the HGT subcommittee that could be given to future researchers submitting HGT proposals so there would not be delays in asking for additional information. It was also suggested that if there are specific sites (ie. centers) for administering these types of vaccines, they could be inspected and certified.

Also under Old Business, from the October 17, 2006 meeting the following was discussed:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under Old Business, Dr. Pierson reported on the following MUA from the November 21, 2006 meeting:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and [REDACTED] subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Lana Hudgins' pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 19, 2006

Page 4

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and [REDACTED] subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Lana Hudgins' pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Daruka Mahadevan Cancer Center	Profiling of CNX1 in GIST Cell Lines (Conxcys, Inc.)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Donna Wolk Path/BIO5	Clinical Evaluation of the Xpert™ MRSA Assay (Cepheid, Inc. Sunnyvale, CA)	BL2

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 19, 2006

Page 5

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	

[REDACTED]

[REDACTED]

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	

[REDACTED]

[REDACTED]

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 19, 2006

Page 6

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Also under New Business, the Committee reviewed an amendment to a Human Gene Therapy proposal from Dr. Andrew Yeager, Cancer Center entitled, "A Phase 2 Clinical Trial to Evaluate the Safety, Immunogenicity and Clinical Benefit of a CMV Immunotherapeutic Vaccine in Donors and CMV-seropositive Recipients Undergoing Allogeneic, Matched, Related Hematopoietic Cell Transplant (HCT)". The Committee asked for 1) training records to assure that the staff handling and administering the vaccine are suitably trained, 2) a description of the procedures for handling, reconstituting and administering the vaccine and what are procedures for dealing with accidental exposures, and 3) a description of the facilities where the patients are treated. They asked that Dr. Yeager describe the physical containment utilized, including specific room numbers for storage, preparation and administration of the vaccine and include a diagram of the facilities.

The next IBC meeting will be January 16, 2007 in the **Pima Room** of the Student Union at noon.

Vice President for Research
Institutional Biosafety Committee
(520) 621-3441
FAX: (520) 621-6159



1230 North Park Avenue, #205
P.O. Box 210420
Tucson, AZ 85721-0420

December 7, 2006

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

Re: Public Records Request Dated March 15, 2006

Dear Mr. Hammond:

Enclosed please find a second and partial response to your public records request of March 15th 2006 for Minutes of the University of Arizona Institutional Biosafety Committee.

The minutes of this committee document the University of Arizona's compliance with Section IV-B-2-a-(7) of the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules, from April 2002.

The enclosed material represents minutes from January through December of 2004. As indicated in our previous correspondence, these documents are part of an incremental response because of the significant amount of time and effort required to complete the request.

Sections of the Minutes have been redacted, in accordance with Arizona law and the guidelines from the NIH Office of Biotechnology Activities general letter of May 14, 2004, to remove information whose disclosure would directly compromise institutional or national security. Also redacted were a few instances of names or other identifying information of students in accordance with the 1974 Family Educational Rights and Privacy Act (FERPA) guidelines, and any personnel information protected from release by Arizona Board of Regents policy 6-912. (You can find this policy at: <http://www.abor.asu.edu/> in Chapter 6, Part 2 on the Policy Manual.) Also, please note that information on all unfunded proposals has been redacted from the "Proposal Title" portion of each month's minutes, in accordance with Arizona public records law.

Edward H. Hammond
December 7, 2006
Page Two

We will forward the additional documents you have requested as soon as we can.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark J. Grushka". The signature is fluid and cursive, with the first name "Mark" being more prominent.

Mark J. Grushka, M.S., CSP
Manager, Biosafety and Biosecurity
520-621-5279 (O)
520-621-6159 (F)
520-331-5580 (C)
mgrushka@u.arizona.edu

Enclosures

Institutional Biosafety Committee

MINUTES

Meeting January 6, 2004

On 6 January 2004, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:00 PM. In attendance were: Nafees Ahmad, David Besselsen, Peter Else, Richard Friedman, John Galgiani, Mark Grushka, Sue Hopf, David Madison, Leland Pierson III (Chair), Michael Rand, Glenn Songer, Margaret Stalker, and Herbert Wagner, Jr. Also attending was Alice Langen, Vice President for Research Office. Not in attendance were: Don Bourque, Susan Ehrlich, Henry Hagedorn, Jeannie Nordstrom, Kris Orsborn, Michael Riggs, and Bruce Walsh.

The minutes of December 2, 2003 Institutional Biosafety Committee meeting were approved.

Mark Grushka reported that he and Dr. Powell had been on their 10th quarterly walk-about. They visited Dr. Besselsen's University Animal Care Pathology Services Laboratory. The article will be appearing soon in Lo Que Pasa.

Chairman Dr. Sandy Pierson introduced the newest Committee member, Dr. David Besselsen, Chief of Pathology Services, University Animal Care and welcomed him to the Committee.

Under Old Business, Mark Grushka gave an update on the Animal Facility Renovation project. He reminded Committee members that he first visited [REDACTED] on October 22, 2003. Glenn Songer has provided a manual of Standard Operating Procedures for his research to be performed in the building. Dr. Colin Kaltenbach, Vice Dean of Agriculture and Life Sciences, has given his assurance that his goal is to get a new building in place within a year. Dr. Pierson reported that he had contacted the Centers for Disease Control and NIH for guidance and was told it was "up to us". Dr. Pierson did a detailed literature search and the information he found indicates the pathogens Dr. Songer plans to use are Risk Group 2 pathogens and not caught by humans through aerosolization. With the modifications Dr. Songer has proposed, the work proposed should be safe. From a biosafety viewpoint, the facility (as Dr. Songer indicated he will use it) meets biosafety requirements. Peter Else reported that a design group has been organized and a master plan and budget are being developed for the new facility. The Committee gave approval for Glenn to begin research in the current facility.

Also under Old Business, Mark Grushka reported he had re-inspected Dr. Judith Brown's laboratory and found the housekeeping had improved, the chemical inventory updated and unnecessary chemicals had been discarded appropriately. He recommends full approval of her BSL-1 registration. David Madison shared with the Committee that Dr. Brown has Plant Pest Permits. Her gemini virus permit is temporary until February. There will be a full containment inspection by the Arizona Department of Agriculture on January 14.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 6, 2004

Page 2

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Barry Pryor Plant Sciences	Evaluation and Development of Biocontrol (Agents Against Sclerotinia minor and Sclerotiorum) Strategies for Lettuce Crop in California (University of California, Davis)	BL1
Christopher Rensing Soil, Water & Env Sci	Biotechnological Exploitation of Halotolerant Enzymes (National Science Foundation)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Nicholas Strausfeld ARL-Neurobiology	Using Split-Brains to Determine the Role of the Mushroom Body Lobes in Learning and Memory (NSF)	BL1

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal which is BL1 except for cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 6, 2004

Page 3

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 6, 2004

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Donald Lightner Veterinary Science	Control of Bacterial Disease in Panaeid Shrimp with Florfenicol (Schering-Plough Animal Health)	BL2

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 6, 2004

Page 5

The following BSL1 Laboratory Registration applications were reviewed by Committee members and approved:

**Principal
Investigator**

Melanie Culver
Sch of Renewable
Natural Resources

Barry Pryor
Plant Sciences

Also under New Business, Mark Grushka reported that Dr. Richard Friedman had brought to his attention that every time Facilities Management does maintenance on the blowers and airflow systems in Life Sciences North, the air pressure in Dr. Friedman's BSL-3 lab (Room 603, Life Sciences North) goes positive from the anteroom out to the hallway. There is no risk when it happens because the BSL3 work is not being done when maintenance is performed. However, there is concern that there is a problem with airflow and the ductwork since it does not shut down the air pressure to at least neutral. It should never go positive. There is a potential for serious health risks and possible lawsuits if a mechanical breakdown or accident should ever happen that could result in exposure to infection. Estimates for getting this problem corrected are being collected and the matter discussed with people in facilities management. A proposal for repairs will be submitted through appropriate channels.

The next scheduled Institutional Biosafety Committee meeting will be at noon on **Tuesday, February 3, 2004** in the Pima Room of the Student Union Building.

Institutional Biosafety Committee

MINUTES

Meeting February 3, 2004

On 3 February 2004, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:00 PM. In attendance were: Nafees Ahmad, Don Bourque, Peter Else, Richard Friedman, John Galgiani, Mark Grushka, Henry Hagedorn, Sue Hopf, David Madison, Leland Pierson III (Chair), Michael Rand, Michael Riggs, Glenn Songer, Margaret Stalker, and Bruce Walsh. Also attending was Alice Langen, Vice President for Research Office. Not in attendance were: David Besselsen, Susan Ehrlich, Jeannie Nordstrom, Kris Orsborn and Herbert Wagner, Jr.

The minutes of January 6, 2004 Institutional Biosafety Committee meeting were approved.

Mark Grushka told the Committee that the next quarterly walk-about with Dr. Powell is scheduled for the Veterinary Diagnostic Laboratory this month.

Margaret Stalker reported to that she had received a request for copies of the two most recent Institutional Biosafety Committee meeting minutes from The Sunshine Project. As referenced in the request letter, the NIH Guidelines on Research Involving Recombinant DNA Molecules do require the release of minutes upon request of the public. However, the NIH Guidelines also provide for protection of privacy and proprietary interests. The Sunshine Project request also asks if the university is registered to handle select agents. There is nothing in the NIH Guidelines on Recombinant DNA or the Select Agent regulations that requires a response to that question. The Sunshine Project is part of an international organization working on biological weapons issues through a three-part approach: human genomics, treaty compliance and biotechnology in the drug war. The Project uses Freedom of Information Act and other laws to uncover and distribute new information and analysis on government programs. Following University policy, the request was given to the Vice President of Research and forwarded to the appropriate individual designated to handle such requests.

Under Old Business, Margaret Stalker also reported to the Committee that 24 proposal routing sheets from labs covered under BSL-1 registration were submitted in January. Upon closer examination four of the projects appeared to be BL2 and the Principle Investigator was asked to submit a Memorandum of Understanding and Agreement form and reminded that the BSL-1 registration only covers BL1 research. Even though only 14 PIs have registered to date, the registration program is already a saving time to both the researcher and the IBC office.

Under Old Business, Mark Grushka, in response the Dr. Ahmad's suggestion for a HIV Medical Surveillance program, posted a query on the "biosafety" list serve to find out if other institutions have a formalized medical surveillance system. Four organizations responded. No institution reported mandatory pre-employment testing for HIV. There was voluntary participation in post employment blood testing for HIV antibodies and required blood testing for HIV antibodies after exposure incidents.

The Committee voted and unanimously support Dr. Ahmad's decision to provide a voluntary annual testing program for HIV for individuals already employed in Dr. Ahmad's laboratory. Dr. Ahmad said money from his grant would be used to cover the cost of this medical surveillance program.

Also under Old Business, Mark Grushka reported he is working with Dr. Friedman, Ralph Banks and Richard Knott to submit an off-cycle Construction Decision Package (CDP) form to cover the cost to upgrade the HVAC system in Dr. Friedman's laboratory.

February 3, 2004

Page 2

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
Vahe Bandarian Biochemistry	Biosynthesis of Deazapurine-containing Metabolites <i>(NIH)</i>	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Serrine Lau Pharm/Toxicology	Southwest Environmental Health Center <i>(NIH)</i>	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 3, 2004

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Patricia Stock Plant Sciences	Collaborative Research: Development, Structure, and Function of the Bacterial Symbiont Colonization Site in Steinernematid Nematodes (NSF)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
Elizabeth Vierling Biochemistry	Genes and Gene Networks Controlling Thermotolerance (USDA)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal which is BL1 except for cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 3, 2004

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
Nathan Cherrington Pharm/Toxicology	Hepatoprotective Mrp3 (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Jorge Giron Micro/Immunology	Novel YcbQ Pili of Enterohemorrhagic E. Coli 0157:H7 (National Foundation for Infectious Diseases)	BL2
Darrel Goll Nutritional Sciences	The Role of Phosphorylation in Regulating Calpain Activity (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Daruka Mahadevan Hematology/Oncol	Molecular Biology of Inhibition of c-Kit by the Inhibitor MP-470 (HPK-56) and Dose-Range Finding and Efficacy Study for MP-470 in the SCID Mouse GIST882 Human GIST Cancer Model (Montigen Pharmaceuticals, Inc)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
Claire M. Payne Micro/Immunology	Cytochrome C Oxidase I: A Biomarker for Colon Cancer Risk (NIH)	BL2

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 3, 2004

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The Committee asked about this project. Dr. Olsen is will be conducting experiments using a container system in her lab. Nothing will be released in the field.

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 3, 2004

Page 6

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Glenn Songer Veterinary Science	Passive Immunity to <i>Clostridium difficile</i> Infection in Piglets (Dow Agrosciences)	BL2

The following MUA was reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

Also under New Business, Mark Grushka reported that Dr. Allan Hamilton, PI for the proposal, "A Multi-Center, Open Label, Two Part, Dose Escalation Study to Determine the Tolerability of Interferon-beta Gene Transfer (BG00001) in the Treatment of Recurrent or progressive Glioblastoma Multiforme" forwarded notification of a serious adverse event. Mark reminded the Committee that Dr. Hamilton's MUA for this research was originally approved January 2002 and involves intracranial injections of a replication defective adenovirus vector (BG0001) into patients with glioblastoma multiforme. The sponsor is Biogen IDEC. Dr. Hamilton is required to inform the IBC if a serious adverse event (SAE) occurs to any patient in the study, including outside the University of Arizona.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 3, 2004

Page 7

Mark received notification of the Manufacturer Report # :30015 dated January 5, 2004 informing of fatal outcome to serious adverse event, that occurred at another study site. The death was reported as a progression of glioblastoma multiforme. The investigator classified the relationship between the event and the study drug (BG00001) as "none". To date 11 patients have received BG00001. Including this case, ten of the patients that received the study drug have died. All ten of the deaths were attributed to progression of glioblastoma multiforme.

Also under New Business, Mark reported on the APHIS inspection of Dr. Judith Brown's laboratory. Dr. Brown works with Begomoviruses and Whiteflies. Dr. Brown was inspected as part of the post 9-11 agency standard for issuing permits. There are no longer automatic renewals. Dr. Brown was informed that her standard permit has been approved, but that she must apply for a specific permit to transmit cloned viruses.

The next scheduled Institutional Biosafety Committee meeting will be at noon on **Tuesday, March 2, 2004** in **GOULD SIMPSON, Room 1027**.

Institutional Biosafety Committee

MINUTES

Meeting March 2, 2004

On March 2 2004, a meeting of the Institutional Biosafety Committee was held in Room 1027 of the Gould Simpson Building from 12:00 to 1:00 PM. In attendance were: Nafees Ahmad, David Besselsen, Don Bourque, Peter Else, John Galgiani, Mark Grushka, Henry Hagedorn, Sue Hopf, David Madison, Jeannie Nordstrom, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Michael Riggs, Margaret Stalker, Herbert Wagner, Jr. and Bruce Walsh. Also attending was Alice Langen, Vice President for Research Office. Not in attendance were: Susan Ehrlich, Richard Friedman, and Glenn Songer.

The minutes of February 3, 2004 Institutional Biosafety Committee meeting were approved.

Margaret Stalker reported that the minutes requested by The Sunshine Project had been mailed. Sensitive items were deleted and no response was given for the question asking if the University of Arizona is registered to handle select agents since this is not public record and a response does not have to be provided.

Mark Grushka showed the Committee a picture of the Veterinary Diagnostic Laboratory quarterly Walkabout last month. Chairman, Sandy Pierson praised Vice President Richard Powell for his appreciation of these opportunities to acknowledge these often-unrecognized people on our campus.

Under Old Business Mark Grushka reported that he had received a Facility Inspection Report Response from the Centers for Disease Control and Prevention thanking him for his response to their report of the inspection of our facility conducted on September 23, 2003. They also said the Select Agent Program does not require any further response at this time. Jeanne Nordstrom reported that the VA had also received a similar memorandum.

Also under Old Business Mark Grushka reported on followup from the February IBC meeting for Dr. Frederick Fisher's proposal entitled, "Complex System Modeling of Biogeologic Habitats of Microbial Soil-borne Human Pathogens: the *Coccidioides* Spp. Example". 1) The Committee had requested more details on the methodology to provide clarification on what is being done in the field and what is being done in the lab. Additional information was provided and clarification given. 2) The Committee also asked that a letter assurance from the collaborators be provided indicating that they have approved facilities and registration to receive and work with this select agent. Dr. Fisher provided a list of the individuals at UC Davis who are collaborating on the projects and urged Mark to contact them. Mark contacted one of the individuals about the BL3 laboratory. 3) Before Dr. Fisher ships any soil, the Committee requested a copy of the required APHIS permit. Dr. Fisher contacted David Madison regarding the soil permit, was given direction and has applied for the proper permits.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 2, 2004

Page 2

Principal Investigator	Proposal Title	Biosafety Level
Bohuslav Dvorak Pediatrics	Mechanisms of EGF-mediated Reduction of Neonatal Necrotizing Enterocolitis (NIH)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The Committee asked if this project involved human tissue and therefore would require a higher biosafety level. Dr. Hammer uses buccal cells and this does not require BL2 containment.

Michael Hammer Anthropology	DDIG: Apportionment of African Genetic Diversity Based on mtDNA, the X and Y Chromosome (NSF)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Elizabeth Vierling Biochemistry	Structure and Function of Small Heat Shock Proteins (NIH)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 2, 2004

Page 3

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal which is BL1 except for cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Lisa Cameron Az Respiratory Ctr	Defining Cis-Activating Elements that Contribute to Transcription of Human IL-13 (American Academy of Allergy Asthma & Immunology)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
Vince Guerriero Animal Sciences	Regulation of Cellular Growth BY HspBP1 (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
Vince Guerriero Animals Sciences	Neuromuscular Diseases and Misfolded Proteins (Muscular Dystrophy Association)	BL2
Michael Hogan IBSB	Population-Scale HLA Typing for Homelands Defense (SIBR with Genomics USA, Inc.)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 2, 2004

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
John Lansing Anthropology	Austronesian Societies: Reading social Structure from the Genome <i>(NSF)</i>	BL2
Lihua Marmorstein Ophthalmology	EFEMP1 and Drusen Formation in the Retina <i>(Research to Prevent Blindness)</i>	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Lisa Rimsza Pathology	Mechanisms of Altered MHC Class II Function in Lymphoma <i>(The Leukemia & Lymphoma Society)</i>	BL2
David Segal Pharm/Toxicology	Protein-protein Interactions of C2H2 Zinc Finger Domains <i>(VP for Research, Faculty Small Grant)</i>	BL2
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 2, 2004

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
Leslie Tolbert ARL – Neurobiology	Intercellular Interactions in Developing Glomeruli (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Jorge Giron Micro/Immunology	Novel YcbQ Pili of Enterohemorrhagic E. Coli 0157:H7 (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 2, 2004

Page 6

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
J. Glenn Songer Veterinary Science	Strain Variation Virulence of <i>Clostridium perfringens</i> for Chicken (Schering-Plough Animal Health)	BL2

The following MUA was reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

Dr. Hagedorn revised this MUA approved on 5/6/03, notifying the Committee that the work will be Performed [REDACTED] that was recently remodeled for this project.

Mark visited the laboratory on March 1 and noticed that the glass on the front of the biological safety cabinet was cracked. Facility Management has been contacted and the glass will be replaced. Mark also tested the lab ventilation flow found it was positive. The lab ventilation should be negative to the corridor. Facilities Management told Randy Ryan of CALS that the HVAC will be modified to create a negative pressure differential to the corridor.

The following BSL1 Laboratory Registration application was reviewed by Committee members and approved with comments:

Principal Investigator	Comments:
Elizabeth Vierling Biochemistry	Mark Grushka inspected the lab and recommends a conditional approval be given. The approval is dependent on improving the housekeeping and providing documentation of MSDSs and a chemical inventory.

Margaret Stalker reported to the Committee that 7 proposal routing sheets from labs covered under BSL-1 registration were submitted in February.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 2, 2004

Page 7

Also under New Business, Margaret Stalker reported that the Annual Report had been submitted to the Vice President for Research. In FY 2002-2003 there was a 14% increase in the total number of projects reviewed and a 7% increase in the number of BL2 or BL3 MUA forms. To date there is a 29% increase in projects reviewed for FY 2003-04 with a 5% increase in the number of BL2 or BL3 projects. We reported that the implementation of the Biosafety Level 1 Registration program is saving the researchers time and also allowing the staff and committee to focus more attention on the high-level biosafety projects. We have been responsive to changing needs (such as the changes in the registration of Select Agents) and had to reorder priorities, that has delayed completion of some of our goals. We continue to request funding for the Research Coordinator position.

Chairman Sandy Pierson raised the question to the Committee, "Should we re-evaluate IBC oversight of rDNA research at the University?" He brought up this issue of rDNA to stimulate discussion of Committee oversight functions and to re-evaluate the level of oversight to determine if it is too strict or too relaxed. The current IBC definition of rDNA exceeds the NIH definition. The IBC currently requires research considered exempt by the NIH guidelines be documented by a Memorandum of Understanding and Agreement form and reviewed and approved by the Committee. Dr. Pierson reviewed what NIH considers exempt experiments.

Dr. Pierson pointed out that the emphasis of what we review has evolved. Our understanding of rDNA risks have improved since the NIH Guidelines were first published in 1976. Pathogenic organisms and employee protection have become an important part of the Committee review. He suggested that the IBC review process might need to focus more on the pathogenicity of the agent rather than the rDNA techniques and that implementation of the Declaration Program will increase our knowledge of what organism(s) laboratories on campus are using.

Committee members responded by saying emphasis on the organism is not sufficient. We need to know what is being produced and if it is creating a toxic DNA molecule. How does one differentiate between pathogenic and nonpathogenic PCR? The Committee also raised the concern that while a project might start out doing exempt work, the research could drift into areas that do fall under review and not be reported. Under the current requirements for review there is at least a base of information. It was also pointed out that there is a need for more field oversight to verify what we review on paper is being done in the laboratory.

Dr. Pierson asked the Committee members to continue to think about this issue for future discussion. From time to time we need to re-evaluate risk assessment criteria to provide the most effective oversight of biological research with our limited resources.

The next scheduled Institutional Biosafety Committee meeting will be at noon on **Tuesday, April 6** in the **Pima Room** of the **Student Union**.

Institutional Biosafety Committee

MINUTES

Meeting April 6, 2004

On April 6 2004, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:00 PM. In attendance were: Nafees Ahmad, David Besselsen, Don Bourque, Peter Else, Richard Friedman, John Galgiani, Mark Grushka, Sue Hopf, Jeannie Nordstrom, Kris Orsborn, Leland Pierson III (Chair), Glenn Songer, Margaret Stalker, Herbert Wagner, Jr. and Bruce Walsh. Not in attendance were: Susan Ehrlich, Henry Hagedorn, David Madison, Michael Rand, and Michael Riggs.

The minutes of March 2, 2004 Institutional Biosafety Committee meeting were approved.

Under Old Business, Mark Grushka reminded Committee members that earlier this year he had reported that Dr. Richard Friedman had brought to his attention that every time Facilities Management does maintenance on the blowers and airflow systems [REDACTED] the air pressure in his BSL-3 lab [REDACTED] goes positive from the anteroom out to the hallway. It should never go positive. There is a potential for serious health risks if a mechanical breakdown or accident should ever happen. Mark informed the Committee that Dr. Powell had been presented a proposal for the repair and he had approved it. Funding has already been approved and the repair can proceed.

Also under Old Business, the Committee continued the discussion on the IBC oversight of rDNA research at the University. Is our oversight too strict, too lax or just right? The current IBC definition of rDNA exceeds the NIH definition and requires research considered exempt by the NIH guidelines to be documented by a MUA form. NIH has revised and in some areas relaxed the guidelines since 1976. Have we changed our view to keep pace with the times as well? The discussion included matching the NIH Guidelines but monitoring the organisms involved.

The Committee considered the basis for retaining the current definition of rDNA: 1) we have always done it this way, 2) to educate the researcher and heighten awareness, 3) keep a tight standard so there is less opportunity to fall out of compliance with the NIH guidelines.

No decision was made to change the current oversight.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Alan Marmorstein Ophthalmology	Microcurrent Stimulation and Photoreceptor Viability (Macular Degeneration Foundation)	BL1

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
April 6, 2004

Page 3

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Yeong-Hau Lien Li-Wen Lai Medicine	Transcriptional Regulation of Calbindin-D28k (DCR)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
Lisa Rimsza Pathology	Mechanisms of Altered MHC Class II Function in Lymphoma (American Cancer Society)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
April 6, 2004

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUA was reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

The next scheduled Institutional Biosafety Committee meeting will be at noon on **Tuesday, May 4** in the **Pima Room** of the **Student Union**.

Institutional Biosafety Committee**MINUTES**

Meeting May 4, 2004

On April 6 2004, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:00 PM. In attendance were: Nafees Ahmad, Don Bourque, Peter Else, Richard Friedman, John Galgiani, Mark Grushka, Henry Hagedorn, Sue Hopf, David Madison, Kris Orsborn, Leland Pierson III (Chair), Margaret Stalker, Herbert Wagner, Jr. and Bruce Walsh. Not in attendance were: David Besselsen, Susan Ehrlich, Jeannie Nordstrom, Michael Rand, Michael Riggs, and Glenn Songer.

The minutes of April 6, 2004 Institutional Biosafety Committee meeting were approved.

Mark recently helped with the language adopted by the UA Faculty Senate that endorsed a policy that expands the number of campus jobs that require criminal background checks. Mark informed the Committee that the IBC and University of Arizona has already been operating under requirements of the USA Patriot Act of 2001 and Public Health Security and Bioterrorism Preparedness Response Act of 2002 and been requiring positions that have direct access to biological and chemical select agents to have security clearance (except where excluded by law because the Principal Investigator does not exceed the select agent regulatory threshold quantities for toxins specified under the applicable regulations).

Mark reported on followup from the April IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
May 4, 2004

Page 2

MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal which is BL1 except for cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
May 4, 2004

Page 3

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
May 4, 2004

Page 4

The following MUA was reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee with the following comments:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

Dr. Brown provided a thorough description of the methodology and the facilities she plans to use for her proposal to operate a gene gun to inoculate plants with viruses from the family Geminiviridae. Although she currently has permits to receive these viruses, she does not hold a permit for plant or insect inoculations. She will need to revise her current permits to allow plant inoculations.

Mark and David Madison will inspect her lab and containment set up after the IBC meeting and advise her of any changes she needs to make to meet permit requirements. The Committee provisionally approved her MUA form based on her receiving the appropriate permits.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Setsuko Chambers Cancer Center	Regulation of CSF-1 in Ovarian Cancer (NCI R01 CA097347)	BL2

The Committee would like Dr. Chambers to provide a map of the vector she is using and identify the genes that are being cloned into the vector. Once she provides the above additional information requested, she can receive conditional approval on the biological aspects of her proposal. She has not yet begun employment and therefore was unable to complete the Profile portion of the Memorandum of Understanding and Agreement form that covers information about her laboratory facility and training.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
May 4, 2004

Page 6

encephalitis. This is significant because in Japan there are bad years and very bad years. It may be that West Nile will be around and a significant problem for a long time.

The major vectors of West Nile Virus in Arizona are the mosquitoes *Culex tarsalis* and *Culex quinquefasciatus*. The latter is more important in Tucson. Elizabeth Willott has found that this mosquito feeds on both birds and humans and is likely to be a very efficient factor in human infection. Humans, however, are "dead-end" hosts, meaning that mosquitoes do not pick up virus from humans.

Birds are the primary host for West Nile Virus. Birds do become immune to it if they survive, but since they have short lives and produce young that are not immune, levels of immunity change continually. Even though birds of some species die, in general the bird population is not decreasing significantly. Because birds are the definitive hosts, movement of birds spreads the virus. Since Southern Arizona is a major bird migration route, we can expect that places that attract birds, such as wetlands, will be sources of infection for the mosquitoes.

The county Office of Public Health has set up a "SWAT" team to follow what is happening in the state and county with this disease.

The next scheduled Institutional Biosafety Committee meeting will be at noon on **Tuesday, June 1** in the **Pima Room** of the **Student Union**.

Institutional Biosafety Committee

MINUTES

Meeting June 1, 2004

On June 1, 2004, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:00 PM. In attendance were: Don Bourque, Peter Else, John Galgiani, Mark Grushka, Henry Hagedorn, Sue Hopf, David Madison, Michael Rand, Michael Riggs, Glenn Songer (Acting Chair), Margaret Stalker, and Herbert Wagner, Jr. Also attending was Alice Langen, Vice President for Research Office. Not in attendance were: Nafees Ahmad, David Besselsen, Susan Ehrlich, Richard Friedman, Jeannie Nordstrom, Kris Orsborn, Leland Pierson III (Chair), and Bruce Walsh.

Margaret Stalker announced that the Institutional Biosafety Committee meetings will be held on the third Tuesday of the month beginning in the fall. The meetings will continue to be held in the Pima Room of the Student Union.

[REDACTED] also announced that she would be retiring the end of June but would continue to work as a retiree 19 hours per week. A request has been made to the Vice President to hire a full time person to be trained but there may not be funding available to do so.

The minutes of May 4, 2004 Institutional Biosafety Committee meeting were approved.

Committee members were given a copy of a memorandum from Amy Patterson, Director of the NIH Office of Biotechnology Activities regarding minutes of Institutional Biosafety Committee meetings. This memo included information about the preparation of minutes and access to the minutes. This information is also available on the Office of Biotechnology Activity website.

Mark reported on followups from the May IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

Dr. Brown is still working with USDA to meet their requirements for getting the necessary permits.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 1, 2004

Page 2

Principal Investigator	Proposal Title	Biosafety Level
Setsuko Chambers Cancer Center	Regulation of CSF-1 in Ovarian Cancer (NCI R01 CA097347)	BL2

Dr. Chambers to provided a map of the vector she is using and identified the genes that are being cloned into the vector. The reviewer found this additional information satisfactory to recommend approval of these proposals.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED] Study

Mark reported that additional information had been found in the files that answered some of the questions the Committee had, but that he is still waiting for answers to: 1) what is known about the mechanism action, 2) the specificity of the toxin. [After the meeting Dr. Ellsworth provided this information. Dr. Ellsworth wrote regarding the mode of action, "VIP3A toxin is proteolytically activated to a toxin core in the lepidopteran larval midgut and forms pores in the gut membranes of sensitive species". In response to specificity of toxin, he provided a table of lepidopteran species that have demonstrated sensitivity to VIP3A protein preparations and/or VIP3 A-expressing plants. He also provided a list of insensitive lepidopteran species identified to date.]

The Committee asked Mark to find out if planting had already begun. [Planting was begun on May 26. As of June 1 seedlings were beginning to emerge.]

Principal Investigator	Proposal Title	Biosafety Level
Lonnie Lybarger Cell Biol & Anatomy	Ubiquitin-mediated Pathways of Viral Immune Invasion (National Institutes of Allergy & Infectious Diseases)	BL2

Dr. Lybarger has now provided information about his new laboratory including the location.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

Mark reported that he is still waiting for Standard Operating Procedures from Dr. Worobey. The proposed BL3 lab construction is due to be completed in three months.

[illegible]

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 1, 2004

Page 5

MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
David Galbraith Plant Sciences	Functional Genomics of Nuclei (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 1, 2004

Page 7

The following MUA was reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		
Keith Joiner Cell Biol & Anatomy	Uptake of Host Cell Cholesterol by <i>T. gondii</i> (NIH)	BL2
Keith Joiner Cell Biol & Anatomy	Phospholipid Metabolism and Traffic in <i>T. gondii</i> (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]

Five proposal routing sheets from labs covered under BSL-1 registration were submitted in May.

Peter Else reported on the progress of renovations at the Veterinary Diagnostic Laboratory. He reported that completion is anticipated in August. The only change since the work was approved by Risk Management has been to create a new receiving area so that packages other than mail would not be going to the main entrance. A walkway and receiving area will be at one end of the observation room. There is a freezer available for deliveries made on weekends.

Peter also reported that renovations to Dr. Songer's lab are on the drawing board for review by Drs. Songer and Collins. Risk Management, the Institutional Biosafety Committee and Fire Marshall will be given an opportunity to review the plans next.

Peter also reported on the progress on the greenhouses above the Sixth Street Garage. He outlined who would be using the support space on the north side. There will be 14 greenhouses. There will be seven BL2 green houses with anti rooms for plant pathology. In the future there will be BL3 space for plants cooled with chilled water. A substantial amount of the project will be completed around July 9 or 10th with plans for move in during August. Phase 1 should be completed by the fall semester.

The next IBC meeting will be in July by email/mail.

Institutional Biosafety Committee**MINUTES**

Meeting July 6, 2004

In July 2004, a meeting of the Institutional Biosafety Committee was held by mail. The following Committee members responded: Nafees Ahmad, David Besselsen, Peter Else, Richard Friedman, John Galgiani, Mark Grushka, Henry Hagedorn, Susan Hopf, Jeannie Nordstrom, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Glenn Songer, and Herb Wagner. No responses to the mailing were received from: Don Bourque, Susan Ehrlich, David Madison, Michael Riggs or Bruce Walsh.

The minutes of June 1, 2004 Institutional Biosafety Committee meeting were approved.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's and Mark Grushka's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
David Galbraith Plant Sciences	Microarray-based QTL Mapping in Rice (USDA)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Joy Logan Medicine	Microarray Analysis of the In vivo Effects of Uninephrectomy on Renal Gene Expression (Southern Arizona Foundation)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
July, 2004

Page 2

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, and Mark Grushka pre-reviewed the following proposals which are BL1 except for cell line being used and/or because human tissue. The Committee approved them based on the pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Bernard Futscher Pharm/Toxicology	Genomic Methylation: A Mechanism to Alter Tumor Phenotype (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Lihua Marmorstein Ophthalmology	EFEMP1 and Drusen Formation in the Retina (NIH)	BL2
Fernando Martinez AZ Respiratory Ctr	IL8- and GATA3-mediated Pathways in Asthma Exacerbations (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
July, 2004

Page 3

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson and Mark Grushka pre-reviewed the following proposals which have been previously approved by the Committee but are 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of the pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Ronald Watson Health Prom Sci	Treatment of Cancer and Heart Disease with Natural Products (Wallace Genetics Foundation)	BL2

Institutional Biosafety Committee
MINUTES (AMENDED)
 Meeting August 2004

In August 2004, a meeting of the Institutional Biosafety Committee was held by mail. The following Committee members responded: David Besselsen, Richard Friedman, John Galgiani, Mark Grushka, Henry Hagedorn, Susan Hopf, David Madison, Jeannie Nordstrom, Leland Pierson III (Chair), Michael Rand, Glenn Songer, and Herb Wagner. No responses to the mailing were received from: Nafees Ahmad, Susan Ehrlich, Peter Else, Kris Orsborn, Michael Riggs or Bruce Walsh.

The minutes of July 6, 2004 Institutional Biosafety Committee meeting were approved.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's and Mark Grushka's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
John Hildebrand Alan Nighorn ARL	Glomeruli as Functional Units for Olfactory Coding (NIH)	BL1
Martha Hunter Entomology	Ecology and Evolution of a Novel Symbiont Causing Cytoplasmic Incompatibility in Insects (NSF)	BL1
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 2004

Page 2

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee
continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 2004

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal which is BL1 except for cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Robert Collier Animal Sciences	Evaluation of Role of Serotonin in Mammary Growth and in Bovine Mammary Tissue (Monsanto Company)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Haiyong Han Cancer Center	Evaluate the Inhibitory Activity of Telik Compound 3D5E and its Analogs Against Aurora A Kinase (Telik Inc.)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 2004

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Lisa Rimsza Pathology	Molecular Signatures to Improve Diagnosis and Outcome Prediction in NHL (University of Nebraska, NIH Subcontract)	BL2
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson and Mark Grushka pre-reviewed the following proposals which have been previously approved by the Committee but are 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of the pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 2004

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

Institutional Biosafety Committee

MINUTES

Meeting September 21, 2004

On September 21, 2004, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:00 PM. In attendance were: Nafees Ahmad, Peter Else, Richard Friedman, John Galgiani, Mark Grushka, Sue Hopf, David Madison, Kris Orsborn, Leland Pierson III (Chair), and Margaret Stalker, and. Also attending was Alice Langen, Vice President for Research Office. Not in attendance were: David Besselsen, Susan Ehrlich, Henry Hagedorn, Jeannie Nordstrom, Michael Rand, Michael Riggs (currently on Sabbatical), Glenn Songer, Herbert Wagner, Jr. and Bruce Walsh.

Dr. Pierson, introduced Dr. Ronald P. Spark, Associate Professor, Clinical Pathology as a prospective new Committee member. Dr. Pierson also introduced the following guests visiting from Arizona State University: Leon Igras, Director of Environmental Health & Safety, Steven Hunter, Associate Director of Environmental Health & Safety, Edward Skibo, Chair, Institutional Biosafety Committee, Shelley Jones, Industrial Hygienist, Diana Hubbard, Occupational Health.

Dr. Ralph Stoaks, Regional Program Manager, Regional Biotechnology for USDA-APHIS, PPQ and WR and Martin Lemon, Technical Resource Manager from Monsanto Corporation, also attended as guests of the Institutional Biosafety Committee.

Mark Grushka, Biosafety Officer, reported that Dr. Powell participated in another walk-about visiting the University of Arizona Animal Hazards Program on July 14.

Mark also reported that he had completed the annual audits of Drs. Nafees Ahmad and Richard Friedman's BSL-3 laboratories. He will provide the details of these audits at a future meeting when there is more time available to present the information.

A Committee member pointed out a typographical error on page 3 of the August minutes. The minutes will be appropriately amended. With the correction of this error, the minutes of the August 2004 Institutional Biosafety Committee meeting were approved.

Dr. Pierson thanked Ralph Stoaks and Martin Lemon for their presentations at the seminar earlier in the day on "Opportunities and Challenges of Genetically Modified Agricultural Field Studies: A Practical Approach". He hoped that Committee members had been able to attend this informative session. Dr. Stoaks spoke about "GMO Agricultural Research: A USDA Permit Compliance Perspective" and Martin Lemon spoke on "Managing Regulations and Compliance for Field Trials Involving Regulated Transgenic Traits". Dr. Vicki Chandler, University of Arizona Director of Bio5 also presented an "Overview of GM Research from the Perspective a Research Using this Technology". Dr. Pierson invited Committee members to ask questions.

Issues regarding permits were discussed, including jurisdictional issues. It was pointed out that companies have a vested interest in compliance ethically, monetarily and legally. The Committee also discussed the issues of confidentiality and the need to protect sensitive information while still providing sufficient information for adequate review of compliance.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 21, 2004

Page 3

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal which is BL1 except for cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Michael Hogan IBSB	PCR & Protein Tests on Gen Vault Elements (Gen Vault Corporation, Carlsbad, CA)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Francisco Moreno Psychiatry	Association and Monoamine Systems Genes and Depression (Institute for Mental Health Research)	BL2
[REDACTED]	[REDACTED]	[REDACTED]

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 21, 2004

Page 5

The Committee reviewed the following MUAs and made the following requests for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
Donald DeYoung Univ Animal Care	Studies into the Infective Dose and Effective Dose of Bio-Engineered Complex in a Murine Model (Berlett, Inc., Scottsdale, Arizona)	BL2

Dr. DeYoung plans to use methicillin resistant staphylococcus aureus. The Committee would like to know: 1) does he have a specific way to distinguish the strain he is using? (*Dr. DeYoung is asking the supplier to characterize the genotype of the strain*). [REDACTED] 3) can he determine the drugs susceptibility for the strain? (*Dr. DeYoung wrote that samples of the material proposed for use have been set up for antibiotic sensitivity determination for this strain*) and 4) is it possible to use a less drug resistant strain? (*Dr. DeYoung responded that this study was designed to study the strain available and while it might be possible to utilize a less resistant strain this would partially defeat the purpose of the study and the results would have less value to the prospective sponsor*)

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 21, 2004

Page 6

MUAS reviewed with requests for additional information continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The Committee was unable to approve this MUA because a Committee member had to leave early and there was no longer quorum. In this MUA, Dr. Kaltenbach is informing the Committee that he is setting up a lab for diagnostic work. Peter Else requested this be put back on the October meeting Agenda and he will provide information about the lab design at that time.

Because there was no longer a quorum present the following two MUAs could not be approved. It was suggested these be sent out electronically to Committee members for approval.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 21, 2004

Page 7

Mark Grushka informed the Committee that BSL-1 Registration applications had been received from Craig Aspinwall, Chemistry and Craig Comiter, Surgery. He inspected these labs and recommends approval.

Five proposal routing sheets from labs covered under BSL-1 registration were submitted in September.

The next IBC meeting will be October 19, 2004 in the Pima Room of the Student Union.

Institutional Biosafety Committee

MINUTES

Meeting November 2, 2004

On November 2, 2004, a meeting of the Institutional Biosafety Committee was held in the Sabino Room of the Student Union from 12:00 to 1:00 PM. In attendance were: David Besselsen, Peter Else, Mark Grushka, Henry Hagedorn, David Madison, Leland Pierson III (Chair), Margaret Stalker, Glenn Songer, and Herbert Wagner, Jr. Also attending were Alice Langen, Vice President for Research Office and Ron Spark, M.D., Pathology (prospective Committee member). Not in attendance were: Nafees Ahmad, Susan Ehrlich, Richard Friedman (on leave), John Galgiani, Sue Hopf, Jeannie Nordstrom, Kris Orsborn, Michael Rand, and Bruce Walsh.

Margaret Stalker shared some highlights from the American Biological Safety Association (ABSA) conference she and Mark Grushka attended in October. Although there was a lot of valuable information learned, she shared some items that were relevant to the Committee's current areas of oversight. These included: 1) upcoming changes in the shipping regulations for classification and transportation of clinical and diagnostic samples; 2) a presentation on the James H. Clark Center, an open laboratory design building at Stanford University similar to the University of Arizona Thomas W. Keating Bioresearch Building currently under construction open laboratory; 3) security is becoming a major concern and "trumping" safety for in demands for funding; and 4) a presentation on privacy, academic freedom and the public's right to know. IBCs may be asked in the future to look at research proposal for inadvertent generation of dangerous biological methods and products.

Mark Grushka shared information with the Committee on presentations on 1) a presentation on Mad Cow disease, 2) a presentation on Herpes B exposures including how to monitor them in the long term, and 3) a presentation on the World Health Organization. The 3rd edition of the WHO Biosafety Manual is due out shortly.

Under Old Business, Mark reported as follow-up from the May 4, 2004 Institutional Biosafety Committee meeting that Judith Brown had been able to obtain the permit required for plant inoculations. The Committee had provisionally approved her request to experimentally transmit molecularly cloned plant viruses pending receipt of required permits.

Also under Old Business, Mark reported on follow-ups from the September 21, 2004 IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
Donald DeYoung Univ Animal Care	Studies into the Infective Dose and Effective Dose of Bio-Engineered Complex in a Murine Model (Berlett, Inc., Scottsdale, Arizona)	BL2

Dr. DeYoung provided information showing the methicillin resistant staphylococcus aureus strain he is using is sensitive to several common antibiotics.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 2, 2004

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee
continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 2, 2004

Page 4

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Margaret Briehl Pathology	Redox Control of Apoptosis Signaling (NIH/NCI)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 2, 2004

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Robert Dorr Cancer Center	Redox-Active Agents for Pancreatic Cancer (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
Jorge Giron Miro/Immunology	YagZ pilus Adhesin of Attaching and Effacing E. coli (NIH)	BL2
Mark Haussler Biochemistry	Vitamin D Hormone Signaling in Bone Mineral Homeostasis (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Claire Payne Cell Biol & Anatomy	Cytochrome C Oxidase I: A Biomarker for Colon Cancer Risk (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 2, 2004

Page 6

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
Donato Romagnolo Nutritional Sciences	Molecular Regulation of the Human BRCA-1 Gene (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
Eva Varga Pharmacology	Trafficking in Human CB1 Cannabinoid Receptor Signaling (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 2, 2004

Page 7

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Donald Lightner Veterinary Science	Shrimp Disease Research: Etiological Studies, Diagnostic Procedure Development and Disease Prevention (US Dept Agric/GCRL Marine Shrimp Farming Consortium)	BL2
Howard Ochman Biochemistry	Elucidating the Origins and Functions of Unknown Genes (NIH)	BL2
Michael Wells Biochemistry	Regulation of Digestion in Blood-Sucking Insects (NIH)	BL2

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 2, 2004

Page 8

MUAs were reviewed by the Committee and approved as submitted continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed at the September but not approved due to loss of a quorum at the end of the meeting. The Committee approved them based on the earlier review:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The Committee reviewed the following MUA and made the following requests for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Mark Grushka informed the Committee that a BSL-1 Registration application had been received from Craig Aspinwall, Chemistry. He inspected this lab and recommends Committee approval.

Eight proposal routing sheets from labs covered under BSL-1 registration were submitted in October.

Also under new business, Mark Grushka informed the Committee there had been a possible rabies exposure during Michael Nachman's mammology field course. A graduate teaching assistant reported being grazed on an ungloved hand by a bat during a mist netting exercise when he was getting a third pre-exposure vaccination in the rabies series. An employee report of injury has been filed. It was also reported that no one from Dr. Nachman's group attend

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 2, 2004

Page 9

the annual Ecology and Evolutionary Biology field safety training held October 29th. Mark reminded Committee members that safety has been an issue in the past in this field course.

[REDACTED]

The Committee recommended that Dr. Nachman provide documentation of completing the SOPs including: 1) a record from students that all pre-exposure rabies immunizations have been received before they take the field course, 2) written certification that students have satisfactorily passed the hands-on training required in the SOPs and 3) a signed form indicating students have read and understand the risks associated with working with wild mammals (such as rabies and Hantavirus). The Committee would like to receive copies of this documentation of compliance with the SOPs before the next year's course is taught. The Committee recommended monitoring of this course.

The Committee also asked [REDACTED] is the current SOP practical? For example, do the required gloves allow for handling of bats and rodents?

The next IBC meeting will be **November 16, 2004** in the **Pima Room** of the Student Union.

Institutional Biosafety Committee
MINUTES

Meeting November 16, 2004

On November 16, 2004, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:00 PM. In attendance were: David Besselsen, Peter Else, John Galgiani, Mark Grushka, Henry Hagedorn, Sue Hopf, David Madison, Leland Pierson III (Chair), Ronald Spark, Margaret Stalker, Herbert Wagner, Jr. and Bruce Walsh. Also attending were Alice Langen, Vice President for Research Office. Not in attendance were: Nafees Ahmad, Susan Ehrlich, Richard Friedman (on leave), Jeannie Nordstrom, Kris Orsborn, Michael Rand, and Glenn Songer.

The minutes of November 2, 2004 Institutional Biosafety Committee meeting were approved.

Committee members were given a copy of a memorandum from Dr. Richard Powell, Vice President for Research, Graduate Studies and Economic Development regarding clarification of compliance responsibilities related to TGen. According to the terms of the agreement between TGen and the Arizona Board of Regents "when the University is the Grantee with a University-Employed principal investigator, the University will be responsible for scientific compliance.... relating to the research". "The University will only be responsible for compliance oversight for projects carried out by UA employees at UA facilities."

Under Old Business, Peter Else showed Committee members an aerial view of the proposed site for the BSL-3 lab for the Arizona Veterinary Diagnostic Laboratory. He also showed the Committee the floor plan for the lab and pointed out the location of the two interlocking doors, the fire exit, a hands-free sink and the biological safety cabinet. He pointed out the autoclave with a pass through above it. He said there would be stainless steel countertops and that the walls, floor and ceiling would have an epoxy covering. Peter also showed the Committee a diagram for the air handler and explained that it was designed so air could be drawn from outside the building to create a sterile room. A Committee member suggested a redundant exhaust fan system be incorporated into the design. They are still looking at security features but are considering either a push button system or a swipe card system. He said they are ready to start work once they receive design approval from the IBC and Risk Management.

Also under Old Business, Mark reported on follow-ups from the May 4, 2004 IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
Michael Worobey Ecol & Evol Biology	Emergence of HIV: A "Molecular Archeology" Approach (NIH)	BL2

The Committee has asked that Dr. Worobey provide SOPS for handling of blood samples and that Mark inspect his lab to insure he has proper containment for the research. Mark said Dr. Worobey has provided the requested SOPS. Mark told the Committee he inspected the lab on October 29. It was renovated to be a BL3 facility. Mark showed the Committee the floor plan. The lab has limited access by card. Mark showed the Committee a photo of the digital air balance control for the lab. Mark explained that currently Dr. Worobey is working at BL2 but wanted to convert the lab to BL3 so that if he expanded his research in the future, he would have appropriate containment.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 16, 2004

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 16, 2004

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 16, 2004

Page 5

The Committee recommended provisional approval pending Human Subjects and RAC approval for the following MUA submission:

Principal Investigator	Proposal Title and Granting Agency	Biosafety Level
Lee D. Cranmer Medicine	A Phase I Study to Evaluate the Safety and Pharmacokinetics of Pro-1, a Liposome-encapsulated Thymidine Kinase Gene Formulation, in Patients with Stage IV Metastatic Melanoma (<i>Protiva Biotherapeutics Inc.</i>)	Human Gene Therapy

This proposal deals with a liposome-encapsulated plasmid expressing an altered Herpes Virus thymidine kinase (TK) gene with enhanced affinity for the prodrug ganciclovir. TK phosphorylates the drug that is subsequently triphosphorylated to its active form. The drug is most active on actively dividing cells (such as found in tumors). The CMV promoter drives the plasmid. The drug is given intravenously and has a long half-life circulating in the blood. The liposomal treatment transfects tumor cells preferentially due to altered blood vessel permeability near tumors. Once inside the cell, Pro-1 induces Programmed Cell Death. This study proposes to enroll twenty-one patients with approximately 8 to 12 patients from Arizona Health Science Center. The study has been tested on animals. In an earlier study, two earlier patients did have adverse events. However, the effects were transient and resolved within 48 hours. In an effort to eliminate or minimize an adverse even, steroids will be administered prior to treatment and patients will be monitored in the hospital for 30 hours.

The Committee reviewed the following MUA and made the following requests for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED] The suggestion that eye protection be worn during sampling was made.

Mark Grushka informed the Committee that a BSL-1 Registration applications had been received from Drs. Xianchun Li and Yeong-Hau Howard Lien. Mark visited these labs and makes the following recommendations be met before Committee approves these laboratories:

Principal Investigator

[REDACTED]

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 16, 2004

Page 6

BSL-1 Registration applications continued:

**Principal
Investigator**

Yeonghau Howard Lien
Medicine

The lab needs to be labeled with a room number, chemical storage needs to be improved and the training documentation needs to be updated.

Five proposal routing sheets from labs covered under BSL-1 registration were submitted in November.

The next IBC meeting will be **December 21** in the **Pima Room** of the Student Union.

Institutional Biosafety Committee

MINUTES

Meeting December 21, 2004

On December 21, 2004, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:00 PM. In attendance were: Nafees Ahmad, Mark Grushka, Henry Hagedorn, Sue Hopf, David Madison, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Glenn Songer, Ronald Spark, Margaret Stalker, Herbert Wagner, Jr. and Bruce Walsh. Also attending was Alice Langen, Vice President for Research Office. Not in attendance were: David Besselsen, Susan Ehrlich, Peter Else, Richard Friedman (on leave), John Galgiani, and Jeannie Nordstrom.

[REDACTED]

Chair, Dr. Sandy Pierson officially welcomed new member Dr. Ronald Spark, Pathology Department.

Under Old Business, Dr. Pierson reported that he had sent a letter to Dr. Michael Nachman, Department of Ecology & Evolutionary Biology with copies to the Vice President for Research, Acting Department Head, Risk Management and Animal Care regarding the incident with one of his graduate teaching assistant possibly receiving a grace from a bat. Dr. Pierson read excerpts of the letter to the Committee outlining the Committee's requirements and expectations. These included: revising his SOPs to require each GTA read and understanding the requirements and "sign a statement to this effect"; require documentation from the student that all pre-exposure rabies immunizations have been received *before* they take the two-day training field course and documented; provide written certification that each student has satisfactorily passed the two-day training and provide a signed form that each student has read and understands the risks associated with working with wild mammals, including rabies and Hantavirus.

Dr. Pierson also mentioned in the letter the new program "New Insurance Coverage for Volunteers and Student Field Trips".

[REDACTED]

Also under Old Business, Mark reported on follow-ups from the November 2, 2004 IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 21, 2004

Page 2

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
Craig Comiter Surgery	Effect of Phosphodiesterase-5 Inhibition with Sildenafil Citrate on Detrusor Hypertrophy in a Mouse Model of Bladder Outlet Obstruction (Pfizer)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Martha Hunter Entomology	Ecological Interactions Among Whiteflies, Parasitoid Wasps and Bacterial Symbionts (Binational (US-Israel) Science Foundation)	BL1

The Committee would like to know how the Whiteflies are being contained.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 21, 2004

Page 3

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Eugene Gerner Cancer Center	Apoptosis on Colon Cancer Chemoprevention, Project 1-Modification of APC-dependent Intestinal Carcinogenesis (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Simon Wong Pediatrics	The Molecular Effects of Diesel Exhaust Particulates on Respiratory Neutral Endopeptidase (Health Effects Institute)	BL2

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 21, 2004

Page 5

MUAs were reviewed by the Committee and approved as submitted continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

The Committee reviewed the following MUA and made the following requests for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

Mark Grushka recommended the Committee approve the following BSL-1 Registration application:

Principal Investigator

Yeonghau Howard Lien
Medicine

The Committee discussed the issue of registering BSL-1 labs working with animals and the potential of zoonotic disease exposures. The Committee wants to continue the discussion.

Two proposal routing sheets from labs covered under BSL-1 registration were submitted in December.

The next IBC meeting will be **January 18, 2005** in the **Pima Room** of the Student Union.

Vice President for Research
Institutional Biosafety Committee
(520) 621-3441
FAX: (520) 621-6159



1230 North Park Avenue, #205
P.O. Box 210420
Tucson, AZ 85721-0420

December 22, 2006

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

Re: Public Records Request Dated March 15, 2006

Dear Mr. Hammond:

Enclosed please find a third and partial response to your public records request of March 15th 2006 for Minutes of the University of Arizona Institutional Biosafety Committee.

The minutes of this committee document the University of Arizona's compliance with Section IV-B-2-a-(7) of the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules, from April 2002.

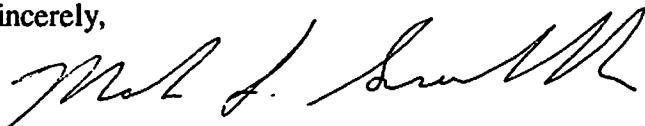
The enclosed material represents minutes from January through December of 2005. As indicated in our previous correspondence, these documents are part of an incremental response because of the significant amount of time and effort required to complete the request.

Sections of the Minutes have been redacted, in accordance with Arizona law and the guidelines from the NIH Office of Biotechnology Activities general letter of May 14, 2004, to remove information whose disclosure would directly compromise institutional or national security. Also redacted were a few instances of names or other identifying information of students in accordance with the 1974 Family Educational Rights and Privacy Act (FERPA) guidelines, one instance of information deemed attorney-client privileged, and any personnel information protected from release by Arizona Board of Regents policy 6-912. (You can find this policy at: <http://www.abor.asu.edu/> in Chapter 6, Part 2 on the Policy Manual.) Also, please note that information on all unfunded proposals has been redacted from the "Proposal Title" portion of each month's minutes, in accordance with Arizona public records law.

Edward H. Hammond
December 22, 2006
Page Two

We will forward our fourth and final response to this request in January of 2007.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark J. Grushka", written in a cursive style.

Mark J. Grushka, M.S., CSP
Manager, Biosafety and Biosecurity
520-621-5279 (O)
520-621-6159 (F)
520-331-5580 (C)
mgrushka@u.arizona.edu

Enclosures

Institutional Biosafety Committee**MINUTES**

Meeting January 18, 2005

On January 18, 2005, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: David Besselsen, Peter Else, Richard Friedman, John Galgiani, Mark Grushka, Henry Hagedorn, Sue Hopf, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Glenn Songer, Ronald Spark, Margaret Stalker, and Herbert Wagner, Jr. Also attending was Alice Langen, Vice President for Research Office. Not in attendance were: Nafees Ahmad, Susan Ehrlich, David Madison, Jeannie Nordstrom and Bruce Walsh.

The minutes of December 21, 2004 Institutional Biosafety Committee meeting were approved with the amendment to page 1 changing "grace from a bat" to read "graze from a bat".

Under Old Business, Mark reported on follow-up from the December 21, 2004 IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
Keith Joiner Cell Biol & Anatomy	Development of New Genetic Tools to Identify Nutrient Uptake Pathways in Malaria Parasites (<i>Ellison Medical Foundation</i>)	BL2

Keith Joiner provided SOPs for minimizing cutaneous surface cuts with sharp objects (glassware, pipettes, etc.) during manipulations in the hood in the presence of the pathogen. He also reported that all samples that are potentially infectious are inactivated before using the cell sorter.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Anne Arnold Plant Path Div	Collaborative Research: Diversity, Distribution and Demographic Effects of Seed-Associated Fungi in Neotropical Cecropia (<i>NSF</i>)	BL1
Danny Brower Mol & Cell Biology	A Rapid and Inexpensive Screen for Mutations that Sensitize Cells to Cancer Drugs (<i>ADCRC</i>)	BL1

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 18, 2005

Page 2

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
William Montfort Biochemistry	Nitric Oxide Signaling through Soluble Guanylyl Cyclase (<i>American Heart Association</i>)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 18, 2005

Page 3

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Katerina Dvorakova Cell Biol & Anatomy	Barrett's Esophagus, Esophageal Adenocarcinoma and Apoptosis (ADCRC)	BL2
Eugene Gerner Cancer Center	SPORE in GI Cancer. Project 1. Genetic Variability as Prognostic or Predictive Factors in Colorectal Intraepithelial Neoplasia (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
Lonnie Lybarger Cell Biol & Anatomy	CD8 T Cell Priming with Engineered MHC Class I Molecules (ADCRC)	BL2

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 18, 2005

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Istvan Molnar Arid Lands	Discovery, Optimization of Production, and Initial Characterization of Novel Anticancer Drug Lead Compounds from Bacteria Collected from the Rhizosphere of Desert Plants (ADCRC)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Daekyu Sun Pharm/Toxicology	Targeting Tumor Angiogenesis with G-quadruplex Interactive Ligands (ADCRC)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 18, 2005

Page 5

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Lynn Joens Veterinary Science	Biofilm Production and the Colonization of Broiler Chickens with <i>Campylobacter jejuni</i> (USDA)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 18, 2005

Page 6

MUAs were reviewed by the Committee and approved as submitted continued:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]

Principal Investigator

Proposal Title

Biosafety Level

Donald Lightner
Vet Sci & Microbiol

Control of Bacterial Disease in Penaeid Shrimp with
Florfenicol
(Schering-Plough Animal Health)

BL2

Principal Investigator

Proposal Title

Biosafety Level

Leland S. Pierson
Plant Path Div

Novel Two Component Regulation of Quorum Sensing and
Secondary Metabolite Production in Bacteria
(NSF)

BL2

Principal Investigator

Proposal Title

Biosafety Level

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

Principal Investigator

Proposal Title

Biosafety Level

Autumn Villarreal
Surgery

Requirement for Hedgehog Signaling in Angiogenesis
(American Heart Association)

BL2

The Committee reviewed the following MUA and made the following requests for additional information and/or clarification:

Principal Investigator

Proposal Title

Biosafety Level

Tom Tsang
Micro/Immunology

Cancer Immunotherapy by TCR Gene-Modified HSC Transfer
(ADCRC)

BL2

The Committee wanted to know how Dr. Tsang was using the human cell line (293) in this research. They also would like him to provide a map of the self-inactivating lentiviral vector he is using.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
January 18, 2005

Page 7

MUAs reviewed with requests for additional information and/or clarification continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

The Committee would like Dr. Yoon to provide a more complete description explaining the specific techniques to be used.

Also under new business, Mark reported to the Committee that Dr. Terrence Monks from the Pharmacology/Toxicology Department wants to use biosafety level 1 for his research, a lower biosafety level than is required by the Institutional Biosafety Handbook. Dr. Monks plans to use the cell line LLC-PK1 from the American Type Culture Collection (ATCC). The host source is *sus scrofa* (pig). Although the ATCC suggests biosafety level one for handling this cell line, the University of Arizona policy per the IBC Handbook is that biosafety level two is required for all cell lines of animal origin (primary or established). Dr. Monks feels this is an unnecessary restriction. Mark asked Dr. Monks to provide the Committee with his scientific rationale why he feels he should be allowed to use BSL-1 containment for this cell line.

The possible concerns when handling animal cell lines are: 1) does the original material contain viruses or other material that may be pathogenic, and 2) could derived products and microorganisms from these cells pose a greater hazard due to activation or altered properties brought on by *in vitro* manipulations. Mark shared with the Committee responses he received from MIT and the Mt. Sinai School of Medicine on how they manage this type of research

It was pointed out that the ATCC doesn't assure their cell lines to be viral free. An institution is allowed to have a higher standard than required in the guidelines. After discussing the issue, the Committee wants Dr. Monks to adhere to the current University standard and requirements. Rather than the Committee justifying the University's position, Dr. Monks should justify his exemption.

Dr. Pierson said that Margaret and Mark are compiling information on the risks of zoonotic infection in the laboratory and would share their findings at a future meeting. Mark invited Committee members to form an ad hoc group to review the current policies and assist in further reevaluation of cell line risks. Glenn Songer volunteered to help in this endeavor.

Three proposal routing sheets from labs covered under BSL-1 registration were submitted in January.

The next IBC meeting will be **February 15, 2005** in the **Pima Room** of the Student Union.

Institutional Biosafety Committee**MINUTES**

Meeting February 15, 2005

On February 15, 2005, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Nafees Ahmad, David Besselsen, John Galgiani, Mark Grushka, Henry Hagedorn, Sue Hopf, Kris Orsborn, Leland Pierson III (Chair), Glenn Songer, Ronald Spark, Margaret Stalker, and Herbert Wagner, Jr. Also attending were Dr. James Collins, Head of Veterinary Sciences and Microbiology, Alice Langen, Vice President for Research Office and Randy Ryan, Assistant Director, Agricultural Experiment Station. Not in attendance were: Susan Ehrlich, Peter Else, Richard Friedman, David Madison, Jeannie Nordstrom, Michael Rand, and Bruce Walsh.

Chairman, Dr. Pierson welcomed guests, Dr. Jim Collins and Randy Ryan who are going to become new members of the Institutional Biosafety Committee.

The minutes of the January 18, 2005 Institutional Biosafety Committee meeting were approved as submitted.

Under Old Business, Mark reported on follow-up from the January 18, 2005 IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
Tom Tsang Micro/Immunology	Cancer Immunotherapy by TCR Gene-Modified HSC Transfer (ADCRC)	BL2

The Committee wanted to know how Dr. Tsang was using the human cell line (293) in this research. They wanted him to provide a map of the self-inactivating lentiviral vector he is using. Mark reported that he has gotten a map of the vector and also asked about the OVA epitope-incorporated IL-2. Dr. Tsang responded that it is a piece of DNA to produce IL-2 in vivo. The reviewer was satisfied with Dr. Tsang's response.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 15, 2005

Page 2

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Xiaohui Hu Biochemistry	Nitric Oxide Signaling through Soluble Guanylyl Cyclase (<i>American Heart Association</i>)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 15, 2005

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Michelle Rhoads Animal Sciences	Characterization of Ghrelin and its Receptor in the Reproductive Tracts of Dairy Cattle Experiencing Different Energetic States (USDA)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 15, 2005

Page 4

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Scot Ebbinghaus Cancer Center	Structure and Functional Role of GGA Repeats in c-myb Promoter Activity in Leukemia (ADCRC)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Robin Harris Cancer Center	Human Papillomavirus (HPV) Infection in Partners (ADCRC)	BL2

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 15, 2005

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
Laurence Hurley Pharm/Toxicology	Drug Targeting the I-Motif in the c-MYC Promoter (ADCRC)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
Douglas Larson Surgery	Immunomodulation: Cardiovascular Structure and Function (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Lihua Marmorstein Ophthalmology	EFEMP1 and Drusen Formation in the Retina (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 15, 2005

Page 6

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 15, 2005

Page 7

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs was reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
February 15, 2005

Page 8

The following MUAs were reviewed with requests for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Dr. Pierson said that Margaret and Mark are compiling information on the risks of zoonotic infection in the laboratory and would share their findings at a future meeting. Mark invited Committee members to form an ad hoc group to review the current policies and assist in further reevaluation of cell line risks. Glenn Songer and Kris Orsborn volunteered to help in this endeavor.

Nine proposal routing sheets from labs covered under BSL-1 registration were submitted in February.

The next IBC meeting will be **March 15, 2005** in the **Pima Room** of the Student Union.

Institutional Biosafety Committee

MINUTES

Meeting March 15, 2005

On March 15, 2005, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Richard Friedman, John Galgiani, Mark Grushka, Henry Hagedorn, Sue Hopf, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Ronald Spark, Margaret Stalker, and Herbert Wagner, Jr. Also attending was Dr. James Collins, Head of Veterinary Sciences and Microbiology. Not in attendance were: Nafees Ahmad, David Besselsen, Susan Ehrlich, David Madison, Jeannie Nordstrom, Glenn Songer, and Bruce Walsh.

The minutes of the February 15, 2005 Institutional Biosafety Committee meeting were approved as submitted.

Chair, Dr. Pierson, reported to the Committee that he had met with Dr. Michael Nachman to discuss the issues associated with the Institutional Biosafety Committee and other oversight committee's concerns regarding his Ecol 485 Mammology field course. Specifically they discussed the event in 1997 requiring immunizations, respiratory training certification issues and the recent graduate teaching assistant bat-grazing incident. Dr. Nachman said his primary concern was for student health and he was not trying to ignore the requests of the Committee

The Committee had recommended that Dr. Nachman revise his SOPs to require each GTA read and understand the requirements for the course and "sign a statement to this effect"; require documentation from the student that all pre-exposure rabies immunizations have been received *before* they take the two-day training field course and documented; provide written certification that each student has satisfactorily passed the two-day training and provide a signed form that each student has read and understands the risks associated with working with wild mammals, including rabies and Hantavirus.

Dr. Nachman informed Dr. Pierson that for the past six years he had all students sign a form ensuring that they understand the health issues with the field course, including rabies, Hantavirus, etc. Since Teaching Assistants assignments are made only a week or two before the course begins, it is difficult for them to complete the entire round of immunizations before the course begins. However, Dr. Nachman said that Occupational Health told him that if the Teaching Assistants had received at least 2 of the 3 pre-exposure immunization shots, it was safe for them to handle the bats. He said if they had received only one shot, he limited their participation to setting up nets and did not allow them to do any of the procedures.

Dr. Nachman also said that he provides booklets he got from Risk Management as part of respiratory training. He told Dr. Pierson his students take the Animal Care training and are known to be good students in the class. He says he goes on every field trip. In addition, he mentioned that he had contacted his peers at other institutions to see how hand field trips. He got a wide range of responses including one from one of his former professor stating that he no longer allows any of his students to handle the animals in the field anymore.

Dr. Nachman told Dr. Pierson that he is going to write a response to the letter. [REDACTED] Dr. Pierson said if he does not hear from Dr. Nachman within a week, he would call him and if he does not hear back within two weeks, he will recommend the course be put on hold.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 15, 2005

Page 2

Under Old Business, Mark reported on follow-up from the January 18, 2005 IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

[REDACTED]

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 15, 2005

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 15, 2005

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 15, 2005

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 15, 2005

Page 6

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
March 15, 2005

Page 7

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUA was reviewed with requests for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Mark Grushka informed the Committee that a BSL-1 Registration application had been received from Walter Klimecki, Arizona Respiratory Center. Mark inspected this lab and recommends Committee approval.

Three proposal routing sheets from labs covered under BSL-1 registration were submitted in March.

The next IBC meeting will be **April 15, 2005** in the **Pima Room** of the Student Union.

Institutional Biosafety Committee**MINUTES**

Meeting April 19, 2005

On April 19, 2005, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:00 PM. In attendance were: Nafees Ahmad, David Besselsen, Richard Friedman, John Galgiani, Mark Grushka, Henry Hagedorn, Sue Hopf, Kris Orsborn, Glenn Songer, and Ronald Spark. Also attending were Alice Langen, Vice President for Research Office and Dr. James Collins, Head of Veterinary Sciences and Microbiology. Not in attendance were: Susan Ehrlich, David Madison, Jeannie Nordstrom, Leland Pierson III (Chair), Michael Rand, Randy Ryan, Margaret Stalker, Herbert Wagner, Jr. and Bruce Walsh.

At Chairman Sandy Pierson's request, Glenn Songer chaired the meeting.

The minutes of the March 15, 2005 Institutional Biosafety Committee meeting were approved as submitted.

Under Old Business, Mark reported on follow-ups from the November 2004 IBC meeting:

Principal Investigator	Proposal Title	Biosafety Level
Lee Cranmer	A phase I study to evaluate the safety and pharmacokinetics of Pro-1, a liposome-encapsulated thymidine kinase gene formulation, in patients with stage IV metastatic melanoma. <i>Protiva Biotherapeutics</i>	BSL-2

The IBC reviewed Dr. Cranmer's Human Gene Therapy protocol in November of last year. A group of three members including Chairman Pierson, John Galgiani and Nafees Ahmad reviewed associated documents including the Investigators Brochure and the Protocol. The IBC did approve the MUA, pending approval from the UA's Institutional Review Board and the DNA Advisory Committee (RAC). Documentation has been received that these oversight groups have reviewed this research. The IBC voted to give approval.

Under Old Business, Mark reported on follow-ups from the February IBC meetings:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

due to lack of funding.

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

Under Old Business, Mark reported on follow-ups from the March IBC meetings:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

Dr. Richard Friedman responded that the information provided to him by Dr. Holmes was adequate to explain how the viral system worked.

The IBC voted to give approval.

Dr. Michael Nachman wrote an official response dated March 22, 2005 to address the concerns from several UA health and safety compliance units/committees regarding his ECOL 485/585 course. Mark summarized the response to the Committee. Dr. Spark expressed a concern about whether the expertise was available to monitor what will actually go on in the field. Mark responded that a meeting of the original health and safety compliance units/committees will meet on April 26th and discuss the adequacy of Dr. Nachman's response. Part of that discussion will cover responsibilities for monitoring compliance. Dr. Spark proposed that the matter be tabled until the outcome of that meeting was determined.

BSL-2 Cell Culture Risk Evaluation Project

Mark reported that the project participants had come up with both areas of agreement and areas that will require further discussion.

The areas of agreement include the following:

- BSL-2 Requirement for All Cell Culture Use Should be Changed
- BSL-2 Requirement Should Remain For:
 - All Primary Cells of Human or Primate Origin
 - Cell Lines of Human Origin or Primate Origin
 - All Cells Lines Purposely Inoculated with an Infectious Agent

The areas requiring further discussion include the following:

- Should BSL-2 be Required for all Primary Mammalian Cell Lines?
- Should BSL-2 be Required for Hybridoma Culture Work?
- What Criteria Would be Used to Require Additional Information from a PI for Non-Human/Non Primate Cell Cultures?
- Should the IBC Encourage the Use of Biological Safety Cabinets to Minimize Cell Culture Contamination?
- Should Laminar Flow Benches with Horizontal Air Flow be Prohibited for Cell Culture Work?
- What Weighting Should the IBC Give to PI's with Many Years of Experience when Reviewing the Risks Associated with Cell Culture?

A question was also posed during the meeting about whether insect cell lines were going to be considered. Glenn, Jim and Kris have agreed to meet before the next IBC and discuss these areas requiring further discussion and develop a position paper that will include recommendations to the IBC for the May meeting.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval:

1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES

Page 4

April 19, 2005

produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

**Principal
Investigator**

Proposal Title

**Biosafety
Level**

Louise Canfield Comprehensive NAU/AZCC Cancer Research Partnership
Biochemistry (NIH/NCI)

BL1

[REDACTED]

[REDACTED]

Ramon Jaime-Garcia Use of Antoxigenic Strain of *Aspergillus flavus* to Reduce
Plant Sci- Aflatoxin Contamination in Corn in Tamaulipas, Mexico
Plant Path Div (USDA)

BL1

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
April 19, 2005

Page 5

Expedited MUAS pre-reviewed and approved continued:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Leslie Gunatilaka Discovery and Development of Novel Inhibitors of Cell Motility BL2
Istvan Molnar from Desert Organisms
Arid Lands (ADCRC)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
April 19, 2005

Page 6

Expedited MUAS pre-reviewed and approved continued:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	
------------	------------	--

[REDACTED]	[REDACTED]	
------------	------------	--

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

Mark Grushka informed the Committee that a BSL-1 Registration applications have been received from Craig Comiter (Surgery), Sanjay Ramakumar (Surgery), Xianchun Li (Entomology). Mark inspected these labs and recommends Committee approval.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
April 19, 2005

Page 7

The following MUAS were pre-reviewed by Sandy and Mark but not listed on the original agenda. Mark gave an overview of each one at the meeting. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]

Howard Ochman
Biochemistry

Comparative Genomics of Gut Microbiota
(*University of CA Ernest Orlando Lawrence Berkeley
National Laboratory*)

BL2

[REDACTED]

[REDACTED]

The next IBC meeting will be **May 17, 2005** in the **Pima Room** of the Student Union.

Institutional Biosafety Committee

MINUTES

Meeting May 17, 2005

On May 17, 2005, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Nafees Ahmad, David Besselsen, Richard Friedman, Mark Grushka, Henry Hagedorn, Jeannie Nordstrom, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Randy Ryan, Glenn Songer, Ronald Spark, Margaret Stalker, and Herbert Wagner, Jr. Also attending were guests Robert Fleming, Barbara Fox-Nellis and Michael Riehle. Not in attendance were: James Collins, John Galgiani, Sue Hopf, David Madison, and Bruce Walsh.

The minutes of the April 19, 2005 Institutional Biosafety Committee meeting were approved as submitted.

Chair, Dr. Pierson, introduced prospective new Institutional Biosafety Committee members Robert Fleming of Fleming & Curti P.L.C., a certified specialist in Estate and Trust Law and certified Elder Law attorney and Michael Riehle, Assistant Professor in the Department of Entomology.

Mark Grushka introduced Barbara Fox-Nellis, Biosafety Officer from Northern Arizona University who was doing an informal assessment of the University of Arizona Biosafety Program at Mark's request.

Mark Grushka thanked Henry Hagedorn on behalf of the Committee for his many years of service as a Committee member and told him he would be giving him a plaque of appreciation. Henry is retiring from the University of Arizona and resigning from the Committee.

Under Old Business, Mark reported the following follow-ups from the February/April Institutional Biosafety Committee meetings:

Principal Investigator	Proposal Title	Biosafety Level
Marc Oshiro Pharm/Toxicology	Mutant p53 and Its Role in the Epigenetic Silencing of Tumor Suppressor Genes (USAMRMC)	BL2/3
Principal Investigator	Proposal Title	Biosafety Level
Jiaqi Shi Pathology	Deregulation of Translational Initiation by eIFe in <i>Breast Cancer</i> (DOD)	BL2/3

Drs. Oshiro and Shi responded that they would handle the vectors they are using with BL3 practices and would produce their own biosafety manuals for their laboratories. They assured Mark that they would not begin working until all the proper documentation had been completed.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
May 17, 2005

Page 2

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Christopher Choi Agr & Biosys Engr	Development of Simulation Models and Biosensors to Detect Biological Agents in Water Distribution Systems (NSF)	BL1
Matt Goode School of Nat Res	Conservation Genetics of the Tiger Rattlesnake (National Park Service)	BL1
Paul Krieg Cell Biol & Anatomy	Regulation of Cardiac MyH7b Expression (NIH)	BL1
Bradley Moore Pharm/Toxicology	Exploiting Marine Actinomycete Genomes for Natural Product Discovery (NOAA)	BL1
S. Patricia Stock Plant Path/Plant Sci	Molecular Diagnostics of Entomopathogenic Nematodes and Symbiotic Bacteria from Turkey (University of Hacettepe, Turkey)	BL1

The Committee requested that a copy of the permit be obtained.

Marlys Witte Surgery	Rodent Models of Lymphedema (uses project FOXC2 in Hereditary Lymphedema and Lymphatic Development) (WAESO)	BL1
-------------------------	---	-----

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
May 17, 2005

Page 3

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
May 17, 2005

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUA was reviewed with requests for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
May 17, 2005

Page 5

Six proposal routing sheets from labs covered under BSL-1 registration were submitted in May.

The next IBC meeting will be **June 21, 2005** in the **Picacho Room** of the Student Union.

Institutional Biosafety Committee

MINUTES

Meeting June 21, 2005

On June 21, 2005, a meeting of the Institutional Biosafety Committee was held in the Picacho Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Nafees Ahmad, David Besselsen, Robert Fleming, Richard Friedman, John Galgiani, Mark Grushka, David Madison, Jeannie Nordstrom, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Michael Riehle, Glenn Songer, Margaret Stalker, and Herbert Wagner, Jr. Also attending was Alice Langen, Vice President for Research Office. Not in attendance were: James Collins, Sue Hopf, Randy Ryan, Ronald Spark, and Bruce Walsh.

The minutes of the May 17, 2005 Institutional Biosafety Committee meeting were approved as submitted.

Under Old Business, Mark reported the following follow-ups from the Institutional April and May Biosafety Committee meetings:

Principal Investigator	Proposal Title	Biosafety Level
Marc Oshiro Pharm/Toxicology	Mutant p53 and Its Role in the Epigenetic Silencing of Tumor Suppressor Genes (USARMC)	BL2/3

Reviewer, Dr. Nafees Ahmad is satisfied with the Standard Operating Procedures that Dr. Marc Oshiro submitted for this research.

Principal Investigator	Proposal Title	Biosafety Level
S. Patricia Stock Plant Path/Plant Sci	Molecular Diagnostics of Entomopathogenic Nematodes and Symbiotic Bacteria from Turkey (University of Hacettepe, Turkey)	BL1

David Madison, Plant Quarantine/Nursery Programs Manager, Arizona Department of Agriculture, reported that Dr. Stock has the relevant permits for this research. Her lab was inspected last year.

Mark Grushka reported the preliminary findings from the Biosafety Program Assessment by Barbara Fox-Nellis, Biosafety Officer and compliance official at North Arizona University. Barbara previously was the Manager of the University of Florida Biosafety Program, a peer institution of the University of Arizona. Mark pointed out that at University of Florida there are five biosafety professionals. Barbara found our current level of staffing at 1.59 FTE's inadequate for the size and complexity of the biological research program at the University. She also noted that there is a lack of integration in the compliance groups. She thought the biosafety professional should be integrated formally into the renovation and construction process. Additionally, she noted there appeared to be no formal medical surveillance assurance system in place. She did comment that one of our BSL-3 labs had the best Standard Operating Procedures she'd ever seen. She also praised the Facilities Management Biological Safety Cabinets

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 21, 2005

Page 2

Preventative Maintenance Program. She liked the training presentation of the UBRP program that she observed as well. She had never seen the use of a teaching laboratory and field course form which she thought was good. A final report is due at the end of the month.

Mark Grushka reported on the BSL-2 Cell Culture Risk Evaluation Project. A subcommittee of Kris Orsborn, Glenn Songer and Jim Collins met to evaluate the current Institutional Biosafety Committee requirements for cell lines of human or animal origin. The current requirement is a BSL-2 level of containment. The subcommittee recommendations are that the BSL-2 requirement should remain for: all primary cells of human or primate origin, all cell lines purposely inoculated with an infectious agent, use of hybridomas and all primary tissues from feral animals. They recommend that when an investigator desires to use a cell culture from a non-human/non-primate source of less than BSL-2 containment, a description of every biological component of the cell culture system be provided. In the case of tissue from feral animals, it must be shown that it is free of disease agents.

The Committee requested that wording to be used in the Biosafety Manual for these changes be drafted before a formal vote on this recommendation is made.

Mark also reported on his annual audit of the BSL-3 laboratory at [REDACTED]. He again mentioned their excellent Standard Operating Procedures. He did mention that the downstream damper (from the HEPA) was not holding pressure. It poses not immediate problems and will be evaluated next month by the outside Biological Safety Cabinet certifier. Mark recommended a form air balance study by FDC to evaluation the significance of air balance issues.

Mark also reported that he had recommended an evaluation of the [REDACTED] and the lab training curriculums be done to ensure consistency. [REDACTED]

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Mark Grushka and Margaret Stalker subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Mark Grushka's and Margaret Stalker's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 21, 2005

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Zhongguo Xiong Plant Path/Plant Sci	Genome Typing of Citrus tristeza Virus Using Resequencing Microarrays (USDA)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
AZ Research Labs	[REDACTED] Presynaptic Calcium Stores (NIH)	BL1

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 21, 2005

Page 4

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Vince Guerriero Animal Sciences	Regulation of Cellular Growth by HspBP1 (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 21, 2005

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 21, 2005

Page 6

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Mark Grushka and Margaret Stalker pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Mark's, and Margaret's review.

Principal Investigator	Proposal Title	Biosafety Level
Stefano Guerra Az Respiratory Ctr	The Relation of Innate Immune Genes to COPD (<i>American Heart Association</i>)	BL2
Lynn Joens Veterinary Science	FS CAP: Food Safety Coordinated Agricultural Project (<i>NCSU</i>)	BL2

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
June 21, 2005

Page 7

MUAs were reviewed by the Committee and approved as submitted continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUA was reviewed with requests for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
Matt Goode SRNR	Health of Free-Ranging Gila Monsters (<i>Heloderma suspectum</i>) and Pathogenicity of Oral and Cloacal Bacteria (<i>T and E, Inc.</i>)	BL2

The Committee requested that Dr. Goode provide information about the specific safety Precautions used in the capturing, transport, laboratory manipulation and release of the Gila Monsters. Dr. Goode also needs to provide a copy of an required permit(s) for this type of collection activity.

Eleven proposal routing sheets from labs covered under BSL-1 registration were submitted in June.

The next IBC meeting will be **July 19, 2005** in the **Pima Room** of the Student Union.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
July 19, 2005

Page 2

[REDACTED]

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson and Mark Grushka subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's and Mark Grushka's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Martha Hunter Entomology	Ecology and Evolution of a Novel Bacterial Symbiont Causing Cytoplasmic Incompatibility (NSF)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
Raina Maier SWES	Kartchner Caverns Slime Study (Arizona State Parks Board)	BL1

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
July 19, 2005

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee
continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED]	[REDACTED]
Andrew Warkman/ Paul Kreig Cell Biology	Cardiac Expression of Myosin Heavy Chain-7B <i>(American Heart Association)</i>	BL1
[REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
July 19, 2005

Page 4

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee
continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's and Mark's review.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
July 19, 2005

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Michael Hogan Bio5	PCR and Protein Tests on GenVault Elements (GenVault Corporation, Carlsbad, CA)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Raymond Runyan Cell Biology	TGFβ Receptor Activities in Heart Valve (American Heart Association, Pacific Mtn. Affiliate)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Leslie Tolbert ARL-Neurobiology	Intercellular Interactions in Developing Glomeruli (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
July 19, 2005

Page 6

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
July 19, 2005

Page 7

The following MUA was reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed with requests for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

The Committee recommended that Dr. Choi provide a map showing where the test plot is and what type of security is provided at the site.

Principal Investigator	Proposal Title	Biosafety Level
Jorge Giron Micro/Immunology	YagZ pilus Adhesion of Attaching and Effacing E. coli (NIAD/NIH)	BL2

The Committee would like to know if Dr. Giron is importing isolated EPEC and EHEC from patient biopsy samples in London. If these are being shipped, the Committee would like to know if Dr. Giron's collaborator will be using IATA procedures. If Dr. Giron will be handling pathogenic microorganisms in his biological safety cabinet, he needs to be sure the certification is up to date.

Seven proposal routing sheets from labs covered under BSL-1 registration were submitted in July.

The next IBC meeting will be **August 23, 2005** in the **Pima Room** of the Student Union.

Institutional Biosafety Committee
MINUTES (AMENDED)
Meeting August 23, 2005

On August 23, 2005, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Nafees Ahmad, David Besselsen, James Collins, Robert Fleming, Mark Grushka, David Madison, Leland Pierson III (Chair), Michael Rand, Michael Riehle, Randy Ryan, Ronald Spark and Margaret Stalker. Also attending was Alice Langen, Vice President for Research Office. Not in attendance were: Richard Friedman, John Galgiani, Sue Hopf, Jeannie Nordstrom, Mike Riggs, Kris Orsborn, Glenn Songer, Herbert Wagner, Jr. and Bruce Walsh.

The minutes of the July 19, 2005 Institutional Biosafety Committee meeting were submitted for approval. Dr. Riehle pointed out that the minutes did not reflect that there had been questions regarding Dr. Jorge Giron's Memorandum of Understanding and Agreement form entitled, "YagZ pilus Adhesion of Attaching and Effacing E. coli". Mark Grushka said he would follow up on these questions and Margaret Stalker said the minutes would be amended. Margaret had not attended the July meeting and had written the minutes based on the information she was provided.

Under Old Business, Mark reported the following follow-up from the July Institutional Biosafety Committee meeting:

[illegible]

Also under Old Business, Mark Grushka and Sandy Pierson reported to the Committee that Dr. Nachman is working to satisfy all five requests made regarding the Fall Mammology course (ECOL 485) he teaches. 1) Dr. Nachman updated his Institutional Biosafety Committee Teaching Laboratory Biosafety Review form. 2) Mark and Sandy reported that Dr. Nachman has revised his SOP's to require that each GTA read and understand the requirements by signing a statement. 3) Dr. Nachman is also making sure that the GTA's have received the three pre-exposure immunizations and provide documentation of such before taking the two-day training field course. 4) Dr. Nachman will provide written certification that each student has satisfactorily pass the two-day training field trip. 5) Each student will also provide a signed form that they have read and understand the risks associated with working with wild mammals. Mark will verify documentation is place before the students go on the field trip.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Mark Grushka subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Mark Grushka's pre-review.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 23, 2005

Page 2

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Anne-Marie Cziko Mol/Cell Biology	Translational Regulation of Synaptic Plasticity (NIH/NRSA)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 23, 2005

Page 3

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Kirsten Limesand Nutritional Sciences	Salivary Acinar Cell Apoptosis: Regulation of p53 by Akt (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
Ryan Pelis Stephen Wright Physiology	Role of MRP2 and MRP4 in Renal Organic Anion Excretion (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 23, 2005

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
Charles Gerba SWES	Development of an Infectivity Assay for Noravovirus in Cell Culture (Battele Memorial Institute – Pacific NW Div)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Sean Limesand Animal Science	Aberrant Ovine Pancreatic Development in IGUR Fetuses (NIH)	BL2

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 23, 2005

Page 5

MUAs were reviewed by the Committee and approved as submitted continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Leland S. Pierson III Plant Sci- Plant Path Div	Novel Two Component Regulation of Quorum Sensing and Secondary Metabolite Production in Bacteria (NSF)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed with requests for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

Also under New Business, Mark Grushka reported that he had performed an annual audit of Dr. Ahmad's Biosafety Level 3 Laboratory. Dr. Ahmad revised his Practices and Procedures Manual last fall. The HIV Risk Assessment Matrix was also revised last fall and incorporated into his SOPs. Mark found that laboratory housekeeping continues to improve and that primary containment (i.e. the biosafety cabinet) is maintained properly by Facilities Management.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 23, 2005

Page 6

For the last several years Mark had recommended the establishment of voluntary HIV surveillance program. There has been an issue of who should pay for this program. Dr. Ahmad shared with the Committee that he had offered to pay the Campus Community Occupational Health for this service out of his own grant funds. [REDACTED]

[REDACTED] Additional concerns were that medical surveillance of an infection that has other modes of transmission (besides what could occur in a lab or at work) could lead to an employer's violation of its employees' rights to privacy and intrusion into their private lives. Committee members were surprised by this pointing out that the University already has a surveillance program for other potentially fatal diseases on campus, including TB, Herpes B, Hepatitis A & B.

The Campus Community Occupational Health Committee (CCOHC) wrote a memorandum to the IBC Chair on September 22, 2004 with their recommendations. The CCOHC recommended if voluntary HIV testing is desired by any of the employees in Dr. Ahmad's lab, it should be done through confidential or anonymous sources in the Tucson community and *not* by the UA as the employer of these individuals. Mark offered to send a copy of this memo to Committee members.

Dr. Ahmad shared that there had been a case when someone had gone to the emergency room for treatment and it was still not resolved who would pay for the bill. Dr. Ahmad said without the University's support it would be difficult for him to continue to keep his lab running and properly staffed when researchers can go to other institutions show they value their employees by providing an in-house surveillance and treatment program. Dr. Pierson suggested contacting peer institutions to find how they handle this issue.

Mark finished reporting his findings from the audit with the following recommendations: 1) complete baseline HIV testing of all potentially exposed employees, 2) consider using BSL1-3 checklists to periodically monitor laboratory biosafety performance standards, 3) use biological monitors for the autoclave and 4) evaluate and correct programs with key card entry reliability.

Also under Old Business, Mark reported that he visited Dr. Charles Gerba's laboratories. The Committee reviews many protocols from this researcher. Dr. Gerba's studies include the use of the following pathogens: Helicobacter, E coli H: 157, rotavirus SA-II, Norovirus, Hepatitis A, Cryptosporidium and the vaccine strain of polio. Dr. Sterling told Mark that he had been doing this type of research for about 30 years. Mark reported that as of June this year, Dr. Gerba had developed a biosafety manual for his BSL-1 agents. His housekeeping was generally good. All lab personnel is required to undergo safety training from Risk Management and Safety and the lab uses a combination of autoclaving, surface denomination, hand washing the PPE to control biohazards. Mark reported that the BSC Class II cabinet is certified annually by Facilities Management and there is a medical surveillance program that includes vaccination against Hepatitis A. Mark noted that the tissue culture room was exceptional for both cleanliness and documentation. Dr. Gerba's lab has had GLP training.

Mark made the following recommendations: 1) risk assessment for biohazards be incorporated into a project-based binder (Mark will be provided training in October), 2) training be completed by all who ship diagnostic/infectious samples and 3) the use of BSL-2 checklists to periodically monitor biosafety performance.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
August 23, 2005

Page 7

[REDACTED]

Two proposal routing sheets from labs covered under BSL-1 registration were submitted in August.

The next IBC meeting will be **September 20, 2005** in the **Pima Room** of the Student Union.

Meeting September 20, 2005

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 20, 2005

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
Ramon Jaime-Garcia Plant Path Div, Plant Sciences	Improved Management of Aflatoxin Contamination with Atoxigenic Strains of <i>Aspergillus flavus</i> in Arizona and South Texas (USDA)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Kathy Tang-Nelson Veterinary Science	Disease Survery and Marketing Prospects for SPF Shrimp Production on Guam (University of Guam – USDA)	BL1
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 20, 2005

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 20, 2005

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 20, 2005

Page 6

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUA was reviewed with the request for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

Also under New Business, Mark Grushka reported that he had performed the annual audit of Dr. Friedman's Biosafety Level 3 Laboratory. Mark found well developed SOPs, housekeeping

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
September 20, 2005

Page 7

was exceptional, the biological safety cabinet is certified annually by facilities management, decontamination procedures are well-developed and the upgraded HVAC system was completed in 2004 to better control pressure differential. Mark recommended implementing biological testing of the autoclave.

Also under New Business, Mark Grushka reported on the proposed "Cell Culture Language Changes" to be made in the University of Arizona Biosafety Handbook. A subcommittee that included Mark Grushka, Kris Orsborn, Glenn Songer and Jim Collins did an evaluation of the current IBC requirements for cell lines of human or animal origin and provided their recommendations to the Committee at the May 2005. From those recommendations, Mark drafted wording for the Handbook. "If a Principal Investigator desires to work with cell culture at less than Biosafety Level Two (BSL-2) he/she must provide the following information to the Institutional Biosafety Committee: A description of every biological component of the cell culture system." The Committee voted and approved this wording and language change to the Handbook.

Eight proposal routing sheets from labs covered under BSL-1 registration were submitted in September.

The next IBC meeting will be **October 18, 2005** in the **Pima Room** of the Student Union.

Institutional Biosafety Committee

MINUTES

Meeting October 18, 2005

On October 18, 2005, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: David Besselsen, Mark Grushka, Sue Hopf, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Michael Riehle, Randy Ryan, Herbert Wagner, Jr. and Bruce Walsh. Also attending was Alice Langen, Vice President for Research Office. Not in attendance were: Nafees Ahmad, Don Bourque, James Collins, Robert Fleming, Richard Friedman, John Galgiani, David Madison, Jeannie Nordstrom, Mike Riggs, Margaret Stalker and Glenn Songer.

Mark Grushka introduced the following guests: Glenn Jackson, a Veterinary student from the University of California, Davis, Robert Gomez, Arizona Department of Health & Safety and guest speaker, Bridgitte Dufour, Arizona Department of Health & Safety, Food Safety Center. An additional guest included Ralph Meer from Nutritional Sciences.

The minutes of the September 20, 2005 Institutional Biosafety Committee meeting were approved as submitted. The amended minutes of the August 23, 2005 meeting were also approved.

Under Old Business, Mark reported the following follow-up from the September Institutional Biosafety Committee meeting:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, and Mark Grushka subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's and Mark Grushka's pre-review.

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 18, 2005

Page 2

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee
continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 18, 2005

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Eugene Gerner Cancer Center	Apoptosis in Colon Cancer Chemoprevention PPG: Project 1 Prevention of APC-Dependent Intestinal Carcinogenesis (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 18, 2005

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 18, 2005

Page 5

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
Greg Bradley Veterinary Science	Classical Swine Fever Surveillance (USDA)	BL2
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 18, 2005

Page 6

The following MUA was reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

The following MUA was reviewed with the request for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
------------------------	----------------	-----------------

[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------

As part of the IBC's desire to enhance the education and training of the Committee on current issues, a speaker was invited to discuss an issue of current concern. The guest speaker was Brigitte Dufour, R.S., Food Biosecurity Specialist, Arizona Department of Health Services. Her topic was **Food Bioterrorism and Biosecurity**. A brief outline of the key points is listed.

The Problem

Deliberate contamination of the food supply:

- Public health consequences
- Devastating economic impact;
- Loss of public confidence in the safety of our food supply

Features of High Risk Foods:

- Batch Size
- Short shelf life
- Uniform mixing
- Ease of access

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
October 18, 2005

Page 7

Outline of talk continued:

Potential Contaminants

Biological Agents/Examples: B. Anthracis (anthrax), C. Botulinum (toxin),
Salmonella, Ricin (toxin)
Chemical Agents/Examples: Pesticides, cyanide, arsenic
Radioactive Contamination

The Solution

Protecting the Food Supply

**FDA
USDA
ADHS**

Food Biosecurity Program

Provide tools for the food industry
Educate food regulatory personnel within the State
Serve as support in the event of a food bioterrorism incident
FERN: Food Emergency Response Network
Foodborne and Waterborne Illness Monitoring

What the food industry can do?

THREE STEPS:

Conduct Vulnerability Assessment;
Implement Biosecurity Procedures;
Create Emergency Response Plan

BRIGITTE DUFOUR, R.S.

Food Biosecurity Specialist
Arizona Department of Health Services
Office of Environment Health
150 N 18th Ave, suite 430
Phoenix, AZ 85007
(602) 364-3130
Dufourb@azdhs.gov

Two proposal routing sheets from labs covered under BSL-1 registration were submitted in October.

The next IBC meeting will be **November 15, 2005** in the **Pima Room** of the Student Union.

Institutional Biosafety Committee
MINUTES

Meeting November 15, 2005

On October 15, 2005, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Nafees Ahmad, James Collins, Robert Fleming, Mark Grushka, Sue Hopf, David Madison, Leland Pierson III (Chair), Michael Rand, Michael Riehle, Mike Riggs, Randy Ryan, Margaret Stalker, Herbert Wagner, Jr. and Bruce Walsh. Also attending was Alice Langen, Vice President for Research Office and . Not in attendance were: David Besselsen (on sabbatical), Don Bourque, Richard Friedman, John Galgiani, Jeannie Nordstrom, Kris Orsborn, and Glenn Songer.

The minutes of the October 18, 2005 Institutional Biosafety Committee meeting were approved as submitted.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Mark Grushka subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's Margaret Stalker's and Mark Grushka's pre-review.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 15, 2005

Page 2

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Carrie Merkle Nursing	Role of NK Cells in Breast Cancer Metastasis in Diabetic Rats (ONS Foundation)	BL2
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 15, 2005

Page 3

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
Donato Romagnolo Nutritional Sciences	Molecular Regulation of the Human BRCA-1 Gene (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
David Lightner Veterinary Science	Shrimp Disease Research: Etiological Studies, Diagnostic Procedure Development and Disease Prevention (USDA/GCRL)	BL2
Alan Marmorstein Ophthalmology	Bestrophin and Lipofusien Accumulation in RPE (Macular Vision Research Foundation)	BL2

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 15, 2005

Page 4

Mark Grushka recommended the Committee approve the following BSL-1 Registration application and the Committee approved his recommendation:

Principal Investigator

Gary Greenburg
Cell Biology & Anatomy

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUA was reviewed with the request for additional information and/or clarification:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 15, 2005

Page 5

The Committee also reviewed the following Human Gene Therapy project with requests for additional information:

Principal Investigator	Proposal Title	Biosafety Level
Thomas Dragovich Cancer Center	A Randomized, Phase II Study of TNFerade Biologic with 4-FU and Radiation Therapy for First-line Treatment of Unresectable Locally Advanced Pancreatic Cancer (Gen Vec, Inc.)	HGT

In reviewing this protocol, the IBC yields authority over patient issues, informed consent forms, and patient follow-ups to the Human Subjects Committee. The IBC focuses its review on the vector, the choice, construction and expression of the transgene, and issues relating to the personal safety of those involved in vector preparation and delivery and possible fates of the vector and transgene after administration.

Dr. Pierson explained to the Committee that this study proposes to use an adenovirus based vector to express the TNF- α gene within a tumor via direct intratumoral injection in conjunction with treatment with 5-FU and radiation therapy to reduce the size and metastatic potential of unresectable pancreatic tumors. Three parts of the vector are missing – the E1 region of the adenovirus type 5 vector is deleted and a partial deletion of the E5 and E4 regions required for replication. Generation of a replication competent virus would require 2 recombination events in a single particle, one being a rare nonhomologous type.

Dr. Pierson pointed out that two Phase I human trials have already been performed. In these trials two Serious Adverse Events (SAEs) were reported, one with a possible connection to the treatment. The protocol was adjusted based on this SAE.

The construction of the vector is clearly described and the vector should perform as expected. The PI appears well versed in the safety issues and sufficient prior trial data indicates that the procedure can be performed and tolerated in the majority of patients. Adenoviral vectors have been successfully used in previous HGT experiments but some risks are present. Although they are likely extremely remote, some mention should be made. There exists the remote possibility that recombination of the administered adenovirus with endogenous adenovirus in the patient could lead to a replication competent virus containing the TNF- α gene. Previous studies with 39 patients indicated no virus was detectable in blood, urine or sputum. Previous work with adenoviral vectors indicates no need for patient isolation. There is the potential for viruses that escape the tumor to be picked up from the patient by others, especially if this procedure is performed on an 'out-patient' basis. The question is what the likely result of this to others is. The transgene is only expressed at high levels after exposure to ionizing radiation. Thus, there will be little expression of the gene outside the patient. The presence of the transgene does not appear to convey any selective advantage to the virus. Thus, the viral titer in another individual would not increase and would likely be maintained at a low level or it would be lost over time.

One committee member asked what post mortem safeguards were in place. Another Committee member asked if there were any statistics on shedding in the animal studies. There was discussion about the risk to other individuals if recombination occurs. The committee asked that this MUA be held over to the December IBC meeting for further review.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
November 15, 2005

Page 6

Seven proposal routing sheets from labs covered under BSL-1 registration were submitted in November.

The next IBC meeting will be **December 20, 2005** in the **Pima Room** of the Student Union.

Institutional Biosafety Committee

MINUTES

Meeting December 20, 2005

On December 20, 2005, a meeting of the Institutional Biosafety Committee was held in the Pima Room of the Student Union from 12:00 to 1:15 PM. In attendance were: Nafees Ahmad, Richard Friedman, John Galgiani, Mark Grushka, Sue Hopf, Jeannie Nordstrom, Kris Orsborn, Leland Pierson III (Chair), Michael Rand, Michael Riehle, Margaret Stalker, Glenn Songer, and Bruce Walsh. Also attending was Alice Langen, Vice President for Research Office and Lana Hudgins. Not in attendance were: David Besselsen (on sabbatical), Don Bourque, James Collins, Robert Fleming, David Madison, Mike Riggs, Randy Ryan and Herbert Wagner, Jr.

The minutes of the November 15, 2005 Institutional Biosafety Committee meeting were approved as submitted.

Under New Business, the following MUAs were pre-reviewed by Dr. Sandy Pierson, Margaret Stalker and Mark Grushka subject to the following conditions and recommended Committee approval: 1) the proposal is clearly BL1; 2) no toxin harmful for animals or humans is to be produced; 3) no field testing or release of known pathogenic or genetically engineered organism will take place; and, 4) no use of viral cloning vectors will occur. The Committee approved them on the basis of Dr. Pierson's, Margaret Stalker's and Mark Grushka's pre-review.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 20, 2005

Page 2

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee
continued:

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 20, 2005

Page 3

BL1 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee
continued:

[illegible]

Also under New Business, the Committee approved the following proposal. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposals which are BL1 except for the cell line being used and/or because human are tissue involved. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

[illegible]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 20, 2005

Page 4

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

[illegible]

Expedited BL2 MUAs pre-reviewed by the Chair and IBC staff and approved by the Committee continued:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
Joy Winzerling Nutritional Science	Iron Metabolism in Mosquitos (NIH)	BL2
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 20, 2005

Page 6

Also under New Business, the Committee approved the following proposals. To expedite review, Dr. Sandy Pierson, Margaret Stalker and Mark Grushka pre-reviewed the following proposal that has been previously approved by the Committee but is 1) being resubmitted to a different granting agency, or 2) are continuations with no significant change to the research being performed. The Committee approved them on the basis of Dr. Pierson's, Margaret's and Mark's review.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed by the Committee and approved as submitted:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The question was raised what had been decided regarding HIV testing. [REDACTED]

[REDACTED] The Committee recommended that a group representing BSL-3 lab users meet with Dr. Leslie Tolbert, Vice President for Research to discuss this continuing challenge.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 20, 2005

Page 7

MUAs reviewed by the Committee and approved as submitted (continued):

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The following MUAs were reviewed and approved contingent upon the biological cabinet certifications being up to date:

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Also under New Business, Mark Grushka presented an Audit Report for Dr. Michael Worobey's BSL-3 laboratory. Mark reported that he found a well developed set of SOPs. Access to the lab was by a key pad offering security. All wastes are disposed of by autoclave. He did make the following recommendations: 1) formalized risk assessment to identify most significant hazards of LAI, 2) document regular decontamination of working and walking surfaces, 3) consideration of biological indicator testing of autoclave effectiveness, 3) sign off-provision for all staff who are required to read and understand the SOPs and 4) contacting Dr. Nafees Ahmad about status of voluntary HIV testing of staff.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 20, 2005

Page 8

Under Old Business, Mark Grushka reported on the following follow-ups:

Follow-up from the September 21, 2004 IBC meeting:

[illegible]

Follow-up from the November 15, 2005 IBC meeting:

[illegible]

The Committee was unable to vote on the following follow-up from the November 15, 2005 meeting because there was no longer a quorum.

Principal Investigator	Proposal Title	Biosafety Level
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Alice Langen mentioned that several other oversight committees (i.e. IRB) were using alternate committee members to overcome this problem. She volunteered to serve as an alternate voting member. It was also suggested that a member on sabbatical be designated as a non-voting member during the absence from the Committee. The Committee will address this at their next meeting in January.

INSTITUTIONAL BIOSAFETY COMMITTEE-MINUTES
December 20, 2005

Page 9

[REDACTED]

One proposal routing sheet from a lab covered under BSL-1 registration was submitted in December.

The next IBC meeting will be January 17, 2006 in the **Pima Room** of the Student Union.