



Institutional Animal Care and Use Committee  
Graduate and Research Affairs  
San Diego State University  
5500 Campanile Drive  
San Diego CA 92182 • 1643  
TEL: 619 • 594 • 0905  
FAX: 619 • 594 • 4109

April 5, 2006

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

Dear Mr. Hammond:

In response to your letter dated March 15, 2006 and in compliance with NIH Guidelines (section IV-B-2-a(7), please find enclosed minutes of SDSU Institutional Biosafety Committee (IBC) meetings held since June 2003.

Sincerely,

Camille Nebeker  
Director, Division of Research Affairs  
Graduate and Research Affairs  
San Diego State University

Enclosures

Copy to: Mr. Allen Shipp, NIH OBA

**Institutional Biosafety Committee Meeting Minutes  
March 27, 2006**

**Present:** S. Maloy, Chair, R. Bizzoco, M. DeMers, M. Goulian, C. Nebeker (Ex-officio), J. Perrault, V. Rodriguez, T. Slimp, M. Tran, B. Wingerd  
**Absent:** J. Cobble  
**Recorder:** C. Cook

The meeting was called to order at 1:15pm.

1. The minutes of the January 25, 2006 meeting were approved.

**2. Sunshine Project Request**

The Sunshine Project has requested a copy of IBC minutes from May 2003 to present. Copies of the requested documents will be sent on or before April 28, 2006.

**3. Codes of Conduct for Dual Use Research**

The Chair informed the committee that the NSABB has started deliberations on the criteria required to distinguish dual use research and will embark upon a process of developing guidelines that may eventually define a role for local review groups, such as IBCs, in the oversight of this arena of research. IBCs and other stakeholders will have a voice in the development of these guidelines. The IBC community will be notified directly of any future changes in their responsibilities.

**4. BSO Report**

Federal and institutional shipping guidelines and requirements will be posted to the website soon. The BUA will be revised to include information about the method of transporting or shipping materials under IBC oversight. Ongoing facility and laboratory inspections will continue throughout April. Minor revisions to the BUA review/approval procedures list were discussed and approved.

**5. CBRA Workshop**

T. Slimp attended the recent CBRA workshop entitled "Harmonization of IACUCs and IBCs: Finding Common Ground." Copies of some of the handouts from the workshop were given to the committee. He also stated that it was very informative and emphasized that our IACUC and IBC are working together exceeding their recommendations. One of the main topics of discussion was the finalization of the rules published in the federal code of regulations with regard to select agents.

**6. BUA Amendment Form**

A revised BUA amendment form was presented and approved. This form will be posted to the website.

**7. BUA Submissions**

**APPROVALS PENDING**

06-02-062R	Phages Detected in Uncultured Pseudomonis Samples from Cystic Fibrosis Patients	BSL2
	<p>The Committee determined that the submission was incomplete, and subsequently, agreed they had many questions that need to be addressed prior to further review as stated below:</p> <p>Section II: Indicate project period and funding agency.</p> <p>Section III: Ensure that appropriate work practices and containment level are maintained even after the process of filtration. The material is still considered biohazardous since viruses may potentially be present in the sample.</p> <p>Section VIA: Include the PI as an authorized user on the BUA.</p> <p>Section VIB: Indicate laboratory room where the biosafety cabinet is located. (See Section VIIC for requiring a biosafety cabinet.)</p> <p>Section VIC: Describe biosafety cabinet being used. (See Section VII C for requiring a biosafety cabinet.)</p> <p>Section VIE: Post biohazard sign at laboratory entrance(s), and indicate biohazard on sign.</p> <p>Section VIIC: Either work inside a biosafety cabinet, preferably Class II, use appropriate personal protective gear (respiratory/ facial protection in addition to eye protection), or use other physical containment devices, whenever procedures with a potential for creating infectious aerosols or splashes are conducted. Thus, when homogenizing the sputum sample in a 10 ml sample cup (a wide and open container), the potential for infectious splashes and aerosols increases. Therefore, appropriate containment equipment or personal protective gear must be used.</p> <p>Section VIID: Ensure that biohazardous containers (red bags) are placed and transported in appropriately labeled secondary container to be dropped-off in the biowaste accumulation site.</p> <p>Section VIIF: Place a biohazard label (sticker) on the secondary packaging (sealed plastic bag) in addition to the outer packaging (cooler). Enclose an itemized list of contents (e.g. sputum samples or sputum samples with <i>P. aeruginosa</i>) between the secondary packaging and outer packaging.</p>	

**8. Other Business**

It has been brought to the attention of the committee that there are two investigators on campus who may need IBC review and approval and are unaware of the requirement. Correspondence will be sent to them individually to inquire about their work.

**8. Future Agenda Items (to be discussed when needed):**

BLS3 Biosafety Manual  
BSL3 Laboratory Updates

Meeting was adjourned at 2:45 pm.

**Institutional Biosafety Committee Meeting Minutes**  
**September 29, 2004**  
**1:15 – 3:15pm**

Present: S. Maloy, Chair, R. Bizzoco, J. Cobble, M. Ginsberg (email), M. Goulian, C. Nebeker (Ex-officio), J. Perrault, Janis Shackelford, M. Tran, B. Wingerd,  
Absent: A. Bakarich, T. Ghio  
Recorder: C. Cook

The meeting was called to order at 1:15pm.

**1. Introductions**

Introductions were made including new member Joanne Cobble, Development Specialist, SDSU Foundation.

**2. The minutes of the April 14, 2004 meeting were approved.**

**3. BSL3 Laboratory Construction Update**

The Biology Department Manager reported that BSL3 laboratory has is complete. The minor revisions as a result of the inspection have all been corrected and an autoclave has been purchased and installed. Only BSL2 work is currently being conducted in the lab, BLS3 work will begin some time this semester. Signage needs to be installed, the manager will contact the Chief Engineer directly to ensure this gets accomplished.

**4. BSL3 Biosafety Manual**

It will be the duty of the Director to develop the safety manual and standard operating procedures (SOP) for the facility. The BSO will provide assistance. In addition, individual safety manual and SOP's will be developed for each project conducted in the facility. The manual and SOP's are still under development.

**5. Biosafety Training**

The BSO reported that materials are being put together for the biosafety training for faculty and staff, including select Physical Plant shops and first responder Public Safety Officers. Several training sessions will be scheduled and will be approximately an hour and a half in length and customized depending on the biological hazard and biosafety level of the lab.

**Safety Guidelines**

The BSO on preparing guidelines for research involving human or non-human primate cell lines. These guidelines will include a list of the SDSU procedures, rules and regulations specifically associated with this type of research and the requirement that this work be conducted under BSL2 conditions.

**6. Shipping Biological Materials to and from SDSU**

The Committee will send a letter to the Director of Environmental Health and Safety strongly recommending that EH&S purchase the current and any subsequent training packages on shipping and receiving rules and regulations of biological materials. Once received, training sessions will start immediately and be required every two years.

**7. BUA Submissions**

Submissions from the School of Nursing have not yet been received but are expected.

**PENDING APPROVALS:**

04-06-042	Project SALSA IIB	BSL2
• This approval is still pending approval of revisions. The Chair and BSO will confirm all conditions have been met		

04-08-044	Anti-spingolipid Antibodies for the Treatment of Cancer	BSL2
<ul style="list-style-type: none"><li>• The work conducted under this BUA must be under BSL2 conditions</li><li>• Recertification of the biosafety cabinet is due.</li><li>• Describe the contingency plan for accidental needle prick while injecting mice?</li></ul> <p>The Committee voted to approve this submission.</p>		

**8. Community Member**

The Chair reported that T. Ghio has had to step down as a community member. She has suggested a recommendation for her replacement. A CV has been requested, once received, it will be forwarded to the committee for their recommendations. An update will be provided at the next meeting.

**9. Sunshine Project**

C. Nebeker reported that she has now forwarded all minutes of the IBC, since June 2003, to the Sunshine Project. No further requests have been made.

**10. Meeting Schedule and Membership List**

The schedule and list were given to the committee.

**11. Additional Issues**

The Chair reported that the campus veterinarian has evaluated and verified that the vivarium does meet the requirements for BSL2 animal work.

It was recommended that BUA revision and amendment forms be developed. C. Cook and M. Tran will work on that.

Meeting was adjourned at 3:15pm.

**Institutional Biosafety Committee Meeting Minutes**  
**January 12, 2005**  
**12:00 – 2:00pm**

Present: S. Maloy, Chair, A. Bakarich, R. Bizzoco, J. Cobble, M. Ginsberg (email), M. Goulian, C. Nebeker (Ex-officio), J. Perrault, M. Tran  
Absent: Janis Shackelford, B. Wingerd  
Recorder: C. Cook

Lunch was served, the meeting was called to order at 12:30pm.

1. The minutes of the September 29, 2004 meeting were approved.

**2. BSL3 Laboratory Construction Update**

In the absence of the Biology Department Manager, J. Perrault stated that there is no BSL3 work being conducted in the laboratory at this time. He also stated that physical plant needs to provide a manual of operation for the controls in the lab. The Biology Department manager has requested this documentation and will report at the next IBC meeting. He also stated that miscellaneous supplies and equipment are still needed in the lab.

**4. BSL3 Biosafety Manual**

It is the duty of the Director to develop the safety manual and standard operating procedures (SOP) for the facility. In addition, individual safety manuals and SOPs will be developed for each project conducted in the facility. The manual and SOPs continue to be under development.

**5. Biosafety Training**

The BSO reported the biosafety training will begin at the end of January, for faculty and staff, including select Physical Plant shops and first responder Public Safety Officers. Several training sessions will be scheduled to last approximately 2 hours and will be customized depending on the biological hazard and biosafety level of the lab or entity. The expected completion date for all training will be March 31, 2005.

**6. Shipping Biological Materials to and from SDSU**

The BSO stated that EH&S has purchased an established training package, which incorporates standards and practices consistent with the federal rules and regulations of shipping and receiving biological materials. Training sessions will start immediately and be required every two years.

**7. BUA Submissions**

Submissions from Engineering and Anthropology are expected.

**APPROVALS since the last meeting:**

04-06-042	Project SALSA IIB	BSL2
04-08-044	Anti-sphingolipid Antibodies for the Treatment of Cancer	BSL2
04-10-045	Blood Glucometer Testing – Fingersticks in Classroom	BSL2

**8. Community Member**

A resume has been distributed to the IBC members for consideration of an additional community member. It was determined that this Ms. Rodriguez would be a qualified candidate for the position. It was requested that additional resumes be accepted for consideration for this community member position as well. Ms. Rodriguez will be invited to attend the next meeting.

**9. Memo dated December 6, 2004 from NIH, Department of Health and Human Services**

The Associate Vice President for Research agreed with the Chair that the Biosafety program on campus is running very effectively and efficiently. If the NIH chose our campus for a site visit, we would be ready.

Meeting was adjourned at 2:05 pm.

**Institutional Biosafety Committee Meeting Minutes**  
**February 16, 2005**  
**1:15 – 3:15pm**

**Present:** S. Maloy, Chair, A. Bakarich, R. Bizzoco, J. Cobble, M. Ginsberg (email), M. Goulian, C. Nebeker (Ex-officio), Janis Shackelford, M. Tran, B. Wingerd  
**Absent:** J. Perrault  
**Guest:** T. Gee  
**Recorder:** C. Cook

1. The minutes of the January 12, 2005 meeting were approved.
2. **BSL3 Laboratory Construction Update** No report given.
3. **BSL3 Biosafety Manual** No report given.
4. **Biosafety Training**  
The BSO reported the biosafety training has been completed. There will be make-up classes for those who could not attend.
5. **On-line Biosafety Training**  
The possibility of including the training on the BlackBoard system was discussed. C. Cook offered to set up the training program on Blackboard. EH&S will send the text, questions and answers to her for input into Blackboard.
6. **Shipping Biological Materials to and from SDSU**  
The BSO stated that EH&S has purchased an established training package, which incorporates standards and practices consistent with the federal rules and regulations of shipping and receiving biological materials. This training is 3 to 4 hours in length and is only available in Windows format. An email will go out to the PIs letting them know this training is available for check out from EH&S.
7. **EH&S Committee Representative**  
The Associate Director of EH&S will fill in as the BSO and IBC member while the current member is out on maternity leave. An appointment letter will be sent.
8. **Responsibilities of IBCs and Public Meeting Issues**  
S. Maloy reported that he met with several federal employees and has been forewarned that the regulations regarding potential dual use agents will be getting more stringent. These items will require IBC review yearly. He also reported that the USDA, CDC and NIH are working on a unified infectious agents list, which will make it a little easier to comply with each entity's regulations. He also noted that the shipping regulations will also be changing. All these changes are expected to come out in the Federal Register by next year.

**9. BUA Submissions**  
**PENDING APPROVALS**

<b>05-01-046M</b>	<b>Exposing Children to Secondhand Smoke in Contaminated Homes</b>	<b>BSL2</b>
Approval is pending the submission of a revised BUA to include the following: Spell out acronyms, define how baby diapers will be disposed of, ensure all personnel handling urine samples have had the appropriate biosafety training, ensure the appropriate signage is being used. In addition, sign and submit the "Guidelines when Dealing with Specimens of Human Origin and/or Potentially Infectious and/or Hazardous Agents."		
<b>05-01-047K</b>	<b>Role of Mushrooms in a Low Carbohydrate Diet</b>	<b>BSL2</b>
The committee voted to approve this submission with the stipulation that the appropriate signage has been installed and is visible, ensure all personnel handling urine samples have had the appropriate biosafety training and it is suggested that all personnel working with blood use eye protection. In addition, sign and submit the "Guidelines when Dealing with Specimens of Human Origin and/or Potentially Infectious and/or Hazardous Agents."		

<b>05-01-048G</b>	<b>Stress Reduction Interventions and Work Stress</b>	<b>BSL2</b>
This submission has been tabled until it has been determined that the work is being conducted on campus.		
<b>05-01-049K</b>	<b>Effect of Skin Blood Flow on Measurement of Tissue Oxygenation</b>	<b>BSL2</b>
Approval is pending the submission of a revised BUA to include the following: Specify that decontamination will be accomplished using 10% bleach solution, ensure personnel use proper protective equipment, ensure all personnel handling blood samples have had the appropriate biosafety training, ensure the appropriate signage is being used, and list the risks associated with finger sticks. In addition, sign and submit the "Guidelines when Dealing with Specimens of Human Origin and/or Potentially Infectious and/or Hazardous Agents."		
<b>05-01-050K</b>	<b>Physiological Effects of the Taser X-26 on Human Subjects</b>	<b>BSL2</b>
Tabled pending Institutional Review Board (IRB) for human subject use review.		

#### 10. Community Member

The search for additional community members is ongoing. Currently, the required number of community members on the committee is in compliance with the regulations.

Meeting was adjourned at 2:45 pm.

**Institutional Biosafety Committee Meeting Minutes  
March 23, 2005**

**Present:** S. Maloy, Chair, A. Bakarich, R. Bizzoco, T. Gee, M. Ginsberg (email), M. Goulian, C. Nebeker (Ex-officio), J. Perrault Janis Shackelford, B. Wingerd  
**Absent:** J. Cobble, M. Tran, V. Rodriguez  
**Recorder:** C. Cook

The meeting was called to order at 1:15pm.

1. The minutes of the February 16, 2005 meeting were approved with minor editorial changes.

**2. BSL3 Laboratory Construction Update**

The Director of the Biology Department presented a draft standard operating procedure (attached) for the BSL3 laboratory controls that he has worked with Physical Plant to develop. He stated that pictures will be included in the final version of the SOP. Signage will be installed prior to any work being conducted in the lab. He will conduct tours for the committee members to view the facility.

**3. BSL3 Biosafety Manual**

The manual is in development.

**4. Biosafety Training Update**

The BSO reported the biosafety training has been completed. There will be make-up classes provided after spring break for those who could not attend. C. Cook has created a training class in the Blackboard system. Once the tutorial and assessment materials are received from the BSO she will set up the training program and send a notice to the PIs when it is available. It will be required that this training be completed by anyone working with biohazardous materials.

**5. Community Member**

A CV of an interested community member was handed out to the committee. Currently the existing membership meets the requirements for community members. This person will be kept in mind for membership.

**6. BUA Submissions**

**PENDING APPROVALS**

<b>05-01-050K</b>	<b>Physiology Effects of the Taser X-26 on Human Subjects</b>	<b>BSL2</b>
Tabled pending Institutional Review Board (IRB) review.		
<b>05-020-051W</b>	<b>The Effect of Acidic and Alkalotic Blood pH on VO2 Kinetics during High Intensity Exercise</b>	<b>BSL2</b>
Approval pending verification of personnel training.		
<b>05-02-052K</b>	<b>Effect of Heat on Lactate Threshold and Muscle Deoxygenation</b>	<b>BSL2</b>
Approval pending verification of personnel training.		

**7. Other Business**

**Shipping Biological Materials to and from SDSU**

The Chair stated that he has reviewed the training package. This training does take about 4 hours to complete and is available only in Windows format. For those who work with Mac's, Graduate and Research Affairs will have a computer available for anyone wishing to view this material.

Meeting was adjourned at 2:45 pm.

**Institutional Biosafety Committee Meeting Minutes  
April 27, 2005**

**Present:** S. Maloy, Chair, R. Bizzoco, J. Cobble, T. Gee, M. Goulian, C. Nebeker (Ex-officio), J. Perrault, J. Shackelford, V. Rodriguez, B. Wingerd  
**Absent:** A. Bakarich  
**Maternity Leave:** M. Tran  
**Guest:** M. Rossi  
**Recorder:** C. Cook

The meeting was called to order at 1:20pm.

1. Introductions were made and the Chair welcomed everyone to the meeting. It was agreed upon to allow SDSU Research Foundation development specialists and fund administrators to attend the meetings as guests so they may gain knowledge of the IBC's role in regulatory compliance and develop a better understanding of how the IBC's review of research fits into the grant administration process.
2. The minutes of the March 23, 2005 meeting were approved with minor editorial changes.
3. **BSL3 Laboratory Construction Update**  
The Manager of the Biology Department stated that a work order has been submitted to physical plant to install signage in the laboratory. There are no immediate plans to conduct BSL3 level work in this lab; however the lab is being used for BSL2 experiments. SOPs will be developed for BSL3 research, on an as needed basis, specific to the planned research and prior to use of the BSL3 for that research.
4. **Biosafety Training Update**  
Training materials are being developed by EH&S. Once developed, the materials will be included in the Blackboard system. Completion of this training will be required by anyone working with biohazardous materials.
5. **Community Member**  
Our community members were acknowledged and appreciation extended for the value their expertise and perspectives bring to the IBC. Given the importance of community members on the IBC, the Chair asked the committee members to consider others they may know in the community who would be interested in serving on the IBC.
6. **Final Rule – Select Agents**  
The U.S. Departments of Health and Human Services (DHHS) and Agriculture (USDA) have published final rules, which set forth the requirements for possession, use and transfer of select agents and toxins. These rules were published in the Federal Register on March 18, 2005 and become effective 30 days after publication. An outline and explanation of the final rules are attached.
7. **Incident Report**  
It has come to the attention of the committee that an accidental finger prick has occurred in a classroom teaching/research activity covered on an approved APF. The student reported the incident to campus police. EH&S conducted an investigation and made recommendations to the PI to provide further verification that the students have been properly trained. A subcommittee of the IBC will schedule a conference with the PI and conduct a site visit to provide any additional guidance and assistance needed to minimize the recurrence of such accidents.

**8. BUA Submissions  
PENDING APPROVALS**

05-01-050K	Physiology Effects of the Taser X-26 on Human Subjects	BSL2
Tabled pending Institutional Review Board (IRB) review.		

<b>05-020-051W</b>	<b>The Effect of Acidic and Alkalotic Blood pH on VO2 Kinetics during High Intensity Exercise</b>	<b>BSL2</b>
Approval pending verification of personnel training and site visit.		
<b>05-02-052K</b>	<b>Effect of Heat on Lactate Threshold and Muscle Deoxygenation</b>	<b>BSL2</b>
Approval pending verification of personnel training and site visit.		

#### **9. Other Business**

The Chair stressed the importance of conducting regularly scheduled IBC meetings, keeping accurate minutes and staying current on the various rules and regulations governing biosafety.

#### **Future Agenda Items (to be discussed on an as needed basis):**

BLS 3 Biosafety Manual

BSL3 Laboratory Updates

Meeting was adjourned at 2:45 pm.

## Attachment A

### FINAL SELECT AGENT RULES

March 18, 2005

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules, which implement the provisions of the *USA PATRIOT Act* and *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products.

The final rules (42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121) were published in the Federal Register on March 18, 2005. All provisions of the final rules supersede those contained in the interim final rules and become effective 30 days after publication in the Federal Register. The final rules are being published in response to public comments received regarding the interim final rules and to harmonize the structure and format of the HHS regulations and the USDA regulations. For the most part, the regulations remain unchanged. The following outlines the most significant revisions:

#### **HHS/Overlap select agents and toxins:**

- Revised the genetic element section to include the regulation of nucleic acids that can produce infectious forms of any of the select agent viruses (e.g. genomes of positive strand RNA viruses on the select agent lists such as Eastern Equine Encephalitis virus, Venezuelan Equine Encephalitis virus, and Tick-borne encephalitis complex (flavi) viruses).
- The list of those eligible to exercise control over unregulated or excluded amounts of toxins was broadened to include not only principal investigators, but also treating physicians and veterinarians, and commercial manufacturers or distributors.

#### **Exemptions for HHS/overlap select agents and toxins:**

- The reporting requirements were clarified that both registered and unregistered entities must report the identification of select agents and toxins presented for diagnosis, verification, or proficiency testing.
- Entities that identify select agents and toxins presented for diagnosis, verification, or proficiency testing are now to secure such agent or toxin against theft, loss, or release during the period between identification and transfer or destruction of such agent or toxin.
- APHIS and CDC have combined their immediate notification list for overlap select agents and toxins: Bacillus anthracis, Botulinum neurotoxins, Francisella tularensis, Brucella melitensis, Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus.

#### **Registration and related security risk assessment**

- Language was added to clarify who would be deemed to own or control an entity, and as such would require a security risk assessment.
- A provision was added to prevent an unnecessary lapse in a certificate of registration when the entity loses the services of the Responsible Official and there is no alternate Responsible Official.
- The notification of destruction for the purpose of discontinuing activities with a select agent or toxin requirement was removed.

#### **Denial, revocation, or suspension of registration**

- A new provision was added to specify that a certificate of registration will be denied, revoked, or

suspended if it is determined that such action is necessary to protect public health and safety.

- New language was added to clarify the specific actions an entity must take when the certificate of registration is suspended or revoked.

#### **Restricting access to select agents and toxins; security risk assessments**

- Provided clarification on what is meant by the term access as “an individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.”
- A new requirement was added to specify that an individual’s access will be denied if it is determined that such action is necessary to protect public health and safety.
- A new provision was added to require the entity to notify CDC when an individual’s access was terminated and the reasons for that termination.

#### **Inspections and Plan Review**

- The language regarding the annual inspection by the Responsible Official was clarified to ensure that all of the requirements of the regulations are met.
- A new requirement was added that drills or exercises of security, biosafety, and incident response plans must be conducted at least annually.

#### **Training**

- The language allowing the Responsible Official to certify that an individual has the required knowledge, skills, and abilities has been removed.

#### **Transfers**

- A new provision was added that a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (e.g., change in the certificate of registration for the sender or recipient, change in the application for transfer).
- The notification of when a select agent or toxin is consumed or destroyed after a transfer was removed.

#### **Records**

- Since the requirements that entities maintain records of all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), the date and time of entry is sufficient in maintaining records of access into areas containing select agents and toxins, the exiting record-keeping provision was deleted.
- A single form number will be used for each of the identical forms used by HHS and USDA (e.g. “Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins” which was previously reference as CDC Form 0.1319 or APHIS Form 2040 will now be reference as APHIS/CDC Form 1).

**Institutional Biosafety Committee Meeting Minutes Revised  
May 25, 2005**

Present: S. Maloy, Chair, A. Bakarich, R. Bizzoco, M. Goulian, C. Nebeker (Ex-officio), J. Perrault, J. Shackelford, B. Wingerd  
Absent: J. Cobble, T. Gee, V. Rodriguez  
Guest: T. Slimp  
Maternity Leave: M. Tran  
Recorder: C. Cook

The meeting was called to order at 1:15pm.

1. Introductions were not needed.
2. The minutes of the April 27, 2005 meeting were approved with a minor editorial change.

**3. Replacement of Animal Expert Committee Member**

The campus veterinarian has resigned from the University effective May 31, 2005. Mr. Tony Slimp, SDSU Office of Laboratory Animal Care Manager will be appointed to the committee effective June 1, 2005.

**4. BSL2 work in BLS3 Laboratory**

Tabled until further notice once more information is obtained.

**5. Animal Care/EH&S Site Visits**

The IACUC conducted its semi-annual facility inspections in April. Minor deficiencies were found in two laboratories, which included changing chemical container identification labels from abbreviations to spelling out the full word and ensuring sharps containers were closed and had nothing sticking out of them. Otherwise, the laboratories inspected were in good shape and compliant with biosafety regulations.

**6. Chronicle of Higher Education Article and Table**

This article spoke of the requests made by the Sunshine Project to those institutions receiving funding from the National Institutes of Health for their IBC minutes. It also spoke of the findings and outcomes of those requests, which revealed that many institutions were not in compliance with the NIH guidelines governing public access and recordkeeping. The table included responses of five institutions to the Sunshine Project, the institutions explanation of the response and the NIH, Office of Biotechnology Activities (OBA) responses and recommendations to the institutions from OBA. The SDSU, IBC Chair reiterated that regular meetings must continue to be held for discussion of project activity on campus that involved work with biohazardous material(s) and the importance of keeping accurate and thorough minutes. He also pointed out that SDSU is meeting or exceeding all the relevant standards set forth.

**7. Training Update**

The EH&S representative will report on this subject at the next meeting.

**8. Incident Report**

A subcommittee of the IBC conducted a site visit to the area where the incident occurred. As a result of the visit the following guidance and recommendations will be provided to the investigator(s):

- a. ENS will post signage with emergency instructions to provide definitive information re: who to call during regular hours and off hours. Unfortunately, after talking with Student Health Services (SHS), there are gaps in the coverage that still need to be discussed and worked out between SHS and Risk Management. SHS will provide more clarification. As it is now: call SHS or show up @ regular hours are 8AM to 4:30 PM, M-F. After hours: call campus 911 for ambulance or police escort to Alvarado Medical Center, urgent care. There are variables in this scenario that need to be clarified.
- b. EHS to provide Blackboard training, with text to be tailored to ENS classes. This means biosafety

information to be consolidated and summarized for student consumption. This will also include guidelines/procedures for finger sticks. Also, the training will include input from the professors so the text will be relevant to class protocols.

c. Blackboard training will allow for a student roster so trained individuals will be documented. This will be very helpful to not only document who has had the training, but reinforce other classroom training, and satisfy regulatory and liability requirements.

d. EHS to assist in an audit of their exercise physiology lab to ensure compliance.

It was also suggested that the "SDSU Health and Safety Guidelines for Dealing with Specimens of Human Origin and/or Potentially Infectious and/or Hazardous Agents" and the "SDSU Health and Safety Guidance on Drawing Human Blood and their Subsequent use in Research" be revised to take out areas which would indicate a specific project and specific area(s) where this work would be performed. The revised forms will be presented at the next meeting.

## 9. Summer Meeting Schedule

These meetings will be held on an as needed basis.

## 10. BUA Submissions

### APPROVALS PENDING

05-01-050K	Physiology Effects of the Taser X-26 on Human Subjects	BSL2
Tabled pending Institutional Review Board (IRB) review.		
05-04-053C	Novel Quantification Methods of Pathogenic Viruses and Analysis on Inhibitors	BSL2
The protocol submitted does not contain the information necessary to conduct a complete review of the proposed research. Specifically, more detail on the overall goal and scope of the research, agents planned for use and experience of investigators and personnel who will be involved is needed. The IBC voted to deny approval of this research until additional information is received for further review.		
05-05-054N	SHAPE Study: Weight Loss in Breast Cancer Survivors	BSL2
The Committee voted to approve once it was understood that DXA stood for "Dual-energy X-ray Absorptiometry."		

## 11. Other Business

It was suggested to include a sentence the IRB and IACUC approval letters whether or not IBC approval may be required.

### Future Agenda Items (to be discussed on an as needed basis):

BLS 3 Biosafety Manual

BSL3 Laboratory Updates

BSL2 work in the BSL3 Laboratory

Meeting was adjourned at 2:45 pm.

**Institutional Biosafety Committee Meeting Minutes  
June 16, 2005**

Present: S. Maloy, Chair, M. Goulian, C. Nebeker (Ex-officio), J. Perrault, J. Shackelford, T. Slimp, M. Tran, B. Wingerd  
Absent: R. Bizzoco, J. Cobble, V. Rodriguez  
Recorder: C. Cook

The meeting was called to order at 1:15pm.

1. T. Slimp, SDSU OLAC Manager has been appointed as the animal expert to the committee effective June 1, 2005.
2. The minutes of the May 25, 2005 meeting were approved with minor editorial changes.

**3. BSL2 work in BLS3 Laboratory**

The work proposed will involve two strains of the LCMV virus. This work can be performed in this lab however the strain will be need to be firmly identified to verify at which biosafety level this work must be conducted under. The BSL 2 work refers to BUA 04-07-043S: Minicells: A novel Vector in Vaccine Development. This approved BUA involves working with LCMV Armstrong strain 7 and 13 in a BSL2 facility. Concerns have been raised regarding the appropriate biosafety facility, practices and procedures for this particular strain of virus. The following issues shall be indicated in the current BUA or addressed in a written correspondence by the investigator to the IBC: 1) Provide any literature or describe the pathogenicity, virulence, infectivity/communicability, and host range for this particular strain of virus. 2) Discuss appropriate hazard awareness or communication procedure i.e. signage to be provided or placed in the facility or equipment pertaining to this study. 3) Discuss appropriate biohazard control procedure i.e. cage washing and disinfection, disposal of soiled bedding, disposal of carcass, glove changing. Once these issues have been addressed by the investigator, the BSO can assess the risk and determine if the current BSL 2 stands or a higher biosafety level is required.

**4. Training Update**

The EH&S representative stated there are some additional people identified who need to take the comprehensive biosafety training, this training will be provided as soon as possible and will continue to be ongoing whenever needed. The on-line training has been developed with the exception of the quizzes. As soon as the questions and answers have been prepared, the training will be included on the Blackboard system. A separate training session is being developed specifically for those in the Department of Exercise and Nutritional Sciences. This will also be included on the Blackboard system and will be required for all enrolled in certain courses. This training will be monitored by the instructors and EH&S.

**5. BUA Submissions  
APPROVALS PENDING**

<b>05-01-050K</b>	<b>Physiology Effects of the Taser X-26 on Human Subjects</b>	<b>BSL2</b>
Tabled pending Institutional Review Board (IRB) review.		
<b>05-05-055K</b>	<b>Serum Testosterone Responses to Different Loading Parameters of the Squat in Male College Athletes</b>	<b>BSL2</b>
Provide verification that a trained phlebotomist will perform the blood draws via intravenous catheters and that the radioactive blood samples and contaminated glass and plastic will be treated as radioactive waste. The Committee voted to approve once these items have been verified.		
<b>05-05-056M</b>	<b>Pterin Effects on Growth of Cultured Cells</b>	<b>BSL2</b>
The Committee voted to approve once all personnel including the PI's have been listed on page 9 of the BUA.		

05-05-057M	Immune Responses to Gram Negative Bacteria	BSL2
This submission was received today and copies were handed out at the meeting. In a preliminary review the committee noted the following items: 1) clearly define the materials being transported and list in section VII, F; 2) further explain where the materials will be transported to and from and is aware note that the animals cannot be returned to the animal care facility once taken out; 3) Once the animals are euthanized, explain that they will be stored in a biosafety freezer until disposed of; 4) List all personnel working on the project including PI's on page 9; and 5) ensure an Animal Protocol Form is submitted to the IACUC for the work with mice.		

**Future Agenda Items (to be discussed on an as needed basis):**

BLS 3 Biosafety Manual

BSL3 Laboratory Updates

Meeting was adjourned at 2:45 pm.

**Institutional Biosafety Committee Meeting Minutes  
September 28, 2005**

**Present:** S. Maloy, Chair, R. Bizzoco, M. Goulian, C. Nebeker (Ex-officio), J. Perrault, T. Slimp, M. Tran, B. Wingerd  
**Absent:** J. Cobble, V. Rodriguez  
**Recorder:** C. Cook

The meeting was called to order at 1:15pm.

1. Janis Shackelford is retiring from the University and has resigned from the IBC. Individuals eligible to replace Ms. Shackelford will be contacted to determine interest in serving as the laboratory technician member on the committee. Recommendations will be forwarded to the VPR who will make the appointment to the IBC.
2. The minutes of the June 16, 2005 meeting were approved.

**3. Training Update**

The Biosafety Officer stated that the on-line training has been developed and inserted into the Blackboard system. She reported that approximately 160 personnel have either taken the online training or have attended the group training. She provides a personnel update form for PI's to use when adding or deleting personnel from their project(s) and requires it to be updated regularly. This form will be posted to the EH&S website for easy access. An email notice is sent to the PI's when training is required. A copy of this email will be sent to the committee for their information and/or comments.

A separate training session is being developed specifically for those in the Department of Exercise and Nutritional Sciences. This will also be included on the Blackboard system and will be required for all enrolled in certain courses. This training will be monitored by the instructors and EH&S.

The Biosafety Officer also stated that laboratory inspections will continue in an on-going basis.

**4. BSL3 Biosafety Manual**

This manual is still in the works. This item will be tabled and discussed on an as needed basis.

**5. BSL3 Laboratory Update**

The Biology Manager reported that the alarm system, all other equipment and the airflow are all functioning properly. No BSL3 work is being performed at the present time. This item will be tabled and discussed on an as needed basis.

**6. BUA Submissions**

**APPROVALS PENDING**

<b>05-01-050K</b>	<b>Physiology Effects of the Taser X-26 on Human Subjects</b>	<b>BSL2</b>
SDSU IRB has conditionally approved this study. The IBC voted to approve once the following questions have been answered: 1. Have the UCSD personnel had the appropriate training? 2. Where will the blood be stored at SDSU? In addition, the SDSU Biosafety Officer will provide instructions and labeling for blood transportation and containment.		
<b>05-08-060H</b>	<b>Murr1 Inhibition of NF-kappaB-dependent HIV Transcription</b>	<b>BSL1</b>

It was determined that this work should be conducted under the BSL1 containment level. The Committee voted to approve once all personnel has been listed on the protocol.			
<b>APPROVALS Via Email:</b>			
<b>05-07-058C</b>	<b>Defective Bile Acid Metabolism as a Cause of Constipation in Children</b>	<b>BSL2</b>	<b>Approved 8-19-05 via email</b>
The email correspondence approving the BUA will be forwarded to the Committee for their information.			
<b>05-08-059K</b>	<b>Comparison of VO2 Kinetics in Moderate and Heavy Exercise</b>	<b>BSL2</b>	<b>Approved 8-23-05 via email</b>
The email correspondence approving the BUA will be forwarded to the Committee for their information.			

## 7. Other Business

BUA #04-07-043S entitled "Minicells: A Novel Vector in Vaccine Development" was approved on August 23, 2004. Since then, the committee has posed some additional questions and/or concerns with regard to the use of LCMV. The text below was received on July 11, 2005, from the laboratory addressing those questions/concerns:

### 1) Provide literature or describe the pathogenicity, virulence, infectivity/communicability, and host range for these particular strains of the virus

Below is a link from the CDC that describes how LCMV causes infection in nature, virus reservoirs, modes of transmission, symptoms and clinical mortality rates. Keep in mind, this is for a non attenuated, neurotropic strain (WE) not the attenuated LCMV armstrong strain we will be using.

<http://www.cdc.gov/ncidod/dvrd/spb/mnpages/dispages/lcmv/qa.htm>

Below is a link to an article published by our collaborator Dr. Maria Salvato at the Institute of Human Virology at the University of Maryland. In this article, the authors specifically use LCMV because only BSL2 facilities are required. Please open to the discussion section, page 1552, left column, paragraph 2, line 11.

<http://immune.chonbuk.ac.kr/%BC%F6%BE%F7/14-%B1%E8%C1%F8%BE%C6.pdf>

Also included are links to articles from non-collaborators who use the LCMV Armstrong virus under BSL-2 facilities.

<http://jvi.asm.org/cgi/content/full/76/10/5140>

<http://pubmedcentral.com/articlerender.fcgi?artid=518669>

Last is a link from the CDC website that gives guidelines for the use and transport of select agents. Select agents are defined by the CDC as being a possible bioterrorism agent as well as having to be used in a BSL3 or 4 facilities. Also included is a link that lists all of the CDC classified select agents. Please note that LCMV is *not* listed.

<http://www.cdc.gov/od/sap/docs/42cfr73.pdf>

<http://www.cdc.gov/od/sap/docs/salist.pdf>

### 2) Discuss appropriate hazard awareness or communication procedure i.e. signage to be provided or placed in the facility or equipment pertaining to this study.

Signage has been placed on the BSL2 approved biosafety cabinet, the incubator where live LCMV virus is solely used in cell culture and the freezer where LCMV is kept for long term storage. In addition, signage has been posted on the outside door of the main lab (NLS 407) as well as

the entrance to the BSL2 cell culture facility within the lab. In preparation for use of this organism, we have installed a sliding glass door to separate the BSL2 cell culture facility from the main lab. Further, we have a sign posted on the sliding portion of that door that states "NO ADMITTANCE WHILE DOOR IS CLOSED" and all other lab personnel have been notified and educated about not entering the BSL2 cell culture room while work with this organism is in progress and/or the door is closed. As a further precaution, a sign is placed on the outside of the main lab entrance while work with this organism is in progress and states "AUTHORIZED PERSONNEL ONLY UNTIL SIGN IS REMOVED" and during that time this door is locked.

**3) Discuss appropriate biohazard control procedure i.e. cage washing and disinfection, disposal of soiled bedding, disposal of carcass, glove changing.**

**Virus handling**

While working with the LCMV virus, personnel are required to wear double gloves, a lab coat designated solely for the purpose of working with the LCMV virus, and goggles. None of these items leaves the BSL2 cell culture facility under any circumstances. Virus is handled under the biosafety cabinet. Syringes, tubes, glass pipets, and plastic pipette tips are disposed of in a red, biohazard labeled, and sealable sharps container that is housed in the hood until  $\frac{3}{4}$  full. Once  $\frac{3}{4}$  full, this sharps container is immediately sealed and brought to the biohazard waste facility for disposal. Following work with the virus, the entire biosafety cabinet is wiped down with 10% bleach solution. Gloves are disposed of in a red, labeled, double biosafety bag that is immediately sealed after use. This is done under the biosafety cabinet and disposed of in the cell culture room biohazardous waste container. Following this procedure, new gloves are worn and 10% bleach applied for a second time.

**Mouse work**

Mice that have been infected with LCMV will be housed in the BSL2 approved biosafety cabinet in the cell culture room of NLS 407 for 10 days. Following the 10 days, mice will be euthanized via CO2 asphyxiation as described in APF # 03-05-015S (approved on July 1, 2005) and carcasses disposed of in double red, LCMV labeled biohazard bags and frozen immediately. Following two days at -20°C, frozen carcasses will be immediately transported to the dead animal storage freezer in LS17.

Dander and bedding from mouse cages will be pooled and collected in a double, red biohazard bag that has been labeled "LCMV BIOHAZARD". Dander and bedding collection will be performed in the biosafety cabinet. Once double bagged, the bag is sprayed with 10% bleach before removal from the biosafety cabinet. Once removed, dander and bedding will be disposed of in the biohazardous waste facility.

After dander and bedding have been collected, cages will be placed in autoclavable biohazard bags in the biosafety cabinet and the bags sprayed with 10% bleach prior to removal from the biosafety cabinet. Once bagged and sealed, the cages will be autoclaved for 30 minutes in the SD County Onsite Medical Waste Treatment approved autoclave in LS 418. After autoclaving, cages and all of their components will be returned to the animal care facility for rewash by the vivarium staff.

While working with the LCMV infected mice, personnel are required to wear double gloves, a lab coat designated solely for the purpose of working with the LCMV virus, and goggles. None of these items leaves the BSL2 cell culture facility under any circumstances. Following removal of cages for autoclaving, the entire biosafety cabinet is wiped down with 10% bleach solution. Gloves are disposed of in a red, labeled, double biosafety bag that is immediately sealed after use. This is done under the biosafety cabinet and disposed of in the cell culture room biohazardous waste container. Following this procedure, new gloves are worn and 10% bleach applied for a second time.

**8. Future Agenda Items (to be discussed on an as needed basis):**

BLS 3 Biosafety Manual

BSL3 Laboratory Updates

Meeting was adjourned at 2:45 pm.

**Institutional Biosafety Committee Meeting Minutes  
January 25, 2006**

Present: R. Bizzoco, J. Cobble, M. DeMers, M. Goulian, C. Nebeker (Ex-officio), J. Perrault, T. Slimp,  
M. Tran, B. Wingerd  
Absent: S. Maloy, Chair, V. Rodriguez  
Recorder: C. Cook

The meeting was called to order at 1:15pm.

1. M. De Mers was welcomed and introduced as the newest IBC member.
2. The minutes of the September 28, 2005 meeting were approved.

**3. Training Update**

The online Biosafety training posted on Blackboard has been well received. Most of those requiring training have now completed it. A separate training session has been developed specifically for those in the Department of Exercise and Nutritional Sciences and is posted in Blackboard, others can be developed as needed.

The Biosafety Officer also stated that laboratory inspections will rotate continually every semester.

A revised BUA form was presented that had minor editorial changes, it will be posted to the web. The Biosafety Officer and her group are working on an amendment form, which should be ready for review by the next meeting.

**4. BUA Submissions  
APPROVALS PENDING**

<b>05-12-061Q</b>	Influence of Diet on Gene Expression and Cancer Prevention in Utero: Effect of Fruit and Vegetable Intake on the Regulation of Maternal and Fetal Protective Enzymes during Pregnancy in Hispanic Women.	<b>BSL2</b>
The Committee voted to approve pending the submission of a revised BUA to address the following issues: 1. Ensure all personnel listed have completed the necessary biosafety training, 2. Indicate the certification expiration date of the biosafety cabinet located in HT 204, 3. Ensure the packaging of diagnostic specimens is correct; 4. Clarify if waste blood tubes are plastic or glass; 5. Clarify what materials will be transported and how they will be transported.		

**5. Other Business**

B. Wingerd informed the committee there is a professor on campus who collects dead, wild animals from around the county to preserve as specimens for use in his laboratory and class. It was determined the professor needed to submit a BUA that describes the potential biohazardous elements he could encounter while collecting these dead, wild animals.

In addition, during a recent Hazmat inspection, the Department of Biology was found to be 100% compliant.

R. Bizzoco informed the committee that if anyone is interested, he could obtain biosafety cabinets and CO2 chambers at no charge or a very minimal charge.

**6. Future Agenda Items (to be discussed when needed):**  
BLS3 Biosafety Manual  
BSL3 Laboratory Updates

Meeting was adjourned at 2:45 pm.

July 9, 2004

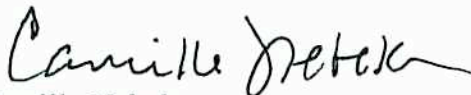
Edward Hammond  
The Sunshine Project  
101 West 6<sup>th</sup> Street, Suite 607  
Austin, TX 78701

Dear Mr. Hammond:

In your letter dated 28 January 2004, you requested copies of the IBC minutes from the two most recent SDSU IBC meetings. Requirements to obtain institutional direction and compliance guidance from the NIH Office of Biotechnology Activities (correspondence dated 5/14/04) in response to your request resulted in a delay. Once guidance was received, SDSU provided minutes from the two most recent IBC meetings.

In your letter dated 24 May 2004, you requested a copy of all IBC minutes from 1 June 2003 to present. In compliance with NIH Guidelines (section IV-B-2-a(7)), please find enclosed minutes for IBC meetings held between June 2003 and January 2004. You should now have all of the SDSU IBC minutes for meetings held since June 2003.

Sincerely,



Camille Nebeker  
Assistant Vice President for Research (Interim)  
Graduate and Research Affairs  
San Diego State University

CN

Enclosures

cc: Mr. Allen Shipp, NIH OBA

**Institutional Biosafety Committee**  
**Meeting Minutes Final - Thursday, June 19, 2003**

Present: J. Zyskind, Chair, R. Bizzoco, S. Maloy, C. Nebeker (Ex-officio), Janis Shackelford, M. Tran  
Absent: A. Bakarich (E-mail), T. Ghio (E-mail), M. Ginsberg (E-mail), J. Perrault (E-mail)  
Recorder: C. Cook

The meeting was called to order at 10:20am.

1. The Chair welcomed members of the committee. The Chair updated members by pointing out that Biosafety issues on this campus are growing rapidly and stressed the importance of ensuring that the Biosafety program is ready for this growth. She stated the importance of having the manual, the protocol form, contact information, training and general information available on-line as soon as possible. AVP for Research will contact the Foundation to coordinate Biological Use Authorization (BUA) form approval with the release of funds.

A motion was made to hire a consultant to assist with inspections of the BSL-2 and 3 laboratories. The motion was seconded and approved. BSO will inquire about the availability and costs for the consultation.

2. **Institutional Biosafety Manual:** Revisions to the SDSU Biosafety Manual have been incorporated. The manual will be added to the Environmental Health and Safety (EH&S) website for easy access. Division of Research Administration and Biology websites will also include a link to the site.
3. **Biological Use Authorization (BUA) Form:** The Biological Use and Authorization form will be included on the (EH&S) website by the first week in July 2003.

It was motioned, seconded and approved to send an email to the department chairs reminding them of regulatory and institutional requirements concerning use of biohazardous materials or experiments involving recombinant DNA within laboratories within their department. They will be asked to forward this information to faculty within their department. This email will include links to guidance and review application materials.

The Environmental Health and Safety Department will continue to maintain all records of BUA submissions.

Approval, approval with stipulations, disapproval, and exempt letters to the PI's will continue to come from the Division of Research Administration signed by the IBC Chair with a copy to the department chair and the SDSU Foundation if applicable.

4. **Protocol Review: BUA# 03-06-001:** Following discussion, a motion was made to approve this BUA pending the inclusion of the room number of location of research and obtaining the investigators signature on the Acknowledgement of Responsibilities form.
5. **Next Meeting Date:** The next meeting will be scheduled for the last week of July or first week in August.
6. **Other Business:** The BSO reported that she will continue to work on the Biosafety training program that will be accessed through Blackboard. In the mean time, links to training available on the web through CDC, etc will be posted to the web site. This information will also be forwarded to the department chairs in the email requesting BUA submissions.

Meeting adjourned 1:00 PM

**Institutional Biosafety Committee  
Meeting Minutes Final  
Friday, August 1, 2003**

Present: J. Zyskind, Chair, A. Bakarich, R. Bizzoco, T. Ghio, S. Maloy, C. Nebeker (Ex-officio),  
J. Perrault, M. Tran  
Absent: M. Ginsberg (E-mail), J. Shackelford (E-mail)  
Guest: B. Wingerd  
Recorder: C. Cook

The meeting was called to order at 12:00pm.

**1. BLS3 Laboratory Construction – Life Sciences Building**

The Biology Department Business Manager, was invited to attend the meeting to provide input on the construction of the BSL3 laboratory. The laboratory was originally designed as a level BSL-2 however, the level of containment was changed to BSL-3. He reported that both the inner door and outer doors of the laboratory and the containment area swing in the wrong direction. Bruce has worked very closely with all construction personnel, the architect and NIH to ensure proper compliance with all applicable regulations. However, the installations of the doors were done in accordance with the State Fire Code and not Biosafety requirements, which in this case could jeopardize the health and safety of the personnel working in and around the laboratory. In speaking with the construction personnel, he determined that the problem could be fixed by reversing the hinges so the doors will swing opposite of what they do now, making minor cosmetic changes after the switch and reinstalling the magnetic closure mechanisms. This repair option would be less costly than replacing the doors. A motion was made to send a letter to Physical Plant from the IBC requesting that this change in the way the doors swing be initiated to meet the various safety requirements as set forth in the NIH Guidelines, CDC Regulations, etc. The motion passed unanimously.

In addition, he was asked if he would be interested in attending future IBC meetings and becoming a member of the Committee. His expertise in the infrastructure of buildings, knowledge of the research activities and safety education/training programs would benefit the Committee tremendously. He agreed to be a member, and the committee's recommendation for appointment will be forwarded to the Associate Vice President for Research (Interim) for confirmation.

- 2. Institutional Biosafety Manual:** A table of contents for the Biohazard Control Program manual was handed out to the members. It was determined that more information on mixed waste be added to Chapter 19.

**3. Biological Use Authorization (BUA) Form E-mail to Chairs and Directors:**

On July 18, 2003, an email was sent to department chairs and directors explaining the responsibilities of the IBC and the BSO and what is expected of any PI doing research involving the use of recombinant DNA or biological or potentially hazardous materials.

**4. BUA Form Submission Procedures:**

A pdf version of the BUA form is currently on the website. This form will be converted to an interactive Word form replacing the pdf version by August 8th. The revised version of the form will allow the PI to download it, save to their computer, and fill it out. Once completed, the form will be submitted electronically to Graduate and Research Affairs along with a signed hard copy via campus mail. All submissions will then be sent electronically to and reviewed by the Chair and BSO. In addition, it was decided that the BSL2 submissions can be reviewed and voted on electronically by the full Committee whereas the BSL 3 submissions will require convened Committee review.

It was determined that only the classes of vectors and/or strains are required to be reported rather than every vector and/or strain the PIs are researching. Therefore, a motion was made to change

the form as noted making the submission less cumbersome to the PIs. The motion passed unanimously.

**5. Training for IBC Members, Principal Investigators and Laboratory Staff:**

The Biosafety Officer will conduct comprehensive group training sessions for each laboratory currently conducting research using biohazardous materials or recombinant DNA. She will also develop online training that will be available through Blackboard. Currently, the Biology Department Business Manager is providing BSL-2 inspections and basic biosafety training for the Biology Department on an as needed basis. This training will compliment the training the BSO provides.

A motion was made to send a letter to Business and Financial Affairs, stressing the importance of mandatory safety training for physical plant and custodial personnel who may need to access the facilities/laboratories housing biohazardous materials and/or recombinant DNA. The motion passed unanimously.

It was also suggested that the Director of Physical Plant, be invited to attend the meeting in September to discuss possible training mechanisms for personnel who need to access these spaces.

**6. Initial Biosafety Laboratory Oversight Issues:**

A consultant has been hired and has agreed to provide oversight for the first round of laboratory inspections and will be designated as the official signatory. The consultant will train Millie Tran to do these inspections in the future and has agreed to provide assistance throughout. The BSL3 laboratory is scheduled for completion the first week of September 2003. A list of expectations and deliverables will be developed for the consultant.

**7. Next Meeting Date:** The next meeting will be scheduled for around September 30, 2003.

Meeting adjourned 12:10 PM

## **Institutional Biosafety Committee Meeting Minutes - October 2, 2003**

Present: J. Zyskind, Chair, A. Bakarich, R. Bizzoco, S. Maloy, C. Nebeker (Ex-officio),  
J. Perrault, Janis Shackelford, M. Tran, B. Wingerd  
Absent: M. Ginsberg (E-mail), T. Ghio (E-mail)  
Recorder: C. Cook

The meeting was called to order at 1:00pm.

### **1. BLS3 Laboratory Construction – Life Sciences Building**

The Biology Department Business Manager reported that BSL3 laboratory construction is around 90% complete. The major issue in the progress of the construction now is the negative pressure airflow, which is being very aggressively addressed. Once that issue has been resolved the direction the doors swing will no longer be relevant. The final inspection and biosafety certification has been postponed until mid October, tentatively, which will be performed by various campus and off campus individuals, the BSO the consultant.

### **2. Institutional Biosafety Manual: The manual will be posted to the web by the end of October.**

### **3. Training for IBC Members, Principal Investigators and Laboratory Staff:**

The Biosafety Officer will soon be conducting comprehensive group training sessions for each laboratory currently conducting research using biohazardous materials or recombinant DNA. The training will include, but not limited to, disposal, disinfection, storage, containment, biohazardous waste, etc. The BSO has also developed the on-line training that will be available through Blackboard for training for all three Biosafety Levels.

### **4. Biosafety Laboratory Oversight Issues:**

Ongoing inspections will occur until all laboratories using biohazardous materials or recombinant DNA are complete. Principal Investigators will be encouraged to take a more active role in managing training and ongoing oversight to minimize the occurrence of violations. NIH requires that BSL-2 laboratories are inspected yearly and that BSL-3 laboratories be inspected twice yearly.

### **5. BSL-1 Containment for Salmonella Enterica sv. Typhimurium Strain LT2:**

The Committee discussed the issue of authorizing PI's to use attenuated Salmonella Enterica sv. Typhimurium strain LT2 under BSL-1 conditions. Further discussion will be required at the next meeting.

There was discussion regarding the implementation of an institutional policy that would require autoclaving of any strain of E-coli to become standard practice. It will be discussed in greater depth at the next meeting. In addition there was discussion about any human or primate cell line to be contained at the BSL-2 level, further discussion at the next meeting.

### **6. BUA Submissions**

#### **PENDING APPROVALS**

#### **BUA # 03-08-002 Detection of Viruses in Human Blood**

Conditions of Approval:

1. List yourself as an authorized user in Section VI A and resubmit that page.
2. Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.

#### **BUA # 03-08-003 Genetics of Flavin Dehydrogenase-Membrane Interact**

Conditions of Approval:

1. This project is currently considered to be BSL-2. However, there will be further discussion at the next IBC meeting regarding lowering the level for the use of Salmonella Enterica sv. Typhimurium Strain LT2.

2. List all authorized users including yourself in Section VI A of the BUA and resubmit that page.
3. Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.

**BUA # 03-08-004 Salmonella Host-specificity**

Conditions of Approval:

1. List all authorized users including yourself in Section VI A of the BUA and resubmit that page.
2. Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.

**BUA #03-09-005 Characterization of Genes in *Hydroides Elegans***

Conditions of Approval:

1. Provide the strain of E-coli that will be used on this project, certain strains require BSL-2 containment.
2. Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.
3. Please read Section III-D-4-a of the NIH Guidelines for use of recombinant DNA, or DNA or RNA in invertebrate organisms.

**BUA #03-09-006 Contractile Proteins of *Drosophila Melanogaster***

Conditions of Approval:

1. The IBC was unable to review, sections of this form are not complete.
2. List genetically modified vectors in Section IV A.
3. List all authorized users including yourself in Section VI A of the BUA.
4. Indicate location where recombinant work will be performed in Section VI B.
5. Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.
6. A complete, revised BUA with more detailed information must be submitted by October 28, 2003.

**BUA #03-09-007 Human Health Risk Assessment for Enterovirus and Hepatitis A in Runoff from the Tijuana River and Waters of Imperial Beach**

Conditions of Approval:

1. BSL2 procedures and containment are required when concentrating the water samples that may potentially contain the Hepatitis A virus.
2. BSL2 procedures and containment are also required when spiking water samples with Hepatitis A.
3. List all authorized users including yourself in Section VI A of the BUA.
4. To prevent cross contamination, since the laboratory is a shared facility, Hepatitis A vaccination is also recommended to all other personnel who may be potentially exposed to the water samples and the Hepatitis A virus.
5. Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.

**BUA #03-09-008 Project SALSA**

Conditions of Approval:

1. The use of blood products will require BSL-2 procedures and containment for this project.
2. Since the laboratory is a shared facility, Hepatitis B vaccination is recommended for all personnel working with or could be potentially exposed to Hepatitis B.
3. List all authorized users including yourself in Section VI A of the BUA.
4. Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.
5. Submit revised BUA taking into account

**BUA #03-09-009 Role of the Placenta in Protection of the Fetus: Effects of Nutrition in Hispanic Mothers**

Conditions of Approval:

1. The IBC has considered this project to be at the BSL-2 containment level because of the use of human tissue. Submit a revised BUA by November 21, 2003 reflecting the BSL-2 containment

requirements.

2. Since the laboratory is a shared facility, to prevent cross-contamination Hepatitis B vaccinations for all personnel working on this project or who may be potentially exposed to the human tissue is highly recommended.

3. Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.

**BUA # 03-09-010 Role of the UPR in Cardioprotection**

Conditions of Approval:

1. BSL1 procedures and containment are required for the use of the transgenic mice for this project.

2. BSL2 procedures and containment are required for the use of adenovirus in tissue cultures

3. List all authorized users including yourself in Section VI A of the BUA.

4. Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.

5. Submit revised BUA taking into account BSL2 procedures and containment by October 28, 2003.

**BUA # 03-09-011 Secondhand Smoke Exposure Reduction in High-risk Preteens: A Controlled Trial**

Conditions of Approval:

1. The IBC has determined that the biosafety level for this project is BSL-2 because of possible exposure to Hepatitis B in urine. Submit revised BUA with more detailed information taking into account the BSL2 procedures and containment level by November 21, 2003.

2. Follow universal precautions when handling urine samples. Hepatitis B vaccinations for all personnel handling urine samples is highly recommended.

3. Contact Environmental Health and Safety for waste disposal, decontamination materials (409 cleanser is not sufficient), biohazard signs and labels as they must be posted in lab entrance and work areas.

4. Once determined, list all authorized users, including yourself, in Section VI A of the BUA.

**BUA # 03-09-012 Healthy Children Health Families**

Conditions of Approval:

1. The IBC has determined that the biosafety level for this project is BSL-2 because of possible exposure to Hepatitis B in urine. Submit revised BUA with more detailed information taking into account the BSL2 procedures and containment level by November 21, 2003.

2. Follow universal precautions when handling urine samples. Hepatitis B vaccinations for all personnel handling urine samples is highly recommended.

3. Contact Environmental Health and Safety for waste disposal, decontamination materials (409 cleanser is not sufficient), biohazard signs and labels as they must be posted in lab entrance and work areas.

4. Once determined, list all authorized users, including yourself, in Section VI A of the BUA.

**BUA # 03-09-013 WIC Families Who Smoke: A Behavioral Counseling Study (Health Tots Project)**

Conditions of Approval:

1. The IBC has determined that the biosafety level for this project is BSL-2 because of possible exposure to Hepatitis B in urine. Submit revised BUA with more detailed information taking into account the BSL2 procedures and containment level by November 21, 2003.

2. Follow universal precautions when handling urine samples. Hepatitis B vaccinations for all personnel handling urine samples is highly recommended.

3. Contact Environmental Health and Safety for waste disposal, decontamination materials (409 cleanser is not sufficient), biohazard signs and labels as they must be posted in lab entrance and work areas.

4. Once determined, list all authorized users, including yourself, in Section VI A of the BUA.

**BUA # 03-09-014 Cholesterol/Isoprenoid Biosynthesis: Role of Peroxisomes**

Further IBC review of this project is required and will be discussed at the next meeting on November 4, 2003.

**BUA # 03-09-015 Laboratory Research**

Conditions of Approval:

- 1.The IBC has determined that the cloning of the tax gene from HTLV-1 is considered to be BSL1 containment level as stated in the NIH Guidelines for Research Involving Recombinant DNA Molecules, Section III E 1. However, the use of human tissues and blood are considered to be BSL2 level. Submit, by November 21, 2003, a separate BUA for the project involving BSL2 materials, which includes more detailed information about the BSL2 procedures and containment level.
- 2.Provide more detailed information regarding the use of mice.
- 3.List yourself as an authorized user in Section VI, A.

**BUA # 03-09-016 Gene Regulation in Ascidian Embryos**

Conditions of Approval:

- 1.The IBC was unable to review, sections of this form are not complete. A complete, revised BUA with more detailed information must be submitted by November 21, 2003.
- 2.List all authorized users including yourself in Section VI of the BUA.
- 3.Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.
- 4.Please read Section III-D-4-a of the NIH Guidelines for use of recombinant DNA, or DNA or RNA in invertebrate organisms.

**BUA # 03-09-017 Potentiation of Cardiac Stem Cells to Retard Aging**

Further IBC review of this project is required and will be discussed at the next meeting on November 4, 2003.

**BUA # 03-09-018 VSV Polymerase Function and Cellular Anti-viral Response 2 Virus Inactivation by Chlorine Dioxide**

Conditions of Approval:

1. List the professor from the Department of Engineering as a co-investigator and have her sign the BUA. In addition, list her as personnel working on the project in section VI, A of the BUA.
2. Describe what her role is in this research and what she will be doing.
3. Identify her laboratory location and how hazardous materials will be transported between the laboratories.

**BUA # 03-09-019 Apo B Translocation and Degradation and Intervention into Atherogenesis by Gene Transfer**

Conditions of Approval:

- 1.List the lentivirus vectors used for this project.
- 2.Describe in more detail the use of adenovirus and lentivirus, use of these vectors requires BSL-2 containment. The use of transgenic mice will remain at the BSL-1 level, however, if adenovirus or lentivirus is put into the mice, arrangements must be made to satisfy the BSL-2 containment procedures.
- 3.Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.
- 4.In general, the form is not complete, submit a complete revised BUA with more detailed information by October 28, 2003.

**BUA # 03-09-020 Promoting ETS Exposure Reduction and Tobacco Cessation: A Pediatric Trial**

Conditions of Approval:

- 1.The IBC has determined that the biosafety level for this project is BSL-2 because of possible exposure to Hepatitis B in urine. Submit revised BUA with more detailed information taking into account the BSL2 procedures and containment level by November 21, 2003.
- 2.Follow universal precautions when handling urine samples. Hepatitis B vaccinations for all personnel handling urine samples are highly recommended.
- 3.Contact Environmental Health and Safety for waste disposal, decontamination materials (409 cleanser is not sufficient), biohazard signs and labels as they must be posted in lab entrance and work

areas.

4. Once determined, list all authorized users, including yourself, in Section VI A of the BUA.

**BUA # 03-09-021 Sphingolipid Metabolism and Disease**

Conditions of Approval:

1. The IBC was unable to review, sections of this form are not complete. A complete, revised BUA with more detailed information must be submitted by November 21, 2003
2. List all authorized users including yourself in Section VI A of the BUA.
3. Contact Environmental Health and Safety for waste disposal, decontamination materials, biohazard signs and labels as they must be posted in lab entrance and work areas.
4. Please read Section III-D-4-a of the NIH Guidelines for use of recombinant DNA, or DNA or RNA in invertebrate organisms.

**Next Meeting Date:** The next meeting will be scheduled for the first of November. Meeting adjourned 3:00PM.

**Institutional Biosafety Committee  
Meeting Minutes November 4, 2003**

Present: J. Zyskind, Chair, R. Bizzoco, S. Maloy, C. Nebeker (Ex-officio), J. Perrault,  
Janis Shackelford, M. Tran,  
Absent: A. Bakarich (E-mail), M. Ginsberg (E-mail), T. Ghio (E-mail), B. Wingerd (E-mail)  
Guest: T. Scott, Interim Associate Vice President for Research  
Recorder: C. Cook

The meeting was called to order at 12:00pm.

**1. The minutes of the August 1, 2003 and October 2, 2003 meetings were approved.**

**2. BSL3 Laboratory Construction Update**

It was reported that there are problems with the software that controls the air circulation in the BSL3 laboratory and is currently being addressed and worked out. It was also stated that the room needs an autoclave and various other types of essential equipment and there is a lack of funds to purchase. The availability of autoclave(s) located in other parts of the building for use by this laboratory will be explored, the procedures for transportation of materials to these other autoclave locations will be verified. Further reports will be given at the next meeting.

**3. Update on the Completion of the Institutional Biosafety Manual**

The Manual is now being reformatted, once the formatting is complete the manual is expected to be placed on the website by November 7, 2003.

**4. BSL1 Laboratories – Posting of Signs**

The CDC guidelines are unclear regarding this issue. A motion was made: The IBC will make recommendations for the posting of signs for infectious agents on BSL1 laboratories on an individual basis and will leave the location of the signs up to the discretion of the BSO. The motion passed unanimously.

**5. Physical Plant Personnel Training**

The BSO reported that she will have the EH&S portion of the biosafety training materials compiled and available by the end of November that will include chemical and Biohazardous material storage, handling, decontamination, disposal, disinfection, working with safety hoods, etc. for web-based, group and one-on-one training.

**6. BUA Revisions that have not been submitted to the IBC**

BUA revisions that have not been submitted by the October 24, 2003 deadline, a 2<sup>nd</sup> URGENT notice will be sent out, stating the importance of compliance, which will give a extended compliance date of November 21, 2003. If the investigators do not comply with this notice the Foundation will be notified and funding will be stopped until they have submitted the information requested and the IBC grants approval of the research.

**9. Institutional Policy on Method of Disposal of *E. coli***

The institutional policy will state: "The methods of disposal of antibiotic resistant *E. coli* will be either to autoclave the material, or mix with a 1% bleach solution and let set for a minimum of 15 minutes, or dispose in red biohazard bag." A motion was made to accept this language and passed unanimously.

**10. BSL1 Containment for *Salmonella enterica* sv. Typhimurium strain LT2**

A motion was made to lower the level of containment for the LT2 strain of *Salmonella enterica* sv. Typhimurium to BSL1 containment level. The Committee voted to approve with one abstention.

**11. Biosafety Level of Human and Primate Cell Lines**

Because of meeting time constraints, this item was tabled until the next meeting.

**12. BUA Submissions**

There were no new submissions for review this meeting. Listed below are previously reviewed BUA's either approved or still pending approval:

<b>APPROVALS</b>		
03-08-002	Detection of Viruses in Human Blood	BSL1
03-08-003	Genetics of Flavin Dehydrogenase-Membrane Interact	BSL2
03-08-004	Salmonella Host-specificity	BSL2
03-09-005	Characterization of Genes in <i>Hydroides Eligans</i>	BSL1
03-09-007	Human Health Risk Assessment for Entrovirus and Hepetitis A in Runoff	BSL2
03-09-008	Project SALSA	BSL2
03-09-010	Role of the UPR in Cardioprotection	BSL1 and BSL2
03-09-014	Cholesterol/Isoperdnoid Biosynthesis: Role of Peroxisomes	BSL2
03-09-016	Gene Regulation in Ascidian Embryos	BSL1
03-09-017	Potentialiation of Cardiac Stem Cells to Retard Aging	BSL1 and BSL2
03-09-021	Sphingolipid Metabolism and Disease	BSL1
<b>APPROVALS PENDING</b>		
03-09-006	Contractile Proteins of <i>Drosophila Melanogaster</i>	BSL1
03-09-009	Role of the Placenta in Protection of the Fetus: Effects of Nutrition in Hispanic Mothers	BSL2
03-09-011	Secondhand Smoke Exposure Reduction in High-risk Preteens: A Controlled Trial	BSL2
03-09-012	Healthy Children Healthy Families	BSL2
03-09-013	WIC Families who Smoke: A Behavioral Counseling Study (Healthy Tots Project)	BSL2
03-09-015	Laboratory Research	BSL2
03-09-018	VSV Polymerase Function and Cellular Anti-viral Response to Virus Inactivation by Chlorine Dioxide	BSL2 and BSL3
03-09-019	Apo B Translocation and Degradation and Intervention into Atherogenesis by Gene Transfer	BSL1 and BSL2
03-09-020	Promoting ETS Exposure Reduction and Tobacco Cessation: A Pediatric Trial	BSL2

**Other Business:**

The BSO will track personnel working on and deleted from projects requiring a BUA, and ensure all have had proper training. The PI's are required to inform the BSO when changes occur regarding personnel immediately.

Questions regarding the existence of a BSL2 animal facility on campus were asked. A report will be given at the next meeting.

**Standard Procedure:** For funded projects, it is not necessary to submit a BUA form until it is known that funding will be granted.

It was determined that all projects being conducted on behalf of SDSU that uses biohazardous materials or recombinant DNA will need to submit a BUA including, but not limited to, projects that only involve needle sticks to draw blood samples.

Meeting was adjourned at 2:00pm. The next meeting will be Wednesday, December 3, 2003.

**Institutional Biosafety Committee  
Final Meeting Minutes - December 3, 2003**

Present: J. Zyskind, Chair, A. Bakarich, R. Bizzoco, S. Maloy, C. Nebeker (Ex-officio),  
J. Perrault, Janis Shackelford, M. Tran, B. Wingerd  
Absent: M. Ginsberg (E-mail), T. Ghio (E-Mail)  
Recorder: C. Cook

The meeting was called to order at 1:00pm.

**1. The minutes of the November 4, 2003 meeting were approved.**

**2. BSL3 Laboratory Construction Update**

The Biology Department Manager reported that, other than the problems with obtaining the correct air flow in the room and with the Biosafety cabinet, the construction has been completed. He stated that he thinks the problems with the air-flow have been remedied but has not received confirmation from the chief engineer. Once confirmation has been received, the necessary inspections will be performed, hopefully during the month of December. An autoclave for the room is still needed, numerous ideas for funding were discussed.

**3. SDSU Environmental Compliance**

On December 4, 2003, environmental compliance training will be provided to the Deans, Directors, Department Chairs and Administrators, which will be presented by the UCSD OSHA Training Institute. This session will be approximately two hours in length and will include topics such as chemical hygiene, hazardous materials, hazardous waste, biohazardous waste and universal waste. Additional training for faculty and staff will be provided in the spring semester 2004.

**4. Biosafety Level of Human and Primate Cell Lines**

Further discussion is necessary, tabled until the next meeting.

**5. BUA Submissions**

**a. Revisions received**

All revision requests have been received with the exception of two. Those people will be contacted.

**b. New Submissions for Professional Studies and Fine Arts, Health and Human Services and Student Health Services**

Exercise and Nutritional Sciences plans to submit 12 BUAs for review at the next meeting.

The BSO has made an inquiry with Student Health Services as to who oversees the biosafety issues for the department and has had no response. A report will be given at the next meeting.

**c. BUA #'s 03-11-024 and 03-09-018**

It was requested by the Committee to split the original BUA submission into two, which would differentiate between the BSL2 and the BSL3 containment levels of research. Separate BUA's were submitted. The BSL3 level project entitled "Engineering VSV with dsRNA-binding Binding Properties" #03-11-024 was approved with one abstention.

The BSL2 level project entitled "VSV Polymerase Function and Cellular Anti-viral Response to Virus Inactivation by Chlorine Dioxide" #03-09-018 was conditionally approved, with one abstention, pending a resubmission of the BUA which includes the response to the following conditions:

1. List the professor from the Department of Engineering as a co-investigator and have her sign the BUA. In addition, list her as personnel working on the project in section VI, A.
2. Describe what her role is in this research and what she will be doing.
3. Identify her laboratory location and how hazardous materials will be transported between the two laboratories.

**d. BUA #03-11-023      Role of Pshingolipids in cardiac Ischemia**

The transgenic animal research portion of this project has been considered to be at the BSL1 containment level and approved. However, the use of human cell lines portion of the project containment level has been tabled pending the Committees decision on what containment level the cell lines should be. Approval has been granted pending the outcome of the Committees decision.

**6. BSL2 Animal Facility**

The North Life Sciences building has a BSL2 certified biosafety cabinet, however the autoclave is not BSL2 certified. This room is currently being used for animal housing. If there becomes a need to work with animals under the BSL2 containment level, arrangements would have to be made with the PI using the room and with the Office of Laboratory Animal Care to use the room and equipment. This issue will be more aggressively addressed as the need arises.

<b>APPROVALS</b>		
03-09-006	Contractile Proteins of Drosophila Melanogaster	BSL1
03-09-011	Secondhand Smoke Exposure Reduction in High-risk Preteens: A Controlled Trial	BSL2
03-09-012	Healthy Children Healthy Families	BSL2
03-09-013	WIC Families who Smoke: A Behavioral Counseling Study (Healthy Tots Project)	BSL2
03-09-019	Apo B Translocation and Degradation and Intervention into Atherogenesis by Gene Transfer	BSL1 and BSL2
03-09-020	Promoting ETS Exposure Reduction and Tobacco Cessation: A Pediatric Trial	BSL2
03-11-022	Tyrosine Kinases in Autoimmunity	BSL1
03-11-024	Engineering VSV with dsRNA-binding Binding Properties	BSL3
<b>APPROVALS PENDING</b>		
03-09-015	Laboratory Research	BSL2
03-09-009	Role of the Placenta in Protection of the Fetus: Effects of Nutrition in Hispanic Mothers	BSL2

**Other Business:**

**Update on the Completion of the Institutional Biosafety Manual**

The manual has been submitted to the webmaster for inclusion on the EH&S website. Expected to be posted within the next two weeks.

Meeting was adjourned at 3:00pm. **The next meeting will be Wednesday, January 21, 2004.**



Graduate and Research Affairs  
Division of Research Administration  
San Diego State University  
5500 Campanile Drive  
San Diego CA 92182-1643  
TEL: 619-594-5938  
FAX: 619-594-4109

June 21, 2004

Edward Hammond  
The Sunshine Project  
101 West 6<sup>th</sup> Street, Suite 607  
Austin, TX 78701

Dear Mr. Hammond:

In January, The Sunshine Project requested that San Diego State University provide minutes from the two most recent Institutional Biosafety Committee meetings. In compliance with NIH Guidelines (section IV-B-2-a(7)), please find enclosed minutes for IBC meetings held thus far in 2004 (January and April).

Sincerely,

Camille Nebeker  
Assistant Vice President for Research (Interim)  
Graduate and Research Affairs  
San Diego State University

**Institutional Biosafety Committee  
Meeting Minutes - January 21, 2004**

Present: J. Zyskind, Chair, A. Bakarich, R. Bizzoco, S. Maloy, C. Nebeker (Ex-officio),  
J. Perrault, Janis Shackelford, M. Tran, B. Wingerd  
M. Ginsberg (email), T. Ghio (email)  
Recorder: C. Cook

The meeting was called to order at 1:00pm.

**1. The minutes of the December 3, 2003 meeting were approved with minor changes.**

The Chair introduced a prospective community representative member to members of the IBC. She will recommend to the Associate Vice President for Research that he be appointed to the committee.

**2. BSL3 Laboratory Construction Update**

The Biology Department Manager reported that the construction is complete on the BSL-3 laboratory. A preliminary facility inspection has been completed. The consultant will be inspecting the laboratory soon. The facility is ready for use as soon as an autoclave has been purchased and the biosafety inspection has been completed. There is an additional minor problem of a great amount of dust accumulating in the lab. Physical Plant insists that the dust is not coming through the ventilation system but through the doors when opened through the windows in the BSL2 lab. Action Item: The Biology Department Manager will make sure that Physical Plant secures and seals the windows to prevent dust from getting in.

**3. Biosafety Training**

Biosafety training for faculty and staff, including select Physical Plant shops and first responder Public Safety Officers, is planned for completion at the end of the spring semester 2004. This training will be ongoing for existing personnel as well as new employees.

**4. Biosafety Level of Human and Non-Human Primate Cell Lines**

The IBC voted unanimously to consider all research involving human and non-human primate cell lines to be conducted at BioSafety Level 2.

The investigator can petition the IBC to reduce this level as the need arises, which will then be evaluated on an individual basis. All work should be performed in a biosafety cabinet, and all material should be decontaminated by autoclaving or disinfecting before discarding. This BSL2 work can be done under Class 2 hoods/biosafety cabinets which have the necessary hepafilters installed, the hoods/cabinets do not have to be hard ducted to the outside of the building unless the investigator is working with adenoviruses. Notification will go out to all investigators working with these cell lines to treat the research at the BSL2 containment level.

**5. BUA Submissions**

a. **Research Involving Human or Non-Human Primate Cell Lines.** The BSO will prepare a list of the SDSU procedures, rules and regulations specifically associated with this type of research which is required to be conducted under BSL2 conditions. This list will then be forwarded to all investigators working under these conditions. They will then be asked to respond with an agreement that they will comply with these procedures, rules and regulations. The confirmation of receipt and agreement to comply will then be included as part of the individual BUA approvals.

b. **Research Involving Human Blood.** The BSO will prepare a list of the SDSU procedures, rules and regulations specifically associated with research involving extracting and handling human blood. This list will then be forwarded to all investigators conducting this work. They will then be asked to respond with an agreement that they will comply with these procedures, rules and regulations when doing this type of research. The confirmation of receipt and agreement to comply will then be included as part of the individual BUA approvals.

- c. **Human Blood Handling During and After Drawing Blood with a Syringe.** The BSO will ask other institutions how experimental procedures involving blood use are carried out. Are all experiments done in a biosafety cabinet or are some procedures carried out on the lab bench?
- d. **Request for BUA Submissions:**  
BUA submissions have not been received from the School of Nursing or Student Health Services. The BSO has made an inquiry with Student Health Services as to who oversees the biosafety issues for the department and has had no response. There will be follow up with those entities.

**APPROVALS**

03-09-009	Role of the Placenta in Protection of the Fetus: Effects of Nutrition in Hispanic Mothers	BSL2 Revisions Approved
03-11-023	Role of Pshingolipids in Cardiac Ischemia	BSL2
03-12-025	Project SPIRIT (Sports Injury Research in Teens)	BSL2
03-12-027	The Relationship between the Vertical Component of the Ground Reaction Force and Running Economy	BSL2
04-01-029	Exercise Physiology Lab 304L	BSL2
04-01-030	Effects of CVAC Treatment on Maximal Oxygen Consumption, Lactate Threshold, Peak Sustained	BSL2
04-01-031	Effect of Heat and Hypoxia on Blood Lactate and Muscle Deoxygenation	BSL2
04-01-033	Advanced Exercise Physiology Lab	BSL2
04-01-035	Human Nutritional Assessment Laboratories	BLS2
Approval Not Needed:		
04-01-034	Advanced Nutrition Lab – Classroom	IBC Approval not Required

**CONDITIONAL APPROVALS:** (Contingent upon acknowledgement of receipt and agreement to abide by SDSU blood draw and BSL2 containment procedures as specified below)

04-01-033	Advanced Exercise Physiology Lab	BSL2
Conditional approval has been granted pending PI agrees to abide by procedures for handling human blood under BSL2 conditions. A list of these procedures will be prepared by the BSO and will accompany this conditional approval. List all personnel on page 9 and identify the Human Subjects (IRB) Protocol number on page10. Follow universal precautions when handling blood samples. Hepatitis B vaccinations for all personnel are highly recommended. The SDSU BSO will visit this laboratory for compliance inspection, which will include ensuring that the Sharps containers are in compliance.		
03-12-027	The Relationship between the Vertical Component of the Ground Reaction Force and Running Economy	BSL2

Conditional approval has been granted pending PI agrees to abide by procedures for handling human blood under BSL2 conditions. A list of these procedures, prepared by the BSO, will accompany this conditional approval. Faculty in charge must be listed as the PI (student can be Co-PI) on page 1, identify lab manager on page 1, list all personnel and complete page 9. All faculty, staff and students working under this BUA must wear protective equipment because of the potential for creating infectious aerosols or splashes when pipetting. (See Section III, Page 24 of the CDC/NIH Biosafety in Microbiological and Biomedical laboratories guidebook). Personal protective clothing and equipment will be provided to SDSU faculty and staff by Environmental Health and Safety, arrangements must be made for the students and must be in place and used this semester before blood can be drawn. Follow universal precautions when handling blood samples. Hepatitis B vaccinations are highly recommended for all personnel. The SDSU BSO will visit this laboratory for compliance inspection, which will include ensuring the Sharps containers are in compliance.

<b>04-01-034</b>	<b>NUTR-302L Advc. Nutrition Lab – Animal Study</b>	<b>Exempt</b>
------------------	---	---------------

This study is exempt from IBC review as long as human blood is not used.

<b>04-01-035</b>	<b>Human Nutritional Assessment Laboratories</b>	<b>BSL2</b>
------------------	--	-------------

Conditional approval has been granted pending PI agrees to abide by procedures for handling human blood under BSL2 conditions. A list of these procedures, prepared by the BSO, will accompany this conditional approval. All faculty, staff and students working under this BUA, because of the potential for creating infectious aerosols or splashes when pipetting, must wear protection equipment. (See Section III, Page 24 of the CDC/NIH Biosafety in Microbiological and Biomedical laboratories guidebook). Personal protective clothing and equipment will be provided to SDSU faculty and staff by Environmental Health and Safety, arrangements must be made for the students. Personal protective clothing and equipment must be in place and used this semester before blood can be drawn. Follow universal precautions when handling blood samples. Hepatitis B vaccinations are highly recommended for all personnel. The SDSU BSO will visit this laboratory for compliance inspection, which will include ensuring the Sharps containers are in compliance.

<b>04-01-029</b>	<b>Exercise Physiology Lab 304L</b>	<b>BSL2</b>
------------------	-------------------------------------	-------------

Conditional approval has been granted pending PI agrees to abide by procedures for handling human blood under BSL2 conditions. A list of these procedures, prepared by the BSO, will accompany this conditional approval. All faculty, staff and students working under this BUA, because of the potential for creating infectious aerosols or splashes when pipetting, must wear protection equipment. (See Section III, Page 24 of the CDC/NIH Biosafety in Microbiological and Biomedical laboratories guidebook). Personal protective clothing and equipment will be provided to SDSU faculty and staff by Environmental Health and Safety. Arrangements must be made for the students. Personal protective clothing and equipment must be in place and used this semester before blood can be drawn. Follow universal precautions when handling blood samples. Hepatitis B vaccinations for all personnel are highly recommended. The SDSU BSO will visit this laboratory for compliance inspection, which will include ensuring the Sharps containers are in compliance.

<b>04-01-030</b>	<b>Effects of CVAC Treatment on Maximal Oxygen Consumption, Lactate Threshold, Peak Sustained Power Out</b>	<b>BSL2</b>
------------------	---	-------------

Conditional approval has been granted pending PI agrees to abide by procedures for handling human blood under BSL2 conditions. A list of these procedures will be prepared by the BSO and will accompany this conditional approval. All faculty, staff and students working under this BUA, because of the potential for creating infectious aerosols or splashes when pipetting, must wear protection equipment. (See Section III, Page 24 of the CDC/NIH Biosafety in Microbiological and Biomedical laboratories guidebook). Personal protective clothing and equipment will be provided to SDSU faculty and staff by Environmental Health and Safety, arrangements must be made for the students. Personal protective clothing and equipment must be in place and used this semester before blood can be drawn. Follow universal precautions when handling blood samples. Hepatitis B vaccinations are highly recommended for all personnel. The SDSU BSO will visit this laboratory for compliance inspection, which will include ensuring the Sharps containers are in compliance.

<b>04-01-031</b>	<b>Effect of Heat and Hypoxia on Blood Lactate and Muscle Deoxygenation</b>	<b>BSL2</b>
------------------	---	-------------

Conditional approval has been granted pending PI agrees to abide by procedures for handling human blood under BSL2 conditions. A list of BSL2 containment procedures specific for drawing blood by finger prick prepared by the BSO will accompany this conditional approval. All faculty, staff and students working under this BUA, because of the potential for creating infectious aerosols or splashes when pipetting, must wear protection equipment. (See Section III, Page 24 of the CDC/NIH Biosafety in Microbiological and Biomedical laboratories guidebook). Personal protective clothing and equipment will be provided to SDSU faculty and staff by Environmental Health and Safety, arrangements must be made for the students. Personal protective clothing and equipment must be in place and used this semester before blood can be drawn. Follow universal precautions when handling blood samples. Hepatitis B vaccinations are highly recommended for all personnel. The SDSU BSO will visit this laboratory for compliance inspection, which will include ensuring the Sharps containers are in compliance. Describe transportation procedures on page

**APPROVALS PENDING (Revisions Required)**

<b>03-12-026</b>	<b>Detection of Pasteurella in Sheep Swabs</b>	<b>BSL2</b>
Will send 2 <sup>nd</sup> notice for PI to submit revised BUA to address BSL2 conditions, complete section IV.D.3 on page 8 to indicate the swab samples of the animals and extracted DNA of the bacteria. Include the PI as an authorized user on page 9.		
<b>03-09-015</b>	<b>Research in the McGuire Lab</b>	<b>BSL2</b>
Revised BUA has been received and reviewed. All contaminated pipets and pipet tips must be discarded directly into a leak proof, puncture resistant red biohazard container or bag. Cardboard biohazard containers are not allowed. Styrofoam box containing blood and thymus tissue during transport must have "Diagnostic Specimen" indicated on the container and the biohazard sign and label affixed on the container. A chain of custody sheet must also accompany the diagnostic specimens.		
<b>03-09-018</b>	<b>VSV Polymerase Function and Cellular Anti-viral Response</b>	<b>BSL2</b>
Revised BUA needs to be submitted. Another letter will be sent.		

**Other Business:****Institutional Biosafety Manual**

The SDSU Biosafety Manual is posted on the web at <http://bfa.sdsu.edu/ehs/biomanual.htm>.

Meeting was adjourned at 3:45pm. The next meeting will be Wednesday, April 14, 2004, 1-3pm.

**Institutional Biosafety Committee  
Meeting Minutes - April 14, 2004**

Present: J. Zyskind, Chair, A. Bakarich, R. Bizzoco, M. Goulian, S. Maloy, C. Nebeker (Ex-officio),  
J. Perrault, Janis Shackelford, M. Tran, B. Wingerd  
M. Ginsberg (email), T. Ghio (email)  
Recorder: C. Cook

The meeting was called to order at 1:00pm.

**1. The hours of the January 21, 2004 meeting were approved with minor changes.**

**2. Report from the Chair**

The Chair announced that she will resign as Chair effective 6/30/04; another Committee member was recommended as a potential replacement. The Chair will forward this recommendation will to the Associate Vice President for Research effective July 1, 2004. The Committee thanked the Chair for all her efforts and hard work on behalf of the Committee.

**3. BSL3 Laboratory Construction Update**

The Biology Department Manager reported that BSL3 laboratory inspection was completed under the direction of a consultant. She was impressed with the design and construction of the facility. She recommended that the sink faucets be upgraded with paddle handles and that eye wash stations be set in place. In addition, the autoclave will be purchased and installed in the very near future. The Biology Department Manager also reported that Physical plant has not sealed the windows in the adjacent BSL2 laboratory. He will draft a letter to Physical Plant regarding the window issue for the Assistant Vice President for Research signature.

**a. Director Appointment and Duties**

The Committee unanimously approved the appointment of the Director of the BSL3 laboratory. His duties will be to oversee all research conducted in the facility and assure all safety and operating requirements are met.

**b. BSL3 Biosafety Manual**

It will be the duty of the Director to develop the safety manual and standard operating procedures (SOP) for the facility. The BSO will provide assistance. In addition, individual safety manual and SOP's will be developed for each project conducted in the facility.

Once the windows have been sealed, the faucets have been upgraded, the eyewash stations installed and the manual and SOP have been developed, the consultant will do a final inspection and will provide certification to the campus that the facility is ready to use.

The Biology Department Manager also reported that there is a laboratory where there is a cot and exposed wood bookshelves in the same room as the biosafety cabinet. The Committee firmly stated that these furniture items must be moved out of that room and/or away from the biosafety cabinet, because of noncompliance with BSL2 regulations. Also, it has been reported that pets were brought into campus laboratories. There are specific regulations in both the NIH Guidelines and the CDC Guidelines prohibiting animals in the laboratory. A letter will be sent to the professors informing them that "animals not involved in the work being preformed are not permitted in the laboratory" and to move the furniture away from the biosafety cabinet.

The Biology Department Manager will follow-up with obtaining (BSL2) certification for the isolation tent in the vivarium. The biosafety officer, veterinarian and OLAC manager will evaluate and certify the vivarium as Animal Biosafety Level 2 (ABSL 2).

#### 4. Report from the Biosafety Officer

##### Biosafety Training

The BSO reported that materials are being put together for the biosafety training for faculty and staff, including select Physical Plant shops and first responder Public Safety Officers. Biosafety training for Student Health Services will start this month. The biosafety training will be customized depending on the biological hazard and biosafety level of the lab. In addition, she reported that in March 2004 she completed a 40-hour training course developed for biosafety officers by the American Biological Safety Association (ABSA) and will also attend a workshop on cell culture techniques and safety, which the Committee highly recommended she attend. The Committee commended her on her completion of the ABSA training.

##### Biosafety Officer Evaluation

The Committee wanted to know how much of her time would be devoted to performing her role as the Institutional Biosafety Officer including training of research personnel. The BSO indicated that performing the functions of a biosafety officer takes a significant amount of time and it is projected to increase in the near future. The BSO's superiors are aware of her workload and said that a re-evaluation of her job would take place after one year from the appointment to Biosafety Officer. The Committee commended the BSO on her outstanding work she has done for the Committee and in her position as the Institutional Biosafety Officer.

##### Safety Guidelines

The BSO is working on preparing guidelines for research involving human or non-human primate cell lines. These guidelines will include a list of the SDSU procedures, rules and regulations specifically associated with this type of research and the requirement that this work be conducted under BSL2 conditions.

She has developed guidance on *"Health and Safety Guidelines when Dealing with Specimens of Human Origin and/or Potentially Infectious and/or Hazardous Agents (Including Animal Blood of Tissues)"* and *"Health and Safety Guidance on Drawing Human Blood and Their Subsequent Use in Research"* which includes a list of the SDSU procedures, rules and regulations specifically associated with research involving extracting and handling blood and tissues. These guidelines will be forwarded to the Committee electronically for approval.

#### 5. BUA Submissions

Submissions from the School of Nursing have not yet been received but are expected.

Either an Amendment Form will be created or the BUA will be revised to include specific questions regarding any changes to the BUA.

APPROVALS		
03-09-015	Laboratory Research	BSL1
03-09-018	VSV Polymerast Function and Cellular Anti-viral Response 2 Virus Inactivation by Chlorine Dioxide	BSL2
03-12-026	Detection of Pasteurella in Sheep Swabs	BSL2
BUA's to be Resubmitted:		
03-12-028	Development of Novel Antimicrobials (To be combined with BUA #04-01-032 and resubmitted)	
04-01-032	Development of Novel Antimicrobials (To be combined with BUA #03-12-025 and resubmitted)	

**CONDITIONAL APPROVALS:** (Contingent upon providing the Chair and BSO with the requested revisions to the BUA)

<b>04-03-039</b>	<b>Identification of Novel Anti-infective Agents</b>	<b>BSL2</b>
Conditional approval has been granted pending PI submits a revised BUA to include the following: <ul style="list-style-type: none"> <li>• List co-investigator and provide all laboratory locations in which work on this project will be conducted.</li> <li>• List the toxicology experiments using human cell lines</li> <li>• Describe tissue culture experiments planned and provide the strain of E-coli</li> <li>• Ensure that all work with haemophilus influenzae will be performed using an approved BSL2 cabinet.</li> <li>• Provide an amendment to the IACUC to include the heamophilus influenzae and describe the procedures that will be used.</li> <li>• Resubmission of the BUA must be received in the IBC office no later than April 30, 2004.</li> </ul>		
<b>04-01-037</b>	<b>Development of Novel Antibiotics</b>	<b>BSL2</b>
Conditional approval has been granted pending PI submits a revised BUA to include the following: <ul style="list-style-type: none"> <li>• These recommendations will be sent to the PI via the laboratory supervisor.</li> <li>• List all personnel working on the project, including all students and co-investigator .</li> <li>• Describe the work being conducted in LSN lab.</li> <li>• The term "Human Fibroblasts" is too generic, provide a detailed list of all human or non-human primate cell lines.</li> <li>• Specify how you plan to carry out BSL2 practices.</li> <li>• The work conducted with vaccinia virus under this BUA must be conducted under BSL2 containment procedures.</li> <li>• More thoroughly describe the experiments that will be conducted using mice.</li> <li>• Note: Sharps should not be autoclaved, once used they are discarded in a sharps container.</li> <li>• Please separate BUA's for all projects being conducted in your laboratory, including the projects involving recombinant DNA.</li> <li>• Resubmission of the BUA must be received in the IBC office no later than April 30, 2004.</li> </ul>		
<b>04-01-036</b>	<b>Biochemistry, Cell and Molecular Biology Lab 1</b>	<b>BSL2</b>
Conditional approval has been granted pending PI submits a revised BUA to include the following: <ul style="list-style-type: none"> <li>• These recommendations will be sent to the PI via the laboratory supervisor.</li> <li>• List all personnel working on the project including yourself and all students.</li> <li>• Revise BUA indicating Risk Group 2.</li> <li>• The term "Human Fibroblasts" is too generic, provide a detailed list of all human or non-human primate cell lines.</li> <li>• Specify how you plan to carry out BSL2 practices.</li> <li>• Describe work being conducted with cell lines.</li> <li>• Evaluate cell line work to see if non-human primate cell lines can be substituted.</li> <li>• Provide separate BUA's for all projects being conducted in your laboratory, including the projects involving recombinant DNA which thoroughly explains the research.</li> <li>• Resubmission of the BUA must be received in the IBC office no later than April 30, 2004.</li> </ul>		

**6.Sunshine Project**

On January 28, 2004 a letter was received from the Sunshine Project, Director Edward Hammond requesting copies of the minutes of the two most recent meetings of the IBC. This organization is "an international non-profit organization with offices in Hamburg, Germany and Austin, Texas, USA. Their mission is to work against the hostile use of biotechnology in the post-Cold War era. They research and publish to strengthen the global consensus against biological warfare and to ensure that international treaties effectively prevent development and use of biological weapons."

The request from this group cites the NIH Guidelines on Research Involving Recombinant DNA Molecules, Section IV-B-2-a-(7) which states, in part: "Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes..." The Division of Research Administration will comply with the request.

**7. Requests to Attend Meetings**

It will be noted that the IBC meetings are closed to anyone who is not a member of the Committee unless they are invited by the Committee to attend.

**Other Business:**

Meeting was adjourned at 3:35pm. **The next meetings will be held on an as needed basis until the beginning of the Fall 2004 semester. The next official meeting will be scheduled for September 15, 2004.**