ENVIROMENTAL HEALTH & SAFETY

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April 3, 2006

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

Dear Edward Hammond,

Per your request, enclosed find the record of NMSU IBC meeting minutes for the period May 1 2003 to the present as specified in your facsimile request of 15 March 2006. Also enclosed is a copy of the NMSU IBC Operating Charter.

At this time, we respectfully decline to respond to your query regarding the National Academy report on *"Biotechnology Research in an Age of Terrorism"*.

Please feel free to contact me by phone at 505-646-4463 or via email at jbalog@nmsu.edu with questions or for clarification of content.

Sincerely,

John T. Balog
Biosafety Manager

Enclosures (7)

NEW MEXICO STATE UNIVERSITY (NMSU)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) OPERATING CHARTER

GENERAL CHARGE

The New Mexico State University (NMSU) Institutional Biosafety Committee (IBC) reviews all institutional activities involving the use of **Biohazardous Agents** and **Recombinant DNA Molecules** that require approval for "biosafety activities" as described by current governmental agencies. These regulatory agencies include but are not limited to:

- Health & Human Services (HHS) Center for Disease Control (CDC) http://www.cdc.gov/od/ohs/biosfty/biosfty.htm
- United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) http://www.aphis.usda.gov/
- United States Department of Agriculture (USDA) Occupational Safety and Health Administration (OSHA) regulations and compliance directives as adopted and adhered to by the New Mexico Occupational Health and Safety Bureau (NMOSHB). http://www.nmenv.state.nm.us/OHSB_website/ohsb_home.htm
- National Institutes of Health (NIH) Recombinant DNA Guidelines (Guidelines) NIH Guidelines April 2002

In recognition of the large amount of information on biohazardous agents, recombinant DNA technologies and changing regulatory environment, the IBC requires the support of the Biosafety Officer and may need additional specialists for technical consultation. As health risks, new technologies and new regulations emerge, the NMSU IBC Operating Charter will be revised accordingly.

DEFINITIONS

Biohazardous Agents:

- Any microorganism (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance that is capable of causing: **1.** death, disease or other biological malfunction in a human, an animal, a plant or another living organism; **2.** deterioration of food, water, equipment, supplies, or materials of any kind; or **3.** a deleterious alteration of the environment.
- Any toxic material or product of plants, animals, microorganisms (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule (whatever the origin and method of production), which includes any poisonous substance or biological product that: **1.** may be engineered as a result of biotechnology; **2.** produced by a living organism; or **3.** is an isomer or biological product, homologue, or derivative of such a substance.
- Infectious or pathogenic biological agent defined by: **1.** CDC as biosafety level (BSL) 2-4 (BMBL 4th Edition), or **2.** NIH as risk group (RG) 2-4 agent (NIH Guidelines April 2002) (also see Additional Definitions on page 5 of this Charter document).
- Regulated biological agent or toxin as identified by 1. HHS 42 Code of Federal Regulations (CFR) Part 73 (Select Agents Program); **2.** USDA-APHIS lists of Biological Agents and Toxins that pose a severe threat to "animal health or animal products" (9 CFR Part 121); or to "plants health or plant products" (7 CFR Part 331) (Federal Register 9CFR 121 7CFR 331). Also see the NACUA Agent and Toxin List as compiled by the National Association of College and University Attorneys (NACUA), as a summary of all of the lists.

Recombinant DNA Molecules:

- Nucleic acid molecules constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can be replicated in a living cell.
- DNA molecules that result from the replication of those molecules described above.

IBC RESPONSIBILITES AND SCOPE

- The IBC is responsible for reviewing all NMSU-IBC application forms submitted by research investigators and their laboratory staff members, teaching faculty, and visiting scientists (collectively defined as PI for Principal Investigator) whose activities involve:
  1. any biohazardous agent as defined above which can cause disease in humans
  2. any biohazardous agent which will be introduced into any animal
  3. any non-exempt recombinant DNA molecules (Exempt experiments are defined by NIH Guidelines Section III-F) (NIH Guidelines April 2002)
  4. any large scale production of viable organisms containing recombinant DNA, or with the potential to produce toxic or hazardous substances (as defined by NIH Guidelines Section III-D-6 and Appendix K). (NIH Guidelines April 2002)
  5. any possession, use, or transfer of HHS Select Agents and Toxins (42 CFR Part 73) (Select Agents Program), or USDA Biological Agents & Toxins (9 CFR Part 121) or listed Plant Pathogens (7 CFR Part 331) (Federal Register 9CFR 121 7CFR 331)

- The IBC will ensure that to the fullest extent practical, that all risks to the health, safety, and well being of laboratory employees, the public, and the environment regarding the use of biohazardous agents, non-exempt recombinant DNA molecules, and large-scale production of recombinant DNA molecules, will be minimized.

- The IBC recommends policies to guide PIs, the University Biosafety Officer (BSO) and Environmental Health & Safety (EH&S) in the administration of NMSU's Biosafety Program with regard to the acquisition, use, transfer, storage, disinfection, disposal of agents, and emergency response procedures for all biosafety activities. The IBC shall ensure that such activities meet standards of good practice consistent with safety of personnel, the general public, and the environment in ways that best facilitate relevant research or teaching activities at NMSU.

- The IBC is vested with the authority to comprehensively review, and approve research applications with or without modifications, or withhold approval of all or any part of an application with regard to biological aspects of the research or activity. The IBC may make recommendations for corrective action on protocols.

- If a BSO review of a suspected or alleged violation of any University policy or external regulation that involves "biosafety activities" indicates that the violation is of a serious or continuing nature, the BSO will report such to the IBC. The IBC holds the authority to suspend any project in which serious or continuing violations have been reported. The IBC will notify the affected PI(s) and will proactively interact with the PI to rectify the situation. If further action is needed, the IBC will inform the Vice Provost for Research.

- Upon request, the IBC shall review and comment on proposed biosafety regulations, including but not limited to federal, state, and local policies. When appropriate, the IBC will formulate draft policies and procedures for approval by the Vice Provost for Research and other institutional officials as needed.

- The IBC shall periodically review the effectiveness of the Biosafety Program and make recommendations for improvements.

- The IBC shall ensure that "Biosafety activities that fall within the responsibility and scope of the IBC" which are official NMSU business conducted by an NMSU employee at a non-NMSU facility have been approved by the non-NMSU facility and adhere to the NMSU biosafety requirements.

IBC APPOINTMENTS and COMPOSITION

- The IBC is appointed by the Vice Provost for Research upon recommendation from but not limited to the Director of EH&S and the IBC Chair.
- The IBC Chair is appointed by the Vice Provost for Research and serves as the link between the Office of the Vice Provost and the IBC.
- A Vice Chair should be appointed to conduct business in the absence of the Chair, or in place of the Chair if and when the Chair has an application before the committee.
- The composition of the IBC should include at least 8 NMSU members and 2 community members that are not affiliated with NMSU.
  1. Individuals, either associated with NMSU or extra -institutional, with the following expertise and/or job duties may be appointed to the IBC:
     - recombinant DNA technology
     - molecular biology
     - biological safety
     - public health and epidemiology
     - virology
     - microbiology
     - infectious diseases
     - animal scientist
     - plant pathogen or plant pest containment principles
     - laboratory technician/non-doctoral
     - facilities management
  2. The community members should represent the interests of the surrounding community with respect to health and protection of the environment and should be knowledgeable in the basic principals of microbiology and recombinant DNA technology, or capable of assimilating these principles within the context of their applicability to the surrounding community and the general public. Individuals with the following expertise and/or job descriptions should be considered:
     - officials of state or local public health or environmental protection agencies
     - persons involved in medical, occupational health or environmental concerns in the community
- The IBC may also include ex-officio non-voting members who may be invited to serve when their expertise is required and can supplement the deliberations of the IBC. These members shall include but not be limited to additional representatives, usually administrative, of the following departments: Environmental Health & Safety, Employee Health Services, Research Administration, University Council, Office of Facilities and Services and/or Planning Design and Construction, and biosafety expert consultants external to NMSU. All other members of the IBC appointed by the Vice Provost for Research will be voting members.

TERMS OF SERVICE

- The term of membership on the IBC is a 12 month renewable period. In general, members will serve 2-3 years. The IBC Chair and the Director of EH&S will make a recommendation for renewal of membership on the committee to the Vice Provost for Research.
- The IBC Chair is a continuous appointment by the Vice Provost for Research, with an annual confirmation from the committee to the Vice Provost for Research.
- The BSO is a continuous position appointment. The BSO is a professional position which reports to the EH&S Director.

IBC GUIDELINES AND PROTOCOL REVIEW PROCEDURES

- The IBC shall meet quarterly or as needed to ensure timely review of applications.
- All biosafety application/registration forms shall be available for review by any member of the IBC. The BSO shall maintain records of research application reviews, minutes of IBC meetings, including records of attendance and IBC deliberations.
- If requested, the minutes of meetings are available to the public under the open records law.
- Applications submitted by PIs for work that falls within the IBC responsibility and scope must be reviewed and approved by the IBC prior to the initiation of that work.
- Approval for biosafety activities is granted for three years after the **initial review** by the IBC, and is contingent upon the ***affirmative*** vote of the majority of a quorum. (The quorum for the NMSU IBC is defined under Additional Definitions on page 5 of this Charter document).
- An activity modification report must be submitted by the PI to the IBC if and when the project changes significantly in terms of experimental activities, facilities; or for any personnel change, during the approval period. If the PI on a project changes, a new application form must be submitted to the IBC.
- The BSO will conduct annual inspections of facilities of approved projects, and initial inspections of facilities of new projects, and report to the IBC.
- The following guidelines are established to aid the IBC in the exercise of its responsibilities:

1. **Biohazardous Agents**
   - Research applications involving RG 1 and/or BSL 1 materials that do not involve recombinant DNA, **do not** require review by the IBC.
   - Dictated by the lack of facilities at NMSU, research using any RG 4 agents or any materials that require BSL 4 containment will not be considered by the IBC for work at any NMSU location or facility.
2. **Toxins**
   - The routine use of most toxins will not require IBC review and approval. However, the possession, use, or transfer of any toxin which is included in 1. HHS Select Agents and Toxins (42 CFR Part 73) (Select Agents Program), 2. the USDA-APHIS Biological Agents and Toxins - severe threat to animal health or animal products list (9 CFR Part 121), or 3. USDA-APHIS Biological Agents and Toxins -severe threat to plants health or plant products list (7 CFR Part 331) (Federal Register 9CFR 121 7CFR 331), will require IBC review and approval prior to initiation of the project. The BSO will notify the IBC if any experiments involve the isolation and production of toxins included in the aforementioned CFRs.
3. **Recombinant DNA**
   - Projects using recombinant DNA (that are not exempt) require IBC review and approval before initiation.
   - Experiments described as "Exempt" in Section III-F of the NIH Guidelines (NIH Guidelines April 2002) do not require IBC review and approval – but will require registration via the IBC application/ registration form for tracking and review by the BSO.
   - Planned release of any organism (e.g. transgenic plants, animals, bacteria) outside of the approved laboratory environment requires registration with the appropriate Federal regulatory agency and must be filed with the IBC.

REPORTING LINE AND ADMINISTRATIVE SUPPORT

- The IBC reports to the Vice Provost for Research at New Mexico State University. The BSO is the administrator of the IBC and is also responsible for the day-to-day operation of the Biosafety Program. The BSO reports to the Director of EH&S and provides the necessary administrative support for the functions and business of the IBC.

ADDITIONAL DEFINTIONS

- **Biosafety Level (BSL).** A description of the degree of physical containment to be employed for managing infectious materials in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents. The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community. The essential elements of the four biosafety levels defined by the CDC for activities involving infectious microorganisms and laboratory animals are summarized in **Sections III and IV** of the **Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Edition.** (BMBL 4th Edition)

- **Risk Groups (RG).** Agents are classified into four Risk Groups (RGs) according to their relative pathogenicity for healthy adult humans by the following criteria: (1) Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans, (2) Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available, (3) Risk Group 3 (RG3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available, (4) Risk Group 4 (RG4) agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. **NIH recombinant DNA Guidelines Section II-I-A, and Appendix B.** (NIH Guidelines April 2002)

- **Quorum for the NMSU IBC.** A quorum is defined as the number of members required to be present for business to be legally transacted. For the purpose of the NMSU IBC, a minimum quorum shall consist of the IBC Chair, the Biosafety Officer (BSO), a committee member representing the department or the research area of the proposed "biosafety activity", a committee member whose expertise is necessary to address all safety issues of the proposed "biosafety activity", and a committee member or members to meet the criteria of specific guidelines (such as the NIH Recombinant DNA Guidelines) when relevant.

MEETING OF THE NMSU-IBC
SKEEN HALL, ROOM 202
JULY 9, 2003

IN ATTENDANCE: Paul Jackson, Willis Fedio, John Kemp, Patti Havstad, Katrina Doolittle, Gloria Acosta, Manuela Quezada-Aragon, Luis Escobedo, Kevin Oshima

Guests: John Gustafson, Geoff Smith

I. Open. The meeting was called to order at 3:00 p.m.

II. Principal Investigator Interviews

WILLIS FEDIO

1. Clarification of procedures on project "Rapid Methods for the Detection of Pathogenic Microorganisms in Foods"

Dr. Willis: a second page of the procedure (that was previously submitted to the IBC) for "spiking" experiments was passed out. Dr. Willis stated that the spiking (*language amended 01-29-04 to state: "use of very low- inoculum levels of cultures*), can be on the bench top per BMBL practices, but are routinely carried out in a biosafety cabinet in his lab, primarily out of consideration of contamination of the cultures from outside agents.

Dr. Willis: disposal bags are not transported and are handled with caution. Will consider implementing Dr. Jackson's suggestion, but does not feel that it is necessary.

2. Posting of Safety Procedures (SOP's), and related issues

Dr. Willis: Students in the lab are working on organizing the laboratories SOPs so that they will be easily available to all lab workers.

Dr. Jackson: stated that MSDS's need to be read by everyone in the lab, not just made available.

The issue of medical treatment availability for students was brought up.

Dr. Doolittle: regarding the availability of medical attention for students should an accident occur, what are the resources and services available to students. How does individual medical insurance interplay with University student health services? Dr. Doolittle will work to clarify this with the Student Health Services

Dr. Jackson: suggested that emergency procedures in the case of a power failure or a fire should be included in SOPs

WILLIAM LOTT

1. **Clarification of time line and infectivity issues on project "Investigation of the HCV 5' Un-translated Region of the Hepatitis C Virus: Translational Control"**

Dr. Kemp: asked for a clarification of the projected start date for the project, which was indicated as "future" by the PI. It was agreed that the PI intends to initiate the project in the "near future" (6months – 1 year), but an exact start date is not known at this time. As such, the IBC focused the interview on committee concerns of the proposed project, including infectivity of the HCV to be used.

Dr. Lott: Explained that he planned to use fractions of the full-length cDNA for Hepatitis C virus (HCV) to produce proteins. The cDNA that he plans to use is not infective, therefore, does not require BL2 containment practices. Dr. Lott agreed to submit another

project form to the IBC if the project ever evolved to include BL2 level (infectious) HCV materials.

Dr. Oshima: asked for further clarification of experimental materials as regards the use of any wild type or clinical samples

Dr. Lott: Answer is no. The study is on regulation. How the translational switch is turned on in the ts5 RNA, called the "t-sense virus dilemma". Lott thinks that feedback shuts down translation and allows replication to start up. The theory is that this occurs at the start codon for translation. This involves mostly non-coding regions and approx 10 HVC amino acids.

A safety concern was voiced regarding the making of the viral proteins and possibility of human antibody response.

Dr. Lott explained that the only possible risk of this kind would be in a future proposal that involves a chimeric virus (BDVD) that would be used to create a plaque assay (relying on cytocytic property of one of the viruses in the chimeric). No human hosts would be used; plan is to use HELA cells in culture for the assay.

Risk elements of this proposed project were reviewed:
Acrylamide – pre-mixed will be used to minimize inhalation risks of toxic acrylamide
Radio- isotopes – may be used. PI has tried non-isotope assays, but is not happy with the results.
Infectivity – not an issue.\

Dr. Doolittle: asked Dr. Lott about the source of his emergency plan, as she would like to use Dr. Lott's submitted emergency plan as an example for other PIs. Dr. Lott responded that it was developed from a variety sources, and agreed that it could be used for distribution to other PIs.

GEOFF SMITH

1. Clarification of project "Detection of Bacterial Pathogens in the Rio Grande"
Dr. Smith: a BL2 project. A list of organisms involved in the project has been sent with an earlier submission to the IBC. For the last 5 years, as an Environmental Microbiologist, has been working on detection systems for enteric bacteria for agencies such as the EPA and FDA. The project co-PI is Dr. Kevin Oshima (Biology, NMSU).

Study focuses on survival of organisms in given environment. Development of new methods based on laser technology to identify pathogens. Involves detection of cell surface chemistry (ion specific) or cell surface physics (laser).
Currently, environmental samples are primarily from the Rio Grande. 10^{10}/L concentration is the high end. All concentrates are plated, so within 1-2 days the contents of the sample are "known".

Dr. Doolittle: asked if the physics lab used for laser analyses is aware of the biohazardous nature of the project.

Dr. Lott: They are aware. The only infective agent concern at this point is viable Salmonella. These samples are transported in cuvettes with parafilm covering.

Committee suggestion to Dr. Lott in regards to the Salmonella testing; consider using commercially available sealed cuvettes and provide the physics lab with a written operation procedure for handling of potentially infectious samples.

Dr. Lott: cuvettes are transported in a sealed or regulation transport container.

Dr. Jackson: concern- any manipulation of samples in physic lab. Strongly recommends that sealed cuvettes be used. Will consult with a colleague who did similar work regarding how samples were handled.

Dr. Lott: will look into the sealed cuvettes.

JOHN GUSTAFSON

1. Discussion of experimental procedure, with particular emphasis on routine USE OF GLOVES, on project "Antibiotic Resistance and House Cleaner Tolerance in *Staphylococcus aureus*".

Regarding the project: *S. aureus* is the top hospital infection, but is rare as a public disease due to implemented hygiene practices by public. It can infect every organ of the body. Infection is highly unlikely as long as an individual is immuno-competent and there are no breaks in the skin. Numerous types of treatment for infections are available. This research focuses on the antibiotic resistant strains of *S. aureus*, and generates nothing unique.

Regarding glove usage: The question is asked "**Are gloves required (mandatory)** for work in BL2 laboratories"?

Both Dr. Smith and Dr. Gustafson state that they do not routinely use gloves, instead they employ the standard procedure of hand washing and disinfecting pre and post handling of any potentially infectious agents that are used in their research projects. Dr. Oshima states that his lab routinely uses gloves and questions how effective a disinfectant is on bare hands.

Dr. Gustafson: states that it is his opinion that: routine glove use requirement is dependent upon the biological agent and at the discretion of the PI. It is his argument that many BL2 level workers tend to not be trained in proper use of gloves (so as to avoid potential of spreading agents with the gloves). Instead, workers are trained in the use of disinfectants.

Dr. Doolittle: there is no federal regulation for mandatory routine glove use in BL2 labs, BUT, it is highly recommended by the NMSU-IBC.

Dr. Gustafson: cites an article that compares gloved to non-gloved personnel in medical settings in both 1st and 3rd world countries. It was shown that those who routinely used gloves tended to practice considerably less overall hygiene.

The BMBL states that a "protective barrier" must be used in handling BL2 agents if there is the potential for "contact" with pathogenic agents.

A discussion on the definitions of "protective barrier" and "contact", from a legal point of view, ensued:

Dr. Gustafson: a glass beaker or tube is a protective barrier. What constitutes contact.

Dr. Doolittle /Dr. Kemp ask: Should the NMSU-IBC policy state that glove use, or some type of hand protection, is mandatory if there are cuts or abrasions on workers hands, and that gloves are always made available?

Dr. Escobedo: suggests that common sense and legalities must both be applied in addressing this issue.

Committee: Agree that it is necessary for the NMSU-IBC to definitively verify what the NIH Guidelines say about routine glove usage in BL2 labs. Is routine glove usage a PI discretionary SOP, based on procedures and pathogens used in a particular project/lab or is it mandatory?
Actions to be taken:
Dr. Oshima/Dr. Doolittle– will talk to the CDC about their policies on this issue
Dr. Fedio – will talk to PIs at the meetings that he is planning to attend, e.g. World Food Conference.
Ms. Havstad – will pose the issue to the web based Biosafety List serve.

The final "working" decision at this time is that the PI will determine what is potentially pathogenic in regards to the mandatory use of gloves. Dr. Smith has indicated that he will write glove usage into his SOPs and Dr. Gustafson indicates that he will reinforce his existing policy that gloves be worn when cleaning up spills.

2. Discussion of SOPs
Dr. Jackson: should screening of all workers in the lab be done to determine a base level of infectivity, and routinely done to determine if base level rises?

After consideration of legal and practical elements implicit in the implementation of a routine screening, the committee decided that Dr. Gustafson should not be required to do this, but, must advise all of his laboratory workers (including students) that, by working in his lab, they are likely to be colonized with antibiotic- resistant forms of *S. aureus*, which may be infective to others outside the laboratory. As such, they are to be advised to habitually exercise caution in the handling and potential spreading of these agents outside of the laboratory environment.
Dr. Gustafson was asked to insert a statement to this effect into his written SOPs.

Dr. Oshima: has agreed to allow his BL2 SOP checklist to be distributed to other PIs, and will forward copies to Drs. Lott and Gustafson. He further states that his standard procedure is to sit down with each new lab personnel and go through the BL2 check list point by point.

OTHER PI ISSUES CURRENTLY UNDER CONSIDERATION BY THE IBC

1. **Natalie Goldberg.** The issue is the certification of her biosafety cabinet. Dr. Kemp has informed her of the necessary steps that she must take via phone conversation, and she will follow suit.
2. **Dr. Wang (Chemistry).** His proposed project involves nanochip experiments with certain Select Agent Toxins. Drs. Kemp and Doolittle have reviewed the list of SA Toxins to be used in the project, and have determined that all toxins proposed for use in the project are in excluded quantities and not subject to Select Agent Program registration. The first 18 months of the project will be work with non-pathogens. Dr. Wang will need to submit a form to the IBC. This brought up the issue of whether or not the NMSU-IBC needs someone with toxin expertise on the committee or as an advisor. Dr. Mueller in Chemistry at NMSU was

suggested. Dr. Jackson indicated that he can recommend someone from LANL. Dr. Oshima suggests that we use colleagues of Dr. Wang at the DOE as toxin advisors. (*Post meeting note: Dr. Wang left NMSU in the spring of 2005 without obtaining toxins or beginning this research project.* jb 03-27-06)

III. Committee Discussion and Approval of Projects

DISCUSSION

Dr. Kemp: reminds the committee that the NIH is not a regulatory agency. It recommends. The University IBC is the regulatory agency for recombinant DNA and biosafety policies.

Dr. Doolittle: brings up the issue that at the present time, the NMSU IACUC does not have anything written into their policies regarding human health. The emphasis is entirely on the welfare of the experimental animals. Should the IBC approach the IACUC about incorporating human welfare issues into their policies? She suggests that PIs who send projects to the IACCUC for approval send copies to the IBC.

The issue of negative pressure requirement in BL2 laboratories was tabled

The issue of additional outside HEPA filters in the BL3 facility was tabled

APPROVAL OF PROJECTS

Dr. Kemp: made a formal motion to extend approval of the projects reviewed at today's meeting.

Dr. Jackson: strongly feels that approvals must be contingent upon resolving the mandatory- routine use of gloves in BL2 laboratories issue.

Dr. Doolittle: the approval date of April 15, 2003 stands. Suggests that a second approval date of July 9, 2003 be added to the form of each of the projects reviewed at today's meeting.

IV. Next meeting and Adjournment

NEXT MEETING

The next quarterly meeting should be scheduled to occur in November 2003, but may be postponed until a new biosafety officer is hired by the University.

ADJOURN

The meeting was adjourned at 5:35 p.m.

Initially submitted by Patti Havstad for IBC review and subsequently amended by the IBC. John Balog incorporated the amendments into this resulting version approved by vote of the IBC as reflected in the IBC meeting minutes of April 5, 2004.

New Mexico State University Institutional Biosafety Committee

Minutes for Meeting of January 29, 2004
Room 206 Skeen Hall

Members Present: John Kemp, Chair, Michael Bromwell, John Balog, Katrina Doolittle, Luis Escobedo, Willis Fedio, Paul Jackson, Kevin Oshima, Manuela Quezada-Aragon (*ex officio*),

Members Absent: P. Lammers, R. MacRorie

Guests: Graciella Unguez

The meeting was called to order at 3:02PM

IBC meeting minutes will be audiotape recorded, a written draft will be circulated for member review and acceptance for the permanent record will be voted at the next scheduled IBC meeting. J. Kemp stated the minutes of the July 9, 2003 IBC meeting were generated from J. Balog's review of audiotape recording of the meeting and a draft submitted by Patti Havstad.

Review of July Meeting Minutes:
The minutes were found to be fairly accurate but need amending to include mention W. Fedio's use of E. coli 0157:H7 at "very, very low inoculum levels on the bench", outside the biological safety cabinet. The 7 projects reviewed at the July meeting were initially reviewed in April and were approved for 3 months contingent upon IBC receipt of additional information. The second review of these projects confirmed receipt of the requested additional information which "filled in the gaps" of applications reviewed during the April meeting. W. Fedio recalled that Dr. Gustafson and Dr. Smith were visitors at the July meeting and minutes should reflect their attendance and comments. K. Doolittle noted that no formal vote was held on final approval of the 7 projects discussed at the July meeting. She further suggested that since all IBC questions and request for further information about the applications initially reviewed in April were resolved either before or at the July IBC meeting and no further issues were identified, the conditional approval granted at the April meeting be continued. J. Kemp agreed by stating that since the Committee was satisfied with the response from each PI the contingent approval granted on April 15 will be considered the final approval date of record. Glove use was the only outstanding issue with Dr. Gustafson's review.

L. Escobedo recalled disagreement between IBC & Dr. Gustafson on the risk assessment for an occupational exposure to *Staphylococcus*. J. Kemp agreed and stated we would discuss the differences later in the meeting under the Glove Use recommendation agenda item. P. Jackson commented that granting a 3-month conditional approval puts the University at risk should an untoward event occur in the interim, and he recommends against issuing such temporary approval. The IBC should ensure all concerns are addressed prior to granting approval to begin a project. Withholding approval to begin work until all issues are addressed would enhance the likelihood of prompt resolution, rather than permit outstanding issues to remain unsolved for 3 months. Each project reviewed often "gets conditions" after the initial committee review, but typically these are easily resolved, and usually cause no more than a minimum delay. Approval to begin work can be granted by Biosafety Office once the IBC-required documents are received from the PI. K. Doolittle said the temporary approval was necessary since the projects were pre-existing projects, and the PI s responded in good faith to comply with the existing IBC rules. At the time of the April meeting, the IBC mandate for oversight was expanded but the new process was not yet widely disseminated to the faculty. The temporary approval was determined to be a fair compromise. Since there was no motion to accept the July minutes, the minutes were tabled for revision to include the above cited information and will be distributed via email for IBC review. The minutes will be voted on at the April meeting.

Glove Use Policy

J. Balog stated that most IBCs discuss nuances of glove use. The debate on the need to wear gloves encompasses a number of issues such as the pathology related to the specific organism, the volume of culture, the assessment on the likelihood of exposure, training of PI & staff, and other issues. But gloves are routinely available in most, if not all laboratories. PI s and staff do wear gloves, yet may not be receptive to an edict to do so. The University, through the IBC is responsible for ensuring safe work practices are identified, implemented, and monitored. The IBC is responsible for establishing and advertising an appropriate glove-use policy to the University community and supporting the Biosafety Officer in enforcement of the glove use policy. Glove use protects hands from exposure to chemical and biological materials and enhances research quality by protecting research materials from potential contamination.

K. Oshima quoted the BMBL BLS-2 section, "manipulating infectious organisms requires use of protective gloves". When you are in the lab, but not manipulating infectious organisms, you don't have to wear gloves. We can implement our own interpretation, currently glove use is solely at the discretion of the PI. In the Oshima lab everyone wears gloves. This is his personal comfort level, but may not be the comfort level for other labs. That's not to say that this committee should not regulate glove use. J. Balog stated NIH Guidelines defer to local IBC authority in the matter of site-specific lab practices.

P. Jackson stated that NIH rDNA guidelines are incorporated by reference into a number of regulations and that means they (rDNA Guidelines, & BMBL) are effectively law. The Los Alamos National Lab (LANL) experience is that "gray areas" in policy tend to be exploited, and he urges the policy be as "black & white" as possible. Problems with safety compliance at LANL often involve students, graduate students and post-docs from universities, because "they don't get it" from the standpoint of following safe work practices.

J. Balog stated that NMSU graduates should be provided appropriate instruction on safe work practices and PPE as part of their education experience.

J. Kemp asked whether or not the use off gloves is a requirement for IBC approval? K. Oshima asked for clarification on "use of gloves" as "all the time or when handling potentially infectious materials"?

J. Kemp asked K. Doolittle about EH&S general lab inspections of Chemistry lab or Biology lab, "when do you expect gloves will be used"? K. Doolittle responded "when they're handling the materials, just like CDC BMBL says". When handling chemicals glove use is required as part of the NMSU Safety Program, the NM Radiation License provides Radiation Safety Committee with authority to require use of gloves. When you handle radioactive materials at NMSU, approval is contingent on use of gloves. J. Kemp stated there are different points in a project when you will use gloves, for instance when using ethidium bromide you'll wear gloves. K. Oshima would require use of gloves on entry into a laboratory because "who knows, the refrigerator door may be contaminated? He can see both sides of debate, but when you wear gloves, you get a false sense of security.

J. Kemp asked W. Fedio for his view. W. Fedio supports use of gloves. However his office is in the lab, and he can't do office work while wearing gloves, so there has to be general guidance on when to use gloves. W. Fedio encourages wearing gloves for mundane tasks (such as checking temperature of water bath) but would not be upset if someone did not wear gloves while doing so. K. Oshima stated that he doesn't want students to have to make the decision to wear gloves or not. He prefers to be conservative in his work practices, but is not comfortable in projecting this view on other laboratories however unless there is clear, widely understood advantages to do so.

J. Kemp asked P. Jackson for the LANL perspective. He responded whenever someone is handling an infectious organism at BSL-2 or DNA from the organism, glove use is required and there is no

option. He added that office space is prohibited from being incorporated in laboratory space to avoid potential conflict with safety policies.

J. Kemp asked L. Escobedo for his view on glove use as a mechanism for the safe handling of pathogens. L. Escobedo commented hospitals have strict policy on following Universal Precautions, the concept mandated by law, is widely accepted and practiced. There are differences in infectious dose among organisms. On a practical level clearly, "there are differences in the focus" on the safety of the community. There are "very young students involved with research" with varying levels of maturity, and not all students may appreciate the importance of following the safety rules. He feels it is prudent to err on the conservative side.

K. Doolittle stated that EH&S is responsible for training on the use of personal protective equipment (PPE) and proper use of gloves, including where not to use gloves. EH&S will not abandon training on proper use of PPE in general and glove use in particular. In review, J. Kemp stated there are certain instances during certain procedures, which involve handling certain compounds for which glove use is required campus-wide. In these cases, there is no discretion for the laboratory workers. K. Doolittle clarified that it is the supervisor's responsibility to ensure safe work practices are followed in the laboratory. This includes conducting a hazard assessment to determine appropriate PPE for the designated task. J. Kemp remarked that this statement appears to echo K. Oshima's previous remarks. K. Doolittle disagreed based on a previous discussion of a hazard assessment scenario which specifically excluded retrieval from storage or handling of a sealed flask or vial of potentially infectious organism from being considered a hazard. K. Doolittle stressed that it is the PI's responsibility to perform a hazard assessment for each experiment, which includes each task performed during the experiment. EH & S cannot be on-site at all times. She further stated that use of acids and corrosives are examples where the use of PPE is "self-evident". EH&S trains people that use of PPE is a requirement.

P. Jackson recommended that the use of gloves be "institutionalized" and that the IBC is empowered to do so.

J. Kemp summarized that gloves be worn at all times when a biological organism is being manipulated. If it is the policy of the University that the PI or person supervising a laboratory is responsible for safety, his question is "what does (will) the IBC require"?

P. Jackson stated that since work cannot be done without the approval of the IBC, the IBC can stipulate requirements for IBC approval. J. Kemp agreed and asked if that was the intention of the Committee. K. Oshima asked about current policy on glove use? K. Doolittle cited the BMBL Section III Laboratory Biosafety Level Criteria Part C item 4 (pp 25) *"Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Disposable gloves are not washed, re-used or used for touching "clean" surfaces (keyboards, telephones etc), and they should not be worn outside the lab. Alternatives to powdered latex gloves should be available. Hands are washed following removal of gloves."* K. Doolittle and K. Oshima agreed that retrieval of stored materials is considered a manipulation. L. Escobedo stated that "manipulation is an imprecise term". For example the outside of a vial may be contaminated from the time the vial was prepared, so retrieving a vial from storage involves a potential for exposure.

J. Kemp directed J. Balog to generate and distribute for IBC member comment a glove use policy statement. The recommended text follows: "Per the CDC/NIH/Public Health Service Publication, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL, 4th Edition), NMSU IBC applications approved for work at Biosafety Level 2 will require the use of gloves during the manipulation of viable organisms. *Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of*

when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Disposable gloves are not washed, re-used or used for touching "clean" surfaces (keyboards, telephones etc), and they should not be worn outside the lab. Alternatives to powdered latex gloves should be available. Hands are washed following removal of gloves." Potentially infectious materials means solid, semi-solid, liquid, or frozen cultures or DNA or rDNA viral constructs greater than 2/3 of a BSL-2 (and BSL-3) organism's genome. Manipulation means opening a refrigerator or freezer to obtain a culture, and activities related to propagation or expansion of the stock culture, concentration or purification of the culture by filtration or centrifugation, transfer and dilution of the culture by pipeting or decanting and up to and including the wipe down of potentially contaminated work surfaces and equipment" at the end of the experiment.

K. Doolittle stated that Dr. Geoff Smith and Dr. Gustafson requested to be informed of the final IBC policy.

Review of New Applications

1) Stephen F. Hanson, Assistant Professor of EPPWS submitted an application entitled: *"Mechanisms of Plant-Pathogen Interactions and Methods for Engineering Pathogen Resistant Plants".*

Dr. Hanson will work with several plant-pathogenic viruses and 2 bacterial phages. He will not work with more than 2/3 of the viral genomes, most DNA is much smaller than 2/3 of the genome. His research seeks to understand plant virus replication in host species and how to create "immunity" in common plants via incorporating viral DNA to produce a resistant plant. J. Kemp agrees that the proposed BSL-1 Plant containment is appropriate. (J. Kemp stated that when cloned into a vector, Geminivirus be virulent, however while this work is not proposed in the application it is covered in the USDA permit.) The USDA has issued a permit for this work. NM State Agricultural station approved as well. Dr. Hanson must provide information on training specifics, speciation of the viruses. Motion to approve contingent upon IBC receipt of information on staff training and the speciation of the Gemini viruses listed on the application and if any of the organisms are listed in the USDA High Consequence Livestock Pathogens and Toxins. Note: BSO review of organisms & toxins at the APHIS website (http://www.aphis.usda.gov/vs/ncie/pdf/agent_toxin_list.pdf) did not find any of Dr. Hanson's bacteria or viruses listed as High Consequence Livestock Pathogens & Toxins. Biosafety Office will contact Dr. Hanson with the IBC request for information. BSO and IBC Chair will review for completeness and inform Dr. Hanson of result.

The vote on the application:

For Approval: J. Balog, M. Bromwell, K. Doolittle, L. Escobedo, W. Fedio, P. Jackson, J. Kemp, K. Oshima
Against Approval: none
Abstention: none

2) Donald F. Caccamise, Professor & Academic Dept Head, Fishery and Wildlife Sciences submitted an application entitled; *West Nile Virus – Patterns in the Establishment and Maintenance of an Exotic Pathogen in an Arid Landscape.*

Dr. Caccamise's proposed research involves both field and laboratory components.

Field Components	Laboratory Components
1) trapping mosquitoes	1) separate the mosquitoes by species,
2) trapping resident and migratory birds (aggressive)	2) pooling the mosquito species
3) obtaining a blot of the bird's blood	3) PCR of the DNA for West Nile Virus
5) use of chickens (2) as sentinels (bait?)	

The occupational risks identified with the field component of this project include potential for exposure to arboviruses endemic to New Mexico, especially WNV, and the potential for a bloodborne

pathogen exposure when using sharps to obtain blood samples or manipulating the DNA.
K. Oshima stated that Dr. Caccamise's experience is with birds, not pathogens. He asked if birds are anesthetized. If not, how will birds be restrained? Will lancet or syringe be used? What PPE? J. Kemp: "our concern is how will you protect yourself in the field and in the lab?"
Dr. Caccamise does not have BSL-2 space and while Dr. Creamer has BSL-2 laboratory space, the IBC is not sure if sufficient space is available.
Other questions: How will chickens be used? One chicken will be used at each collection site, sheltered, fed and watered. What are the specific locations? (NMSU or non-NMSU property.)

The Committee did not feel sufficient information was available to review the application. It was agreed that future applications must be administratively reviewed for completeness. When necessary, the BSO is to meet with the Principal Investigator to review the content of the application, and do a risk assessment on the research. Incomplete applications are not to be distributed for review. Based on the projected start date of April/May 2004, the application was tabled to permit Biosafety consultation with the Dr. Caccamise and Dr. Creamer in revising the application and answering the questions brought forth at today's meeting. The application will be reviewed at the next meeting (April 5).

New Business

1) The 2nd Quarterly IBC meeting was scheduled for Monday April 5 at 2:00 PM.
The 3rd Quarterly IBC meeting was scheduled for Monday July 12 at 2:00 PM.
The 4th Quarterly IBC meeting was tentatively scheduled for Monday October 18 at 2:00 PM

2) J. Balog requested copy of curriculum vitae or biosketch from those who have yet to provide one. The NIH Office of Biotechnology Activities requires copy of IBC members as part of an entity's initial registration and for new members.

3) J. Balog presented a preview of Dr. Kathryn Hanley's application to work with Dengue virus (type 1 – 4) in non-biting mosquito vector. The summary is attached. The Committee expressed concern about the exposure control plan and post exposure treatment. P. Jackson stated that persons infected with one type of Dengue virus often recover, but the antibody response will not carry over to a subsequent infection from a different Dengue genotype. He believes a second event with a different genotype would be fatal.

There being no further business, the meeting adjourned at 5:03 PM

Submitted by John Balog and approved by vote of the IBC as reflected in the meeting minutes of June 30, 2005.

ENVIROMENTAL HEALTH & SAFETY

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March 12, 2004

Memorandum

To: NMSU Faculty, Staff & Students

From: John T. Balog, Program Manager,
Biosafety Officer, Environmental Health & Safety

c: John Kemp, Ph.D., Chair, NMSU Institutional Biosafety Committee

Subject: Glove Use Policy

It is the policy of the NMSU Institutional Biosafety Committee and EH&S that "Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Disposable gloves are not washed, reused, or used for touching "clean" surfaces (keyboards, telephones, etc.), and they should not be worn outside the lab. Alternatives to powdered latex gloves should be available. Hands are washed following removal of gloves". The previous is a direct quote from the U.S. Department of Health & Human Services publication Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, May 1999, pp 25.

The policy applies to laboratory and other research environments. The following is offered as interpretive guidance for the glove use policy. Contact with potentially infectious materials means physically obtaining vials, tubes and other containers of stocks, cultures, and other specimens of bacteria, mold, fungi, yeast, virus (plant and animal), viral constructs (plant and animal), toxins, animal, and human tissues, and materials derived from animal and human tissue (including human blood) in the laboratory or the environment (as in field procedures that present risks i.e., trapping mosquitoes or feral animals in the field). Gloves are to be worn during each step of an experimental procedure until the material is used up, decontaminated, or otherwise rendered biologically inactive and the procedure is completed. Gloves are not to be worn while handling doorknobs, telephones, or office equipment in the laboratory or outside of the laboratory or in areas of public access like elevator lobbies, lounges and offices. Each laboratory will designate common equipment and work areas or activities where gloves will always be worn and where gloves are prohibited from being worn. Each supervisor shall provide training on area-specific glove use.

Contact EH&S at 505.646.3327 with questions.

New Mexico State University Institutional Biosafety Committee

Minutes for Meeting of April 5, 2004
Room 102 Genesis Bldg. Unit B

Members Present:	John Kemp, Chair, Michael Bromwell (Unaffiliated member), John Balog, Katrina Doolittle, Luis Escobedo, Willis Fedio, Paul Jackson (Unaffiliated member), Pete Lammers, Kevin Oshima, Manuela Quezada-Aragon (*ex officio*),
Members Absent:	R. MacRorie
Guests:	Dr. Donald Caccamise, Dr. Rebecca Creamer

The meeting was called to order at 2:02PM

Review of July 9, 2003 Meeting Minutes:
P. Jackson initially requested modification of his comments on W. Fedio's project entitled "Rapid Methods for the Detection of Pathogenic Microorganisms" reflected in the minutes of July 9, 2003 meeting. Further discussion resulted in deletion of the comments. No further additions or corrections were noted. Motion to approve July 9, 2003 meeting minutes as amended (by J. Balog, L. Escobedo second) approved without further discussion.
NMSU IBC vote by show of hands to approve meeting minutes of July 9, 2003.

For Approval:	J. Balog, M. Bromwell, K. Doolittle, L. Escobedo, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against Approval:	none
Abstention:	none

Review of January 29, 2004 Meeting Minutes
Two typographical errors 1) the header incorrectly dated the meeting on January 29, 3003 instead of 2004 and 2) the date of the July 9 2003 meeting was incorrectly listed as July 19, 2003. No further additions or corrections were noted. Motion to approve the January 29, 2004 meeting minutes as amended (by J. Balog, W. Fedio second) approved without further discussion. NMSU IBC vote by show of hands to approve meeting minutes of January 29, 2004.

For Approval:	J. Balog, M. Bromwell, K. Doolittle, L. Escobedo, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against Approval:	none
Abstention:	none

Review of Quarterly Administrative Approvals (Table I)
J. Kemp reviewed the list and briefly described the process of granting administrative approval for field trials of genetically modified crops, BSL-1 w/o a recombinant DNA component, and materials not regulated by the IBC.
Discussion ensued on Dr. Wang's proposed use of toxins. J. Balog stated that Dr. Wang does not intend or anticipate the need to possess toxins in regulated quantities. As implied by the title of the project the goal is to detect minute quantities of each particular toxin. This means the stock toxins will be diluted from the 1 µg / ml concentration to the parts per million or parts per billion concentration. J. Balog distributed copy of CDC Select Agent Program FAQ on the interpretation of "excluded quantity" in terms of the regulations (http://www.cdc.gov/od/sap/faq.htm, #36, attached). The CDC FAQ states that... "the practical effect is exemption of excluded quantities" from the select agent regulations. J. Kemp remarked that beyond the Select Agent regulations, the IBC views toxins as a hazardous chemical under the jurisdiction of EH&S. K. Doolittle commented that EH&S does not monitor specific laboratory protocols. Ensuing discussion included comments that while review of toxin use in research is not a stipulated responsibility in the NMSU IBC Charter, it would not be unreasonable for the Committee to assume such responsibility. A poll of the committee in general, and N. Quezada-Aragon (representing the Office of the Vice Provost for Research) in particular

confirmed that there is no other standing NMSU committee charged with oversight of safety issues related to the use of toxins in research. P. Jackson remarked that exclusive of the regulations, toxin research is potentially hazardous and that the University is ultimately responsible for the consequences of any untoward event. He questioned whether the persons intending to handle the toxins had prior experience with toxins and whether or not a toxin expert (either in-house or consultant) is available to the University. (There is none.) His concern is based on the risk of handling toxins (prior to and during reconstitution of the powder) at a concentration representing multiple lethal doses of the toxin. J. Balog and L. Escobedo suggested that an outside consultant may not be available, and perhaps is not essential for this particular IBC application. However, the PI must spare no effort in accounting for safe work practices in handling toxins and provide this account to the IBC. L. Escobedo stressed the importance communicating the essence of IBC deliberations to the PI. The issue remains open for future discussion. The select agent toxin component of Dr. Wang's application remains pending.

The IBC accepted without comment Table #1, Summary of Administrative Approval of IBC Applications. The IBC accepted without comment Table #2, Activity Modification Report Summary. Activity modification reports will be attached to the PI's initial IBC-approved application. J. Balog noted the usefulness of these reports in discovering information on research material, an example is commercially available sheep blood used by Dr. Geoff Smith. His lab has purchased sheep blood for years and accepted the vendor's word that the product was "sterile". A phone call to the vendor revealed that a sterility test was not performed. The product was labeled as "sterile" and misled the users into believing there was no risk to using the product. The vendor stated they will discontinue the claim of sterility for the sheep blood. The Committee accepted Table I, Administrative Approvals and Table II Activity Modification Reports received this year to date. J. Kemp stated that Administrative approval is granted for applications at BSL-1 after a review of the proposed research compliance with EH&S program requirements are met. (*Note that program requirements are a laboratory survey, personnel training, and establishing or updating an on-line chemical inventory at the EH&S website.*)

Review of New Applications

1) Donald F. Caccamise & Rebecca Creamer (co-PI) entitled: "*West Nile Virus-Patterns in the Establishment and Maintenance of an Exotic Pathogen in an Arid Landscape*", (revised)

Dr. Caccamise initially submitted this application in November of 2003 and it was reviewed at the IBC meeting on January 29, 2004. The IBC tabled the application and instructed J. Balog to confer with Dr. Caccamise and Dr. Creamer on the revision of the application to include clarification on the scope of field research procedures, complete the requisite safety training and survey Dr. Creamer's BSL-2 laboratory. The lab was surveyed, and the Investigators were informed of the requirements to achieve safety and regulatory compliance.

Dr. Caccamise's proposed research involves both field and laboratory components.

Field Components	Laboratory Components
1) trapping mosquitoes	1) separate the mosquitoes by species,
2) trapping resident and migratory birds (aggressive)	2) pooling the mosquito species
3) obtaining a blot of the bird's blood	3) PCR of the DNA for West Nile Virus
5) use of chickens (2) as sentinels (essentially as bait)	

L. Escobedo provided primary review of the revised Application and a copy of his "IBC Outline Project Review" is attached. M. Bromwell provided secondary review for this application.

L. Escobedo recommended approval of the application. He commented that tips to reduce the risk of injury due to scratches and bites while handling and bleeding captured birds would be helpful. Also mentioned was the need to do post-injury and post-exposure follow up of affected employees. M. Bromwell indicated that if the persons working on the protocol were employees, Workers Compensation regulations have specific

record keeping requirements. L. Escobedo asked if it was possible to isolate offending birds for confirmatory testing in the event of a bite or scratch. Dr. Creamer responded that injured persons would be directed to the Employee Health Services for evaluation and that it was impractical to isolate each trapped bird until the potential for "downstream" exposures was eliminated or for post-exposure follow up. M. Bromwell commented that employees exposed or injured are covered by Workers Compensation regulations. J. Balog referred to the NMSU Bloodborne Pathogen training presentation (distributed to the IBC for review) that clearly states University policy on mandatory reporting of all occupational injuries, and includes contact information for the Student Health Center and the Employee Health Center. As a prevention measure Dr. Caccamise stated he will make insect repellant available to field personnel, but will not require its use since he believes the DEET-containing repellant presents a risk that may rival or exceed the potential consequences of an occupational arbovirus exposure. The certification of Dr. Creamer's biosafety cabinet is pending, and the HEPA filter replacement is delayed since the filters are on back order with the vendor. As secondary reviewer, M. Bromwell recommended approval. J. Kemp asked Dr. Caccamise to forward a brief addendum responding to L. Escobedo's recommendations. Dr. Creamer wasn't clear on item 3, safety procedures for bleeding birds. The ensuing discussion between L. Escobedo and Dr. Caccamise revealed that two persons usually handle trapped birds, and that placing a bag over the bird's head substantially reduced the anxiety level, making the bird easier to handle. And Dr. Caccamise will forward an addendum to address concerns raised during the review. M. Bromwell also recommended approval of the application. J. Kemp asked for and received Committee authorization to administratively approve the application after the requested addendum is received. The IBC moved to a vote on the application.

For Approval: J. Balog, M. Bromwell, K. Doolittle, L. Escobedo, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against Approval: none
Abstention: none

2) Kathryn Hanley entitled: "*Evolutionary Consequences of Dengue Virus Emergence*"
Dr. Hanley is a new Biology Dept. faculty member due to arrive at NMSU in July 2004. She submitted an NMSU IBC application in December of 2003 that was reviewed at the January 29, 2004 IBC meeting. The project proposes culturing dengue hemorrhagic fever virus (DHF) serotypes I, II, II, & IV and infecting mosquitoes with an overall goal of learning about the interaction between the serotypes and genotypes during co-infection of mosquito vector, and discovery of factors affecting selection, i.e. which serotype or genotype is will dominate the co-infection. The IBC tabled the application and instructed J. Balog to confer with Dr. Hanley on regulatory and policy compliance, and assist with completing the information missing from the application. P. Jackson provided primary review of the revised application and noted the following information was missing; staff names, biosafety cabinet serial number, and laboratory location. With regard to the risk assessment for working with DHF virus he mentioned the potential for a fatal outcome if a person experiences multiple infections involving different serotypes of dengue virus. He stated that he had no problems with the proposed laboratory operations. L. Escobedo noted dengue fever seemed to resolve, usually without fatality, but the more serious dengue hemorrhagic fever had a mortality rate for an untreated infection of approximately 50%, and if treated, 1% or 2% mortality.
K. Doolittle wanted information on the Harvard Apparatus microinjector used do infect the *Toxorhynchites* and the potential for the operator to be inoculated when operating the device. J. Balog relayed Dr. Hanley's comment that the microinjector tip is very fragile, and is likely to shatter before puncturing a latex glove. Several committee members suggested an initial and annual follow up blood test be done to determine if anyone in the lab had developed antibody to dengue since their last blood test. Unless this is contraindicated for some reason, it should be suggested to Dr. Hanley on her arrival.
P. Jackson suggested getting copies of the NIH review of this project and if their review process fulfills our criteria, we can accept their review and add it to our files.

Since the IBC is due to convene the July meeting proximate to Dr. Hanley's arrival, the Committee agreed to postpone the vote until Dr. Hanley arrives on campus and provides the information missing on the application;

(lab room, training requirements, exposure control plan) and the laboratory survey is completed. Apart from a clarification on the need for medical surveillance at NMSU, and the type of surveillance conducted at NIH, there were no significant concerns expressed about this protocol. The formal vote on this application is tabled until details of the facilities and safety plans are known. J. Balog will inform the Committee on the facility and safety plans, after Dr. Hanley has arrived and established her research laboratory.

New Business

1) Biosafety Program Review
   a. Printed copies of EH&S OSHA Bloodborne Pathogen training module were distributed for IBC review.
   b. Printed copies of the EH&S Biosafety training module were distributed for IBC review.
   c. Viewed *CBS News 60 Minutes News* Magazine 02-04 interview with Thomas Butler

Committee members will review and provide comments (if any) on the training handouts anytime between now and the next meeting.

There being no further business, the meeting adjourned at 5:03 PM

Submitted by John Balog and approved by vote of the IBC as reflected in the meeting minutes of December 15, 2004.

New Mexico State University Institutional Biosafety Committee

Minutes for Meeting of December 15, 2004
Room 102 Genesis Bldg. Unit B

Members Present:	John Kemp, Chair, Michael Bromwell (Unaffiliated member), John Balog, Katrina Doolittle, Willis Fedio, Paul Jackson (Unaffiliated member), Pete Lammers, Kevin Oshima (arrived 2:20 PM), Manuela Quezada-Aragon (*ex officio*)
Members Absent:	Richard MacRorie, Luis Escobedo
Guests:	Dr. Kathryn Hanley, Dr. Charles Ross

The meeting was called to order at 2:02PM

Review of April 5, 2004 Meeting Minutes:
K. Doolittle asked that the minutes be amended to clarify that "EH&S does not monitor specific laboratory protocols", the draft copy distributed for review stated "EH&S does not monitor laboratory projects". No further additions or corrections were offered. M. Bromwell and P. Jackson motioned to vote on the April 5, 2004 IBC meeting minutes with the above amendment.

The result of the vote was:
For approval: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

Review of Quarterly Administrative Approvals (Table I)
J. Kemp reviewed the list in Table 1 and began a discussion of IBC review of the applications described in the handout entitled *Review of IBC Applications for Teaching and Research at NMSU.* Initial discussion centered on establishing an appropriate time frame for submission of the Activity Modification Report that fulfills the requirement without imposing an undue burden on the PIs. After discussion among the committee J. Kemp motioned that an AMR must be filed with EH&S within 60 days of a PI-proposed change to an IBC-approved application. P. Lammers and W. Fedio seconded the motion. The result of the vote was:

For approval: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

J. Kemp summarized the review process by stating that applications for work with rDNA at BSL-1 would be reviewed by the IBC only when first submitted and subsequent renewal applications would be administratively approved (barring receipt of an Activity Modification Report indicating a major change to the initially approved application). He further stated that all applications for work with rDNA at BSL-2 and BSL-3 would be reviewed by the full IBC both at the time of initial submission and subsequent renewals of the application at the end of the initial three-year approval period.

J. Kemp then remarked that the NMSU IBC charter does not stipulate IBC review of non-rDNA work at BSL-1 (and the IBC will not review these applications), but that it was appropriate to capture information on work at BSL-1, and that is why item 2.1 of *Review of IBC Applications for Teaching and Research at NMSU* specifies administrative review of these applications. K. Doolittle and P. Lammers motioned to delete the requirement stated in item 2.1 for an IBC application for non-rDNA work at BSL-1. Subsequent discussion resulted in an additional motion recommending that EH&S establish a procedure to capture information on BSL-1 research at NMSU and this procedure will be independent of IBC oversight. P. Jackson and K. Doolittle motioned to accept the changes to the handout entitled *Review of IBC Applications for Teaching and Research at NMSU.* The result of the vote including the combined motions to delete the requirement for IBC review of BSL-1 work and that

EH&S establish a procedure for capturing BSL-1 research was:

For Approval: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

The amended Activity Modification Report and handout *Review of IBC Applications for Teaching and Research at NMSU* are attached.

Review of New Applications at BSL-1

1. Daniel Howard, *"The Origin and Barriers to Fertilization and Their Role in Speciation: From Populations to Proteins"* for work at BSL-1.

P. Jackson commented on the substance disposal and decontamination procedure in Section V-C. He noted that household bleach contains 6% sodium hypochlorite and 10% dilution is 0. 6%. J. Balog stated that in the future PIs will be provided with information on appropriate compounds and dilutions to be used for decontamination of research materials. P. Jackson and M. Bromwell motioned to vote on the application with approval being contingent on Dr. Howard's accepting the above modification on the sodium hypochlorite dilution.

For Approval: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

2. Barbara Lyons,*"The Study of Protein Involvement in Cell Migration"* for work at BSL-1.

P. Jackson again noted that substance disposal and decontamination is not accurate. J. Balog stated that the PI would be provided with information on the dilution of sodium hypochlorite. He also stated that the laboratory was not yet surveyed and will be scheduled after the holiday. Willis Fedio and M. Bromwell motioned to vote on the application. The result of the vote was:

For Approval: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

3. Tim Ross, "Evaluation *of the Potential Public Health Impact of Antibiotic Effluence and Antibiotic Resistant Micro-organism Release from Confined Feeding Operations (CAFO) on US-Mexico Border Health"*

After noting that the manure specimens will be transported to the USDA for testing, the committee remanded the application to administrative review and there was no vote on the application.

4. Graciela Unguez, *"Expression of Myogenic Regulatory Factors in Muscle-Derived Tissues"* for work at BSL-1.

J. Kemp informed the committee that the application has been changed from BSL-2 to BSL-1. The committee remanded the application for administrative review and there was no vote on the application.

Review of New Applications at BSL-2

1. Kathryn Hanley, *"Evolutionary Consequences of Dengue Virus Emergence"* for work at BSL-2.
J. Kemp directed that the laboratory research component and facility and equipment be discussed separately. He asked P. Jackson to comment on the laboratory research component and J. Balog to present a review of the facility and equipment. P. Jackson recommended that K. Hanley document that persons working with dengue virus notify their personal physicians that they work with the virus. K. Hanley commented that she has recommended this to her personnel. P. Jackson commented that there are different forms in the meeting packet, and Dr. Hanley's did not have the most recent Section VI (Personnel) that asks the PI to indicated

personnel experience. Dr. Hanley agreed to forward the information requested in Section VI of the most recent revision to the application. P. Jackson further suggested and Dr. Hanley agreed that persons who have been exposed to dengue be restricted to work only with that dengue genotype. The use of bleach to decontaminate equipment and work surfaces will be amended to reflect a 10% dilution of 6% sodium hypo chlorite. J. Balog commented that renovation of Chemistry W357J (Dr. Hanley's BSL-2 laboratory) is behind schedule and the completion date is unknown. K. Doolittle stated this was the first she had heard that this renovation was "stagnant", and that the renovation was not initiated until the beginning of this semester. K. Hanley agreed and added that the project design was completed many months ago, and she has been "kicking and screaming" to get the renovations started. P. Jackson noted the application was initially reviewed in January of 2004. He further stated that the IBC can approve the application independent of the completeness of the renovation since the laboratory would be surveyed in any event. K. Hanley expressed a desire to at least begin tissue culture work during this funding cycle. A motion was made to approve the application and accept the result of the lab survey for approval. P. Jackson said the survey was not necessary for IBC approval. J. Kemp stated he is extremely sympathetic to Dr. Hanley's plight and asked N. Quezada-Aragon if the Vice Provost for Research could assist with moving the project forward. She suggested once approval is granted to Dr. Hanley, her Department Head may write a letter of concern to the Vice Provost of Research. J. Kemp asked to move forward with a conditional approval. P. Jackson disagreed noting such an approval would not provide Dr. Hanley with the necessary leverage and that the IBC has approved of the application. J. Kemp agreed with P. Jackson that the application is approved with the understanding that work would not begin until the facility is completed. J. Balog commented that if the application is approved, then concerns with the facility become a policy matter between the PI and EH&S. Paul commented there were previously mentioned conditions for correcting "minor things" in the application. J. Balog noted that since Dr. Hanley accepted each recommendation and agreed to forward the necessary documentation, there is no need to make the application conditional.
P. Lammers and P. Jackson motioned for approval. J. Balog stated that Dr. Hanley should not be present while the vote is recorded. The committee thanked her for providing information on her research. P. Jackson and K. Doolittle moved to vote on Dr. Hanley's application. The result of the vote was:

For Approval: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

2. Rebecca Creamer, *"Etiology and Management of Plant Pathogens in New Mexico"* for work at BSL-2P.

This project was initially approved in 2002 for work at BSL-1, but Dr. Creamer has requested approval for work at BSL-2P. J. Balog noted that since beet curly top virus is endemic to New Mexico an accidental release does not pose a threat to the environment. There is no permit requirement for this plant virus. J. Kemp commented that Dr. Creamer will be working with the full-length of the viral genome and that BSL-2P is appropriate. W. Fedio and M. Bromwell motioned to vote on the application. The result of the vote was:

For Approval: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

7. Stephen Hanson, *"Gemini Virus Replication Mechanisms and Engineered Resistance Strategies"* for work at BSL-2.

As with previous applications the committee asked that the PI be informed of the correct dilution of sodium hypochlorite and that description of work experience be provided for personnel working on this application. P. Jackson noted that autoclaving chlorine-containing solutions poses a respiratory hazard, and will damage the autoclave chamber. He further noted that autoclaving for 30 minutes does not always result in an effective kill of microorganisms. He suggested autoclaving for 60 minutes would be sufficient. P. Jackson and P. Lammers motioned to vote on the application. The result was:

For Approval: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

8. Elba Serrano, *"Gene Expression in the Nervous System"* for work at BSL-1, BSL-2.
P. Jackson commented that the use of 70% ethanol is inappropriate for use in the event of an exposure to skin and that that the use of 70% ethanol be deleted from the post-exposure response. This version of the application does not provide the work experience for personnel, and the BSO must request this information from Dr. Serrano. Also, the IBC does not consider *E. coli* K-12 derivatives to be biohazardous agents and the *E. coli* should be deleted from Section IVA of the application (Use of Biohazardous Agents). Katrina Doolittle and P. Jackson motioned to vote on the application. The result was:

For Approval: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

9) Mary O'Connell, *"Molecular Genetics in Crop Plants and Wild relatives, and Natural Product Isolation and Analysis"* for work at BSL-1 and BSL-2.
J. Kemp described the nature of the proposed research activities as involving culturing organisms in 5 ml volumes in a bench top shaker. Once the culture reached the desired density (as measured by a spectrophotometer) the organisms would be exposed to plant extracts to determine if the extracts demonstrate an inhibitory effect to the bacteria. P. Jackson, W. Fedio, and K. Oshima each remarked that culturing the organisms on solid media may be preferable to using liquid media. P. Jackson felt that a Biosafety cabinet was necessary for culturing these organisms. K. Doolittle drew a diagram of room 155 on the whiteboard that showed the room is divided into two rooms and does not have a door separating the rooms. Dr. O'Connell proposes to designate 155B as the BSL-2 laboratory. P. Lammers expressed concern that there was no indication that the PI recognizes the hazards associated with the organisms proposed for work in the application. J. Kemp said that Dr. O'Connell considers the organisms proposed for use in the application as "having a low human hazard" and are not easily transmitted via aerosol. The committee did not agree with these assessments. J. Balog commented that the PI's area of expertise is with plant research and not manipulation of potentially infectious bacteria. There is no biosafety cabinet in the proposed BSL-2 laboratory. He asked the committee for a consensus on the requirement for a biosafety cabinet in a BSL-2 laboratory. The consensus of the committee was that a Biosafety cabinet is required for manipulating organisms that are potentially infectious to humans or animals at BSL-2. J. Kemp asked that the committee respond to Dr. O'Connell's application with the statement "the committee will not approve this work at BSL-2 if she doesn't use a biosafety cabinet". P. Lammers suggested that controlling assess to the laboratory was a requirement as well for work at BSL-2. J. Kemp described the facility in Gerald Thomas Hall proposed for this application as lacking negative pressure. J. Balog asked that the committee agree that renovations to a building intended to support BSL-2 research include negative room pressurization. P. Jackson disputed making this a requirement due to the prohibitive cost associated with upgrading older buildings. J. Balog suggested that facilities that do not meet BSL-2 facility requirements should not be permitted to house BSL-2 work. M. Bromwell agreed, but P. Jackson remained opposed to the requirement due to expense. J. Kemp stated that the committee is not going to approve the BSL-2 component of this application until the room has lockable doors and a biosafety cabinet. P. Lammers feels that details on the manipulation of each of the organisms and occupational safety information should be provided as well. W. Fedio commented that the ATCC recommends the organisms listed in the application be handled at BSL-2. He further stated that he didn't understand the description of activities and therefore didn't know what Dr. O'Connell intended to do, especially for BSL-2. He asked that the BSL-1 and BSL-2 work should be described separately the description of activities. J. Kemp stated that the BSO does not approve of the facility for work at BSL-2. J. Kemp asked if the IBC required

separate applications from Dr. O'Connell describing the BSL-1 work and BSL-2 work. M. Bromwell felt that two applications (one for BSL-1 work and one for BSL-2 work) are necessary. W. Fedio suggested that approval of the BSL-1 work could be handled by the BSO.

J. Kemp stated that the rDNA at BSL-1 described in the application did not contain any major modifications and he is willing to approve the rDNA component. He further stated that the existing application couldn't be approved as submitted and that he could administratively approve a separate application for the BSL-1 work (including rDNA). W. Fedio offered the use of his laboratory for the proposed BSL-2 work. K. Oshima, P. Jackson, and P. Lammers agreed that Dr. O'Connell would benefit by working with W. Fedio on this project. J. Kemp asked for a motion to disapprove the application stating that he would then approach Dr. O'Connell to resubmit the proposal for consideration at BSL-1 and deleting the BSL-2 component. P. Jackson motioned to 1) reject the proposal as written, 2) that Dr. O'Connell submits a BSL-1 proposal 3) that she consult with appropriate experts in submitting an application for the BSL-2 work. K. Doolittle seconded the motion. The result was:

For approval of the motion to reject the application: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima

Against approval: none
Abstention: none

P. Lammers motioned that the IBC require separate applications be submitted for BSL-1 and BSL-2 work. J. Kemp agreed. K. Doolittle seconded the above motion. The result was:

For approval: J. Balog, M. Bromwell, K. Doolittle, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

Old Business

1. J. Balog reported that Dr. Joseph Wang has left the University and his application entitled *"Sensitive Diagnosis of Biowarfare Agents on Microchip"* is terminated.

2. J. Balog reported that Dr. Caccamise's project entitled *"West Nile Virus-Patterns in the Establishment and Maintenance of an Exotic Pathogen is an Arid Landscape"* has gathered approximately 1300 mosquito pools and is suspended due to their inability to obtain a positive control Access to a BSL-3 laboratory is a prerequisite for obtaining an APHIS permit to transport and possess a positive-control of the West Nile Virus.

3. The outstanding IBC request for a copy of the USDA permit for Jinfa Zhang and Scott Bundy is withdrawn due to the material being deregulated.

New Business

a. Biosafety Manual Review: J. Balog asked that the committee members review the Biosafety manual and return the review's form by the middle of January.
b. K. Doolittle distributed a copy of the Memorandum of Understanding between EH&S, the BSL-3 Users group, and the Department Heads of Chemistry and Biochemistry, Biology

There being no further business, the meeting adjourned at 4:50 PM

Addendum as of 12-21-04: On 12-16-04 L. Escobedo submitted one minor comment on the Tim Ross application that persons obtaining bovine fecal specimens be made aware of the potential for aerosol exposure to pathogens and be afforded the option of wearing a surgical mask. He had no further concerns with the other IBC applications.

Attachments:

1. IBC policy on *Review of IBC Applications for Teaching and Research at* NMSU (approved

12-15-04)

2. Activity Modification Report revised 12-15-04
3. Table I, Summary of Administrative Approval of IBC Applications for the 3rd and 4th Quarters of 2004 and Table II, Activity Modification Reports for the 3rd and 4th Quarters of 2004, updated 12-21-04
4. Memorandum of Understanding on Use of the BSL-3 Laboratory (Chemistry & Biochemistry W350)

Submitted by John Balog and approved by vote of the IBC as reflected in the meeting minutes of June 30, 2005.

New Mexico State University Institutional Biosafety Committee

Minutes of Meeting of June 30, 2005
Room 110 Academic Research Center Unit C

Members Present:	John Kemp (Chair), Michael Bromwell (Non-affiliated member), John Balog, Katrina Doolittle, Luis Escobedo, Willis Fedio, Paul Jackson (Non-affiliated member participated via phone), Pete Lammers, Kevin Oshima, Manuela Quezada-Aragon (*ex officio*)
Members Absent:	Richard MacRorie
Guests:	None

The meeting was called to order at 2:08PM

J. Kemp added the following items to the agenda; under Old Business; *Biosafety Manual* and *Future Meeting Dates* and under New Business added *NMOSH Inspection of 06-29-05.* The additions were accepted without comment.

Review of December 15, 2004 Meeting Minutes:
P. Jackson identified several typographical errors that need to be corrected and stated he had no objections to "substance or content". No further comments were offered. M. Bromwell and P. Jackson motioned to vote on approving the December 15, 2004 IBC meeting minutes pending the noted corrections.
The result of the vote was:
For approval: P. Jackson by voice, all others by show of hands. J. Balog, M. Bromwell, K. Doolittle, L. Escobedo, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval: none
Abstention: none

Review of Quarterly Report Tables

a. Administrative Approvals
J. Kemp stated that there were no administrative approvals of IBC applications since the 12-15-04 IBC meeting.

b. Activity Modification Reports
J. Kemp stated that there were no Activity Modification Reports submitted since the 12-15-04 IBC meeting.

Review of New Applications at BSL-1

a. Ian Ray, "*Genetic Characterization of Drought and Salt-Stress Tolerance in Alfalfa*"
W. Fedio provided primary review of Dr. Ray's application. He requested that Dr. Ray (and all PI's) need to identify the strain of *E. coli* and *Agrobacterium tumafaciens* and the source of the material (commercial source or from a collaborator). P. Jackson stated that the narrative on waste disposal was vague about the use of bleach and autoclaving to decontaminate waste and asked for details i.e., duration of autoclave cycle and concentration of sodium hypochlorite to be used. K. Doolittle referred to the 12-15-04 meeting minutes that J. Balog would provide direction on proper dilution of sodium hypochlorite used for decontamination of work surfaces and autoclave operation. W. Fedio noted that the narrative provided in Section V E "Environmental Impact" of the form states that waste disposal will observe NMED Solid Waste Bureau regulations and NMSU Policy. J. Balog proposed revising the form to merge Section V part C "SUBSTANCE DISPOSAL AND DECONTAMINATION PROCEDURES" with Section V part E "ENVIRONMENTAL IMPACT" to avoid confusing the issue of decontamination and disposal with the closely related issue of environmental impact. J. Balog also noted that laboratory adapted strains of *E. coli* (*K*-12 derivatives) are susceptible (decontaminated/inactivated) to mild dish detergent and do not require treatment with 0.6% sodium hypochlorite. He asked for comments from the Committee. P. Jackson stated use of dish detergent for decontamination of spills and liquid cultures should be restricted to BSL-1. W. Fedio again remarked that we must ask PIs for the identity of the specific strains (bacterial and viral) used in their research. J. Kemp suggested establishing standard procedures for decontamination at BSL-1 and BSL-2. W. Fedio asked for references for autoclaving soil samples to ensure decontamination. P.

Jackson noted soil was difficult to sterilize. K. Doolittle commented that use of an integrator embedded in the load would provide confirmation. P. Jackson stated this is not usually done for BSL-1 work. P. Lammers commented against applying BSL-2 standards to BSL-1 work. J. Balog remarked that the USDA has established requirements for autoclaving transgenic materials and items contaminated by transgenic materials but the NM Solid Waste Bureau regulations do not specify such requirements. For research involving permitted materials, the USDA permit will stipulate procedures for decontamination of materials and abatement of the field trial site. P. Lammers referenced a previous IBC discussion recognizing that there was no hazard associated with the release of beet curly top virus because it is endemic to New Mexico so decontaminating anything Dr. Ray brings back from the field is not an issue with this application. J. Kemp remarked that the IBC does not review non-rDNA BSL-1 projects, only transgenic plants (and decontamination by autoclaving) in the lab and greenhouse. M. Bromwell asked that since the specific strain was not identified, are we assuming the *E. coli* strains proposed for use in the application are BSL-1. J. Balog pointed out a Section V part B of the application stated the source of the organism is a commercial prep using laboratory-adapted strains of *E. coli*. J. Kemp remarked that is appropriate to ask for kit number. (*A post meeting review of the Stratagene® website revealed this cloning kit to be Lambda EMBL3/BamH I, product #241612 and the host strains provided with this kit are XL-1 Blue MRA and XL-1 Blue MRA P2 – these are BSL-1 strains.*) P. Jackson commented on Biosafety Awareness training being "recommended" versus "required" for all persons listed on IBC applications. He feels that training should be required prior to working even at BSL-1 P. P. Lammers suggested this issue be tabled for discussion at a later date. The issue was tabled with consent of the Chair. J. Kemp asked if personnel completed the required EH&S training. J. Balog remarked that Dr. Ray is in the field and will complete the training at the next opportunity, as will all personnel listed on the application. The IBC agreed to accept PI and staff enrollment in required EH&S training in lieu of having completed the training, for release of IBC approval letter. (*Note: training requirements for all personnel were completed on 07-27-05*) J. Kemp asked that Dr. Ray provide information on the strain of *E. coli* and *Agrobacterium tumafaciens*, including the binary vector and that the decontamination information be corrected. (*Per Dr. Ray email of 07-01-05, Agrobacterium strain is LBA4401 and the binary vector that it contains is Bin19, and collaborators provided the Agrobacterium.*) There being no further comments or questions, and pending completion of the record (identification of bacterial strains and completion of the training requirements) J. Kemp asked for motion to vote on the application. P. Lammers and W. Fedio motioned to vote.

For Approval:	P. Jackson by voice, all others by show of hands. J. Balog, M. Bromwell, K. Doolittle, L. Escobedo, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval:	none
Abstention:	none

b. Wayne Van Voorhies, "*RNA: Metabolic Effects of RNAi Mediated Gene Disruption in Caenborhavdius elegans*"

P. Lammers provided primary review. He remarked that the title was unfortunate since the research does not actually do gene disruption or create recombinant organisms. He stated RNAi is a technique used to interfere with gene expression and requires processing RNA into 23 nucleotide segments. A series of *E. coli* strains have been engineered to make every single gene of this nematode and the genes were inserted into about 6000 or 8000 different *E. coli* strains that are now available either commercially or from collaborators. The strains are fed to the nematodes. When the nematode eats the *E. coli* they take up the RNA and process it into smaller interfering RNA that disrupts the expression of the nematode's RNA. He stated the proposal is a straightforward, non-controversial BSL-1 proposal. J. Kemp reminded everyone that regardless of the commercial availability of the *E. coli*, this type of research involves rDNA and requires an application and IBC review. P. Lammers summarized the hypothesis of the research as being based on the assumption that each genetic defect leads to an increase in longevity and lowers the metabolic rate. L. Escobedo asked about complications related to accidental ingestion. P. Lammers responded that it would be difficult for the RNA from the *E. coli* to enter a human cell and that it is a widely accepted notion that "existing barriers" and "evolutionary divergence" militate against uptake of *C. elegans* RNA by human cells. P. Jackson stated that RNA "doesn't go"

directly into human cells, it must be ingested or injected and the RNA is not likely to survive either of those routes. J. Kemp stated the rules for making synthetic RNAi in mammalian systems are fairly rigorous, and that he would be surprised if one could produce RNA that would get into the body, and have an RNA that is going to be effective.

P. Lammers stated that every gene of *C. elegans* is known and Dr. Van Voorhies will be working with a small portion of a gene, and not the entire gene. J. Kemp stated that changes could be administratively reviewed. L. Escobedo asked that the PI to provide a statement on human impact of the research. P. Jackson stated that this is addressed in the Risk Group classification and Biosafety Level. P. Jackson remarked that the "Personnel" section of the application was not completed. J. Balog will ask Dr. Van Voohies to complete the "Personnel" section. P. Lammers said the PI would attend the required training. There being no further discussion, J. Kemp asked for a motion to vote on the application. P. Lammers and P. Jackson motioned to accept the application pending PI completion of the "Personnel" section and completion of EH&S training. (*Post meeting note: Dr. Van Voohies completed the Personnel section on 07-05-05.*)

The result of the vote was:

For Approval:	P. Jackson by voice, all others by show of hands. J. Balog, M. Bromwell, K. Doolittle, L. Escobedo, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval:	none
Abstention:	none

Review of New Applications at BSL-2

1. Kathryn Hanley, "*Vector Driven Selection in Dengue Virus*" for work at BSL-2".

J. Kemp provided primary review of Dr. Hanley's application. Dr. Hanley wants to determine the mechanisms of propagation by making certain modifications in dengue virus. She will use dengue virus type 4 as the model organism. The 3' untranslated region of various dengue virus genes will be exchanged with 3' regions from dengue virus type 4. Note that the dengue virus type 4 is a mosquito-vectored organism. (The other types of dengue virus are transmitted by tick bite and mechanical means –contact.) A central research question is whether these 3' prime ends for different genes of dengue virus can change the vector preference in dengue virus transmission. Full-length cDNA of dengue virus type 4 will be generated exclusively. No cDNAs of dengue virus type 1,2, or 3 will be generated. She will replace ~20 – 50 base pairs of the 3' region with the other two types of dengue virus. She will not make full-length clones of the tick-borne or mechanically transmitted dengue viruses. She will make full-length cDNA clones of dengue virus type 4, and that clone is not virulent. Upon inoculation in a human host, the cDNA on its own cannot produce the disease. However, she will use the full-length cDNA of dengue virus type 4 to make a synthetic + strand full–length RNA transcript, and that transcript is infectious. This full-length transcript will be transfected into the tissue culture cell line and will produce a virulent dengue virus type 4. She has a number of years working with dengue virus and she stated explicitly that she would be the only person in her lab performing the transfection with the virulent RNA.

The IACUC has granted approval to inoculate SCID mice ip with a human kidney tumor cell line infected with these modified dengue viruses and determine whether the virus is propagated within the tumor. J. Kemp asked about safety issues related to rodent housing and personnel, noting that the IACUC has explored these safety issues. He noted the rather short period of time the mice would be housed in W357 (approximately 4 weeks) and that they would be contained in micro-isolator cages. He also noted it likely that the environment posed a greater threat to the SCID mice than the mice posed to personnel. The mice will be euthanized by cervical dislocation. This method of euthanasia is approved by the American Veterinary Medical Association Guidelines on Euthanasia, 2002 as described in the IACUC-approved protocol. J. Balog informed the IBC that the certified room air balance report prepared for W357J confirms the airflow is negative with respect to the surrounding area by a factor 0.01 W.G. (water gage). J. Balog recommended to the committee that in consideration of the number of mice to be housed in micro-isolator cages within W357J the negative room air pressurization and the number of air changes per hour is not a cause for concern. The dimensions of the cages purchased will dictate the number of mice housed in each

cage; small cages will hold 4 mice and large cages will hold 6 mice. He also stated that the IACUC protocol approval was granted prior to IBC approval to expedite release of funds from the NIH and in the future animal projects that have an rDNA or infectious agent component should be reviewed by the IBC prior to IACUC review. The animal component of Dr. Hanley's project will not begin for approximately twelve months.

The final component of the project seeks to learn if the viral constructs can establish infection in mosquitoes. *Toxorhychities amboinensis* (*T. a*) mosquitoes will be used to determine the infectivity of the dengue constructs. J. Kemp noted that T.a are unusually large and have iridescent scales and are unlikely to be confused with *Aedes aegypti* (*A. a*), even by an untrained observer. *T.a.* is non-biting and will be fed larvae and pupae of *A. a.* P. Lammers asked how the mosquitoes would be contained. J. Balog stated that there are four levels of containment. Uninfected adult mosquitoes will be contained in a screened cardboard container (1) that is itself contained in a screened metal container (2), in a locked separate room (3) that is in the greater lab (4). The building itself can be considered a fifth level of containment. In addition, a UV light/ fan trap (Insectovorous®) will be installed in the holding area to capture escaped mosquitoes. K. Oshima asked where SCID mice would be housed. J. Balog stated the mice would be held in W357J. He further stated that the mosquitoes would be housed in W357, immediately outside of W357J. (*Subsequent discussion with Dr. Hanley after the meeting revealed this statement to be incorrect. A room has not yet been identified for housing the mosquitoes. The Foster Hall renovation will include an arthropod holding room designed to Arthropod Containment Guidelines ACG-2.*) J. Balog stated and J. Kemp agreed with the interpretation that the SCID mice and infected mosquitoes would not co-exist at any time during this project. (*Subsequent discussion with Dr. Hanley confirmed this statement.*) L. Escobedo asked how mosquitoes would be processed and what, if any risk is there to employees. J. Kemp replied that T.a is a non-biting mosquito and a Harvard apparatus microinjector (image attached) will be used to inject these large mosquitoes. J. Balog stated that dengue virus type 4 is not transmitted via aerosol exposure and Dr. Hanley will be the only person injecting the SCID mice (ip). Tumor growth will be monitored by palpation and will not exceed approximately 5% to 10% of the mass of the SCID mice. Dr. Hanley's past experience reveals that optimal tumor size (as determined by virus recovered post-mortem) is achieved within seven to ten days post injection. Several committee members asked if Dr. Hanley would be able to personally perform all of the high-risk procedures (microinjection of mosquitoes, husbandry, euthanasia and tumor excision of the SCID mice). J. Balog explained that the total number of SCID mice proposed and approved by the IACUC for use in this protocol is 180. The duration of the protocol is January 2006 through January 2008. Since NMSU does not have dedicated rodent holding facilities, work involving an appreciable increase in the number of SCID mice could not be supported at NMSU. K. Doolittle stated that IACUC does not look at worker safety, so the IBC has to review the protocol for worker safety, especially the safe use and disposal of sharps. L. Escobedo asked where the tumor would be induced, if there were a possibility of the tumor rupturing the dermis. J. Balog repeated that the IACUC stipulated that the tumor would not be permitted to grow to a grossly excessive size (beyond approximately 5% to 10% of the mass of the mouse) and that the NIH has favorably reviewed this protocol prior to her relocation to NMSU. L. Escobedo stated that this is a complex protocol involving many steps with insects and rodents and he could foresee at some future time other laboratory personnel would be involved in at least some of the manipulations. He asked that Dr. Hanley outline what protection she affords to these personnel. K. Doolittle said "we believe she has already drafted a procedure where she would protect herself, and anyone who would assist" with the operations. J. Kemp reminded the committee that Dr. Hanley stated she would personally perform the hazardous manipulations and that the IBC can remind her that that she must notify the IBC if this changes. P. Jackson pointed out that apart from the Lab Manager; all other personnel have no laboratory experience whatsoever. He further stated that regardless of the fact these persons might not be handling the materials they still need to be trained. He suggested that they be trained and the training be documented. J. Balog recalled a speakerphone discussion between Dr. Hanley and J. Kemp where Dr. Hanley adamantly stated that this was a short-term, one-time experiment and she would personally perform the hazardous tasks in question. He then stated that if the duration of the experiment is extended and a substantial increase in the number of rodents is requested, the work would have to be performed elsewhere due to the aforementioned a lack of dedicated rodent housing space at NMSU. With respect to the request that all lab personnel be trained, he reiterated Dr. Hanley's remark that the proposed experimental procedures are indeed complex and the techniques do require a level of knowledge, skill,

and experience unattainable for other lab personnel in the short time frame for the experiments. There will not be an opportunity to provide on the job training in rodent surgery with this protocol. He also repeated the requirement of PIs to notify the IBC of changes by submitting an Activity Modification Report. P. Jackson expressed concern that persons without any laboratory experience would be working in a BSL-2 laboratory. He said that they need to be trained and documentation on training needs to be provided. K. Doolittle responded that all personnel have attended EH&S OSHA training on Employee Safety and Hazard Communication, Laboratory Standard, and Hazardous Waste, and Bloodborne Pathogens exposure control. All but one (and this person is enrolled for the 07-28-05 session) has attended Laboratory Biosafety Awareness training. (*Note as of 07-28-05 all persons have completed EH&S training requirements.*) P. Jackson said this coursework is not the same as on-the-job training and is concerned about University liability in the event of an occupational exposure and illness. He suggested a generic statement be included in the application that each person would be trained and directly supervised until such time as they satisfactorily demonstrate competence in performing experimental tasks. K. Doolittle stated, and P. Jackson agreed that the laboratory safety plan was quite explicit. She suggested adding specific comments that personnel would be trained and supervised would address concerns on the lack of personnel experience. P. Jackson agreed that this would be acceptable. (*Such a statement has been added to the Hanley Lab Safety Plan.*) J. Balog summarized the requested modifications as a statement that "personnel will be directly supervised (and not left unattended) while performing experimental tasks until such time they have been observed to be competent in performing the procedures at BSL-2. J. Kemp asked if everyone understood the amendments, and if there was a need for further discussion. There were no further comments.

P. Jackson motioned to accept the proposal as amended and P. Lammers seconded the motion to vote on Dr. Hanley's application. The result of the vote was:

For Approval:	P. Jackson by voice, all others by show of hands. J. Balog, M. Bromwell, K. Doolittle, L. Escobedo, W. Fedio, P. Jackson, J. Kemp, P. Lammers, K. Oshima
Against approval:	none
Abstention:	none

Old Business

a. Room W350 Chemistry and Biochemistry, the BSL-3 Laboratory
J. Balog reported that Phase II renovations have begun. The walls have been sanded smooth, and the autoclave has been installed. It is not clear when the renovation will be completed and there are discussions on the leak testing protocol. J. Balog has taken digital photos over the past month or so documenting the progress in support of facility commissioning by CRC Consulting. J. Balog suggested the project might be completed in August. K. Doolittle remarked that the Memorandum of Understanding between EH&S, Department of Chemistry, Department of Biology and the Users group prohibits research involving airborne transmissible organisms in W350, the BSL-3 laboratory.

b. Final and approved Policy on Review of IBC Applications.
P. Jackson asked about how NMSU will exercise oversight of work with exempted quantities of Select Agent Toxins. J. Kemp, K. Doolittle, and J. Balog stated that the IBC would provide review and approval of this type of work. The BSO will ensure inventory quantity will not exceed exempted quantity. P. Jackson cautioned about illegal transport across the borders. J. Balog remarked that there is no way EH&S and the IBC can prevent someone from willfully violating the regulations.

c. Biosafety Manual
K. Doolittle wanted to verify receipt of comments from the IBC on the manual and invited comments from anyone who had not yet submitted comments. We are waiting on the final draft of the NM Solid Waste Bureau regulations because the first draft affected waste decontamination of all laboratory waste. The current draft is in line with existing NMSU policy, and doesn't appear to have any negative impact on what we are doing so we can finish the Biosafety manual with the appropriate protocols for decontamination. She asked if the IBC wanted to see the final version. She then suggested EH&S would send out the revised waste decontamination section for review and comment. Otherwise the revised section would be accepted and would be incorporated into the manual and the

manual would be distributed. The final version of the manual would include a brief, signed statement of approval by the Chair, and then the manual would be distributed campus wide. P. Jackson and W. Fedio asked if the manual would be on-line. K. Doolittle said this would take some time. She also said it could go out as an email. J. Kemp summarized that K. Doolittle will send an email to the IBC of the final version of the manual simultaneous with submitting a hard copy for his review. P. Lammers offered assistance with making the manual available on-line. K. Doolittle stated that the on-line manual would include hyperlinks to regulatory citations on the Internet.

d. Future Meeting Dates
J. Kemp stated the IBC will meet in March 2006 and asked the members to forward their availability via email to J. Balog. Based on our intent to convene quarterly meetings the next meeting should be in September, but only if we need to. We intend to notify PIs (via EH&S website and campus email) of submission deadlines for each projected meeting in September, December, March and June. J. Balog will establish the submission deadline and notify the PIs. The decision to meet will be based on the receipt of applications that require full-IBC review. If no applications are submitted, we will not meet. J. Kemp directed J. Balog to email the IBC members and ask if they are available to meet on Friday September 23, 2005.

New Business

a. Noted distribution of the conclusions of Boston Public Health Commission Report on the Boston University Laboratory Acquired Tularemia.

b. Noted the distribution of the OSHA Region 1 News Release of Boston University Laboratory Acquired Tularemia. J. Kemp noted the release of the Boston Public Health Commission Report on the Boston University Tularemia exposures in conjunction with the OSHA report and reviewed the violations on personal protection, and training. The IBC must also ensure that training is completed.

c. NMOSHA Inspection of 06-29-05.
K. Doolittle informed the IBC that OSHA could inspect at any time for any reason. They had recently been at NMSU to investigate an anonymous complaint about improper use and a lack of training on hazardous materials. The complaint was later expanded to include biologicals based on a complaint that cholera was being stored in a refrigerator with food items. OSHA is not obligated to provide details on the origin of the complaint. She said it was very important that that there was an application on file with a list of organisms that was reviewed and approved by the committee. They wanted copies of all the documents and to visit the lab to observe work practices. They complimented Willis on his lab, and that he knew what he was doing. The complaint about training was valid, but no monetary penalty was assessed since this was an initial event. However similar citations in the future will be considered "willful" and result in a fine.

There being no further business, the meeting adjourned at 4:08 PM

Attachments:
1. Final approved Policy on Review of IBC Applications
2. Conclusions of Boston Public Health Commission Report on the Boston University Laboratory Acquired Tularemia.
3. OSHA Region 1 News Release

Submitted by John Balog and approved by vote of the IBC as reflected in the meeting minutes of September 23, 2005.

Attachment to 06-25-05 IBC meeting minutes.

REVIEW OF IBC APPLICATIONS FOR TEACHING AND RESEARCH AT NMSU

1. An Application for IBC review must be submitted for the following rDNA teaching and research activities.
   - 1.1. For rDNA at BSL-1, BSL-2, and BSL-3 Applications must be reviewed and voted upon by the IBC prior to starting work.
   - 1.2. IBC approval is granted in 3-year increments.
   - 1.3. Submission of a new application is required prior to the end of the 3-year expiration
     - 1.3.1. An Activity Modification Report (AMR) is used to communicate Major and Minor changes in research, facilities, and personnel. See the Report form for details.
     - 1.1.1. Previously approved rDNA applications at BSL-1 that report minor changes are qualified for administrative approval. (Administrative approval means review and approval by the BSO & IBC Chair)
     - 1.1.2. Previously approved rDNA applications at BSL-1 that reports major changes and all BSL-2 and BSL-3 applications will be reviewed and voted upon prior to granting a second 3-year term of approval.
2. An IBC Application must be submitted for the following non-rDNA teaching and research i.e., work with potentially infectious agents, pathogen, and toxins
   - 2.1. Infectious agent, pathogen and toxin research at BSL-2 and BSL-3 is reviewed by the IBC every three years.
3. Components of Administrative Review and Approval
   - 3.1. Biosafety Officer surveys each laboratory identified on an IBC application for compliance with BMBL.
   - 3.2. Biosafety Officer checks for compliance with EH&S on-line hazardous chemical inventory for areas identified on the IBC application.
   - 3.3. Biosafety Officer checks for compliance with NMSU policy on EH&S and OSHA training requirements. Employee Safety/Hazard Communication and Lab Standard are the minimum training requirements for all personnel. Bloodborne pathogen exposure control, hazardous waste management, and laboratory Biosafety awareness training requirements are based on review of the IBC application.
   - 3.4. The PI is responsible for reporting changes to the IBC within 60 days of the change. Refer to attached copy of AMR.

CONCLUSIONS OF BOSTON PUBLIC HEALTH COMMISSIONS INVESTIGATION OF LAB ACQUIRED TULAREMIA (Edited)

1. **At this time, the source of Type A *F. tularensis* in the BU laboratory remains unknown.**

2. **The extensive investigation to date has found no evidence to indicate that either the contamination of the LVS stock or the infections of the BU researchers were intentional.**

3. **The tularemia outbreak at BU was limited to three BU employees and never posed a risk to the public at large.**

4. **The failure to identify work-related illness in laboratory staff is a major concern for health officials.** BU should have had stronger procedures in place to monitor its laboratory personnel.

5. **The failure to immediately report suspicious work-related illness to local and state health departments is a major concern.** BU should have reported the suspect cases of tularemia as soon as they were identified.

6. **Appropriate infection control practices in laboratories must be clearly documented for all workers and enforced.** The BU tularemia laboratory failed to consistently utilize adequate precautions when handling and manipulating laboratory specimens. A systematic approach to retraining laboratory personnel is essential to insure that the required knowledge and skill levels are met and maintained. Special attention needs to be paid to the training and monitoring of laboratory personnel working with Select Agents.

7. **The BU Institutional Biosafety Committee was not able to ensure compliance with appropriate laboratory protocols and procedures.** BU should review staffing, resources and designated authority of this critically important body to insure it has the means to guarantee maximal safety in the future.

The following documents related to research with *F. tularensis* were submitted by BU and reviewed by the BPHC:

1. NIH grant
2. Correspondence between NIH and BU Re: tularemia grant application
3. Institutional Biosafety Committee (IBC) records and approvals
4. IRB consent forms for research related phlebotomy and antibody testing
5. Laboratory notebooks of the three researchers who were tularemia cases
6. Research protocols and methodologies as described by the tularemia cases for the periods surrounding their illness
7. Shipping and receiving documents
8. Invoice for clinical agglutination kit purchased 4/2004
9. Research abstracts presented by the tularemia researchers
10. Chronological account of all research performed with *F. tularensis*

OSHA News Release
2005 - 05/09/2005 - OSHA Completes Investigation and Issues Citations and Letter of Significant Findings and Recommendations in Boston University Biosafety Lab Case

OSHA News Release - Table of Contents

OSHA Regional News Release

U.S. Department of Labor
Office of Public Affairs **Region 1**

Region 1 News Release: 05-795-BOS / BOS 2005-106
Monday, May 9, 2005
Contact: John M. Chavez
Phone: (617) 565-2075

OSHA Completes Investigation and Issues Citations and Letter of Significant Findings and Recommendations in Boston University Biosafety Lab Case

BOSTON -- The U.S. Labor Department's Occupational Safety and Health Administration (OSHA) has completed its investigation of researcher exposure to tularemia bacteria at Boston University and Boston Medical Center, Evans Biomedical Research Center. Three employees became ill following their exposure to a highly infectious strain of the bacteria during the course of their work.

According to Brenda Gordon, OSHA's area director in Braintree, her office conducted an investigation between Jan. 21 and April 27 after learning through media accounts of the exposures, which took place late last summer and early fall. OSHA has issued to Boston University and Boston Medical Center Corporation identical sets of citations alleging three serious violations each of OSHA's personal protective equipment standard, including: failure to ensure that all employees wore gloves and eye protection when working with tularemia live vaccine strain (LVS); failure to certify in writing the required workplace hazard assessment for work with tularemia LVS; and failure to retrain employees who were working with tularemia LVS and who were not using gloves and eye protection.

OSHA defines a serious violation as one where there is a substantial probability that death or serious physical harm could result and that the employer knew, or should have known, of the hazard. The total proposed penalty for the alleged violations is $8,100.

Gordon also issued a letter of significant findings and recommendations to the director of the Office of Environmental Health and Safety at BU and Boston Medical Center recommending additional steps to eliminate or reduce hazards to employees at the Evans Biomedical Research Center Biosafety Level 2 laboratory working with attenuated biological agents, such as tularemia LVS, that have a highly infectious parent strain. Gordon's letter asks BU and Boston Medical Center to provide OSHA with progress reports on the employer's efforts to reduce employee exposure to biological materials.

"Employers who hire researchers to work with potentially infectious biological materials have a significant duty under the law to make every effort to ensure that their employees are protected at all times from exposure to such materials," Gordon said. "Proper training in the precautionary procedures to be followed, the use of personal protective equipment, and the use of safety equipment in the lab can help assure such protection."

Boston University and Boston Medical Center Corporation have 15 business days from receipt of the citations and proposed penalties to elect to comply with them, to request and participate in an informal conference with the OSHA area director, or to contest them before the Independent Occupational Safety and Health Review Commission. OSHA's Braintree office can be reached at 617-565-6924.

Employers are responsible for providing a safe and healthful workplace for their employees. OSHA's role is to assure the safety and health of America's workers by setting and enforcing standards; providing training, outreach and education; establishing partnerships; and encouraging continual improvement in workplace safety and health. For more information, visit www.osha.gov.

New Mexico State University Institutional Biosafety Committee

Minutes of Meeting of September 23, 2005
Room 110 Academic Research Center Unit C

Members Present:	John Kemp (Chair), Michael Bromwell (Non-affiliated member), John Balog, Luis Escobedo, Willis Fedio, Bryan Gabitzsch (Non-affiliated member), Paul Jackson, Pete Lammers, Manuela Quezada-Aragon (*ex officio*)
Members Absent:	Champa Sengupta-Gopalan, Katrina Doolittle
Guests:	Kathryn Hanley (3:15), Debra Ponds (3:15) and Timothy Wright (3:30)

The meeting was called to order at 2:18PM

J. Kemp informed the committee of the following changes to the membership of the IBC. Kevin Oshima resigned from NMSU this past July. He stated that Champa Gopalan, Professor of Agronomy & Horticulture has been appointed to the IBC. Also, NIH OBA issued an opinion that Paul Jackson can no longer be considered a non-affiliated member under the Guidelines since he resides in Livermore, CA. Paul has agreed to continue serving as a full voting member of the IBC. Bryan Gabitzsch is the newly appointed non-affiliated member of our IBC. He is the Science Dept Chair & Science Teacher at Mayfield High School. Finally, due to persistent schedule conflicts that have prevented Rich MacRorie from attending past IBC meetings, it was agreed to alter his membership to *ex-officio* status. Rich remains committed to support of the IBC and he will make himself available when circumstances dictate a need for his participation.

Review of June 30, 2005 Meeting Minutes:
There were no recommendations for addition or correction to the draft of the June 30, 2005 minutes. P. Lammers motioned to approve the minutes. L. Escobedo seconded the motion. The vote was taken by a show of hands of the members.

The result of the vote was:

For approval: J. Balog, M. Bromwell, L. Escobedo, W. Fedio, B. Gabitzsch, P. Jackson, J. Kemp, P. Lammers,
Against approval: none
Abstention: none

Review of Quarterly Report Tables

a) Administrative Approvals
J. Kemp stated that there were no administrative approvals of IBC applications since the 06-30-05 IBC meeting.

b) Activity Modification Reports (AMRs)
There were four Activity Modification Reports submitted since the 06-30-05 meeting
   i) Elba Serrano added a new human cell line (glial) & subunit B of cholera toxin.
   ii) Kathy Hanley removed one person from her list of personnel.
   iii) Geoff Smith added 10 BSL-1 soil bacteria strains purchased from the ATCC.
   iv) Donald Reed (CEMRC) added 10 BSL-1 soil bacteria strains purchased from the ATCC.

J. Kemp stated that the proposed changes do not alter the risk assessment of the previously approved research and asked for comment from the committee. There were no comments from the committee. The AMRs stand administratively approved.

Review of New Applications at BSL-1

a) Jennifer Curtiss, "*Eye Development in Drosophila melanogaster*"

P. Lammers provided primary review of Dr. Curtiss' application and recommended approval. He stated that the protocol describes standard developmental biology procedures using clones in bacteria and yeast to examine pathways that govern eye development. He stated that M. Burnett would need to complete Hazardous Waste disposal training. (*Follow up note: M. Burnett completed this training on 08-30-05. Dr. Curtiss needs to attend Lab Standard training.*) He suggested and the Committee verbally approved of the following text changes to the IBC application; Section II part A to "Use of Vertebrate Animals" and Section VII part 5 Exposure Response Procedure to "Available evidence suggests that materials used in the research are/are not implicated in illness due to occupational exposure". *(Follow up note: The IBC application template has been amended and subsequent applications will include each of the above changes.)* He did not identify further concerns with the application and recommended approval. There were no comments from the committee. J. Kemp asked for a motion to vote on the application. P. Lammers motioned to vote on the application. W. Fedio seconded the motion. The vote was taken by a show of hands of the members.
The result of the vote was:

For Approval:	J. Balog, M. Bromwell, L. Escobedo, W. Fedio, B. Gabitzsch, P. Jackson, J. Kemp, P. Lammers
Against approval:	none
Abstention:	none

b) Stephen Hanson, "*Biotech Improvement of Crop Plants*"

P. Jackson provided primary review of Dr. Hanson's application and recommended approval. He noted the application was broadly written and includes a number of plant viruses, and bacteria. He identified an inconsistency within the application with regard to federal permits. Section II D states no permits are required, and Section IV part A states "potyvirus Y was obtained with an APHIS permit". He asked that a note be added to the application stating that no new federal permits are required, but that a permit may have been previously issued. J. Kemp stated that Dr. Hanson was aware of the notification requirement. *(Follow up note: Dr. Hanson accepted the recommendation to add a note to the first page of the final version of the application and Section IV A clarifying that the IBC would be notified of new permit applications via submission of an Activity Modification Report. He also accepted the amendment to Section VII part 5 as described above.)* P. Jackson noted that the statement in Section IV part A (Rhizosphere bacteria) on the potential to isolate *B. anthracis* from environmental samples is very remote and the statement should be deleted. *(Follow up note: Dr. Hanson has accepted this recommendation and the statement is deleted from the final application document.)* The certification has expired for the BSCs listed in Section V part C. *(Follow up note: Dr. Hanson had forwarded copies of the BSC test reports to EH&S on 11-07-05.)* The training records indicate five persons have not yet completed required OSHA training and the approval is contingent upon completion of the required training. *(Follow up note: All personnel have completed the required training by 11-07-05.)* There were no further comments from the committee. As the committee prepared to move to a vote, J. Kemp informed the committee that as a Co-PI on this application, he would abstain from voting and asked the Committee to authorize J. Balog to conduct the formal vote and if the motion passed, sign the final approved application. P. Jackson motioned that J. Balog be authorized to conduct the vote and if approved, sign the final approved application. By a show of hands, the IBC granted J. Balog the authority to conduct the vote and if the application is approved, to sign the final application.
J. Kemp left the room. P. Jackson motioned to vote on the application. P. Lammers seconded the motion. The vote was taken by a show of hands of the members.

The result of the vote was:

For Approval:	J. Balog, M. Bromwell, L. Escobedo, W. Fedio, B. Gabitzsch, P. Jackson, P. Lammers
Against approval:	none
Abstention:	J. Kemp

Review of New Applications at BSL-2

a) John Gustafson, *"Antibiotic Resistance and Epidemiology of Antibiotic Resistance in Staphylococcus aureus"*

W. Fedio provided primary review of Dr. Gustafson's application and recommended approval. He expressed confidence that appropriate precautions would be used in the research. The work involves challenging *Staphylococcus aureus* (clinical isolates and collaborator-provided strains) with various disinfectants to see what genes are involved or "turned on" by exposure to the disinfectant compounds. They will make DNA arrays and isolate mRNAs and Dr. Gustafson's application specifies high-risk steps that will be performed under containment in the BSC. W. Fedio remarked that the application contained appropriate information on equipment certification and use but that almost all personnel have not completed the training requirements. Dr. Gustafson told W. Fedio that he would ask everyone to complete the training as soon as possible. W. Fedio noted that this application is submitted several months in advance of the expiration of the initial IBC approval and should allow ample time for personnel to complete the required training. *(Follow up note: Dr. Gustafson and all laboratory personnel completed the Biosafety Awareness training on 12-02-05, on 12-06-05 he said outstanding trainings in Hazardous Waste and Lab Standard would be completed in January 2006. Kathryn Girard is not currently working on the BSL-2 project and has been removed from the list of personnel. However she will be restored to the list of personnel working at BSL-2 upon completion of the Biosafety Awareness training.)* W. Fedio also stated that Dr. Gustafson engages laboratory personnel in laboratory-specific training on the potential hazards of working with *S. aureus*, and resistant strains of *S. aureus* and that each person signs a form acknowledging an understanding of the "biological threat of working with *Staphylococcus aureus* and the rules of working in a BSL-2 laboratory". *(Note that this document template is included under Section VII of Dr. Gustafson's application.)* W. Fedio suggested that the Section VIII of the Safety Plan (Recommended Precautions) should be modified to require glove use at all times when handling cultures of viable organisms per the NMSU glove use policy. *(Follow up note: All PIs with BSL-2 IBC applications, including Dr. Gustafson were given a copy of the glove use memorandum shortly after it was approved by the IBC in March of 2004. This section of the lab safety plan has been amended and submitted to Dr. Gustafson for acceptance.)* J. Balog asked if a similar statement on eye protection should be added in consideration of the OSHA Region 1 press release of May 2005 on the findings of the OSHA investigation into occupational exposures resulting in tularemia infection of three workers at Boston University (BU) in 2004. The press release stated that employers have a "significant duty under the law" to protect employees from exposure to infectious agents and that BU failed to retrain employees working with tularemia without gloves and eye protection. A number of comments were offered for discussion but the committee was unable to reach a consensus on eye protection. J. Kemp tabled further discussion for a later date when EH&S would provide guidance and language that the IBC would consider in developing a policy on eye protection for infectious agent research at NMSU. W. Fedio repeated his recommendation that the application be amended to reflect glove use when handling infectious agents and deleting the phrase "when skin contact with the organism is unavoidable". He also expressed concern about laundering soiled lab coats and that the plan seemed to imply that personnel would take their lab coat home for washing. Dr. Hanley stated the Biology Department provides a washer and dryer for laundering lab coats, although this service is temporarily unavailable due to the Foster Hall renovation. She explained that soiled lab coats are being stored (and not being taken home for laundering) and new lab coats have been purchased. *(Follow up note: Dr. Gustafson informed J. Balog that a washing machine is available for use on the third floor of Foster Hall and that is where his personnel launder their lab coats.)* P. Jackson recommended that the safety plan include specific language directing that personnel notify the supervisor in the event of a spill. W. Fedio agreed that this would be appropriate. P. Jackson identified an apparent conflict between the statement in Section V Description of Activity and the transformation of *E. coli*. Specifically, the statement in part A that " no novel antimicrobial resistant strains of *S. aureus* will be constructed that do not exist in the extant clinical or wild populations" conflicts with and the use of recombinant methodology (which involves moving genetic elements of S. aureus into and recovering genetic elements from *E.coli* - a process that results in a new strain of *E. coli*.). J. Kemp and P. Lammers agreed that the transformation using *E. coli* is not a focus of the research, but is merely an intermediate step and neither J. Kemp nor P. Lammers considered the description to be in conflict with the description of the main research objective.
L. Escobedo, M. Bromwell, and P. Jackson expressed concern that personnel had not attended EH&S training. J.

Kemp then summarized the requested amendments as: 1) harmonize language in the safety plan to reflect NMSU protective glove use policy, 2) incorporate language in the safety plan that specifies new personnel will not be allowed to work until they have observed a demonstration of proper technique and then are able demonstrate proficiency to the satisfaction of the PI prior to being permitted to work independently, 3) add a requirement for personnel to report spill incidents to the PI, and 4) ensure personnel complete the OSHA-required training. W. Fedio will follow up with Dr. Gustafson on the completion of OSHA training, glove use, and how soiled laundry is being handled during the Foster Hall renovation. There were no further comments from the committee. W. Fedio then motioned to vote on the application. P. Lammers seconded the motion. The vote was taken by a show of hands of the members.

The result of the vote was:

For Approval: J. Balog, W. Fedio, B. Gabitzsch, J. Kemp, P. Lammers,
Against approval: M. Bromwell, L. Escobedo, and P. Jackson
Abstention: none

b) Kathryn Hanley, "*The Effect of Morphology and Metabolic Processing on Permissiveness of Primary Hepatocytes to Hepatitis C Infection*"

J. Kemp provided primary review of Dr. Hanley's application and recommended approval. The application describes the graduate research project of Ms. Debra Ponds. The project is BSL-2 and will be conducted in the laboratories identified on Dr. Hanley's previously approved IBC applications (W357, W357J) involving dengue fever virus. Currently, there is no tissue culture model for Hepatitis C. A construct using the n-terminus of the non-structural protein has been generated and will be incorporated into a standard BSL-1 expression system using a recombinant baculoviral construct to express virus-like particles. Ms. Pond's research will test the proposition that cells in a rotary cell culture system will approximate the zero gravity conditions of liver cells *in vivo* and if so, this model system will subsequently enhance Hepatitis C virus binding *in vitro*. The virus will be purchased commercially. Tissues will be fixed prior to removal from the lab for microscopic study. Ms. Ponds has completed the requisite OSHA training. L. Escobedo asked about the potential for oral transmission Hepatitis C virus, and Dr. Hanley responded that there are no known instances where Hepatitis C virus has been transmitted via inhalation or ingestion. L. Escobedo favorably commented on the safety plan. There were no further comments or questions from the committee. Dr. Hanley and Ms. Ponds thanked the IBC for their consideration and then left the room. J. Kemp motioned to vote on the application. P. Lammers seconded the motion. The vote was taken by a show of hands of the members.

The result of the vote was:

For Approval: J. Balog, M. Bromwell, L. Escobedo, W. Fedio, B. Gabitzsch, P. Jackson, J. Kemp, P. Lammers
Against approval: none
Abstention: none

c) Timothy Wright, "*Avian Phylogeny and Population Genetics*"

J. Kemp provided a brief background summary stating that because of a lack of available lab space due to the Foster Hall renovation, Dr. Wright will share space in W357 Chemistry. He has voluntarily chosen to conduct his BSL-1 research using BSL-2 work practices in W357 of the Chemistry Building. The IBC has previously approved Dr. Hanley's work in W357at BSL-2 and the IBC will not approve of different biosafety level work practices within a single laboratory. All personnel have completed the OSHA and biosafety awareness training.

L. Escobedo provided primary review and recommended approval. The research will construct a family tree of parrot lineages for the purpose of "understanding basic structure for conservation". Blood and tissue specimens will be obtained and DNA will be extracted for analysis. L. Escobedo provided the following written text of points to consider. (Italicized comments in parenthesis address each point as discussed at the meeting.)

Recommendation: Approve, with consideration of the following questions and issues:

UDSA inspection of Dr. Wright's lab on July 12, 2005 with safety report expected soon. Please share report with Biosafety Officer. *(J. Balog was present during the USDA inspection and is aware of the report content. The laboratory was in good order and no items for correction were identified. The permit was issued on 09-30-05 and Dr. Wright has provided a copy for the file.)*

There is the possibility of fieldwork to identify 42 parrot species not currently available in Costa Rican zoos, which per protocol will provide blood or feathers to Dr. Wright. Please notify Biosafety Officer about prospects for doing fieldwork (to bleed parrots), if this activity is ever likely or being planned for, and submit information regarding safety measures to be used in the field. *(At the outset of this project specimens will be obtained from museum collections and from zoos. The attending veterinarian at the zoo will obtain specimens from live animals and ship the specimens to Dr. Wright. Fieldwork is not anticipated in the near future. Dr. Wright agrees to notify the Biosafety Officer and discuss necessary precautions prior to beginning fieldwork. P. Jackson suggested Dr. Wright maintain written record of training events.)*

There is the theoretical risk of transmission of certain exotic diseases from parrots to humans through contact with parrot blood. The major risk may be from contact with contaminated blood (through splash of blood to mucous membranes or to respiratory airways) that could result in chlamydia disease, an acute disease of the upper respiratory tract that can present with or without pneumonia. *(Dr. Wright stated he is aware of the risk associated with parrot blood. Current plans call for the attending veterinarian to obtain blood specimens and ship the specimen in a buffer. As mentioned previously, Dr. Wright will discuss necessary precautions prior to beginning fieldwork.)*

It is stated that there might be importation of parrot samples from areas known endemic for avian influenza, and that the Biosafety Officer will be notified. Because of the serious nature of avian influenza in humans, notification and careful planning for importation of samples from endemic areas would be a priority and should also be discussed with the biosafety committee. *(Section V Description of Activity states "We do not anticipate and will make every effort to avoid importation of samples from regions identified under quarantine for the pathogenic avian influenza, namely Cambodia, Indonesia, Japan, Laos, South Korea, Thailand, and Vietnam." Follow up note: As of October 2005, the USDA has prohibited importation of avian species and tissues from all areas endemic for avian influenza.)*

It is stated in several parts of the application that there will be use of gloves and lab coats inside the laboratory (p 7), handling of tissues using standard protocols (p8), and training of co-workers for relevant techniques (p 9), and on proper use of equipment and operation (p 13). However, there is need to add safety precaution to each of these instances. *(In a post meeting exchange of emails and a phone call, J. Balog and L. Escobedo agreed that the safety precautions described in the laboratory safety plan are appropriate and sufficient for the proposed work.)*

Respectfully submitted,

Luis G. Escobedo

There were no further comments and L. Escobedo motioned to vote on the application. J. Balog seconded the motion. The vote was taken by a show of hands.
The result of the vote was.

For Approval:	J. Balog, M. Bromwell, L. Escobedo, W. Fedio, B. Gabitzsch, P. Jackson, J. Kemp, P. Lammers
Against approval:	none
Abstention:	none

Old Business

Each member in attendance signed off indicating his approval to release the Biosafety manual. The committee authorized J. Kemp to review the final pre-publication copy prior to posting on the manual on the EH&S website. The IBC and each PI that has an approved will be provided with a hard copy of the manual. P. Jackson suggested it would be beneficial for the manual to be reviewed by someone uninvolved to evaluate the readability and identify any remaining typographical errors.

P. Lammers agreed to remind Dr. Van Voorhies to complete the lone outstanding training session (Hazardous Waste Management).

New Business

L. Escobedo commented on the reliance of personnel mastering experimental techniques and asked if there was a baseline of "safety skills" deemed acceptable in order to approve an application. In response, J. Balog stated that EH&S provides required OSHA training, and extended an invitation to all the committee members to attend EH&S training sessions. He asked that anyone enroll on-line at http://www.nmsu.edu/safety/training-link.htm. J. Kemp endorsed this recommendation to the committee.

J. Kemp asked that the committee consider their availability to meet in March 2006.

M. Bromwell stressed the emphasis that OSHA places on job hazard analysis in incident investigations and that there is criminal liability associated with non-compliance. L. Escobedo asked how NMSU inspects facilities. J. Balog stated that he inspects labs identified on IBC applications and other EH&S staff inspects buildings for compliance with building occupancy codes, the Fire Department inspects for fire safety.

There being no further business, the meeting adjourned at 4:25 PM.

Submitted by John Balog and approved by vote of the IBC as reflected in the meeting minutes of March 30, 2006.