



The University of New Mexico

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Date: April 25, 2006

To: The Sunshine Project
Attn: Edward H. Hammond, Director
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RE: University of New Mexico IBC minutes

As requested, included in this packet are the University of New Mexico's (UNM) minutes from our Institutional Biosafety Committee (IBC) meetings since May 1, 2003. A total of 76 pages of meeting minutes have been submitted. Information that could jeopardize UNM's proprietary/privacy interests, and/or security interests has been redacted. The redacted information includes: all staff names or identifiers when associated with a specific protocol or exposure incident, all references to specific protocol agents, and all identifiers of protocol locations (areas, buildings, or room numbers).

CC: Terry Yates & Rick Lyons (IBC Co-Chairs); Jo Ann Stringfield (IBC legal representative); Richard Larson, file copy

UNM BIOSAFETY COMMITTEE MEETING MINUTES

July 9, 2003

9:00 AM - 11:00 PM

BMSB, Room B-85

Present:

Judy Pointer, Biosafety Officer
Gary Cseko, M.S.P.H., Director of Research Protections
Larry Watson, Environmental Affairs/Industrial Hygiene, SHEA
Karen B. Mulloy, D.O., Dept. of Internal Medicine
Susan Kellie, M.D., HSC Epidemiology
Robert Bienstock, Senior Associate University Counsel
Rick Lyons, M.D., Dept. of Medicine
David Peterson, Esq., Keleher & McLeod
Barbara Masten, Ph.D., Dept. of Pathology
Brian Hjelle, M.D., Dept. of Pathology
Lynn Fondren, Environmental Affairs/Industrial Hygiene, SHEA
Laurie Hudson, HSC College of Pharmacy
Jac Nickoloff, HSC Molecular Genetics and Microbiology
Mary Donato, A.R.M., Risk Management

Absent:

Terry Yates, Ph.D., Vice Provost for Research
Hector Sanchez, New Mexico State Health Laboratory
David Faguy, Ph.D., Dept. of Biology
Denece Kesler, M.D., Dept. of Occupational Health
Ann Powell, Office of Research Services
Daniel Theele, Director Animal Research Facility

1. The meeting was called to order at 9:00 A.M. by the Biosafety Officer because the Chair was delayed by a conference call.
2. **Approval of Minutes-** The minutes of the March 10, 2003 meeting were approved as written.
3. **Protocols Pending**

a. APPROVED: all contingencies met,

- 1.) N [REDACTED] 02-12-01
PI: [REDACTED] N [REDACTED]
Title: Regulation of Myb Activity
Agent: [REDACTED] and [REDACTED] Vectors rDNA, [REDACTED], Human Cell Lines
Approved: all contingencies met

a.) APPROVED: all contingencies met, cont....

- 2.) L [REDACTED] 03-03-01
PI: [REDACTED] L [REDACTED]
Title: [REDACTED] and lung dendritic cell interactions
Agent: [REDACTED]
Approved: all contingencies met
- 3.) H [REDACTED] 03-03-01
PI: [REDACTED] H [REDACTED]
Title: Signaling Molecules in Epithelial Cancers
Agent: [REDACTED] Human Serotype 5 rDNA, [REDACTED], Human Cell Lines
Approved: all contingencies met

4. Protocols New

- 1.) IBC #: H [REDACTED] 03-07-01
PI: [REDACTED] H [REDACTED]
Title: Diagnosis and Pathogenesis of [REDACTED]
Agent: [REDACTED], [REDACTED] plasmid constructs vectors, [REDACTED], Human Cell Lines.
Primary Reviewer: Lynn Fondren

The Primary Reviewer presented a synopsis of Dr. H [REDACTED]'s protocol to develop diagnostic tests suitable for screening for human disease and/or animal infection. He will be evaluating replication mechanisms and designing anti-[REDACTED] ([REDACTED]) inhibitors. All the work with the viable virus will be done in the BSL-3 labs in accordance with established guidelines and procedures. He will not be doing any animal work with the live virus at this time. Some of the virus produced will be used to obtain genomic DNA. Some work will be done with UV killed Virus, and he will be determining how much UV radiation must be used to get 100% kill of the virus. He will use twice that level of UV before he removes the virus from the BSL3 suite for the DNA work.

[REDACTED] H [REDACTED] was questioned by some members about;

- The total amount of virus to be stored & on hand. Dr. H [REDACTED] clarified that the registration form and safety plan should reflect 100 mL's.
- The UV killing process.
Dr. H [REDACTED] responded "we have a very specific procedure. We put 100µLs/well in a plate. We leave the top off and irradiate it from 3.8cm for various lengths of time."
- Availability of various plaque assays
- Status of his import permit for [REDACTED] from Canada.

Dr. H [REDACTED] excused himself from the meeting before further discussion and voting.
After discussion, the protocol was approved with 2 contingencies,

1. Hazardous Awareness Training for those authorized to enter the [REDACTED] facility, and
2. The development of a [REDACTED] post exposure protocol

2.) IBC #: L [REDACTED] 03-07-01

PI: [REDACTED] L [REDACTED]

Title: [REDACTED] in Deer Mice (*Peromyscus*) and Its Effect on Host Reproductive Allocation

Agent: [REDACTED]; Deer Mice

Primary Reviewer: Judy Pointer

The Primary Reviewer provided a summary of the protocol. Dr. L [REDACTED] will be studying [REDACTED] (a parasite) in mice. There is no risk group rating for this agent. It can be assumed to be Risk Group 1, because at this time it has not been known to cause disease in humans. He will be handling the agent in the Biology Labs in [REDACTED] Room [REDACTED]. Dr. L [REDACTED] proposes to study offspring sex ratio effects on deer mice after female mice are infected with this parasite, before breeding them with non-infected male mice. The [REDACTED] life cycle requires the production of cercariae (larvae) in a snail; followed by the infection of a mammalian host (the deer mice); followed by the production and release of parasitic eggs in the mice feces and tissues about 30 days after infection. At that time mice livers and or feces are ground in sterile water to release parasitic eggs. The eggs must re-infest a snail for the parasite to reproduce. The snails and the mice are housed in separate rooms, thus breaking the reproductive cycle of the parasite. The parasite naturally causes "swimmers itch" after swimmers have been swimming in waters infested with snails. Per Dr. L [REDACTED]'s Assistant, the deer mice are the offspring of in-house bred mice screened for diseases.

After IBC Committee discussion this protocol was approved contingent upon

1. [REDACTED] H [REDACTED], [REDACTED] S [REDACTED], and [REDACTED] L [REDACTED] each contact EOH services to complete and submit the EOH services animal handler questionnaire (initial and or annual questionnaire as it applies to each individual).
2. Eliminate the use of 10% bleach applied to skin, use soap and water instead and [REDACTED] L [REDACTED] contacting Brian Hjelle and/or Dan Theel regarding the source of the Deer Mice.

3.) IBC #: W [REDACTED] 03-07-01

PI: [REDACTED] W [REDACTED]

Title: Regulation of Neurotransmission and Behavior

Agent: Replication Defective [REDACTED] Vector, [REDACTED], Mice, Human Cell Lines

Primary Reviewer: Rick Lyons substituted for Dan Theele who was absent.

Dr. W [REDACTED] is addressing the effect of over expressing 2 proteins derived from primary neuro cell lines. The primary neuro cell lines will come from mouse brains. He will also be using the HEK293 cells which are a well defined human cell line, often used in transfections. The genes can not replicate outside the cells. Because these cell lines are very difficult to transfect he intends to use a [REDACTED] vector. This vector is essentially comprised of circular pieces of DNA that have sequence on them that allow them to be inserted inside the chromosomes of the cell lines. After transfection the gene sequences in the vector is now transcribed, RNA is made, and then protein is made. The gene sequence will replicate along with the cells. But they don't jump from dish to dish or transmit from animal to animal. This [REDACTED] vector is a published vector from MIT. Dr. W [REDACTED] will be using an EK1 host vector system [REDACTED], and doing the plasmid work at BSL-2.

The protocol was approved as written.

4.) IBC #: B [REDACTED] 03-07-01

PI: [REDACTED] B [REDACTED]

Title: Quantification of the Expression of [REDACTED] and [REDACTED] in Rhabdomyosarcoma and Correlation with Clinical Outcome and Subtype

Agent: Human Cell Lines, [REDACTED] and [REDACTED] RNA are Exempt from the NIH Guidelines

Primary Reviewer: Karen Mulloy

Dr. B [REDACTED] will be probing for the [REDACTED] and [REDACTED] genes which are exempt from the NIH guidelines because he is not using viable microbes. The only hazard is work with human cells. He will be using pediatric specimens from an aggressive sarcoma probably originating in muscle cells. He will measure the levels & localization of the [REDACTED] and [REDACTED] messenger RNA and resultant protein within the two samples. Overall there goal is to correlate what they learned about the distribution of proteins and compare it with the clinical outcome. The purpose is to improve diagnostic as well as treatment and stratification for patients. Tissue samples will come from the Cooperative Human Tissue Network and it has HRRC approval. However the HRRC approval number for tissue culture procurement was not supplied. Primary cell cultures from UNM Hospital will be obtained from the cytogenetics lab and handled in Dr. B [REDACTED]'s lab under BSL-2 conditions. These samples will be used for immuno-localization *in situ* hybridization studies. Cell samples will be fixed in formaldehyde prior to removing from the BSL2 lab. The only potential hazard from this material is, if the samples are infected with a transmissible agent like [REDACTED] or [REDACTED] which could be passed to employees. They are using all the appropriate barriers. The cells will be taken out of the BSL2 lab for imaging, after fixing. The samples will be used for messenger RNA protein extractions, and will be handled in designated areas with proper bleach clean-up procedures.

After discussion the protocol was approved pending 3 contingencies:

1. The motion is approved contingent upon the submittal of documentation verifying Biosafety and Infectious Waste training for all named individuals to the IBC office.,
2. Submittal of documentation of those working with the agent receiving [REDACTED] vaccination or declination.
3. Supply to the IBC office the HRRC approval number for obtaining the samples from UNMH.
5. **Continual Review – None**
6. **Notifications - None**
7. **Standing Reports**

a.) Report of the Biosafety Officer

- A UNM Institutional Biosafety Committee: IBC Orientation, July 7, 2003 was distributed to each membership.
- A revised draft copy of the IBC application for registration was distributed and members were asked to review it and return comments to the BSO.
- Members were asked to review the membership contact list and notify the IBC Coordinator of any changes, including changes related to their specialties.

- Members were asked to supply the IBC coordinator with a short CV, NIH biosketch or resume within the next 2 weeks, so that federal requirements related to NIH registration of UNM's IBC could be finalized. This requirement also applied to member appointed alternates.
- The IBC Administrative Process document, which sets down the basic review methods of the Committee, was discussed among the membership.

Concerns related to the federal requirement for public meetings versus the security concerns of some University non-rDNA research protocols were discussed. It was noted that Los Alamos National Lab's IBC announces their meetings to the public while neither University of Alabama nor UT MD Anderson Cancer Center did so. It was noted that at the federal level for rDNA research there is a requirement for public meetings; however it was uncertain if this was so at the state level. The committee's legal advisor offered to check New Mexico state law to see if the state requires public announcements of IBC meetings.

Alternate responsibility and reporting was discussed. Members may appoint one alternate to attend meetings in their stead if they can not attend. However, alternates must be persons familiar with the research protocols before the Committee, be capable of collaborative discussions related to it, and have similar expertise as the member they are alternating for. Alternate member contact and expertise information should be submitted to the IBC Coordinator as soon as possible.

Division of expertise and responsibilities of the two newly established Primary Review subcommittees was discussed. The subcommittee membership lists were devised to ensure uniform expertise on each subcommittee. If the Committee should come upon a situation where appropriate expertise is not available from within the current membership, the Committee will have the ability to bring in outside consultation, i.e., such as for plant recombinant DNA research, or ethical review of a proposal.

A draft Research Biosafety Policy was discussed. This Policy would be presented to the Board of Regents for approval. Contents of this policy will need to be decided by the membership and discussion covered what items might need to be included. It was decided that the Policy should be general, non-controversial, establish authority for IBC decision enforcement and not overlap authority or activities of other committees such as the Radiation Safety of the Animal Care and Use Committee. Before the policy could be finalized the IBC Bylaws would need to be revised. The Committee's legal adviser said that from the IBC Administrative Process document that he could produce a draft revision of the IBC Bylaws and present it for the Committee's review.

b.) Report of Safety (SHEA) committee member

NONE

c.) Report of Occupational Health Services Committee Member

NONE

d.) Select Agent Responsible Official Report

Dr. Lyons presented Dr. Yates' report in his absence. Dr. Lyons spoke about the CDC inspection outcome. He said, we passed and they gave us a lot of kudos for all the hard work we put into it and we will now be good for 3 to 5 years until the next inspection. We now have an interim CDC approval number for transfer and possession of Select Agents. We are currently in the process of finalizing the Biosecurity Plan of this program. We will not receive final approval from the CDC until the regulation becomes final November 13, 2003. The Biosafety Officer added that all individuals granted unescorted access to UNM's Select Agent labs have submitted the necessary documentation to the Department of Justice to enable the back-ground checks required by the Select Agent regulations to go forward.

e.) Ad hoc committee report, if applicable

NONE

f.) Other

NONE

8. Old Business

NONE

9.) New Business

a.) The Biosafety Officer reported on an exposure incident where an employee was exposed to BBP containing material (direct face-splash of viable human materials) from an unprotected vacuum pump. The incident took place in a BSL2 lab. While there is no federal requirement to maintain vacuum pump protection in BSL2 labs, the Committee decided to recommend that SHEA include "checking for vacuum pump protection" during routine BSL2 lab inspections. The SHEA committee member indicated this item had already been changed on their inspection list and in the future it would be done. The Committee Chair requested that all future exposure incidents be reported to the Biosafety Officer who will conduct a follow-up investigation then copy the follow-up report to SHEA, the IBC Chairs and others involved in the incident.

b.) One member had concerns that Dr. [REDACTED]'s protocol only contained one hazard, BBP-type materials. She questioned whether our IBC should formally review these types of hazards. The subject was opened for debate. Methods employed at other institutes for reviewing this hazard were discussed. It was noted that some institutes do take this type of research to the IBC and some do not. It was decided that the IBC Administrative Process document and the IBC Application form would be rewritten to reflect a change in the review process for viable human and non-human material hazards. The new process will require review by the Biosafety Officer and the IBC Chair, rather than review by the full Committee. Also decided was that a generic BBP Plan template would be devised by the Biosafety Officer and made available to Principal Investigators whose work involved this type of material. Submission of a customized BBP Plan derived from the generic template, by a Principal Investigator, would suffice as a blanket approval for all work done under their direction that involved these materials for a period of 5 years.

c.) The IBC Chair expressed his wish that the IBC move towards approving research safety proposals on the basis of the specific hazardous material per the method of use per the location of use. This would allow investigators to submit only one application when the agent, location, and method of use are identical, though the titles of grants or projects may differ; i.e. work with viable human materials at BSL2.

d.) IBC training. In the remaining time the Biosafety Officer presented the first of a presentation entitled The Role of University of New Mexico's Institutional Biosafety Committee (IBC).

10.) The meeting was adjourned at 11:00 A.M.

UNM BIOSAFETY COMMITTEE MEETING MINUTES

October 8, 2003

9:00 AM - 11:00 PM

BMSB, Room B-85

Present: voting members have been highlighted

Judy Pointer, Biosafety Officer

Gary Cseko, M.S.P.H., Director of Research Protections

Larry Watson, Environmental Affairs/Industrial Hygiene, SHEA

Karen B. Mulloy, D.O., Dept. of Internal Medicine

Susan Kellie, M.D., HSC Epidemiology

Robert Bienstock, Senior Associate University Counsel

David Peterson, Esq., Keleher & McLeod

Barbara Masten, Ph.D., Dept. of Pathology

Brian Hjelle, M.D., Dept. of Pathology

Jac Nickoloff, HSC Molecular Genetics and Microbiology

Denece Kesler, M.D., Dept. of Occupational Health

Larry Barton, Professor of Biology

Ann Powell, Office of Research Services

Terry Yates, VPR, Office of Research

Daniel Theele, Director Animal Research Facility

Elizabeth Minet, Assistant University Counsel

Gail Keiser, Training Specialist, SHEA

Absent:

Rick Lyons, M.D., Dept. of Medicine

Hector Sanchez, New Mexico State Health Laboratory - Deceased

David Faguy, Ph.D., Dept. of Biology

Laurie Hudson, HSC College of Pharmacy

1. The meeting was called to order at 9:00 A.M. by Dr. Terry Yates.
2. **Approval of Minutes-** The minutes of the July 9, 2003 meeting were approved as written.
3. **Protocols Pending**

b. APPROVED: all contingencies met,

- 1.) **IBC #: H** [REDACTED] **03-07-01**
PI: [REDACTED] **H** [REDACTED]
Title: Diagnosis and Pathogenesis of [REDACTED]
Agent: [REDACTED], [REDACTED] plasmid constructs vectors, [REDACTED], Human Cell Lines.
Primary Reviewer: Lynn Fondren
Approved: all contingencies met

a.) APPROVED: all contingencies met, cont....

- 2.) IBC #: L [REDACTED] 03-07-01
PI: [REDACTED] L [REDACTED]
Title: [REDACTED] in Deer Mice (*Peromyscus*) and Its Effect on Host Reproductive Allocation
Agent: [REDACTED]; Deer Mice
Primary Reviewer: Judy Pointer
Approved: all contingencies met
- 3.) IBC #: W [REDACTED] 03-07-01
PI: [REDACTED] W [REDACTED]
Title: Regulation of Neurotransmission and Behavior
Agent: Replication Defective [REDACTED] Vector, [REDACTED], Mice, Human Cell Lines
Primary Reviewer: Rick Lyons substituted for Dan Theele who was absent.
Approved: all contingencies met
- 4.) IBC #: B [REDACTED] 03-07-01
PI: [REDACTED] B [REDACTED]
Title: Quantification of the Expression of [REDACTED] and [REDACTED] in Rhabdomyosarcoma and Correlation with Clinical Outcome and Subtype
Agent: Human Cell Lines, [REDACTED] and [REDACTED] RNA – Exempt
Primary Reviewer: Karen Mulloy
Approved: all contingencies met

4. Protocols New

- 1.) IBC #: B [REDACTED] 03-10-01
PI: [REDACTED] B [REDACTED]
Title: Expression of [REDACTED]-[REDACTED] 1 in [REDACTED] Vector-infected Mouse Myoblasts
Agent: [REDACTED] Vector; insert [REDACTED]; Human Cell Lines; [REDACTED]
Primary Reviewer: Brian Hjelle

- The Primary Reviewer provided a summary of the protocol. Dr. B [REDACTED] proposes to use the Clontech [REDACTED] Tet-On system to induce expression of [REDACTED]-[REDACTED] in cultured mouse muscle cells (using an established myoblast cell line, C2C12). The plasmids will be amplified in [REDACTED] and their expression secured under desired regulatory constraints using the [REDACTED] vector.

After discussion, the protocol was approved with 2 contingencies,

1. Dr. Z [REDACTED] complete and document completion of Biosafety, Infectious Waste and Bloodborne Pathogen training.
2. Applicant must estimate expected maximum viral titers based upon manufacturer's claims in an addendum to or revision of the application.

5. Continual Review – None

6. Notifications

1.) S [REDACTED] 03-10-01

PI: [REDACTED] S [REDACTED]

Title: Isolation of patient lung cells and culture of patient's allogeneic peripheral blood cells

Agent: Human Cell Lines

Primary Reviewer: NA

- The Biosafety Officer provided a summary of the protocol. [REDACTED] S [REDACTED] is using dendritic cells isolated from patient's lungs and their peripheral blood cells. The safety handling procedures appeared more than adequate and all documentation concerning training and medical surveillance was submitted with the initial application. This protocol application did not fall under rDNA guidelines and therefore it did not require a review by the full committee membership. To expedite the work, the Biosafety Officer and the IBC chair reviewed the application jointly, and Co-Chair Rick Lyons approved it prior to the meeting.
- Barbara Masten asked if she should stay during the discussion because of a possible conflict of interest. Because the committee would not be voting on the application, it was decided that this was not necessary in this particular case. Discussion was then opened, and after consideration the committee had no objections to letting this protocol proceed with out further modification.

Standing Reports:

a.) Report of the Biosafety Officer

Rick Lyons Lab, anthrax

Investigation of [REDACTED] exposure in [REDACTED] lab, PI: [REDACTED] L [REDACTED]

- The BSO reported on an accident involving an exposure to [REDACTED] spores in the [REDACTED] lab [REDACTED] which is under the direction of Dr. L [REDACTED]. The incident involved a complicated procedure to inoculate [REDACTED] spores into the trachea of mice. The affected individual's left thumb was stuck with a needle containing viable spore inoculum. The incident was reported to EOHS and the exposed employee received appropriate prophylactic treatment. The exposed person did not develop any signs of infection. At a later date, the BSO performed a follow-up investigation and provided several recommendations in a formal report, to Dr. L [REDACTED]. In the report, the BSO requested Dr. L [REDACTED] review the current procedures and consider alternate methods for intra-tracheal spore delivery to mice that would allow for a greater margin of human error. Members were asked to call Dr. L [REDACTED] with any suggestions they may have concerning safer methods for spore delivery. Currently Dr. L [REDACTED], who was unable to attend this meeting, is reviewing alternate procedures to see if they will enable the same level of precision while offering a greater safety margin. Also discussed was the applicability of the recent sharps precautions amendments of the OSHA Bloodborne Pathogen Standard as this accident did not involve the types of materials controlled by that standard but did involve sharps. As a result, Legal Counsel offered to look into the current Bloodborne Pathogen Standard regarding needle-less systems and its applicability to this situation and report his findings to the IBC at the next meeting. The Occupational Health Services representative offered that the [REDACTED] vaccine shipment was now on-site and she would be arranging for those individuals involved in [REDACTED] projects to receive it.

IBC Administrative Procedures & Public Meeting Requirements

- The BSO informed the IBC of changes made to the IBC Administrative Process document to reflect UNM Legal Department's interpretations. Legal Counsel has clarified the public meeting requirements as follows: Minutes and other information related to IBC meetings are not subject to the NM State Open Meetings Act. However, in light of the NIH Guidelines, the Public may attend IBC meetings when requested and/or request to have access to official IBC documents when it is not in conflict with UNM's Privacy and Proprietary interests. To do so, any member of the Public may contact the IBC Office and make a request to attend a meeting or see a document, two weeks prior to any regularly scheduled meeting. The IBC chairs, in consultation with UNM legal counsel, may close all or part of any meeting in order to protect UNM's privacy or proprietary interests, to protect security, or for other compelling reasons.
- Members had questions related to their personal privacy and identification as an IBC member to the public in the IBC minutes. The Biosafety Officer clarified that when the Committee is in deliberation, they are acting as a committee and not as individuals, and therefore their names would not be used in relationship to any specific opinions or actions taken. However, Principal Investigators submitting applications and Primary Reviewers of these protocols will be named in the official minutes as accepting that responsibility.
- Legal Counsel introduced Elizabeth Minet, UNM Assistant University Counsel as an alternate should he be unable to attend a meeting.

UNM/HSC Policy/Draft

- Legal Counsel reported that the Draft is still in progress, and he hopes to have a draft ready by the January 14th IBC meeting.

IBC Application Revision/Draft

- The BSO reported some additional changes had been made to the revised draft of the IBC Application. She requested that IBC members beta test this form if at all possible and send their comments and concerns within two weeks to Biosafety Office so they could be incorporated into the final document by the next meeting.

IBC Administrative Updates

- The BSO informed the IBC members that Michelle Durham has accepted the permanent position as the IBC Coordinator. She will be available 75% of the time from 10AM to 4PM, Monday through Friday. Official correspondence and documentation should flow through the IBC@saludl.unm.edu e-mail address which both the BSO and the IBC Coordinator have access to.

b.) Report of Safety (SHEA) committee member

- The SHEA representative informed the Committee that their Industrial Hygienist, who was an IBC member, has left the University for another position. This IH person was also proficient in Biosafety and a great help to the IBC. It looks unlikely that another individual with those dual capabilities will be available as a replacement. So SHEA will concentrate mostly on hiring someone qualified to carry out the IH functions for SHEA, as a first priority.
- The Committee discussed the roles, jurisdiction, and funding of two positions, the IH in SHEA and a new position posted as Biosafety Specialist in HSC Research Protections/Biosafety. The SHEA IH will be primarily oriented to Chemical safety and monitoring. It is hoped that when the Biosafety Office's Biosafety Specialist

position is filled, this person can take up some of the biosafety functions formerly carried out by the SHEA IH. Until the SHEA position is filled, Larry Watson will serve as IBC support from SHEA and as the SHEA voting member to the IBC.

c.) Report of Occupational Health Services Committee Member

█████ CDC recommendations & BSL3 training for █████ in the █████ lab

- The EOHS representative stated the █████, agent-specific, hazard awareness training session for █████ H█████'s █████ protocol approved contingent at the last meeting, was held in August. She asked the Biosafety Officer to describe how the training session went. The Biosafety Officer reported that she and the University Hospital Infection Control Officer presented about 50 minutes of information related to the nature of the virus, the containment parameters needed, and the isolation and quarantine procedures for █████ exposures. The session was followed by open discussion and questions from the group. The training was mandatory for everybody that routinely enters the lab where the █████ work will be conducted. One hundred percent of these individuals attended the training session and documentation of their attendance has been sent to SHEA for entry into the Online Training database.
- The EOHS representative said that a █████ information sheet has been prepared for the University Hospital emergency room staff in the event of a █████ exposure to a lab worker. This information sheet should ensure that the exposed lab worker is treated appropriately in the most efficient manner and that the appropriate federal agencies are informed if there is an exposure involving █████. Because █████ symptoms are difficult to distinguish from █████ symptoms, early clinical diagnosis between the two infections is expected to be problematic. Therefore, █████ vaccines will be offered to the █████ lab workers free of charge, to diminish the possibility of misdiagnosis after a █████ incident. In addition, presumed █████ exposed workers will need to be quarantined at home [if not in University Hospital isolation], check their temperature twice a day, and keep in contact with Employee Occupational Health Services for follow-up medical surveillance until the matter is resolved.
- The Committee discussed the recent report of a case of laboratory acquired █████ in a Singapore BSL3 laboratory. Further guidance from CDC and the WHO is anticipated as more information about █████ transmission becomes available.
- Dr. H█████ reported that he has not yet received the █████ virus from Canada and has not started working with it yet. As soon as he receives it, he will inform the Biosafety Office before he opens the vial.

d.) Select Agent Responsible Official Report (RO)

CDC Inspection Update

- The RO said, the CDC representative Barbara Ellis, stated to him that our system for Select Agent university laboratory oversight is being used as a national model of how universities should be conducting work with Select Agents. She requested that he make a November presentation in Washington at a meeting sponsored by CDC, regarding problems encountered implementing the Select Agent legislation from a University perspective. The RO requested committee members to please inform him of any specific points they would like included in that presentation.

FBI Background Checks for SA Lab Users

- The RO reported that the FBI background clearance checks for Select Agent users are about 75% complete. Currently we are making phone calls about the remaining 25% that we haven't received paperwork on yet. We have a letter from the CDC stating that if an individual has not been cleared by November 13, 2003 (the interim rule compliance date) we lock that individual out of the lab. So we're trying to get some clarification on that point. There has been discussion nation-wide about extending the compliance date because federal agencies have not been able to process all the clearance forms submitted by universities in timely manner.

Biosafety and Biosecurity Compliance monitoring update

- The RO explained that a new campus wide Animal Care and Use Committee office has been created. Applicants for director of that office will be reviewed by [REDACTED] and himself. The director will be a .25 FTE position initially. Overall there have been more and more compliance requirements, inspections, and fewer and fewer people to get this job done. It is getting to be too much work to be done on a volunteer basis. The new Biosafety Specialist position in Research Protections/HSC is being created because of increased federal regulatory compliance requirements regarding microbial research projects. This position is funded 50/50 by the Office of the UNM Vice Provost and the HSC. It will support both sides of the campus as the current IBC does. We hope to eventually get a single university-wide office of compliance – a sort of one stop shopping for PIs. A campus wide office for all compliance issues would help to ensure that the main campus is not doing it one way and the HSC is doing it another and it will enable better communication amongst the compliance oversight committees. The federal compliance regulations hold the Institution responsible – not the Health Sciences Center – so the office must cover the whole gamut of compliance and not leave some chunk out. We are still going to keep two separate committees (IBC and IACUC), but they will be working through this office, who will keep all the records and provide the committees support. This approach should make it easier for investigators to comply. The IBC members discussed the various compliance committees' responsibilities, possible duplication of committee efforts (such as having two Conflict of Interest Committees), and how these committees integrate into the various University departments such as SHEA, EOHS, Research Protections, Grants and Contracts, etc.
- The Main campus' security officer developed the Biosecurity Plan for the Select Agent labs. The document has been approved by the CDC and the DOJ. But it was thought that an on-site Biosecurity Officer was needed for the HSC North campus, so Vito Capobianco will be appointed to fill that position. Vito will remain the primary University Hospital security officer. With this new responsibility he will also be appointed an Alternate Responsible Official of the Laboratory Registration/Select Agent Transfer Program (LR/SAT) and will be required to obtain security clearance from the DOJ.

e.) Ad hoc committee report, if applicable

NONE

f.) Other

NONE

8. Old Business

NONE

9.) New Business

Job Description of New Biosafety Specialist

- The Biosafety Officer distributed information about the new Biosafety Specialist position. The position has been advertised at UNM, in professional publications, and in the local newspaper.

IBC Training – 15 Minutes (approximately)

- The Biosafety Officer completed the IBC orientation and training presentation entitled The Role of University of New Mexico's Institutional Biosafety Committee (IBC).

10.) The meeting was adjourned at 11:00 A.M.

UNM BIOSAFETY COMMITTEE MEETING MINUTES

January 14, 2004

9:00 AM - 11:00 PM

BMSB, Room B-85

Present:

Judy Pointer, Research Protection/Biosafety
Gary Cseko, Research Protections
Larry Watson, Safety Health & Environmental Affairs
Karen B. Mulloy, Department of Internal Medicine
Susan Kellie, Epidemiology
Robert Bienstock, University Counsel
Barbara Masten, Department of Pathology
Brian Hjelle, Department of Pathology
Denece Kesler, Department of Occupational Health
Ann Powell, Office of Research Services
Daniel Theele, Animal Research Facility
John Nihart, New Mexico State Health Laboratory
Laurie Hudson, College of Pharmacy
Julie Lovchik, Department of Internal Medicine
Leroy Garcia, Safety Health & Environmental Affairs

Absent:

Rick Lyons, Department of Internal Medicine
David Faguy, Department of Biology
David Peterson, Keleher & McLeod Attorneys at Law
Larry Barton, Department of Biology
Jac Nickoloff, Molecular Genetics and Microbiology
Terry Yates, Office of Research Protections

1. **Call to Order** - The meeting was called to order at 9:00 A.M. by the BSO, Judy Pointer, as both chairs were absent due to out-of-town commitments.

The BSO announced the death of IBC Community Member Hector Sanchez, John Nihart has graciously consented to substitute for him until a replacement is hired at the State Health Lab. Timothy Muller, a new Biosafety Specialist who is now part of the Biosafety Staff was introduced. The BSO requested that the members speak up for the purpose of completing accurate minutes. Larry Watson introduced the addition of Leroy Garcia, Industrial Hygienist to the SHEA Staff.

4. **Approval of Minutes** - The minutes of the October 8, 2003 meeting were approved as written.

5. Protocols Pending –

a.) APPROVED: all contingencies met:

1.) **IBC #:** B [REDACTED] 03-10-01

PI: [REDACTED] B [REDACTED]

Title: Expression of [REDACTED] in [REDACTED] Vector-infected Mouse Myoblasts

Agent: [REDACTED] Vector; insert [REDACTED]; Human Cell Lines; [REDACTED]

Primary Reviewer: Brian Hjelle
Approved at BSL-2 practices all contingencies met

4. Protocols New

IBC #: A [REDACTED] 04-01-01

PI: [REDACTED] A [REDACTED]

Title: Anti-pathogen responses in *Biomphalaria glabrata*

Agent: [REDACTED], [REDACTED], [REDACTED] and [REDACTED]

Primary Reviewer: Daniel Theele

Approved as written at BSL-2 practices, after discussion.

IBC #: L [REDACTED] 04-01-01

PI: [REDACTED] L [REDACTED]

Title: Phase III, Open-label, Randomized, Study to Compare the Effectiveness and Safety of Intratumoral Administration in [REDACTED] 201 in combination with Chemotherapy vs. Chemotherapy Alone in Patients with Recurrent Unresectable Squamous Cell Carcinoma of the Head and Neck

Agent: [REDACTED]; human gene transfer

Primary Reviewer: Judy Pointer

Approved at BSL-2 practices with the following three contingencies, after discussion.

- 1.) The University Biosafety Officer, will investigate the airflow parameters of the vector administration treatment room [REDACTED] [REDACTED] by arranging for a qualified HVAC engineer to ensure that the room is negative pressure and no air re-circulates to other rooms in the facility. If the room does not meet these parameters, the viral vector administration process must take place inside of an isolation tent placed inside of the room.
- 2.) A patient hazardous communication hand-out must be devised to warn the patient to avoid young children and immunosuppressed individuals during the three day period after each vector administration. A box of surgical masks must be given to the patient upon first treatment and the patient be advised to wear these masks when returning to the hospital during the three day period for further treatment.
- 3.) Procedural documents related to safe handling of patients and viral vector preparations must be devised to include the following items. These documents must be reviewed and approved by the University Biosafety Officer.
 - Spill clean-up procedures and materials
 - Administration room/area procedures and post treatment room/area clean-up. (these should include the isolation-tent use and mask wearing)
 - Training and medical surveillance requirements (monitor BBP, [REDACTED], respirator use, agent specific hazardous awareness training - HAZCOM - use an FAQ)
 - Health Care Worker response to accidental inoculations (where to go, what to take with them - info sheets)
 - Transport of materials from [REDACTED] prep area to administration area
 - Inpatient procedures, if the patient must be hospitalized due to complications

- Handling of patient samples and specimens post vector administration. (If you are handling these then it's BSL2 for lab work.)

IBC #: Z [REDACTED] 04-01-01

PI: [REDACTED] Z [REDACTED]

Title: Identification factors that regulate neural stem cell proliferation and differentiation in vitro

Agent: [REDACTED]; [REDACTED]

Primary Reviewer: Jac Nickoloff (Absent, summary provided by the BSO)

Approved at BSL-2 practices with the following two contingencies, after discussion.

- 1.) The University Biosafety Officer inspects the lab.
- 2.) All necessary training is complete.

5. Continual Review – None

6. Notifications - None

7. Standing Reports:

a.) Report of the Biosafety Officer

- **Lab Accident Investigations:**

Investigation of [REDACTED] exposure in [REDACTED] lab, PI: [REDACTED] L [REDACTED].

The BSO read the accident report to the IBC, discussion followed.

Investigation of [REDACTED] [REDACTED] splash to eyes in [REDACTED] lab, PI: [REDACTED] L [REDACTED].

The BSO read the accident report to the IBC, discussion followed

Investigation of [REDACTED] accident needle stick in [REDACTED]-lab PI: [REDACTED] B [REDACTED]

The BSO read the accident report to the IBC, discussion followed

Preliminary investigation of possible exposure to [REDACTED] in Autopsy personnel at Office of the Medical Investigator (OMI).

The investigation has not been completed at this time and will be discussed at the next full committee meeting.

- **IBC Administrative Procedures & Public Meeting Requirements**

Needle stick applicability to be reported on by legal counsel at next full committee meeting.

- **UNM/HSC Policy/Draft**

Discussed by legal counsel. A draft document was given to the IBC members and Legal Counsel asked members to review it. It will be discussed at the next full-committee meeting.

- **IBC Application Revision/Draft**

IBC application revisions were approved by the committee.

b.) Report of Safety (SHEA) committee member -NONE

c.) Report of Occupational Health Services Committee Member - NONE

d.) Select Agent Responsible Official Report (RO) – Absent – Report given by BSO.

- Biosafety and Biosecurity Compliance monitoring updates for Select Agent Labs
Select Agent Area Emergency Response Plan (AEP)
- SAIC inspection completed. No written report received yet, but they did want some changes to some security parameters in Select Agent Labs. DoD contractors liked our Select Agent Area Emergency Plan (AEP) and encouraged us to finalize it. The plan was approved by the IBC and it will be voted upon at the next Emergency Management Committee meeting.

e.) Ad hoc committee report, if applicable

NONE

f.) Other

NONE

8. Old Business

NONE

9.) New Business

Director of Research Protections queried the committee members as to their preferences for schedules of regularly scheduled IBC meetings. Members preferred that meetings be scheduled a year in advance. The IBC coordinator will determine next FY meeting dates and inform members as soon as possible.

10.) The meeting was adjourned at 11:24 A.M.

UNM BIOSAFETY COMMITTEE MEETING MINUTES

April 14, 2004

9:00 AM - 11:00 PM

BMSB, Room B-85

Voting Members Present:

Judy Pointer, Biosafety Officer
Karen B. Mulloy, D.O., Dept. of Internal Medicine
Susan Kellie, M.D., HSC Epidemiology
Brian Hjelle, M.D., Dept. of Pathology
Denece Kesler, M.D., Dept. of Occupational Health
Ann Powell, Office of Research Services
Daniel Theele, Director Animal Research Facility
Laurie Hudson, HSC College of Pharmacy
Leroy Garcia, Industrial Hygienist, SHEA
Jac Nickoloff, HSC Molecular Genetics and Microbiology
Rick Lyons, M.D., Dept. of Medicine

Voting Members Absent:

David Faguy, Ph.D., Dept. of Biology
David Peterson, Esq., Keleher & McLeod
Terry Yates, VPR, Office of Research
Barbara Masten, Ph.D., Dept. of Pathology
John Nihart, New Mexico State Health Laboratory

Non-voting members Present:

Gary Cseko, M.S.P.H., Director of Research Protections
Robert Bienstock, Senior Associate University Counsel
Larry Watson, Environmental Affairs/Industrial Hygiene, SHEA

Visitors & Alternates present:

Timothy Muller, Biosafety Specialist
Elizabeth Minet, Assistant University Counsel

1. **CALL TO ORDER:** The meeting was called to order at 9:00 A.M. by the Co-chair, Rick Lyons. The following announcements were made:
 - a. Mary Donato, Director of Safety Health and Environmental Affairs (SHEA) is retiring.
 - b. The Co-chair thanked the ad-hoc committee for their rapid response regarding the protocol L [REDACTED] 04-01-01.
2. **MINUTES:** The January 14 meeting minutes were approved as written.
3. **PROTOCOL REVIEW**

a. Tentative Approval Post Expedited Review: none

b. Pending Approval

i. IBC #: A [REDACTED] 04-01-01

PI: [REDACTED] A [REDACTED]

Title: Anti-pathogen responses in *Biomphalaria glabrata*

Agent: [REDACTED], [REDACTED], [REDACTED] and [REDACTED]

BSL: 2

Primary Reviewer: Daniel Theele

Approved: all contingencies met

ii. IBC #: Z [REDACTED] 04-01-01

PI: [REDACTED] Z [REDACTED]

Title: Identification factors that regulate neural stem cell proliferation and differentiation in vitro

Agent: [REDACTED]; [REDACTED]

BSL: 2

Primary Reviewer: Jac Nickoloff

Approved: all contingencies met

iii. IBC #: L [REDACTED] 04-01-01

PI: [REDACTED] L [REDACTED]

Title: Phase III, Open-label, Randomized, Study to Compare the Effectiveness and Safety of Intratumoral Administration in [REDACTED] [REDACTED] in Combination with Chemotherapy vs Chemotherapy Alone in Patients With Recurrent Unresectable Squamous Cell Carcinoma of the Head and Neck.

BSL: 2

Agent: [REDACTED]; human gene transfer

Primary Reviewer: Judy Pointer

Approved: all contingencies met

c. New Protocols for Review

i. IBC #: V [REDACTED] 04-14-01

PI: [REDACTED] V [REDACTED]

Title: Feasibility, Phase I and Pharmacological Study of Aerosolized [REDACTED] ([REDACTED]) Gene-Polyethylenimine (PEI) in patients with Advanced Pulmonary Malignancies.

Agent: [REDACTED] ([REDACTED]) Gene-Polyethylenimine (PEI)

BSL proposed: BL3

Primary Reviewer: Jac Nickoloff

Tabled: for more information*

The protocol was summarized by the Primary Reviewer. After discussion it was determined that the protocol will need more information before approval. The protocol will be tabled until the following issues are addressed and satisfactorily met.

- 1 We would like Clarification on the toxicity level of [REDACTED], clarification upon the role of the fragment clarification of [REDACTED], whether or not it is included, and a gene map

- 2 Clarification of how delivery will be delivered at home and SOP to protect other family members, how to set up machine to protect from overexposure and who will be mixing up the medications.
- 3 How do you intend to decon the tent, and how will you use it.
- 4 If the tent is to be disposed, dispose of in the appropriate biohazardous waste container
- 5 Please Correct: Section 2a facility, set up as a biosafety level 2, not biosafety level 3
- 6 Recommend that eye protection should be used, by anyone handling the liquid compound, including pharmacy staff
- 7 Page 3 under objectives and handling, clarify that they are mixing under flow laminar hood or class 2 biological safety cabinets
- 8 Ensure that all staff has completed the pertinent training, BBP, waste modules, etc...
- 9 When UNM HRRC is obtained approval, RAC, FDA, and any comments from RAC, they are forwarded to the IBC

*A letter will be sent to the PI asking for the above information requesting for a status report

4. NOTIFICATIONS

i. IBC #: F [REDACTED] 04-01-01

PI: [REDACTED] F [REDACTED]

Title: Chromosome Segregation in Archaea

BSL: 1

Agent: [REDACTED], [REDACTED], methanogens (exempt rDNA)

Primary Reviewer: Judy Pointer

Notification: of rDNA work exempt from IBC approval

The primary reviewer provided a summary of the protocol to the committee, as follows:

These microbes are Methanogens and can only survive in a methane gas atmosphere, utilizing this carbon source exclusively for metabolism. It is the kind of organism that typically can only be found in hot springs. They are considered extremophiles, and have not been found to be pathogens of animals or plants.

Therefore they are unlikely to cause any harm to the staff, public, or environment. Considering this fact the proposed Biosafety level 1 is appropriate and this research work is classified as exempt from the NIH rDNA Guide.

5. STANDING REPORTS

a. Report of Biosafety Officer

- i. The Biosafety Officer asked Legal Counsel to address the UNM/Bylaws/Draft – [Proposed Institutional Biosafety Committee Policy] (document 1219, attached) which was distributed by him to the committee for comments, review, and discussion at the July meeting. He noted the faculty has the authority to legally adopt it, but the committee needs first to review it and then acquire administration consent. This process involves taking the policy before the Faculty Senate for approval and then on to the UNM Board of Regents. The process can take as long as three years to obtain final approval. Items he wished the committee to consider are:

- 1 Does the committee wish biosecurity for UNM's Select Agent labs to be reviewed by the IBC? Handling of Select Agents is legally handled per regulation, through the BSO as the Alternate Responsible Official under the direction of UNM's Responsible Official, Dr. Terry Yates. Does the

committee wish to review the protocols conducted in these labs through the IBC routine protocol review process? If so, these items would be included in Section IIA of this policy.

- 2 Should research conducted at UNM that is also reviewed by the HRRC and the IACUC, be reviewed by the IBC? If we are going to do any kind of review, should we do an all encompassing review of contractual work when we are the contractors? We are responsible for our subcontractors. We should be able to verify that there is a compliance mechanism in place. When it involves pure contract compliance we would like to leave some ambiguity to allow for flexibility. The IBC does not duplicate what the sub award contractor is doing.
- 3 We don't want to rubber-stamp things, but in the case of a UNM employee serving as an adjunct faculty member at another place, consider whether we need to review their work conducted outside of the university. The paradigms in general, for at least IACUC, are that it has been approved by an outside institute so it does not need to be reviewed again by our IACUC. Should we require that these individuals give to our IBC, a review conducted by an outside IBC when the work is conducted somewhere else? It happens so rarely, do we really want to track it? From the IRB standpoint, when any person of our University is conducting research at another place, there is a requirement that the research be approved by their appropriate screening entity that has some compliance requirements. A copy of their biosafety approval is forwarded to our IRB.
- 4 Section II, C, 2, Legal counsel reviewed this section and indicated to the IBC that it is our responsibility to regulate research classified as risk group 2 or higher.
- 5 Section II, C, 4, Provide fair notice to our PI's outlining what the regulations are.
- 6 Section II, D, 4, Legal counsel reviewed this section and indicated to the IBC that it is our duty to provide fair notice to our PI's outlining what the regulations are.
- 7 Page 5Ca, Legal counsel reviewed this section and indicated to the IBC that it is our job to provide clarification of IBC member's objectivity.

Additional discussion will continue at the next meeting.

i. Accident/Exposure Follow-Up Investigations – Autopsy

The Biosafety Officer provided a summary of possible exposure to [REDACTED] in Autopsy personnel at Office of the Medical Investigator (OMI). The incident was reported before the prior IBC meeting but a complete investigation had not been completed at that time. Since then follow up inspections of autopsy procedures have been reviewed and the BSO and BS specialist have observed actual autopsies and took notes. Medical surveillance conducted by Employee Occupational Health has determined that none of the potentially exposed 10 employees have converted to testing positive for [REDACTED]. Of note, the biological safety cabinet used in their highest level area was outdated. The cabinet was originally purchase in 1967, and did not meet NSF requirements for certification, as these requirements were not established at that time. The Biosafety Specialist provided OMI with quotes on new biological safety cabinets, negative pressure room monitors, UV light insect control devises, and publications on evacuated bones saws. The BSO and biosafety specialist evaluated OMI suite airflow and safety practices and found them both insufficient to adequately contain the potential hazards associated with conducting autopsies on bodies suspected of containing pathogenic microorganisms. A meeting was held with the OMI director and staff to relay their findings. Currently OMI is in the process of administrative approvals for the purchase of new equipment.

ii. Accident/Exposure Follow-Up Investigations – Dr. H [REDACTED] lab - [REDACTED] - [REDACTED] p [REDACTED] Vector]

A needle stick of this agent, in Dr. H [REDACTED] lab, was reported just prior to the IBC meeting. This rDNA work was not recorded in prior IBC documents and the Biosafety Officer has asked Dr. H [REDACTED] to provide

the IBC with an application for its use so that the committee can determine if the agent was hazardous and practices for its use were appropriate. The BSO requested the members help in analyzing this agent when the agent application is submitted and to advise her how to proceed.

- iii. Legal Counsel – Bylaws, the policy draft related to this topic was discussed as in item 5ai of this document.
 - iv. Protocols for handling requests for reconsideration of IBC decisions (e.g. L █ protocol) were discussed. Legal Counsel advised the BSO that he would work with her to include words in next fiscal year's IBC Administrative Processes document to address this concern.
 - v. Legal issues concerning the parameters of implementation of the OSHA Bloodborne Pathogen needlestick amendment were discussed. Legal Counsel and the Director of Employee Occupational Health Services will address this concern outside of the IBC as these issues are not solely restricted to research concerns at UNM.
- b. Report of Safety (SHEA) committee member – as in Announcements
 - c. Report of Employee Occupational Health Services committee member – none
 - d. Select Agent Responsible Official Terry Yates – none
 - e. Ad hoc committee report, if applicable - none
 - f. Other- none

6. Old Business

7. New Business

8. Adjourn - Meeting adjourned at 11:02AM

UNM IBC MINUTES

July 21st 2004

9:00 AM – 11:00 PM

BRF Room 318

Voting Members Present:

Judy Espinoza, (New Mexico State Health Laboratory (Community Member) alternate substituting for Hector Sanchez
Lynn Fondren, Director EH&S, LRRI (Community Member)
Brian Hjelle, M.D., Dept. of Pathology
Susan Kellie, M.D., HSC Epidemiology
Denece Kesler, M.D., Dept. of Occupational Health, Ex officio
Rick Lyons, M.D., Dept. of Medicine, Co-Chair
Jac Nickoloff, HSC Molecular Genetics and Microbiology
Judy Pointer, Biosafety Officer, Ex officio
Ann Powell, Office of Research Services
Daniel Theele, Director Animal Research Facility, Ex officio
Mary Walker, alternate substituting for Laurie Hudson, HSC College of Pharmacy
Larry Watson, Environmental Affairs/Industrial Hygiene, SHEA, Ex officio
Terry Yates, VPR, Office of Research (Responsible Official Select Agent Program) Ex officio, Co-Chair

Voting Members Absent:

Barbara Masten, Ph.D., Dept. of Pathology
Karen B. Mulloy, D.O., Dept. of Internal Medicine
David Peterson, Esq., Keleher & McLeod (Community Member)

Non-voting Members Present:

Robert Bienstock, Senior Associate University Counsel Ex officio
Gary Cseko, M.S.P.H., Director of Research Protections Ex officio

Visitors & Alternates present (Non-Voting Members):

Coenraad Adema, Biology Department
Leroy Garcia, Industrial Hygienist, SHEA
Elizabeth Minet, Assistant University Counsel
Timothy Muller, Biosafety Specialist
James De Zetter, RSO, & Interim Director of SHEA

Quorum = 8 voting members, present =13

6. **CALL TO ORDER:** The meeting was called to order at 9:10AM by Co-Chair, Dr. Rick Lyons. Introductions were made and those voting as alternates for absent voting members were recognized. The following announcements were made:
- a. Lynn Fondren, Director of Environmental Health and Safety at Lovelace Respiratory Research Institute was introduced. She has volunteered to be one of our voting community members.
 - b. Dr. Coenraad Adema was introduced and may serve as a new voting member representing the UNM Biology Department
 - c. The Biosafety Officer will provide IBC training for the new members or any others wanting to attend, after the meeting.

7. **Approval of last meeting minutes:** Minutes of the April 2004 were approved with corrections.

8. **Protocols Pending**

- a. Tentative Approval Post Expedited Review:

- i. BSC #: L [REDACTED] 04-07-01

PI: [REDACTED] L [REDACTED]

Title: Dendritic Cell Regulation of pulmonary Immunity

Agent: [REDACTED]

BSL: 2

Primary Reviewer: Judy Pointer

Status: Tentative approval granted 6/17/04 per Yates. Review comments delivered to L [REDACTED] 6/28/04

Dr. L [REDACTED] requested expedited review as this work was part of a graduate student's summer project. The Biosafety Office disseminated the application in June to the committee members. Six member comments were received. The Biosafety Office delivered risk-based & hazard awareness training to the individuals that will be handling [REDACTED]. Dr. Yates reviewed the comments and the protocol and granted tentative approval, on June 28th. The Biosafety Officer sent a tentative approval letter to Dr. L [REDACTED] containing the member comments. The protocol was discussed in full at the meeting. Items related to the worker's experience and the hazard associated with [REDACTED] were discussed.

Approved at BSL 2

- b. Approved with Contingencies: none

- c. Tabled or Withdrawn:

- i. IBC #: V [REDACTED] 04-14-01

PI: [REDACTED] V [REDACTED]

Title: Feasibility, Phase I and Pharmacological Study of Aerosolized [REDACTED] ([REDACTED]) Gene-Polyethylenimine (PEI) in patients with Advanced Pulmonary Malignancies.

Agent: [REDACTED] ([REDACTED]) Gene-Polyethylenimine (PEI)

BSL proposed: BL2

Primary Reviewer: Jac Nickoloff

Status: Tabled at the April 2004 meeting. A memorandum with the committee's concerns was sent to Dr. V [REDACTED]. Since then, her representative acknowledged its receipt and said that Dr. V [REDACTED] is working with the FDA and the protocol's sponsor to supply the additional information requested. This protocol will remain on the agenda until the committee's concerns are addressed and all regulatory approvals are obtained.

Remain Tabled

9. New Protocols for Review

- i. IBC #: H [REDACTED] 04-07-01 [Michael Holbrook. Works with flaviviruses and arboviruses.]
 PI: [REDACTED] H [REDACTED]
 Title: Molecular mechanisms of pathogenesis of [REDACTED] (BSL-3)
 Agent: [REDACTED] virus (multiple strains)*; [REDACTED] virus ([REDACTED]); [REDACTED]
 [REDACTED], subtype, [REDACTED] ([REDACTED]), derivative of [REDACTED] virus ([REDACTED] and [REDACTED],
 strains and [REDACTED])*; [REDACTED] Virus (multiple strains); [REDACTED] Virus (multiple strains).
 * indicates a Select Agent
 BSL proposed: BL3
 Primary Reviewer: Brian Hjelle

The Primary Reviewer presented a synopsis of the protocol. Dr. H [REDACTED] is a new principal investigator, from the Tropical Infectious Disease Center at UTMB-Galveston, who will start working in the [REDACTED] Department in August. Issues related to hazards of working with all these agents were discussed. Concerns about working with [REDACTED] Borne virus (which is listed in the CDC BMBL as a BSL 4 arbovirus) in the BSL3 lab, were discussed. It was noted that the BMBL states that the agent can be handled at BSL3 if the workers are vaccinated. [This agent appears to be Central European Tick-borne (encephalitis) virus.]

- Discussion involved the restriction of viable [REDACTED] to the [REDACTED] procedure room in the [REDACTED] lab, thereby diminishing the number of people needing vaccine.
- Issues related to the capacity of the [REDACTED] suite to safely house all of the protocols that have been approved for this core facility were addressed. The possibility of repairing and activating an older [REDACTED] lab and moving some of the [REDACTED] work to that area was discussed. The BSO and the chair will address these issues by requesting the [REDACTED] core facility space issues be considered by the Space Committee and the SOM Dean's Office.
- Decontamination methods proposed were discussed in relation to the standard decon methods published on the SHEA web site. SHEA members consented to review their published methods and consult with the IBC Chair, the EOHS representative, and the Biosafety Officer about revisions needed to ensure standardized decon procedures are appropriate.
- The Chair postponed discussion of the related vaccination issues because a sub committee, headed by Dr. Denece Kesler from Employee Occupational Health Services is working on these issues.
- Biosecurity issues related to the Select Agents and viral RNA from these agents, were also discussed. The Biosafety Officer noted that amendments to UNM's Select Agent registration were already in process. Dr. H [REDACTED] already has security risk assessment (SRA) approval from CDC for handling these Select Agents while at UTMB-Galveston.
- There was a discussion related to required USDA permits for some of these agents.
- Discussion related to future animal work with [REDACTED] in the [REDACTED] lab was postponed because at present animal inoculations will not be involved. However, [REDACTED] stocks will be stored in the animal

facility freezers, until that work begins. Before animal work begins another application will be submitted for the committee's consideration.

Approval at BSL3 with the following contingencies

1. CDC and USDA approval of UNM's amendment to our SA registration # [REDACTED] to include [REDACTED] and [REDACTED] with Dr. H [REDACTED] as principal investigator is received by UNM's Responsible Official.
2. The Responsible Official is notified that H [REDACTED] has received approval from CDC to access Select Agents.
3. H [REDACTED] completes all safety and security training and medical surveillance requirements for entry into both SA labs and forwards documentation of such to the Biosafety Office
4. Equipment needed to contain all operations with infectious, viable, agents inside of [REDACTED] [REDACTED] (microscopes, centrifuges, secure freezers, incubators, etc.) are purchased and operational before work begins. Additional equipment will be needed for security. A final inspection to ensure equipment is operational will be conducted by the Biosafety Officer.
5. Vaccinations and medical surveillance (as determined by the Director of EOHS) of all personnel at risk, including Dr. H [REDACTED], in the area(s) of operation are completed and documentation is submitted to the Biosafety Office.
6. USDA permits for transport (shipping documents) of [REDACTED] and [REDACTED] [REDACTED] [REDACTED]s are acquired before these agents are shipped to UNM. Copies of permits are forwarded to the Biosafety Office.
7. Delete the reference to the use of animals from the abstract of this submission.
8. Modify the Safety Plans submitted for these agents to better reflect operational parameters of UNM's [REDACTED] lab. Delete references to no use of the [REDACTED] [REDACTED] room for 24 hours after [REDACTED] handling and work with the Biosafety Officer on the Safety Plans' development.

ii. **IBC #: H [REDACTED] 04-07-02**

PI: [REDACTED] H [REDACTED]

Title: Molecular mechanisms of pathogenesis of [REDACTED] (BSL-2)

Agent: rDNA (plasmids [REDACTED], [REDACTED], [REDACTED] with [REDACTED] protein [REDACTED] inserts); [REDACTED] virus ([REDACTED] strains); [REDACTED] virus ([REDACTED]); [REDACTED] vaccine strains ([REDACTED], [REDACTED])

BSL proposed: BL2

Primary Reviewer: Brian Hjelle

The Primary Reviewer presented a synopsis of the protocol. This protocol includes recombinant DNA studies associated with some of the agents used in the [REDACTED] lab, plus recombinant DNA work with less hazardous [REDACTED], rated as BSL 2 microbes. Discussion involved issues with handling these agents, the viral RNA of these microbes, and the lack of security in the BSL 2 lab. It was decided that the viral RNA from these [REDACTED] could not produce an infection resulting in disease, if workers were accidentally exposed. However, fully infectious viral particles could be regenerated from the viral RNA if some very

arduous procedures were followed. It was decided that it was not realistic to consider work with the viral RNA to involve biosecurity concerns; therefore work with these agents in a non-secure BSL 2 lab was appropriate. After discussion the following contingencies for approval, were agreed upon.

Approved at BSL2 with the following contingencies.

1. [REDACTED] virus propagation and handling of large volumes or high concentrations are denied at BSL 2 and these activities should be conducted in the BSL 3 lab, instead. Please amend protocols appropriately to reflect this change and submit to the Biosafety Office.
2. Eye protection is needed to substitute for the lack of PAPR face protection and should be worn while working with these agents in the BSL 2 lab.
3. Work cannot begin until all handlers are cleared by EOHS (medical surveillance) and handlers have completed the standard Biosafety, Infectious Waste, and Bloodborne Pathogen training modules.
4. The currently vacant BSL 2 laboratory is equipped and fully operational and able to contain associated activities inside this lab. A final inspection to ensure equipment is operational will be conducted by the Biosafety Officer.

Approved at BSL 2 with the above contingencies.

iii. IBC #: H [REDACTED] 04-07-01

PI: [REDACTED] H [REDACTED]

Title: Molecular Transcriptional Regulation of Development (BSL-3)

Agent: rDNA ([REDACTED] plasmids [REDACTED], [REDACTED], [REDACTED]); [REDACTED], [REDACTED], [REDACTED] virus based vectors ([REDACTED], [REDACTED], [REDACTED]) with DNA inserts [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED] (transcriptional, regulation, DNA repair, Cytokine, Chemokine functions)

BSL proposed: BL2

Primary Reviewer: Susan Kellie

Hematopoietic cell lines or murine bone marrow cells will be used to study the genes of interest for this study. These cells will be transfected with [REDACTED] [REDACTED] vectors to over-express the genes and only clones of the transfected cells will be inoculated into mice. He states that his studies do not require biosafety level 2 containment and do not require regulation per the NIH guidelines, however he will use that level anyway. He states his personnel have completed infectious waste training. Discussions involved whether training and medical surveillance requirements had been met, whether the [REDACTED] vectors were amphotrophic rather than ecotropic, thus requiring regulation per the Guide. It was determined that amphotrophic [REDACTED] vectors were rated Risk Group 2 and thus the protocol required IBC review and approval and viral vector handling required BSL 2 practices and facilities.

Approved at BSL2 with the following contingencies

1. Strike the comment in the investigator's abstract that "these studies do not require BL-2 Containment...." because the committee has determined due the fact that some of the vectors are propagated in human cultures, at least some of the [REDACTED] vectors are amphotrophic and are considered Risk Group 2 agents requiring BSL 2 containment. Please refer to Appendix B-V of the NIH Guide at http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm

2. Supply documentation (EOD/SHEA training transcripts) to the IBC Office that the following people have completed Blood Borne Pathogen training.
 - [REDACTED] D [REDACTED]
 - [REDACTED] W [REDACTED]
 - [REDACTED] H [REDACTED]
3. Supply documentation (EOD/SHEA training transcripts) to the IBC Office that the following people have completed Biosafety Training.
 - [REDACTED] D [REDACTED]
 - [REDACTED] W [REDACTED]
 - [REDACTED] H [REDACTED]
 - [REDACTED] R [REDACTED]
 - [REDACTED] H [REDACTED]
4. Supply documentation (EOD/SHEA training transcripts) to the IBC Office that the following people have completed Infectious Waste Training.
 - [REDACTED] D [REDACTED]
 - [REDACTED] W [REDACTED]
 - [REDACTED] H [REDACTED]
5. Supply documentation (EOHS encounter form) to the IBC Office that the following people have completed the medical surveillance required for this work.
 - [REDACTED] D [REDACTED]
 - [REDACTED] W [REDACTED]
 - [REDACTED] H [REDACTED]
 - [REDACTED] R [REDACTED]
 - [REDACTED] H [REDACTED]
6. Because this work involves animals, supply documentation as below:
 - IACUC approval number
 - IACUC approval date
 - Documentation to the IBC Office for staff handling animals of completion of the ARF Animal Handler training module.
 - Note that animal housing and cage handling of rodents inoculated with transfected somatic cells can be conducted at BSL1 containment (conventional housing), because the cells would not survive in the animal bedding. However, inoculation of [REDACTED] transfected cells should be carried out following the Bloodborne Pathogen Standard and BSL2 practices.

10. Notifications - none

11. Standing Reports

a. Report of Biosafety Officer

- i. The IBC Processes document has been updated to reflect current working parameters of the Institutional Biosafety Committee. The new document was discussed. The committee members asked that the IBC Office find a way to eliminate those appendix of the application form that do not apply to a specific application from the packets of information sent to the reviewers. Handouts of the revised IBC Processes document and the new fiscal member's contact list information were made available.
- ii. Biosafety level for established human cell lines: not discussed.

- iii. Brief updates were given by the Biosafety Specialist and the IBC Coordinator on the progress of the Campus-wide Biosafety Inventory Database project and the Biosafety Web Page project.
- b. Report from Safety (SHEA) committee member.
 - i. 24/7 Emergency Contact for Shipping Hazardous Materials: The interim acting director of SHEA discussed the regulatory requirements for shipping dangerous goods and stressed that very heavy fines can be levied for non-compliance. The regulation requires that a "knowledgeable person" be available 24/7 during all dangerous goods shipments (both chemical and biological). The committee discussed and decided that UNM PD would not qualify as knowledgeable enough to guide clean-up of these materials off-site, or out-of-state, if a spill should happen. Paging PIs from UNM PD would not be an adequate means as the emergency contact number needs to be answered immediately and not result in a call-back situation. Possible solutions were discussed, such as hiring a contractor like ChemTrec to respond and supplying them with information before each shipment, or handling these situations institutionally in one central office devoted to shipping dangerous goods. A consensus was reached that the best solution would be to require PIs listed on shipping documents to carry a "shipping" cell-phone 24/7 until their shipments are received safely. This should apply to anything that qualifies as a hazardous shipment. SHEA has the list of chemical agents. Biosafety has the list of biological agents.
- c. Report of Employee Occupational Health Services committee member - none
- d. Select Agent Report Responsible Official Terry Yates - none
- e. Ad hoc committee report, if applicable - none
- f. Other - none

12. Old Business: Proposed UNM Bylaws Draft - Legal Counsel

The Committee discussed and decided several issues related to IBC's, Biosafety Officer's, and the Administrations' authority and where to draw lines of distinction. The policy should capture everything that is required by federal law and list it somewhere. The members will have one more meeting to finalize the UNM IBC Policy draft after which legal counsel will take the document to the Faculty Senate's Research Policy Committee. After their review it will go to the Regents for their approval.

- It was decided that the IBC was the appropriate body to review issues related to biosecurity and biosafety before they are sent to the Faculty Senate for endorsement. The IBC should have authority over safety training, safety protocol review, emergency plans, etc. as spelled out in the NIH Guide.
- It was decided that the IBC should not have jurisdiction over Dangerous Goods shipping issues, and thinks this federal requirement should be handled administratively as it applies to a broader range of agents than the IBC normally considers. The IBC may endorse related infectious agent shipping procedures, but should not set a universal DG shipping policy for the institute.
- The IBC Procedures document should require majority vote approval of the Committee.
- The IBC should delegate authority to allow the Biosafety Officer to screen protocols before going to Committee.
- It should remain the Principal Investigator's responsibility to ensure any protocols involving biohazardous agents are submitted to the IBC and no work involving biohazardous agents will be done prior to IBC

approval. An informal system whereby the Biosafety Officer can advise the Grants Department as to whether a particular protocol requires IBC review should be adopted.

- Law does currently not require it, but it was decided that the Responsible Official should be an ex-officio voting member of the Committee.
- It was decided that the IBC may delegate authority for compliance to the Biosafety Officer for those issues which the IBC has jurisdiction over and the Biosafety Officer will have the force of the Committee behind them to enforce compliance.
- The Biosafety Officer will address compliance issues accordingly thru one of two reporting lines available to them; 1) the IBC to the Regents, and/or 2) thru the Administration chain of command.
- It was decided that for those issues that involve the administration of safety issues, such as who pays for it, space issues, etc. should be taken up the chain of command of the Biosafety Officer to Administration.
- It was decided when non-regulatory safety issues or any safety issue outside of the Committee's jurisdiction, is identified by the IBC, the Committee should function in an advisory role to the Administration. The IBC Chair sending a letter to the appropriate Vice-president(s) could accomplish this.
- IBC compliance enforcement will be at the level of the Provost who has the final authority over faculty members.

13. New Business - none

14. Adjournment

UNM IBC MINUTES

October 20th 2004

9:00 AM – 11:00 PM

BMSB Room B53

Voting Members Present:

Lynn Fondren, M., CIH, MS, Director EH&S, LRRI (Community Member)
Brian Hjelle, M.D., Dept. of Pathology
Susan Kellie, M.D., HSC Epidemiology
Denece Kesler, M.D., Dept. of Occupational Health, Ex officio
Rick Lyons, M.D., Dept. of Medicine, Co-Chair
Jac Nickoloff, Ph.D., HSC Molecular Genetics and Microbiology
Larry Watson, Environmental Affairs/Industrial Hygiene, SHEA, Ex officio
Coenraad Adema, Ph.D., Biology Department
Barbara Masten, Ph.D., Dept. of Pathology
Karen B. Mulloy, D.O., Dept. of Internal Medicine
Julie Hutt, Ph.D., UNM Department of Internal Medicine (Alt. for Daniel Theele)
David Girox, Physicians Assistant, UNM Department of Internal Medicine (Alt. for Denece Kesler)
Gary Oty, Director of Quality, Safety, Security & Emergency Preparedness, NM Department of Health (Alt. for Pascale Leonard)

Voting Members Absent:

David Peterson, Esq., Keleher & McLeod (Community Member)
Terry Yates, VPR, Office of Research (Responsible Official Select Agent Program) Ex officio, Co-Chair
Laurie Hudson, Ph.D., HSC College of Pharmacy
Ann Powell, Office of Research Services
Judy Pointer, MS, CBSP, SM (AAM), UNM Biosafety Officer

Non-voting Members Present:

Gary Cseko, M.S.P.H., Director of Research Protections Ex officio

Visitors & Alternates present (Non-Voting Members):

Leroy Garcia, Industrial Hygienist, SHEA
James De Zetter, RSO, & Interim Director of SHEA

Quorum = 8 voting members, present =13

15. CALL TO ORDER: The meeting was called to order at 9:00AM by Co-Chair, Dr. Rick Lyons. Introductions were made and those voting as alternates for absent voting members were recognized. The following announcements were made:

- Pascale M. Leonard; new member serving as a community member from the State Health Lab. Represented by Gary who is the State Lab's director of Quality Assurance and Quality Control and the Biosafety Office, Pascale is the supervisor of the State Lab Molecular Biology section.
- Coenraad Adema has consented to being an IBC voting member representing Biology Dept. Background in Molecular Biology, Parasitology
- Julie Hutt, a veterinary Ph.D. at UNM is serving as proxy for Dan Theele.

16. Approval of last meeting minutes: Minutes of the July 2004 IBC Meeting were approved with corrections.

17. Protocols Pending

a. Tentative Approval Post Expedited Review:

i. **IBC #: D [REDACTED] 04-10-01**

PI: [REDACTED] D [REDACTED]

Title: [REDACTED] in Cystic Fibrosis; Regulation of Mucoidy

Agent: [REDACTED], Mouse

BSL proposed: BL2

Primary Reviewer: Judy Pointer

• Approved with Contingencies 10/5/04. The following contingency is outstanding:

9. [REDACTED] D [REDACTED] and [REDACTED] M [REDACTED] must complete Biosafety and Infectious Waste Training and supply IBC Coordinator with training transcripts confirming competencies have been met.

Response: received; Status: not complete

ii. **IBC #: H [REDACTED] 04-07-01**

PI: [REDACTED] H [REDACTED]

Title: Molecular mechanisms of pathogenesis of [REDACTED] (BSL-3)

Agent: [REDACTED] virus (multiple strains)*; [REDACTED] virus ([REDACTED], [REDACTED]); [REDACTED] subtype, [REDACTED], derivative of [REDACTED] virus ([REDACTED], [REDACTED], [REDACTED])*; [REDACTED] (multiple strains); [REDACTED] Virus (multiple strains). * indicates agents are Select Agents

BSL proposed: BL3

Primary Reviewer: Brian Hjelle

• The protocol was Approved with Contingencies 7/21/04; PI's response to contingencies and the current status of the protocol was discussed by the committee members. The Committee Members determined that the PI has satisfactorily met all the contingencies set forth by the IBC. The protocol is approved as written with following modifications noted:

1) The IBC reviewed your response and agree the [REDACTED] Virus can be appropriately contained in the BSL2 lab [REDACTED] with BSL2 practices. [REDACTED] is fully equipped, posted as BSL2, and the BSO has inspected it.

iii. **IBC #: H [REDACTED] 04-07-02**

PI: [REDACTED]

Title: Molecular mechanisms of pathogenesis of [REDACTED] (BSL-2)

Agent: rDNA (plasmids [REDACTED], [REDACTED], [REDACTED] with [REDACTED] proteins); [REDACTED] virus ([REDACTED] strains); [REDACTED] virus ([REDACTED], [REDACTED]); [REDACTED] vaccine strains ([REDACTED], [REDACTED])

BSL proposed: BL2

Primary Reviewer: Brian Hjelle

• The IBC Approved with Contingencies 7/21/04. The IBC reviewed PI's responses to the contingencies originally set forth at the July, 2004 meeting concerning [REDACTED] virus handling, and agreed that [REDACTED] Virus can be appropriately contained using the BSL2 lab, [REDACTED], while utilizing BSL2 practices. All other contingencies

have been satisfied and the protocol submission is now fully approved. Protocol is approved as written with modifications noted.

b. Tabled or Withdrawn:

i. IBC #: V [REDACTED] 04-14-01

PI: [REDACTED] V [REDACTED]

Title: Feasibility, Phase I and Pharmacological Study of Aerosolized [REDACTED] ([REDACTED]) Gene-Polyethylenimine (PEI) in patients with Advanced Pulmonary Malignancies.

Agent: [REDACTED] ([REDACTED]) Gene-Polyethylenimine (PEI)

BSL proposed: BL2

Primary Reviewer: Jac Nickoloff

Status: Tabled at the April 2004 meeting. A memorandum with the committee's concerns was sent to Dr. V [REDACTED]. Since then, her representative acknowledged its receipt and said that Dr. V [REDACTED] is working with the FDA and the protocol's sponsor to supply the additional information requested. This protocol will remain on the agenda until the committee's concerns are addressed and all regulatory approvals are obtained.

Status: no further communication with the IBC office has taken place since the last meeting. Protocol will be placed on "Inactive Status" and removed from further agendas. If at some future date it is reactivated, it will placed on the agenda at that time.

- Protocol Remains Tabled

18. New Protocols for Review

i. IBC #: V [REDACTED] 04-10-01

PI: [REDACTED] V [REDACTED]

Title: GPCR trafficking in Eukaryotic Cells

Agent: [REDACTED] derivatives ([REDACTED], [REDACTED], [REDACTED]); plasmids ([REDACTED], [REDACTED]); viral vector ([REDACTED], [REDACTED]; [REDACTED])

BSL proposed: BSL1 (plasmids & [REDACTED])

BSL2 ([REDACTED] - [REDACTED] and [REDACTED] [REDACTED] viruses)

Primary Reviewer: Barbara Masten

- The protocol was discussed by the committee members and the protocol was Approved as written.

ii. IBC #: C [REDACTED] 04-10-01

PI: [REDACTED] [REDACTED] [REDACTED]

Title: Inhibition of [REDACTED] infection using antibodies against CCR5

Agent: [REDACTED], [REDACTED], Non-Human Primate Sera, Human HeLa cells

BSL proposed: BL2

Primary Reviewer: Daniel Theele

- The protocol was discussed by the committee members and the following contingency was set forth

1) Provide an answer to section III question #12 re: serum banking to Addendum D.

19. Notifications/Annual Reviews & Significant Modifications

i. IBC #: H [REDACTED] 04-07-02

PI: [REDACTED] H [REDACTED]

Title: Molecular mechanisms of pathogenesis of f [REDACTED] (BSL-2)

Agent: rDNA (plasmids [REDACTED], [REDACTED], [REDACTED] with [REDACTED] proteins); [REDACTED] virus ([REDACTED] strains); [REDACTED] virus ([REDACTED], [REDACTED]); [REDACTED] vaccine strains ([REDACTED], [REDACTED])

BSL proposed: BL2

Dr. H [REDACTED] has submitted a modification to add a newly hired person ([REDACTED] B [REDACTED], research tech III) to this protocol and to change the area for the infectious agent work to a tissue culture facility ([REDACTED]) equipped with Biological Safety Cabinets, posted as BSL 2.

IBC #: H [REDACTED] 04-07-01

PI: [REDACTED] H [REDACTED]

Title: Molecular mechanisms of pathogenesis of [REDACTED] (BSL-3)

Agent: [REDACTED] (multiple strains)*; [REDACTED] virus ([REDACTED], [REDACTED]); [REDACTED], [REDACTED] subtype, [REDACTED], derivative of [REDACTED] virus ([REDACTED], [REDACTED], [REDACTED])*; [REDACTED] Virus (multiple strains); [REDACTED] Virus (multiple strains). * indicates agents are Select Agents

BSL proposed: BL3

Dr. H [REDACTED] has submitted a modification (Addendum G & D) to add a new BSL 3 pathogen ([REDACTED] virus), and to change the room number where the work will take place from [REDACTED] to [REDACTED]. This is one tissue culture room inside the [REDACTED] suite. Only Dr. H [REDACTED] (or new staff vaccinated for the agents as indicated) will use the [REDACTED] room for the agents listed above. It will be equipped with a card reader, restricting access to others while in use.

ii. IBC #: Z [REDACTED] 04-01-01

PI: [REDACTED] Z [REDACTED]

Title: Identification factors that regulate neural stem cell proliferation and differentiation in vitro

Agent: [REDACTED]; [REDACTED]

Dr. Z [REDACTED] has submitted a modification (Addendum G) to add new persons ([REDACTED] S [REDACTED] & [REDACTED] E [REDACTED]), add a new room ([REDACTED] [REDACTED] – BSL2 [REDACTED]), and add animals to this previously approved protocol. *Status: original protocol approved Jan. 2004 at BSL2 (in vitro work only). Amendment to ACUC # [REDACTED] pending.*

IACUC has been approved with minor amendments. Dan wanted us to include the info provided to IACUC to the IBC, it has been provided.

iii. IBC # H [REDACTED] 95-04-01 Investigations of mammalian virology

IBC # H [REDACTED] 00-02-01 Pathogenic Microbes

IBC # H [REDACTED] 00-02-02 Techniques and Standard Protocols for the [REDACTED] Virus animal Model

IBC # H [REDACTED] 01-08-01 Pathogens of [REDACTED] and Other Biosafety Level 3 Viruses

IBC # H [REDACTED] 03-07-01 Diagnosis and Pathogenesis of [REDACTED] [REDACTED]

Dr. H [REDACTED] has submitted Annual Reviews (Addendum Gs) for each of the above titles which updates all of the personnel currently working on them. We do not have a lot of specifics about the four older ones and will eventually ask Dr. H [REDACTED] to submit a new form for those over 5 years old. However, the individuals he has designated on each protocol have completed all of the required training for entry into the BSL 3 lab, including training, security, and medical surveillance.

- The committee members discussed the annual reviews and modifications and voted to approve all the modifications and annual reviews.

20. Standing Reports

- a. Report of Biosafety Officer-NA
- b. Report from Safety (SHEA) Committee Member.
 - i. 24/7 Emergency Contact for Shipping Hazardous Materials:

The Committee discussed the option of a subscription service and SHEA will look into.

- c. Report of Employee Occupational Health Services Committee Member- none
- d. Select Agent Report Responsible Official Terry Yates - none
- e. Ad hoc committee report, if applicable - none
- f. Other - none

21. Old Business: Proposed UNM Bylaws Draft - Legal Counsel

- a) OSHA BBP needle-stick amendment applicability to biomedical research lab operations.
 - The Committee discussed the Draft document provided by Legal Counsel. The draft was found to be sound and many members complimented Legal Counsel's work.

22. New Business

- a. The IACUC has requested that the IBC endorse a new policy entitled: *Policy for Animal Research in University of New Mexico Hospitals*
 - The Committee discussed and agreed to endorse with the following conditions. Susan Kellie will relay this information to Hospital Epidemiology.
 - o Use of the hospital facilities will not impinge on any clinical processes, use of technicians, critical equipment, etc.,
 - o All hospital arrangements in place.
 - o Every effort must be made to complete the procedure in the Animal Facility if at all possible, ensure it is absolutely necessary before bringing the animals in.
 - o Strike the IRB/HRRC signature line.

23. Adjournment

Meeting Adjourned at 10:45AM by Co-Chair Rick Lyons.

UNM IBC MINUTES
January 19th 2005
9:00 AM – 11:00 PM
BMSB Room B85

Voting Members Present:

Brian Hjelle, M.D., Dept. of Pathology
Susan Kellie, M.D., HSC Epidemiology
Denece Kesler, M.D., Dept. of Occupational Health, Ex officio
Rick Lyons, M.D., Dept. of Medicine, Co-Chair
Terry Yates, VPR, Office of Research (Responsible Official Select Agent Program) Ex officio, Co-Chair
Jac Nickoloff, Ph.D., HSC Molecular Genetics and Microbiology
Larry Watson, Environmental Affairs/Industrial Hygiene, SHEA, Ex officio
Coenraad Adema, Ph.D., Biology Department
Barbara Masten, Ph.D., Dept. of Pathology
Karen B. Mulloy, D.O., Dept. of Internal Medicine
Denece Kesler, M.D., Dept. of Occupational Health
Pascale Leonard, NM State Lab Supervisor Molecular Biology Section
Judy Pointer, MS, CBSP, SM (AAM), UNM Biosafety Officer
Laurie Hudson, Ph.D., HSC College of Pharmacy

Voting Members Absent:

David Peterson, Esq., Keleher & McLeod (Community Member)
Ann Powell, Office of Research Services
Lynn Fondren, M., CIH, MS, Director EH&S, LRRI (Community Member)
Daniel Theele, Director Animal Research Facility

Non-voting Members Present:

Robert Bienstock, Senior Associate University Counsel

Visitors & Alternates present (Non-Voting Members):

Timothy Muller, BS, CBSP, UNM Biosafety Specialist

Quorum = 8 voting members, present =14

24. CALL TO ORDER: The meeting was called to order at 9:00AM by Co-Chair, Dr. Rick Lyons. Introductions were made. The following announcements were made:

- Timothy Muller, Biosafety Specialist is now a Certified Biosafety Professional.
- Pascale Leonard was introduced as new community member.

25. Approval of last meeting minutes: Minutes of the October 2004 IBC Meeting were approved.

26. Protocols Pending

a. Tentative Approval Post Expedited Review:

- i. **IBC #:** D [REDACTED] 04-10-01
PI: [REDACTED] D [REDACTED]
Title: [REDACTED] in Cystic Fibrosis; Regulation of Mucoidy
Agent: [REDACTED]

BSL proposed: BSL2
Primary Reviewer: Judy Pointer

- The Committee reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies, the protocol was approved at BSL2.

ii. IBC #: H [REDACTED] 04-07-01

PI: [REDACTED]

Title: Molecular mechanisms of pathogenesis of [REDACTED] (BSL-3)

Agent: [REDACTED] virus (multiple strains)*; [REDACTED] virus ([REDACTED]); [REDACTED], [REDACTED] subtype, [REDACTED], derivative of [REDACTED] virus ([REDACTED], [REDACTED], [REDACTED])*; [REDACTED] Virus (multiple strains); [REDACTED] Virus (multiple strains). * indicates agents are Select Agents

BSL proposed: BSL3

Primary Reviewer: Brian Hjelle

- Approved with Contingencies 7/21/04; The following contingencies remain to be fulfilled:
 - CDC and USDA approval of UNM's amendment to our SA registration # [REDACTED] to include [REDACTED] and [REDACTED] with Dr. H [REDACTED] as principal investigator is received by UNM's responsible official.
Response: Agreed; Status: pending
 - The Responsible Official is notified that H [REDACTED] has received approval from CDC to possess Select Agents.
Response: Agreed; Status: pending
 - Equipment, needed to contain all operations with infectious, viable, agents inside [REDACTED] B are purchased and operational before work begins. Additional equipment will be needed for security. A final inspection to ensure equipment is operational will be conducted by the Biosafety Officer.
Response: Agreed; Status: Final Inspection of equipped Facility by BSO.
 - USDA permit for transport (shipping documents) of [REDACTED] is required before the agent is shipped to UNM. Copy of permit must be forwarded to the Biosafety Office.
Response: Agreed; Status: [REDACTED] pending
- The Biosafety Office is answering questions posed by the CDC and USDA. Currently at issue is who is going in which rooms of the [REDACTED] suite and which individuals will need vaccinations. The vaccination cost is exorbitant for [REDACTED]. We will need to strategically find the most effective approach to this issue if CDC/USDA reviewers require all individuals in the [REDACTED] handling rooms be vaccinated before approving this modification to our Select Agent Registration.

iii. IBC #: H [REDACTED] 04-07-02

PI: [REDACTED] H [REDACTED]

Title: Molecular mechanisms of pathogenesis of [REDACTED] (BSL-2)

Agent: rDNA (plasmids [REDACTED], [REDACTED], [REDACTED] with [REDACTED] proteins); [REDACTED] virus ([REDACTED] strains); [REDACTED] virus ([REDACTED], [REDACTED]); [REDACTED] vaccine strains ([REDACTED], [REDACTED])

BSL proposed: BSL2

Primary Reviewer: Brian Hjelle

- The IBC members discussed the protocol and found that all contingencies have been met. The protocol was approved at BSL2.

iv. IBC #: C [REDACTED] 04-10-01

PI: [REDACTED] C [REDACTED]

Title: Inhibition of [REDACTED] infection using antibodies against CCR5

Agent: [REDACTED], [REDACTED], Non-Human Primate Sera, Human HeLa cells
BSL proposed: BSL2
Primary Reviewer: Daniel Theele

- The IBC members discussed the protocol and found that all contingencies have been met. The protocol was approved at BSL2.

b. Tabled or Withdrawn: NONE

27. New Protocols for Review

i. IBC #: B [REDACTED] 05-01-01

PI: [REDACTED], B [REDACTED]
Title: The role of [REDACTED] glycopeptidolipid in colonization and invasion
Agent: [REDACTED]
BSL proposed: BSL2
Primary Reviewer: Brian Hjelle

- The IBC members discussed the protocol and the protocol was approved as written at BSL2.

ii. IBC #: B [REDACTED] 05-01-02

PI: [REDACTED], B [REDACTED]
Title: The role of iron in [REDACTED] intracellular infection
Agent: [REDACTED] ([REDACTED])
BSL proposed: BSL3
Primary Reviewer: Laurie Hudson

- The IBC members discussed the protocol and the protocol was approved upon satisfaction of the following contingencies.
 - 1 Note Informal Administrative Action: Advice Dr. B [REDACTED] to be certain that the work study to be hired goes through the appropriate training and background screening and ensure that there is clarity with the container labeling, taking into consideration the fact that the work study employee will be gone from the lab for breaks, etc.
 - 2 In Addendum D, III, 5 please indicate "YES" because PPD skin testing for [REDACTED] conversion is needed.
 - 3 Provide a standardized operating procedure (SOP) for propagation of growing [REDACTED] B in vitro including an SOP for the macrophage and monocyte assays with [REDACTED].
 - 4 Provide a standardize Spill Cleanup Procedure that correlates with the SHEA biological spill clean-up posted on their web site.

iii. IBC #: B [REDACTED] 05-01-01

PI: [REDACTED] B [REDACTED]
Title: The molecular evolution and Pathogenicity of [REDACTED]
Agent: [REDACTED] ([REDACTED])
BSL proposed: BSL3
Primary Reviewer: Daniel Theele

- In the absence of the primary reviewer, the protocol was discussed by the full committee membership. After discussion, the protocol was tabled upon satisfaction of the following contingencies:
 - 1 Dr. B [REDACTED] will call the Co-Chair to discuss the exact nature of the mutant antibiotic resistant [REDACTED] strains he will test. Dr. B [REDACTED] needs to be specific about the drug resistant strains he is using so appropriate prophylactic treatment can be administered in case of exposure.
 - 2 The rodent work is conducted in ABSL3 facilities.

iv. IBC #: O [REDACTED] 05-01-01

PI: [REDACTED] O [REDACTED]

Title: The differentiation-dependent life cycle of Human [REDACTED]

Agent: Human [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Coenraad Adema

- The IBC members discussed the protocol and the protocol was approved upon satisfaction of the following contingencies:
 - 1 Handle all strains of [REDACTED] at the same Biosafety level as Human [REDACTED].
 - 2 Supply an Addendum D for each strain of [REDACTED] used (i.e. [REDACTED] [REDACTED] and [REDACTED] [REDACTED])

28. Notifications/Annual Reviews & Significant Modifications

- i. The following protocols have expired and have been closed.

W [REDACTED] 98-12-01 Terminate per PI
Cellular Immune Responses in [REDACTED] VLP Vaccine Volunteers

R [REDACTED] 98-05-01 Terminate per PI
Plasmid immunization in a mouse tumor model

H [REDACTED] 98-10-01 Terminate per PI
Receptor Matrix Interactions in Mammary Gland Development

H [REDACTED] 98-10-02 Terminate per PI
Cell Interaction and Apoptosis in mammary cell growth

S [REDACTED] 95-05-01 Terminate per PI
Expression of neutrophil adhesion molecules in heterologous cells

S [REDACTED] 95-05-02 Terminate per PI
Expression of neutrophil N-formyl peptid receptor in heterologous cells

M [REDACTED] 95-05-01 Terminate per PI
Immunological development in a marsupial

M██████ 95-05-02 Terminate per PI
MHC Variation in gray whales

M██████ 95-05-03 Terminate per PI
Identification of the Mouse SCID DNA Repair Gene

C██████ 95-05-01 Terminate per PI
Neurotropic Factor Delivery Using Transgenic Astrocytes

L██████ 95-09-01 Terminate per PI
Phylogeny of ███████ worms

O██████ 98-09-01 Resubmitted by PI as O██████ 05-01-01 on this agenda
The Differentiation Dependent Life Cycle of Human ███████

W██████ 95-04-01 Terminated Administratively (No Response by PI to IBC)
Immunobiology of Interleukin-2 Regulation

N██████ 95-05-01 Terminate per PI
Comparative analysis of mating and meiotic functions in the filamentous fungi, ███████ ███████ and ███████
██████

N██████ 95-05-02 Terminate per PI
Molecular Analysis of sexual development in ███████

P██████ 99-10-01 Terminated Administratively (PI Departed UNM)
Regulation of Tendon Development

V██████ 98-11-01 Terminated Administratively (PI Departed UNM)
Phosphorylation and actions of Ethanol on Ion channels

P██████ 98-02-01 Terminate per PI
Mechanisms of Chemoattractant Receptor Activation Leading to Chemotaxis

W██████ 95-05-01 Terminate per PI
Characterization of stationary phase genes/gene expression in the yeast ███████ ███████

29. Standing Reports

a. Report of Biosafety Officer

1. The appropriate biosafety level for established human cell lines was discussed. It was decided that established Human Cell Lines present less of a hazard than primary cell cultures. The ATCC designations of BSL1 for some established Human Cell Lines is only given for the purpose of shipping cultures and is not a recommended biosafety level for handling the cultures. Regardless, the biosafety level door postings need to indicate the lab room's current practices level and this performance criteria needs to be clear to all staff entering the lab. We must be consistent, in how we are posting. In the CDC BMBL the "Laboratory practices" for BSL-2, are appropriate for handling Human Materials. This is a very big issue for the University and requires a sub-committee of the IBC, to provide a centralized unified discussion point for Medical Surveillance, Immunizations, etc.

Action Item: The updated lab postings for BSL2 and BSL1 labs will go out to the committee members for their review and comment after which the postings should be implemented campus-wide.

2. OMI Audit. An audit of the Office of the Medical Investigator (OMI) was conducted by the Biosafety Officer. A report was given to Dr. [REDACTED] Z [REDACTED], itemizing 8 items of concern 10/6/04. A response to this audit was received from Dr. Z [REDACTED] 1/10/05. The report and response were discussed by the committee as follows.

The response addressed items 1-8 as follows. OMI staff are being encouraged to use the assigned break room located outside of the autopsy suite of rooms and reminded that no food or drink is allowed outside of the departmental break room. OMI prosectors are now required to wear fit-tested N95 respirators or HEPA PAPRs rather than surgical masks. The BSL3 area air-lock doors have been secured so that administrative staff can not use this area as a corridor to the administrative offices. UV flytraps have been installed and are working well to contain flies from the anthropology suite. Attempts to purchase an NSF compliant Class II biological safety cabinet for the BSL3 room have been unsuccessful do to lack of finances. OMI is currently exploring ventilation options to address the problem of odors and hazards escaping the building as detailed in items 6-8 of the audit report.

SHEA has tested the quality of the OMI air and found Formaldehyde so SHEA is working on the chemical issues at OMI. Per the SHEA representative there are additional chemical and physical hazards. OMI funding issues were discussed and it was determined that OMI and University funding is a fuzzy area. Moneys for a future new building that would correct the airflow problems have been slow in coming from the state legislature.

Action item: Copies of the audit report and the response were given to the Vice Provost of Research to follow-up on OMI funding issues.

3. [REDACTED] Floor Flood (12/24/04) On Christmas eve day (a work holiday) there was a flood on this floor due to a safety shower that had been pulled and left on inside of a locked lab. The emergency contact information posted on the lab doors had recently been updated and several floor occupants were called to respond by the facility maintenance personnel on-call. Several members of the lab staff came in and cleaned up the spill with shop vacs. They did not use PPE during the spill clean-up, however it was later determined by the Biosafety Officer that no leakage of biological agents had occurred. UNM PD was initially notified that there was a plumbing leak and they referred the incident to Facilities maintenance staff on call. Neither UNM PD nor Facilities staff, followed the call tree for biological spill emergency response. Later that day, the incident was called in to UNM PD as possible vandalism and at that time UNM PD responded. The chief of police asked that we please give them time to go through a full investigation as to whether the incident involved vandalism or other adverse human behavior. IBC members were asked to please call UNM PD with any eye-witness information they may have regarding this incident.

IBC members discussed the incident and response from both the security and biosafety aspects. While no microbes were released in this instance, it was a wake-up call and served as a dry-run for emergency response to the [REDACTED] building. Due to the safety as well as the security aspects it was discussed if perhaps we need to train dispatchers (not just PD officers), to ensure biological spill response procedures are followed for incidents involving the biomedical labs that have high hazard substances in them in the [REDACTED] building. The responders to such an incident should know if there are any physical or environmental dangers to sucking up water from lab floors before proceeding with clean-up. In addition UNM PD dispatchers need to be aware that emergency incidents, on off-hours at particular locales, could jeopardize biosecurity in some instances.

Action items are:

- UNM PD dispatchers need more direction on Emergency Response and selecting the proper call-tree. The Biosafety Officer will address this concern with the Chief of Police.
- UNM needs to beef up security and response time to high hazard areas of the [REDACTED]. This concern should be addressed by the Biosecurity Officer (Vito Capobianco), and UNM's Industrial Security Officer (Greg Halstrom)

with the Chief of Police. The IBC chair will contact the Dean's Office to ensure that there is appropriate handling of the security risks associated with this incident in this area

- Options such as spring-loaded safety showers and floor drains should be considered. The SHEA representative will discuss options for safety showers with SHEA safety staff.
- A thorough security analysis is needed and a formal root cause analysis by Risk Management would reveal weaknesses in the current system. The SHEA representative will inquire about handling this task with the new Risk Management Director, Donna Smith.

b. Report of Safety (SHEA) committee member

1. Staff Vacancies: The SHEA committee member announced the addition of Donna Smith, UNM's new Director of Risk Management & Safety, Health, and Environmental Affairs (Risk/SHEA). Also, SHEA Office Manager Sandra Medina has retired and SHEA Training Specialist Gail Keiser has resigned.
2. 24-hour Emergency Contact for Hazardous Materials Shipping Papers: There are currently two primary companies, CHEMTEL and CHEMTREC, that provide a this service on a 24-7 basis for hazardous materials shipments. Stanford University uses CHEMTEL and Cornell uses CHEMTREC thus their respective websites are good indicators of how easy it is for campus shippers to access the service. At present, CHEMTEL offers 100 notifications per year for \$500 and CHEMTREC offers unlimited notifications per year for \$585.

Action Item: after discussion, it was decided that CHEMTREC's services will be utilized, the Vice President for Research will provide the funding for the service, and the SHEA representative will coordinate setting up the service and installing a shipper-friendly site on the SHEA homepage so shippers can easily access CHEMTREC emergency contact service for shipments of hazardous materials.

c. Report of Employee Occupational Health Services committee member - no report

d. Select Agent Responsible Official (RO) Terry Yates

Federal consultants and lobbyists are working on issues of concern to UNM such as the Select Agent issues. We need to be working on a bill that has been introduced. The bill would not allow individuals into biomedical classes who are not American citizen. We feel that these changes would restrict basic laboratory knowledge. Presently we restrict only those allowed to work with Select Agents. We know exactly which labs, what incubators and what times they are in the Select Agent labs. But these new restrictions and screenings are proposed for individuals working in/around any labs with secure access and questions are being asked like, "Did anyone visit any foreign country, etc.?" This is a concern for UNM's RO that he is working on with federal officials.

e. Ad hoc committee report, if applicable - none

f. Other

30. Old Business:

a. IBC By-laws

The IBC members reviewed and discussed the changes that the committee asked for and concluded that all comments would be given by February 2nd 2005 to the Co-Chair and then forwarded to Legal Counsel.

31. New Business

32. Adjourn 11:11

UNM IBC MINUTES

April 20th, 2005

9:00 am – 11:00 PM

BMSB, Room B-85

Voting Members Present:

Rick Lyons, M.D., Department of Medicine, Co-Chair
Terry Yates, VPR, Office of Research (Responsible Official Select Agent Program, Co-Chair)
Coenraad Adema, Ph.D., Biology Department
Brian Hjelle, M.D., Department of Pathology
Susan Kellie, M.D., HSC Epidemiology
Denece Kesler, M.D., Dept. of Occupational Health
Pascale Leonard, Ph.D., NM State Lab Supervisor Molecular Biology Section (Community Member)
Barbara Masten, Ph.D., Department of Pathology
Karen Mulloy, D.O., Department of Internal Medicine
Jac Nickoloff, Ph.D., HSC Molecular Genetics and Microbiology
Judy Pointer, MS, CBSP, SM (AAM), UNM Biosafety Officer
Ann Powell, Office of Research Services
Daniel Theele, Director, Animal Research Facility
Larry Watson, Environmental Affairs/Industrial Hygiene, SHEA

Voting Members Absent:

Lynn Fondren, CIH, MS (Community Member)
Laurie Hudson, Ph.D., HSC College of Pharmacy
David Peterson, Esq., Keleher & McLeod (Community Member)

Non-voting Members Present:

Gary Cseko, M.S.P.H., Director of Research Protections Ex officio

Visitors & Alternates present (Non-Voting Members)

Timothy Muller, BS, CBSP, UNM Biosafety Specialist (BSO alternate)
John Archuleta, SHEA
Leroy Garcia, SHEA

Quorum = 9 voting members, present = 14

- 1) **CALL TO ORDER:** The meeting was called to order at 9:02 AM by Co-Chair, Dr. Rick Lyons.
- 2) **Approval of last meeting minutes:** Minutes of the January 2005 IBC Meeting were approved as written.
- 3) **Old Business**
 - a. IBC Bylaws
The committee approved the Bylaws. Dr. Lyons received one change request from Occupational Safety; that change was sent over to Robert Bienstock and he incorporated it into the current Bylaws revision. That was the only comment Dr. Lyons got. The Bylaws are approved and will be presented to the Faculty Senate and UNM Regents for their approval.
- 4) **Protocols Pending**
 - i. IBC #: B [REDACTED] 05-01-02
PI: [REDACTED] B [REDACTED]

Title: The role of iron in [REDACTED] intracellular infection

Agent: [REDACTED] ([REDACTED])

BSL proposed: BSL3

Primary Reviewer: In Laurie Hudson's absence Rick Lyons presented the review.

- The PI has satisfactorily met all contingencies, the protocol was approved.

ii. **IBC #: B [REDACTED] 05-01-01**

PI: [REDACTED] B [REDACTED]

Title: The molecular evolution and Pathogenicity of [REDACTED]

Agent: [REDACTED] ([REDACTED])

BSL proposed: BSL3

Primary Reviewer: Daniel Theele

- The PI has satisfactorily met all contingencies, the protocol was approved.

iii. **IBC #: O [REDACTED] 05-01-01**

PI: [REDACTED] O [REDACTED]

Title: The differentiation-dependent life cycle of Human [REDACTED]

Agent: Human [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Coenraad Adema

- The PI satisfied all contingencies except for supplying addendum D's for 2 agents. It was decided this item could be handled administratively by the IBC office. The protocol was approved

iv. **IBC #: H [REDACTED] 04-07-01**

PI: [REDACTED] H [REDACTED]

Title: Molecular mechanisms of pathogenesis of [REDACTED] (BSL-3)

Agent: [REDACTED] s virus (multiple strains)*; [REDACTED] virus ([REDACTED], [REDACTED]); [REDACTED] n subtype, [REDACTED], derivative of [REDACTED] virus ([REDACTED], [REDACTED], [REDACTED])*; [REDACTED] Virus (multiple strains); [REDACTED] Virus (multiple strains). * indicates agents are Select Agents

BSL proposed: BSL3

Primary Reviewer: Brian Hjelle

- The following contingency remains to be fulfilled:
 6. USDA permit for transport (shipping documents) of [REDACTED] is required before the agent is shipped to UNM. Copy of permit must be forwarded to the Biosafety Office.
Response: Agreed; Status: [REDACTED] pending
- Approved: USDA permit if needed, will be handled administratively by the BSO.

5. New Protocols for Review

i. **L [REDACTED] 05-04-01**

PI: [REDACTED] L [REDACTED]

Title: In vitro propagation of [REDACTED] at BSL2 for biosensor development

Agent: [REDACTED] [REDACTED] [REDACTED] strain; Monkey kidney cells ([REDACTED])

BSL proposed: BSL2

Primary Reviewer: Barbara Masten

- The IBC members discussed the protocol and the protocol was approved. Barbara Masten will write a letter addressed to Dr. L [REDACTED] incorporating the questions the reviewers had regarding his protocol and his answers to the questions. The letter will be attached to Dr. L [REDACTED] approval letter from the IBC Coordinator.

ii. L [REDACTED] 05-04-01 (Dr. L [REDACTED] left the room while his protocol was reviewed)

PI: [REDACTED] L [REDACTED]

Title: Population genetics analysis program: Immunity to vaccines/infections

Agent: [REDACTED] [REDACTED]; [REDACTED] ([REDACTED]); [REDACTED] [REDACTED] strain);
[REDACTED]; human material.

BSL proposed: BSL3

Primary Reviewer: Susan Kellie

- The IBC members discussed the protocol and the protocol was approved upon receipt of documentation by the IBC Coordinator from the PI that the following contingencies have been satisfied.
 1. Ensure lab staff that do not have current BSL3 work practices training and that will be working in the future BSL3 facility, [REDACTED] [REDACTED], have this training.
 2. Ensure all participating staffs' [REDACTED] [REDACTED] serologies are confirmed in the EOHS database.
 3. Ensure [REDACTED] vaccines needed are coordinated for all lab staff, as required per EOHS
 4. Supply an SOP for transport container decontamination and contained transport of agents between labs of use
 5. Detail how long and where the cell cultures will be exposed to the agents in an SOP
 6. On Addendum D for [REDACTED] #III 5, correct to show Yes – medical surveillance is recommended and indicate how often ppd skin testing will be required, and on #III 6, correct to show No – a clinically approved assay is not available for serum testing

iii. W [REDACTED] 05-04-01

PI: [REDACTED] W [REDACTED]

Title: Discovery of molecular signatures in [REDACTED] infection

Agent: [REDACTED] positive human blood

BSL proposed: BSL2

Primary Reviewer: Denece Kesler

- The IBC members discussed the protocol and the protocol was approved upon receipt of documentation by the IBC Coordinator from the PI that the following contingencies have been satisfied.
 1. The protocol states that an N95 respirator will be worn for spill clean up. If you state that the use of a respirator is required for spill clean-up, those employees using the respirator need to complete medical clearance for respirator use with EOHS, followed by respirator fit-testing through SHEA.
 2. Ensure Dr. [REDACTED] vaccine compliance is recorded with EOHS. Currently they do not have record of such.

iv. W [REDACTED] 05-04-02 (Dr. Masten left the room as she is listed on this protocol)

PI: [REDACTED] W [REDACTED]

Title: Major histocompatibility complex typing (MHC) technologies for non-human primates

Agent: Monkey blood (possible endogenous [REDACTED] virus); monkey cell lines (with endogenous [REDACTED] & [REDACTED] viruses)

BSL proposed: BSL1, BSL2

Primary Reviewer: Karen Mulloy

- The IBC members discussed the protocol and the protocol was approved upon receipt of documentation by the IBC Coordinator from the PI that the following contingencies have been satisfied.
 1. The protocol states that an N95 respirator will be worn for spill clean up. If you state that the use of a respirator is required for spill clean-up, those employees using the respirator need to complete medical clearance for respirator use with EOHS, followed by respirator fit-testing through SHEA.
 2. An animal tissue-use protocol for use of monkey blood, needs to be filed with the Animal Care and Use Committee (ACUC).
 3. A blood exposure SOP is written and the Biosafety Office delivers hazardous awareness training to the effected staff concerning risks associated with handling monkey blood. Please make arrangements with the Biosafety Office for the training session after the SOP is composed.

v. P [REDACTED] 05-04-01

PI: [REDACTED] P [REDACTED] - [REDACTED]

Title: Mechanisms of control of the [REDACTED] gene in normal development and in patients with schizophrenia and alcohol abuse

Agent: [REDACTED] & [REDACTED] viral vector; exempt rDNA (plasmids & [REDACTED]); human cells

BSL proposed: A/BSL2

Primary Reviewer: Judy Pointer

- The IBC members discussed the protocol and the protocol was approved upon receipt of documentation by the IBC Coordinator from the PI that the following contingencies have been satisfied.
 1. ACUC protocol approval is completed
 2. Documentation that B [REDACTED] and P [REDACTED] have completed the required medical surveillance for working with human materials with potential BBP contamination

6. Notifications/Annual Reviews & Significant Modifications

i. Annual Reviews

A [REDACTED] 04-01-01

PI: [REDACTED] A [REDACTED]

Title: Anti-pathogen responses in *Biomphalaria glabrata*

Agent: [REDACTED] ; [REDACTED]

BSL1 proposed: BSL-2

Dr. A [REDACTED] has submitted an annual review with no significant modifications made in the last year.

ii. The following protocols have expired and have been closed.

O [REDACTED] 01-12-01 Terminated administratively
Prostate Cancer and Repression of Cytochrome P450C1 Gene Expression

H [REDACTED] 00-02-01 Terminated administratively
Pathogenic Microbes

H [REDACTED] 00-02-02 Terminated administratively
Techniques and Standard Protocols for the [REDACTED] Virus Animal Model

H [REDACTED] 95-04-01 Terminated administratively
Investigations of mammalian virology and genetics

H [REDACTED] 99-01-01 Terminate per PI
Contributions of Activated [REDACTED] Receptor to Ovarian Cancer Metastasis

R [REDACTED] 99-01-01 Terminate per PI
Replication and Assembly of [REDACTED] Bacteriophage

A [REDACTED] 99-01-01 Terminate per PI
Over-expression of [REDACTED] Receptor in the Mouse

P [REDACTED] 99-01-01 Terminated Administratively (No Response by PI to IBC)
Mechanisms of Control of the [REDACTED] gene [REDACTED]: Impact on Synaptic Plasticity Mechanisms

S [REDACTED] 99-06-01 Terminate per PI
A Phase II/III Trial of Chemotherapy Alone Versus Chemotherapy Plus [REDACTED] in Newly Diagnosed Stage III Ovarian and Primary Peritoneal Cancer Patients with > or = 0.5cm and < or = 2cm Residual Disease Following Surgery

iii. Significant Modifications

H [REDACTED] 04-07-01

PI: [REDACTED]

Title: Molecular mechanisms of pathogenesis of [REDACTED] (BSL-3)

Agent: Add [REDACTED] virus*([REDACTED]) to protocol; add animal work with [REDACTED] virus and [REDACTED] virus. * [REDACTED] virus is a select agent.

BSL proposed: BSL3 and ABSL3

Primary Reviewer: Rick Lyons

- Discussion related to the Select Agent status of [REDACTED] virus clarified that this agent is not on the USDA or CDC list of current Select Agents and therefore does not require registration with federal agencies.
- The IBC members discussed the protocol modification and it was approved upon receipt of documentation by the IBC Coordinator from the PI that the following contingencies have been satisfied.
 1. Arrangements with the [REDACTED] director must be made for on-site training optimizing methodology for injecting animals for all ABSL3 lab staff involved
 2. Arrangements with the Biosafety Office are made to deliver a HAZCOM training session to the [REDACTED] Facility staff regarding these viruses and the risk.

H [REDACTED] 04-07-02

PI: [REDACTED] H [REDACTED]

Title: Molecular mechanisms of pathogenesis of [REDACTED] (BSL-2)
Agent: [REDACTED] virus, [REDACTED] virus (add agents and animal work)
BSL proposed: BSL2 and ABSL2
Primary Reviewer: Rick Lyons

- The IBC members discussed the protocol modification and it was approved upon receipt of documentation by the IBC Coordinator from the PI that the following contingencies have been satisfied.
 1. Arrangements with the [REDACTED] director must be made for on-site training optimizing methodology for injecting animals for all ABSL2 lab staff involved
 2. Arrangements with the Biosafety Office are made to deliver a HAZCOM training session to the Animal Resource Facility staff regarding these viruses and the risk.

7. Standing Reports

a. Report of Biosafety Officer

1. Judy reported that the CDC inspection will be on Monday and Tuesday (April 25 & 26). On Monday in [REDACTED], Room [REDACTED] from 9:00 to 10:00 there will be introductions and presentations by [REDACTED] L [REDACTED] and [REDACTED] H [REDACTED]. There are 2 inspectors, Paul Mehta and Sabrina Frank-DeBose, secondary inspector. After the introductions and presentations, both facilities will be inspected and during the rest of that day and the next morning the inspectors will be going through all of our documents. Judy has a phone list so that if the inspectors have questions that she can't answer, people on the list may be called in to help.
2. Next FY membership list. Members whose terms are expiring are: Brian Hjelle, Ann Powell, Terry Yates and Barbara Masten. Those who wish to remain on the committee should let Judy or Kathy know before the July meeting. Those wishing to be relieved of duty, post their term expiration, should discuss their replacement with their department chairs. The IBC Coordinator must be informed of their replacement before the July meeting.
3. IBC form – InfoEd conversion. In order to put the protocols into InfoEd's electronic system, the IBC form needs to be rewritten. Start looking at the form and let Judy know if there is any particular part of the form that is confusing and hard for PIs to answer easily. An example is; the medical surveillance portions often generate contingencies that need further follow-up. Please give Judy any suggestions of how to reword portions of the form for better clarity before we convert it to the electronic form at the end of summer.

b. Report of Safety (SHEA)

1. Larry reported that they now have an institutional emergency phone number for HazMat shipments which is CHEMTREC. He will draft a memo to all HazMat shippers giving them the 800 number and how to access the service. He will ask that SHEA be notified of all shipments in advance. Shippers should copy shipping documents to SHEA before shipment and make sure that CHEMTREC has a copy of the specific MSDS on file.

SHEA offers a HazMat shipping training class for those who ship any kind hazardous material including chemical and radioisotopes. The Biosafety Office has a more specialized hazardous materials shipping training CD that concentrates on only Infectious agents, dry ice, and recombinant DNA molecule shipping. This CD can be checked out thru the Biosafety Office. Either kind of training certifies shippers for a 2 year period, after which shippers must re-take the training to continue to be certified to sign Dangerous Good manifests. Penalties for non-compliance are very steep.

c. Report of Employee Occupational Health Services committee member

1. EOHS will order [REDACTED] vaccines as needed but the material is only good for 90 days so please let Denece know when you will be needing the vaccine, in advance, within that time frame.

d. Select Agent Responsible Official (RO) – No report

7. New Business - none

8. Adjourn 10:29

UNM IBC MINUTES

July 20th, 2005

9:00 am – 11:00 PM

BMSB, Room B-85

Voting Members Present:

Rick Lyons, M.D., Department of Medicine, Co-Chair
Marco Bisoffi, Ph.D., Department of Biochemistry
Oscar Bizzozero, Ph.D., Department of Cell Biology
Lynn Fondren, CIH, MS (Community Member)
Susan Kellie, M.D., HSC Epidemiology
Pascale Leonard, Ph.D., NM State Lab Supervisor Molecular Biology Section (Community Member)
Barbara Masten, Ph.D., Department of Pathology
Jac Nickoloff, Ph.D., HSC Molecular Genetics and Microbiology
Judy Pointer, MS, CBSP, SM (AAM), UNM Biosafety Officer
Larry Watson, Environmental Affairs/Industrial Hygiene, SHEA

Voting Members Absent:

Coenraad Adema, Ph.D., Biology Department
Denece Kesler, M.D., Dept. of Occupational Health
Karen Mulloy, D.O., Department of Internal Medicine
Ann Powell, Office of Research Services
Daniel Theele, Director, Animal Research Facility
Terry Yates, Vice Provost

Visitors & Alternates present (Non-Voting Members)

Leroy Garcia, SHEA

Quorum = 10 voting members, present = 10

- 5) **CALL TO ORDER:** The meeting was called to order at 9:07 AM by Co-Chair, Dr. Rick Lyons.
Dr. Lyons welcomed new members: Marco Bisoffi from the Department of Biochemistry and Oscar Bizzozero from the Department of Cell Biology.
- 6) **Approval of last meeting minutes:** Minutes of the April 2005 IBC Meeting were approved with one correction: Larry Watson did distribute a memo to all HazMat shippers notifying them of the 800 number and how to access CHEMTREC.

7) Protocols Pending

i. L [REDACTED] 05-04-01

PI: [REDACTED] L [REDACTED]

Title: Population genetics analysis program: Immunity to vaccines/infections

Agent: [REDACTED]; [REDACTED]; [REDACTED] ([REDACTED]); [REDACTED]; [REDACTED] strain);
[REDACTED]; human material.

BSL proposed: BSL3

Primary Reviewer: Susan Kellie

- o All contingencies met. Approved at BSL3

ii. W [REDACTED] 05-04-01

PI: [REDACTED] W [REDACTED]

Title: Discovery of molecular signatures in [REDACTED] infection

Agent: [REDACTED] positive human blood

BSL proposed: BSL2

Primary Reviewer: Denece Kesler

- All contingencies met. Approved at BSL2

iii. W [REDACTED] 05-04-02 (Dr. Masten left the room as she is listed on this protocol)

PI: [REDACTED] W [REDACTED]

Title: Major histocompatibility complex typing (MHC) technologies for non-human primates

Agent: Monkey blood (possible endogenous [REDACTED] [REDACTED]); monkey cell lines (with endogenous [REDACTED]s [REDACTED] & [REDACTED] [REDACTED] viruses)

BSL proposed: BSL1, BSL2

Primary Reviewer: Karen Mulloy

- All contingencies met. Approved at BSL2

iv. P 05-04-01

PI: P

Title: Mechanisms of control of the **DISC1** gene in normal development and in patients with schizophrenia and alcohol abuse

Agent: [REDACTED] & [REDACTED] viral vector; exempt rDNA (plasmids & [REDACTED]); human cells

BSL proposed: A/BSL2

Primary Reviewer: Judy Pointer

- All contingencies met. Approved at A/BSL2

4. New Protocols for Review

i. H[REDACTED] 05-07-01

PI: [REDACTED] H [REDACTED]

Title: Investigations of Mammalian Virology and Genetics

Agent: [REDACTED], Strain [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Jac Nickoloff

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following.

1. Documentation that T [REDACTED], G [REDACTED]-[REDACTED] and B [REDACTED]-H [REDACTED] have completed the required biosafety training must be received by the IBC Coordinator.

ii. H[REDACTED] 05-07-02

PI: [REDACTED] H [REDACTED]

Title: Pathogenic Microbes

Agent: [REDACTED]
[REDACTED] ([REDACTED]);
[REDACTED] ([REDACTED]); virus, virus.

BSL proposed: BSL3

Primary Reviewer: Susan Kellie

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following.
 1. There was confusion related to whether the work included recombinant DNA. Committee members thought this entry in Addendum C was a mistake. Please clarify in your response memo.
 2. No agents handled in BSL3 laboratories should be removed to BSL2 labs at a later date, even if rated as BSL2 microorganisms. All new strains of [REDACTED] or [REDACTED] viruses, if included in this approval, must be documented to the IBC Coordinator by submission of an Addendum D for each before use.

iii. H [REDACTED] 05-07-03

PI: [REDACTED] H [REDACTED]

Title: Techniques and Standard Protocols for the [REDACTED] Virus
Animal Model

Agent: [REDACTED] or [REDACTED] (Taxonomy [REDACTED])

BSL proposed: N/A (outdoor work)

Primary Reviewer: Daniel Theele

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following.
 1. Supply documentation to IBC Coordinator that G [REDACTED]-[REDACTED] has completed the Bloodborne Pathogen, Infectious waste and Biosafety training

iv. G [REDACTED] 05-07-01

PI: [REDACTED] G [REDACTED]

Title: In vitro [REDACTED] Virus work at BSL3

Agent: [REDACTED] Virus ([REDACTED]) Strain [REDACTED]

BSL proposed: BSL3

Primary Reviewer: Barbara Masten

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following.
 1. Explain the CPE evaluation technique in more detail. Please supply the titer of your viral stock of [REDACTED].
 2. Explain the methods used to minimize potential viral aerosols resulting from this work (centrifugation techniques, tissue grinders, etc.). Explain your techniques for isolation of nucleic acids from patient samples.

v. S [REDACTED] 05-07-01

PI: [REDACTED] S [REDACTED]

Title: Mammalian DNA damage response and cancer intervention

Agent: [REDACTED] vector type [REDACTED]; [REDACTED] Vector ([REDACTED] [REDACTED]);
[REDACTED] ([REDACTED], [REDACTED], [REDACTED]); Human Cells Lines, Animal Cell Lines

BSL proposed: BSL2

Primary Reviewer: Jac Nickoloff

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following.
 1. Supply documentation to the IBC Coordinator that lab personnel listed in Addendum F have completed BBP training and visited EOHS for inclusion in the University's BBP medical surveillance protocol.
 2. Supply a memo stating that all handling of viable viral vectors and viable human cell lines takes place in BSL2 lab, [REDACTED] [REDACTED]. Non-viable materials may be handled in the BSL1 facilities available to the PI.

vi. M [REDACTED] 05-07-01

PI: [REDACTED] M [REDACTED]

Title: Molecular Actions of Heat Shock Proteins

Agent: [REDACTED] vector, [REDACTED] [REDACTED]; Human Cell Lines

BSL proposed: BSL2

Primary Reviewer: Judy Pointer

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following.
 1. Supply documentation to the IBC Coordinator that lab personnel listed in Addendum F have completed BBP and Infectious Waste training and visited EOHS for inclusion in the University's BBP medical surveillance protocol.

vii. H [REDACTED] 05-07-01

PI: [REDACTED] H [REDACTED]

Title: Creation of novel mammary epithelial cell lines from genetically modified mice

Agent: [REDACTED] [REDACTED] [REDACTED] Virus vector; [REDACTED] [REDACTED]; Animal Cell Lines;
Human Cell Lines

BSL proposed: BSL2

Primary Reviewer: Daniel Theele

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following.
 1. Work with the Biosafety Officer to develop a safety SOP and supply a copy to the IBC Coordinator.
 2. Arrange for the Biosafety Officer to conduct a staff HAZCOM training session specifically for work with [REDACTED] vectors.

5. Notifications/Annual Reviews & Significant Modifications

iv. Annual Reviews

B[REDACTED] 03-07-01

PI: [REDACTED] B[REDACTED]

Title: Quantification of the Expression of [REDACTED] and [REDACTED] in Rhabdomyosarcoma and Correlation with Clinical Outcome and Subtype

Agent: Human Cell Lines, [REDACTED] and [REDACTED] RNA - Exempt

Dr. B[REDACTED] has submitted an annual review adding a MD/PhD student.

B[REDACTED] 03-10-01

PI: [REDACTED] B[REDACTED]

Title: Expression of [REDACTED]-[REDACTED] in [REDACTED] Vector-infected Mouse Myoblasts

Agent: [REDACTED] Vector; insert [REDACTED]; Human Cell Lines; [REDACTED]

Dr. B[REDACTED] has submitted an annual review with no significant modifications made in the last year.

B[REDACTED] 05-01-01

PI: [REDACTED] B[REDACTED]

Title: The Molecular Evolution and pathogenicity of [REDACTED]

Agent: [REDACTED] [REDACTED] ([REDACTED])

Dr. B[REDACTED]s has submitted an annual review adding a visiting scholar.

v. The following protocols have expired and have been closed.

F[REDACTED] 04-04-01 ([REDACTED] F[REDACTED]) Terminated Administratively
Chromosome Segregation in Archaea

H[REDACTED] 04-07-01 ([REDACTED] H[REDACTED]) Terminated per PI
Molecular Mechanisms of Pathogenesis of [REDACTED] (BSL-3)

H[REDACTED] 04-07-02 ([REDACTED] H[REDACTED]) Terminated per PI
Molecular Mechanisms of pathogenesis of [REDACTED] (BSL-2)

M[REDACTED] 01-05-01 ([REDACTED] M[REDACTED]) Terminated Administratively
Association of Segmental Jumping Translocations/Controlled [REDACTED] Gene Amplification
With Secondary Cancers

M[REDACTED] 00-02-01 ([REDACTED] M[REDACTED]) Terminated Administratively
Gut Epithelial Permeability

N[REDACTED] 00-02-01 ([REDACTED] N[REDACTED]) Terminated per PI
Geomicrobiological Investigations in Luchuguilla Cave

T[REDACTED] 00-05-01 ([REDACTED] T[REDACTED]) Terminated per PI
A Phase II Double-Blind, Randomized, Placebo Controlled Study to Assess the Efficacy

and Safety of [REDACTED] ([REDACTED]) Vaccine for the Treatment of Recurrent Genital Herpes

V [REDACTED] 04-14-01 ([REDACTED] V [REDACTED]) Terminated per PI
Feasibility and Phase I Study of Aerosolized [REDACTED] Gene Complexed with Polyethylenimine in Patients with Advanced Pulmonary Malignancies

vi. Significant Modifications

IBC #: B [REDACTED] 05-01-01

PI: [REDACTED] J. B [REDACTED]

Title: The role of [REDACTED] [REDACTED] glycopeptidolipid in colonization and invasion

Agent: [REDACTED] [REDACTED]

BSL proposed: A/BSL2

Primary Reviewer: Brian Hjelle

- Modification adding animal work with [REDACTED] [REDACTED]
Approved at A/BSL2

7. Standing Reports

a. Report of Biosafety Officer

1. Judy reported that this is the first meeting of the new fiscal year and we have two new members. We selected the departments that we asked to appoint an IBC member from, after we had reviewed the 2004 Biological Inventory for departments with significant holdings of infectious agents, recombinant DNA, or human materials. We are waiting for Dr. S [REDACTED] from Neurosciences and Dr. M [REDACTED] from the College of Pharmacy to announce who will be the members from their departments. After they do, the total membership for the fiscal year will be 18 voting members. We will be registering our committee with the NIH as soon as we get the names and information about the last two members.
2. Administrative updates for the orientation books were handed out. Judy asked that the two new members in attendance stay after the meeting for an orientation/training session.
3. The CDC inspection happened right after the last IBC meeting. The inspectors spent a day reviewing files and labs. Later we received a memo with 15 questions that we needed to respond to. Which we did by deadline. Our response to their questions is still in a CDC committee and there is no word on the status at this time. Judy has completed the BSL3 training for the Select Agent labs, with the exception of a few make-up classes. In this year's training an emergency response drill was added to comply with new requirements of the regulation. Left to be done are biosecurity protocol/plans and training/drills to be done by Vito Capobianco, the biosecurity officer.
4. Discussion of the OSHA BBP standard compliance for cell lines was postponed until the next meeting.

b. Report of Safety (SHEA)

1. Dr. Kellie and Larry are looking at some proposed changes to the New Mexico solid waste regulations; part of it has to do with the definition of infectious waste. The hospital is putting together the clinical side but they need input from the basic science and animal side; comments are due by mid September.

c. Report of Employee Occupational Health Services committee member – No Report

d. Select Agent Responsible Official (RO) – No report

7. New Business - none

8. Adjourn 10:45

- The Co-Chair (Rick Lyons) reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol was approved at BSL2.

ix. H[REDACTED] 05-07-02

PI: [REDACTED] H: [REDACTED]

Title: Pathogenic Microbes

Agent: [REDACTED]
[REDACTED] ([REDACTED]);
[REDACTED] ([REDACTED]); l virus, virus.

BSL proposed: BSL3

Primary Reviewer: Susan Kellie

- The Co-Chair (Rick Lyons) reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol was approved at BSL3.

ii. H[REDACTED] 05-07-03

PI: [REDACTED] H [REDACTED]

Title: Techniques and Standard Protocols for the [REDACTED] [REDACTED] Virus Animal Model

Agent: [REDACTED] or [REDACTED] (Taxonomy [REDACTED])

BSL proposed: N/A (outdoor work)

Primary Reviewer: Daniel Theele

- The Co-Chair (Rick Lyons) reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies, the protocol was approved.

iii. G [REDACTED] 05-07-01

PI: [REDACTED] G [REDACTED]

Title: In vitro [REDACTED] Virus work at BSL3

Agent: [REDACTED] Virus ([REDACTED]) Strain [REDACTED]

BSL proposed: BSL3

Primary Reviewer: Barbara Masten

- Response received from PI; the Co-Chair will review the response and administratively approve the protocol.

iv. S [REDACTED] 05-07-01

PI: [REDACTED] S [REDACTED]

Title: Mammalian DNA damage response and cancer intervention

Agent: [REDACTED] vector type [REDACTED]; [REDACTED] Vector ([REDACTED], [REDACTED]);

(b) (4), (b) (7)(C); Human Cells Lines, Animal Cell Lines

BSL proposed: BSL2

Primary Reviewer: Jac Nickoloff

- The Co-Chair (Rick Lyons) reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol was approved at BSL2.

v. M [REDACTED] 05-07-01

PI: [REDACTED] M [REDACTED]

Title: Molecular Actions of Heat Shock Proteins

Agent: [REDACTED] vector, [REDACTED] [REDACTED]; Human Cell Lines

BSL proposed: BSL2

Primary Reviewer: Judy Pointer

- The Co-Chair (Rick Lyons) reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies, the protocol was approved at BSL2.

vi. H [REDACTED] 05-07-01

PI: [REDACTED] H [REDACTED]

Title: Creation of novel mammary epithelial cell lines from genetically modified mice

Agent: [REDACTED] [REDACTED] [REDACTED] Virus vector; [REDACTED] [REDACTED]; Animal Cell Lines;

Human Cell Lines

BSL proposed: BSL2

Primary Reviewer: Daniel Theele

- The Co-Chair (Rick Lyons) reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies, the protocol was approved at BSL2.

11) New Protocols for Review

i. B [REDACTED] 05-10-01

PI: [REDACTED] B [REDACTED]

Title: Expression of cancer progression protein markers using [REDACTED] vectors

Agent: Rep-def [REDACTED] vectors, human cancer primary and established cell lines

BSL proposed: BSL2

Primary Reviewer: Karen Mulloy

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following:
 1. Dr. B [REDACTED] and [REDACTED] J [REDACTED] must complete Infectious Waste Training and supply documentation of such to the IBC Office.
 2. Restrict handling of live viral vector to posted BSL2 labs only. [REDACTED] [REDACTED], [REDACTED] [REDACTED], [REDACTED] [REDACTED] and [REDACTED] [REDACTED] are currently empty and have not been posted at this time. Contact Biosafety Office to inspect and approve facilities as BSL2 (lab posting) prior to work with [REDACTED] vectors.
 3. Indicate on page 8 of protocol, IV-3r that this viral vector is rated as "RG2" rather than "not classified."

4. Indicate on page 7 of protocol, under II-13, that [REDACTED] and [REDACTED] 9 are "not classified" rather than RG2. [REDACTED] derivatives have been exempted from the NIH guide and can be handled at BSL1.
5. Indicate on Page 7 of protocol under II-9, the concentration of the [REDACTED].
6. Submit Addendum F of IBC form for work with viable human cells

ii. B [REDACTED] 05-10-01

PI: [REDACTED] B [REDACTED]

Title: Attenuated attaching/effacing [REDACTED] as [REDACTED] vaccine vectors

Agent: Attenuated [REDACTED] [REDACTED] vectors ([REDACTED]) Strain: [REDACTED]
[REDACTED] [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Rick Lyons

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following:
 1. Supply documentation to the IBC Office that Drs. Z [REDACTED] and R [REDACTED] have completed Biosafety and Infectious Waste training.
 2. The PPE needs to be addressed in Sec. III. Please complete this Section.
 3. Section V, Addendums C and D need to be completed. Indicate [REDACTED] [REDACTED] work will be conducted at BSL2 in Addendum D.
 4. Complete Addendum C indicating rDNA work has Exempt status under the NIH Guidelines.

iii. L [REDACTED] 05-10-01

PI: [REDACTED] L [REDACTED]

Title: Effect of [REDACTED] on pulmonary dendritic cells

Agent: [REDACTED] Strain: [REDACTED] ([REDACTED]) vaccine strain

BSL proposed: BSL2

Primary Reviewer: Denece Kesler

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following:
 1. Supply conditions for transport of agent between labs & [REDACTED] to the IBC Office.
 2. Supply completed training documentation for [REDACTED] H [REDACTED] and [REDACTED] P [REDACTED] to the IBC Office.

3. PPD testing of staff needs to be completed as a baseline and annually thereafter while the work is ongoing.
4. The Flow Cytometry Operator needs EOHS medical surveillance also, as stated in #3. Please supply documentation of such to the IBC Office.

iv. L [REDACTED] 05-10-01

PI: L

Title: BSL2 procedures utilized in L [REDACTED] lab for working with BSL2 pathogens

Agent: [REDACTED], [REDACTED] mouse adapted; [REDACTED] virus, [REDACTED]; [REDACTED], [REDACTED]
virus, [REDACTED] strains & mutants; [REDACTED], [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Judy Pointer

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following:
 1. Arrange for the Biosafety Office to conduct HAZCOM training on these BSL2 agents to the ARF staff.
 2. Complete and supply Addendum F to the IBC Office.

The committee agreed to down-regulating the [REDACTED] strain of [REDACTED] to BSL2 because of documentation from the CDC that it has not been harmful to military personnel being vaccinated.

V. L [REDACTED] 05-10-02

PI: L

Title: BSL3 procedures

Agent: [REDACTED], [REDACTED], [REDACTED], [REDACTED];
Yersinia, strains: [REDACTED], [REDACTED];

BSL proposed: BSL3

Primary Reviewer: Judy Pointer

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following:
 1. The committee thought the risk to humans from the accidental release from the lab of infected animals (living or dead) was understated in the abstract. Please reconsider the statements supplied taking into account the possibility of accidental dispersal of these agents into the environment from infected rodent feces, decomposing bodies, etc. and the impact that may have on a human within close proximity.
 2. Supply name of assays for serum testing for each Addendum D submitted to the IBC Office.
 3. Submit the first page of Addendum E to the IBC Office indicating the Select Agents included in this protocol.

4. Complete and supply Addendum F to the IBC Office.

vi. P [REDACTED] 05-10-01

PI: [REDACTED] P [REDACTED]

Title: [REDACTED] and [REDACTED] RNA encapsidation and VLP Formation

Agent: [REDACTED], strain [REDACTED]; [REDACTED]; [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Marco Bisoffi

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following:
 1. In your abstract you mentioned the possibility of using a BSL3 facility for work with the [REDACTED] agents you identified in this submission. The IBC agrees that work with these agents can take place at BSL2. Please respond to the IBC Office that you acknowledge work with these agents will take place utilizing BSL2 practices and facilities, not BSL3.
 2. Your protocol abstract indicates that Hela and Vero cell cultures will be handled. These [REDACTED] materials require compliance with the OSHA Blood borne Pathogen Standard. This standard requires annual retraining in BBP precautions. A review of the training transcripts you supplied indicate that all four persons and yourself have not taken the BBP training within the past year. To remedy this situation please visit <http://shea.unm.edu/modules.html> and update the BBP training requirements then supply updated transcripts to the IBC Office. Arrange for these individuals to visit EOHS for medical surveillance for BBP material handling (i.e. [REDACTED] vaccine offer - Encounter form). In addition, one staff member (K [REDACTED]) has not completed the Biosafety training module. This is a one-time requirement. Please supply documentation of completion regarding these items also.
 3. Please clarify if the proposed work will involve extraction of nucleic acids from these viruses. If so, please indicate how the extractions will be performed (Trizol, equivalent, or other) and if the viruses' will be destroyed in the process.

vii. P [REDACTED] 05-10-02

PI: [REDACTED] P [REDACTED]

Title: [REDACTED] RNA Encapsidation

Agent: [REDACTED] virus, [REDACTED] strain [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Marco Bisoffi

- The IBC members discussed the protocol and the protocol was approved contingent upon satisfaction of the following:
 1. The protocol application has both BSL 3 and BSL2 agents listed on it. Please exclude those agents that will be handled at BSL2 (DNA subclones of [REDACTED] virus & DNA subclones of [REDACTED] virus) from this submission. These agents are not considered Select Agents and may be handled in BSL2 facilities. Instead add these agents to P [REDACTED] 05-10-

01 (above) and reserve this application for only BSL3 work with the [REDACTED] virus [REDACTED] strain [REDACTED] at BSL 3.

2. Addendum C section II 13 was left blank. Please indicate these agents are "not classified" in this box.
3. Your protocol abstract indicated that Hela and Vero cell cultures will be handled. These materials require compliance with the OSHA Blood borne Pathogen Standard. Please ensure BBP training and medical surveillance of all working with these materials has been completed. Then ensure Addendum F and required documentation of completion is forwarded to the IBC Office.

viii. Y [REDACTED] 05-10-01

PI: [REDACTED] Y [REDACTED]

Title: Clinical Virology Research and Development

Agent: Human clinical material; [REDACTED] virus [REDACTED] & [REDACTED] ([REDACTED] & [REDACTED]); [REDACTED]; [REDACTED] types [REDACTED] & [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Susan Kellie

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following:
 1. Documentation of Dr. Y [REDACTED] completion of Biosafety and Infectious Waste training is supplied to the IBC Office. Visit <http://shea.unm.edu/modules.html> for on-line training modules.
 2. Provide documentation to the IBC Office that [REDACTED] handlers are offered this year's [REDACTED] vaccine before beginning work. If work with these materials will extend into next year, a booster vaccination should be considered after six months.
 3. On page 9, under III-1 of your submission, change "Yes" to "No" because there is no current FDA approved vaccine for [REDACTED]. The one available is for investigational use only.
 4. Clarify the methods for safe transport of infectious materials thru UNM hallways and safe ground transport from [REDACTED] labs to UNM facilities. Please consult the Biosafety Officer (272-8001) for applicable transport regulations and guidelines. Supply transport SOP to the IBC Office.

5) Notifications/Annual Reviews & Significant Modifications

vii. Annual Reviews

B [REDACTED] 02-01-01

PI: [REDACTED] B [REDACTED]

Title: AhR and Non-AhR Mechanisms of Human Mammary Epithelial Cell Growth Regulation by [REDACTED]

Agent: BBP material, human cells MCF 10A, plasmid propagated in [REDACTED]

B [REDACTED] 02-12-01

PI: **B** [REDACTED]

Title: Development of Flow-Cytometry NK Assays for Rhesus Monkey Blood
LRRI Protocol FY03-005

Agent: Rhesus monkey leukocytes

Dr. **B** [REDACTED] has submitted an annual review changing the agent storage area.

C [REDACTED] 04-10-01

PI: **C** [REDACTED]

Title: Inhibition of HIV infection using antibodies against CCR5

Agent: [REDACTED] Virus 1 ([REDACTED]); [REDACTED] Virus ([REDACTED])

Dr. **C** [REDACTED] has submitted an annual review with no significant modifications made in the last year.

D [REDACTED] 02-07-01

PI: **D** [REDACTED]

Title: Pre-Clinical Animal Models in Endometrial Cancer

Agent: [REDACTED] and human material

Dr. **D** [REDACTED] has submitted an annual review changing the agent storage areas.

H [REDACTED] 03-07-01

PI: **H** [REDACTED]

Title: Diagnosis and Pathogenesis of [REDACTED] [REDACTED]

Agent: [REDACTED]; [REDACTED]

Dr. **H** [REDACTED] has submitted an annual review adding new personnel to the protocol.

H [REDACTED] 03-03-01

PI: **H** [REDACTED]

Title: Signaling Molecules in Epithelial Cancers

Agent: [REDACTED]; [REDACTED], [REDACTED], stratagene

Dr. **H** [REDACTED] has submitted an annual review with no significant modifications made in the last year.

L [REDACTED] 04-01-01

PI: **L** [REDACTED]

Title: Open-label, Randomized, Study to Compare the Effectiveness and Safety of Intratumoral Administration in [REDACTED] in combination with Chemotherapy vs Chemotherapy Alone in patients with Recurrent Unresectable Squamous Cell Carcinoma of the Head and Neck

Agent: [REDACTED];

Dr. **L** [REDACTED] has submitted an annual review with no significant modifications made in the last year.

L [REDACTED] 04-07-01

PI: L [REDACTED]

Title: Dendritic Cell Regulation of Pulmonary Immunity

Agent: [REDACTED], Strain ATCC [REDACTED], [REDACTED]

Dr. L [REDACTED] has submitted an annual review changing agent handling and storage areas and adding new personnel to the protocol.

L [REDACTED] 02-06-01

PI: L [REDACTED]

Title: Biology of [REDACTED]-Snail Association

Agent: [REDACTED], [REDACTED], [REDACTED]

Dr. L [REDACTED] has submitted an annual review with no significant modifications within the last year.

L [REDACTED] 02-06-02

PI: L [REDACTED]

Title: Evolution and Biogeography of [REDACTED] and its Molluscan Hosts

Agent: [REDACTED], [REDACTED], [REDACTED]

Dr. L [REDACTED] has submitted an annual review with no significant modifications within the last year.

L [REDACTED] 03-07-01

PI: L [REDACTED]

Title: Parasitic infection by [REDACTED] in Deer mice, and its effects on host reproductive allocation

Agent: [REDACTED], [REDACTED], [REDACTED]

Dr. L [REDACTED] has submitted an annual review with no significant modifications within the last year.

N [REDACTED] 02-12-01

PI: N [REDACTED]

Title: Regulation of Myb Activity

Agent: [REDACTED] vector, [REDACTED] Vector, [REDACTED]

Dr. N [REDACTED] has submitted an annual review with no significant modifications within the last year.

O [REDACTED] 02-03-01

PI: O [REDACTED]

Title: Investigations of Heat Shock Proteins in the Life Cycles of [REDACTED]

Agent: [REDACTED] type [REDACTED]; Human [REDACTED] ([REDACTED])

Dr. O [REDACTED] has submitted an annual review adding a graduate student.

S [REDACTED] 03-10-01

PI: S [REDACTED]

Title: Isolation of patient lung cells and culture of patient's allogeneic peripheral blood cells
Agent: BBP material, human lung, human blood

Dr. S [REDACTED] has submitted an annual review changing the agent handling and storage areas.

S [REDACTED] 01-01-01

PI: [REDACTED] S [REDACTED]

Title: Roles of Breast Cancer Genes in DNA Homologous Recombination and Cellular Sensitivity to Anti-Cancer Drugs

Agent: [REDACTED], Mammalian cells, rDNA

Dr. S [REDACTED] has submitted an annual review with no significant modifications within the last year.

W [REDACTED] 03-07-01

PI: [REDACTED] W [REDACTED]

Title: Regulation of Neurotransmission and Behavior

Agent: [REDACTED]; human cells

Dr. W [REDACTED] has submitted an annual review adding new personnel.

Z [REDACTED] 04-01-01

PI: [REDACTED] Z [REDACTED]

Title: Identification factors that regulate neural stem proliferation and differentiation in vitro

Agent: BBP material, Human 293T cells, [REDACTED] vector, [REDACTED], Mice SWISS 3T3 Cells, Mice neural cells

Dr. Z [REDACTED] has submitted an annual review with no significant modifications in the last year.

viii. The following protocols have expired and have been closed.

A [REDACTED] 01-01-01 Terminate per PI

Demonstration that an mRNA Binding Protein is Responsible for [REDACTED] mRNA Destabilization (DoD/Army Breast Cancer Research Program Concept Grant (# [REDACTED]))

H [REDACTED] 01-08-01 Terminate per PI

Pathogens of [REDACTED] and Other Biosafety Level 3 Viruses

L [REDACTED] 03-03-01 Terminate per PI

[REDACTED] and Lung Dendritic Cell Interactions

M [REDACTED] 02-03-01 Terminate per PI

[REDACTED]—Heat Shock Protein Vectors and Use in Infection of [REDACTED]-Infected Cells

N [REDACTED] 00-08-01 Terminate per PI

Regulation of Myb Activity

V [REDACTED] 04-10-01 Terminated Administratively

GPCR Trafficking in Eukaryotic Cells,

ix. Significant Modifications

None

7) Standing Reports

a. Report of Biosafety Officer

1. The BSO reported that UNM's IBC has been officially registered by NIH.
2. On September 7, CDC said no further response was required regarding the 18 questions asked after the 4/25 inspection. We are officially approved for our select agent laboratory from CDC.
3. The BSO showed the committee the Biosafety Webpage and talked about some of the other things that eventually will be on the webpage.
4. InfoEd – The BSO discussed the future implementation of the InfoEd database with the committee. The system administrator from Library Informatics and the BSO will be going to Galveston to discuss InfoEd because they are in the process of implementing InfoEd. The IBC will be starting with the management module and she was not sure if or when we will implement the online submission process at UNM.
5. The Biosafety Specialist talked about the biological inventory database for the whole campus that he has been setting up. Last year he sent out a survey to all the investigators who have research labs asking them to list all the materials they possess. This database is used for the door postings and also for medical surveillance. He audited the IBC protocol database against the inventory database and discovered ten investigators that need to submit IBC protocols for their work. Five of those individuals have submitted new IBC protocols and five are still outstanding. He is hoping to get the five to submit protocols by the next meeting. He will send the IBC Chair a list of the investigators who need to submit protocols and the IBC Chair will contact them.
6. The committee discussed dropping Addendum F (blood borne pathogens). There is a need for a mechanism to capture all who are working with human blood or body fluids as well as non human primate materials for regulatory compliance monitoring. For management purposes we need to handle all human cells and all non-human primate material with blood borne pathogen precautions, regardless of IBC registrations (which only apply to research at UNM). Some users are not involved with research so an alternate method must be developed. Further discussions will take place and once the best approach is decided, the committee will be asked to endorse it.

b. Report of Safety (RSHEA)

1. Larry reported to the committee that Donna Smith sent her regret that she couldn't make today's meeting.

2. The training position has been posted and they hope to have someone to fill this position after the first of the year.

c. Report of Employee Occupational Health Services committee member – No Report

d. Select Agent Responsible Official (RO) – No report

8) Old Business - none

9) Adjourn 11:10

UNM Institutional Biosafety Committee (IBC)

MINUTES

January 18th, 2006

9:00 am – 11:00 PM

BMSB, Room B-85

Voting Members Present:

Rick Lyons, M.D., Department of Medicine, Co-Chair
Susan Kellie, M.D., HSC Epidemiology
Denece Kesler, M.D., Dept. of Occupational Health
Pascale Leonard, Ph.D., NM State Lab Supervisor Molecular Biology Section (Community Member)
Barbara Masten, Assistant Professor, HSC Pathology
Karen B. Mulloy, Assistant Professor, HSC Internal Medicine
Jac Nickoloff, HSC/Chair, Molecular Genetics & Microbiology
Judy Pointer, MS, CBSP, SM (AAM), UNM Biosafety Officer
Ann Powell, Office of Research Services
Graham Timmins, Ph.D., College of Pharmacy
James Wallace, Ph.D., Department of Neurosciences
Larry Watson, Manager, Risk, Environmental Affairs/Industrial Hygiene, RSHEA

Voting Members Absent:

Coenraad Adema, Ph.D., Biology Department
Oscar Bizzozero, Ph.D., Department of Cell Biology
Lynn Fondren, CIH, MS (Community Member)
Sonya Swing, Director, Animal Research Facility
Terry Yates, Vice President for Research & Economic Development

Visitors & Alternates present (Non-Voting Members)

Gary Cseko, HSC/Director Research Protections
Jo Ann Stringfield, Interim Senior Associate Counsel, Technology and Research Law
Tim Muller, Office of Research, Biosafety Compliance Specialist
Donna Smith, Director, Risk, Safety and Environmental Health, RSHEA
Leroy Garcia, IH, Risk, Environmental Affairs, Safety Heath, RSHEA

Quorum = 10 voting members, present = 12

1) **Call to Order:** Dr. Lyons chaired the meeting, and welcomed new members and visitors:

- Sophia M. Garcia, IBC Coordinator
- Sonya Swing (absent), Interim ARF Director/Veterinarian
- Jo Ann Stringfield, Representative for Legal Counsel
- Donna Smith, Director, Risk, Safety and Environmental Health, RSHEA
- Hand out Draft Risk Assessment survey – for IBC Committee review and comment

2) **Approval of last meeting minutes:** Minutes of the October 2005 IBC Meeting were approved, as written.

3) **Pending Protocols:** Brief discussions took place regarding October 2005 IBC Meeting

v. B [REDACTED] 05-10-01

PI: [REDACTED] B [REDACTED]

Title: Expression of cancer progression protein markers using [REDACTED] vectors

Agent: Rep-def [REDACTED] vectors, human cancer primary and established cell lines

BSL proposed: BSL2

Primary Reviewer: Karen Mulloy

- The Co-Chair, Dr. Lyons, reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol is approved at **BSL2**.

vi. B [REDACTED] 05-10-01

PI: [REDACTED] B [REDACTED]

Title: Attenuated [REDACTED] as [REDACTED] vaccine vectors

Agent: Attenuated [REDACTED] vectors ([REDACTED]) Strain: [REDACTED]

[REDACTED]

BSL proposed: BSL2

Primary Reviewer: Rick Lyons

- The Co-Chair, Dr. Lyons, reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol is approved at **BSL2**.

vii. L [REDACTED] 05-10-01

PI: [REDACTED] L [REDACTED]

Title: Effect of [REDACTED] on pulmonary dendritic cells

Agent: [REDACTED] Strain: [REDACTED] ([REDACTED]) vaccine strain

BSL proposed: BSL2

Primary Reviewer: Denece Kesler

- The Co-Chair, Dr. Yates, reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol is approved at **BSL2**.

viii. L [REDACTED] 05-10-01

PI: [REDACTED] L [REDACTED]

Title: BSL2 procedures utilized in L [REDACTED] lab for working with BSL2 pathogens

Agent: [REDACTED], [REDACTED] mouse adapted; [REDACTED] virus, [REDACTED]; [REDACTED], [REDACTED] virus, [REDACTED] strains & mutants; [REDACTED], [REDACTED], [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Judy Pointer

- The Co-Chair, Dr. Yates, reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol is approved at **BSL2**.

ix. L [REDACTED] 05-10-02

PI: [REDACTED]

Title: BSL3 procedures

Agent: [REDACTED], [REDACTED], [REDACTED], [REDACTED]; [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED]

_____, strains: _____;

BSL proposed: BSL3

Primary Reviewer: Judy Pointer

- The Co-Chair, Dr. Yates, reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol is approved at **BSL3**.

vi. P [REDACTED] 05-10-01

PI: [REDACTED] P [REDACTED]

Title: [REDACTED] and [REDACTED] RNA encapsidation and VLP Formation

Agent: [REDACTED] type [REDACTED], strain [REDACTED]; [REDACTED] type [REDACTED]; [REDACTED] [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Marco Bisoffi

- The Co-Chair, Dr. Lyons, reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol is approved at **BSL2**.

vii. P [REDACTED] 05-10-02

PI: [REDACTED] P [REDACTED]

Title: RNA Encapsidation

Agent: [REDACTED] virus, [REDACTED] strain [REDACTED]

BSL proposed: BSL3

Primary Reviewer: Marco Bisoffi

- The Co-Chair, Dr. Lyons, reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol is approved at **BSL3**.

viii.Y 05-10-01

PI: [REDACTED] Y [REDACTED]

Title: Clinical Virology Research and Development

Agent: Human clinical material; [REDACTED] virus Types [REDACTED] & [REDACTED] ([REDACTED] & [REDACTED]); [REDACTED]; [REDACTED] types [REDACTED] & B

BSL proposed: BSL2

Primary Reviewer: Susan Kellie

- The Co-Chair, Dr. Lyons, reviewed the PI's response to the contingencies set forth by the IBC and concluded that the PI has satisfactorily met all contingencies; the protocol is approved at **BSL2**.

4) New Protocols For Review

x. M [REDACTED] 06-01-01

PI: [REDACTED] M [REDACTED]

Title: Association Between Mortality, Patient Risk Factors and [REDACTED] Strain Virulence

Agent: [REDACTED], [REDACTED], [REDACTED], and [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Susan Kellie

- The IBC members discussed the protocol, and the protocol was tabled. The information provided in the protocol needs additional information, as listed below. The PI must submit the information prior to the April 19, 2006, IBC Committee Review:
 1. In the Abstract, supply a brief description of the actual experimental procedures, and what each procedure's associated risks are.
 2. In the Abstract, specify how virulence is being measured; whether other cell lines will be used.
 3. In the Abstract, specifically state if [REDACTED] strain [REDACTED] is to be used. All strains of [REDACTED] may colonize healthy hosts and could cause infection in lab personnel or their contacts. If [REDACTED] strain [REDACTED] or [REDACTED] is being used, this should be reflected in the risk assessment, as these strains are associated with high risks of infection after colonization.
 4. In the Abstract, clarify the use of a chemical fume hood, and add to Section II, Facility. Also, in Section III, Occupational Health, list Questions 5 and 6 as 'No'
 5. In Addendum D, specify where the cultures are coming from – archived or clinical specimens.
 6. In Addendum D, describe the risk of the three different organisms; differentially done by supplying an Addendum D for each organism. Also, list Occupational Health, Section III, Questions 5 and 6 as "No" on each.
 7. Arrange, through the Biosafety Office, a training session to include all protocol personnel, emphasizing glove use, alcohol hand hygiene; and specific agent risks at BSL2 precautionary level. The training session should include education on the mechanism and risks of colonization with [REDACTED].

ii. G [REDACTED] 06-01-01

PI: [REDACTED] G [REDACTED]

Title: Innate Immunity and Bacterial Quorum Sensing

Agent: [REDACTED] (clinical isolate)

BSL proposed: BSL2

Primary Reviewer: Karen Mulloy

- The IBC members discussed the protocol and the protocol was approved contingent on satisfaction of the following:
 1. Provide summary description of the post-exposure acquisition and handling of tissue
 2. Please cite reference in Addendum D, Section I, # 4b

iii. D [REDACTED] 06-01-01

PI: [REDACTED] I. D [REDACTED]

Title: Mechanism of [REDACTED] phagosome maturation arrest

Agent: [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Barbara Masten

- The IBC members discussed the protocol, and the protocol was *approved contingent* on satisfaction of the following:
 1. In the Abstract, provide a statement assuring the electroporation (transformation) procedures will be conducted inside a bio-cabinet/hood, to avoid arcing.
 2. Correct Addendum C, Section I; Questions 5-7—by checking appropriate boxes.
 3. Correct Addendum C, Section II 6, by indicating the [REDACTED] can infect human cells, by checking appropriate box.
 4. Correct Addendum D, Section III, Occupational Health, Questions 5 & 6, by indicating regular ppd tests will be performed by checking “yes” for #5 and “yes” for #6.

iv. G [REDACTED] 06-01-01

PI: [REDACTED] G [REDACTED]

Title: [REDACTED] Type: Reactivation Studies

Agent: [REDACTED] or [REDACTED]; Strain: [REDACTED], [REDACTED], [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Pascale Leonard

- The IBC members discussed the protocol, and the protocol was approved contingent on satisfaction of the following:
 - Provide more information about the work done with the infected mice and the hazards associated with this work. How are the mice used; are tissues/fluids harvested, or are lesions tested? Are post-infected mice tissue/fluids centrifuged or homogenized. Are post-infection procedures conducted in a Biological Safety Cabinet?
 - Complete Addendum F – because this work involves handling of NHP (Vero) cells.

v. W [REDACTED] 06-01-01

PI: [REDACTED] N [REDACTED]

Title: Membrane Trafficking and Cell Adhesion

Agents:

[REDACTED] viral vector – BSL2

[REDACTED] viral vector ([REDACTED]) – BSL2

[REDACTED] – [REDACTED] - exempt

Primary and established human kidney cells – BSL2

Gene Inserts: [REDACTED], [REDACTED], [REDACTED], [REDACTED]; and [REDACTED]

BSL proposed: BSL2

Primary Reviewer: Jac Nickoloff

- The IBC members discussed the protocol, and the protocol was *approved contingent* on satisfaction of the following:
 1. Correct Addendum C ([REDACTED]), Section IV, 3l. Indicate “yes” for virulence factor.
 2. Submit Addendum F, Section II, 3c – supply documentation (encounter form) to the IBC Office, for [REDACTED] C [REDACTED]
 3. Correct Application item V – check “no” to microorganisms.
 4. Document that the following personnel visit EOHS for [REDACTED] vaccine offer, and vaccine counseling – and provide to the IBC Office:
 - i. [REDACTED] W [REDACTED]
 - ii. [REDACTED] R [REDACTED]
 - iii. [REDACTED] C [REDACTED]

5) **Notifications/Annual Reviews & Significant Modifications** - none

6) **Standing Reports**

A. Report of Biosafety Officer:

A presentation was given on a *Biosafety Compliance Risk Survey for Biomedical/Biological Research Employees & Students*. A draft of a survey, previously used at another institute, was introduced. The BSO wants to know how UNM employees and students currently feel about the risks they must take and whether they are being addressed by the administration adequately. She thought that a once a year survey could be used as a biosafety performance tracking method to accomplish that. The IBC Committee gave feedback about how to improve the survey, and believed that going forward with it would improve the biosafety culture at UNM.

The Co-Chair then led a more general discussion on ways of enhancing safety awareness at UNM. The members discussed their thoughts. Key points were that the committee supported initial hands-on biosafety training for front-line (at the bench) students and employees, especially emphasizing prudent lab techniques and practices. They thought that consideration should be given to offering a course (at the graduate or undergraduate level) that specifically addressed lab operations, and the ethical considerations of conducting biomedical research. Also it was recommended that the Biosafety Officer travel department to department and present a short training session to PIs about how to conduct risk assessments of their research protocols and their biosafety regulatory obligations, including the need to monitor their staffs' biosafety compliance. It was felt that these two approaches together would enhance both bottom-up and top-down awareness of biosafety issues.

B. Report of Safety (RSHEA) committee member

1. Learning Central information. Can now set up on-line lesson plans per individual, which are offered
Employees can view own records, not others. Their listed supervisors can view their employees' training transcripts. Biosafety office staff can view all employees' training transcripts records.
2. Larry Watson stated RSHEA is ready to make a selection for a training position – should have employee on-board shortly.

C. Report of Employee Occupational Health Services committee member – None

D. Select Agent Responsible Official - None

E. Ad hoc committee report, if applicable - None

F. Other

7) Old Business

- Update: Outstanding IBC Submissions: Biosafety Officer stated that every PI that has a BSL Level 2 lab, now has an IBC protocol on file
- Update: Use of Addendum F for BBP Work: Biosafety Officer and Occupational Health Director have met, and are continuing to work on this.

8) New Business – None

9) Adjourn: Meeting was adjourned at 11:00 am